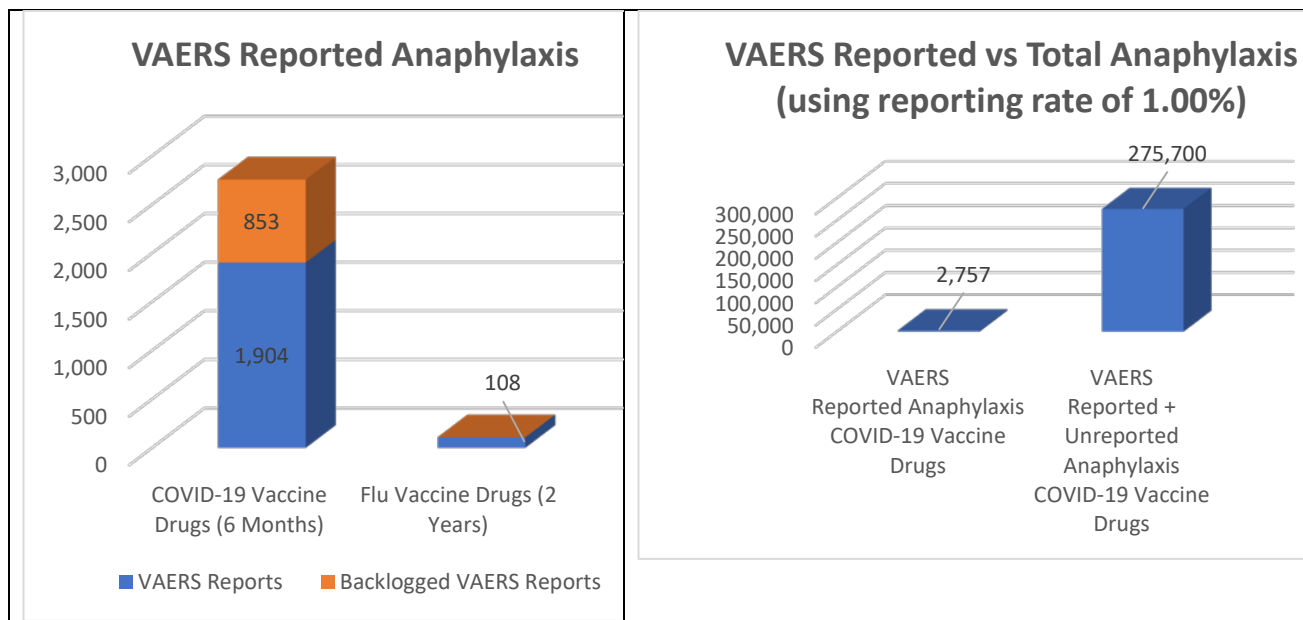


COVID-19 Vaccine Drug Reactions: Anaphylaxis

Preliminary Notes – Reactions Listings Start on Page 2 Below



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

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

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

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

3. The cases listed below were pulled from the VAERS raw data files with a query that looked for anaphylaxis reactions. As you read through the cases below, it is possible that there will be an occasional erroneous case not related to anaphylaxis problems. Please keep in mind that a physician may submit a very serious allergic reaction to VAERS as “anaphylaxis,” but the reaction may not meet the very specific set of criteria that researchers use to define “anaphylaxis.” The exact query is as follows:
 (symptom_text Like "*anaphylax*") and symptom_text not like "*history of anaphylax*" and symptom_text not like "*(anaphylaxis)*" and symptom_text not like "*anaphylaxis in past*";

Anaphylaxis: COVID-19 Vaccine Drugs

<i>VAERS_ID</i>	<i>RECVDATE</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
1374513	6/4/2021		12	M	6/3/2021	6/3/2021	Pt w/ hx of allergy to Amoxicillin (anaphylaxis, lip/face swelling). Pt c/o dizziness at 1410. Pt had a syncopal episode for a few seconds and woke up when reclined. Patient is A/O x4. Patient is cooperative, and denies pain or SOB. VS taken at triage, BP 86/54, HR 60, O2 97, RR 20, Temp 97.3. CN, nurse, and onsite provider were notified. Pt reports sweating, but denies tremor, numbness, tingling, nausea or vomiting. Offered juice and cracker to pt, no new medication ordered. VS repeated at 1420, BP 111/93, HR 85, O2 97, RR 16. pt reports improvement and denies dizziness, pt left triage with steady gait with family at 1430 and have further observation. Pt left clinic with family. Pt was advised to seek for emergency service if s/s worsen. All needs met, safety maintained.
1374477	6/4/2021		42	F	1/5/2021	1/6/2021	Starting the following it started with a really big hive that looked like a welt on my right arm, it was about half the size of my arm, Day 8 I left work early because I didnt feel right, My throat was closing up. Was treated at the ER for anaphylaxis. It persisted for a few days, was sent home with a epi-pens, I had to take meds for about a week,

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1374390	6/4/2021	CA	36	F	6/3/2021	6/3/2021	<p>Client received her first dose of the Pfizer Covid-19 vaccine (Lot # EW0187 Exp. 08/2021) on 6/3/21 at 2:48 PM. Client's husband whistled to EMT and paramedic, signaling that he needed assistance. Client was a 36-year-old female found sitting upright in an observation chair, alert and tracking and appeared to be in mild distress. Client had a chief complaint of throat irritation. Client's husband stated that the client was complaining of itchiness in her throat and on her chest. Client stated that she had a history of heart murmurs and frequent anxiety. Client denied prescription medication. Client had no known allergies. Assessment revealed no hives, swelling, discoloration, rash, accessory muscle use or other signs of anaphylaxis. Client stated that she began to feel the itchiness in her throat immediately after she received her shot but was hesitant to signal for assistance and waited a few minutes to notify staff. Client then added that her throat felt "swollen" and that she felt an itch on her chest as well. However, the client was able to make these statements without difficulty other than some mild fatigue. Airway, breathing and circulation were intact. Client was alert and oriented to person, place, date and event. Client's first set of vitals at 1503 were heart rate 138, respirations 28, blood pressure 152/98, O2 saturation 100% on room air, eyes equal and reactive to light, lung sounds clear bilaterally, and skin signs were normal throughout her body. Client was assisted from the observation chair to an observation bed by her husband and EMT. After lying down, the client briefly fell asleep and was laid supine. Client was asleep for approximately a minute before waking up. The client was then sat up and her vitals were retaken and had improved with a blood pressure of 138/98, heart rate 88, respirations 24 and O2 sat at 100%. After some brief monitoring, the client consented to an RN's administration of Benadryl 50mg (Lot # 020020 Exp. 02/2022) Intramuscular at 1512 on her right arm. Client then remained lying down and stated that she felt "better" approximately 10 minutes after Benadryl administration. However, five minutes later the client complained of a headache and chest pain which she later described as itchiness on her chest once again. Client then briefly became extremely anxious again before becoming calmer and consenting to staff dialing 911. Client consented to 911 at 1522 and Paramedics arrived at 1530. Client's vitals were</p>

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							assessed at five minute intervals until paramedics arrived: 138/100 (BP), 112 (HR), 99% (O2), 24 (RR); 1512 - 138/100 (BP), 88 (HR), 100% (O2), 20 (RR), 1517 - 130/92, 76, 100%, 20, 1522 - 128/94, 76, 99%, 20, 1524 (Anxiety episode)- 158/98, 92, 100%, 28 1529 - 130/ 98, 76, 99%, 24. Client consented to transport with paramedics at 1540 to the nearest hospital.
1374085	6/4/2021	OR	39	M	5/13/2021	5/13/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Medium, Additional Details: Patient reported throat closure about 9 hours after Pfizer COVID injection. He did not seek medical treatment and it resolved. He called it an anaphylactic reaction. I did not administer the second dose of Pfizer vaccine as a precaution. I told him to seek advice from his doctor and if he chooses to get the second dose, he should get it at a medical facility or doctor's office.

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1373722	6/4/2021	NJ	40	F	3/16/2021	3/17/2021	violently vomiting; nauseous; losing weight; my labs are a mess; losing hair; short of breath; dizzy; I have never felt so awful for so long.; can barely eat; This is a spontaneous report from a contactable consumer (patient). A 40-year-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration, administered in Arm Right on 16Mar2021 09:00 (Batch/Lot number was not reported) at single dose for COVID-19 immunization. Medical history included Lupus, Postural orthostatic tachycardia syndrome (POTS), depression, Axial Spondyloarthritis, Degenerative Disc Disease. Concomitant medications included unspecified medications, the patient was on quite a few, she didn't fit. The patient's known allergies Ambient, augmentin, doxycycline (not anaphylaxis). No other vaccine in four weeks. Vaccine 16Mar2021, day after she started violently vomiting. She had vomited almost every day since, she was nauseous 24/7, she can barely eat so she was losing weight and her labs were a mess, she had to get IV Iron yesterday (19May2021), and she had a ton other GI tests coming up. She was losing hair, I'm getting barely any nutrients. She was now short of breath and dizzy too. She had never felt so awful for so long. Adverse event start date was 17Mar2021. Adverse event start time was 07:00 AM. Adverse events resulted in Doctor or other healthcare professional office/clinic visit. The patient received treatment for the events included intravenous Iron, tried different medicine, lots of appts. No covid prior vaccination. No covid tested post vaccination. The adverse events did not result in death, did not cause/prolong hospitalization, was not life threatening, disabling/incapacitating, congenital anomaly/birth defect. All events considered as serious due to being medically significant. The outcome of the events was not recovered. Information on the lot/batch number has been requested.

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1373419	6/4/2021	NC	57	F	2/28/2021	3/3/2021	B cold feeling (like stepping on cold water or ice) at the arch of the foot/cold feeling at the R deltoid, R biceps and triceps, and R upper leg; B cold feeling (like stepping on cold water or ice) at the arch of the foot/cold feeling at the R deltoid, R biceps and triceps, and R upper leg; Feeling less energetic but able to do ADL; This is a spontaneous report from a contactable other HCP (health care professional, who reported for herself). A 57-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, formulation solution for injection, Lot Number: EN6203, expiration date unknown) 1st dose, via an unspecified route of administration administered in Arm Right on 28Feb2021 at 11:00 am, as single dose for covid-19 immunization. Medical history included B peripheral neuropathy post op (L5- S1), urinary retention postoperative, superficial melanoma (excision required, no treatments) and seasonal allergies. Concomitant medication included estrogens esterified, methyltestosterone (ESTRATEST); progesterone (PROMETRIUM [PROGESTERONE]); tamsulosin hydrochloride (FLOMAX [TAMSULOSIN HYDROCHLORIDE]); cyanocobalamin (B12 [CYANOCOBALAMIN]); collagen (COLLAGEN) and Biot. The patient previously took IV Infed on which experienced anaphylaxis) and IC Feraheme on which experienced hives. The patient had not received prior covid vaccination and had not tested covid post vaccination. The caller stated that after receiving the first dose of vaccine on 03Mar2021 she experienced B cold feeling (like stepping on cold water or ice) at the arch of the foot, cold feeling at the R deltoid, R biceps and triceps, and R upper leg and was feeling less energetic but able to do ADL. The patient had not received any treatment to treat the event. The outcome of the events was not recovered. No Follow-up attempts are possible. No further information is expected.
1373136	6/4/2021	AK	22	F	5/11/2021	5/11/2021	Anaphylaxis, SOB, tremoring, chest discomfort. Very poor lung air movement upon arrival. Treated with epi x1 IV and epi nebulized. Solumedrol 125mg IV. Famotidine 40mg IV. IV saline 1L. Diphenhydramine 50mg IV then 4 hours later additional dose 50mg oral. Rapidly improved and monitored in ED for 4 hours. Discharged stable.

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1374550	6/4/2021	OR	55	F	5/29/2021	5/29/2021	Less than 30 minutes after injection (1st dose), patient-reported chest tightness, SOB, flushing; immediately perioral tightness. PE flushing face and chest, perioral hives. Lungs clear. RRR Cannot r/o anaphylaxis Epi 0.3 mg administered LLE BP 193/103 Sat 98% RA Paramedics called; pt transported
1370612	6/3/2021			F	2/1/2021		Anaphylactic reaction; This is a spontaneous report from a contactable pharmacist. A 3-decade-old (in her 20s) female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on Feb2021 as 1st dose, single for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The pharmacist stated a patient in her 20's had first dose in Feb2021, resulting in anaphylaxis. HCP asking patient to receive an additional dose, followed by a second dose. The pharmacist was doing vaccines with patients and she was getting ready to restart the vaccine for a patient that had the vaccine done at another location and had a reaction back in Feb2021. The pharmacist stated she needed to find out if there has been any instances like that and what she should do. The pharmacist stated the patient had an anaphylactic reaction and had to be taken to the hospital. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on known drug safety profile and temporal association, the causal relationship between bnt162b2 and the event anaphylactic reaction cannot be excluded.

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1370605	6/3/2021	IN	75	F	1/22/2021	1/22/2021	<p>She couldn't swallow 30 minutes after receiving the vaccine/difficulty swallowing; light headiness; dry mouth; This is a spontaneous report from a contactable nurse (patient). A 75-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in right arm at age of 75 years old on 22Jan2021 (Batch/Lot Number: EL1283) as single dose for covid-19 immunization. Medical history included anaphylaxis. The patient's concomitant medications were not reported. After receiving the first dose of the vaccine on 22Jan2021, patient reported extreme dry mouth and light headiness. She couldn't swallow (difficulty swallowing) 30 minutes after receiving the vaccine. She wasn't sure if this was related to the dry mouth or not. It all went away the same day. Patient wanted to know if she can receive the second dose of the vaccine or not. The patient had odd symptoms after the vaccination, after she left the clinic area. The first symptom she experienced was extreme dry mouth. She was slammed with dry mouth. Right after she left her 15 minutes wait period. She also experienced light headedness. Then, on the way home about a half an hour (30min) after the injection (she only stayed 15 min) she couldn't swallow. She went to take a sip of water because of her dry mouth and couldn't swallow. Then, 10 minutes later she was fine. It could of been because of the dry mouth that she couldn't swallow. She stayed light headed at home for an hour. She took Benadryl and went to sleep. This all happened the same day on 22Jan2021. She recovered completely. She hasn't received the second dose because of the odd reaction. It has been 3 months this week from her initial dose. She is not sure whether to go have the second injection or not. This report was provided as non-serious. Therapeutic measures were taken as a result of dry mouth, light headiness, couldn't swallow and included Benadryl. The outcome of the events were recovered on 22Jan2021. Follow up needed, further information was requested.</p>

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1370653	6/3/2021	GA	17	F	4/2/2021	4/4/2021	Fever; Joint pain; facial and tongue swelling/broken out in a rash broken out in a rash that moved to her face and lips/anaphylaxis/daughter's eye started to swell; Serum sickness; elevated CRP; Hives/an allergic reaction/lip and face swelling; This is a spontaneous report from a contactable consumer (the mother) reported for her daughter. A 17-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via intramuscular, administered in left arm on 02Apr2021 10:00 (Batch/Lot Number: EN6207) as 2ND DOSE, SINGLE for covid-19 immunisation. Medical history included Colitis ulcerative from 2014 and ongoing, Genetic immune deficiency, additional Information for other conditions: Caller describes it as "22q". patient was born with this but wasn't actually diagnosed until patient was 11 years old. They checked with patient's Immunologist before getting the vaccine especially with her daughter's history. Thyroid disease from 2015 to an unknown date, additional Information for other conditions: patient didn't have a thyroid- her thyroid was removed. Concomitant medications included cetirizine; famotidine; montelukast sodium (SINGULAIR); and epinephrine (EPIPEN) all taken for an unspecified indication, start and stop date were not reported; aloe vera, pramocaine hydrochloride (ATARAX ANTI ITCH LOTION) taken for itching, swelling and hives, start and stop date were not reported. The patient took first dose of Pfizer COVID vaccine on 12Mar2021 10:00 (Lot: EN6207) for COVID-19 immunization and patient had no side effects after the first dose. No additional vaccines administered on same date of the Pfizer suspect. No prior vaccinations (within 4 weeks). The patient just saw her Immunologist and her Immunologist instructed her to report what is going on with patient. Caller clarifies patient's immunologist plans to call and report as well but also instructed her to call and report the side effects her daughter is experiencing. Her daughter was cleared to have the COVID vaccine. The caller explains they always check with her immunologist because of her daughter's immune issues. Her daughter received the second dose of the COVID vaccine on 02Apr2021. On the evening of 04Apr2021, her daughter broke out in hives. They didn't think it was a big deal, they thought it was just an allergic reaction. She tried Benadryl and several other things. They went and saw her daughters regular general practitioner and the

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doctor believed it was just a delayed skin reaction, which seems to be common with the Pfizer COVID vaccine. The doctor told her he's seen one other person with this delayed reaction. He gave her daughter a steroid injection, a Steroid Dose Pack and Pepcid. She was also placed on Benadryl as needed. About 2 weeks after this, her daughter and lip and face swelling and ended up in the Emergency Room (ER). At this ER visit, they initiated the allergic reaction protocol and it was not an anaphylactic reaction at that point. Her daughter received IV Benadryl and IV steroids, the caller is not sure what else. She confirms she has no NDC, Lot number and expiry dates for the medication her daughter received in the ER. The ER doctor contacted the Immunologist on call and the Immunologist had seen a few cases with a delayed reaction. Caller clarifies the ER doctor discussed her daughter's delayed skin reaction with the on-call Immunologist. The oncologist put her daughter on generic Zyrtec, 20mg in the morning and 20mg at night. The following week, her daughter woke her up with facial and tongue swelling. She clarifies further her daughter had fever, joint pain, and had broken out in a rash that moved to her face and lips. She immediately took her to the ER. The ER followed the whole anaphylaxis protocol and was given an EpiPen. She explains her daughter was diagnosed serum/covid sickness. This has been going on for over 6 weeks. The reaction will come and go. She was told as her daughter's body develops immunity, she is basically allergic to it. She clarifies at her ER visits, they checked her daughters liver and kidneys. It was noted her daughter had an elevated CRP, which is an inflammatory marker. The caller was told they thought her daughter had serum sickness from the vaccine which may last 4-6 weeks or it may be prolonged, so they just went with it. They told her as long as it didn't move to her lips or affect her daughters breathings, eventually it would wax and wane and go away. Her daughter started breaking out on her arms and legs and last Saturday, she woke up and her face was swelling. She clarifies her daughter's eye started to swell and her tongue. She took her straight to the ER and the ER followed the anaphylaxis protocol and injected her with an EpiPen. They contacted her Immunologist to check and make sure it wasn't anything else and consulted with the Covid Vaccine Clinic and it was found

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3 other patients had this happen. No further details were provided regarding the 3 other patients. Right now, her daughter is on 4 different medications and an EpiPen. They contacted her insurance about her being placed on a biologic because not even the current medications her daughter is on is making everything going away. Caller verifies her daughter was never admitted into the hospital. When she was last seen in the ER Monday, she her daughter was monitored for 4 hours after the EpiPen was administered. The events require a visit to Emergency Room (total of three ER visits) and Physician Office. She known the last/third ER visit was Monday, 17May2021. The second ER visit was 04May2021. She believes the initial/first ER visit was probably a week or so before the second one. She clarifies she broke out in hives on 04 Apr2021 and went to the doctor on 07Apr2021 or 08Apr2021 so the ER visit was around the next week. Since her daughter had such a good response from the EpiPen the ER doctor took pictures before and after. She clarifies the name of the biologic they want to put her daughter on is Xolair, it is a monthly injection. She explains the current cocktail they have her daughter on is not working. She provides the following product information for these 4 medications and EpiPen. Relevant Tests included she knows they are testing for any other thing that it could be to rule it out. She knows they ran a CIS-tray, a complete CIQ , a Histamine release something and Tryptase. She knows they checked her CRP (inflammatory marker) because it was elevated. Every time her daughter went to the ER, they did a CBC and all of that was normal except for the CRP inflammatory marker, however her CRP was normal at the last ER visit. The outcome of events was unknown. No follow-up attempts are needed. No further information is expected.

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1370658	6/3/2021		70	F	2/26/2021	2/26/2021	<p>Ear ache; Sore throat; could feel her heart doing somersaults; headache; she had some breathing issues after the first vaccine/was not able to breathe; swelling of the throat; The buildup was itchy; cold; she was miserable; Runny nose/She always has a little snuffle; she also had SVT in her heart; inflammation was worsened after the first vaccine/a lot of inflammation/arthritis inflammation; she had fibrin buildup in her hands; This is a spontaneous report from a contactable consumer (patient). A 70-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in left upper arm on 26Feb2021 11:00 (Batch/Lot Number: EN6200) as 1ST DOSE, SINGLE for covid-19 immunisation. Medical history included Spondylitis, Spondylitis in neck, Inflammation and Arthritis. The caller states that she fell on her knee and got a big bump and with further inquiry, this was prior to the vaccine. Family Medical History Relevant to AE(s) included her father had similar kinds of inflammatory problems, bones, muscle tissue growth. In Jul2020 (at age of 69 years old), patient received shingles vaccine, she wondered if it was still in her system, patient felt awful and more inflammation. The patient's concomitant medications were not reported. History of all previous immunization with no Pfizer vaccine considered as suspect. No additional Vaccines Administered on Same Date of the Pfizer Suspect. Prior Vaccinations (within 4 weeks), no other vaccinations within four weeks prior to the first administration date of the suspect vaccine(s). No other products. She provided only the birth year, 1951, and said within the first six months. She stated that her weight can fluctuate from 120 pounds to a pound up or a pound or three down. Patient had a runny nose since about a week after the first dose of the vaccine (05Mar2021). She was reluctant to get the second dose because she continued to have a runny nose, almost every day, all day long, sometimes it's worse, sometimes it's better. Her friend was visiting and said that he too has had a runny nose, and he thought it was from wearing a mask, but she didn't wear a mask, but she didn't wear a mask, well she only wear them when she goes out and she's not out that much. When asking for clarification the caller states that the runny nose has been happening for weeks. The runny nose comes and goes. Sometimes she thinks it's</p>

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getting better and then it got worse again. It's not like a side cold, she always has a little snuffle. It hadn't been bothering her the last couple hours and now it's started to well up and she's thinking what is this about. It started about a week after the first shot and definitely after the second shot. The runny nose was sometimes accompanied with ear ache and sore throat both of which continue to come and go. She didn't know when the ear ache and sore throat started. They come and go quickly, and had happened maybe half a dozen times or more. Her husband would say it's just a cold and maybe it was. She had been treating the symptoms with Elderberry and Zinc lozenges. The caller remarks that she gets a lot of inflammation, described as arthritic inflammation and this inflammation was worsened after the first vaccine on 26Feb2021. She states that this response happened about 4-5 hours later. She also complained of headache, and other symptoms and when asked to repeat the other symptoms she clarified as inflammation in whole body. The caller also reported that something new happened, she had fibrin buildup in her hands on 26Feb2021, she watched it grow on her hands, it was like a science fiction movie; that was still there. She's had fibrin before but never watched it happen. The buildup was itchy and she describes it as an inflammatory response. The fibrin buildup began that night after first dose of the vaccine on 26Feb2021. This started Friday night. The fibrin and inflammation are still there, the only way it will go away was to have it cut out. That was how her body reacts. The caller did report that she had some breathing issues after the first vaccine and was told that it wasn't anaphylaxis, it was probably swelling of the throat, but it didn't last. After the first vaccine she also had SVT in her heart, that night when she was having the inflammation, she remarks that she could feel her heart doing somersaults. The SVT began on the evening of the first vaccine (26Feb2021) and into the next day and into Sunday late afternoon. That was weird, she thought she was doing to die, she was not able to breathe, she was miserable, she thought to sleep it off, she was trying to get away from the headache, it was her whole head. All events did not require a visit to Emergency Room or Physician Office. At the time of this report, the outcome of Runny nose was not recovered, of other events were unknown.; Sender's Comments: Linked Report(s) : US-

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PFIZER INC-2021569236 same patient, different drug
dose/event.

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1370588	6/3/2021	WI	15	M	5/14/2021	5/14/2021	<p>it looked like the blood vessels or veins in the bend of elbow, inside of the elbow that looked like possibly a blood vessels that burst there.; feels sick; his body didn't feel right and he felt that way again yesterday when he felt so bad.; numbness and tingling right arm; tingling/numbness and tingling right arm; rash on the right arm; he has pain and a rash on his right arm; feeling like passing out; dizziness/lightheadedness; nausea; chest tightness/ chest was so tight and pulling.; pain in the arm at the injection site; headache; This is a spontaneous report from a contactable consumer (patient's mother). A 15-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 14May2021 11:15 (Batch/Lot Number: EW0173; Expiration Date: Aug2021) as 1ST DOSE, SINGLE for covid-19 immunisation (Age at vaccination: 15 years). Medical history included asthma, allergy, acne, pain, Gastroparesis, eczema, red blotches /bright red dots on his whole body and anaphylaxis. Concomitant medications included cetirizine (CETIRIZINE) taken for allergy; beclometasone dipropionate (QVAR) taken for asthma; mometasone furoate (MOMETASONE FUROATE) taken for allergy; isotretinoin (ZENATANE) taken for acne; paracetamol (TYLENOL) taken for pain; sodium chloride (AYR SALINE, both nasal spray and nasal gel) taken for allergy; herbal extract nos, homeopathics nos (SIMILASAN) taken for allergy, all are ongoing. The patient previously took advil [ibuprofen] and experienced anaphylactic reaction (when he was about 4 years old in about 2009 or 2010.). The reporter who is mother of patient calling regarding the Pfizer Covid 19 vaccine. States she wanted to call and report some side effects from the vaccine for her son. Reports he received the first dose of the Pfizer Covid 19 vaccine 14May2021 at 11 15 AM in the upper left arm. He stayed extra minutes after the shot because he had anaphylaxis before and had red blotches before in the past. Reports after receiving the first dose of the Pfizer Covid 19 vaccine, when they got to the car he said his chest was so tight and pulling. That lasted 1 to 2 minutes only on that day (on 14May2021, 12:00). Since then and even on the very first day he has had dizziness; lightheadedness; and felt like passing out (on 14May2021, 12:00). Adds he</p>

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has been having to go to the nurse's office for headaches for the last two days (occurred on 14May2021). The reporter states her son has been very disappointed and mad at her for making him have the vaccine. Nausea - she adds her son also had some nausea (on 14May2021, 12:00). Right arm - he has pain and a rash on his right arm, the opposite arm from the shot, with numbness and tingling right arm (occurred on 17May2021); tingling. When he went to the nurse someone in that office mentioned that it looked like the blood vessels or veins in the bend of elbow, inside of the elbow that looked like possibly a blood vessels that burst there on an unspecified date. Pain in the arm at the injection site (occurred on 14May2021, 12:00) from the first day that is improved. The patient's body didn't feel right - when they started walking to the car his body didn't feel right and he felt that way again yesterday when he felt so bad. The first day and yesterday he felt his body didn't feel right (occurred on 17May2021, 11:45). Dizziness - is mostly when standing up and is lasting a lesser amount of time and getting better. Feels the sensation of like passing out with the dizziness on standing. Headaches - he has every day but yesterday was terribly bad and today were the worst. The reporter mentions that the patient stated the he feels sick on an unspecified date. Outcome of the events loss of consciousness, dizziness and vaccination site pain was recovering. Outcome of the event chest tightness was recovered on 14May2021 while outcome of the events numbness and tingling right arm was recovered on 18May2021. Outcome of the events pain in arm, vascular injury and malaise was unknown. Outcome of the remaining events was not recovered.

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1366784	6/2/2021			U			<p>BELL'S PALSY; BLOOD CLOT; GUILLAIN BARRE SYNDROME; ANAPHYLAXIS; This spontaneous report received from a patient via a company representative (other manufacturer Pfizer) concerned multiple patients. The patient height and weight was not reported .No past medical history or concurrent conditions were reported.The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported)frequency one total , dose, start therapy date were not reported for prophylactic vaccination.The batch no was not reported ,The Company is unable to performed follow up to request batch /Lot numbers. No concomitant medications were reported. On an unspecified date, the subject experienced bell's palsy, blood clot, guillain barre syndrome, and anaphylaxis. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the bell's palsy, blood clot, guillain barre syndrome and anaphylaxis was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0. 20210556206-COVID-19 VACCINE AD26.COV2.S. Bell's palsy, Blood clot, Guillain Barre syndrome. This events is considered unassessable. The events has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the events. 20210556206-COVID-19 VACCINE AD26.COV2.S. Anaphylaxis. This event is labeled per RSI and is therefore considered potentially related.</p>

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1368817	6/2/2021	NJ	21	M	6/2/2021	6/2/2021	After administration, patient did not report any reaction and was asked to wait 15 minutes for monitoring. A few minutes later, he started feeling lightheaded and called his father. His father notified me that he was "spazzing out/seizing" with his head jerking backwards "for a couple seconds". When I saw the patient, he was sitting and unresponsive to verbal and physical stimuli with his father patting his cheek. After a minute or so, the patient was able to respond, but his voice was faint. He reported having a "severe headache" and feeling "sweaty". He had no fever or difficulty breathing. Father said there was no anaphylaxis, and asked for a bucket since the patient felt very nauseous. I then called 911 for emergency services. When I returned to the patient after the call, the father said he was feeling much better and that the "color had returned". Patient was unwilling to stand, and remaining symptom(s) was headache. Emergency services came and checked blood pressure, which was normotensive (SBP 111). Father insisted ER visit was not necessary.

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1368370	6/2/2021	CO	28	F	5/20/2021	5/20/2021	28 year old female administered Pfizer vaccine, 0.3 mL, EW0179 at 1610. At 1617 she reported feeling a tightness in her throat, accompanied by difficulty swallowing and agreed to be monitored more closely. She stated that she had not experienced this level of a throat sensation after the first Pfizer dose, but that this sensation was more similar to the throat swelling she experienced after exposure to shell fish, which was followed by anaphylaxis. She carries her own epi pen and diphenhydramine for such emergencies. She stated that she self administered diphenhydramine after her first immunization, which controlled the throat sensation at that time. She agreed to take a 50mg diphenhydramine at 1625. BP was approximately 152/107, 97% pulse ox on room air, HR 112. At 1635 no change in how her throat was feeling, or that it was any easier to swallow. She agreed to have EMT services called. 911 was called and the dispatch instructions were followed, including the administration of 0.3mg of epinephrine via an Mylan EpiPen (Mylan, Lot 0FM544, Exp 9/22) at 1642. Soon after, she stated she was feeling significantly better and breathing was easier. At 1645 EMT teams from arrived and assessed the situation; the patient agreed to be transported to for further evaluation.
1368292	6/2/2021	KS	57	F	5/25/2021	5/25/2021	At 1140 AM, following a second dose of Moderna Covid vaccine, patient reports itching to her ears, back, and scalp. No hives, welts, or redness noted. patient denies any mouth, lips, tongue, or throat swelling. patient reports she has had anaphylaxis to NSAIDS in the past but no other medications. Nurse Practitioner onsite notified, VO rec'd for Diphenhydramine 50 mg PO x1 dose now. medication administered to patient. patient reports she has benadryl at home if she needs it later and is comfortable going home at this point. no s/s of distress. patient discharged home at 1200 PM.
1368282	6/2/2021	OR	32	M	5/29/2021	5/29/2021	Pt noted mild rash 30 min post vaccine. No resp or OP sx. No other skin involvement. PE blanching erythema UE only Probably sunburn -Advised sunscreen -Warned of sx of anaphylaxis (unlikely)

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1368005	6/2/2021	MD	42	F	6/2/2021	6/2/2021	Patient was given 0.5mL of Janssen vaccine IM into her right deltoid muscle. Post vaccine patient, fainted during the 15 minute wait period. She was promptly attended to, and did not exhibit signs of anaphylaxis. EMS came to assess patient even though she felt "completely normal" after she fainted.
1367338	6/2/2021	IL	26	M	4/26/2021	4/26/2021	heart was racing; throat getting a little tight; This is a spontaneous report received from a contactable pharmacist via a Pfizer- sponsored program and Medical Information Team. A 26-year-old male patient received first dose of BNT162b2 (COMIRNATY, solution for injection, lot number: EW0153), via an unspecified route of administration on 26Apr2021 as 1st dose, single for COVID-19 immunization. The patient medical history and concomitant medications were reported as none. It was reported that, the patient got the first shot on 26Apr2021, instantly he's heart was racing and 5 minutes after he felt his throat getting a little tight, after 5 minutes still tight, 2-3 minutes it resolved on its own without any medication, no Benadryl and no medical assistance, he was okay after that. Patient confirmed that he did not experienced difficulty of breathing. The patient was advised to go to the doctor's office or hospital for the second shot in case he gets an anaphylaxis or worse reactions to the second dose. He states that the symptoms were resolved in about 2 minutes on the same day. The pharmacist was asking if these were considered as a severe allergic reaction and he wants to know if the patient should get the second dose or not. The outcome of the events heart was racing and throat getting a little tight was recovered on 26Apr2021.

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1367261	6/2/2021			F			runny nose/My nose was running a little bit; cold; This is a spontaneous report from a contactable consumer or other non hcp. A female patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, formulation solution for injection), via an unspecified route of administration on an unspecified date (Batch/Lot Number: EW0164, Expiration date: Unknown) as 1ST DOSE, SINGLE for COVID-19 immunization. Medical history included severe allergic reaction from an unknown date and unknown if ongoing history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine. There were no concomitant medications. On an unspecified date the patient experienced runny nose/my nose was running a little bit and cold. The reporter stated that she is scheduled to receive her second dose of the {Pfizer COVID-19 vaccine tomorrow, but yesterday she got wet in the rain, went into job and it was cold in there, and today has a runny nose/. my nose was running a little bit. is it okay to get vaccine tomorrow. Outcome of the events were reported as not recovered at this time of the report. Information about batch/lot number has been requested.
1367219	6/2/2021			U	4/3/2021		anaphylaxis; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route single dose for COVID-19 immunization on 03Apr2021. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced anaphylaxis on an unspecified date. Patient reaction required 2 EPI pen shots and 24 hours of medications on the neuro trauma floor and was still having issues. Outcome of the event was not resolved. Information about Lot/Batch number has been requested.

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1366983	6/2/2021	FL	76	F	2/21/2021	2/21/2021	<p>blood pressure was 174/106/blood pressure shot up to 198/116/blood pressure shot up to 175/106; 93 pulse/99 pulse/109 pulse; This is a spontaneous report from a contactable consumer, the patient. A 76-years-old non-pregnant female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EL1284), via an unspecified route of administration, administered in right arm on 21Feb2021 16:00 (at the age of 76-years-old) as a single dose for covid-19 immunization. Patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Lot number: EN5318), via an unspecified route of administration, administered in right arm on 31Jan2021 16:00 (at the age of 76-years-old) as a single dose for covid-19 immunization. Medical history included, blood pressure abnormal, blood cholesterol abnormal (was on blood pressure medication for many years; after losing 20 pounds did not need it anymore; take Crestor 10mg for cholesterol (total around 160)) and had allergy with rubber (latex band aids). Concomitant medication(s) included vitamin d3; rosuvastatin calcium (CRESTOR). On 21Feb2021 16:30, the patient reported about 1-2 minutes after receiving 2nd shot on 21Feb2021 "I could feel a reaction. I waited 30 minutes before leaving to make sure it wasn't anaphylaxis. When I got home my blood pressure was 174/106/93 pulse. The patient had no other vaccine within four weeks. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 24Feb2021 blood pressure shot up to 198/116/99 pulse. On 01Mar2021 blood pressure shot up to 175/106/109 pulse. After the first shot, the patient had slight rise in blood pressure and pulse after about 5 days but otherwise just felt tired". The patient received treatment with benicar 40 mg and lorazepam 5 mg, zicam. Outcome of the event was recovered with sequelae (recovered with lasting effects). No follow-up attempts are possible. No further information is expected.</p>

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1366945	6/2/2021			F			My face is swollen; scars started to tingling.; This is a spontaneous report from a contactable consumer (patient). This 54-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number was unknown) via unknown route of administration on an unknown date, first dose, single for COVID-19 Immunisation. The patient's medical history included facelift on 23Nov2020. The concomitant medications were not reported. On an unknown date, it was reported that she received her first dose of the Pfizer vaccine on Saturday. She reported her face is swollen. "It's not anaphylaxis. I'm assuming it's because I had facelift on 23Nov and It is impacting her lymph nodes. She reported she afraid to take the second dose. I don't even know if the water pills are the right path. My face is drained from one ear to ear and under the jaw line. It happened 40 minutes after the injection. It's not Botox no fillers. That's not applicable to me because I haven't had fillers or Botox. I had no other reactions. 40 minutes after all the scars started to tingling. The past 3 days, it looks like it's draining below the jawline. The outcome of the events was unknown. The lot/batch number is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

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1366553	6/1/2021	TN	19	F	5/15/2021	5/15/2021	We left the store and got a bite to eat at the drive through. After driving about 7 minutes she grabbed her throat and started acting like she was not able to swallow. I asked her was she ok? She stated no in a raspy voice. She shook her head and said she felt like molasses was in her throat. She seemed pale and began to sweat. I am a former EMT-Paramedic. I remembered there was a store about 2 miles away. I called and got the Pharmacist on the phone. I ran into the after driving 92 miles an hour and she converted children's Benadryl for me and stayed on the phone. I gave her 1/2 a bottle. began to be more responsive. I had a medical bag with me with airways and other medical devices I use for work but no Epi Pen. After giving her all the Benadryl she said she felt better but she stayed hoarse for the remainder of the day and was sleepy. I kept an eye on her and Called her physician on Monday morning as this was a Saturday and they called in Epi pens in case this happens again. The first shot she felt like she swallowed a potato chip wrong and started acting the same way then through up but never got this bad. We just thought she ate something and it went down the wrong way. Never giving it a second thought. Then after the second shot it was much worse. Had I not the pharmacist on the phone, Benadryl liquid and a medical bag, I would have called an ambulance. In the county we live in though we do not have enough ambulances and I am afraid she would have went into full anaphylaxis and died. I did what I thought was the best for my only child.

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1364592	6/1/2021	NE	59	F	5/26/2021	5/29/2021	Patient received the vaccine around 7:17pm on Wednesday, May 26th, 2021. She waited for 30 minutes after receiving the vaccine. She reported a funny/metal taste in her mouth and upon investigation, case reports showed this is a possible side effect of the Moderna vaccine. The reports said this was a self-limiting side effect with an unknown cause. The patient did not report any other side effects such as pulse rate, sweating, nausea/vomiting, headache, anaphylaxis, etc. Patient did not seem concerned. She called a week later to report that she had a stroke 72 hours later on Saturday, 5/29, in the evening. She reported experiencing a similar taste change when she received the contrast dye during her CT scan. She also had muscle cramps prior to the stroke. She is now out of the hospital and can no longer walk.

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1364295	6/1/2021	SC		F	3/23/2021		<p>fatigued; sick; mild low fever; This is a spontaneous report from a contactable consumer (patient). A non-pregnant adult female patient of an unspecified age received bnt162b2 (BNT162B2 reported as PFIZER/BIONTECH COVID-19 VACCINE), dose 2 intramuscularly administered in the left arm on 23Mar2021 15:30 (Lot Number: EN6207) as 2nd dose, single dose for covid-19 immunization. Medical history included viral hepatitis B chronic carrier ongoing since 1976 (contracted at age 20 when wisdom teeth were removed stable -no liver damage at all), hypothyroidism ongoing since 2014 (Thyroid lobectomy 2014), Low blood pressure ongoing since 2014 (began to feel dizzy about 2013-2014 of started fludrocortisone controlled by medication), temporary colitis from Nov2020 to unknown date and multiple cancer (4 family members have died of multiple cancers). The patient received the first dose of bnt162b2 (BNT162B2 reported as PFIZER/BIONTECH COVID-19 VACCINE) at vaccination age of 64-year-old intramuscularly in the left arm on 01Mar2021 (lot number: EN6205) 06:30 PM for covid-19 immunization but had anaphylaxis. In Nov2020, the patient had multiple scans & tests related to a gastrointestinal issue- a coloscopy. The patient experienced temporary colitis- other than the inflammation of the gastrointestinal system- no negative results. They did find a very small pre-cancerous polyp which was removed. Uncertain diagnosis could have been that the patient consumed contaminated food (but not clear)- did take cipro or ischemic colitis was hypothesized. The patient recuperated nicely (multiple inimalysis, blood test involved-all ok). She mentioned that that she typically have no respiratory issues, and less allergic reactions to environmental factors than the average person. She was mostly healthy, active, 64year old female- still walks, not overweight, no heart problems (just low BP). Concomitant medications included levothyroxine taken for post thyroid lobectomy ongoing since 2014; fludrocortisone taken for hypotension ongoing since 2014; bifidobacterium bifidum, bifidobacterium lactis, lactobacillus acidophilus, lactobacillus brevis, lactobacillus bulgaricus, lactobacillus casei, lactobacillus paracasei, lactobacillus plantarum, lactobacillus rhamnosus, lactobacillus salivarius (PROBIOTIC 10) taken for supplements (supplementation therapy) ongoing since an unspecified</p>

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							start date; ascorbic acid, biotin, carbohydrates nos, choline, fats nos, fibre, dietary, folic acid, minerals nos, nicotinic acid, pantothenic acid, proteins nos, pyridoxine hydrochloride, retinol, riboflavin, thiamine, vitamin b12 nos, vitamin d nos, vitamin e nos, vitamin k nos (FIBERSOURCE) taken for supplementation therapy ongoing since an unspecified start date; calcium taken for supplementation therapy ongoing since an unspecified start date; magnesium taken for supplementation therapy ongoing since an unspecified start date; unspecified multivitamins; unspecified vitamins and diphenhydramine hydrochloride (BENADRYL) on 23Mar2021 as premedication. The patient previously took antibiotics but had experienced throat tightness (In the mid-nineties I did have minor throat tightening w/antibiotics being administered at home by IV), sulfa [sulfadiazine] but had rash/hives w/ Sulfa drugs during her 20's, and Shingrix vaccine but had extreme nerve pain in legs in recent years (2019). The patient mentioned that she did not have anaphylaxis after second dose as she took 50 mg Benadryl per MD but she was relatively sick & fatigue after 2nd dose with mild low fever. She took 10-11 days to feel normal. She will still follow through with her primary care. The outcome of the event was recovered on an unspecified date in 2021.
1364284	6/1/2021	IL	18	M	5/16/2021	5/23/2021	Patient developed urticarial rash 1 week after receiving 1st dose of Moderna vaccine. Has had 4 ED visits for worsening urticarial rash despite receiving treatment. Saw patient in ED tonight with rash and throat tightness concerning for anaphylaxis, responded well to medications.

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1364043	6/1/2021	PA	56	F	1/30/2021	1/30/2021	bottom of face is still swollen- Feels like there's liquid in it; Had plastic surgery and those scars are redder today; headache; arm was hurting; swollen face/ swelling in face/ bottom of face is still swollen- Feels like there's liquid in it; This is a spontaneous report from a contactable consumer (patient). A 56-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 30Jan2021 (Batch/Lot number was not reported) (at the age of 56-years-old) as 1STD0SE, SINGLE for covid-19 immunisation. Medical history included facial surgery/face lift on Nov2020 and plastic surgery from an unknown date and unknown if ongoing. The concomitant medications were not reported. The patient previously took botox on Nov2020. The patient stated that had a face lift in Nov2020 and her face was slow to heal. Patient reported a swollen face after receiving the first dose of the pfizer covid 19 vaccine along with a headache on 30Jan2021. Patient wanted to know was the swollen face because her facial surgery had not healed or was it a reaction to the vaccine. On Sat- 30-40 min later, patient had swelling in face and her arm was hurting yesterday- headache today and bottom of face was still swollen and Feels like there's liquid in it. In Nov caller had plastic surgery and those scars were redder today. Patient wanted to know what she could take for her headache that she thought was related to the pfizer covid 19 vaccine. The patient was enquiring about any information regarding the use of the pfizer-bioNTech covid-19 Vaccine in people who have cosmetic fillers or Botox. Patient stated that she never had anaphylaxis to a vaccine and she had face lift surgery in Nov. Wanted to know if she had an allergic reaction to the vaccine or if it was from the surgery and she was not fully healed. Also stated that her left arm was hurting yesterday but was fine today. Outcome of the events swollen face/swelling in face/ bottom of face is still swollen- Feels like there's liquid in it and headache was not recovered. Outcome of the events arm was hurting, bottom of face is still swollen- Feels like there's liquid in it and had plastic surgery and those scars are redder today was unknown. Information on the lot/batch number has been requested. Follow-up (16Apr2021): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up

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							attempts have been completed and no further information is expected.
1362679	5/31/2021	WA	36	F	5/27/2021	5/30/2021	She received her second dose of the Pfizer Covid vaccine on 5/27 and had expected fatigue/chills/myalgias for the first 2 days. On Sunday evening she developed a full-body rash which started on her back and torso. The rash was itchy, small, red, raised lesions which coalesced into multiple patches on her bilateral upper and lower extremities. The rash is worst now on her lower extremities. She took one half of a tablet of Benadryl at 11:00. She began to develop left-sided angioedema of her lips and bilateral eyelid swelling. She took a full tablet of Benadryl at 1600 and called to the nursing line for her PCP and was advised to present to the ED. She did not have any trouble breathing. She has no voice changes. She did feel lightheaded this morning. She has not felt nauseous or had vomiting or diarrhea. She has had no new exposures, no new detergents/soaps/clothing, has not spent extra time outside. She has no known allergies but notes sensitive skin and some food sensitivities. Upon arrival to the ED, she is afebrile with elevated heart rate and blood pressure, with normal oxygen saturation and no respiratory distress on room air. On exam, she has bilateral eyelid swelling, mild left lip angioedema, and diffuse maculopapular rash. Differential diagnosis includes anaphylaxis, vaccine reaction, allergic reaction to unknown allergen, viral process. She shows no signs of severe anaphylaxis, shock, or respiratory compromise. She was given cetirizine and famotidine for histamine blockade. Based on the lack of other systemic symptoms, steroids were not indicated.
1362246	5/31/2021	TX	32	M	5/29/2021	5/30/2021	Anaphylaxis including full body urticaria and pruritis, coughing, and bronchial constriction. Immediately took Benadryl and albuterol which helped improve symptoms over about an hour. I had COVID infection about six months ago and recovered without incident from that.
1362090	5/31/2021	TX	49	F	5/29/2021	5/30/2021	Angioedema of mouth, hives, nausea and vomiting concerning for anaphylaxis

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1361908	5/30/2021	GA	55	F	5/30/2021	5/30/2021	01:25 pm: Patient felt lightheaded and warm (despite being cold prior to vaccine since it was "cold" inside), breathing was normal. Patient was still seated but legs were elevated. Patient given cool cloth to put on her forehead/neck.; 01:30 pm: Patient was still lightheaded, was slightly pale and had clammy hands. Blood pressure via automatic blood pressure monitor with arm cuff on the right upper arm was 63/47 with a pulse of 41. Breathing was normal. No signs/symptoms of anaphylaxis, therefore NO Epi-pen was administered. Patient was lied down with legs slightly elevated.; 01:32 pm: 911 was called. Patient states her right arm, primarily her right hand was tingly with loss of feeling. Patient reports no pain.; 1:38 pm: Patient reports blurred vision. Patient is pale and still a little lightheaded. Patient reports only having some yogurt today and no history of hypo/hyperglycemia. Blood pressure via automatic blood pressure monitor with arm cuff on the right upper arm was 100/70 with a pulse of 62. Breathing still normal. Still no signs/symptoms of anaphylaxis, therefore NO Epi-pen was administered. ~01:40 pm EMS arrives and leaves building to parking lot with patient on stretcher at ~01:50 pm.
1361812	5/30/2021	UT	15	F	5/29/2021	5/29/2021	Developed anaphylaxis with abdominal pain, nausea, vomiting, shortness of breath, chest pressure, hypotension and urticaria. Required IM epinephrine -> epinephrine drip as well as steroids and antihistamines.
1361663	5/30/2021	OK	37	F	4/20/2021	5/29/2021	I have never had any food allergies, but I ate roasted peanuts yesterday for the first time since my covid vaccines. I had anaphylaxis, throat swollen shut, swollen lips tongue and face. shortness of breath, runny nose, coughing, vomiting, chest pain about 15 minutes after eating.

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1361160	5/29/2021	IA	28	M	5/29/2021	5/29/2021	Syncope. Patient felt dizzy initially after receiving vaccine, moments later (within 1 to 2 minutes) the patient loss consciousness and started sliding out of chair as patients wife caught him and sat him down on the floor. Patient regained consciousness just as we were coming out to assist (within 5 to 10 seconds). We had him remain on the floor for a couple minutes before we sat him back in his chair and we watched him for an additional 15 minutes (30 minutes total). Also questioned and monitored patient, evaluating for any signs of anaphylaxis/allergy type symptoms as he recovered.
1361302	5/29/2021		16	M	5/29/2021	5/29/2021	Pt. with parent for second pfizer vaccine. Pt. had no reaction with first vaccine. After 20 minutes, pt noted hives on his legs and chest. EMS alerted. No SOB, no difficulty breathing. No hx of anaphylaxis from vaccines. Pt. given 25mg benadryl at 1657. After rest of allotted wait time pt. states hives are decreasing and pt. has no worsening symptoms. Pt. exited facility with parent.
1361161	5/29/2021		28	F	5/2/2021	5/2/2021	High Fever (104), Tinnitus, Felt like floating, Skin sensitive (pain) to touch things, Nausea, waited it out, lasted 24 hours after onset. Most intense first 12 hours after onset. 4 hours previous to onset began to sense swelling and tingling internally -- like anaphylaxis
1361068	5/29/2021	NJ	35	M	5/29/2021	5/29/2021	Patient felt dizzy and weak. Lost color and lips were very pale. Was awake, but confused and semi unresponsive via talking Requested water and sucking candy. We called 911. He started to improve. Color was coming back, but he was in a cold sweat. No signs of anaphylaxis. Was much improved by the time paramedics arrived. Checked out as precaution

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1360588	5/29/2021		70	F	3/19/2021		runny nose; had cold symptoms for "weeks"; sore throat; arm hurt; This is a spontaneous report from a contactable consumer (patient). A 70-years-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number: ER2613), via an unspecified route of administration, administered in Arm Left on 19Mar2021 as single dose for COVID-19 immunisation. The patient medical history included Spondylitis in neck, Inflammation/Arthritis, start and stop date not reported. The patient's concomitant medications were not reported. Historical vaccine included patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number: EN6200). On an unspecified date in 2021, the patient experienced runny nose, had cold symptoms for "weeks", sore throat, arm hurt. Reported that patient received treatment for the symptoms with Elderberry and Zinc lozenges. Reported that patient complaining of runny nose since receiving the Pfizer Covid vaccine. The first dose on 26 Feb 2021 and the second dose on 19Mar2021. Caller states she has had cold symptoms for "weeks" that include sore throat and runny nose, and this has been going on for a little while. The sore throat goes away, but the runny nose is persistent. Caller wants to know if these side effects have been reported?. Reported that patient question: Is it possible that I have Covid 19, I can still test positive with the vaccine right?, What do I do about the runny nose that does not go away?. When do these symptoms go away? On which response include beyond what is described in the Pfizer Covid vaccine Prescribing Information, Pfizer does not provide any recommendations regarding the management or treatment of potential adverse events/reactions/symptoms that a patient /consumer may experience. Beyond what is described in the <Pfizer Covid vaccine> Prescribing Information, Pfizer does not have information on how long what you are experiencing may last. There may be many factors to consider including your medical history and medical condition. Please consult with your doctor/healthcare provider about what you have experienced/are experiencing. Your doctor/healthcare provider is in the best position to advise you about the appropriate action to take as your doctor/healthcare provider is most familiar with your

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medical condition, clinical history, how your treatment has been conducted and any relevant information to your specific case. Reported that Dates for Runny nose: (From: 5Mar2021 To: Ongoing), Reporter seriousness for Runny nose: Unspecified; Dates for Ear ache: (From: Unknown To: Unspecified), Reporter seriousness for Ear ache: Unspecified; Dates for Sore throat: (From: Unknown To: Unspecified); Reporter seriousness for Sore throat: Unspecified; Dates for inflammation worsened: (From: 26Feb2021 To: Unspecified), Reporter seriousness for inflammation worsened: Unspecified Dates for fibrin buildup in hands: (From: 26Feb2021 To: Unspecified) Reporter seriousness for fibrin buildup in hands: Unspecified Dates for could feel her heart doing somersaults: (From: Unspecified To: Unspecified) Reporter seriousness for could feel her heart doing somersaults: Unspecified Dates for arm hurt: second dose: (From: Unspecified To: Unspecified) Reporter seriousness for arm hurt: second dose: Unspecified, Dates for covid 19 vaccine: (Start: 26Feb2021 Stop: Unspecified). Reported that patient take vaccination for indication freedom and to protect herself. Patient stated that she received her second dose on 19Mar2021 and she said that one would think that things would clear up and be okay but she's had a runny nose since about a week after the first dose of the vaccine. She was reluctant to get the second dose because she continued to have a runny nose, almost every day, all day long, sometimes it's worse, sometimes it's better. Her friend was visiting and said that he too has had a runny nose, and he thought it was from wearing a mask, but she doesn't wear a mask, but she doesn't wear a mask, well she only wear them when she goes out and she's not out that much. She just read something that said you can be carrying COVID, even though you've had the vaccine, is that a possibility?. Patient stated that her weight can fluctuate from 120 pounds to a pound up or a pound or three down. Reported that patient needs to know what they know about this, she is not the only one out there who has had side effects for a long time from the vaccine. Reported that patient stated that the runny nose has been happening for weeks. The runny nose comes and goes. Sometimes she thinks it's getting better and then it gets worse again. It's not like a side cold, she always has a little sniffle. It hadn't been bothering her the

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last couple hours and now it's started to well up and she's thinking what is this about? It started about a week after the first shot and definitely after the second shot. The runny nose is sometimes accompanied with earache and sore throat both of which continue to come and go. She doesn't know when the ear ache and sore throat started. They come and go quickly, and have happened maybe half a dozen times or more. Her husband would say it's just a cold and maybe it was. Reported that she gets a lot of inflammation, described as arthritic inflammation and this inflammation was worsened after the first vaccine. reported that this response happened about 4-5 hours later. She also complained of headache, and other symptoms and when asked to repeat the other symptoms she clarified as inflammation in whole body. reported that something new happened, she had fibrin buildup in her hands, she watched it grow on her hands, it was like a science fiction movie; that is still there. She's had fibrin before but never watched it happen. The buildup was itchy and she describes it as an inflammatory response. The fibrin buildup began that night after first dose of the vaccine. This started Friday night. Adds with the second dose her arm hurt. The caller does clarify that she felt fabulous after second dose, except her arm hurt. The fibrin and inflammation are still there, the only way it will go away is to have it cut out. That is how her body reacts. Patient reported that she fell on her knee and got a big bump and with further inquiry, this was prior to the vaccine. reported that she had some breathing issues after the first vaccine and was told that it wasn't anaphylaxis, it was probably swelling of her throat, but it didn't last. Reported that the second vaccine she didn't have any side effects except the arm hurt. In fact, she felt better than she does today, it put her in a good mood, it was like a happy pill. After the first vaccine she also had SVT in her heart, that night when she was having the inflammation, she remarks that she could feel her heart doing somersaults. The SVT began on the evening of the first vaccine and into the next day and into Sunday late afternoon. That was weird, she thought she was doing to die, she was not able to breathe, she was miserable, she thought to sleep it off, she was trying to get away from the headache, it was her whole head. Has anyone else reported this?. VACCINE SUPPLEMENTAL FORM include time the Vaccination Was Given:1100 first dose,

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second dose a little later Anatomical Location of Administration of Pfizer vaccine considered as suspect: Left upper arm. Vaccine was not Administered at Facility. Reported that no history of previous immunization with the Pfizer vaccine considered as suspect (or patient age at first and subsequent immunizations if dates of birth or immunizations are not available), no additional Vaccines Administered on Same Date of the Pfizer Suspect. No AE require a visit to emergency room and physician Office. Not received prior Vaccinations (within 4 weeks) but reported that patient received prior vaccinations: In Jul2020 shingles vaccine, she wondered if it was still in her system. Adverse Event: felt awful, more inflammation, Age was 69, Vaccine/Brand Name: Unknown Vaccination Date: July2020. Reported that family medical History Relevant to AE(s) included Father had similar kinds of inflammatory problems, bones, muscle tissue growth. The outcome of event sore throat was recovered on an unspecified date in 2021, outcome of event runny nose was not recovered and outcome of events arm hurt and had cold symptoms for "weeks" was unknown. No follow-up attempts are needed. No further information is expected.

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1360587	5/29/2021	CA	58	F	5/13/2021	5/1/2021	bladder infection; This is a spontaneous report from a contactable consumer via a Pfizer-sponsored program. A 58-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Batch/Lot Number: unknown) via an unspecified route of administration on 13May2021, as a single dose for covid-19 immunization. The patient medical history included asthma. The patient's concomitant medications were not reported. The patient previously took penicillin for Lung stuff and experienced Anaphylaxis. On May2021, the patient experienced bladder infection. It was reported as received her first dose of the vaccine on 13May2021 and started taking antibiotics for a bladder infection on Monday. Her antibiotic regimen will last for 5 days. Reports her reaction to penicillin was a long time ago, she has asthma and was always treated with penicillin for lung stuff, but that was a long time ago. Caller states since then, she never took penicillin, even the pills, she tries to avoid that. Stated earlier she got the first dose of the vaccine and right now she was taking antibiotics and she was scheduled for the second dose on 03Jun2021. Transferring agent states the caller is wondering if that was okay if she can get the second dose. The outcome of the event was unknown. Information about batch/Lot number has been requested.

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1360539	5/29/2021			U			<p>lot of dizziness / felt that patient is going to faint; Having lot of trouble getting out of the bed and not having somewhat balance; Nauseous / pretty severe nausea; Trouble sleeping; numbness; ache sometimes in the colon and it feels that I am going to faint; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (PFIZER BIONTECH COVID-19 VACCINE, solution for injection) via an unspecified route of administration on an unspecified date (Lot number was not reported) as unknown, single dose for COVID-19 immunisation. Medical history included anaphylactic shock syndrome and allergies to some chemicals and fluids. The patient's concomitant medications were not reported. Patient stated, "I am having, I do get anaphylactic shock syndrome or symptoms with certain allergies to some chemicals and fluids." Patient had the vaccine on an unspecified date. On an unspecified date, patient had a lot of nausea and had trouble sleeping, Patient was so nauseous in the morning with pretty severe nausea that has ease somewhat. Patient also a had lot of dizziness. Patient was having lot of trouble getting out of the bed and not having somewhat balance. Patient claimed that these are usual signs that some kind of reaction patient experiences but patient doesn't consider it even though these are on the verge to be anaphylaxis problem usually. Patient stated "When I am actually on the road, I get numbness and ache sometimes in the colon and it feels that I am going to faint and I have not had that." Patient felt slightly better at the time of report. The outcome of the events was recovering. No follow-up attempts are needed; information about lot/batch number cannot be obtained.</p>

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1360126	5/29/2021	OH	50	F	2/6/2021	2/1/2021	she had allergic reaction; Rash under her breast is, all over chest, back, and sides and it has moved up into her hairline; fever; achiness; body aches; sore arm; Massive headache; loss of appetite; extremely tired; Chills; This is a spontaneous report from a contactable consumer. A 50-year-old female patient received BNT162B2 (BNT162B2 PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for Injection, Lot Number: EL9269) via an unspecified route of administration on 06Feb2021 at 12:30 (at the age of 50-year-old) as a 1st dose, single dose in left arm for COVID-19 immunisation in School/Student Health Clinic. The patient's medical history included allergic to sulfa products taken for bad kidney, bladder infections 30 years ago; flu shots every year in the Fall around September or October and experienced soreness in arms, achiness and never had any other reactions and had COVID virus infection back during the end of the year. Concomitant medications were not reported. On 06Feb2021 Saturday night, the patient experienced sore arm and it was hard to lift like when she had flu shots in past. On 07Feb2021 Sunday, the patient experienced fever, achiness, body aches. The patient felt fine on 08Feb2021 Monday. Later on 08Feb2021, she experienced rash under her breast is, all over chest, back, and sides and it has moved up into her hairline. It does not itched, but irritating under her breast. On 09Feb2021, the patient went to urgent care, visited doctor in physician office and told she had allergic reaction and to not get the second dose, it could turn into anaphylaxis. On an unspecified date in Feb2021, the patient experienced massive headache, chills, loss of appetite, and was extremely tired. Patient enquired whether sulfa products is present in the Pfizer Biontech vaccine, as Sulfa is the only medicine she has been allergic to. The patient underwent lab tests and procedures included SARS-CoV-2 antibody test: unknown result on an unknown date. The clinical outcome of all the events was not recovered. Follow-up attempts are completed. No further information is expected.

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1359983	5/29/2021	AL	23	F	4/25/2021	4/25/2021	feeling like passing out; paleness; injection site pain; she felt tired, exhausted; headache; feeling like a golf ball is under the skin; inability to move her arm above her heart because the pain was so severe. Patient reports inability to use her arm and intense pain when changing clothes; feeling horrible; she couldn't function; she couldn't or eat; wanting to sleep; This spontaneous case was reported by a consumer and describes the occurrence of NEAR DEATH EXPERIENCE (feeling like passing out) in a 23-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 003B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included COVID-19 in April 2021, Narcolepsy, Depression, Anxiety, Loss of smell on 02-Apr-2021 and Loss of taste on 02-Apr-2021. Concurrent medical conditions included Drug allergy (Biaxin) and Drug allergy (Adderall generics-anaphylaxis related to an unidentified inactive ingredient in certain). Concomitant products included PARACETAMOL (TYLENOL), VITAMIN C [ASCORBIC ACID], COLECALCIFEROL (VITAMIN D3), FISH OIL and ZINC for an unknown indication. On 25-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Apr-2021, the patient experienced SWELLING (feeling like a golf ball is under the skin), MOBILITY DECREASED (inability to move her arm above her heart because the pain was so severe. Patient reports inability to use her arm and intense pain when changing clothes), FEELING ABNORMAL (feeling horrible), MOVEMENT DISORDER (she couldn't function), EATING DISORDER (she couldn't or eat), SOMNOLENCE (wanting to sleep), VACCINATION SITE PAIN (injection site pain), FATIGUE (she felt tired, exhausted) and HEADACHE (headache). On 26-Apr-2021, the patient experienced NEAR DEATH EXPERIENCE (feeling like passing out) (seriousness criterion medically significant) and PALLOR (paleness). The patient was treated with CHLORPHENAMINE MALEATE, PARACETAMOL, PSEUDOEPHEDRINE HYDROCHLORIDE (TYLENOL COLD MEDICATION) from 25-Apr-2021 to 30-Apr-2021 at a dose of 1 dosage form. On 26-Apr-2021, NEAR DEATH EXPERIENCE (feeling like passing out) and PALLOR (paleness) had resolved. On 02-May-2021, SWELLING (feeling like a

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							golf ball is under the skin), MOBILITY DECREASED (inability to move her arm above her heart because the pain was so severe. Patient reports inability to use her arm and intense pain when changing clothes) and VACCINATION SITE PAIN (injection site pain) had resolved. On 06-May-2021, FEELING ABNORMAL (feeling horrible), MOVEMENT DISORDER (she couldn't function), EATING DISORDER (she couldn't or eat), SOMNOLENCE (wanting to sleep), FATIGUE (she felt tired, exhausted) and HEADACHE (headache) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Apr-2021, SARS-CoV-2 test: positive. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Patient administered two Tylenol tablets per day from 25Apr2021 to 30Apr2021 to treat her symptoms. Patient reports these symptoms [unrelated to injected site] lasted 10-11 days. Patient reports no previous reactions to any past vaccinations. Patient reports loss of sense of smell and taste on 2Apr2021, which prompted her to get a rapid COVID-19 test, that initially resulted in a negative result. Patient reports receiving a phone call on 5Apr2021 notifying her that upon further laboratory testing of her sample, she was COVID-19 positive. Patient reports quarantining until 11Apr2021. Patient reports she was symptom free by 11Apr2021 when she discontinued isolation. Company comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.
1359901	5/29/2021	AK	30	F	5/28/2021	5/28/2021	The patient started vomiting about an hour after her second dose of Moderna. She then got hives and took Benadryl. Then she got short of breath and came to the ED. She was in respiratory distress on arrival but not clear that this was asthma or anaphylaxis. She was treated aggressively with epi, solumedrol, albuterol, and epinephrine

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1360979	5/29/2021	MD	37	M	5/27/2021	5/27/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Flushed / Sweating-Severe, Additional Details: He had blurred vision, sweating a lot and dizziness
1358078	5/28/2021	CA	33	F	5/27/2021	5/27/2021	Client received her first dose of the Pfizer Covid-19 Vaccine (lot # EW0185 exp. 08/2021) at 14:58. At approximately 15:14 the client walked over to the EMT station. The client was a 33-year-old female alert and tracking with her eyes. The chief complaint was arm numbness. The client stated that she started noticing arm numbness approximately 4 minutes after receiving her first Pfizer vaccination. The client was alert and oriented to person, place, time, and event. The primary assessment revealed that the client's airway, breathing, circulation were intact. The client denied any pertinent medical history such as medications and allergies. The client did not present with any hives, swelling, discoloration, signs, and symptoms of shortness of breath, or other signs of anaphylaxis. The client stated that her arm numbness started gradually and was only present on her inner forearm without any discomfort around the injection site. After the primary assessment was done the client agreed for EMTs to take a set of vital signs in a seated position. Vital signs are as follows: blood pressure 118/84, pulse 70, O2 saturation 99%, respirations 14. After the first set of vital signs was taken, EMT recommended the patient stay an additional 30 minutes for observation and the client consented. However, approximately 5 minutes into observation the client stated that she was feeling better and refused to remain for the remainder of the 30-minute observation. It was recommended that she contact her primary care doctor and received all pertinent information before her next dose. The client was instructed to call 911 if a severe allergic reaction were to occur. The client then departed in a positive disposition with steady gait at 15:20.

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1359711	5/28/2021	CA	49	F	5/28/2021	5/28/2021	49 y/o female without significant PMH other than anaphylaxis from a dental procedure, who presents to the emergency room with multiple complaints after receiving her second SARS-CoV-2 Pfizer vaccination today at about 3-3:30 PM, lot number not current available. The patient's significant other/boyfriend was driving when he noticed the patient suddenly started to complain of shortness of breath with chest pain and a maculopapular rash which later was followed by expressive aphasia and left hemiparalysis. She received Pepcid, solumedrol and Benadryl for the rash in the ER with improvement. Code neuro was called and TPA was given. Post TPA she was alert and oriented and she could currently write with her right hand and think of the words she has to say. She had associated blurry vision which has resolved after TPA was administered. She also was not able to move her left lower extremity nor her left upper extremity which is also improving to some extent after TPA administration. So far CT/CTA head and CTA neck are negative and she has been admitted for likely acute cerebral vascular accident.
1359303	5/28/2021	WA	39	F	5/28/2021	5/28/2021	Pt. arrived for first Pfizer vaccine, pt. alerted staff to anaphylaxis risk to bees and trees but stated she has never had an adverse reaction to vaccinations. Pt. has not used her epi pen in 10 years. Approx 10 minutes into observation pt. complains of lip tingling, swollen lips and states "half of face is swollen". EMS contacted and vital signs stable except for elevated blood pressure. Pt. given 25mg Benadryl and water. Second dose of Benadryl 25mg given at 1733. Pt. educated to seek medical attention if reaction increases. Cleared by EMS, pt. exited facility in stable condition with partner.
1359296	5/28/2021	AZ	23	F	5/27/2021	5/28/2021	Pt presented to ED at apx 1pm on 5/28/21 with signs of anaphylaxis. Swollen upper and lower lips, sensation of swollen throat, and facial swelling, with urticarial lesions to upper chest wall and arms. No GI symptoms. No hypotension. Received 0.3mg IM epinephrine, 50mg IV benadryl, 125mg IV solumedrol, and 20mg IV pepcid. Symptoms slowly resolved over 3-4 hours. Pt could not recall any other now inciting event or product other than vaccine she had yesterday around 4pm. No reaction to first pfizer vaccine noted.

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1359014	5/28/2021	NM	13	F	5/14/2021	5/15/2021	She had an upset stomach and was feeling really tired. Then the next morning, she had a rash - itchy and bumpy - torso, back arms and face. Went to the Doctor and she said it looked like an allergic rash. She told us that based on my daughter's genetics and her asthma - (I (her mother) had an anaphylaxis with my second Moderna shot - my entire body was giant hives.)- That he did not recommend her to have the 2nd shot. My daughter still has some of the rash - a little on her left cheek, stomach and back still. The itching is gone. She did take Benadryl for it.
1358812	5/28/2021	MD	47	F	5/26/2021	5/26/2021	About 15 min after the shot, I started to feel dizzy, but the BP was just little higher than my normal - 120-130/90 - 100 with pulse 70-88. No epi was administered and my husband (came with me due to my history of hypertensive anaphylactic reaction to an allergy shot) drove us home. By the time we got home, I was nauseated and my husband could see some fluid in my ear with an otoscope. He called an allergist office and the medrol pack was prescribed (also prescribed at the time of anaphylaxis previously). About 16 hours post-vaccine, I felt chills, then, low grade fever, headaches, bodyaches and heaviness/fatigue followed. Those symptoms came and went a few times. By 48 hours post dose, all flu-like symptoms dissappeared.
1358753	5/28/2021	CA	51	M	5/28/2021	5/28/2021	Per Dr. "The patient had an adverse reaction to his first dose 4/30. Initially, patient at first c/o tingling on the left upper lip, headache and feeling "sleepy." No e/o angioedema. He seems to initially be anxious about developing something similar to the prior reaction. Patient given water and plan to monitor. Patient has had long covid syndrome from prior dg of COVID in 1/2021. Reassured patient and told him to stay calm. While laying in the medical area. The patient c/o throat tightening and difficulty speaking. Daughter confirms that his voice has changed. The patient has had normal vital signs. No hives. Activated anaphylaxis pathway. He is now saying he can barely swallow his saliva. Patient is objectively handling secretions well. Epi administered and benadryl 50 PO given.~~

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1358721	5/28/2021	NY	29	M	5/25/2021	5/25/2021	Moderna COVID-19 Vaccine EUA Per EMT Chief Complaint: Dizziness 10:23 AM B/P 128/82 Pulse 46 Respirations 18 10:33 AM B/P 126/80 Pulse 48 Respirations 16 Patient CAO X 4, complaining of dizziness, pupils dilated, fisting with hands, appears nervous, vitals stable, pulse rate low but patient states he is a runner/soccer player. BLS assessment conducted, no issues noted, had breakfast, denies diabetic or similar history. Physician on site evaluated patient, appears to be anxiety, patient declined EMS, released when dizziness subsided. Instructed to monitor symptoms, seek medical attention for anaphylaxis or near syncope symptoms.
1358443	5/28/2021	PA	19	F	5/28/2021	5/28/2021	Mother alerted pharmacists before administration that their daughter experiences syncope with needles. The mother sat by her side as I administered the vaccine. The patient said that the vaccine hurt and sat their for about 5 minutes . At that time the patient said she did not feel well and laid on the ground. It is unclear if patient passed out for a few seconds. I spoke with patient to make sure she was conscious and then monitored her to look for signs of anaphylaxis. Her symptoms appeared to be related to anxiety rather than anaphylaxis. The pharmacy did call 911, but the patient and her family turned down the emergency service. I sat with patient for about 45 minutes to monitor her condition. When she improved they decided to leave that pharmacy. I did suggest they be looked at by a physician. We also called and check on patients well being and she seems to be doing fine.

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1357149	5/28/2021	TN		F	3/1/2021		<p>Pt States flare after covid vaccine; This is a spontaneous report from a contactable other hcp (nurse, reported for herself. A 59-years old female patient received BNT162B2 (Pfizer-Biontech Covid-19 Vaccine, Formulation: solution for injection, Lot Number and expiration date was not reported), via an unspecified route of administration on an unspecified date as 1st DOSE, SINGLE for covid-19 immunization. The patient also received tofacitinib citrate (XELJANZ XR), oral from Mar2021 (Lot Number: Unknown; Expiration Date: 30Jan2023) to an unspecified date, at 11 mg, daily for rheumatoid arthritis. Medical history included leukocytosis, hypertension, staphylococcal infection, Anaphylaxis from an unknown date, the patient had an unspecified surgery for ankle, also had rheumatoid arthritis from an unknown date. The patient's concomitant medications were not reported. On an unknown date, the patient states flare after covid vaccine. Patient states off medication for 1 week after covid vaccine. The outcome of the event was unknown at the time of report. No Follow-up attempts are needed. No Information about lot/batch number cannot be obtained.; Sender's Comments: The reported event flare up arthritis is assessed as unrelated to suspected drug BNT162b2 based from known patient's medical history or condition. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate</p>

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1358103	5/28/2021	NY	20	M	5/14/2021	5/15/2021	Received Moderna vaccine on 5/14/21. The morning of 5/15/21 the patient awoke with a pruritic rash on the trunk, which spread to the upper and lower extremities, and face. Patient went to emergency room and was given oral Benadryl x1, oral Prednisone 40mg x1, and sent home the same day with a topical steroid cream. Seen again at my office on 5/28/21. Rash had mostly resolved, but pruritic rash still present on lower back and buttocks. Rash has resulted in small open wounds due to scratching, with surrounding cellulitis. Currently treating with 7-day course of Bactrim for cellulitis. No evidence of anaphylaxis.
1357803	5/28/2021		43	F	1/21/2021	1/21/2021	Severe anaphylaxis with SOB, angioedema requiring 3 doses of Epipen, 1 dose of Benadryl 25 mg, Solumedrol. Transported to ER and was on Epinephrine drip for 10 hours.

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1358047	5/28/2021	CA	12	F	5/27/2021	5/28/2021	Client received her first dose of the Pfizer Covid-19 Vaccine (lot # EW0185 exp. 08/2021) at 11:28 AM. The client was brought to the EMT station by lead RN stating that the client was feeling "dizzy?" at 11:46 AM. The client was a 12-year-old female alert and tracking with her eyes and appeared anxious. The client had a chief complaint of lightheadedness. The client stated that she "began to feel lightheaded?" after her initial 15-minute observation had completed. This was the client's first dose of the Pfizer Vaccine and she stated reluctance to receive her first dose. The client denied any allergies and her parents stated that the client had a history of unspecified behavioral disturbances that require her to see a therapist. The assessment revealed no hives, swelling, discoloration, shortness of breath, or other signs and symptoms of anaphylaxis. The client denied a headache or wanting to throw up. The client refused to have her vitals taken by EMT but agreed at 1150 to remain lying down until she felt better. The client was encouraged to drink water while she waited. After 15 minutes and drinking a bottle of water, the client stated "I feel all better" but "I think I'm overthinking this" and stated that she was now experiencing a "headache?". RN asked the client's parents' permission to speak to the client. RN came over to reassess the client and that client finally agreed to have her vitals taken at 1208: 148/84 blood pressure, Pulse 94, 100% O2 on room air, Respirations 16, alert and oriented to person, place, date, and event. The client revealed to RN that she was experiencing anxiety from her vaccination but became much calmer after discussing her concerns further. Client also revealed that she engages in acts of self-harm but has no intent to end her life. The client's last set of vitals at 1216 were 128/76 BP, HR 96, O2 100%, Resp. 16. The client then stated that she was "ready to go?" after her last set of vitals. Lead RN asked to speak to client's mother in private. Lead RN provided mother with crisis hotline. Mother informed lead RN that client was in therapy and already seeking help. The client's parents were instructed to seek emergency care if a significant allergic reaction occurred later in the evening and were provided with all relevant vaccine-related information by RN. The client departed at 1220 in a positive disposition with her parents.

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

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1357924	5/28/2021	CA	43	F	5/27/2021	5/27/2021	Client received her second dose of the Pfizer Covid-19 Vaccine (Lot #EW0185 exp. 08/2021) on 5/27/21 at 09:41 AM. At approximately 1005 the client walked to the EMT station complaining of cramping on her right lateral side. EMT and RN responded. The client was a 43-year-old female who was alert and tracking with her eyes. The client had a chief complaint of shortness of breath. The client stated that she began to feel pain on her right side and that it was giving her mild shortness of breath. This was the client's second dose of the Pfizer vaccine. The client denied any known allergies or significant medical history. The client was not on medications. The primary assessment revealed that the client's airway, breathing, and circulation are intact. The client was negative for hives, swelling, discoloration, signs or symptoms of shortness of breath, or other signs of anaphylaxis. The client was alert and oriented to person, place, time, and event. The client stated that she "did not have anything to drink?" and was "feeling a bit nervous?". EMT had the client lay down on the cot and took the first set of vitals at 1007 and were as follows: Blood pressure: 124/88, Pulse: 68 and regular, O2 saturation 98%, and lung sounds clear, respirations 20. The client then consented to stay an additional 30 minutes after her initial observation. After 5 minutes the client stated she was feeling better after drinking some water. The second set of vitals was taken at 1014 and are as follows: BP 122/82, pulse 72, O2 saturation 98%, lung sounds clear., respirations 18. After her first 15-minutes of observation, the client stated that she was "feeling better?" and refused to complete the remainder of her thirty-minute observation. All pertinent information was given to her and her husband by EMT and RN. The client was also instructed to call 911 if a severe allergic reaction occurred later in the evening and was educated on the signs and symptoms to watch out for. The client departed at 1020 in positive disposition with her husband.

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1357768	5/28/2021	MD	59	M	4/2/2021	4/2/2021	Had covid infection Dec 2020. He received Moderna shot#1 on 2 Apr 2021: received shot, waited 15 min, went home (30 min drive), went bike riding outdoors, stopped riding after 15 min due to cold weather, went inside, while undressing for shower he noted redness of skin from waist up involving trunk and face, called nurse hotline, while talking to her he felt scratchy throat, was advised to call 911, 911 responded in 5 min, transport to Hospital, arrived ER in 5 min, given IV Benadryl but not epi. VS were nl on admission to the ER. He denies dizziness, SOB, cough, wheeze, chest tightness, diarrhea, abd cramping. Flushing improved over a period of five hours, discharged while still residually flushed. Redness fully resolved over two days. The redness of his skin was similar to what he experienced after an allergic reaction to a food spice in 2003. He has covid infection in Nov2020, had high fever, lost taste and smell. Self-treated w/ Tylenol at home, had + positive at Clinic (results verified on Database). Flushing and respiratory sx within an hour of receiving Moderna covid vaccine #1, in setting of a previous clinical infection/positive covid PCR testing in Dec2020, suggests anaphylaxis to Moderna vaccine. He may have developed ab during actual infection that caused IgE reaction to vaccine. I advised him to avoid further covid vaccines until further developments. He is most likely immune given previous clinical infection and positive PCR testing and receiving one vaccine. It is unknown how long immunity will last, what current covid ab titers mean, and whether he might be able to take an alternate vaccine in the future. He might merit skin testing with Miralax in anticipation for further PEG2000 containing vaccines in the future. Fol allergy at Location Note written 25 May 2021 during appointment w/ patient.

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1357364	5/28/2021	NM	60	F	5/20/2021	5/21/2021	anaphylaxis; This is a spontaneous report from a contactable consumer or other non hcp (Patient). A 60-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 2 via an unspecified route of administration, administered in Arm Left on 20May2021 11:00 (Batch/Lot Number: EW0165) as single dose for covid-19 immunisation (age at vaccination was of 60 years). Medical history included rheumatoid arthritis, surgical asplenia. Patient also allergic to Pineapple. No other vaccine was recieved by the patient in four weeks. The patient received other concomitant medications in two weeks. Historical vaccine included bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 1 via an unspecified route of administration, administered in Arm Left on 30Apr2021 14:30 (Batch/Lot Number: EW0169) as single dose for covid-19 immunisation (age at vaccination was of 60 years). On 21May2021 12:15, the patient experienced short of breath, increasing difficulty breathing, anaphylaxis, in order hoarseness, voice sounds like laryngitis, in order hoarseness, voice sounds like laryngitis, lips tingling, eyes swelling, wheezing, dizziness. Patient took 50mg Benadryl at 12:30 with no relief and went to ER. The ER (emergency room) diagnosed anaphylaxis and started treatment at 13:37. EpiPen, famotidine (Pepsid), SoluMedrol PF was given as treatment. Patient recovered with lasting effects. No covid prior vaccination was reported. Patient was not tested for covid post vaccination. Outcome of all events was recovered with sequelae. Follow up attempts are needed. Further information has been requested.

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1357308	5/28/2021	TN	22	F	5/14/2021	5/14/2021	Anaphylaxis; This is a spontaneous report from a contactable consumer (patient). A 22-years-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration, administered in arm left on 14May2021 11:00 (Batch/Lot number was not reported) as 2nd dose, single for covid-19 immunisation. Medical history included asthma, rocky mt spotted fever, MRSA, sepsis x2, mono (monocytes) from an unknown date. The patient's concomitant medications were none. No other vaccines within 4 weeks prior to the COVID vaccine. No any other medications the patient received within 2 weeks of vaccination. The patient received first dose of bnt162b2 on 23Apr2021 for covid-19 immunization at 22-year-old. Prior to vaccination, the patient was not diagnosed with COVID 19. Since the vaccination, the patient has been tested for COVID 19. The patient experienced Anaphylaxis, swollen closing throat,sob, wheezing, itching, dizziness on 14May2021 11:45. The adverse event result in Emergency room/department or urgent care. Therapeutic measures were taken as a result of all the events, treatment included Epi,Prednisone,Benedryl, IV. The outcome of the events was recovering. Information about lot/batch number cannot be obtained. Additional information has been requested.; Sender's Comments: Based on the known safety profile of the drug and plausible temporal relationship, a causal association between the event of Anaphylactic reaction and suspect drug BNT162B2 cannot be excluded

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1357254	5/28/2021	CO	44	F	4/18/2021	4/18/2021	have had off and on spotty bleeding but no monthly period; ringing in her ears; nausea; fever; eat half of what she normally ate; have had off and on spotty bleeding but no monthly period; anaphylaxis reaction; throat to stop feeling like it was closing up; severe headache; sinus pain that felt like someone punched her in the face; all over tingling sensation 20 minutes after getting the shot; chills; This is a spontaneous report from a non-contactable consumer (patient) via COVAES. A 44-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in the left arm on 18Apr2021 13:15 (Batch/Lot Number: ew0151) as 2nd dose, single dose (at the age of 44-years-old) for COVID-19 immunisation. Medical history was not reported. The patient did not have any concomitant medications. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and did not have any other medication within 2 weeks of vaccination. The patient has not been diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient has not been tested for COVID-19. The patient received his first dose of BNT162B2 on the left arm on 26Mar2021 17:30 (batch/lot number: er8127) for COVID-19 immunisation and experienced extreme structural pain and severe flu like symptoms for 4 days. The patient reported that on the second shot, she had anaphylaxis reaction along with severe headache, sinus pain that felt like someone punched her in the face, and all over tingling sensation 20 minutes after getting the shot. She had to drink 3 doses of BENADRYL for her throat to stop feeling like it was closing up. She then had ringing in her ears, nausea, fever, headache, and chills for 3 days. Since then, she can only eat half of what she normally ate. She has felt nauseated for a month and have had off and on spotty bleeding but no monthly period and a lingering headache that will not go away. The patient has yet to see her doctor due to COVID restrictions. The patient recovered from chills on an unspecified date. The patient has not recovered from headache. The outcome of the remaining events was unknown. No follow-up attempts are possible. No further information expected.

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1357149	5/28/2021	TN		F	3/1/2021		Pt States flare after covid vaccine; This is a spontaneous report from a contactable other hcp (nurse, reported for herself. A 59-years old female patient received BNT162B2 (Pfizer-Biontech Covid-19 Vaccine, Formulation: solution for injection, Lot Number and expiration date was not reported), via an unspecified route of administration on an unspecified date as 1st DOSE, SINGLE for covid-19 immunization. The patient also received tofacitinib citrate (XELJANZ XR), oral from Mar2021 (Lot Number: Unknown; Expiration Date: 30Jan2023) to an unspecified date, at 11 mg, daily for rheumatoid arthritis. Medical history included leukocytosis, hypertension, staphylococcal infection, Anaphylaxis from an unknown date, the patient had an unspecified surgery for ankle, also had rheumatoid arthritis from an unknown date. The patient's concomitant medications were not reported. On an unknown date, the patient states flare after covid vaccine. Patient states off medication for 1 week after covid vaccine. The outcome of the event was unknown at the time of report. No Follow-up attempts are needed. No Information about lot/batch number cannot be obtained.; Sender's Comments: The reported event flare up arthritis is assessed as unrelated to suspected drug BNT162b2 based from known patient's medical history or condition. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate
1358252	5/28/2021	CA	71	F	2/19/2021	2/19/2021	Patient developed hives and itching all over her body that are starting to resolve after using Zyrtec 4 times per day. No other symptoms of anaphylaxis. Second dose not recommended.

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1357662	5/28/2021	MA	33	F	5/27/2021	5/27/2021	Patient had a reaction to first Pfizer vaccine on 5-5-21 was treated and released with prescription for Prednisone. Patient was told by physician to receive her second dose but to pre-medicate with prednisone 50mg and Benadryl 25mg. Pt did as she was advised and received second Pfizer vaccine. She started exhibiting s/s of anaphylaxis within 5 minutes of the vaccine. Treated with 50mg benadryl and 2 epi pen injections of .3mg 5 minutes apart while awaiting EMS. Patient treated and released later in the day.
1354398	5/27/2021	UT	43	F	5/25/2021	5/25/2021	I started feeling nausea, extreme flushing of skin, heat radiating throughout body, vomiting, and swelling in throat within 3 minutes of injection. I started to actively throw up and shortness of breath I could feel my throat closing off and was struggling to breath. Within the first 10-15 minutes, I could not breath, swallow, and my body started to contract. I was given epinephrine, steroids, and other medications and emergency services dispatched. I was in Anaphylaxis

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1353344	5/27/2021	PA	65	M	3/7/2021	3/7/2021	5-10 minutes after injection, I noticed a small, itchy bump on my forehead-it feels like a tiny hive; the itching mostly subsided after an hour or so.I had no definite symptoms, but did feel a bit of rash around same time; This is a spontaneous report from a contactable consumer (patient). This 65-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, formulation: solution for injection, Batch/Lot Number: EN6199), via an unspecified route of administration, in left arm on 07Mar2021 18:30 (at the age 65 years) as single dose for covid-19 immunisation. Medical history included irritable bowel syndrome, possible pityriasis lichenoides, respiratory allergy (many respiratory allergies, some of them severe), skin tests for food allergies (had strong reactions to many food, unclear whether those are allergies), ragweed allergy (treated for years & a few times had strong reactions to those shots (not anaphylaxis)). Concomitant medications included montelukast; budesonide (NASOCORT) and cetirizine. It was reported that 5-10 minutes after injection, on 07Mar2021 18:45 patient noticed a small, itchy bump on my forehead -it felt like a tiny hive. The itching mostly subsided after an hour or so. Patient had no other definite symptoms but did feel a bit of a rush (maybe like feel when he take sudafed) around the same time. The clinical outcome of the events was resolved on an unknown date. No follow-up attempts are possible. No further information is expected.

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1354440	5/27/2021	UT	20	F	5/27/2021	5/27/2021	Patient received vaccine and said it was painless. She was accompanied by her mother, shortly in to her 15 minute waiting period her mother approached and said the patient felt light headed. I asked patient to remove her mask and assessed for any swelling of the lips or the face. Patient stated she did not have any issues breathing but felt very faint. Her eyes were very dilated, and she wanted to lay down. So we assisted patient to the floor, called Code White and 911. I stayed with patient as she lay down, she began to recover, but still looked very pale. I continually assessed patient for anaphylaxis, but patient reported no pain in injection site or issues breathing. Paramedics arrived and assessed patient, BP was normal, blood sugar was in the low normal range, paramedics determined that issue was not related to vaccine, but that she was dehydrated and had not eaten, which exacerbated the light headedness.
1354445	5/27/2021	MN	22	F	5/22/2021	5/23/2021	Patient obtained her 1st dose of the Moderna vaccine on May 22nd subsequent development erythema roughly 4 fingers below the injection site, roughly 24 hours after the injection. Notes associated swelling, warmth and discomfort. Denies any open wound, fevers, chills or malaise. Since then, erythema and swelling have progressed by increasing roughly 1 cm in diameter. Notes pruritus and discomfort have improved by the time of today's (5/27/21) clinic visit. She has tried no medications or topicals to treat the rash. No additional sites of rash. She denies syncope, lightheadedness, dizziness, lip swelling, tongue swelling, shortness of breath, wheezing, abdominal pain, nausea, vomiting. No PEG allergy history. No documented vaccine allergies. No allergies causing anaphylaxis.
1354502	5/27/2021	IL	13	M	5/26/2021	5/26/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Medium, Systemic: Headache-Medium, Systemic: Weakness-Severe, Additional Details: pt was mostly unresponsive and turning white and motionless; throat closing up; no other choice but to give the epi-jr shot; after administering the shot the patient started to feel better but we decided to still call 911 to be on the safe side

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1355237	5/27/2021	VA	32	F	5/27/2021	5/27/2021	Patient received vaccine and did not get and sit down, was watching her husband get his and about 5 minutes after giving the shot, she fainted and fell backwards, was alert in about 10 seconds after hitting the ground, ems was called, vitals monitored until they arrived, no anaphylaxis

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1351041	5/26/2021		60	M	4/21/2021	4/21/2021	Per triage notes on 4/21/21: Pt had his 2nd COVID vaccine today at 0800. At 0900 developed lip swelling. Took two doses of Benadryl and has now developed chest tightness and throat swelling. Per doctor's notes: Patient is a very pleasant 60-year-old gentleman who comes in for evaluation after a possible allergic reaction today, possibly related to a second dose of Pfizer Covid vaccine that he got at 8 AM this morning. About an hour later he started to feel flushed. He felt like his face was warm and his ears were warm. He started to feel like the inside of his mouth had filled with a rubber ball. His tongue felt full and he started noticed progressively that he felt like he was having difficulty swallowing. States that he never actually had any lip swelling, contrary to the triage note, just felt funny in the interior of his mouth. Did feel like his tongue was slightly swollen, both based on the fact that it felt "thick" when he was talking, and on direct inspection, as well. Took 50 mg of Benadryl around the time that his symptoms started, and lay down to nap for a little while. When he woke up he was still feeling like he was having more difficulty swallowing. He also felt like his face was a little bit puffy, prickly under each eye. He also felt like he had a blotchy rash on his chest and upper back, which his wife corroborates. He felt like his chest was a little bit tight and that something was heavy on his chest, though he was not wheezing or acutely short of breath, per se. Took another 50 mg of Benadryl at about 2:15 PM, and presented to the emergency department for further evaluation. Currently still has a little bit of chest tightness and throat tightness. He feels flushed. Symptoms have not worsened, but they have not completely resolved, either. He has had anaphylaxis in the past and has had to be admitted to the hospital. And this was in relation to taking doxycycline, it sounds like. Patient presented again to the ED on 4/22/21 with the same symptoms. He was admitted with anaphylaxis. Per ED notes, also diagnosed with Angioedema, improved. Likely related to second covid vaccine. Cant rule out secondary to Lisinopril.

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1349496	5/26/2021	FL	55	M	4/24/2021	4/24/2021	anxiety attack; heart racing; intense feeling of heat in body; tired; shortness of breath; This is a spontaneous report from a contactable other HCP (patient). A 55-year-old male patient received BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in arm left on 24Apr2021 16:30 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included allergy. There were no concomitant medications and the patient did not receive any other medications within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. The patient previously took levofloxacin and experienced allergy. The patient reported that approximately three minutes after taking the vaccine 24Apr2021 16:33 (also reported as 17:15), still waiting for the recommended 15 minutes to be released, he started to feel his heart racing and a very intense feeling of heat in body. After reporting to the nurse at the location, she listened to his heart asking him to take a deep breath several times. According to the nurse, he had an anxiety attack, as she did not show any signs of anaphylaxis. However, he felt very tired and the night with a little shortness of breath. He would like to know if he go for the second dose or look for another vaccine. the patient did not receive treatment for the events and the outcome of the events was resolved in 2021. Information on the lot/batch number has been requested.

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1349536	5/26/2021	VA	37	M	5/1/2021	5/1/2021	assuming it was an allergic reaction; slightly dizzy and a bit sick to my stomach (likely from the dizzy feeling).; slightly dizzy and a bit sick to my stomach (likely from the dizzy feeling).; This is a spontaneous report from a non contactable consumer (patient). A 37-years-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 01May2021 14:30 (Lot Number: EW0176) as 1ST DOSE, SINGLE for covid-19 immunization. Medical history included multiple sclerosis and known allergies: All mammalian meats (alpha gal protein), shellfish, and tree nuts. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. On 01May2021 02:45 PM, within a few minutes of receiving his first dose of the Pfizer vaccine, the patient became slightly dizzy and a bit sick to my stomach (likely from the dizzy feeling). Since it occurred within minutes, he was assuming it was an allergic reaction to the vaccine itself. He was obviously nervous about getting his second dose now. Often times anaphylaxis occurs the 2nd time you encounter a reaction inducing stimuli. No treatment received. Since the vaccination, the patient has not been tested for COVID-19. The outcome was recovered on May2021. This case was reported as not serious. No follow-up attempts are possible. No further information is expected.

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1349737	5/26/2021	SC	35	F	3/4/2021	3/4/2021	Anaphylactoid reaction; Dyspnoea; Swollen tongue; Throat tightness; This case was received via FDA VAERS (Reference number: 1072186) on 11-May-2021 and was forwarded to Moderna on 11-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ANAPHYLACTOID REACTION (Anaphylactoid reaction) in a 35-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 041L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for an unreported indication: FLU VACCINE VII. Concurrent medical conditions included Egg allergy and Allergy to vaccine (flu vaccine). On 04-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Mar-2021, the patient experienced ANAPHYLACTOID REACTION (Anaphylactoid reaction) (seriousness criterion medically significant), DYSPNOEA (Dyspnoea), SWOLLEN TONGUE (Swollen tongue) and THROAT TIGHTNESS (Throat tightness). At the time of the report, ANAPHYLACTOID REACTION (Anaphylactoid reaction), DYSPNOEA (Dyspnoea), SWOLLEN TONGUE (Swollen tongue) and THROAT TIGHTNESS (Throat tightness) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication reported. Waiting on the EMS to arrive the patient started having rebound anaphylaxis so was given shot of another EpiPen. Patient was then put into EMS and left for the hospital. Company Comment : Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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1350299	5/26/2021	OH	26	M	5/25/2021	5/25/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Hyperventilation-Severe, Systemic: Seizure-Severe
1350606	5/26/2021	WI	58	F	5/22/2021	5/22/2021	APPROXIMATELY 22 MIN. AFTER RECEIVING VACCINE, CLIENT BECAME LIGHT HEADED, DIZZY, SHORT OF BREATH, THROAT SWELLING, EYES WATERING, BLOOD PRESSURE DROPPED, TIGHTNESS IN CHEST. 911 CALLED. PARAMEDICS GAVE IV EPI. AND TRANSPORTED CLIENT TO HOSPITAL ER. MD DIAGNOSED ANAPHYLAXIS DUE TO COVID VACCINE. IN ER, CLIENT WAS GIVEN PREDNISOLONE AND ALBUTEROL TREATMENT. CLIENT RESTED IN ER WHILE BEING MONITORED. CLIENT THEN RELEASED TO GO HOME.
1350815	5/26/2021		52	F	5/25/2021	5/25/2021	Pt w/ hx of DM currently on Glipizide 10mg BID and Insulin Glargine 12units QHS. Pt vomited 50mL of digested food. Pt c/o flushing/sweating, nausea, and tingling at upper lip. Pt given PO fluid 1120mL inc. orange juice. Pt likely had a vasovagal episode given flushed and nauseous. No hives, stridor, wheezing, c/f anaphylaxis. Given lip tingling (as swelling or problem swallowing), given 50mg PO benadryl. BP 178/115, HR 95, RR 18 -- > 148/100 -- > 145/96, 90, 16 -- > 138/93 -- > 146/97, 86, 16. Pt feels much improved and requests to leave 30mins after initial adverse reaction began. Pt stable and released from the vaccination site. ER precautions discussed.
1351569	5/26/2021	HI	16	M	5/15/2021	5/15/2021	5/15/2021 1120: EW0182 1st dose QMC -BVC Pt c/o itching to throat, chest tightness immediately. Mother gave benadryl at 1207. Epi pen at 1235. Pt taken to ED by mother. Pt rec'd prednisone, famotidine after observation and dx of anaphylaxis to Pfizer Covid 19 vaccine.

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1351028	5/26/2021	TN	37	M	3/17/2021	3/18/2021	Patient adverse events and reactions the following: Breakout in rashes, hives and wheals all of his body. He had to be injected with two epipens and other meds to avoid anaphylaxis shock. Patient has an abnormal heart rate and gets monitored weekly on the effects of the shot. Breakout in rashes, hives, wheals, and have fast/pounding heartbeat daily.
1350913	5/26/2021	FL	48	F	5/25/2021	5/25/2021	Patient is a 48 y/o female who speaks only Spanish. Patient had interpreter present during client registration, vaccination and post vaccine occurrence. Patient was given Janssen COVID vaccine Lot # 1805031 in the left deltoid by this nurse at approximately 2:00PM. Client left the event without c/o after 15-minute observation. 2:55PM Client returned to the event and according to the RN client c/o drowsiness and dizziness. RN reports client HR 80 bmp (strong & regular); client B/P in right arm 152/100. Client c/o a headache at #8, on the pain scale of 1-10. Client also c/o pain in the front of her head. Client was alert and oriented skin warm and dry, color WNL and no gross dyspnea noted; client c/o left side chest pain traveling up the left side of her arm. 2:57PM Explained to client 911 will be called and 911 will decide if emergency room visit was warranted. 3PM Client remains alert and oriented with some diaphoresis and change in color noted. 3:02PM Client color returned diaphoresis improved 3:04PM Client reports she is ?feeling better?. 3:05PM Paramedics arrived. Client evaluated by paramedics. Paramedics applied oxygen and checked client vital signs. According to the paramedic client breathing was normal with good oxygenation. Client reports to paramedics she had COVID last year. The paramedic conducting the client assessment reports he felt client is hyperventilating and has no s/s of an anaphylaxis reaction. Client relayed to paramedic her headache is gone but her head, left arm and leg feels ?numb?. Client agreed to go to the emergency room. 3:25PM client left with via stretcher for ambulance transport to Emergency Room (according to paramedic ED was on diversion). 5/26/21 1:00PM Spoke with RN who reports client was discharged from the ED 5/25/21 to home and is feeling better. Per RN client plans to return to work 5/27/21.

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1348620	5/25/2021		12	M	5/15/2021	5/16/2021	Patient received vaccine at outside institution so lot number is not available. PCP is also at outside organization so limited information available. Below is information from Emergency room visit. 12 y.o. male who presented to the emergency department for Rash that the patient noticed around noon today while at his friends house after a sleep over. Patient received his first COVID vaccine yesterday at outside retail pharmacy at 1030am. Mother states it was Pfizer. Patient states "noticed the rash last night when they went to and has no other symptoms such as fever, chills, runny nose, head congestion, difficulty breathing, swelling of the lips, tongue, mouth, throat. Denies nausea, vomiting, abdominal pain. Patient states that is very itchy and they have been spreading and more been popping up since he noticed them. He denies any history of eczema, sensitive skin, food allergies. Mother does state that 2 years ago, the patient had a severe to the influenza vaccine in which she describes it as 8 inch area of redness, hot to touch, swelling around the injection site. No anaphylaxis reaction at that time either. Discharged with oral decadron and benadryl. Follow-up with PCP next day.
1348324	5/25/2021	UT	37	M	5/25/2021	5/25/2021	Patient returned to Pharmacy approximately 20 minutes after administration. He stated that his arm felt really sore, and he had tingling/numbness in his hand on the same side that he received his vaccine. No outward signs of Anaphylaxis, had patient remain under observation for approximately 20 more minutes after which time patient stated that his arm felt slightly better but still had that "tingling" feeling. He said it wasn't worsening or spreading. I counseled patient to seek additional medical care with primary care physician within the next 3 days even if the sensation goes away, and strongly recommended going to an ER immediately if he experiences any increase/ worsening of symptoms. I also asked patient to follow up with as and informed him that I would submit a VAERs report.

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1347791	5/25/2021	CA	47	F	5/22/2021	5/22/2021	<p>Patient started to not feel well almost immediately after the vaccine was given per certified pharmacy technician on 5/22/21 around 4:05 P.M. Patient started to experience symptoms not related to anaphylaxis, but more so related to hypotension and/or anxiety. Symptoms include dizziness, body fatigue, pins/needles throughout her body, and also patient started to "see dark spots" when she had her eyes open. No other immediate symptoms were present. Patient's condition improved over time and was able to get up from the chair by herself approximately 15-20 minutes post injection. Patient initially had a normal body temperature of 98.6 F. Temperature was taken every 5 minutes starting from 4:11 P.M for a total of 5 readings, which gradually increased to 100.5 F. Patient's condition started to worsen approximately 30 minutes post injection after improvement and looked like she was going to become unconscious. Ambulance was called due to worsening of symptoms again, and patient's care was transferred over at around 4:45 P.M. Patient was called on 5/25/21 at around 2:40 P.M. for follow-up. Patient has not fully recovered, but is on her way to recovery. Currently, her only symptoms are feelings of pins/needles throughout her body while all other symptoms are gone. Advised patient to follow-up with physician for her current symptom. Patient acknowledged and will see doctor soon. No date was given.</p>

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1347600	5/25/2021	OR	34	M	5/22/2021	5/22/2021	As a clinical monitor, I was called over to assess a driver slumped over in his seat. He had just received the second dose of the Pfizer vaccine approximately 10 minutes earlier. The passenger (his fiancé) said he was acting normal until she heard him grunt and then realized that he was passed out. While attempting to lay flat, I performed a jaw thrust that yielded a stridulous inspiration but was still unresponsive. He did not have a palpable carotid pulse. Paramedics was summoned emergently. Within 30-45 seconds, he awoke but was confused and amnesic to the event. He had no physical complaints and no significant medical or allergy history. I auscultated his larynx (no stridor) and his lungs (CTA). His initial vitals: BP 90/51 HR 61 VR 16 SaO2 100% An electrocardiogram demonstrated a sinus rhythm without ischemic changes or evidence of conduction delay. His glucose was 119. Over the next 30 minutes, he was able to drink two bottles of water and some orange juice. That said, he still said he "felt off." Repeat vital signs: BP 118/62 HR 69 SaO2 100%. The medics advised him to follow up with his doctor, preferably today. His fiancé agreed to drive him to an ED near their home for a more thorough evaluation. I provided her my phone number to provide to the ED for any questions. His clinical syndrome was consistent with a syncopal episode associated with orthostatic hypotension. Low suspicion for anaphylaxis.
1347484	5/25/2021	NC	85	F	5/25/2021	5/25/2021	Patient departed from vaccination clinic in no distress with no changes. Presented to ER with left sided facial droop which started on her drive home. Per ER note, patient did have aphasia and shortness of breath. Patient had quick change of respiratory sounds with suspected flash pulmonary edema. Noted to also have facial swelling. Anaphylaxis suspected. Patient intubated and admitted to ICU with guarded condition.

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1347318	5/25/2021	CA	15	F	5/24/2021	5/24/2021	Site: Pain at Injection Site-Mild, Systemic: Allergic: Anaphylaxis-Severe, Systemic: Chills-Severe, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Turning very pale, passed out and unresponsive, sweating-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Nausea-Medium, Systemic: Shakiness-Medium, Systemic: Weakness-Medium, Additional Details: After 5 minutes of vaccination, mom called for help in the waiting area. The patient passed out for a few minutes and responded after we both called her several times. We called 911. She was feeling nauseous. She sipped a little water and was looking very pale and was starting to become unconscious again. Mother thought it was an allergic reaction and asked for EpiPen. Epinephrine was administered, and patient became alert and less pale. EMS came and took her away due to low blood pressure
1347268	5/25/2021	CA	27	F	5/24/2021	5/24/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Difficulty Breathing-Severe, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Shakiness-Mild, Systemic: Weakness-Mild
1346820	5/25/2021	IL	35	F	5/19/2021	5/19/2021	Anaphylaxis: 1:45pm- Immediately upon receiving vaccine noted dry mouth 1:45-2:15pm- Waited at facility to monitor for reactions. Dry mouth sx increased and noted increased sweating from under arms. Cleared to go home as no other sx noted. 3:00-5:00pm- intermittent dry cough started 5:00-6:30pm- interior mouth, cheeks, lips and tongue started to feel like they were swelling, took 2 Benadryl 6:30pm-7:00pm- tongue, lips. and cheeks swelling increased. Lisp when speaking. 7:23pm Took 1st Epi-pen and headed to ER. On route to ER chest developed rash and voice became hoarse with episodes of nausea. In ER hands and forearms showed rash. Received IV Benadryl, Epi, and Pepcid. Discharged after 3 hours observation.

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1346691	5/25/2021	NY	14	F	5/25/2021	5/25/2021	8:50AM- patient started exhibiting symptoms of anaphylaxis (difficulty swallowing, difficulty breathing, lip tingling and tenderness. 9:30AM- Benadryl was administered (25mg chewable POx1) 9:30AM vital signs: HR 115, RR 22, O2Sat 98% on room air, BP 123/95, 9:33AM- EMS arrived 9:34AM- Epi pen administered . Patient tolerated well, school nurse notified. 9:45AM- Breathing appears better, still having difficulty swallowing 9:45AM vital signs: HR 120, RR 22, O2sat 95% on room air, BP 132/74 9:53AM EMS administered 10mg dexamethasone IM left deltoid, tele monitor placed on patient
1346469	5/25/2021		22	F	1/5/2021	1/5/2021	Unknown site. Unknown lot. Reported to patient's PCP. Anaphylaxis.
1346459	5/25/2021	MD	39	F	4/17/2021	4/17/2021	Anaphylaxis Saturday, April 17th Day of Vaccination: under 5 minutes - lips tingle, injection site incredibly itchy within 10 minutes, itching spread across back, hives/rash appeared, face became beet red, confusion, throat began to swell Alerted EMT at 5 minute mark, taken to triage, Transported to Hospital by ambulance, treated for anaphylaxis- given steroid injection (left thigh) and benedryl (right arm) Post-ER treatment - benedryl Continued Allergic Reaction Rash continued and got worse, returned to primary care doctor on April 27th Red rash protruded down arm and across back, throat swelled, thought to lymph-nodes swelling Primary care physician proscribed prednisone - 7 day course to stop allergic reaction ER doctor and primary care doctor recommended no second dose
1344202	5/24/2021	DC	24	F	5/8/2021	5/8/2021	Patient developed symptoms of throat swelling within 6-10 minutes of receiving the vaccine. She did not have any other symptoms. She was sent to the ER and evaluated. In the ER, vitals were normal and she was not dx w/ anaphylaxis. She was offered epinephrine and prednisone and declined. There was no edema noted on the ER exam. She was given Benadryl and says she improved within 20 minutes of the dose. She was d/c'd home and felt well after that with only some mild fatigue. She has had similar sx in the past assoc w/ eating eggs - this also involved shortness of breath, which did not occur w/ the COVID vaccine.

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1344241	5/24/2021	TX	40	F	4/8/2021	4/8/2021	That night, starting around 11:00, I started getting chills and feeling abnormally fatigued and achy. Pretty quickly, the chills got really violent and I felt really bad; like I had the flu. I noticed I was having trouble breathing. I have had anaphylaxis in the past before this. I did have a fever, it was low. I was up most of the night - bad night sweats; hurt all over, couldn't sleep as I was really miserable. The next day, I took Tylenol - around 03:00 am, but the next day I couldn't get out of bed and I had really violent chills, fever, body aches and headache was coming and going. I was still having trouble breathing. I took one Tylenol twice that day - one in the late morning and one in the evening sometime. Two days post vaccination, I started feel less bad, I still had a bit of a headache and I still had trouble breathing - chest was really tight. I was very low energy. I finally contacted my doctor after four days with trouble breathing. He told me to take an Advil or Tylenol and thought it was allergic response to vaccine. I took an Advil. The tightness decreased a bit. Didn't go away but noticeably better. The tightness was just continuing. The next day all the news came out about J&J vaccine, I called the doctor to tell him I was still having chest tightness and trouble breathing and they told me to call my PCP because they couldn't get me in. I called my PCP and she called back 2 hour later and I had just seen her the day before the vaccine and everything was very good that day she had seen me with oxygen, etc. . I went and go a pulse oximeter at Target - it came back at 100% and it would vacillate between 90-100%. My oxygen seemed fine. I thought it was a mass cell reaction to the vaccine - that's what I felt - and I continued to take Advil every so often. It was about a week post vaccine when the tightness in my chest finally normalized. I continued to have fatigue. I felt pretty bad for two weeks post vaccine - tired, blah, and flared up with my disease and run down but no trouble breathing after about a week.
1343971	5/24/2021	CT	29	F	2/17/2021	2/17/2021	within 15-30min of getting the vaccine the rashes and hives began to appear on my arms and shortly after my throat got tight and hard to breath. Went to the ER were they treated me. They determined it was anaphylaxis and prescribed an EpiPen.

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1342593	5/24/2021	NY	27	F	4/19/2021	5/10/2021	The patient presented to hospital with anaphylaxis without clear precipitating cause, possibly secondary to Pfizer COVID 19 vaccine. She presented to hospital on 5/22 with a lacy rash over the entire body and a change in her voice with a sensation that she couldn't breathe. She was given several doses of epinephrine, and steroids and improved, and was admitted to medicine for observation. She reported getting initially COVID-19 vaccine dose on 4/19/21. Thereafter had lacy rash over entire body for 3 days which she took as needed benadryl with improvement. After her second dose on 5/10/21 she initially had no symptoms. Approximately 6-7 days after her second dose lacy whole-body rash returned, worse than when she initially had it after first vaccine dose. She took benadryl several times but rash worsened. She had an odd sensation in her throat and noticed a change in the tone of her voice, and felt like she was having difficulty breathing. She presented to the emergency department.
1343780	5/24/2021	FL	19	F	5/19/2021	5/19/2021	Site: Pain at Injection Site-Mild, Systemic: Allergic: Anaphylaxis-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Flushed / Sweating-Severe
1343363	5/24/2021	TX	66	F	5/20/2021	5/20/2021	Within 5 minutes of vaccine administration, patient appeared shaky and reported tightness in throat. Pharmacy staff suspected anxiety/panic attack as symptoms appeared to be triggered by pharmacist stating that patient must remain on site for a 15 minute observation period in case of an immediate and serious reaction. Out of an abundance of caution, EMS was called and reported to the pharmacy. EMS stated airway was clear, and patient did not appear to be in anaphylaxis. Because patient was wheezing, epinephrine was administered, and patient was taken to local hospital. Patient was discharged around 10:00pm (approximately 5 hours after the incident).

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1345016	5/24/2021	CA	63	F	4/12/2021	4/12/2021	9:25 tongue had slight reaction, funny taste 10:23Anaphylaxis, took homeopathic Antihistimine, and Benadryl 25mg , Throat & Tongue swelling, funny chemical taste more intense. Tired all day, and pain at injection site. Day #2 Body aches, tired Day #3 Flu like symptoms Day #4 Flu like symptoms and SOB Chemical Taste more intense Day #5 Tongue Throat swelling all week, Benadryl all week. PM Start Prednisone ... Day #6 Throat better on the L side. Day #8 Tongue swollen & Chemical taste, throat esp on R, PM go to ER. shakey. Day#8-Day#14 Dry cough, more SOB, same symptoms, continue Prednisone Day #15 Saw Pulmonologist, hot w/ head rush, productive cough for 2wks; Day # 42 Not good, call for current status
1343345	5/24/2021	AZ	52	F	12/21/2020	3/16/2021	rash arms legs, itchy no desquamation or anaphylaxis occurring months later 3/16/2021

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1343189	5/24/2021	MA	56	F	5/20/2021	5/20/2021	She got her vaccine, she told her about the medicine that she had anaphylaxis too, she asked if she had any lip fillers. She waited the 15 minutes and then left, then started with a really bad headache and nausea, which she was fine before that. On the way home her husband wanted to stop and she said no as she was sick, made it home and started throwing up, very tired and went to bed which she never does but was extremely sick. Had fever of 100.1. She would go from sweating to fever, aches and pains, flu-like symptoms, everything hurt, pain in the arm, couldn't use her dominant arm but has lymphedema in the other arm due to having her breast removed due to cancer. Her lips were hurting her and never has chapped lips and had a lot of pain in them. Looked in the mirror on Friday as her lips were really hurting and found they were swollen and her eyes looked like somebody had punched her in them. She called her doctor and they did not return her call. She didn't feel it was anaphylaxis as she did not have any other symptoms. She put ice on her lips, had take a Zyrtec before the vaccine, but did use the Nasacort and couldn't figure out was going on. She had not used anything new on her lips or anything. Was thinking she had partial anaphylaxis. Went online and saw the reactions as they did not give her a list of them. She called her doctor and they told her to go to the ER. She still has some swelling and redness with pain, but not an emergency for her to go to the ER. Her lips are swollen, very tiny flat things in her mouth. Wants to know if she's OK to get 2nd vaccine as her PCP will not call her back.

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1343176	5/24/2021	MA	56	F	5/20/2021	5/20/2021	She got her vaccine, she told her about the medicine that she had anaphylaxis too, she asked if she had any lip fillers. She waited the 15 minutes and then left, then started with a really bad headache and nausea, which she was fine before that. On the way home her husband wanted to stop and she said no as she was sick, made it home and started throwing up, very tired and went to bed which she never does but was extremely sick. Had fever of 100.1. She would go from sweating to fever, aches and pains, flu-like symptoms, everything hurt, pain in the arm, couldn't use her dominant arm but has lymphedema in the other arm due to having her breast removed due to cancer. Her lips were hurting her and never has chapped lips and had a lot of pain in them. Looked in the mirror on Friday as her lips were really hurting and found they were swollen and her eyes looked like somebody had punched her in them. She called her doctor and they did not return her call. She didn't feel it was anaphylaxis as she did not have any other symptoms. She put ice on her lips, had take a Zyrtec before the vaccine, but did use the Nasacort and couldn't figure out was going on. She had not used anything new on her lips or anything. Was thinking she had partial anaphylaxis. Went online and saw the reactions as they did not give her a list of them. She called her doctor and they told her to go to the ER. She still has some swelling and redness with pain, but not an emergency for her to go to the ER. Her lips are swollen, very tiny flat things in her mouth. Wants to know if she's OK to get 2nd vaccine as her PCP will not call her back.
1343074	5/24/2021		58	F	4/18/2021	4/18/2021	Pt comes to the ER via EMS after getting her first dose of Moderna covid vaccine. She has hx of anaphylaxis. Shortly after her shot, the pt felt throat fullness, she began to cough, and she felt like she might not be able to breathe. She gave herself her own epi-pen injection. EMS was called. She continued to feel unwell en route and got a second dose of epi. Here, she is still coughing, though her throat doesn't feel as tight. No rash. No facial swelling; ordered dexamethasone 10mg inj, famotidine 20mg inj

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1343047	5/24/2021		29	F	5/21/2021	5/21/2021	Pt came to desk stating felt like throat was "closing up and tongue swelling". Pt able to speak clearly, no audible wheezing or stridor noted, denies difficulty breathing. Taken immediately to ED, placed into room, nurse with pt and report given, Dr. with pt. No overt signs of anaphylaxis, but discharged with steroids, epi-pen, and benadryl and consulted on returning if new, worsening, or concerning symptoms arise
1343823	5/24/2021	NV	17	F	5/22/2021	5/22/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Fainting / Unresponsive-Severe
1341640	5/23/2021	VA	15	F	5/21/2021	5/21/2021	Site: Redness at Injection Site-Mild, Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Systemic: Allergic: Itch (specify: facial area, extremities)-Severe, Systemic: Allergic: Swelling of Face / Eyes / Mouth / Tongue-Severe, Additional Details: pt's tongue felt funny, then her throat felt tingly, progressed to throat beginning to close. given 50mg benedryl and 20mg pepcid at pharmacy and she went by ambulance to ER. she will undergo further testing this week at allergist to see if she is allergic to polysorbate and peg.

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1342071	5/23/2021	CA	14	F	5/23/2021	5/23/2021	Client was feeling "cold." Client was a 14-year-old female sitting upright in her observation chair, alert and tracking with her eyes. Client had a chief complaint of dizziness and feeling cold. Client stated that she began to feel cold and dizzy a few minutes after her observation had begun. This was the client's first dose of the Pfizer vaccine. Client denied any medical history or known allergies. Assessment revealed no swelling, hives, discoloration, shortness of breath or other signs and symptoms of anaphylaxis. Client stated that she felt "cold" and "dizzy." Client stated that her only meal was the snacks provided at the vaccination site. Airway, breathing and circulation were intact. Client's initial set of vitals at 1006 was 116/78 blood pressure, 80 heart rate, respirations 16, alert and oriented to person, place, date and event. Temperature 97.8*f. EMTs present were unable to obtain an O2 sat due to client's nail but client was negative for signs of shortness of breath. Client was asked to lie down until her complaint was resolved. Client was provided with food and was able to eat without difficulty. Client was reassessed every 15 minutes due to her stability. Vitals were as follows: 1011 - 108/78, 84, resp. 14 1021 108/78, 88, resp 14 1029 - 108/78, 80, resp 16. After approximately 10 minutes, the client denied any symptoms and was asked to sit up in an observation chair for the remainder of her observation. Client and her mother were instructed to seek emergency care if signs or symptoms of an allergic reaction occur later this evening.

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1342002	5/23/2021	CA	17	U	5/23/2021	5/23/2021	On 05.23.21 client received her second dose of the Pfizer Covid-19 Vaccine (LOT # EW0185 EXP. 08/2021). Client approached EMT and stated that they felt "nausea." Lead nurse and Co-Lead nurse also responded. Client was a 17-year-old non-binary individual alert and tracking with their eyes. Client had a chief complaint of nausea. Client stated that they noticed their nausea a few minutes after beginning their observation. This was the clients second dose of the Pfizer vaccine. Client denied any medical history and stated they only take melatonin at bedtime. Assessment revealed no swelling, hives, discoloration, shortness of breath or other signs of anaphylaxis. Client was complaining of nausea that came on abruptly after their vaccination. Client stated they had breakfast this morning but not very much water. Client also stated they felt nervous after their vaccination. Airway, breathing and circulation are intact. Client's initial vitals at 0915 were: 92/64 blood pressure, 68 heartrate, respirations 14, O2 100% on room air, alert and oriented to person, place, date and event. Temperature 97.8*f. Client consented to an additional 30-minute observation and was asked to lie down for at least 15 minutes. Client was provided with water and was reassessed every five minutes until their complaint was resolved. After lying down for 15 minutes, the client stated that their nausea had resolved. Client sat up in an observation chair for the last 15 minutes and stated that their nausea was all gone at the completion of their observation. Clients remaining vitals were 0920 - 110/74, 84, 100%, resp. 14. 0925 - 110/74, 84, 100%, resp 14, 0925- 110/74, 84, 100%, 0930 - 110/74, 88, 100% resp. 14, 0940- 120/78, 88, 100%, resp. 16, 0945 - 118/78, 80, 100% resp 14. Client was provided with relevant vaccine information and instructed to seek emergency care if a severe reaction happened later. RN and EMT worked together to educate client about possible symptoms they could experience. Client acknowledged what they were told and departed facility at 0947 with their mother in positive disposition with steady gait.

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1341205	5/22/2021	WA	53	F	5/22/2021	5/22/2021	Patient has history of a history of idiopathic anaphylaxis and has allergies to many medications. Patient had premedicated herself with Symbicort, Montelukast, diphenhydramine 50 prior to coming in. But 5 minutes after receiving the Covid vaccination she developed throat itching itching all over her skin/lungs, and chest tightness with intermittent coughing. Code Blue was called, and patient was taken to the ER. Patient received epinephrine, famotidine, benadryl and methylprednisone. Patient was monitored in the ER and eventually discharged home.
1341187	5/22/2021	VA	28	M	5/22/2021	5/22/2021	Patient received the vaccine in the left arm and was fine. Patient sat and talk to family members and about 10 minutes he felt light headed and wanted to lie down. His breathing was normal, no allergic or anaphylaxis reactions or symptoms, 3 times patient declined the need of 911 call. Patient declined any medical service, as does not need it. Patient rested on the chair with his leg up and then patient wanted to rest on the floor with his leg elevated for a few minutes. Pharmacist called the manager to be present, again we offered water, drink or any foods patient would like. He said that he was fine and that he just needed to sit and rest for a few minutes. After about 10 minutes, he was fine, stood up and walked away without further light head symptom.

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1340328	5/22/2021	LA	40	F	2/3/2021	2/3/2021	<p>broke out in canker sores all over mouth again; Slept 17 hours q day; severe fatigue; Sinus and ear pressure; Sinus and ear pressure; Generalized aching; break out in canker sores all over my mouth; sore muscles all over; joint pain; mild itching to upper torso, breasts and under arms; low grade fever; chills; face became pink and warm; felt burning sensation throughout my body; This is a spontaneous report from a contactable nurse (patient). A 41-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 intramuscular, administered in deltoid left on 03Feb2021 12:00 (Batch/Lot number was not reported) as 1st dose, single at age of 40-years-old for covid-19 immunization. Medical history included Asthma, 3 herniated discs in neck, hx of pneumonia, hypertension (HTN). Known allergies included: Ceclor, PCN, Doxycycline, Bactrim DS, Codiene, berries and anaphylaxis to Latex. Concomitant medications the patient received within 2 weeks of vaccination included: lisinopril; hydrocodone bitartrate, paracetamol (HYDROCODONE/ACETAMINOPHEN). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Adverse event started on 03Feb2021 14:00 PM, within first 24 hours the patient experienced mild itching to upper torso, breasts and under arms, also had low grade fever and chills in this time. Within first 24 hours, face became pink and warm, and felt burning sensation throughout her body. At this point the patient took Pepcid and Benedryl and it seemed to control symptoms. On 09Feb2021, the patient begun to break out in canker sores all over her mouth, total of 5 (the patient did not have a canker sore since high school), began to develop sore muscles all over and joint pain that progressed to severe by 12Feb2021. Worse in mornings. Got a flu and covid test (Nasal Swab). They were negative. 17Feb-20Feb2021 severe fatigue and cont. Joint pain. Slept 17 hours q day. Sinus and ear pressure. Generalized aching. The patient did not get 2nd vaccine. 01Mar2021 broke out in canker sores all over mouth again. Took 4 days to resolve. The patient was still having significant joint pain throughout her body, worse in mornings. The patient never had this before vaccine. Events resulted in disability or permanent damage. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the</p>

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patient has not been tested for COVID-19. Outcome of the event canker sores was recovered, of other events was not recovered. Follow up needed, further information has been requested.; Sender's Comments: "Based on the information in the case report and a plausible temporal relationship, a possible causal relationship between the events and suspect drug BNT162B2 cannot be excluded" The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

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

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

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1340279	5/22/2021	PA	52	F	4/1/2021	4/1/2021	Headache, like her head was being squeezed in a vice and a screwdriver was in the right side of her skull; Vomiting; Coughing; Anaphylactic Reaction; Blood pressure was very high; started rubbing chest, did not feel the same way as when they first arrived at the facility; Dizzy; Vertigo; Feeling unwell; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of ANAPHYLACTIC REACTION (Anaphylactic Reaction) in a 52-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 018B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Anaphylaxis, Hypersensitivity reaction, Asthma, Hives (Hives/urticaria), Drug allergy (Codeine-Severe Vomiting. Morphine-Fell asleep within minutes of receiving Medication.), Hives (Severe Hives (High Tryptase Level). Under Care of Allergist, taking Bee Sting Shots and Xolair Shots. No hives since November of 2020,) since 01-Aug-2019 and Hydrocephalus on 01-Aug-2004. Concomitant products included CETIRIZINE HYDROCHLORIDE (CETRIZINE) from 01-May-2020 to an unknown date and FAMOTIDINE from 01-May-2020 to an unknown date for Hives. On 01-Apr-2021 at 1:00 PM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Apr-2021, the patient experienced VERTIGO (Vertigo), MALAISE (Feeling unwell) and DIZZINESS (Dizzy). On 01-Apr-2021 at 1:15 PM, the patient experienced CHEST DISCOMFORT (started rubbing chest, did not feel the same way as when they first arrived at the facility). On 01-Apr-2021 at 1:20 PM, the patient experienced ANAPHYLACTIC REACTION (Anaphylactic Reaction) (seriousness criterion medically significant) and BLOOD PRESSURE INCREASED (Blood pressure was very high). On 01-Apr-2021 at 1:30 PM, the patient experienced COUGH (Coughing). On 01-Apr-2021 at 1:35 PM, the patient experienced VOMITING (Vomiting). On 01-Apr-2021 at 5:30 PM, the patient experienced HEADACHE (Headache, like her head was being squeezed in a vice and a screwdriver was in the right side of her skull). On 02-Apr-2021 at 1:00 PM, ANAPHYLACTIC REACTION (Anaphylactic Reaction) had resolved. At the time of the report, VERTIGO

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(Vertigo), COUGH (Coughing), MALAISE (Feeling unwell), DIZZINESS (Dizzy), CHEST DISCOMFORT (started rubbing chest, did not feel the same way as when they first arrived at the facility), VOMITING (Vomiting) and HEADACHE (Headache, like her head was being squeezed in a vice and a screwdriver was in the right side of her skull) had resolved and BLOOD PRESSURE INCREASED (Blood pressure was very high) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-Apr-2021, Blood chloride (96-106): 109 mmol/l High. On 01-Apr-2021, Blood pressure measurement (unk-unk mmHg): 224/107 mmHg (High) The nurse called the EMT who took her blood pressure about 20 minutes after receiving the injection. Her blood pressure was very high. She didn't remember exact numbers, but stated it was something like 224/107. The EMT asked her if she had taken her blood pressure medications that morning and she told him she does not take blood pressure medications., 194/107 mmHg (High) @15:15 and 194/110 mmHg (High) @16:30. On 01-Apr-2021, Carbon dioxide (24-32): 22 mmol/l Low. On 01-Apr-2021, Chest X-ray: normal (normal) Clear lungs. Thoracic portion of a ventriculoperitoneal shunt catheter was seen to the right of midline and appeared intact. On 01-Apr-2021, Electrocardiogram: normal (normal) EMT did an EKG and stated it was normal. On 01-Apr-2021, Full blood count: normal (normal) normal. On 01-Apr-2021, Metabolic function test: normal (normal) normal. mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was withdrawn on an unknown date. Patient was given two baby aspirin by mouth on 01 Apr 2021 and was then sent to the emergency room (ER) due to her blood pressure. Patient was not given anything for vomiting, but had continued to fill multiple emesis bags. Additional tests included cardiac monitor and continuous pulse oximetry. On 01 Apr 2021 at 19:30, the nurse started an IV and administered Zofran plus another medication the patient could not recall. The patient began to feel better, finished the IV and was able to stand without dizziness. The patient saw another ER physician at 23:30 who did not think the event were related to the vaccine. This physician sent the patient home (discharged at approximately 1:00 on 02 Apr 2021). On 08 Apr 2021, the patient saw her allergist who confirmed it was an

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anaphylactic reaction to the vaccine. Patient indicated that nausea/vomiting, difficulty breathing, chest tightness, and cough were signs and symptoms experienced. The patient's allergist informed the patient they were not to get the second Moderna shot. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 06-May-2021: No New Information (NNI). On 19-May-2021: ADR response received which provided additional event details, outcomes, treatments, ER lab/diagnostic results.

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1340340	5/22/2021	AR	65	F	4/26/2021	4/26/2021	Throat was swollen, started having anaphylaxis; Throat was swollen, started having anaphylaxis; Blood pressure got totally out of control, it just spiked; had like a fever; Injection site turned red, swollen, angry, itching; Injection site turned red, swollen, angry, itching; Injection site turned red, swollen, angry, itching; got a very bad headache; nausea; chills; Brain fog; fatigue; This is a spontaneous report from a contactable consumer (patient). A 65-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: EW0162 and expiration date not provided), via an unspecified route of administration, in left arm, on 26Apr2021 09:30 (at the age of 65-year-old), at single dose, for COVID-19 immunization. Medical history included blood pressure, patient had anaphylaxis to other drugs in the past, the medication was an ace inhibitor caller took years ago when trying to help blood pressure. Family Medical History provided as "no". Concomitant medications included losartan for blood pressure (patient had been on this medication for years); and progesterone (began taking this medication probably last summer). The patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EW0153 and expiration date not provided), via an unspecified route of administration, in left arm, on 05Apr2021 13:30 (at the age of 65-year-old), at single dose, for COVID-19 immunization. No additional vaccines administered on same date. The patient got a very bad headache from 26Apr2021 (about an hour after received second vaccine); nausea from 26Apr2021; chills from 26Apr2021; brain fog from 26Apr2021; fatigue from 26Apr2021; throat was swollen, started having anaphylaxis from 28Apr2021 (in the evening) to 02May2021 (it had eased up enough and patient could swallow); blood pressure got totally out of control, it just spiked from 28Apr2021, patient was still having trouble getting it back down. Patient had to double up on blood pressure medication. Patient stated it was persisting a little bit. Patient's blood pressure was going way higher than what it would normally. Patient only took 25mg of losartan. Patient's blood pressure usually never went over 125. Injection site turned red, swollen, "angry", itching and had like a fever from 28Apr2021. On 26Apr2021, patient got a very bad headache, nausea,

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							chills and fatigue. Patient was expecting all of this. Patient was sick on 26Apr2021 and 27Apr2021 and had to stay in bed, clarified she was sick with headache, chills and fatigue. On 28Apr2021 (Wednesday), patient's throat was swollen, started having anaphylaxis. The outcome of the events "headache, nausea, chills, brain fog" was recovered on 27Apr2021; of "fatigue" was recovering; of "throat was swollen, started having anaphylaxis" was recovered on 02May2021; of "blood pressure got totally out of control, it just spiked" was not recovered; of "injection site turned red, swollen, angry, itching and had like a fever" was recovered on 03May2021.
1336259	5/21/2021	OR	92	F	2/2/2021	5/20/2021	Anaphylaxis
1337617	5/21/2021	NY	14	F	5/19/2021	5/19/2021	Child had hives on all 4 extremities, no flank or head. No additional body system complaints. VVS except for elevated pulse of 118. Pt was assessed in the presence of mother. They agreed to administer Benadryl 25mg po - brought to site by mother, given at 1710. Child remained for full 30 minutes, rash subsided but did not disappear. No additional complaints/concerns noted. Pulse decreased to 103 with no discomfort or distress. both reviewed indications for calling PCP and/or EMS. Mother noted that pt's sister has anaphylaxis allergies and the family is well versed in management and has EpiPens. Pt's MD was contacted following day and advised parents that she may receive the second dose of Pfizer. Her symptoms have completely resolved with no adverse effects.
1336133	5/21/2021	WA	67	F	5/3/2021	5/3/2021	5-3-2021: at 11:54 am got J&J Covid-19 vaccine at Pharmacy. No anaphylaxis or other severe reactions within first four hours. By 8:00 pm began feeling fatigued and generally warm. No nausea or vomiting. By 11:00 pm developed diffuse soreness of left deltoid at injection site, mild chilling, muscle aches, T 98.8. Then developed severe shaking chills and profuse sweating, generalized, systemic burning sensation, nausea, light-headedness. This reaction lasted through the night, about 8 hrs. I spent 5-4-2021 in bed, and started feeling a bit better by 7:00 pm. By the next day felt very weak, light-headed and tired, and a little short of breath with movement. By 5-8-2021 felt pretty much back to normal, but tired. Arm soreness resolved. Reported reaction to my MD.

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1339031	5/21/2021	NY	17	F	5/21/2021	5/21/2021	Initially developed hives then swelling of lips, face and difficulty breathing with cough (anaphylaxis reaction). Treated by school nurse with epipen then ambulance paramedics arrived and administered nebulizer treatment, IM benedryl, dexamethasone and transported to ER for follow up stabilization. ER administered additional antihistamine. Patient was discharged from ER stable and in much improved condition.

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1336288	5/21/2021	CA	56	F	5/17/2021		<p>TIREDDNESS; TINGLING FACE FOR 5 MINUTES; CLOSING OF THROAT ABOUT 5 MINS BUT AIRWAY CLEAR; TONGUE SWELLING FEW MINUTES; HOT FACE; HIGH BLOOD PRESSURE; HIGH HEART RATE; FEVER; This spontaneous report received from a pharmacist concerned a 56-year-old female. The patient's height, and weight were not reported. The patient's past medical history included anaphylaxis reaction to flu shot, and concurrent conditions included hypertension, hypocholesteremia, and migraines. The patient was previously treated with Lisinopril, Atorvastatin, Zonisamide for migraine, Tizanidine for muscle pain related to migraine, Promethazine, Ketorolac, Trazodone for sleep, Influenza vaccine (Flu shot); and experienced drug allergy when treated with Epinephrine for unknown indication. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 201A21A, expiry: 23-JUN-2021) dose was not reported, administered 01 total, on 17-MAY-2021 in left arm for prophylactic vaccination. No concomitant medications were reported. On 17-MAY-2021, about 15 minutes after vaccination, the patient experienced tingling face for 5 minutes, closing of throat about 5 mins but were airway clear, tongue swelling for few minutes, hot face, high blood pressure, high heart rate, and fever, was given Benadryl (diphenhydramine hydrochloride) 50mg IM (intramuscular) to right arm after 30 mins of vaccination. On 18-May-2021, the patient experienced tiredness. Laboratory data included: Body temperature (NR: not provided) 99.2 F. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from tingling face for 5 minutes, closing of throat about 5 mins but airway clear, tongue swelling few minutes, hot face, high blood pressure, and high heart rate on 17-MAY-2021, and had not recovered from fever, and tiredness. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 20210535640-COVID-19 VACCINE AD26.COV2.S- Tingling face for 5 minutes, closing of throat about 5 mins but airway clear, tongue swelling few minutes, hot face, and high heart rate . This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other</p>

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1338096	5/21/2021	CA	15	F	5/21/2021	5/21/2021	<p>factors potentially associated with the event(s). V0 20210535640-COVID-19 VACCINE AD26.COVID-19 blood pressure. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY. V0 20210535640-COVID-19 VACCINE AD26.COVID-19 Fever. This event(s) is labeled per RSI and is therefore considered potentially related.</p> <p>Per Dr. 1. Did the patient have an immediate allergic reaction of any severity such as urticaria, angioedema, respiratory distress, or anaphylaxis (<4 hours following administration of the COVID vaccine)? Yes. 2. Did the patient previously have an immediate allergic reaction of any severity to polysorbate or polyethylene glycol? No. 3. Has the patient had prior anaphylactic reactions from another vaccine, medication or any other cause? Yes. 4. Did the patient have an allergic reaction >4 hours after administration? OR have an expected side effect of the COVID vaccine? No. Pt received COVID vaccine, Pfizer 1st dose. Approximate 5 minutes in the observation area pt complained of headache, throat discomfort, and stomach upset. She has a history of food additive allergy (dough additive), has an epi pen but has never needed to use it per mother at bedside. Initial VS: T 98.2 P 84 BP 119/70 RR 20 SpO2 99% on room air. She was monitored in the adverse reactions area. She was given Benadryl 25 mg oral x 2, and cetirizine 10 mg oral x 1. During observation period she had observed worsening oropharynx swelling, and stridor/inspiratory wheezing. VS prior to transfer was P 78 BP 102/69 RR 18 SpO2 100% on room air. EMS was called and pt transferred to ER for further monitoring, Tryptase level, and epinephrine if needed. Pt was recommended to see her pediatrician or allergist to discuss 2nd dose options prior to scheduling appointment. Signed: DO, 5/21/2021 2:59 PM".</p>

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1336279	5/21/2021	OH		F	4/1/2021		<p>SUSPICION OF FLUID LEAK INTO EARS; DECREASED LUNG FUNCTION; LOSS OF PERIPHERAL VISION; NUMB LEGS; DIFFICULTY WALKING ACROSS THE ROOM/UNSTEADY GAIT; DIARRHEA; SHORTNESS OF BREATH; EXTREME VERTIGO; WEAK LEGS; HEADACHE/OCCIPITAL HEADACHE; ARTHRALGIA; SORE ARMS; MYALGIA; FATIGUE; FOGGY HEADED; ANAPHYLAXIS; FEVER; This spontaneous report received from a physician concerned a 30-year-old patient The patient's height, and weight were not reported. The patient's concurrent conditions included attention deficit hyperactivity disorder (ADHD), asthma, and milk allergy. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration was not reported, batch number and expiry date were unknown) dose was not reported, 1 total, administered on left arm on 10-APR-2021 for prophylactic vaccination. The batch number was not reported has been requested. No concomitant medications were reported. On 10-APR-2021, within 30 minutes of vaccination, the patient developed anaphylaxis with no airway compromise, hives, swelling of limbs, face and administration site. The patient could not get immediate treatment for about an hour and then received Benadryl (diphenhydramine hydrochloride). On an unspecified date, in APR-2021, the patient experienced fever with a temperature of 100s (unit not provided). On 11-APR-2021, the hives started to go down with Benadryl treatment but it was not completely gone. On the same day, the patient experienced headache/occipital headache, arthralgia, sore arms, myalgia, fatigue and was foggy headed. On 12-APR-2021, the patient experienced shortness of breath, difficulty walking across the room (unsteady gait), extreme vertigo, diarrhea, numbness of legs and weakness of legs. It seemed like the patient was exhibiting symptoms of coronavirus disease (COVID-19). On 14-APR-2021, she eventually went to the emergency room (ER). The patient was tested for COVID-19 (swab test) and titres but both were negative. On an unspecified date, in APR-2021 (within 5 days of start of symptoms), a magnetic resonance imaging (MRI) without contrast was done and it did not show any blood clot, and D-dimer test was negative. The physician suspected a fluid leakage into the patient's ear and wanted to know if adenovirus</p>

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from vaccine could be implicated. The patient was prescribed meclizine, but it did not help. On an unspecified date, a pulmonary function test (PFT) was done which showed decreased lung function. The patient also had steroid (unspecified) for 4 days. On an unspecified date, in MAY-2021 (about 8 days before report), the patient started to lose peripheral vision and her vertigo escalated. It was reported that the patient was due for an MRI on 12-MAY-2021. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the sore arms, fatigue, foggy headed, myalgia, arthralgia, shortness of breath, difficulty walking across the room/unsteady gait, extreme vertigo, diarrhea, weak legs, fever, headache/occipital headache, loss of peripheral vision, anaphylaxis, numb legs, suspicion of fluid leak into ears and decreased lung function was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210520835-COVID-19 VACCINE AD26.COV2.S-Anaphylaxis. This event(s) is labeled and is therefore considered potentially related.

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1332730	5/20/2021	NC	62	F	3/31/2021	3/1/2021	severe arm pain; Nausea; Dizziness; klebsiella pneumoniae, 50,000 to 100,000 cfu; Headache; Urine retention; blood and blood clots in her urine; blood and blood clots in her urine; tore or messed up a ligament in her hand; This is a spontaneous report received via a Pfizer-sponsored program, from a contactable nurse (patient). A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number not reported), via an unspecified route of administration, administered in arm right on 31Mar2021 (at the age of 62-years-old) as 2nd dose, single for COVID-19 immunisation. Medical history included fibromyalgia from 1996 and ongoing, allergies from 1981 and ongoing, hypothyroidism and is pre-diabetic from 2012 and ongoing, Lyme disease from an unknown date and unknown if ongoing, concussion from Sep2019 to an unknown date, post-concussion syndrome from Sep2019 and ongoing , seasonal, food and chemical allergies from an unknown date and unknown if ongoing and had wisdom teeth extracted on an unknown date. The patient's concomitant medications were not reported. The patient previously took nalbuphine hydrochloride (NUBAIN) and experienced anaphylaxis. The patient previously received the first dose of BNT162B2 (Batch/Lot Number: EN6206), administered in right arm on 10Mar2021 for COVID-19 immunisation and experienced Face and ears became very flushed, red, and itchy, Headache, headache was more like a migraine/felt like a migraine, but worse, Post concussion syndrome was retriggered, not eating well and had lost some weight, feeling more worn out, she is allergic to alcohol and thought maybe it was the glycol in the COVID-19 vaccine that caused the reaction, flu like symptoms, achiness all over, pelvic pain and pressure, some burning during urination, did not have the energy level and stamina that she used to, blood in her urine and clots, she was not able to release the urine (urine retention), Nausea and Dizziness. About a week after receiving the second dose of the Covid-19 vaccine on 31Mar2021, she noticed the feeling again of retaining the urine. She was not swollen or anything and immediately went with increased fluids. The urine retention was not as severe at that point. It really showed up and intensified quickly with groin pain, pelvic pain, abdominal pain, and some back pain. She woke up the next morning after

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being doubled over in pain the night before and there was so much blood in her urine that she couldn't see any urine. Her urine was the darkest burgundy and the color of the darkest wine. She did not have anything in her urine the night before when she was doubled over in pain. She was increasing fluids and even drinking Propel for the electrolytes to make sure she was not making things worse. She woke up around 5 AM and felt so sick to her stomach. She had nausea the night before, but she was really nauseated the morning that she discovered blood in her urine. She woke up with severe nausea last Friday, 30Apr2021. Her doctor performed a urine culture. The urine culture returned positive for Klebsiella Pneumoniae with 50,000 to 100,000 CFU/mL on 30Apr2021. She does not have the urine culture results from her first doctor visit. Her friend is an RN that is administering the Covid-19 vaccine, was talking to company representatives and told the caller that she needed to call company to make a report and see if anyone else has experienced the same adverse events. Urinary retention came back in Apr2021 following her second dose of the Covid-19 vaccine on 31Mar2021. She can really go to the bathroom, but she is still feeling the abdominal and pelvic pressure as well as some burning and pain. Her symptoms are improving but not enough. It feels like she always has a full bladder still. She tore or messed up a ligament in her hand and she has been going to occupational therapy. She can't seem to be able to handle a pain level like she used to. It seems like pain is triggering her feelings of nausea and dizziness. Her body is not doing things well right now. The day before, of, and after getting the Covid-19 vaccine, someone suggested taking electrolytes before the second dose of the Covid-19 vaccine, so she drank Powerade. She was expecting the symptoms following the second dose of the Covid-19 vaccine to be a lot worse and they were a walk in the park in comparison. She had a mild headache the first day, 31Mar2021. She woke up in the morning of 01Apr2021 and her headache was gone. Following the second dose of the Covid-19 vaccine, she had severe arm pain. It felt like she was walking around with someone constantly punching her. She was moving her arm all around trying to get it to stop hurting. She saw blood and blood clots in her urine for over 24 hours. The blood and clots were lessening over

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the 24-hour time period. She probably saw in a 2-hour period at least 60 clots about the size of a quarter to a half dollar. The pain was excruciating. She was taking Phenazopyridine but is still feeling a sense of urgency, burning, and sometimes pain during urination. Her doctor did give her a prescription for phenazopyridine, but it was cheaper for her to buy over the counter and take the same dosage. She has been taking generic Macrobid, Nitrofurantoin Mono, 100 mg twice daily. It was dispensed in a pharmacy bottle. She is seeing a urogynecologist tomorrow, 06May2021. The patient underwent lab tests and procedures which included culture urine: unknown cfu on 26Mar2021 and culture urine: klebsiella pneumoniae, 50,000 to 100,000 cfu on 30Apr2021. The outcome of the event Headache was recovered on 01Apr2021 while of the rest was unknown. No follow-up attempts are possible. No further information is expected. Information on lot number already obtained.; Sender's Comments: Based on the compatible temporal association, there was a reasonable possibility that the vaccination with BNT162B2 played a contributory role in triggering the onset of the reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1332727	5/20/2021	NC	62	F	3/10/2021	3/1/2021	<p>This is a spontaneous report received from a contactable nurse (patient) via a Pfizer-sponsored program. A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6206), via an unspecified route of administration in the right arm, on 10Mar2021, as 1st dose, single, for COVID-19 immunisation. Medical history included ongoing fibromyalgia (diagnosed in 1996), ongoing allergies from 1981, ongoing food allergies and chemical allergies, ongoing allergy to alcohol, ongoing hypothyroidism from 2012, ongoing pre-diabetic from 2012, Lyme disease for 11 years before being correctly diagnosed and treated, concussion in Sep2019, and post concussion syndrome in Sep2019. The patient previously took nalbuphine hydrochloride (NUBAIN) in 1981 and experienced anaphylaxis; and paracetamol (TYLENOL) and was very sensitive, had rash and high blood pressure. Within the first 15 to 20 minutes following the administration of the first dose of the Covid-19 vaccine, on 10Mar2021, the patient's face and ears got very red, flushed, and itchy. The patient reported that she is allergic to alcohol and thought maybe it was the glycol in the COVID-19 vaccine that caused the reaction. She reported that she has had glycol before and has never reacted quite like that. The flushing, redness, and itchiness of her face and ears subsided within an hour and were gone by 4 hours. Her allergist instructed her to take 2 Zyrtec before getting the second dose of the Covid-19 vaccine. After her face and ears became flushed, red, and itchy, she ended up having a really bad headache that continued until the next day. Her headache was severe for about 12 hours and continued for a total of a day and a half. She stated that her headache was more like a migraine during the 12 hours when it was severe. It felt like a migraine, but worse. On 10Mar2021, the patient reported that she experienced flu-like symptoms like being nauseous, had dizziness, achiness all over, and was not feeling well, her post-concussion syndrome was triggered and had more headaches, dizziness, nausea. She reported that things have been going awry in her body since she had the COVID-19 vaccine. She reported that the increase in headaches seemed to have improved, but the nausea and dizziness have in some ways improved and then some days it feels like "here we go again" when it hits. About a week after she received the first dose of the</p>

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Covid-19 vaccine, in Mar2021, the patient noticed a change in her urination. It wasn't severe or anything at that point, she just felt like she was not able to release the urine (urine retention). She thought to increase her intake to see if it would help her urinate and it didn't seem to help much. She received a prescription on 26Mar2021, and during that week, she noticed that she was having more issues with some burning during urination and was developing pelvic pain and pressure. The patient stated that the scent and color of her urine looked fine. She reported that the frequency started to increase with not much urine coming out. When she finished her antibiotics about 7 days later, the urine retention had really improved and went away at the end of March. In the morning of 26Mar2021, when the patient woke up, she had blood in her urine and clots. The clots were about the size of a pea and a couple were about the size of a dime. The blood and blood clots in her urine were what made her go to the doctor. She reported she has never had blood in her urine that she remembers. She was put on Macrobid for 5 days. She reported that Macrobid wasn't relieving enough of her symptoms and her provider ended up adding a couple more days. The patient reported feeling more worn out in Mar2021, since she received the first dose of the COVID-19 vaccine. This did not improve and some days it was worse. The patient did not have the energy level and stamina that she used to (Mar2021). She reported that whether it's combined with the retriggering of her post-concussion syndrome, it is significant for her life. She was also not eating well and had lost some weight (Mar2021). She reported that her appetite is improving but it is still not normal for her. She mentioned it was harder for her to want to eat something because of feeling nauseated. The patient assessed the events "face and ears became very flushed, red, and itchy", headache, "headache was more like a migraine/felt like a migraine, but worse", "post concussion syndrome was retriggered", "blood in her urine and clots", "not eating well and had lost some weight" and "feeling more worn out" as serious (medically significant). The patient recovered from "face and ears became very flushed, red, and itchy" and "she is allergic to alcohol and thought maybe it was the glycol in the COVID-19 vaccine that caused the reaction" on 10Mar2021; headache, "headache was more like a

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migraine/felt like a migraine, but worse", "she was not able to release the urine (urine retention)", "blood in her urine and clots", "flu like symptoms", dizziness, "achiness all over", "pelvic pain and pressure", and "some burning during urination" in Mar2021; and was recovering from "not eating well and had lost some weight". The outcome of the remaining events was unknown. The patient assessed the causality of events headache, flu like symptoms, nausea, "face and ears became very flushed, red, and itchy", dizziness, "post concussion syndrome was retriggered", and "not eating well and had lost some weight" as related to BNT162B2.; Sender's Comments: Based on the information in the case report and a plausible temporal association, A possible causal relationship between urinary retention, hemorrhage urinary tract and suspect drug BNT162B2 cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

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1332762	5/20/2021	FL	60	F	4/27/2021	4/27/2021	about 1+ hours ago, she came down with a massive headache; it as a "bright, red, rashy and blotchy"/her (left) arm was bright red with a (blotchy) rash (across her left arm); it was "hot as hell"/her (left) arm was hot as hell; She had a blotchy rash across her left arm; She had injection site soreness for 3 days after receiving her first COVID-19 Vaccine; couldn't move her arm at all; left arm was a little tender to move; This is a spontaneous report from a contactable nurse (patient). A 60-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via intramuscular in left arm on 27Apr2021 (lot number: EW0171) at single dose for COVID-19 immunization. The relevant medical history included ongoing multiple allergies, ongoing peanut allergy, ongoing reaction to sulfites (sulfites in wine gave her a headache), ongoing reaction to preservatives (She said she would become anxious & then turn bright red & become short of breath. She said sometimes her tongue would turn pale & white looking & she would faint. She said she carried Benadryl with her & the Benadryl took care of her reactions. She said Benadryl had been her "MO" for treating reactions. She said the doctors don't want to give her an EpiPen unless her reaction is a documented as an anaphylactic reaction) and sensitive to the epinephrine (used in dental treatments caused her to become short of breath, and faint). Concomitant medications included potassium acetate from Apr2021 and ongoing for an unspecified indication. The patient previously took Benadryl from unspecified date to treat her peanut allergy and won't help her allergic reaction to peanuts; also took Benadryl from unspecified date for reaction to preservatives. The patient said that 8 days after the injection, she experienced a massive headache and the left arm where she received the vaccine had a red "circle" around the injection site. She described it as a "bright, red, rashy and blotchy" and said it was "hot as hell". She explained her son and husband were vaccinated right after her, by the same person, and they didn't develop anything. She explained she thought her reaction was due to the preservative in the vaccine as she had a lot of allergies. She expressed her concern about potentially developing anaphylaxis to the second dose of the vaccine after her reaction to the first. She asked for the risk associated with taking the second dose of the vaccine after such

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reaction to the first. The nurse furtherly reported that about 1+ hours prior to the report (clarified as the time of the report, 06May2021), she came down with a massive headache. She said her husband brought her home something for her headache. She said her (left) arm was bright red with a (blotchy) rash (across her left arm). She said her (left) arm was hot as hell. Reported she had a hesitation to take the COVID-19 Vaccine because she had a lot of allergies to begin with, but nothing that caused an anaphylactic reaction. On 27Apr2021, she had injection site soreness for 3 days after receiving her first COVID-19 Vaccine and her left arm was a little tender to move at that time, but not as bad as after receiving a TB (vaccine) shot. She said after the TB vaccine shot, she couldn't move her arm at all. She reported her symptoms came out of nowhere, and she believed her headache and left arm rash were directly related to the COVID-19 Vaccine. She said her son and husband went immediately after her for their COVID-19 Vaccines, and had the same exact person administer the COVID-19 Vaccine. She said neither her son, nor husband, had a reaction from the COVID-19 Vaccine. No further details provided. The events did not require a visit to Emergency Room or Physician Office. Treatment for headache included 1 Extra Strength Tylenol 500mg caplet. Treatment for left arm blotchy rash included a cold compress on her left arm. She said she also took Benadryl (clarified as Walgreens Children's Dye Free liquid "Wal-Dryl" Diphenhydramine). She said she preferred to use the children's liquid Diphenhydramine because when she had a reaction, sometimes her throat felt like it was swelling. The outcome of the event left arm was a little tender to move and couldn't move her arm at all were recovered on an unspecified date, for event injection site soreness for 3 days after receiving her first COVID-19 Vaccine was recovered in Apr2021, while the other events were not recovered.; Sender's Comments: Based on known drug safety profile, there is reasonable possibility of causal association between the events headache, Vaccination site erythema, Vaccination site warmth, and Vaccination site rash and the suspect drug. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern

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							identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
1333398	5/20/2021	NC	60	F	5/20/2021	5/20/2021	Anaphylaxis 2 minutes after administration; gagging and heaving; throat swelling until she couldn't breathe; 0.3 mg EPIPEN administered into left thigh; EPIPEN relieved acute throat swelling so that patient was able to breathe; blood pressure 182/127 and pounding headache; transported to hospital by EMS.
1334333	5/20/2021	MT	63	F	5/20/2021	5/20/2021	anaphylaxis. SOB, dizziness, double vision, tongue swelling, wheezing
1335980	5/20/2021	MD	52	F	5/20/2021	5/20/2021	VOMITING, DIZZINES AND SWEATING AFTER VACCINE. BLOOD PRESSURE TAKEN, AND PATIENT MONITORED FOR SIGNS OF ANAPHYLAXIS. STORE MANAGEMENT CALLED 911 FOR EMERGENCY, MEDIC ARRIVED AND TOOK OVER THE TREATMENT

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1331046	5/19/2021	CA	13	F	5/19/2021	5/19/2021	On 5/19/2021 client received her first dose of the Pfizer Covid-19 Vaccine (lot #EW0185, expiration 08/2022) at 12:42. Client was found sitting upright in her chair with her mother and appeared melancholy. Client was a 13-year-old female, alert and tracking with her eyes. Client had a chief complaint of headache at 12:48. EMT and RN responded. Client stated that she began to have a headache a few minutes after her observation had begun. This was the client's first dose of the Pfizer vaccine. Client's mother did not report any allergies or medical history. Assessment revealed no hives, rash, discoloration, shortness of breath or other signs of anaphylaxis. Client described a generalized headache with dizziness and stated that she had eaten breakfast this morning. Airway, breathing and circulation were intact. Client denied pain throughout the rest of her body. Vitals at 12:52 were blood pressure 122/74, pulse 84, respirations 18, O2 100% on room air, temperature 97.6*f, lung sounds clear bilaterally, and client was alert and oriented to person, place, date and time. Client's mother consented to allowing the client to lie down for 15 extra minutes but refused to remain for the entire 30-minute additional observation. Client's mother was instructed to seek emergency care or medical attention if condition becomes severe after leaving vaccination site. Client's final vitals were consistent at 13:07: blood pressure 118/78, pulse 84, O2 100% and respirations 18. Client's mother was provided with all vaccine related information and acknowledged that she already knew what signs and symptoms to look for as she was already vaccinated as well. departed facility with her mother at 13:07 with client's mother stating "I have another appointment.~~

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1329875	5/19/2021	OK	18	M	5/17/2021	5/17/2021	Site: Pain at Injection Site-Medium, Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Weakness-Severe, Additional Details: Patient lost consciousness a few minutes after dose was given. Patient was unresponsive for approximately 2 minutes. Neck felt tight, difficulty breathing, was not alert/oriented when finally awoken. Patient was given 1 shot of epi 0.3 due to a temporary interruption in breathing that lasted seconds. By the time paramedics arrived, he was becoming more alert. Was taken to the ER and discharged.

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1329493	5/19/2021	MI	47	F	4/27/2021	4/27/2021	Anaphylaxis; Vocal cord tightened; immediate severe headache on left half; tongue swelling; tingling across face just above upper lip; face and neck turned red and swollen/ arms turned red under sleeves; face and neck turned red and swollen; dizzy; brain fog; Existing Tinnitus in left ear is louder; This is a spontaneous report from a contactable consumer reported for herself. This 47-year-old female (non-pregnant) patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in left arm on 27Apr2021 15:15 (Batch/Lot Number: Unknown) as single dose (at 47 years old) for COVID-19 immunisation. Medical history included fibromyalgia from (previously diagnosed as Rheumatoid Arthritis). Concomitant medications included fenofibrate, escitalopram, hydrochlorothiazide, losartan potassium (LOSARTAN/HCT), herbal sup, all taken for an unspecified indication, start and stop date were not reported. The patient previously took monosodium glutamate and experienced allergy, hydroxychloroquine sulfate and experienced allergy. On 27Apr2021 15:15, the patient experienced anaphylaxis, vocal cord tightened, immediate severe headache on left half, tongue swelling, tingling across face just above upper lip, face and neck turned red and swollen/ arms turned red under sleeves, dizzy, brain fog, existing tinnitus in left ear is louder, all with outcome of not recovered (as reported). Therapeutic measures were taken as a result of the events included Diphenhydramine, Epinephrine, Famotidine, Zofran. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. The patient stated that: "Sent to ER via ambulance: Diagnosed with Anaphylaxis. Vocal cord tightened, immediate severe headache on left half, tongue swelling, tingling across face just above upper lip, face and neck turned red and swollen, arms turned red under sleeves, dizzy, brain fog. Existing Tinnitus in left ear is louder, and as of 04May2021, I still have the headache". Seriousness criteria of the events was reported as serious due to disability. The information on the Lot / Batch number has been requested.

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1329331	5/19/2021	MI	60	F	3/5/2021	3/5/2021	Rash on face; Rash on neck; swollen tongue; swollen lips; swollen face; itchy hands/Itchy; Lip tingling; Swelling of the arms; swelling and tingling; swelling and tingling; This is a spontaneous report from a Pfizer sponsored program support. A contactable consumer (patient) reported that a 60-year-old non pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot Number: EN6206, Expiry Date of Covid-19 Vaccine: Unknown), via an unspecified route of administration on 05Mar2021 03:00 PM in the left arm at 1st dose, single for COVID-19 immunisation. The patient age at vaccination was 60 Years. Medical history included vertigo, migraines, Sjogren's syndrome (diagnosed about 10 year ago), thyroid cancer, diabetes and high blood pressure. known allergies included Latex, daptomycin, ceftaroline fosamil, doxycycline, fremanezumab-vfrm. The patient had second shingles shot with Shingrex and she got a few chicken pox rash around the shot itself but that's pretty normal, the onset age was 58 years and at the age of 60 years old at the time of the last flu vaccine, and has received multiple flu shots in the past with unknown brand of flu vaccine. On 05Mar2021 03:15 PM, the patient experienced rash on face, rash on neck, swollen tongue, swollen lips, swollen face, itchy hands/Itchy, lip tingling, swelling of the arms and swelling and tingling. The report received as, on 05Mar2021, received her first Pfizer Covid vaccine dose. 10 minutes later patient had an allergic reaction which included swelling of her lips and tongue, rash on her body, and swollen and itchy hands. The patient reported a second reaction on 07Mar2021, which were the same symptoms as the first and then another (3rd) reaction on 12Mar2021. She has been to the ER 3 times and was prescribed oral steroids and was given a steroid injection each time. She feels that each time the steroid injection wears off, the symptoms return. She wants to know how long this side effect could last. The patient had allergic reactions to it and patient as now had three allergic reactions to it and was wondering have you had other people that have had multiple allergic reactions if the steroid they were given has run out. The patient was given Decadron on day 1 and it ran out in a couple of days because it's a short-acting steroid, then they gave her the longer-acting five-day steroid, betamethasone, patient was taking oral, but it's not as

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good as the beta methasone shot, patient was asking to have we had other people who have needed more steroids even though the shots have stayed in their system. She wants to know if she is going to have more allergic reactions down the road as the steroids' run out. The patient had three injectable rounds of steroid shots on 05Mar2021, 07Mar2021, and 12Mar2021 and had two courses of oral steroids on 05Mar2021 and 12Mar2021. The patient said 10 to 15 minutes after receiving the shot, had lip swelling and tingling, rash on face, then within a half hour started to swell up. The patient stated that at the center where she got her vaccination, they gave her Benadryl but noticed her symptoms getting worse, packed her up in an ambulance to hospital, and there they gave her Decadron and Pepcid and more Benadryl. The patient states it wasn't anaphylaxis but was an allergic reaction. This was on 05Mar2021, right after getting the shot. It is explained the events improved when given the medications at the ER. She still gets a little itchy once in a while but she is on oral steroids and 50 mg of Benadryl every day. This is her third injectable and second round of oral steroids. Caller has not NDC, Lot, or Expiry for those product as they are from the pharmacy. She also has no NDC, Lot, or Expiry for the Benadryl being used, it is also from the pharmacy. The patient informed as, this was her first Covid vaccination and she was not getting the second one. The patient husband and daughter have had their Covid vaccines and had no reactions at all. The patient was not had covid prior and post vaccination. The patient was not received other vaccine in four weeks. Abd received many daily prescriptions and supplements medications in two weeks. Adverse events resulted in emergency room/department or urgent care. Therapeutic measures were taken as a result of events and treated with Benedryl, Steroids, Pepcid. Outcome of the events itchy hands/Itchy, swelling of the arms, swelling and tingling was unknown, for remaining events outcome was recovering. Follow-up attempts are required. Further information was expected.

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1329071	5/19/2021	CA	40	F		5/10/2021	ANAPHYLAXIS; HOT AND BRUISED SHOULDER; FLUSHING; BODY ACHES; LOSS OF FEELING IN FACE; LOSS OF APPETITE; VOMITING; CAN NOT SLEEP; CAN NOT DRINK WATER; STOMACH FEELS LIKE SODA; SWOLLEN ARM AND SHOULDER; COULD NOT MOVE FINGER; VERY HOT LEFT ARM; LEFT ARM SENSITIVE TO TOUCH; HOT SHOULDER; LOWER BACK PAIN; DEHYDRATED; SORE ARM; RASH; HIVES AND BUMPS AROUND THE INJECTION SITE; WEAKNESS; INJECTION SITE PAIN; HEADACHE; VERY TENDER ARM AND SHOULDER; TERRIBLE NAUSEA; FEVER; LOSS OF TASTE; LOSS OF SMELL; BRUISE ON LEFT WRIST; PALMS TURNED BLUE FROM CLAPPING; This spontaneous report received from a patient concerned a 40 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included smoker, non-alcoholic, crohn's disease, heart murmur, chronic vertigo, panic attack disorder, depression, drug allergy, fish allergy, and perimenopause, anxiety and other pre-existing medical conditions included patient had no drug abuse or illicit drug, patient is allergic to all the narcotics, passes large clots of blood during menstruation. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 043A21A, and expiry: unknown) dose was not reported, administered on 06-MAY-2021 13:15 for prophylactic vaccination. Concomitant medication included meclizine for vertigo. After receiving vaccination the first thing she felt like there was hot lava going down her left arm (where she got injected) and she could not move her finger then that went away after 10-15 minutes later. they told her that symptom was normal and everyone experience the same kind of symptom. She completely lost her appetite, the smell of food made her sick ever since she got the shot. Patient stated her left arm was very hot, sensitive to the touch, bumpy around the injection site and sore. all these symptoms were the same day of her shot (on 6-MAY-2021). since the injection she had the headache and it wont go away and she still has the headache today. her relative was telling her that her shoulder was hot. she had body aches (lower back pain and everywhere, the pain was moving though her body). the second day everything got worse; her arm where she received the

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injection her whole shoulder was black it looks like if someone threw brick at her, she had hives and bumps around the injection site. she cannot sleep, she cannot eat and she cannot drink water. she was tired and she was not feeling good. she had anaphylaxis 30 hours, dizziness, loss of feeling in her face, her heart was racing. she took two tablets of antihistamine to manage the anaphylaxis reaction. 30 hours after the vaccination she has dizziness, wheezing, she had flushing , rapid pulse, she was throwing up for hours then she had to take the antihistamine. On an unspecified date patient had weakness. Patient said that her fever gets worse every day. On the day of vaccination (on 6-MAY-2021) her temperature was 99.4, and has checked it 5 to 6 times with the same reading. on 7-MAY-2021 it was 99.6 and on 8-MAY-2021 it was 100.3. she said it felt like both sides of her throat were touching. Patient had barely been able to eat since 6-MAY-2021, but has been able to drink small amounts of water. Patient stated her saliva makes her nauseated. On 10-MAY-2021 she clapped her hands and they turned blue and also developed an egg shaped bump/hematoma on her left wrist after bumping it. She went to urgent care where she was instructed to use ice pack for bump, which gave her no relief. There, she was stuck with a needle 4 times to get blood work because she was dehydrated. Patient stated that her whole body felt like a walking pin cushion and skin was hypersensitive. Urgent care checked platelets and hemoglobin which came back normal. Patient stated her menstrual cycle started on 10-MAY-2021 was different than usual with super heavy, red flow, no clots, and soaked pad in an hour, it was slowed down since but flow was heavy. Urgent care advised this may be normal due to change of hormone during perimenopause. As of today, patient could not smell or taste anything. Patient was taking antihistamines 2 a day. Temperature was normal. Patient stated nausea and vomiting were better but would definitely come back if she stopped taking meclizine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from could not move finger, had not recovered from sore arm, headache, loss of appetite, vomiting, injection site pain, stomach feels like soda, terrible nausea, swollen arm and shoulder, feels like both sides of throat are touching, weakness, bruise on left wrist, loss of taste,

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							and loss of smell, and the outcome of sore body, hot and bruised shoulder, rash, anaphylaxis, flushing, body aches, not feeling good, dizziness, loss of feeling in face, wheezing, rapid pulse, hives and bumps around the injection site, can not sleep, can not drink water, fever, very tender arm and shoulder, very hot left arm, left arm sensitive to touch, hot shoulder, lower back pain, palms turned blue from clapping and dehydrated was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 20210516682-COVID-19 VACCINE AD26.COV2.S-Anaphylaxis. This event(s) is labeled per RSI and is therefore considered potentially related.
1331735	5/19/2021	CA	15	F	5/19/2021	5/19/2021	Pt received vaccine with mother present at 1419, c/o dizziness, lightheadedness, blurry vision, difficulty hearing, at 1439. Pt states she did not eat lunch. Nursing team intervened by taking vitals, placing wet towel on forehead, lying pt in supine position with legs elevated. Pt VS stable, pulse in 80s, BP(120s/80s), 99% on RA, RR 16-18, no respiratory distress, no s/sx anaphylaxis. Pt states she did not eat lunch. Gatorade offered to pt. Dizziness improves in supine position but returns upon sitting. At 1532 pt states she has facial numbness. EMS called at 1535. EMS arrived at 1557 and assessed pt. Pt's BG is 93, VS stable. Pt reports feeling dazed, unable to focus, blurry vision and difficulty hearing. At 1602 EMS informed pt that they will take her to Medical Center, pt immediately got agitated and started crying and hyperventilating. 1604 pt stated she had difficulty breathing and a light localized rash began to appear on her chest. 1605 EMS transported pt. Pt's mother to follow.

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1327256	5/18/2021	MA	16	F	5/15/2021	5/16/2021	Briefly, patient with history of asthma and food allergies, presenting with hives, nausea, and swelling, in setting of receiving Covid vaccine 36 hours ago. Family had given benadryl and zyrtec without improvement, and symptoms were worsening to presents for evaluation. My exam (after Epipen) showed: Gen: nontoxic appearing; HEENT: no lip/tongue/uvular edema, PERRL, EOMI, normal conjunctiva, neck supple without LAN; Card: RRR, no murmur, good perfusion; Lungs: CTAB, good air entry, no increased WOB, no wheezing; Abd: soft, non-tender, non-distended, no masses; Ext: warm and well perfused, moving all extremities; Skin: hives over hands, arms, abdomen, and legs, including between fingers and on soles of feet Patient presenting with allergic reaction after Covid vaccine, could be more benign allergic reaction such as urticaria multiforme, but given constellation of symptoms and history of severe allergic reaction in past, will treat as anaphylaxis. Therefore given Epipen, steroids, and will plan for observation. Observed 4 hours and continued to be well appearing without symptoms of rebound anaphylaxis. Therefore, patient safe for discharge to home with supportive care and PCP follow up. Given Rx for benadryl and steroids, refilled Epipen. Family in agreement with plan and verbalize understanding of signs and symptoms to return to care. Final Diagnosis 1. Anaphylaxis T80.52XA
1326638	5/18/2021	TN	66	M	5/6/2021	5/9/2021	On 5/8/2021 I was stung by a wasp. I have always had a very mild response to bee/wasp or other insect bites. This was initially the same with little or no swelling or redness at the site (my left index finger). However, the next day I noticed red bumps on my arms. The rash continued to develop spreading across my entire body including palms and bottom of feet. It persisted for six days before resolving. I took benedryl and it had an effect on the itching but no impact on reducing the rash. As this is a significant change in immune response from historical, and it was within 2days of the second Covid shot, this potential to increased immune activity to wasp venom should be considered. What if I was already sensitive? Would it move to anaphylaxis?

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1326241	5/18/2021	NY	40	M	4/16/2021	4/16/2021	HCP indicated tracheitis; Less of a passageway; Fair amount of coughing/Dry cough; Swelling in the neck area; Fatigue; Is there any correlation between the delayed anaphylaxis and ingredient?; Throat tightening with difficulty breathing; Throat tightening with difficulty breathing; This is a spontaneous report received from a contactable consumer (reported for himself). A 40-years-old male patient received first dose of bnt162b2 (BNT162B2, solution for injection, Batch/Lot Number: EW0164) administered in left deltoid via an unknown route of administration on 16Apr2021 at 12:50 pm as 1st dose single for COVID-19 immunization. It was reported that that he received the vaccine in his left arm, the bicep muscle, or above the bicep. He states the muscle on the shoulder area. Patient states that asthma was in the lungs and chest. He has had mild intermittent asthma and gets it 4 times a year. There was no prior Vaccinations, no adverse events within 4 weeks. Medical history included asthma (patient was diagnosed 30 years ago), allergic to shellfish. The patient's concomitant medications were not reported. On 16Apr2021 patient experienced is there any correlation between the delayed anaphylaxis and ingredient, throat tightening with difficulty breathing (Throat tightness and dyspnea), less of a passageway, fair amount of coughing/dry cough swelling in the neck area and fatigue. On 19Apr2021 at 10:15 HCP indicated tracheitis. The patient states that he got the vaccine on 16Apr2021 at 12:50 pm and isn't sure exactly when the swelling started because he got a little fatigued. Patient states that it was about 3-5 hours after and at a certain point he noticed it. It was reported that a half an hour to an hour later patient throat started to tighten, it gets triggered by certain stimuli, steam and vocalization, and rubbing the area. patient states that he could reproduce the issue if he rubs the area, the frequency has decreased, and in that case, it has improved. It was reported that patient was diagnosed with tracheitis on 19Apr2021 at 10:15 and it was still ongoing, or the effects of it are. Patient states that what he feels in the front of his throat near the trachea and up a little further was inflammation. Patient gets the symptoms of the tightening of the throat, and it is inflamed there is less area to breath. Patient states that his understanding of the tightening of the throat and dry cough are all symptoms of the tracheitis. It was reported

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that the first symptom experienced after the injection (at least 2-3 -4 hours), patient had fatigue first then probably a half an hour to an hour later the swelling started. patient believes the fatigue has gone away, but not 100 percent sure. patient states that there are times he has felt fatigue and is not 100 percent of the cause. patient states that if he does feel fatigue, he assumes it because of the tracheitis. patient states that these events happen when he needs to get area in his throat, and it might cause the fatigue. patient states that the coughing is parallel with the throat tightening, when he wants to open his airway or pass way the coughing seems to occur. Patient states he gets relief or a more open passageway and the coughing reflex or coughing bouts are less, when he gets the tightness of the throat or the inflammation he sort of goes into coughing. The outcome of the event for hcp indicated tracheitis was not recovered and unknown for the other events, whereas the outcome of the event fatigue was recovered. Follow up were needed, further information has been requested. 07May2021: Follow-up spontaneous report received from a contactable consumer. No new information was reported.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021524696 Pfizer

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1327345	5/18/2021	CA	16	M	5/17/2021	5/17/2021	<p>On 05.17.21 patient received his first dose of the Pfizer Covid-19 vaccine (lot # EW0182 exp. 08/2022). Client's mother signaled to EMT that they needed assistance. EMT and RN responded. Client was a 16-year-old male found sitting upright and leaning forward while alert and tracking. Client had a chief complaint of ringing ears and uneasiness. Client stated that he began to notice his ears ringing a few minutes after observation began. Client's mother was unable to console the client prompting her to calmly wave for assistance. This was the client's first dose of the Pfizer vaccine. He and his mother both deny any medical history, allergies, or regular medication use. Assessment revealed no hives, rashes, discoloration, swelling, shortness of breath or other signs of anaphylaxis. Client complained of unspecified uneasiness while leaning forward but exhibited no accessory muscle use. Client denied any pain throughout his body. Airway, breathing and circulation were intact. Client stated that he was "nervous" before receiving his vaccine today due to stories he had heard from his peers. Client then stated that he felt like he "couldn't move [his] hands" despite there being no obvious range of motion compromise. Vitals at 1332 were pulse 76, O2 100%, lung sounds clear bilaterally, alert and oriented to person, place, date and event, respirations 20. Client and mother both consented to an additional 30 minutes. Client was assisted from his observation chair to a bed by EMT and mother and stayed there for the remainder of his observation. After approximately five minutes of lying down, the client stated that he felt "much better."</p> <p>Remaining vitals: 1337 - 118/78, O2 99%, Resp. 16, HR 76, 1349 - 110/76, HR 72, O2 99%, Resp. 16. 1402 118/78, O2 100%, HR 72, Resp. 16. Client's mother was provided with all relevant vaccine information and instructed to seek medical attention if further concerns arise in the evening. Client denied EMS transport. Client completed his observation at 1402 and departed with his mother at 1402 in positive disposition with steady gait asking his mother if he could go out and "skate".</p>

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1326658	5/18/2021	PA	32	F	5/17/2021	5/17/2021	Systemic: Allergic: Anaphylaxis-Mild, Systemic: Allergic: Itch (specify: facial area, extremities)-Mild, Systemic: Allergic: Itch Generalized-Mild, Systemic: Allergic: Rash (specify: facial area, extremities)-Mild, Systemic: Allergic: Rash Generalized-Mild, Systemic: Allergic: Swelling of Face / Eyes / Mouth / Tongue-Mild, Systemic: Numbness (specify: facial area, extremities)-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Additional Details: Swelling and tingling occurred in tongue, lips and throat. Symptoms began to abate 3-4 minutes after administration of epinephrine (Epinephrine 0.3 mg via autoinjector to the pt's left thigh at approximately 1730). Patient was taken to ER by EMS. EMS arrived at approximately 1737.
1327190	5/18/2021		14	M	5/13/2021	5/13/2021	Throat felt tight, hx of allergy to shellfish-has epi-pen at home. This feels similar to his prior anaphylaxis. Pt. and mom agreed to epi and EMS transport. R. thigh epi administered and care was turned over to onsite EMS. Blood sugar was 210. Pt. has type 1 diabetes and uses insulin pump.
1323917	5/17/2021	OH	47	F	5/14/2021	5/14/2021	vaccine given at 0915, pt c/o of chest feeling funny,tight, voice became hoarse and cough started at 0923. 0925 12.5ml Benedryl given , 0930 @ puffs Albuterol given one minute apart 935 c/o hard to get air in and lump in throat, 937 c/o knot in throat feels larger can't take deep breathe, pt requested we give her Epi pen to her. Epi-Pen 0.3mg given IM right lateral thigh at 0937. 0939 she can take a deep breath, lump in throat feels smaller and she is sitting on the side of the bed. 0940 sitting on side of bed still coughing, 0943 Cough improving talking better no longer hoarse voice. Squad arrived at 0945 and transported to hospital ER. Patient has dealt with anaphylaxis for years due to allergies and per her PCP ok to get Moderna vaccine but she needed to be monitored for two hours after injection.

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1323687	5/17/2021	CA	15	M	5/16/2021	5/16/2021	client signaled to EMT for assistance. Client was a 15 year-old male found sitting upright, alert and tracking and stating he was dizzy. Client had a chief complaint of dizziness. Client stated that he began to feel dizzy approximately "2-3 minutes" after his vaccination. Client denied falling and denied any injury. Client denied any allergies or past medical history. Assessment revealed no swelling, discoloration, hives, shortness of breath or other signs of anaphylaxis. Client stated that he felt dizzy but denied any pain throughout his body. Client appeared mildly pale but was alert and oriented to person, place, date and event. Client's airway, breathing and circulation were intact. Vital signs: pulse 78, O2 99%, Respirations 12, Blood pressure 118/82, Eyes equal and reactive to light, lung sounds clear bilaterally. Temperature 97.8. Client and his mother consented to an additional 30 minute observation. Client had a granola bar and juice while waiting and his color pallor subsided. After lying down for five minutes, client stated that he felt better. Remaining vitals were: 0945 - 99% O2, pulse 76, respirations 18, blood pressure 118/78, 1000 - 116/78, Pulse 70, respirations 16 99% O2, 1010 - 118/78, Pulse 76, Respirations 16, 99% O2. Client's mother was provided with all relevant information and instructed to seek medical care or the emergency room if signs of a severe allergic reaction occur later. No medications were administered.
1322837	5/17/2021	IN	26	F	5/15/2021	5/15/2021	Anaphylaxis 2 hours after vaccine. Extreme swelling/tightening of throat, difficulty breathing, talking, dizziness and feeling faint, spots in vision, choking, coughing, chest tightness.

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1322550	5/17/2021			F		4/1/2021	NECK PAIN; LOW BLOOD CIRCULATION; SINUSITIS; STIFF LEG; VISION WAS VERY VERY UNUSUALLY SHARP; RASH ON LEG; HEAVY HEADACHE; COULDN'T CONCENTRATE; ANAPHYLAXIS; SWOLLEN LYMPH NODE; MUSCULAR PROBLEM; ITCHY LEGS; LITTLE ANXIOUS; This spontaneous report received from a patient concerned a 42 year old female unspecified race and ethnic origin. The patient's height, and weight were not reported. The patient's concurrent conditions included microcytic anemia (which was inherited). She had her period on the day of the vaccine. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number: Unknown, expiry date: unknown) dose was not reported, 1 total administered on 07-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On the first day of vaccination (07-APR-2021), she was feeling very alert and she had very heavy headaches, as if her head was heating up like the laptop when overheated. On the second day (08-APR-2021), she woke up with a very stiff leg, and a rash on the same leg, which went away after she took a cold shower. She blamed the walk from the day before. Her headaches continued, but her vision was very unusually sharp. She couldn't concentrate or be in front of the computer for very long, which was also very unusual. On Monday (unspecified date in APR-2021), she experienced more headaches and strange sensations on the left side of my face. However, she suffered from sinusitis so she blamed that. On an unspecified date, she was driving. Her leg was still stiff; it was less stiff than before but it, intensified with the driving. She made sure that she was taking regular stops and did some icing, which however didn't seem to help. Her blood circulation was quite slow. On an unspecified date in APR-2021, she suddenly had anaphylaxis (rush of heat all over the body, confused) which she never had before. Her head was still feeling very weird. She was taken to hospital that night. It looked like it could have been a delayed reaction from the vaccine, since she never had any of these episodes before. She had similar intense episode on 25-APR-2021. Very intense leg stiffness, followed by a rush of heat all over the body, headaches and neck pain. She was very confused and

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scared because none of these intense episodes ever happened to her before. The hospital didn't find anything, other than muscular problems, but it seemed very weird to her that these effects happened so close to each other. She had a few lymphatic massages from a friend, who said the lymph nodes were very swollen, and that was possibly from the vaccine. The massages reignited the circulation, the legs were now feeling very itchy and she began to feel a little better. However, the doctors were investigating these events further with allergy tests. At the time of report, she felt like her body had returned to normal, she was just a little anxious (unspecified date) it would happen again. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from anaphylaxis, sinusitis, rash on leg, stiff leg, low blood circulation, swollen lymph node, couldn't concentrate, neck pain, muscular problem, itchy legs, and heavy headache, and the outcome of little anxious and vision was very unusually sharp was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210511816-COVID-19 VACCINE AD26.COV2.S-Anaphylaxis. This event(s) is labeled per RSI and is therefore considered potentially related.

1322517 5/17/2021

40 F

5/6/2021

5/6/2021 Pt received vaccination at 0955. At approximately 10;15 another patient came over to the admin desk and notified us that pt wasn't doing well. I went over to evaluate and pt told me she felt fine and she would take a Benadryl when she got to the car. I assisted her to the back where we further evaluate her. She had clear signs of anaphylaxis (blood shot eyes, hives, swollen tongue, rapid heart beat) but did not want EPI. I advised her that EPI is NEEDED quickly and that Benadryl was not enough. She then agreed to let me EPI her. Epi was administer in the left thigh at 10;18. A set of vitals were then taken and patient was places on o2. The emergency department was called at 10;20 and arrived at 10;25. During this time another set of vitals were taken. Patient expressed feeling better but jittery. Hives and tongue swelling had significant improvement but patient still had some symptoms so we advised the follow up team of our recommendation for second dose epi. Emergency team took control of patient.

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1322204	5/16/2021	FL	38	F	3/2/2021	3/2/2021	anaphylaxis. 8 days in ICU on Epi due to rebounding anaphylaxis. then 2 weeks on a critical care floor before d/c. still regaining my full strength .
1321937	5/16/2021	MD	36	F	5/14/2021	5/15/2021	Anaphylaxis
1321740	5/16/2021	KS	14	F	5/15/2021	5/15/2021	Patient started to get hives around the cheeks of the face within the 15 minutes of waiting after the shot. Patient was advised to take Benadryl to prevent it from further spreading/anaphylaxis.
1320359	5/15/2021	CA	71	F	3/11/2021	4/1/2021	Anaphylaxis reaction; This is a spontaneous report from a contactable consumer (patient). A 71-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6026) at the age of 71-years-old, via an unspecified route of administration in left arm on 11Mar2021 at 15:30 at 1st dose, single for COVID-19 immunization. Medical history included allergies to fluorescein. Prior to vaccination, the patient diagnosed with COVID-19. Concomitant medications included lisinopril, nebivolol hydrochloride (BYSTOLIC), and amlodipine. She did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient received the COVID vaccine at a clinic. On 01Apr2021 at 14:00, she was getting ready to leave for her 2nd shot at 14:00 and realized that her tongue and throat felt strange. On the way, the patient's husband felt they needed to go to a walk-in emergency center and get checked out. They realized, she was having an anaphylaxis reaction in which she was given an epi shot and ambulance was called. The patient was kept in the emergency room for 3 hours. The event resulted in doctor or other healthcare professional office/clinic and emergency room/department or urgent care visit. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the event was recovered with sequel on an unspecified date in 2021. The event was reported as serious due to being life-threatening.

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1321376	5/15/2021	OR	16	M	5/14/2021	5/14/2021	reports "throat feels a little tight " and "hard to swallowing". Brought to observation area. Vss (baseline HTN per his report). reports seasonal allergies. Oropharynx red upon inspection and drainage noted at back of throat. Able to drink fluids with difficulty. Reports immediate improvement of symptoms after PO fluids. Discussed symptoms of anaphylaxis with him. Released him to home after discussion of serious symptoms and what to contact ems for
1321163	5/15/2021		18	F	4/29/2021	4/29/2021	swelling of throat, difficulty swallowing. patient went to emergency room after leaving and reported diagnosis of anaphylaxis
1321127	5/15/2021	NJ	30	M	5/14/2021	5/14/2021	Vaccine given on right arm. After 5 minutes the patient reported hive-like spots on left forearm/wrist/knuckles (diffuse and approximately 6-7 red spots). After another 5-10 minutes a few more spots appeared on the left arm as well. No itching or pain or tingling was related. No signs of anaphylaxis noted (no trouble swallowing/breathing, no laryngoedema, no dizziness or weakness, no cough, no tingling or redness on skin other than spots. Patient was lucid and calm. Patient was offered 50 mg diphenhydramine IM as per clinic protocol and refused. Patient was observed for a total of 40 minutes after injection and spots did not spread further, and no new spots formed. Patient was advised to go to the nearest pharmacy and get liquid diphenhydramine and take 50 mg immediately. No follow-up or final outcome available.
1320500	5/15/2021	MD	16	M	5/11/2021	5/11/2021	patient developed dizziness about 5 hours after vaccine and began sweating profusely. initial blood pressure was quite low in the 77/46 however subsequent reading was 108/76 and patient exhibited no other signs of anaphylaxis. paramedics were called in case reaction became more severe but patient recovered and was back to baseline within 15 minutes or so. no intervention given.

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1320399	5/15/2021	GA	26	F	5/14/2021	5/14/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Systemic: Chest Tightness / Heaviness / Pain-Severe, Systemic: dizziness-Medium, Additional Details: patient was taken to the er after receiving the epipen. She was monitored for a couple of hours and released. I spoke with husband, when they were home, and was informed that she was feeling well.

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1320380	5/15/2021		33	F	12/1/2020		<p>angioedema; hives; in lips tingling at times; itching; rash; This is a spontaneous report from a non-contactable other hcp. A 33-year-old female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, lot number: Unknown) dose 1 via an unspecified route of administration on Dec2020 (at the age of 32-year-old) as single, and dose 2 via an unspecified route of administration on Jan2021 as single for covid-19 immunization. The patient medical history and patient's concomitant medications were not reported. On 2021, Reporter's daughter had the first Pfizer vaccine in DEC 2020. The second in JAN 2021, 10 days after she broke out in hives and had some angioedema, in lips tingling at times, no throat closures. Eye angioedema was the first sign, around the eyes, that went away and was off and on. On day 10 she woke up with this and has had it ever since. angioedema of the lips on and off. Since Jan 21 she's been headed to toe with hives they never go away, some days her legs are just covered. On 2021, the reporter sated that, 5 days after 2nd vaccine angioedema around both eyes and that was gone now, she's been to dermatologist, immunologist and primary care physician and they've tried, prednisone, IV Benadryl, Zyrtec, Allegra, also done oatmeal baths for itching, dermatologist wanted to put her on cyclosporine, she didn't want to go on it because it's a strong antibiotic. They also gave her pepcid. Reporter asked to have anyone else had anything like this and why it is lasting so long. Reporter stated that everyone was saying, it's an immune response, and give it time and see if it goes away. her daughter woke up in a huge snowstorm the first time she had the angioedema with Mouth, she went to the Emergency Room, they gave her IV Benadryl, kept her there for a little while, sent her home on prednisone pack, not tapered, just 5 days of high dose prednisone. When the prednisone was finished, it came back with a vengeance. Then she went to her Primary Care Physician to see if she had any suggestions. They wanted her to go back on the Prednisone but on a tapered dose, but, she didn't want to take it because she was afraid it would come back worse than ever. It never got better, not even on the high dose prednisone. Other than put her on the prednisone, there wasn't really anything more. 4 Months later it hasn't settled down.</p>

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Reporter asked her daughter to come to where she lives and see Dermatologist, and he ordered a bunch of labs and got it back and it all looked fine. He wanted to start her on cyclosporine, she wanted to wait, didn't want to take it. Reporter stated, "It wipes the immune system out. They give it to transplant patients. they all say It's an immune response, it should settle down. Her daughter has been trying to change her diet, eating things low in histamines, cut out tomatoes, cut out cheeses, everything high in histamines, it doesn't make a difference. Reporter stated, One day they are not quite so bad and then she wake's up and she was covered. Her daughter can't walk, or swim cause hot and cold makes her break out, or makes it worse, because it never goes away. The following adverse reactions have been identified during post authorization use of Pfizer BioNTech COVID-19 Vaccine. Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. Immune System Disorders: severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema). The outcome of the events was reported as unknown. No follow up attempts are possible. Information about lot/batch number cannot be obtained.; Sender's Comments: As there is limited information in the case provided, the causal association between the events and the suspect vaccine BNT162B2 cannot be excluded. The case will be reassessed once new information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

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1320351	5/15/2021	IN	75	F	4/9/2021	4/9/2021	Anaphylaxis reaction (itching, rash, tingling, insomnia); This is a spontaneous report from a contactable Nurse. This 75-years-old female Nurse (patient) reported herself that she received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE Lot number and expiration date unknown), via an intramuscular route of administration, administered in arm left on 09Apr2021 09:45 at age of 75-year-old at a single dose for COVID-19 immunization. Medical history included ongoing hypertension and patient was diagnosed with high blood pressure probably 30 years ago. Patient reported that she was put on amlodipine because her other blood pressure medication wasn't keeping her blood pressure down. patient unable to provide details for blood pressure medication she took before amlodipine, ongoing reflux gastritis patient reported that she was diagnosed with acid reflux 25 years ago, ongoing osteoporosis patient was diagnosed with osteoporosis 3.5 years ago, ongoing scoliosis patient was diagnosed with scoliosis as a child when she was 11 years old. Patient reported that she had surgery 3.5 years ago and her spine was fused from T3 to her coccyx. Patient reported that when she was diagnosed with scoliosis, the doctors back then said that surgery was too drastic. Patient reported that an orthopedic back specialist advised her parents not to let anyone touch the caller, ongoing blood cholesterol increased patient was diagnosed with high cholesterol a year and a half ago, hysterectomy from an unknown date and unknown if ongoing Caller reported that she had a hysterectomy when she was 40. Family Medical History Relevant: Caller reported that she has a grandson that has a severe reaction to tree nuts. Caller reported that her grandson is the only one in her family that she knows of that has a severe allergy to something specific. The patient did not have a history of any previous allergies to specific products or any conditions indicative of an allergy. Concomitant medications included calcium taken for hysterectomy from an unspecified start date and ongoing, esomeprazole taken for reflux gastritis from an unspecified start date and ongoing, Atorvastatin taken for blood cholesterol from an unspecified start date and ongoing, losartan potassium taken for blood pressure measurement from an unspecified start date and ongoing, amlodipine besylate taken for blood pressure measurement from an unspecified start date and

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ongoing, alendronate sodium taken for osteoporosis from an unspecified start date to Apr2021. Calcium: Caller reported that she has been taking Calcium for years. Fosamax: Caller reported that her doctor cancelled the Fosamax because it was causing a problem with reflux, burning and so forth. Caller reported that her physician is trying to get her one something that is given by an infusion once a year to replace the Fosamax. Caller reported that she took the Fosamax in the morning with water, no food, and didn't lay down afterward. Caller reported that she knew that it would cause problems if she laid down after taking the Fosamax. Fosamax Product Info: NDC: 69097-224-16, Lot Number: GC00501, Expiration Date: Apr2023. Caller reported that she used another medication for 2 years before Fosamax that was given via injection that can only be given for 2 years. Losartan: Caller reported that she was on another blood pressure medication and the pharmacy called and told the caller to stop taking that blood pressure medicine. Caller reported that the pharmacy informed her that they had gotten reports that her blood medication was bad medication. Caller reported that she received the medication and phone call from the Pharmacy. Caller reported that the pharmacy instructed her not to take any more of the blood pressure medication and to go back to her doctor and have him prescribe something else. Caller reported that the pharmacy informed her that the product had something in it that is not good for your health. Caller was queried for details on her old blood pressure medication. Caller reported that she threw the medication in the trash because the pharmacy explained that it could be deadly to her health. Caller unable to provide details of the blood pressure medication she took before Losartan. Scoliosis: Caller reported that her brother found out that there are surgeons that are taking care of scoliosis in older patients at the hospital. Caller reported that she had the surgery done and it has allowed her to have her life back because she was going down very fast in what she could do. Caller reported that the pain was just too much at times. Caller reported that her quality of life was poor and now it's very good. Caller reported that she didn't go to see her physician for the rash or itching, she just took Benadryl and waited it out. The patient did not receive any recent vaccines for any other conditions prior to the event being reported, the patient did not

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receive any recent vaccines for SARS-CoV2 other than Pfizer BIONTECH COVID-19 Vaccine prior to the event being reported, the patient did not received any other vaccines around the time of the Pfizer BIONTECH COVID-19 Vaccine vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced anaphylaxis reaction, (itching all over just severely from head to toe, small rash on back, lips tingle a little) on 09Apr2021, patient itching so bad she couldn't sleep. Patient reported that she received her first dose of the Pfizer Covid-19 vaccine on 09Apr2021. She was supposed to have her second dose of the Covid-19 vaccine today, 07May2021, but she called and cancelled the appointment. The lady that gave the caller the Covid-19 vaccine called her wondering why she had cancelled her appointment. Patient had a reaction from the first dose of the Covid-19 vaccine where she was itching all over just severely from head to toe. Patient was miserable and took Benadryl. Patient reported that the Benadryl helped her get to sleep. Patient reported that she also had a small rash on her back that she put Benadryl cream on. Patient reported that the rash lasted 2 days or so. Patient reported that she has a little itching now but it's nothing, the itching could be just normal for her. Patient reported that for 2 days the itching was not normal at all, it was severe itching. Patient reported that she didn't know if she should even have the second dose of the Covid-19 vaccine following her reaction to the first dose. Patient reported that she called the pharmacist who instructed the caller to call her physician. Caller reported that she called her physician and he informed the Patient that there is not enough information for him to be able to tell the caller what she should do. Caller reported that she asked her physician if she took a Benadryl before she went to get the second dose of the Covid-19 vaccine and took someone with her to the vaccination facility, would that be enough. Patient reported that her physician informed her that he would definitely recommend that the caller take Benadryl if she gets the second dose of the COVID-19 vaccine, but would not tell the caller whether or not she should get the second dose. Patient reported that she didn't know how long you had to decide to get the second dose of the Covid-19 vaccine or not. Caller reported that someone told her that you have 3 weeks

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after the first dose of the Covid-19 vaccine and 3 weeks after you're supposed to have the second dose. Caller inquired how much longer she has to decide whether or not to get the second dose of the Covid-19 vaccine. Patient reported that the itching began about 5 hours after she received the first dose of the Covid-19 vaccine on 09Apr2021 and the itching was severe for at least 2 days. Patient he has itched a little here and there, patient is always out in the yard doing something. Patient nose itched so bad that she couldn't stand it, not having any trouble with breathing and lips tingled a little and she wondered if that was just from itching. Patient was trying to use her knowledge to figure all of this out on her own. Caller reported that's all she could figure out and it was mainly severe itching. Patient had no swelling of the lips and no difficulty swallowing or breathing. Patient couldn't sleep due to the itching, so she would say that the itching was at least almost definitely medically significant, patient reported that it wasn't life or death, the itching was just annoying. Patient was constantly just scratching her head a little and she feels a little itchy at places. Patient did not know if in the past she has been itchy before but she doesn't think that she has. Small rash on back: Caller reported that when the severe itching began, there was one place on her back that she started scratching. Caller reported that she had her husband look at her back and he informed her that there was a little rash back there. Patient reported that her husband stated the rash was probably about 5 inches but only maybe 2 inches the other way. Caller reported that the rash was not a big area. Patient didn't have her husband look at the rash after that. Caller reported that when she took Benadryl orally, the itching stopped and she just let it go. Caller reported that she did have her husband look the other day and the rash was no longer there, itching, rash, tingling, insomnia was diagnosis as anaphylaxis. The patient did not required medical intervention, the patient did not visit in the Emergency Department or physician office, not hospitalized and not admitted to an Intensive Care Unit. Seriousness of the event was reported as always serious, medically significant. The outcome of event was recovering. Additional information has been requested.; Sender's Comments: Based on known drug safety profile, there is reasonable possibility of causal association between the event anaphylactic reaction and

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							the suspect drug BNT162B2.
1319820	5/15/2021	OH	77	F		3/26/2021	SEVERE ARM PAIN; This spontaneous report received from a patient concerned a 77 year old female. The patient's weight was 155 pounds, and height was 65 inches. The patient's past medical history included anaphylaxis, and concurrent conditions included no alcohol use, and non smoker, and other pre-existing medical conditions included the patient was not pregnant at the time of vaccination. the patient had no history of drug abuse or illicit drug use. The patient experienced drug allergy when treated with formaldehyde solution. The patient received covid-19 vaccine (suspension for injection, route of admin not reported, batch number: Unk) dose was not reported, administered on 26-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 26-MAR-2021, the subject experienced severe arm pain. The action taken with covid-19 vaccine was not applicable. The outcome of severe arm pain was not reported. This report was non-serious.
1317735	5/14/2021	NC	14	F	5/14/2021	5/14/2021	Immediate syncope lasting about 15 seconds with 5 seconds of tonic-clonic activity and brief emesis. Normal mental status within 30 seconds. Initial heart rate 50, and BP 90/60, recovered to normal with BP 100/60 and heart rate 70 within 30 minutes. No signs of allergic reaction or anaphylaxis. Taking fluids and felt well upon discharge.

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1316227	5/14/2021	CA	71	F	4/22/2021	4/22/2021	I also woke up in the evening drenched with sweat and chills, completely sweat; I also woke up in the evening drenched with sweat and chills, completely sweat; shaking so badly; I was that sick; First shot was February 25, the second shot was April 22nd; First shot was February 25, the second shot was April 22nd; have anaphylaxis at 30 minutes/probably something in the medication that she was allergic to; This is a spontaneous report from a contactable (patient) reported for herself that a 71-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Batch/Lot Number reported as EDOL71/ENOL71, unsure) via an unspecified route of administration on 22Apr2021 12:15 pm as 2nd dose, single for covid-19 immunisation. Medical history included shortness of breath, asthma. Concomitant medications included albuterol (SALBUTAMOL) and budesonide/formoterol fumarate (inhalation aerosol). Patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 25Feb2021 at the age of 71 years for covid-19 immunisation and she did fine. Patient stated that lot number for shot 2 looked like EDOL71. It could be ENOL71. The lady didn't write it very well. It could be EN or ED. She was calling to report she had a terrible side effect and she want to document it in the data. She couldn't give that to computer right now, she didn't feel well, she had the Pfizer shot 1 and Pfizer shot 2. She had anaphylaxis at 30 minutes and almost she had crashed her car just after the highway. First shot was February 25, she did fine, the second shot was April 22nd and she had a horrible reaction at 30 min. Patient stated that the problem is they didn't asked her if she was short of breath or if she had any pulmonary complication and so on the second shot she didn't say anything and she forgot to say she has asthma and no one asked her. she forgot to say and so they had her sit in 15min observation and she was fine and she had gone out after she got her vaccination record card sign, she got in her car and 15min. Later while she was driving she went into anaphylaxis. She had to pull over, thank god she didn't hit anybody, she pulled over and parked and she had her inhaler with her so she used the inhaler and she got in the back seat for half an hour to make sure that she drove home, she did not call 911. Patient further stated that she wanted to put it in documentation, if someone is

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taking something for asthma that probably should not have the second shot one medication is not good enough, the second dose and she also woke up in the evening drenched with sweat and chills, completely sweat and that happened about 8 to 10 hours after the shot on 22Apr2021. After the shot at 12:15 pm and she had the sweat about 11 O'clock at night when she had to lay down and she was shaking so badly she thought she was going to call 911, she was that sick. That's scary, patient stated "I must, I did have crashed in 3 or 4 people during that." So, it was very dangerous to someone who has asthma. That was probably something in the medication that she was allergic to. Outcome of the events was unknown.; Sender's Comments: Based on the very close temporal association, there was a reasonable possibility that the vaccination with BNT162B2 played a contributory role in triggering the onset of the anaphylaxis.

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1313011	5/13/2021	NY	30	F	4/6/2021	4/7/2021	hard to hear at times; horrible pain from head to toe; couldn't see anything; couldn't breathe at all; face turned green; fever; aching in her legs; extreme exhaustion; blacking out; diarrhea; sweating; unable to talk; This is a spontaneous report from a contactable consumer. A 30-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 06Apr2021 12:00 (Batch/Lot Number: EW0150) as 1st dose, single, at the age of 30-years-old for COVID-19 immunization. The patient had no medical/family history and concomitant medications. The patient went to go get her second shot of Pfizer covid vaccine but they wouldn't give it to her based on her reactions to the first dose. They said there was a chance of anaphylaxis reaction to the second shot. The patient reported blacking out, diarrhea, sweating and unable to talk. She consulted with her healthcare professional regarding whether to get the second shot and they didn't know. She asked if her reactions were normal. She doesn't know what to do whether to get a second shot given her reaction. It was mentioned that the patient was hard to hear at times. She got the vaccine on 06Apr2021 around noon and she was fine until around 3:30 am. She woke up in horrible pain from head to toe, she thought maybe she just needed to pee, she didn't know what was going on. She stood up and she blacked out like she was about to faint. She couldn't see anything, like it was completely black. She got to bathroom and she couldn't breathe at all, she couldn't talk. She thought she needs to go to the hospital, but she couldn't talk. Her face turned green, she had diarrhea, she was like dripping wet. At this point, she could sort of breathe. She felt like she was being held under water, still dripping sweat. She has recovered completely from these symptoms. The severity of symptoms was so severe she doesn't know if she had a fever at the same time, it was hard to tell. With the breathing part, she was so freaked out by that, so it's hard to know for sure, maybe yes. She may have had a low fever. She had a fever that night to the point where she was dripping on the floor. She has aching in her legs. She went to the doctor thinking she had Lyme disease, which she doesn't. Since that vaccine, she's had very, somewhat severe leg aches and extreme exhaustion like all the time. she can hardly go to work sometimes.

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Everybody has days they are tired, but this was different. She had to come home at 2pm and lay down for like five hours. She stated it was persisting. She had a blood test recently and everything came back perfect on 26Apr2021. She thought she had Lyme disease because of all the symptoms she was having, and it all came back negative. She didn't exactly get turned away. They said they didn't feel comfortable giving her the second dose of vaccine. The patient stated if a nurse tells her they don't feel comfortable, she wouldn't feel comfortable until she speaks to Pfizer. The nurse told her she had to go to an allergist and rheumatologist. The nurse said the same thing, the nurse told her that she should have gone to the hospital, but she wasn't thinking at that moment. She was just at a loss of what to do. That day at the hospital, they were scared with the second vaccine that she could go into anaphylaxis and she's not sure what to do. The patient had no other vaccines administered on the same date of Pfizer suspect and no other vaccinations within 4 weeks. The event hard to hear at times started on an unknown date while other events started on 07Apr2021 and ended the same day. The outcome of the events aching in her legs and exhaustion was not recovered, hard to hear at times was unknown while for other events was recovered. The events "she blacked out, like she was about to faint" was assessed as serious medically significant. No follow-up attempts are needed. No further information expected.

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1314608	5/13/2021	OH	32	F	3/7/2021	3/7/2021	5 minutes after vaccination, I felt unwell. I sat with EMS that was onsite. HR was 160's, BP 160's systolic. Right arm went numb in first 5 minutes and my face went numb after 15 minutes post injection. After sitting 45 minutes with EMS my vitals stabilized and no numbness present. I walked to the car, sat in the car for 10 minutes and then I went into anaphylaxis. My airways began to close. My husband got the EMS on site and I was taken by ambulance to the ER. I was given IM Benadryl in the ambulance. In the ER I was given IV Benadryl and IV steroids. After anaphylaxis event I had difficulty breathing for 3 weeks from enlarged lymph nodes. I had extreme shortness of breath for the 2 weeks following injection in that I had to crawl up the flight of stairs to the second level of our home. About the 3rd week after injection, I began having full body itching with no known stimuli. Only benadryl would treat it. I was on allegra or zyrtec daily. I would also develop 1 or 2 hives on my right arm. 4 weeks after injections I was reacting to food and drink. I could not drink alcohol- gin or vodka- it would result in full body itching and a few hives. I did a course of prednisone, and it decreased my allergic reactions and I felt almost normal for several months. On May 8th, 2021 I had be experiencing great stress since February from a family member's cancer diagnosis. I had a crying event and immediately after I had an allergic reaction to gin, which had not occurred since the course of steroids. Today is 5/13 and I have had 2 additional allergic reactions: one involving food and the other flowers. None of which I have ever been allergic to before. I have full body itching and I am now developing hives more often.

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1314415	5/13/2021	MN	28	F	5/12/2021	5/12/2021	immediately post-vaccination pt experienced flushing/warm sensation L side of arm/neck/face. Patient sat in chair x15min, given water. Pt states continued flushing with dizziness and inability to focus vision/blurry vision. Had patient continue to sit and observed additional 30 min. Pt reported no change in symptoms, moved pt back to vaccination room to reduce noise/traffic. Checked BP 144/100, pulse 77. Pt given more water and observed. No labored breathing or obvious distress noted. Pt reported tingling of tongue/throat. No signs of swelling of tongue/throat with examination but increased flushing of face/throat/ears. Pt offered benadryl, she disclosed anaphylaxis to benadryl and refused antihistamine. discussed concern of reaction and use of epipen/EMS services. Patient declined, asked for continued observation. observed x 15 min, no change in status. observed additional 15min, offered loratadine (pt states taken safely in past) pt declined. observed 15min, pt states continued tingling in mouth/throat with slight difficulty swallowing, no observed labored breathing, pt able to carry conversation without effort. Recommended epipen and EMS, pt refused. Pharmacist advised against driving and recommended seeking emergent care. Patient refused EMS and left with friend with request from pharmacist to go to ER. F/u with pt 2 hrs later, pt was at ER but no updated status. Phone call F/u with pt next day (5/13, 1pm). pt states given 1 medication (unknown) that reduced symptoms of tingling but HR/BP continued to fluctuate. ER discharged pt home evening of 5/12 and pt has f/u with primary care 5/14/21.

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1314302	5/13/2021	NV	53	F	4/14/2021	4/16/2021	1st Shot on 3/18/2021 - delayed adverse reaction, 24 hours later developed anaphylaxis to everything I ate for 3/5 days. Difficulty swallowing water. This ended on 3/22/2021. 2nd Shot on 4/14/21 - for two days normal expected reactions, joint pain, sore arm, chills, etc. This went away and I went to work on 4/16/21. Then at 2 pm on 4/16/21, my arm swelled to twice its size and I developed a rash at the injection site. That is when the adverse reaction began with relentless itching from head to toe, non-stop, 24/7. It has been a month now, and am still experiencing these symptoms. I am unable to work. I have been going to an allergy specialist every week and receiving Dupixent shots and taking Gabapentin every 4 hours around the clock. on 5/11/21 the itching seemed to be going away and I was getting better, but today 5/13/21 it has returned with a vengeance. I am again itching from head to toe like fire ants all over my body. It never stops.
1314140	5/13/2021	CO	52	F	4/13/2021	5/13/2021	4:11 pm tightness and swelling of throat; 4:30 pm anaphylaxis - s/sx swelling of throat and tongue, difficulty swallowing, dysphonia, hypertension, low saturation, hoarseness; 4:35pm Tx Epinephrine 0.3 mg IM, ECG, Benadryl 75 mg IV, 5:05pm transport to hospital, ECG, 5:15pm ECG, 5:35 pm famotidine IV, methylprednisolone sodium succinate IV Have had chronic dysphonia since.

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1309205	5/12/2021	NY	76	F		4/30/2021	<p>CONFUSION STATE AS CLOSED TO SUFFERING OF DEMENTIA; PAIN IN BOTH EARS; INJECTION SITE PAIN; HIGH FEVER; This spontaneous report received from a patient concerned a 76 year old female. The patient's weight was 145 pounds, and height was 162 centimeters. The patient's past medical history included covid 19, and concurrent conditions included fibromyalgia, contrast dye allergy, kiwi allergy, raw shellfish anaphylaxis, non alcohol user, and non smoker, and other pre-existing medical conditions included the patient was not pregnant at the time of reporting and had no history of drug abuse or illicit drug use. The patient was previously treated with influenza vaccine. The patient received covid-19 vaccine (suspension for injection, intramuscular, batch number: 206AZIA, and expiry: UNKNOWN) dose was not reported, administered on 30-APR-2021 14:00 for prophylactic vaccination. No concomitant medications were reported. On 30-APR-2021, the subject experienced confusion state as closed to suffering of dementia. On 30-APR-2021, the subject experienced injection site pain. On 30-APR-2021, the subject experienced high fever. On 30-APR-2021, the subject experienced pain in both ears. Laboratory data included: Body temperature (NR: not provided) 104 F. On 01-MAY-2021, Laboratory data included: Body temperature (NR: not provided) 104 F, 103 F. Treatment medications (dates unspecified) included: acetylsalicylic acid, and paracetamol. The action taken with covid-19 vaccine was not applicable. The patient recovered from confusion state as closed to suffering of dementia, injection site pain, high fever, and pain in both ears on 02-MAY-2021. This report was non-serious.; Sender's Comments: V0: Medical assessment comment not required as per standard procedure since case was assessed as non serious</p>

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1309562	5/12/2021	TN	45	M	4/13/2021	4/13/2021	Anaphylaxis with swollen lips; Anaphylaxis with swollen lips; felt like throat was closing; difficulty breathing, could not take a deep breath; This is a spontaneous report from a contactable consumer (patient). A 45-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in left arm on 13Apr2021 at 12:00 (Lot Number: ER8B2) as SINGLE DOSE for COVID-19 immunization. Medical history included possible rheumatoid arthritis from an unknown date and allergy to poultry from an unknown date. There were no concomitant medications. No other medications were received by the patient within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Since the vaccination, the patient had not been tested for COVID-19. On 13Apr2021 at 23:00, the patient experienced anaphylaxis with swollen lips and reported that he felt like his throat was closing and had difficulty breathing, could not take a deep breath. The patient went to emergency room as well as the physician office for the reported events. As therapeutic measures multiple Intravenous (IVs), oral benadryl and steroids were taken by the patient for the reported events. The outcome was reported as recovered with sequel for the reported events.

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1309607	5/12/2021	NY	67	F	5/1/2021	5/1/2021	Lips started burning, tongue started, lost taste buds, throat drying/Basically an anaphylaxis but my throat did not close up; This is a spontaneous report received from a contactable consumer, the patient. A 67-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 01May2021 11:15 (Batch/Lot Number: EW0172) (at the age of 67-year-old) as 2nd dose, single for covid-19 immunisation. Medical history included heart, hashimoto, high cholesterol, fibromyalgia and allergies. Concomitant medication(s) included levothyroxine sodium (SYNTHROID); amitriptyline (MANUFACTURER UNKNOWN); carvedilol (MANUFACTURER UNKNOWN); clopidogrel (MANUFACTURER UNKNOWN); all taken (received within 2 weeks of vaccination) for an unspecified indication, start and stop date were not reported. The patient previously received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 1 administered in Arm Left on 10Apr2021 11:15 (Batch/Lot Number: EW0162) for covid-19 immunisation and had no adverse event. The patient did not receive any other vaccines within four weeks prior to the vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 01May2021 20:00, the patient lips started burning, tongue started, lost taste buds, throat drying. Basically, an anaphylaxis but my throat did not close up. The seriousness criteria were considered as non-serious. No treatment was given for the events. The outcome of the event was recovering.

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1309996	5/12/2021	IN	30	F	5/10/2021	5/10/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Medium, Systemic: Allergic: Itch (specify: facial area, extremities)-Medium, Systemic: Allergic: Itch Generalized-Medium, Systemic: Allergic: Rash (specify: facial area, extremities)-Severe, Systemic: Allergic: Rash Generalized-Severe, Systemic: Allergic: Swelling of Face / Eyes / Mouth / Tongue-Medium, Systemic: Chest Tightness / Heaviness / Pain-Mild, Systemic: Flushed / Sweating-Severe, Systemic: Headache-Medium, Systemic: Hyperventilation-Mild, Systemic: Numbness (specify: facial area, extremities)-Mild, Systemic: Tachycardia-Medium
1310847	5/12/2021	IL	46	M	5/6/2021	5/6/2021	Site: Pain at Injection Site-Mild, Systemic: Allergic: Anaphylaxis-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: patient was unresponsive for few seconds less than a min and came back 911 paramedics evaluated him and took to emergency for further evaluation
1312242	5/12/2021	GA	12	M	5/11/2021	5/11/2021	Vaccine was given at 3pm. At 4:30pm patient had a tight chest so he used his inhaler. At 8:30pm he went into anaphylaxis---red from head to toe, swollen hands and feet, could not move fingers or toes, lips blue and swollen. He was transported to the ER.
1310942	5/12/2021		54	F	5/11/2021	5/11/2021	10 minutes after getting the Johnson and Johnson vaccine, while patient was waiting in the waiting area for 30 minutes due to history of bee allergy and anaphylaxis, she reported shortness of breath and dizziness to nurse. Assisted her to the floor with her legs up- obtaining pulse ox and BP/HR, which were stables. Patient reported shortness of breath and dizziness, worsening symptoms, she was tearful, and stated symptoms are the same as her previous anaphylaxis reaction. I informed her I was giving her a dose of epi, and injected 0.3 ml of epi, adult dose to left thigh. Patient reported immediate relief, EMT arrived, At 15 minutes, patient was crying and laughing, reporting worsening SOB again. EMTs arrived and took over the scene. Patient was transported to hospital.

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1306306	5/11/2021	NY		F		4/1/2021	DEEP VEIN THROMBOSIS; This spontaneous report was received from 66-year-old, White, not Hispanic or Latino female patient. The patient's height, and weight were not reported. The patient's past medical history included Factor 5 Leiden positive (no clot issues since 1998 and did not take any standard medication for it as per guidelines), and anaphylaxis due to drug and shellfish allergies. The patient underwent a surgery (unspecified) and was immobilized and developed multiple clots in her right leg. Concurrent condition included shellfish allergy. The patient drinks alcohol socially (rarely), does not smoke and had no drug abuse or illicit drug use. The patient experienced drug allergy when treated with Aspirin (acetylsalicylic acid), and ibuprofen. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration was not reported, batch number: 1805022 and expiry: unknown) dose was not reported, 1 total, administered on left arm on 08-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 15-APR-2021 (approximate date), the patient experienced persistent leg pains. On 29-APR-2021, the patient developed pitting edema, experienced ankle redness and ankle pain. On 01-May-2021, the patient saw a retired orthopedic surgeon who advised the patient to go to a doctor immediately. On 02-May-2021, the patient went to the primary care office, saw a nurse practitioner and was immediately sent to the Emergency room (ER). On the same day, many blood tests were done (including differential, routine chemistry and coagulation), all of which showed normal results and a computed tomography (CT) scan showed thrombus in left posterior tibial vein below the knee (blood clot in left calf) following which a diagnosis of deep vein thrombosis (DVT) was made. On 02-May-2021, the patient started with Xarelto (rivaroxaban) 15 mg twice daily for 21 days then decrease to once daily as part of treatment for DVT. The patient completed 6 doses of Xarelto at the time of report. Both the ER doctor and the primary care doctor stated that the cause of DVT was the vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of deep vein thrombosis was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210509051- covid-19 vaccine ad26.cov2.s - Deep

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							Vein Thrombosis. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY, UNDERLYING DISEASE.
1308485	5/11/2021	MN	25	M	5/10/2021	5/10/2021	Delayed anaphylaxis reaction (2 hour)
1304836	5/11/2021	WA	50	F	5/7/2021	5/7/2021	I received my second Moderna dose at about 16:25 in the afternoon. Within a minute or two, I then felt a strange flushing sensation in my left shoulder, neck and left side of the head (the same side where the shot was injected) . This made me very uneasy but I went outside to wait while my husband got his shot. Within five minutes, I felt my heart begin to race and pound extremely hard, like a hammer against my chest. My whole body began to feel hot and I felt weak and shaky. I put my fist on my breastbone and tried to breathe slowly. I wasn't sure if this was anaphylaxis because I've never experienced that before, but this did not feel normal. I texted to my sisters what I was feeling in case something bad happened. I almost got up to tell the pharmacist that I needed help but felt too shaky and didn't want to make a scene. When my husband came out to join me, I told him I wasn't feeling right and my heart was pounding. But I was breathing okay. My tongue started to feel "fuzzy" and thick, so I kept breathing slowly and talking as a way to check if I was going to be okay or get worse. After about ten minutes this strange reaction started to pass. By 16:50, I texted my sisters that I was feeling well enough to get up and complete my shopping. The strangest part was that my heart was beating extremely fast and very hard, like a fist beating against my chest. And that my whole body felt weak and shaky while that was happening.

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1305668	5/11/2021	NY	56	F	3/18/2021	3/18/2021	anaphylaxis; headache with numbness; headache with numbness; blurred vision and nausea from headache; blurred vision and nausea from headache; has been trapping food since in her throat; had irritation in her throat; coughing; coughing; off balance; couldn't see straight; This is a spontaneous report from a contactable consumer (patient). A 56-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot Number: EN6207), via an unspecified route of administration, administered in Left Arm on 18Mar2021 10:30 (at age of 56 years old) as single dose for COVID-19 immunisation. Relevant medical history included: Asthma, immune problems, upper respiratory stuff, all ongoing; Her Diagnosed allergies include iodine fish, Propofol, and preservatives, sleep apnea, had COVID in Jan2021, and had a cough (Jan2021) from that. There were no concomitant medications. The patient previously took iodine, propofol and had allergies. Patient took first dose on 18Mar for reason that patient has lost all allergies that cannot be detected by blood work. After first shot she was told to wait an extra 15 mins not vitals taken she can leave a felt like a specimen unpaid but paying with life. Patient started coughing while everyone watched her so she said she better take Benadryl cause she doesn't wanna die. Patient left had off balance couldn't see straight. She was the one that had all side effects from vaccine as well as COVID signs. She had research medicine/food that cause her to have anaphylaxis. Patient found same ingredients in vaccine but food and drug said it ok. Patient was an experiment. She need to no from your board it is ok for me to take 2nd vaccine. Patient should be getting paid. Her doctor making it seem it up to her she gotta go out and get and epi pen she cant afford. In running out of gloves and mask. The patient experienced Anaphylaxis, has been trapping food since in her throat, headache with numbness, Cough, blurred vision and nausea from headache, all on 18Mar2021. Caller has been coordinating with the CDC by email. Since day one she had a bad reaction to the COVID vaccine. This has been going on a month now. The CDC advised her not to get the second shot. She has went back and forth with the doctor. She had anaphylaxis from the vaccine. Her throat closed. She had irritation in her throat. She has been trapping food since in her throat.

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This has been since the anaphylactic reaction. She has to chew her food as fine as possible. She tries not to eat that much. This is still the same. It hasn't improved or worsened. She has also had a headache with numbness that is pretty much 24 hours a day. This started right after. She really felt it the next day. She tried to take Tylenol for four days, three times a day, and nothing happened. It was not going away. Her doctor also put her on a migraine medication, but it didn't work either. The headache has worsened over time. No medication is helping, and the doctors are confused. The migraine medicine is not helping. Her pressure is going up and down. She is wondering if she needs an emergency echo to see what is going on. She is still having bad effects. No doctor knows what to do. She has been to a lung specialist. Her cough just keeps getting worse. The cough started to get worse after the vaccine. She had COVID in Jan2021, and had a cough from that, but the vaccine made it worse. It is a ruff cough. She is on cough suppressant medication. Caller did not have a prescribing doctor. She got it at the hospital. She figured that was the safest, and since she is a patient there they emailed her because she was eligible to get it. She is mostly calling because the doctors don't know how to help. She is about to pass out from this headache. She is even losing vision from the headache. She feels like she is going to have a heart attack before her time. They are trying to figure out why her head is hurting. They do not think it is a migraine. Her headache is a 9/11 or a 10/12. She feels like after the vaccine she has been chemically off balance. She wants to get her thyroid checked too. Mostly because her food is getting trapped in her throat. Her throat is irritated and hoarse. The headache has given her blurred vision, and a felling like she is going to throw up. She feels off balance from the blurred vision. Caller had difficulty seeing information on Tylenol and Nurtec. She asked her husband to help. They cannot read the lot on the Tylenol. She has been to so many specialists to try to find answers, and no one has a clue. She saw on Pfizer's paperwork that she needs to reach out to a immunologist. Her allergist had no clue. From the world trade centers falling she has ongoing issues from that. She has sleep apnea, allergies, asthma, etc. She spent 30 minutes being monitored at the hospital. She had started coughing. Her husband said she needed

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							water. She always carries Benadryl with her. Finally she felt like she needed to take her Benadryl. It saved her. She knows the Benadryl probably won't work forever, but she cannot afford an epi Pen. Time of Onset (24 hours clock): right after vaccine (18Mar2021). All events require a visit to Physician Office. She didn't have to go the ER. She was lucky with the Benadryl. She takes Benadryl with her everywhere even to restaurants. No Prior Vaccinations (within 4 weeks). Treatment received for coughing, headache with numbness, blurred vision and nausea from headache. The outcome of the event has been trapping food since in her throat, had irritation in her throat, headache with numbness, blurred vision and nausea from headache was not recovered, for other events was unknown.
1307329	5/11/2021		57	F	4/30/2021	5/4/2021	Presented to the emergency room 5/3/21 after the development of multiple symptoms after her second COVID vaccine on Friday. Symptoms consisted of perioral tingling, some possible oral swelling, and then subsequent shortness of breath with labored breathing. Initial treatments in the emergency room did result in some symptomatic benefit, however, the patient continued to have an oxygen requirement and demonstrated persistent symptoms of anaphylaxis. She was then admitted to the intensive care unit for higher level intervention.
1306552	5/11/2021	NJ	49	F	5/10/2021	5/10/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Chest Tightness / Heaviness / Pain-Medium, Systemic: Exhaustion / Lethargy-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Weakness-Severe
1302150	5/10/2021		61	M	5/10/2021	5/10/2021	Pt complained of SOB. He had a normal pulse ox and RR. He was not exhibiting signs of angioedema or anaphylaxis.
1301694	5/10/2021	NJ	48	F	5/3/2021	5/3/2021	Severe anaphylaxis- Red on face and arm (hives/itching), severe shortness of breath, and severe swelling of face and under the arms.

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1302817	5/10/2021	CA	55	F	5/10/2021	5/10/2021	Janssen COVID EUA 2021: During post vaccine observations the patient stated feeling localized itching. Patient did not show signs of anaphylaxis, no rash or urticaria, no angioedema and had clear lungs with no complaint of SOB, Difficulty breathing or chest pain. Patient signed AMA via Hospital.
1303210	5/10/2021	MI	27	M	5/5/2021	5/9/2021	Hives appeared and covered the whole body overnight 3 days after the vaccine but no anaphylaxis. Took Benadryl in the morning and the hives slowly went away during the course of the day. The following night, woke up at 4am covered head-to-toe in hives, swollen face, lips, difficulty swallowing. Called 911 and was treated with an epinephrine pen, symptoms slowly subsided over the next few hours after being monitored at the ER. No previous experience with allergic reactions or anaphylaxis.
1303493	5/10/2021	IN	35	F	5/10/2021	5/10/2021	Anaphylaxis within 1 hour of receiving the vaccine: difficulty breathing, feeling of itchiness and swelling in throat.
1303507	5/10/2021	NY	56	M	5/9/2021	5/10/2021	Pt presented with tongue and throat swelling associated with scattered hives. Pt was treated for anaphylaxis and responded to IM epinephrine x1. He was observed in the emergency department and then discharged safely.
1300105	5/8/2021	GA	52	F	5/8/2021	5/8/2021	Within 10 minutes patient requested Benadryl. She felt a strong tingle sensation. Her skin was warm to the touch. Blood pressure elevated at 152/98. Two doses of Benadryl 25mg given. One at 1:18 pm and one at 1:55pm. Benadryl worked well and her skin was a normal temperature but she described a tightness in her chest. She took two puffs of albuterol 90 mcg and the nurse at the Dr. office stated that she needed to go straight to the emergency room for evaluation. at 2:30 pm she should no more signs of an allergic reaction or any signs of anaphylaxis but reported a headache. Husband picked her up and was instructed to go to emergency department for evaluation.

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1299886	5/8/2021	MI	16	M	5/8/2021	5/8/2021	Patient being observed post covid vaccination for hx of anaphylaxis with nuts and many foods. At 30 minute mark, he was observed to have faint hives at left side of face and under chin. Trunk clear. No s/sx of distress. Evaluated by EMS - mouth, throat, lungs clear to auscultation . Patient and his mom decline Benadryl IM - discharged to home. Intends to take PO Benadryl.

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1299370	5/8/2021	MD		F			<p>Anaphylaxis After the Covid-19 Vaccine; This is a literature report. Authors reported a case of the first patient at the (Hospital), who had immediate anaphylaxis after administration of the Pfizer-BioNTech Covid-19 vaccine. Authors highlighted that the patient never had an episode of anaphylaxis previously and had nonreactive skin testing for polyethylene glycol, polysorbate-containing vaccines, as well as the Covid-19 vaccine itself. Importantly, she had an underlying condition that predisposed her to non-IgE-mediated anaphylaxis. The case is a 34-year-old female healthcare professional, who presented to the Allergy and Immunology clinic for evaluation of an anaphylaxis event that occurred after administration of the first dose of the Pfizer-BioNTech Covid-19 vaccine. The patient had negative SARS-CoV-2 nucleic acid tests 109 and 39 days before immunization. She noted in the interview to have been subjectively overheated while standing in line waiting to receive the first dose of the vaccine. Within 3 min of vaccine administration, she developed flushing, urticaria on her extremities and face, generalized pruritus, tongue swelling, nausea, light-headedness, racing pulse, and shortness of breath with absence of wheezing. Emergency medical personnel responded and administered intramuscular epinephrine and diphenhydramine. She noted substantial relief within minutes of administration of these medicines. The patient was transported to the emergency department for monitoring and had no further reaction. After discharge, she noted erythema and hives around the site of injection, which were nearly resolved by the time of our evaluation 2 days later. Two years earlier, she noted a large hive at the site of injection that took days to resolve after receiving preservative free quadrivalent influenza vaccine, Fluarix (GlaxoSmithKline) without associated systemic symptoms. Two months before the anaphylaxis event, she received Afluria (Seqirus), quadrivalent preservative-free influenza vaccine. Again, she noted a large local hive at the site of injection without a systemic reaction. She also described a history of childhood asthma and eczema but had never had an episode of anaphylaxis. She lastly described a greater than 10-year history of inducible episodes of pruritus, swelling, and hives that were most notable at times of sweating. She noted an inability to take warm showers as well as</p>

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limitations with exercise due to pruritus and hives in what was suspicious for cholinergic urticaria. Authors performed an examination, laboratory studies, and several procedures for evaluating her anaphylaxis episode. Laboratory evaluation showed elevation in C-reactive protein (CRP) (1.27 mg/dL) 2 days following immunization, negative chronic urticaria (CU) index (4.3), and IgE levels (74.98 IU/mL) within the reference range. Dermatographism was not present. Skin examination revealed no skin findings of cutaneous mastocytosis. Serum tryptase was 4.7 ug/L and 5.4 ug/L checked 7 and 26 days, respectively, after the event and was within reference range; tryptase was not checked before or during the event. The tryptase alpha/beta 1 (TPSAB1) copy number variation test did not reveal tandem duplication(s) of TPSAB1 by allele-specific PCR. Prick puncture skin testing for polyethylene glycol, Prevnar 23 (Merck), and Pfizer-BioNTech Covid-19 (Pfizer) was negative. She scored 11 of 21 on the cholinergic urticaria disease severity standardized scale, suggesting moderate level of the disease. Authors further confirmed cholinergic urticaria via exercise provocation challenge guided by a standardized protocol. Based on the history and findings, her systemic reaction after receiving the Covid-19 vaccine was most consistent with anaphylaxis from a severe episode of cholinergic urticaria. Cholinergic urticaria has a known association with anaphylaxis although most people usually have only cutaneous symptoms. Because of her newly diagnosed cholinergic urticaria and recent anaphylaxis episode, authors recommended she carry an epinephrine auto-injector. Authors also recommended non-sedating antihistamine therapy for prevention of urticaria during bathing and exercise once she was done breastfeeding. Lastly, authors recommended all vaccines including the second dose of the Covid-19 vaccine be administered under supervision in a cool room without excessive clothing. The protection data after a single dose of the vaccine was unclear at the time so administering a single dose was not considered ideal. Based on the evaluation and the patient's increased risk for SARS-CoV-2 exposure, she, after informed decision making, accepted a second dose of the Pfizer-BioNTech Covid-19 vaccine. Authors recommended against pre-medications since they were able to perform the challenge in a cool room and

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confirm that she was not sweating or overheating. Authors also did not want to mask an IgE-mediated reaction in the event of false-negative skin testing. In addition, the patient did not want to use any antihistamines as her infant was not weaned and still breastfeeding. She tolerated her second dose, without premedication, exhibiting only transient, mild nausea and a sense of warmth, but without any objective findings. Vaccines have an overall excellent safety profile; this includes data from Covid-19 vaccine clinical trials. Authors highlighted that the patient showed propensity for allergic reactions even before administration of the Covid-19 vaccine based on her localized reaction to the influenza vaccines and her history of cholinergic urticaria. It was important for them to evaluate whether IgE-mediated anaphylaxis might underlie her case. Authors showed that the patient had nonreactive skin testing with both 1:1 epicutaneous and 1:100 and 1:10 intradermal Covid-19 vaccine and drugs containing polysorbate 80. However, more data are needed to determine skin testing's role in predicting IgE-mediated Covid-19 vaccine allergy. Likewise, evaluation of mast cell activation in addition to IgE-mediated allergy needs to be considered after any episode of anaphylaxis or potentially severe cutaneous reaction to Covid-19 vaccinations. Evaluations should include the evaluation of inducible urticaria disorders, hereditary alpha tryptasemia, mastocytosis, and idiopathic mast cell activation disorders. Assuming that immediate Covid-19 vaccine reactions correlate to an IgE-mediated allergy ignores other non-contraindicating etiologies and potentially erroneously denies patients the benefit of immunization. Thus, the general public should be aware of immune conditions that may place a person at risk of anaphylaxis, but that these may not be specific to the Covid-19 vaccine. Distinctly, CDC guidance notes "If you had an immediate allergic reaction after getting a shot of a Covid-19 vaccine, you should not get a second shot of that vaccine, even if your allergic reaction was not severe enough to require emergency care." The fact that the patient with a common mast cell disorder was able to safely receive the second dose of the Covid-19 vaccine following anaphylaxis suggests that anaphylaxis may not represent an absolute contraindication but validates the recommendation that these cases should be evaluated

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by an allergist and an immunologist for directed care and not be categorically denied the Covid-19 vaccine. Prior patient reactions and cholinergic urticaria exercise provocation test. Left Upper: Large local hive after influenza vaccine. Left Lower: Prior cholinergic urticaria around the cheeks triggered by heat. Middle: Baseline skin before cholinergic urticaria exercise provocation test. Right: Urticaria in face and arms after exercise provocation challenge. Skin test for Covid-19 vaccine and components. Left: Skin test results corresponding to components labels on right. Top Image is right arm. Bottom image is left arm. Right: Organized skin test panel with further component and administration details along with flare and wheal size. (Note: Actual test location varies to organized panel.). No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on the current available information and the consistency with the known safety profile of the suspect product BNT162B2, a possible contributory role of the suspect product BNT162B2 to the development of event Anaphylaxis cannot be totally excluded.

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1299331	5/8/2021			F	4/19/2021	4/19/2021	<p>Nausea; Chills; Blurry brain; When the needle got in, she felt warmth in her body; Felt pressure in her head; Left side of the face got numb; Felt lightheadedness/dizziness; Her nervous system started tingling; Redness at the hand; Headaches; severe allergic reactions, including anaphylaxis; Severe allergic reaction; This is a spontaneous report from a contactable consumer (patient herself) via a medical information team. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection), via an unspecified route of administration on 19Apr2021 as a single dose for COVID-19 immunization. The patient's medical history included diabetes type 2. Concomitant medications were not reported. It was reported that, "severe allergic reactions, including anaphylaxis, have been reported following administration of the Pfizer-BioNTech COVID-19 vaccine outside of clinical trials." She received the first dose of the vaccine on 19Apr2021. She was due for the second dose on 10May2021. She says she had a severe allergic reaction after the first dose on an unspecified date in 2021. When the needle got in, she felt warmth in her body on 19Apr2021. After the shot, she felt pressure in her head, her left side of the face got numb, she felt lightheadedness/dizziness, her nervous system started tingling on 19Apr2021. She stayed at the vaccination site 1 hour until they told her it was ok to go. She added that she had redness at the hand on 19Apr2021. The next day (20Apr2021), she had nausea, chills, blurry brain. She says she's still getting headaches/dizziness on an unspecified date in 2021. Enquired what was the efficacy after one dose. Referred to her healthcare professional. Enquired how many severe allergic reactions were reported. Response: No specific numbers found. Enquired should she get the second dose or not. The outcome of the events headache, dizziness was not recovered and unknown for the other events. Information on the lot/batch number has been requested.</p>

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1300635	5/8/2021	MI	55	F	3/31/2021	4/28/2021	For over the past week, I have had hives everyday, and anaphylaxis episodes after most meals. I've been to the ER and am scheduled for allergy testing. I believe my Modena vaccines kicked my Hashimoto disease into over drive.
1295141	5/7/2021	IL	44	M	5/6/2021	5/6/2021	Site: Pain at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Headache-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Systemic: Tinnitus-Mild, Systemic: Visual Changes/Disturbances-Mild, Additional Details: Within a few minutes, pt began to sweat/feel light headed/dizzy/ringing in the ears. Pt stated he felt like he was going to pass out. Pt reported no symptoms related to anaphylaxis. Pt did not lose consciousness and symptoms started improving within 10 minutes. Pt then noticed blurry vision which resolved. Pt's BP was checked: 120/90, pulse WNL. Pt. was feeling fine but per PCP guidance, went to ER for a follow up when I followed up via phone. Reported no further issues after leaving pharmacy
1296044	5/7/2021	NC	30	F	3/1/2021	3/1/2021	Immediate large welts and hives on arm then appeared on the entire body; confusion reported (and observed by me when she called me that afternoon on the phone) later, throat began to swell and constrict. She has Biphasic delayed protracted anaphylaxis as a result of multi drug allergy syndrome and her symptoms were consistent with that in this case as she has had this kind of on going response to other anaphylaxis events in the past. She had severe joint pain for more than 2 weeks and has ongoing recurrent hives on the injection site that have not completely subsided yet. She developed additional allergic responses and ultimately ended up in the ER after this and was seen by local allergist who advised DO NOT take next shot/vaccination.

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1295524	5/7/2021		32	F	4/1/2021	4/1/2021	32 yo F with H of anaphylaxis to SMP/TMP, Pip/Tazo, PCN; multiple environmental allergies; Crohn's dx; asthma. Pt received 1st dose of Pfizer COVID vaccine on 4/1/21 and 10 minutes after her dose she felt her throat closing up, cough, SOB, and rash. Given benadryl, IM epi x2, IM solumedrol 125 mg, albuterol, and famotidine at vaccine center and transported to ED as this failed to help her symptoms. Pt received 5 rounds of IM epinephrine total (3x 0.01mg doses, 1x 0.3 mg dose, and 2 doses at vaccine center) with improvement in symptoms hours after her last dose of epi on night of admission. She was monitored overnight and given IV solumedrol x1 in the morning. Received PRN pepcid with resolution of rash;...
1291840	5/6/2021	CA	69	F	5/4/2021	5/4/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Systemic: Allergic: Itch (specify: facial area, extremities)-Severe, Systemic: Allergic: Itch Generalized-Severe, Systemic: Allergic: Rash (specify: facial area, extremities)-Severe, Systemic: Allergic: Rash Generalized-Severe, Systemic: Allergic: Swelling of Face / Eyes / Mouth / Tongue-Severe, Additional Details: symptoms started 2 hours after the 2nd Covid a injection. Lower lip was protruding and severely swollen, spasms in left ear, itching and tingling of the face and throat, hived around eyes and on back. Pt tried Benadryl at home but did not help and was rushed to emergency room where was started immediately on an IV. Was also given epinephrine, Benadryl and Pepcid. Pt stayed at emergency room for 5 hours.

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1291537	5/6/2021		53	F	5/4/2021	5/4/2021	The patient is a 53yo F with history of asthma, non-epileptic seizures who on 5/4/21 received the 1st Pfizer vaccine of her vaccination series. Immediately afterward, she developed full-body shaking and SOB. She was immediately sent to the ER where she was found to have stridor but without angioedema, hypoxia, urticaria, vomiting, hypotension, or other signs of anaphylaxis. During her stay in the ER, I oversaw her care and her symptoms completely resolved after IM Epi, benadryl, famotidine, albuterol/ipratropium, steroids, and magnesium. After an observation period in the ED, she had no recurrence of symptoms and was ultimately discharged.
1291422	5/5/2021	TX	31	F	5/3/2021	5/4/2021	10 hours after vaccination, began fever, sweating, muscle aches and cramping, chills, and vomiting. 30 hours after vaccine lips swelled and began experiencing angioedema and anaphylaxis.
1290080	5/5/2021	NV	39	F	5/4/2021	5/4/2021	Angioedema and anaphylaxis approximately 15 minutes after the vaccine was administered. She was given IV solumedrol, benadryl, and famotidine which improved her tongue swelling. Afterwards she was admitted to an inpatient observation unit at the hospital. Around 9pm patient developed recurrent tongue swelling and difficulty swallowing. 0.5 mg of epi was administered. There was some initial improvement followed by additional worsening after 5 minutes. She was ultimately transferred to the ICU for a continuous epi infusion.

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1289692	5/5/2021	WA	32	F	4/28/2021	4/28/2021	<p>Patient is a 32-year-old female new patient 5 months post partum & currently breastfeeding, with seasonal and perennial allergic rhinitis and history of childhood asthma, referred by the emergency department to discuss anaphylaxis like reaction to the Johnson Johnson COVID-19 vaccination on 4/28/21. She received her vaccine around 2:00 p.m. She began developing itchiness in her palms/soles of feet and scalp that quickly developed into a a welt like rash about 3-1/2 hours after receiving the vaccine while on a walk with her husband; this was shortly followed by facial swelling over her right eye. They made it home and she got in a cold shower to cool down, became dizzy, started seeing spots and had difficulty breathing. Her husband called EMS and she was hypotensive when they arrived. She was given 2 doses of epinephrine (0.2 mg each per ED note) and a dose of Benadryl which helped. Shortly after the 2nd dose, she began having difficulty swallowing, maintaining the ability to breathe through her nose. She was given a 3rd dose of epinephrine and transferred to the ED; during transport an IV was started with an epinephrine drip. She was seen at Emergency Department; she was given IV fluids, solu medrol, tryptase level and had a normal EKG. She was discharged with an epi pen prescription. Tryptase is still pending at the time of her visit. She started a new prenatal vitamin at 11 am 4/28/21. Otherwise, she reports no new foods, medications or topical products. She did eat before going on a walk, pepper jack cheese, wheat thins, and black bean hummus. She is pretty sure she was not stung by a bee prior to onset of symptoms yesterday. Interestingly she reports recent urticarial episodes that occurred in February of 2021. These occurred when she was visiting her in-laws and occurred in the middle of the night, 2 nights in a row during the middle of her visit. She has never had hives previously. She reports no family history of hives or anaphylaxis. She reports no use of new topical products or medications.</p>

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1288445	5/5/2021	IL	66	F	3/8/2021	3/8/2021	Anaphylaxis reaction immediately post-vaccine; Difficulty speaking; hoarseness; tightness in throat and chest; tightness in throat and chest; dizziness; disorientation; This is a spontaneous report from a contactable consumer (patient). A 66-year-old non-pregnant female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number was not reported), via an unspecified route of administration, administered in Arm Left on 08Mar2021 17:30 as single dose for covid-19 immunization in an hospital. Medical history included reaction to preservatives in foods, products, and medications from an unknown date. The patient's concomitant medications were not reported. The patient previously took sodium metabisulfite and experienced anaphylaxis. No other vaccines taken in four weeks. No COVID-19 prior to vaccination. On 08Mar2021 18:00 the patient experienced anaphylaxis reaction immediately post-vaccine, difficulty speaking, hoarseness, tightness in throat and chest, dizziness, and disorientation. The events required emergency room and physicians office visit and were considered life threatening by the reporter. The patient was treated with Epinephrine, Benadryl, Prednisone, and Pepcid. The patient was tested for COVID-19 via nasal swab post vaccination on 08Mar2021 with a negative result. The outcome of the events were recovered with sequel. Information about lot/batch number has been requested.
1285161	5/4/2021		56	F	4/5/2021	4/5/2021	anaphylaxis (SOB, rash, diarrhea, nausea, myalgias) within 24 hours of vaccine administration
1285373	5/4/2021	NH	38	M	5/4/2021	5/4/2021	Shortly after vaccination, pt developed dizziness, tremulousness, nausea and anxiety. Symptoms were persistent and EMS was summoned and the pt was transported to the hospital. There were not symptoms to suggest anaphylaxis. SP02: 97%, HR 92, BP 141/82.

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1285332	5/4/2021	NH	57	M	5/4/2021	5/4/2021	Shortly after vaccination, the pt developed dizziness, and nausea. There was no shortness of breath, rash, GI symptoms or airway involvement reported. HR: 82, BP: 130/82, SP02: 97%. Pt reported persistent, mild dizziness after 30+ minutes of observation. Continued observation and/or EMS transport to the ER were offered but the pt declined and chose to have his significant other drive him home. There were no signs/symptoms to suggest anaphylaxis.
1282207	5/3/2021	CA	44	F	4/29/2021	4/29/2021	Pt presented to ER 1 hour after receipt of 2nd Pfizer vaccine, presenting with angioedema/anaphylaxis. In ER received epi, racemic epi, solumedrol, mambotidine, benadryl, then intubated and moved to ICU. Was hemodynamically stable, unremarkable airway pressures.
1282347	5/3/2021	CA	32	M	4/30/2021	4/30/2021	Anaphylaxis , hospitalized , hives , extreme high blood pressure , loss of consciousness

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1283743	5/3/2021	FL	40	M	5/3/2021	5/3/2021	Got injected, didn't hurt much. Was told to wait 15 minutes in case of reaction. They walked away and left me sitting in a chair in a public space with everyone else who was waiting. I texted my wife to check in, when I started tearing up and crying for no real reason, then started feeling nauseous so I closed my eyes. Suddenly I felt like I had been given a shot of adrenaline out of nowhere so I'm just trying to figure out if it's nerves or a physiological response to something. I'm trying to control my breathing but having a hard time breathing. Then the fever hit. The most intense flash of heat. I was hyperventilating. I couldn't open my eyes or move or make a sound, I could just sit there struggling to breathe. My phone was in my hand and I couldn't lift it. I just simply didn't have the strength or energy to move. At some point I legit thought I was about to die. I managed to angle my wrist so I could check my heart rate with my watch. It was 47bpm. I was fading away but I made myself get control of my breathing and forced myself to take long deep slow breaths. It hurt, and I felt like passing out, but I kept doing it. Fever turned into chills and then I soaked through my jeans and T-shirt in under a minute. I was finally thinking clearly and breathing and getting oxygen. Everyone else near me was fine. Nobody checked on me the entire time including the 3 people who sat there and watched me suffer through this. I told the pharmacist about my reaction and asked if it was normal and didn't receive any indication that I should be concerned, so I went home since I felt better. It wasn't until my friend pointed out that this sounds like anaphylaxis that I thought I should report it. So here I am. Hopefully I'll be okay.

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1283671	5/3/2021	FL	65	F	5/3/2021	5/3/2021	The patient was given Janssen vaccine @ 11:38am. She stated she had anaphylaxis reaction before after colonoscopy was not sure exactly what from. Made sure this vaccine didn't have PEG in it. Asked her to stay for 30 minutes after vaccine so I could monitor her. Around 12:10pm she said her mouth felt like anaphylaxis may happen. Asked her if she felt like she could swallow she said yes gave her (2) 25mg diphenhydramine. Had her sit and took her blood pressure which was BP 202/101 hr 70 I asked her if maybe she was anxious she said no she was very calm. Around 12:20pm she said felt throat was closing like before told partner to call 911. Got out Epi pen 0.3mg but she had her own administered 1 dose in right thigh. Shortly after EMS arrived and took over. The whole time she was awake and alert and responsive. Spoke to her around 4pm she was just leaving ER and said she was doing better.
1280576	5/2/2021	NC	57	F	5/2/2021	5/2/2021	Anaphylaxis. Patient experienced shortness of breath, tingling in hands and arms, cold chills, and feeling faint.
1280225	5/2/2021	FL	27	M	4/30/2021	5/1/2021	Pre- Anaphylaxis, Severe prolonged Asthmatic episodes, Fever (103) Severe diarrhea
1280159	5/2/2021	FL	53	F	5/2/2021	5/2/2021	At 11:40am on 5-2-21, patient went into anaphylaxis approximately 10 minutes after receiving vaccine. Patient's breathing was labored and patient indicated that her throat was constricted. 0.3mg of epinephrine was administered IM via EpiPen into left thigh at 11:45am. Patient breathing improved, began coughing and deep breathing noted. HR stable at 55 BPM: BP machine was registering BP at >200/100 but machine constricted her arm so numbers were unclear. Patient remained conscious and responded to verbal commands until EMS arrived and took over care at approximately at 11:50am. EMS ordered another dose of epinephrine at approximately 12:05pm. Albuterol administered at 11:50am. Pt transported to Clinic in Hospital via EMS

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1277115	5/1/2021	MA	60	F	4/12/2021	4/12/2021	Anaphylactic reaction; it started like a flushed feeling; She felt woozy; she still feels a little tight in her throat/she does feel tight, scratchy, and hoarse; she still feels a little tight in her throat/she does feel tight, scratchy, and hoarse; she still feels a little tight in her throat/she does feel tight, scratchy, and hoarse; she is just a little uncomfortable, just a little today, not too bad; She adds that she is having a hard time focusing; This is a spontaneous report from a contactable consumer (patient). This 60-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: ER8731 and expiry date unknown, Solution for injection), via an unknown route on 12Apr2021 at 15:05 (at the age of 60-years-old) at single dose on left arm for COVID-19 immunization. Relevant medical history included allergies, asthma, she had anaphylaxis in the past to allergies. (Unspecified allergens). The patient added that she had issues for about a year before her surgeon had to do a surgery on her throat. She added she was fortunate because her thyroid was in her airways 14 years ago and her body exploded with allergies and her throat closed a lot. When the doctor did the surgery, the doctor opened her throat up more so that if she had another anaphylaxis it would not result in death. Concomitant medications was not reported. On the same date, after the vaccination the patient had anaphylactic reaction. She stated that happened 62 minutes, it might have been 64 minutes and also stated a few minutes after 60 minutes. The vaccination facility released her after 30 minutes at 15:35 and when she realized something was happening it was 16:10 when the patient realized what it was that she was experiencing. The vaccine facility held onto her for 30 minutes, so she got the vaccine around 15:05 and they watched her for 30 minutes. She believed it was around 65 minutes later that she started noticing something was happening. The patient started like a flushed feeling. She does not know to describe it, it was like she had a drink or something like she felt flush or something over her system like a wave or something. It was like a strong drink or something. She does not drink a lot but it was like woohooo, a wave of something, and then she felt woozy. It was not too bad at first, she was at a bank drive through and she was not driving. The patient was going to pick something up so she stopped for 5 to 10 minutes.

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1277506	5/1/2021	VA	43	F	4/30/2021	4/30/2021	<p>She was on the phone with a friend. She felt woozy. The patient asked her husband to buy diphenhydramine (Benadryl). Her husband called back when she got done at the bank, and she was only 10 minutes from her house. The patient had her EpiPen with her. The patient was feeling better and she still feels a little tight in her throat and the way she explained it yesterday was that it was like someone had their finger down her throat, it was uncomfortable. She was just a little uncomfortable, just a little today, not too bad. She added that she was having a hard time focusing. Today, the patient felt tight, scratchy, and hoarse. It was not like it was last night. The patient did not receive any treatment for the events. Outcome of the events were unknown. Description of Product Complaint: Description of complaint: Consumer reporting an AE for the Pfizer COVID 19 vaccine mentions that they told her not to take the flu vaccine because she would get sick. Her flu symptoms would go on for 2-3 months. If she got the flu shot in September or October, she would not feel well through Christmas. Caller adds that she never got the flu again when she stopped the vaccine. Caller does not know manufacturer, NDC, lot or expiration date for the flu vaccine she had that made her sick. Caller does not have any information about the Benadryl - and she does not have the bottle that she took that made her sleepy because she added that the only bottle she had was the one that her husband bought yesterday and it was not opened and she had not taken it. Caller added that she had not taken Benadryl in 14 years since before her surgery. Caller adds it might have been 15 years, she would have to remember that. AE identified after call completed. No NDC, lot or expiration date provided for Benadryl caller took 14 to 15 years ago. Follow-up attempts completed. No further information is expected.</p> <p>Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Additional Details: Patient received the injection. After a couple of minutes, patients breathing became rapid. I tried to calm her down. A couple of minutes the patient said her throat was closing. She made some gasping sounds. I gave her an injection of epinephrine 0.3mg. i called 911. EMS took her to unspecified hospital after treating her.</p>

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1276436	5/1/2021	MO	74	F	4/9/2021		<p>SHORTNESS OF BREATH; STOMACH CRAMPS; HEADACHE; LEFT ARM SORENESS; TIREDNESS; WORSENING OF FLUTTERING OF HEART; This spontaneous report received from a patient concerned a 74 year old female. The patient's weight was 266 pounds, and height was 62 inches. The patient's past medical history included concussion in 2019, spinal injuries, anaphylaxis shock after medicine took for bone and swelling, and concurrent conditions included non alcohol user, non-smoker, and reaction to iv dye, fluttering of the heart, and other pre-existing medical conditions included the patient did not have any drug abuse/illicit drug use. The patient was previously treated with steroids for swelling. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 203A21A, and expiry: UNKNOWN) dose was not reported, administered one total, on 08-APR-2021 in left arm for prophylactic vaccination. Concomitant medications included roprinolil, atorvastatin, lisinopril, propranolol, salbutamol sulfate(inhaler) as needed, oxybutynin, and paracetamol as needed, all drugs were used for unknown indications. On 09-APR-2021, the patient experienced worsening of fluttering of heart, tiredness. On 10-APR-2021, the patient experienced left arm soreness. On 13-APR-2021, the patient experienced headache. On 17-APR-2021, the patient experienced stomach cramps and recovered on 21-APR-2021. On 19-APR-2021, the patient experienced shortness of breath. It was reported that patient had experienced shortness of breath before shot but not as often. The action taken with covid-19 vaccine ad26.cov2.s was not reported. The patient recovered from stomach cramps on 21-APR-2021, and was recovering from headache, worsening of fluttering of heart, left arm soreness, shortness of breath, and tiredness. This report was serious (Other Medically Important Condition).; Sender's Comments: v0:20210447945: covid-19 vaccine ad26.cov2.s - Worsening of fluttering of heart. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY</p>

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1276425	5/1/2021	LA	35	F	3/1/2021		<p>DIFFICULTY BREATHING(LOW OXYGEN); ELEVATED D-DIMER; INABILITY TO MOVE; LOW BODY TEMPERATURE; TINGLY FACE; RED FACE; FELT BAD AND AWFUL; This spontaneous report received from a patient concerned a 35 year old female. The patient's height, and weight were not reported. The patient's past medical history included anaphylaxis reaction, and concurrent conditions included fibromyalgia. The patient did not had previous history of allergy to vaccine. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1605018,expiry: unknown) dose was not reported,1 total administered on 20-MAR-2021 to the right arm for prophylactic vaccination. No concomitant medications were reported. On 20-MAR-2021, 20 minutes after vaccination, the patient's felt her face red and tingly and it went away. On 29-APR-2021, nine days after receiving the vaccine, the patient woke up not able to breathe or move and had a temperature of 94 degree F. The patient went to hospital and had low oxygen, an elevated d-dimer and had no evidence of blood clots in CT (computed tomography) scan. The patient was treated in ER (emergency room) with epinephrine, steroids, diphenhydramine (Benadryl) and a unspecified nebulizer and then she could breathe. The patient's physician tested her d-dimer for second time following the patient's visit to the hospital and it was elevated, but not as high. The patient had history of fibromyalgia and mysterious health condition but it was reported that she did not have anything like what she experienced after vaccination and she felt really bad and super awful. The patient was not feeling great, but better and can breathe again at the time of this report; her oxygen level also was normal. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from difficulty breathing(low oxygen) on 2021, and red face, was recovering from felt bad and awful, had not recovered from elevated d-dimer, and the outcome of tingly face, inability to move and low body temperature was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210446229- covid-19 vaccine ad26.cov2.s -Difficulty breathing(Oxygen). This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown</p>

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1278325	5/1/2021	CA	32	F	4/30/2021	4/30/2021	<p>scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p> <p>Fine for 4.5 hours after shot (was not doing any physical activity, only reading) then sudden anaphylaxis aura (sense of impending doom) and realized heartrate (measured with pulse ox) had gone up to 160bpm with mild cheek, tongue and throat swelling. Took a Pepcid then my Epi-pen around 1500, called 911 for ambulance. EMTs gave me 50mg of Benadryl through IV at 1530. Heartrate persisted above 140. At ER was given another Epi injection and Decadron at 1630. Heartrate very slowly decreased each hour following the second Epi; at 1730 it was consistently reading under 130bpm, at 1830 under 120bpm, at 1930 under 110bpm. Discharged around 2030, heartrate around 100bpm. Heart rate has been consistently under 100 at rest since I've been home and then today (May 1) it's been consistently under 80 at rest.</p>

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1278570	5/1/2021	CA	45	M	4/1/2021	4/2/2021	a raging rash / rash started on his right arm/ rash did spread to his other arm/ rash is super itchy; This is a spontaneous report from a contactable consumer (patient). A 45-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in arm left on 01Apr2021 (Lot Number: ER8737) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient received first Pfizer COVID vaccine on 01Apr2021 and experienced a raging rash 24 hours later (02Apr2021), still had the rash, he was due for second dose on 23Apr2021. He's had this rash 13 plus days. The rash started on his right arm, not the arm where he received the Covid 19 vaccine. The rash was super itchy, super annoying. The rash did spread to his other arm. He did see his doctor as soon as he could. His doctor told him maybe the rash was related to the Covid 19 vaccine, maybe it's herpes zoster, maybe it's contact dermatitis, it's probably not the Covid 19 vaccine. His primary care doctor prescribed him a topical steroid, Clobetasol and Benadryl for itching. He then saw a dermatologist. The dermatologist took a closer look and decided to prescribe an oral steroid, Prednisone, he's on his second day of taking the Prednisone. The dermatologist told him to get the second Covid 19 vaccine even if his rash isn't resolved by then but the first doctor her saw said he might need to worry about anaphylaxis. That's scary. He wanted to get the second Covid 19 vaccine. He stated maybe his body started making all these T-cells the next thing he knew he had this rash. He stated his PCP and dermatologist advised him to call Pfizer regarding the treatment of his rash, he wanted Pfizer to recommend what to do to get rid of the rash. The outcome of the event was unknown. No follow-up attempts are needed. No further information is expected.

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1276894	5/1/2021	LA	70	F	1/29/2021	2/2/2021	1st dose developed a red, raised, itchy rash on RUQ of abdomen/ after 2nd dose aggravates; 1st dose developed a red, raised, itchy rash on RUQ of abdomen/ after 2nd dose aggravates; 1st dose developed a red, raised, itchy rash on RUQ of abdomen/ after 2nd dose aggravates; 1st dose developed a red, raised, itchy rash on RUQ of abdomen/ after 2nd dose aggravates; This is a spontaneous report from a contactable other health care professional (Nurse- patient herself), report received from a Pfizer-sponsored program. A 71-year-old female (non-pregnant) patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, formulation: solution for injection, lot number: EL3249, Expiration date and NDC number: Unknown), via an unspecified route of administration in left arm on 29Jan2021 at 11:15 (at the age 70-year-old) for COVID-19 immunisation and second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, formulation: solution for injection, lot number: EN6202, Expiration date and NDC number: Unknown), via an unspecified route of administration in left arm on 26Feb2021 at 11:15 (at the age 71-year-old) for COVID-19 immunisation. Medical history included diabetes possibly diagnosed in 1998 and ongoing, obesity from an unspecified date and ongoing, anemia diagnosed about probably in the past 5-6 years and ongoing, allergies diagnosed around 2000 and ongoing, sleep apnea diagnosed around 2000 and ongoing, and reaction to the small pox vaccine when patient was a small child. The patient had anaphylaxis to cephalosporin, Keflex and rocuronium and allergic to food. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Concomitant medications were reported as none. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 02Feb2021 20:00, the patient developed a red, raised, itchy rash on RUQ of abdomen. By time of 2nd dose of vaccine, rash was still present but seemed to be fading. Approximately 4-5 days after the 2nd dose a red, raised, itchy rash developed on chest, upper abdomen, across lower back, up the middle of back and on buttocks and upper outer thighs. The patient reported that no investigations were done. The treatment received for the events were Benadryl, Zyrtec, and OTC cortisone creams and over the next 30 days

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							rash did not improve, and medical treatment was sought. The patient tried triamcinolone (KENALOG) cream, pepcid twice a day, for two weeks and the rash was still spreading down her abdomen and up her back, so patient started on prednisone, 20 mg for 7 days and 10 mg 7 days, along with pepcid, zyrtec and benadryl, rash is still profuse. The patient was also treated with xzyl. The event was reported as serious (medically significant). Outcome of the events was reported as not recovered; Sender's Comments: Based on temporal relation, the association between BNT162B2 and the events, erythematous, papular, pruritic rash cannot be excluded. The impact of this report on benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethic committees, and Investigators, as appropriate.
1275033	4/30/2021	OH	63	M	4/3/2021	4/10/2021	4-3-21- received my first covid 19 shot 4-10-21 went to have foot blister examined- they admitted me and started an IV of Vancomycin which sent me into anaphylaxis and this stopped my heart. I required cpr, defibrillator to get things going again. I was on life support for the better part of 4 days and then finally come back
1273843	4/30/2021	OK	56	F	2/3/2021	2/3/2021	Anaphylaxis
1273123	4/30/2021	MI	29	F	4/28/2021	4/29/2021	Pt called nurse triage stating that at approx. 1PM the day after her dose, she developed hives on her right breast, leg, and thigh that was very itchy. She also reported her face and ears feeling hot and flushed and that she felt hoarse and like she had phlegm in her throat and needed to keep clearing her throat. Pt went to ED and was diagnosed with anaphylaxis, was given benadryl, pepcid, methylprednisolone, and epinephrine. Pt was discharged from the ED upon resolution of symptoms and was instructed to follow-up with allergy.

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1271203	4/29/2021		18	F	4/28/2021	4/29/2021	Began to have paresthesias of L upper lip No swelling of pharynx or other signs or symptoms of anaphylaxis - no rash, nausea, vomiting, diarrhea, wheezing, dyspnea Given steroids/benadryl Swelling was stable and patient was discharged home

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1269695	4/29/2021	GA	52	F	4/14/2021	4/14/2021	anaphylaxis; acute respiratory failure; short of breath; This is a spontaneous report from a contactable consumer. A 52-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) dose 2 via an unspecified route of administration on 14Apr2021 10:00 (at age 52 years old) (Lot Number: EW0151) as single dose for covid-19 immunisation. Not pregnant at the time of vaccination. Medical history included diabetes mellitus (DM), hyperlipidemia, hypothyroidism, morbid obesity, mild mitral regurgitation (MR), hypertension (HTN), and known allergies to latex, all from unspecified date date and unknown if ongoing. No covid prior to vaccination. Covid tested post vaccination on 14Apr2021 with negative result. Concomitant medications included carvedilol (CARVEDILOL 1A PHARMA); lisinopril; fenofibrate; sitagliptin (JANUVIA); insulin lispro (HUMALOG); levothyroxine sodium (SYNTHROID); metformin; amlodipine besilate (NORVASC); vitamin d nos; magnesium; pravastatin; ASA; cinnamomum verum (CINNAMON); ferrous sulfate; all taken for unspecified indications, start and stop date were not reported. The patient previously received the first dose of BNT162B2 on 24Mar2021 (at age 52 years old) (lot no: ER8753 or ER 8733??) for COVID-19 immunization. No other vaccine in four weeks. The patient received second Pfizer COVID injection at 10 am. She waited 15 minutes then left facility. Within the next 5-10 minutes she became short of breath. She went to ER around 10:45 am and treated for anaphylaxis. She was put on the vent by 11 am or so for acute respiratory failure. She was negative for COVID, pulmonary emboli, and pneumonia. She had to be transferred to higher acuity hospital by critical care ambulance. She now is in ICU at a hospital on ventilator. The events occurred on 14Apr2021 at 10:30 AM. The events results in emergency room/department or urgent care, hospitalization. Treatment for events was reported as medical ER treatment then transferred to a hospital. The patient had not recovered from the events.

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1269719	4/29/2021	PA	55	F	4/2/2021	4/8/2021	And it most definitely looks like the measles; bad rash developing on her left arm between her elbow down to her wrist; This is a spontaneous report from a contactable consumer (patient). A 55-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration, administered in left arm on 02Apr2021 10:00 (Batch/Lot Number: EWO150) as single dose for COVID-19 immunisation. Medical history included lupus, ovarian cancer, trigeminal neuralgia, interstitial cystitis (IC), and idiopathic anaphylaxis. The patient has many, many prescription and OTC meds (unspecified). No other vaccine in four weeks. It was unknown if the patient had COVID prior to vaccination. The patient has not been tested for COVID post vaccination. The patient first noticed a bad rash developing on her left arm between her elbow down to her wrist on 08Apr2021. She chalked it up to the sun & warmer weather and the fact that she has lupus. A day or so later, she noticed very clearly, the same rash appeared on her left thigh. Just mid thigh to knee cap. And it most definitely looked like the measles. She added that nothing itched. And her thigh has not been exposed to any sun. She consulted her doctor via e-mail who has seen pictures of the rashes. She wanted her to get her blood work checked the next day (unknown results) to make sure her lupus hasn't been compromised by the Covid rash side effect. The event resulted in a doctor clinic visit. The patient has not recovered from the events.
1270103	4/29/2021	WI	61	F	4/22/2021	4/22/2021	Anaphylaxis- patient unconscious briefly prior to receiving Epinephrine. After injection, patient slightly arousable- transferred to ED via EMS.
1270645	4/29/2021	TX	70	F	4/29/2021	4/29/2021	Anaphylaxis
1272411	4/29/2021	ME	41	F	4/27/2021	4/27/2021	Anaphylaxis. EMT and ambulance used at vaccine site. Hospitalization necessary. Two doses of epinephrine and steroids needed.

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1270596	4/29/2021	CA	50	F	3/26/2021	3/27/2021	Anaphylaxis. 36 hours after 2nd vaccination. Closing of chest muscles, lungs, esophageal tract up to back of throat. Resting heart rate of 133 BPM at triage in ER. Severe coughing which caused vomiting. Slight pink flushing of nose and cheekbones 30 minutes after shot, after leaving vaccination site, with no adverse reaction.
1265932	4/28/2021	MA	57	F	4/24/2021	4/24/2021	4/24/21 1:05pm first dose Pfizer vaccine 1:10pm huge allergic reaction, felt like pre-anaphylaxis, like I was going to die 1:13pm took 2 Benadryl 25mg 5:30pm took 1 Benadryl 25 mg Loose stools all day, stayed home as Benadryl was working 4/25/21 12:30am took 1 Benadryl 25mg (weird feeling in my tongue) 1:25pm took 1 Benadryl 25mg for pain in my cheekbones & teeth and rash on both cheeks below eyes 1:58pm took 1 Benadryl 25mg " " 2:19pm took 1 Benadryl 25mg " " 2:49pm checked into hospital emergency room as allergic reaction would not subside 4:30pm got IV with Benadryl 25mg, Methylprednisolone & Pepcid (throat felt strange) 7:26pm discharged from ER 4/26/21 Medrol 24g 4/27 Medrol 20g

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1269486	4/28/2021	NY	41	F	3/21/2021	3/1/2021	asthmatic reaction like hard time breathing; hard time walking; weak; No appetite; anapylactic reaction; felt itching of her throat; fingertip started turning purple; coughing a lot; hard time breathing; hot feeling around her arms and left side of body; it has been three days since she has been really sick; she is easily tired.; This is a spontaneous report from a contactable consumer, the patient. A 41-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 1 via an unspecified route of administration, administered in Arm left on 21Mar2021 around 16:15 (Batch/Lot Number: ER2613) (at the age of 41-year-old) as single dose for covid-19 immunisation. Medical history included allergic to shellfish, ongoing systemic scleroderma, ongoing raynaud's syndrome (6 years ago) and interstitial lung disease (6 years ago). Concomitant medications included amlodipine besilate (NORVASC), at 5mg three times a day, prednisone (MANUFACTURER UNKNOWN) via oral at 5mg once a day; mycophenolate mofetil (CELLCEPT) at 1000 mg twice a day, hydroxychloroquine phosphate (PLAQUENIL) at 200mg twice a day, omeprazole (PROTONIX) at 40mg twice a day, sildenafil citrate (MANUFACTURER UNKNOWN) at 20mg three times a day, atorvastatin (LIPITOR) at 40mg once a day, gabapentin (MANUFACTURER UNKNOWN) at 300mg once a day; all are ongoing and taken for systemic scleroderma. The patient did not receive any other vaccines within four weeks prior to the vaccination. History of all previous immunization with the Pfizer vaccine considered as suspect was none. On 21Mar2021, the patient experienced anaphylactic reaction and was rushed into to the emergency room after 25 minutes of receiving the vaccine. The patient stated she called the CDC they recommend not to take vaccine of the second dose. The patient stated now she just called and it has been three days since she has been really sick and they told her to call us because doctor at the emergency room at the hospital and specialist because she has an underlying disease (Scleroderma) and told her to double check if she does not take booster of Pfizer vaccine what is the effect in her body? patient stated they are giving her advice that if she does not take it can she can take the J&J. The patient explained after she was administered the vaccine, she went to the waiting area where they told her she should be held for

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30 minutes then in about 15 minutes she started getting a hot feeling around her arms and left side of her body so she took off her sweater thinking that would make her comfortable because she was uncomfortable. The patient stated 25 minutes after sitting there the nurse asked if she was ok, so she went out for fresh air that day it was not hot in the hospital but the temperature was around 60 on Sunday so it was really nice weather and she went outside for a fresh breath of air for 5 minutes, stayed took off mask, and felt relieved. The patient went back inside of the room and felt itching of her throat, 25 minutes receiving the vaccine and it stopped when she received the epi pen. The patient stated she thinks she recovered from because since Sunday she has had different effects. Then coughing started 25 minutes so probably roughly around 4:45pm on 21Mar2021 and stated when they administered epi pen not sure time but probably after an hour was when she was reviving in the ER. The patient experienced fingertip started turning purple and this started 30 to 45 minutes when she was rushed to emergency room and because of everything going on she does not remember when it stopped. The patient stated the doctor gave her a shot of epi pen and hooked her up. They did a lot of things in the emergency room that she does not remember. She only remembers her whole hand was purple and they gave her the epi shot. The doctor asked does she know what he was holding, she responded an epi pen, and the doctor said yes. She confirmed she has never used an epi pen before since she has not had any other allergic life-threatening reaction from a vaccine. The doctor said he was going to administer it right now because she cannot breathe. At this time, she was conscious and had a hard time breathing, but was listening. The doctor administered the shot and the hard time breathing and coughing stopped like 30 seconds after. However, she is still having a hard time to breathe. The patient stated the purple hands probably wore off after an hour but since she has Raynaud's disease it was hard for her to recover from circulation of oxygen in body. The patient had hard time breathing because Tuesday she still felt like asthma attack so around Tuesday still having hard time of breathing and still coughing a lot. The patient stated on Wednesday (on 24Mar2021) coughing was regulated a little bit and every time she was walking, she would

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cough. The patient commented she was discharged from the hospital Sunday. Later confirmed she was not actually admitted, just in the emergency room. The patient stated after the anaphylaxis reaction she was discharged at 9:30 in the evening and the following day she emailed her specialists and then replied and gave her advice that they could give and that she needed to call CDC vaccine and then they check on her. The patient confirmed she did actually go to her physician's office. On 22Mar2021, the patient felt weak she was lying in her house the whole Monday and lying-in bed week and had no appetite. The patient had an asthmatic reaction on Tuesday (on 23Mar2021), like hard time breathing, and she called her pulmonologist, and it was not like emergency and she knows that because she has an underlying lung disease, so she used nebulizer every 6 hours and also used inhaler albuterol inhaler. The patient had hard time walking and stated on Monday and Tuesday she did not get up from bed only just to go to the bathroom and to clean herself but yesterday she started walking around the house and it was hard for her because she was still coughing but today, she was walking already. The patient stated yesterday she was ok but had a hard time if walking it was hard for her to get up from bed and she can walk but she is easily tired. The patient underwent lab tests and procedures which included CT exam as part of her diagnosis for medical condition on an unspecified date and results are unknown. The patient stated she did not have an exam in the emergency room. Therapeutic measures were taken as a result of events anaphylactic reaction, felt itching of her throat, coughing a lot, fingertip started turning purple, hard time breathing, asthmatic reaction like hard time breathing included Epi Pen, Benadryl, she had an IV and the medicine administered through IV was a steroid combination of Benadryl pepa something, and stated she did not know the spelling, but it was a steroid mix that she received in the emergency room. The patient stated when she was home, on Tuesday, she had taken a nebulizer albuterol every 6 hours. She mentioned she just took Tylenol one time Tuesday night because she felt she was getting a fever. Her temperature was 99, not yet fever, but temperature was 99. The outcome of the events asthmatic reaction like hard time breathing was recovered on 24Mar2021, it has been three days since

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1269470	4/28/2021			F			<p>she has been really sick and she is easily tired was unknown and all other events were recovering. Information on the lot/batch number has been requested. Follow-up attempts are completed. No further information is expected.</p> <p>Anaphylaxis (dyspnea, stridor, drooling, tongue swelling); This is a spontaneous report from a non-contactable other Health Care Professional. A 74-year-old female patient received second dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, Solution for injection, lot Number: EN6204 and expiry date was not provided) and received first dose of BNT162B2: both were via an unspecified route of administration, on an unknown date, as SINGLE DOSE for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that, during her 30 minute waiting period after the injection, the patient began to experience hoarse voice. She denied rash, difficulty breathing, difficulty swallowing, dizziness, facial swelling, lip swelling and tongue swelling. Patient complained of chest tightness (she later developed chest tightness when she was in the bay prior to epi-pen administration). Patient denies chills, fever, malaise/fatigue, facial swelling, cough, shortness of breath, wheezing, rash, hives, eczema, itching of skin and abdominal pain. The patient experienced anaphylaxis (dyspnea, stridor, drooling, tongue swelling) with early onset of presumed anaphylaxis that responded well to epi-pen. Patient sent to ED for closer observation/treatment by ambulance. Treatment was good, she started to have return of symptoms when AMR was leaving with her. The outcome of the events was reported as unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on known drug safety profile and close temporal association, the event of Anaphylactic reaction is assessed as related to the suspect vaccine BNT162B2.</p>
1267193	4/28/2021		34	F	4/26/2021	4/26/2021	Severe anaphylaxis, requiring epinephrine drip and stay in ICU, now resolved.

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1265983	4/28/2021	PA	54	F	3/10/2021	3/10/2021	<p>Felt funny in her chest, like a really weird, really warm and heavy feeling, almost like she couldn't breathe; almost like she couldn't breathe/Difficulty Breathing; Felt funny in her chest, like a really weird, really warm and heavy feeling/ warm feeling in the chest; having an anaphylactic reaction from the vaccine; Respiratory, Wheezing, Difficulty Breathing and Respiratory Distress; Respiratory, Wheezing, Difficulty Breathing and Respiratory Distress; Very sore right arm where she was given the injection; felt like she was punched several times in her arm; Injection site bruising; This is a spontaneous report from a contactable nurse(patient). The nurse reported similar events for herself and her husband. This is the first of two reports. A 54-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) (at 54 years of age), dose 1 intramuscular, administered in arm right on 10Mar2021 16:00 (Batch/Lot number was not reported) as a single dose for COVID-19 immunisation. Medical history included severe asthma which started as a child and then it went away and then as an adult it got severe around 2010 and ongoing, she was an asthmatic and would panic and start feeling worse. She had ongoing chronic obstructive pulmonary disease (COPD), brain surgery in 2007, low immune system, allergies to cephalosporins, pulmonary and stomach issues; and bradycardia (as her BP usually runs 90/45 and she is bradycardic). Concomitant medications included tiotropium bromide (SPIRIVA RESPIMAT), salbutamol sulfate (PROAIR HFA), fluticasone propionate, salmeterol xinafoate (ADVAIR HFA), salbutamol (VENTOLIN [SALBUTAMOL]), and montelukast (MONTELUKAST), all taken for asthma, chronic obstructive pulmonary disease from an unspecified start date and ongoing; clarithromycin (CLARITIN [CLARITHROMYCIN], omeprazole, phenytoin sodium, azelastine, ipratropium bromide, fluticasone propionate (FLONASE [FLUTICASONE PROPIONATE]), and ipratropium bromide, salbutamol sulfate (DUONEB), all taken for an unspecified indication from an unspecified start date and ongoing; prednisone taken for an unspecified indication from 2021 and ongoing as she was on this steroid 2 weeks before the vaccine; and azithromycin which she takes prophylactically for her low immune system from an unspecified start date and</p>

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ongoing. She was on a lot of medications period and most are for her pulmonary and stomach issues. The patient previously took propofol, Versed, Nitrous Oxide, and Percocet wherein the patient had drug hypersensitivity and anaphylactic shock with these; adhesive from nicotine patch made her arm to get red and swollen (Dermatitis contact). She previously took EpiPen for anaphylaxis. It was reported that on 10Mar2021, the patient had the first dose of the vaccine and it felt funny in her chest, like a really weird, really warm and heavy feeling, almost like she couldn't breathe. She got her vaccine at a hospital in their clinic and she was transferred from the vaccine clinic to the ER. Stated she was given a shot with an Epi-pen in her thigh at the clinic and transferred to the ER. In the ER, she was given Benadryl and watched for 4 hours. She would state this was medically significant because of airway, breathing, circulation and she felt like she couldn't breathe. She added that it was kind of weird and freaky. She mentioned that along with that, shortly before she was released from the ER, she experienced a very sore arm where she was given the injection. She heard that was very common so she dealt with it. However as the night progressed, it got increasingly worse, it almost felt like she was punched several times in her arm. It probably started between hour 3 and 4 after receiving the vaccine. She added that she had a very sore right arm where she was given the injection; felt like she was punched several times in her arm. It was not serious, just annoying and it was gone 3 days later. She had injection site bruising on 10Mar2021. She stated that she knows this because she was a nurse, but a lot of times, people experienced this reaction when they are given Dilaudid wherein they get a warm feeling in their chest, so they push it really slow and dilute it with saline so it doesn't have the respiratory factor. She stated that this was kind of what the feeling was like for her and it was scary because she didn't expect it. She stated that the ER team that assessed her said, because she wasn't used to that feeling, she may have had a panic attack and that may have made it worse. After she was treated, she spoke with her husband and he had the shot two minutes before her and he had the same feeling but he didn't freak out and didn't want to appear weak. Stated he told her he had the same feeling and it lasted 5 minutes and then it went away.

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Stated since she got scared, it made it worse. She doesn't know if she had a panic attack that made it worse. She stated that of course her husband didn't tell her that until she was out of the ER, that it does go away. That made her feel better because she wasn't the only one that experienced that. States he didn't say anything about it, because he was worried about her, he said it was a warm feeling in the chest and not being able to breathe but he didn't want to say anything because she was an asthmatic and would panic and start feeling worse. She mentioned that they weren't going to let her get the second dose, so she went to an allergy doctor and told them what happened and about her husband having the same reaction and because she was severely immunocompromised. Stated the hospital said they were not giving her the second dose unless an allergist says it is safe and sets a protocol and he had to write a letter to the hospital. Stated she was pre-medicated 24 hours before the vaccine with 50mg Benadryl, 50mg Benadryl the day of the shot and 50mg of Benadryl two days after the shot. Stated she will have full immunity on 14Apr2021. She added that she had a pulmonary doctor, brain cancer doctor, ENT doctor, stated they don't know if it was caused by the vaccine, but they are pretty sure she had a reaction but they can handle it with pre-medicating her. She received the second vaccine on 31Mar2021. She mentioned that she was happy to be able to get her second shot. She stated that at first they didn't want to give it to her because of her reaction but she kept calling. So she went to a hospital to saw an allergist and he had to sign off that it was safe to give her the second shot and under what circumstances. Stated she had the letter from the hospital that she was seen by them and she needed to be pre-medicated and it had to be given at a hospital that had the ability to intervene quickly and she needed to be watched for at least 30 minutes after the vaccine. She mentioned that to go through what she went though, and not be able to get would have been disappointing. Because of her immune system, it is important to get the shot and there was a way around the reaction which worked for her. She added that even having an anaphylactic reaction from the vaccine, she was able to recover quickly. Stated with having asthma, COPD and a low immune system, she may not recover from Covid. It makes sense they evaluated it and came

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up with a solution and a pre medication protocol and when and how long and she was still able to get the shot because it is important. Answers to follow up questions indicated that on 10Mar2021, the patient had the first dose of the vaccine and it felt funny in her chest, like a really weird, really warm and heavy feeling, almost like she couldn't breathe. She was given the shot and getting ready to get out of the chair and her husband was about to sit down for his shot. Stated she would say the time of the course of the reaction was within under 5 minutes of her injection. The patient required medical intervention with Epi-Pen, Benadryl, and Duo-Neb. The patient was not hospitalized because she was immunocompromised, it was better to watch herself at home and because she had an Epi Pen at home in case she has that sort of reaction returning over a 72 hour period. Stated they instructed her husband and told them if she felt any different to come back to ER. She was not admitted to the ICU. Organ involvement included: Respiratory, Wheezing, Difficulty Breathing and Respiratory Distress. The event required initiation of new medication or other treatment or procedure including Epi-Pen, Benadryl, DuoNeb. Patient have a history of previous allergies: Medication Allergies to Cephalosporins, Anesthesia medications: Propofol, Versed, Nitrous Oxide, Percocet: Anaphylactic shock; Adhesive from nicotine patch, caused her arm to get red and swollen. She takes EpiPen as she had previous history of allergies and since she had multiple medication allergies and had a history of quickly going into anaphylaxis, stated her BP usually runs 90/45 and she was Bradycardic. She did not receive any recent vaccines for any other conditions prior to the events being reported. She did not receive any recent vaccines for SARS-CoV2 other than Pfizer-BioNTech COVID-19 Vaccine prior to the event being reported. She has not received any other vaccines around the time of the Pfizer-BioNTech COVID-19 Vaccine vaccination. The patient recovered from 'felt funny in her chest, like a really weird, really warm and heavy feeling, almost like she couldn't breathe', Difficulty breathing, and 'warm feeling in the chest' on 10Mar2021; while having an anaphylactic reaction from the vaccine, Respiratory, Wheezing, Difficulty Breathing and Respiratory Distress were recovered on an unknown date; Vaccination site pain recovered on 13Mar2021 and Injection site bruising

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recovered on 18Mar2021. Therapeutic measures were taken as a result of all events except Vaccination site pain and Injection site bruising. Relatedness of drug to reactions/events: Reaction assessed for events "felt funny in her chest, like a really weird, really warm and heavy feeling, almost like she couldn't breathe", 'very sore right arm where she was given the injection; felt like she was punched several times in her arm.' and Injection site bruising: Method of assessment: Global Introspection: Drug result: Related. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, the Company considered all serious and non-serious events as possibly associated to BNT162B2 injection, due to a plausible chronological sequence. Current patient conditions of asthma, chronic obstructive pulmonary disease and allergic diathesis may have been considered as favoring factors in development of reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate, Linked Report(s) : US-PFIZER INC-2021406773 same reporter and drug, similar events, different patient

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1261934	4/27/2021	OR	34	M	4/5/2021	4/5/2021	anaphylaxis reaction; severe allergic reaction; throat closing up/throat started swelling; dizzy; lack of appetite; vertigo; headaches; started to feel hot; breaking out in a rash/skin began to break out; This spontaneous case was reported by a consumer and describes the occurrence of ANAPHYLACTIC REACTION (anaphylaxis reaction) in a 34-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 039A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 05-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Apr-2021, the patient experienced ANAPHYLACTIC REACTION (anaphylaxis reaction) (seriousness criterion medically significant), ALLERGY TO VACCINE (severe allergic reaction), PHARYNGEAL SWELLING (throat closing up/throat started swelling), DIZZINESS (dizzy), DECREASED APPETITE (lack of appetite), VERTIGO (vertigo), HEADACHE (headaches), FEELING HOT (started to feel hot) and RASH (breaking out in a rash/skin began to break out). At the time of the report, ANAPHYLACTIC REACTION (anaphylaxis reaction), ALLERGY TO VACCINE (severe allergic reaction), PHARYNGEAL SWELLING (throat closing up/throat started swelling), DIZZINESS (dizzy), DECREASED APPETITE (lack of appetite), HEADACHE (headaches), FEELING HOT (started to feel hot) and RASH (breaking out in a rash/skin began to break out) had resolved and VERTIGO (vertigo) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment included: Epinephrine given in hospital, Benadryl and Predisone Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.

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1261528	4/27/2021		63	M	4/15/2021	4/15/2021	Anaphylaxis reaction; fast heartbeats; stomach ache; shortness of breath; orthostatic hypotension; sore shoulder; headache; minor nausea which increased the third day; dizziness; body ache; This spontaneous case was reported by a consumer and describes the occurrence of ANAPHYLACTIC REACTION (Anaphylaxis reaction) in a 63-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 036B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 15-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Apr-2021, the patient experienced PAIN (body ache). On 16-Apr-2021, the patient experienced DIZZINESS (dizziness) and NAUSEA (minor nausea which increased the third day). On 21-Apr-2021, the patient experienced ANAPHYLACTIC REACTION (Anaphylaxis reaction) (seriousness criterion medically significant), HEART RATE IRREGULAR (fast heartbeats), ABDOMINAL PAIN UPPER (stomach ache), DYSPNOEA (shortness of breath), ORTHOSTATIC HYPOTENSION (orthostatic hypotension), ARTHRALGIA (sore shoulder) and HEADACHE (headache). At the time of the report, ANAPHYLACTIC REACTION (Anaphylaxis reaction), HEART RATE IRREGULAR (fast heartbeats), ABDOMINAL PAIN UPPER (stomach ache), DYSPNOEA (shortness of breath), DIZZINESS (dizziness), ORTHOSTATIC HYPOTENSION (orthostatic hypotension), PAIN (body ache), ARTHRALGIA (sore shoulder), NAUSEA (minor nausea which increased the third day) and HEADACHE (headache) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant meds were reported. No treatment information was provided. Company comment:Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine and onset of the reported events, and excluding other etiologies, a causal relationship with the product use cannot be excluded. Arthralgia, myalgia, nausea and headache are consistent with the product known safety profile.; Sender's Comments: Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine and onset of the reported

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events, and excluding other etiologies, a causal relationship with the product use cannot be excluded. Arthralgia, myalgia, nausea and headache are consistent with the product known safety profile.

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1261759	4/27/2021	CT	53	F	4/11/2021	4/11/2021	<p>This is a spontaneous report from a contactable consumer. A 53-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Deltoid Left on 11Apr2021 09:15 (Lot Number: EP7533; Expiration Date: 31Jul2021) as SINGLE DOSE for covid-19 immunisation (Age at vaccination: 53 years). Medical history included asthma, Blood pressure high, acid reflux , allergies: Sulfa, Lactose intolerant and allergies: Latex. The patient's concomitant medications were not reported. The patient had a historical vaccine of Flu shot (INFLUENZA) on an unspecified date for immunisation and experienced bad side effects. The patient previously took bactrim, minocycline, doxycycline, ciprofloxacin, Moxifloxacin, demerol, avelox, nitrofurantoin, naprosyn, motrin, perocet, tramadol and aleve and experienced allergies. The patient experienced anaphylaxis on 11Apr2021. It was also reported that she had an appointment for COVID Vaccine at 9:15AM. Received COVID Vaccine and was told to wait for 30 minutes. Within 10 minutes her chest starting getting tight with difficulty of breathing. Her throat was closing up, and she was light headed. She explained this to the administrator who asked if caller could get up to see the paramedic. As caller tried to stand up, she almost passed out. Had to sit there for a second and the second time was able to get up and made it in to the room. Was going in and out of consciousness. Had to stab her with an Epi Pen. She couldn't breathe. Her throat was closing up. Her tongue was swollen. She was in and out of consciousness. First Epi Pen didn't work. An IV was put in and was given something through it. She was jabbed with a second Epi Pen. Was still in and out of consciousness but she was starting to come back. Was given oxygen and a nebulizer. She does have asthma. Ambulance was called. Was told she was worked on for 20 minutes. When ambulance arrived she was able to get up and get on the cart. She was taken to the hospital. Was given medicine through her IV. Had to be kept at hospital because she had two Epi Pens and medication at the vaccine facility. Hospital wanted to make sure when the Epi Pens wore off she didn't go back into anaphylaxis. Was kept in ER for over four hours. Was given IV fluids. Her oxygen, heart rate, and blood pressure dropped at</p>

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vaccination facility. Oxygen was 81. Blood pressure was 94. At hospital, her levels started to get better. Once she was given the second Epi Pen and whatever else she was given, the medication started to work and she had come through. At the hospital, someone came in and did bloodwork for research to see why this happened. Was prescribed Epi Pens by the doctor in the hospital and was advised to carry Epi Pens with her at all times. If she has another anaphylaxis, was advised to jab herself with Epi Pen and call right away. Was told her tongue was swelling. Attempted to obtain the outcome of the anaphylaxis. At the hospital, she was so out of breath walking to the bathroom. Was told at hospital now she is having side effects from the COVID Vaccine including the tiredness and headache she is experiences. Was told to take Tylenol and Benadryl, lay down and rest, and to make sure she drinks so she does not get dehydrated. Today, she feels nauseous, lightheaded and tired with a little headache. She feels better from yesterday. Is getting better and is having a little chills maybe an hour ago. She checked her temperature and does not have a temperature, but her insides feel warm . The patient was hospitalized for the event anaphylaxis on an unspecified date. Therapeutic measures were taken as a result of was going in and out of consciousness. Events for anaphylaxis, consciousness fluctuating, chest discomfort. dyspnea, throat tightness, presyncope and swollen tongue occurred on 11Apr2021 while the remaining events occurred on an unspecified date. The patient underwent lab tests and procedures which included blood pressure: dropped and 94, blood work: unknown results, heart rate: dropped, oxygen saturation: 81 and dropped on an unspecified date. Therapeutic measures were taken as a result of all the events. Outcome of the events was unknown.

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1261394	4/27/2021	FL		F		4/1/2021	<p>APPETITE ABSENT; WEAKNESS; FEVER 102.3; NAUSEA; LOOSE GREENISH STOOL; HEART RATE INCREASED; BODY ACHES; CHILLS; SLEEPING DIFFICULTY; FEELS AWFUL; HEADACHE; FLATULENCE; TIREDNESS; DIARRHEA; This spontaneous report received from a patient concerned a 73 year old female. The patient's height, and weight were not reported. The patient's past medical history included anaphylaxis to penicillin, accident, vomiting, hives, low blood pressure, hospitalised, on iv fluids, redness of arm, swelling of arm, fever, anaphylaxis to tetanus vaccine, reaction to pneumovax vaccine, whipple surgery, adenocarcinoma in situ in pancreas, urinary tract infection, and yeast infection. The patient was previously treated with benzylpenicillin for accident, tetanus vaccine for accident, pneumococcal vaccine, pancrelipase for pancreas adenocarcinoma, and for urinary tract infection. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose was not reported, administered on 09-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 09-APR-2021, the subject experienced flatulence. On 09-APR-2021, the subject experienced tiredness. On 10-APR-2021, the subject experienced sleeping difficulty. On 10-APR-2021, the subject experienced feels awful. On 10-APR-2021, the subject experienced headache. On 10-APR-2021 03:00, the subject experienced body aches. On 10-APR-2021 03:00, the subject experienced chills. On 11-APR-2021, the subject experienced loose greenish stool. On 11-APR-2021, the subject experienced heart rate increased. On 11-APR-2021, the subject experienced fever 102.3. On 11-APR-2021, the subject experienced nausea. Laboratory data included: Body temperature (NR: not provided) 102.3 F. On 12-APR-2021, the subject experienced appetite absent. On 12-APR-2021, the subject experienced weakness. On APR-2021, the subject experienced diarrhea. Treatment medications (dates unspecified) included: acetylsalicylic acid, and oxycodone/paracetamol. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the tiredness, flatulence, chills, body aches, sleeping difficulty, feels awful, headache, fever 102.3, nausea,</p>

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							loose greenish stool, heart rate increased, weakness, appetite absent and diarrhea was not reported. This report was non-serious.
1263824	4/27/2021		36	F	4/22/2021	4/22/2021	Pt seen on 4/22/2021 by healthcare provider, allergic reaction, initial encounter, felt pt. had mild allergic reaction to 2nd Moderna vaccine, no anaphylaxis, received one dose of Benadryl, monitored for 1 and 1/2 hours without incident, first 15 minutes after vaccine she felt fine, started tingling in her legs, hands, face and flushed feeling over her arms and chest, no wheezing, no facial swelling, some soreness in arm and after first vaccine, pt. is 22 week gestation. Pt discharged home and follow up PRN.
1262233	4/27/2021	WA	45	F	4/17/2021	4/17/2021	Dr consult EMS called to assess via 911 Dr visit in person Urgent Care Trouble breathing, dizziness, heart pain, numbness and tingling in extremities, blurred vision, muscle spasms, poor muscle tone, rapid heart rate, drop in blood pressure, elevated heart pressure, trouble talking, brain fog, intestinal upset, cold sweats, tremor, poor coordination, restlessness, fatigue Onset at time of vaccine administration Labeled NOT anaphylaxis

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1262159	4/27/2021	CA	32	F	4/27/2021	4/27/2021	<p>Client received her first Pfizer dose of 0.3mL in left deltoid on 04/27/21 at 09:32am with lot number EW0179 expiring on 08/31/2021. Client who is 32-year-old female with no race or ethnicity was disclosed, was brought to EMT station by ancillary staff after complaining of tingling in her toes. Client remained alert and tracking with her eyes and appeared in no apparent distress. Client had a chief complaint of tingling in her toes bilaterally at 10:01am on 04/27/2021. Client stated that she completed her 15-minute observation and was walking to her car, when she noticed tingling in her toes bilaterally and returned to the site/EMT station. toes that was painless and localized. Client's airway, breathing and circulation were intact. Client's initial set of vitals was blood pressure 132/84, pulse 80, alert and oriented to person, place, event and time, respiration 16, eyes equal and reactive to light and lung sounds clear bilaterally. EMT was unable to obtain an SPO2 due to client's acrylic fingernails. Client noted that she had spoken to her doctor recently and her doctor stated to her that she had "poor circulation," but did not specify any diagnosis. Client also stated that she tested positive for Covid in early January and has a history of seasonal allergies. No other pertinent medical history was noted or disclosed. Assessment revealed no swelling, pain, hives, shortness of breath, chest pain, discoloration, or other signs of anaphylaxis. Client consented to staying an additional 30 minutes for observation and vitals were monitored every 15 minutes due to the stability of the client and no signs or symptoms of allergic reaction. Vital signs at 1001 were blood pressure of 132/84, pulse of 80 and respiratory rate of 16 breaths per minute. Vital signs at 1016 were blood pressure of 128/80, pulse of 76 and respiratory rate of 16 breaths per minute. Client was provided with fact sheet and areas of interest were highlighted for convince. After approximately 15 minutes, client stated that her numbness had "gone away" and laughed stating "it's probably because I'm not walking." At the completion of her additional 30-minute observation, client remained stable and was instructed to follow up with her primary care doctor at the soonest possibility. Vital signs at 1031 were blood pressure of 128/80, pulse of 76 and respiratory rate of 16 breaths per minute. Client was also instructed to seek medical care or dial 911 if a severe reaction occurred in the future. Situation did not warrant</p>

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1263572	4/27/2021	CA	48	F	3/17/2021	3/17/2021	<p>EMS and client declined service being offered. No interventions or medications were administered or indicated. Client acknowledged what she was told and exited Border View YMCA at 1032 in positive disposition by self.</p> <p>Anaphylaxis. Patient with a h/o anaphylaxis with sulfa experienced itchiness, hives, neck swelling, lightheadedness, hoarse voice, cough, and shortness of breath that began minutes after the 1st Pfizer vaccine dose, lot EN6208. Patient was seen in ED on 3/17 and treated with prednisone and Pepcid. Patient had a return of symptoms of throat closing and shortness of breath and self-medicated with epiPen at home and was then seen by PCP on 3/18. Restarted Singulair and added Pepcid. Patient came back to ED on 3/19 with continued symptoms. On 3/19 ED visit, patient was given Benadryl, Pepcid, Solu-medrol, epinephrine IM, and albuterol inhalation. Patient was admitted to ICU for observation. Continued Benadryl, Pepcid, and Solu-medrol scheduled doses. In ICU x 48 hours without further escalation in care. No lip swelling, stridor or wheezes noted. Urticarial rash has improved. Discharged home on tapered prednisone and Pepcid.</p>

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1261837	4/27/2021	WV		F	4/15/2021	4/15/2021	Anaphylaxis, after the second dose.; Throat swelling, after second dose.; This is a spontaneous report from a contactable pharmacist. A female patient of unspecified age received the 2nd dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EW0158, expiration date: 31Jul2021) via an unspecified route of administration on 15Apr2021 at single dose for COVID-19 immunization. Medical history and concomitant medications were unknown. The patient previously received the 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date for COVID-19 immunization, experienced tingling in throat, after first vaccine. The reporter stated the throat swelling was resolved and she was given Benadryl IM and transferred to the emergency department. There, she was given Epinephrine, and she had an increased heart rate. The reporter was not sure if that was a complication, but did not know for sure. The reporter did not have any information specifically. Eventually the patient improved. Anaphylaxis was resolved after treatment in the emergency room, but was unsure exactly. The reporter stated that 14 prime, or first doses were given and 21 boosters, or second doses were given. No additional Vaccines Administered on Same Date of the Pfizer Suspect. The patient required visit to the Emergency Room for events. About the medical intervention, the reporter stated that a Rapid Response was called at the site of the vaccination, and an intravenous line was started and the patient was given Solumedrol. In the emergency room, the patient was given Benadryl intramuscularly and Epinephrine was given. The heart rate increased after the Epinephrine, and then the employee had a good outcome. The patient was hospitalized. There was no multiorgan involvement, respiratory involved. Outcome of the events was recovered. Reporter seriousness for Throat swelling and anaphylaxis was Life threatening. Event relatedness was reported as related.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported events throat swelling and anaphylaxis based on the known safety profile. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse

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events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

1258404	4/26/2021	MD	22	F	4/24/2021	4/24/2021	Wheezes, mild angioedema, anaphylaxis
1259611	4/26/2021	MI	18	F	4/26/2021	4/26/2021	Patient's mom called saying that about 4 hours post Pfizer vaccine administration of her 2nd shot. She was having red bumps on her arm and small patches on her leg. Mom said she did not have any type of reaction when she received her first Pfizer vaccine. I recommended patient to take benadryl and monitor for any additional signs of anaphylaxis. If rash spreads or other signs such as trouble breath, swelling of face, etc happen she should go to emergency room. I will be filling out the VAERS form as soon as I submit this event.
1257677	4/26/2021	AZ	37	F	4/25/2021	4/25/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Medium, Additional Details: Patient was seated at observation area, she said she was feeling throat tightness. she says she had got other reactions in the past and she always carries an epipen. Epipen was taken for emergency kit and administered. 911 was called, she was feeling better after 20 minutes but emergency personal recommended to take her to the ER as the vaccine can do another reaction. pt was talking to us all the time with a gaspy voice.
1257674	4/26/2021	CA	29	F	4/25/2021	4/25/2021	Site: Itching at Injection Site-Mild, Systemic: Allergic: Anaphylaxis-Mild, Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Mild, Systemic: Allergic: Swelling of Face / Eyes / Mouth / Tongue-Mild
1257449	4/26/2021	FL	64	F	4/5/2021	4/15/2021	Anaphylaxis in the form of swelling of the tongue after eating pineapple. Patient had never had an allergy to any food prior to this.
1257666	4/26/2021	CA	29	F	4/25/2021	4/25/2021	Systemic: Allergic: Anaphylaxis-Mild, Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Mild, Systemic: Allergic: Swelling of Face / Eyes / Mouth / Tongue-Mild

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1257637	4/26/2021	NY	25	F	4/25/2021	4/25/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Systemic: Allergic: Rash Generalized-Mild, Systemic: Chills-Severe, Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hyperventilation-Mild, Systemic: Nausea-Mild, Systemic: Shakiness-Severe, Systemic: Weakness-Mild, Additional Details: Patient recieved vaccination. 15 minutes later patient stated she wanted to stay a little longer with a feeling of uneasiness and muscle trembling/shaking and feeling cold. 27 minutes later patient stated she felt a sudden tightness in her chest and a shortness of breathing. Patient requested to get an epi-pen injection due to the difficulty in breathing. Patient had epi-pen injected into left thigh at 4:46 pm .
1255226	4/25/2021	MI	61	F	4/5/2021	4/5/2021	Anaphylaxis-swelling of eyes, tongue, and injection site, rash/hives, shortness of breath, and dizziness; Anaphylaxis-swelling of eyes, tongue, and injection site.; This is a spontaneous report from a contactable consumer (patient). A 61-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date unspecified), via an unspecified route of administration, administered in right arm on 05Apr2021 16:00 as single dose for COVID-19 immunization. Medical history included known allergies: yes and hypertension. The patient was not pregnant. Concomitant medications included metoprolol succinate (TOPROL XL), lisinopril dihydrate (LISINOPRIL), and cetirizine hydrochloride (ZYRTEC). The patient had no other vaccine in 4 weeks. On 05Apr2021 16:15, the patient experienced anaphylaxis-swelling of eyes, tongue, and injection site, rash/hives, shortness of breath, and dizziness. The events resulted in emergency room/ department or urgent care. Therapy for the events included prednisone, antihistamine, and intravenous (IV) fluid. The patient did not have covid prior vaccination and was not Covid tested post vaccination. Outcome of events was recovering. Information about lot/batch number has been requested.

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1254727	4/25/2021	NY	32	M	4/6/2021	4/6/2021	fear of death/doom; I went into a full Anaphylaxis shock; This is a spontaneous report from a contactable consumer (patient). A 32-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; Lot Number: EW0150) via an unspecified route of administration, administered in Arm Left, at the age of 32-year-old, on 06Apr2021 09:45, as SINGLE DOSE for covid-19 immunisation. Medical history included allergy to shrimp. The patient was not diagnosed with COVID nor was he tested post vaccine. The patient's concomitant medications were not reported. On 06Apr2021 at 10:00 am, 15 mins after the vaccine, a large hive appeared on his forehead and then 1.5 hours later the patient went into a full Anaphylaxis shock with difficulty breathing, throat closing up, fear of death/doom, tingling sensation in whole body, heart pounding rapidly, chest pain, dizziness. The patient went to the emergency room/urgent care and was hospitalized for 1 day. Therapeutic measures taken in response to the events included administration of Steroids, antihistamines, and pain killers. Outcome was recovering at the time of the report.

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1255141	4/25/2021		37	M			Anaphylaxis; drooling; This is a spontaneous report from a non-contactable health care professional. A 37-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot number: EP7533, Expiration date: Not reported), via an unspecified route of administration on 08Apr2021 as a single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. It was reported that patient had facial/throat swelling after the 15 min waiting period while driving home. No medical treatment, self-resolved with Benadryl at home, Differential Diagnosis: Anaphylaxis (dyspnea, stridor, drooling, tongue swelling). The patient underwent lab tests and procedures which includes patient Vital parameters results included: BP (138/89), HR (81), O2 (96%) at 11:45 am and BP (141/89), HR (68), O2 (97%) at 12:04.. Treatment included: Antihistamines, Epinephrine and IM steroids. Pre-treatment with Benadryl, Pepcid, and Zyrtec. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. ; Sender's Comments: The event anaphylaxis and drooling was considered related to suspect drug based on strong temporal association and known safety profile of the drug. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

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1255126	4/25/2021	OH	40	F	4/6/2021	4/6/2021	anaphylaxis; rash/hives on face; rash/hives on face; progressed to swollen lips, tongue; progressed to swollen lips, tongue; cough; throat irritation; wheezing; This is a spontaneous report from a contactable consumer (patient). The 40-year-old non pregnant female patient received first dose of BNT162B2 (Pfizer Covid-19 vaccine, lot number: EW0150 expiry date unknown) via an unspecified route of administration on Left arm as a single dose on 06Apr2021 09:30 AM. Medical history included asthma, known allergies: Biaxin, albuterol, xopenex, apples, pears, stone fruit (peaches, plums, apricot, etc), almond, hazel-nut. Concomitant medications included Zyrtec, Nasonex, Flovent, Singulair and Zoloft. On 06Apr2021 10:00 AM, started with rash/hives on face, then progressed to swollen lips, tongue, cough, throat irritation/swelling and wheezing. Initially treated in emergency room (ER) for anaphylaxis then released. Within 30 minutes, symptoms returned and was treated ER for anaphylaxis and was admitted for observation. She was discharged in the morning of 07Apr2021, but had to return to ER that evening, and was discharged in the morning of 09Apr2021. She was treated with Epinephrine, Benadryl, steroids and Pepcid. She did not receive any other vaccine in four weeks prior to the suspect. The patient was not suffering from covid prior vaccination. On 06Apr2021, she was tested through Nasal Swab for Covid and results were found to be negative. The outcome of events was recovering. No further information was available.

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1254886	4/25/2021			M	3/20/2021	3/21/2021	anaphylaxis; very tired; infection; lump that was very itchy on his elbow; bottom lip was really swollen; bumps on his back and they were really itchy; the muscle became painful for the itchiness.; thing on his ankle looked like a ring, looked like ring worm; Rashes; on the right side of his face, he lost all muscle control and urgent care thought it was Bell's palsy/facial paralysis/facial issues; redness and itching and a little bit of swelling behind his right ear; redness and itching and a little bit of swelling behind his right ear/itchy spots/foot and ankle being very itchy/ intense itching on his foot; redness and itching and a little bit of swelling behind his right ear; This is a spontaneous report from contactable consumers (patient and patient's mother) and from a contactable healthcare professional (physical therapist, patient's father) via medical information team. A 29-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration on 20Mar2021 (lot number and expiration date were not reported) as single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient got his first dose of the vaccine on 20Mar2021. He was very tired at first, on Sunday (21Mar2021) at night he noticed redness and itching and a little bit of swelling behind his right ear. He saw a dermatologist on Tuesday (unspecified date) and gave him clindamycin but they think it may be an infection of some kind. That same night, he had a lump that was very itchy on his elbow and the next morning it was flat and completely gone. The next day on the right side of his face, he lost all muscle control and urgent care thought it was Bell's palsy and had him go to the ER. By the time he got to the ER the symptoms resolved enough that they weren't concerned. A few days after, he woke up and his bottom lip was really swollen and that has never happened before. He took BENADRYL and that resolved. The patient got bumps on his back and they were really itchy, which resolved overnight. A couple days after, he got a patch on his palm and has been getting itchy spots on him that clear up. Last night (07Apr2021), he noticed his foot and ankle being very itchy and the muscle became painful for the itchiness. It subsided overnight and then woke up with intense itching on his foot. The thing on his ankle looked like a ring, looked like ring worm. The patient wanted to know if

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there was an increased chance of fungal infection. The patient wanted to know if these were normal reactions and what should he do. The patient's father was concerned about his son's (patient) reaction and was concerned with anaphylaxis after 48 hours and wanted to know if that could happen. The father added that the patient had rashes and facial paralysis. The patient saw his primary care provider who told the patient to go to an allergist. It has been 3 weeks since the patient's injection but the father was worried and does not know if the patient was in the clear of anaphylaxis. The father stated that the facial issues were 3 days after the vaccine (23Mar2021). The father wanted to know if the patient was in danger now from this one and was wondering if the patient should take the second vaccine. The patient's allergist said no until they decide if the patient was allergic to something within the vaccine. The events were considered non-serious by the reporters. The patient recovered from Bell's palsy on 23Mar2021; recovered from "bottom lip was really swollen" and "bumps on his back and they were really itchy" on unspecified dates. The outcome of the remaining events was unknown. Information on the lot/batch number has been requested.

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1254833	4/25/2021	TX	48	F	2/28/2021	2/28/2021	Throat got tight; cholesterol is off and thyroid; thyroid function test: off; minor anaphylactic shock; discomfort throat; her heart rate accelerated; flushed face; unsteady; pain; This spontaneous report from contactable consumer (patient) via a Pfizer-sponsored program. A 48-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/Lot Number: EJ6202), first dose via an unspecified route of administration, administered in left arm on 28Feb2021 10:40 (at the age of 48-year-old) as SINGLE DOSE for covid-19 immunization. Patient was 48 years old at the time of vaccination. Medical history included partial thyroid removal allergies to iodine, shellfish and bees, she also stated that she saw an endocrinologist who put on thyroid regimen of two different medications and she had a reaction, hives and that regimen had to be discontinued. No Prior Vaccinations within 4 weeks. Concomitant medications included levothyroxine sodium (SYNTHROID) 0.1mg tablet orally once per day in the morning been taking for at least four-fives years and epinephrine (EPIPEN). On 28Feb2021 the patient had small reaction, minor anaphylactic shock, discomfort throat, her heart rate accelerated, flushed face, pain and the patient was unsteady. The patient also stated that her throat got tight Epi Pen was not administered. Clinical course of the events includes, the patient stated that, after she received the vaccine she was instructed to stay 30 minutes instead of the 15 because she was sensitive to stuff and within about 5 minutes she started feeling discomfort in her throat. and was given Benadryl, when she has anaphylactic reactions her body goes in shock. By an hour later the heart acceleration, flush, and feeling unsteady these were completely gone. Benadryl knocked her out and she went to sleep for like 4 hours, woke up and her body was just hurting, but that only lasted a couple of days. She experienced pain for two days after. Had went for 2nd dose and facility denied her due to last reaction. Has been over 3 weeks and wants to know if there is an alternative for 2nd dose of vaccine. The patient underwent lab tests and procedures which included blood cholesterol: off, heart rate: accelerated, thyroid function test: off, all on unspecified date. Outcome of the events discomfort throat, body was just hurting was recovered. Outcome of rest of the events throat anaphylaxis, flushed face got tight, heart rate increased,

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1254737	4/25/2021	WI	51	F	3/11/2021		<p>unsteadiness, cholesterol low, thyroid hormones decreased was unknown.</p> <p>A spike in her BP; This is a spontaneous report from a contactable pharmacist. A 52-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; solution for injection) intramuscularly in the left arm on 11Mar2021 (at the age of 51-years-old) as a single dose for COVID-19 immunisation. Medical history included hypertension from an unspecified date and unspecified if ongoing (not taking meds for this prior to this event) and strawberries - anaphylaxis from an unspecified date and unspecified if ongoing. It was unknown whether the patient was diagnosed with COVID-19 prior to vaccination. It was unknown if the patient was pregnant. Concomitant medications ("other medications in two weeks") included acetaminophen taken for an unspecified indication from an unspecified date and unspecified if ongoing, as needed. It was unknown whether the patient received any other vaccine within four weeks of the COVID-19 vaccine. The patient experienced a spike in her BP (blood pressure) on an unspecified date ("with her first dose"). The clinical outcome of the event a spike in her BP was unknown. Since the vaccine, it was unknown whether the patient was tested for COVID-19. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected; Sender's Comments: Based on the information currently available, a possible contributory role of the suspect vaccine BNT162B2 in triggering the onset of "a spike in her BP" cannot be excluded. The event was confounded by underlying hypertension. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>

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1255215	4/25/2021	IL	57	F	4/8/2021	4/8/2021	possible seizure; fainting; chills; headache; joint and long bone pain; dizziness; Right abdominal pain; temperature spike at 101; unquenchable thirst; sweating; This is a spontaneous report from a contactable consumer (patient) reported for herself that the 57-year-old female patient received second dose of bnt162b2 (BNT162B2), intramuscular, administered in Arm Right on 08Apr2021 04:00 PM (Lot Number: EW0151) at single dose for covid-19 immunization. Medical history included multiple allergies from an unknown date and unknown if ongoing, asthma from an unknown date and unknown if ongoing, chronic obstructive pulmonary disease from an unknown date and unknown if ongoing, orthostatic hypotension from an unknown date and unknown if ongoing, traumatic lung injury from an unknown date and unknown if ongoing, metaplasia from an unknown date and unknown if ongoing, hiatus hernia from an unknown date and unknown if ongoing, polyp from an unknown date and unknown if ongoing, diverticulum intestinal from an unknown date and unknown if ongoing, exposure to toxic agent from an unknown date and unknown if ongoing. Concomitant medications included pantoprazole taken for an unspecified indication, start and stop date were not reported; famotidine taken for an unspecified indication, start and stop date were not reported; cyclobenzaprine taken for an unspecified indication, start and stop date were not reported; calcium carbonate;soya isoflavones;vitamin d nos taken for an unspecified indication, start and stop date were not reported; ibuprofen;phenylephrine hydrochloride taken for an unspecified indication, start and stop date were not reported. The patient previously took firs dose of bnt162b2 (BNT162B2) intramuscular, administered in Arm Right on 18Mar2021 04:15 PM(Batch/Lot Number: ER2613) at single dose for covid-19 immunisation. The patient experienced possible seizure on 08Apr2021 20:00 with outcome of recovering, chills on 08Apr2021 with outcome of recovering, headache on 08Apr2021 with outcome of recovering, joint and long bone pain on 08Apr2021 with outcome of recovering, dizziness on 08Apr2021 with outcome of recovering, fainting on 08Apr2021 with outcome of recovering, right abdominal pain on 08Apr2021 with outcome of recovering, temperature spike at 101 on 08Apr2021 with outcome of recovering, unquenchable thirst on 08Apr2021 with

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outcome of recovering , sweating on 08Apr2021 with outcome of recovering. The patient underwent lab tests and procedures which included body temperature: temperature spike at 101 on 08Apr2021. Therapeutic measures were taken as a result of possible seizure. She is not pregnant at the time of vaccination. Facility where the most recent COVID-19 vaccine was administered was other. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The clinical course was reported as follows: 4 hrs post vax: chills, sub normal temperature drop >96 f oral, eat, and airmptit , sub normal low BP, headache, joint and long bone pain, dizziness, 2 episodes of warned fainting (vasovagal); followed by temperature spike at 101 F oral onset @21 hrs. post vax rigors and falls, with warned loss of consciousness & possible seizure, followed by lower right abdominal pain w/rebound tenderness, sweating, unquenchable thirst, until fever broke 30 hrs post onset. At febrile onset 400 mg ibuprofen, followed by 200 mg every 8 hrs until symptom resolution. The adverse event result in any of the following Doctor or other healthcare professional office/clinic visit. Treatment was received for the adverse event included Public Health RN telephone consult, ibuprofen see. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Allergies to medications, food, or other products:Yes a long list that does not include PG. Other diagnosed illnesses/medical history/chronic health conditions:IMMUNE SYSTEM: multiple allergies including anaphylaxis; R.A., reactive asthma; CARDIOPULMONARY: reactive asthma, chemical exposure lung injury scaring, COPD, orthostatic hypotension; GI: Barrets esophagial metaplasia, hiatal hernia, colonic polyps adenocarcinoma, diverticula. Follow-up (20APR2021): Follow-up attempts completed. No further information expected.

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1254580	4/25/2021	CA	47	F	3/30/2021	3/30/2021	<p>kidneys started hurting; UTI; heart pain; nausea; heart racing; blood pressure started going up; cold sweat; weak/did not have energy to talk; blood pressure was too low; This is spontaneous report from a contactable consumer reported for self. This 47-year-old female patient (not pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot#: ER8732) at single dose in left arm on 30Mar2021 01:45 PM for COVID-19 immunization. Medical history included nephrocalcinosis. Patient had allergies to contrast of iodine, had an anaphylaxis when they injected with iodine for checking her kidney, it was over 20 years ago. Concomitant medication included ethinylestradiol/ferrous fumarate/norethisterone acetate (LO LOESTRIN FE) for birth control. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 30Mar2021, with a minute taken the covid vaccine, patient started feeling nausea and heart racing. Her blood pressure started going up. The facility kept checking blood pressure and oxygen. After a bit, patient had no idea of time she felt a cold sweat and very weak. Patient did not have energy to talk. However, patient saw the nurse with an epi pen and she was able to tell that she was breathing. Doctor said that her blood pressure was too low. It had dropped to low 80. Patient kept trying to relax and suddenly it went all the way up again. Her normal blood pressure was 110/70 or 120/80 and it was 150/98. Patient started getting heart pain was taken to the ER and an ECG was made and her heart was ok. Her blood pressure stayed high. Patient kidney disease. Specifically, nephrocalcinosis; however, her kidney function still good. In the second day after the vaccine, on 31Mar2021, her kidneys started hurting and she felt like she was having an UTI (urinary tract infection) what she did not have had in the last year or so. All the adverse events result in doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. Treatment received for all events was reported as unknown. The outcome of events was resolving.</p>

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1254571	4/25/2021	CO	66	F	4/2/2021	4/2/2021	anaphylaxis; This is a spontaneous report received from a contactable nurse. A 66-years-old female received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Batch/Lot Number: Unknown), 1st dose via intramuscular route of administration, on 02Apr2021 09:30 AM (at the age of 66-years-old) as single dose for COVID-19 immunisation. Patient's medical history included asthma, GERD. Concomitant medications were not reported. The patient previously took keflex, peanut, fentanyl, pcn ms and experienced known allergies. On 02Apr2021 09:30 AM, the patient experienced anaphylaxis chest/throat tightness, which resulted in emergency room visit. Treatment received for the adverse events included epi, albuterol, and Benadryl. It was unknown that the patient was diagnosed with COVID-19, prior to vaccination and whether the patient had been tested for COVID-19 since the vaccination. The outcome of the events was recovered on Apr2021. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on known drug safety profile, there is reasonable possibility of causal association between the event anaphylaxis and the suspect drug BNT162B2.
1255230	4/25/2021	MA		F	4/9/2021	4/9/2021	anaphylactic shock and was transported to hospital ER/swollen lips and throat; This is a spontaneous report from a contactable consumer. An adult female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 09Apr2021 (Batch/Lot number was not reported) as single dose for covid-19 immunisation at a clinic. Medical history included allergic to penicillin and history of previous anaphylaxis reactions. The patient has no covid prior to vaccination. The patient's concomitant medications were not reported. The patient previously took IV iron and experienced allergy. The patient received the vaccine at clinic and within 10 minutes, the patient experienced swollen lips and throat like anaphylactic shock and was transported to hospital ER. The patient received IV benadryl and Pepcid as treatment. The outcome of the events was recovered on an unspecified date. Information on the lot/batch number has been requested.

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1255274	4/25/2021	NY	58	F	3/30/2021	3/30/2021	<p>Sinuses felt congested/Feels like left side of head is congested; Left ear ache/inflammation; Momentary buzzing sound in left ear; Vertigo at night; Feeling foggy; Autoimmune fluid response (injection left arm); Left eye felt inflamed; Face felt swollen/fluid; This is a spontaneous report from a contactable consumer (patient). A 58-year-old female patient received BNT162b2 (BNT162B2), dose 1, via an unspecified route of administration, administered in the left arm, on 30Mar2021 at 14:00 (Batch/Lot Number: 8733), at the age of 58 years old, as a single dose, for COVID-19 immunisation. The patient was not pregnant at the time of vaccination. The patient's medical history included asthma, Crohn's disease, and asymptomatic mild thrombocytopenia. The patient had allergy to penicillin, sulfa, preservatives, azithromycin (ZPACK), dust, mold, and sulfites; she also had seasonal allergies. Additionally, allergy to food included wheat, rye, oats, barley, quinoa, tomato, potato, celery, peas, banana, cantaloupe, strawberries, chocolate, tea, beef, and caffeine. In 1982 the patient reacted to an unspecified allergy shot with anaphylaxis and 4-day delayed reaction of serum sickness including liver dysfunction, swelling, rash, nausea, not being able to keep food or liquid down, treated with hydroxyzine (ATRAX) (started at day 5 of serum sickness which helped clear it up). The patient had not had COVID-19 prior to vaccination with BNT162b2. Concomitant medications included mesalazine (LIALDA), cetirizine hydrochloride (ZYRTEC), mometasone furoate (ASMANEX), fluticasone propionate (FLONASE), and vitamin D. The patient had not received any other vaccines during the 4 weeks prior to BNT162b2 administration. The patient stated that 20 minutes after vaccination her left eye felt inflamed and 3 hours after vaccination her face felt swollen/fluid. The patient stated waking-up on 04Apr2021 at 06:00 AM with momentary buzzing sound in the left ear, ear ache/inflammation, sinuses feeling congested, lightheaded/dizziness all day, vertigo at night and on the following morning when lying on the left side, and feeling dizzy/lightheaded for 3 more days. The patient also reported feeling foggy, feeling like her left side of head was congested, and autoimmune fluid response (injection left arm) (as reported), all on 04Apr2021. Due to the events, the patient consulted a doctor or other healthcare professional office/clinic visit.</p>

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							No treatment was required for the events. The patient was not tested for COVID-19 after vaccination. The patient was recovering from all reported events with the exception of buzzing year which resolved on 04Apr2021.
1256777	4/25/2021	CO	30	F	4/16/2021	4/16/2021	About two hours after my second shot, I started feeling tingling in my legs. Within half an hour, the tingling spread to my arms and face and my lips and tongue started to swell and my throat felt like it was closing. I called 911, and they gave me an epipen, shot of steroids, and a shot of benadryl and said I went into anaphylaxis shock. I was released from the hospital Friday night, but on Monday night I had another (milder) allergic reaction and the following day began to have shortness of breath. I went to my doctor's on Tuesday, who prescribed me steroids and histamine blockers. I began taking them but on Wednesday my difficulty breathing increased and it got to the point where I had difficulty swallowing and couldn't eat so I went to the ER again. I have had some sort of rash and hives every day since my second shot, which my doctor says is a continuing allergic reaction from the shot. I am going to see an allergist, but I have no history of allergies or allergic reactions to vaccines.
1255464	4/25/2021	SC	49	F	4/22/2021	4/22/2021	I waited about 30 minutes. Felt tingly and a bit light headed but cracked it up to being tired from the shot. I got in my car and about 5 minutes out driving in the middle of traffic, I felt like I was going to pass out like I had once before with anaphylaxis- at the wheel. There is no mistaking the feeling. I could not feel my pulse at all. Fortunately I had a EpiPin in my car and I was able to jab it in my leg and within a minute or two I had the energy to turn the car around and get back to the folks at site who were wonderful. I then took benadryl as advised and the EMS were called. I was taken to site where they gave me a steroid, pepsid and monitored me until I went home later that evening. I was told to take benadryl for the next 24 hours and I did.

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1255724	4/25/2021	MD	41	M	1/16/2021	1/16/2021	I developed full anaphylaxis within 30 minutes of receiving my Covid-19 vaccine.; dizziness; nausea; inability to swallow; mouth going dry; unable to speak; This is a spontaneous report from a contactable consumer (patient). A 41-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 16Jan2021 12:00 (Lot Number: el3248) as single dose (at the age of 41-years-old) for covid-19 immunisation. Medical history included Heart disease, hyperlipidaemia, hypertension, pituitary adenoma. It was reported that patient received concomitant medications in two weeks prior to the vaccination, no details reported. Patient did not receive other vaccine in four weeks prior to the COVID vaccine. Patient stated that he developed full anaphylaxis within 30 minutes of receiving his Covid-19 vaccine on 16Jan2021 (Adverse event start time reported as 12:00 P.M.). It started with dizziness, then nausea, then inability to swallow and mouth going dry, finally unable to speak. Events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Life threatening illness (immediate risk of death from the event). Patient was treated for the events with epinephrine (EPIPEN) on site by emergency medical services (EMS) and transport to hospital. The patient was not diagnosed with COVID-19 prior to vaccination and had been tested for COVID-19 post vaccination. The patient underwent laboratory tests and procedures which included sars-cov-2 test (Nasal Swab) negative on 11Feb2021. Patient had no known allergies other than the Covid-19 vaccine. Patient recovered from the events on unknown date.
1252103	4/24/2021	MI	60	F	3/28/2021	3/29/2021	Rashes, hives and total face, neck, and torso and arms completely red as the hives grow. Several episodes where it was so bad I had anaphylaxis requiring epinephrine injections with O2 sat down to 70! This went on every day for 3 1/2 weeks. I was already taking Allegra, Xyzal, singularity, and famotidine to stabilize my mast cells. Cromolyn and Benadryl added.

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1252271	4/24/2021			F		3/11/2021	BODY ACHE; CHILLS; HEADACHE; FATIGUE; SHORTNESS OF BREATH; This spontaneous report received from a patient concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's concurrent conditions included severe anaphylaxis with tree nuts, anaphylaxis with nsais (angioedema), and anaphylaxis with fish. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, and batch number: 1802072 expiry: UNKNOWN) dose was not reported, administered on 11-MAR-2021 14:15 for prophylactic vaccination. Concomitant medications included epinephrine. On 11-MAR-2021 approximately 8:45 p.m-9:45 p.m., the subject experienced shortness of breath. On an unspecified date, the subject experienced body ache, chills, headache, and fatigue. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from shortness of breath on 11-MAR-2021, and the outcome of chills, headache, fatigue and body ache was not reported. The reporter causality and Company causality between JNJ-78436735 and shortness of breath, chills, headache, fatigue and body ache was possible. This report was non-serious.
1251528	4/24/2021	KY	24	F	3/26/2021	4/1/2021	A week later, I had an anaphylactic reaction to a kit kat bar. I had previously ate kit kats with no issue. I had to be intubated and hospitalized. After extubation, I continued to have anaphylaxis at least once a day with no correlation to what I was eating or drinking. I also began having a severe auto immune flare up with body pains in my legs, back, and stomach immobilizing me with generalized weakness.

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1251456	4/24/2021	MA	31	F	4/8/2021	4/10/2021	Vaccine was given in multiple doses over the course of 5 hours due to history of MCAS. Post second dose GI manifestations of mast cell activation. Syndrome started - abdominal and esophageal pain which were treated with Pepcid ac. 48 hours post vaccine facial flushing and hives appeared all over both arms. Extreme fatigue, shaking, gi pain, etc. Mast cell activation syndrome was well controlled pre vaccine post vaccine it is out of control with increased scores. Serious anaphylaxis first occurred two days post vaccine (10 April 21) and required two epi pens to stop. since then there have been daily mast cell attacks consisting of headaches, fatigue, gipain, hives all over arms, and legs, shaking,. Patients Xolair dose was increased and Zyrtec was increased on 22 Apr 2021) to no avail. I continue to have daily debilitating mast cell symptoms. I had serious anaphylaxis again on 23 APR 2021 - full body hives, flushing, vomiting, difficulty breathing, low blood pressure is chin required epinephrine. I fear for my life and wish I had never gotten the vaccine. This is completely debilitating.
1250805	4/24/2021	NY	43	M	4/18/2021	4/19/2021	Delayed anaphylaxis
1246099	4/23/2021	CA	25	M	4/22/2021	4/22/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hyperventilation-Medium, Systemic: Hypotension-Medium, Systemic: Shakiness-Medium, Systemic: Weakness-Medium, Additional Details: immediately after first dose pt head started to lower, eyes closed, slid down in chair. respiratory rate decreased for several seconds then panic breathing occurred thereafter. pt was sweating profusely and skin was cold and clammy. could not verbally respond for 30-45 seconds. after a minute pt could talk and answer question. blood pressure was taken 3 different times 5 minutes apart 75/43, 87/46, 93/52. Pt was feeling fine a half hour later and was called 4 hours later to follow up.

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1245670	4/23/2021	FL		F		3/4/2021	FEVER; CHILLS; MUSCLE ACHE; This spontaneous report was received from a patient and concerned a 65 year old female. The patient's height, and weight were not reported. The patient's past medical history included prone to side effects. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: unknown) dose was not reported, administered on 04-MAR-2021 at 11:30 AM to left arm for prophylactic vaccination. No concomitant medications were reported. On 04-MAR-2021, around 6:30, the subject experienced fever, chills, muscle ache (right arm more than left arm, though the shot was given left arm). Since prone to side effects, she stayed at the vaccine facility for 1 hour after vaccine administration to make sure she did not experience anaphylaxis. Action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the fever, chills, and muscle ache was not reported. This report was non-serious.

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1245505	4/23/2021	AL	41	F	2/2/2021	2/2/2021	Tongue felt like it was swelling; Itching; Tickle in her throat; This is a spontaneous report from a contactable pharmacist. A 41-year-old not pregnant female patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: EN3518), via intramuscular route of administration in left arm on 02Feb2021 at 11:45 AM at single dose for COVID-19 immunization. The patient previously took first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: E1283), via intramuscular route of administration in left arm on 01Jan2021 at single dose for COVID-19 immunization and had no problem post 1st dose. Medical history and concomitant medications were not reported. The patient was allergic to shellfish anaphylaxis. On 02Feb2021 at 12:15 PM, the patient experienced tongue felt like it was swelling, tickle in her throat and itching. During observation period post second dose patient began itching and felt like she had a tickle in her throat. Patient began clearing her throat and asked for some water. RN noted she was rubbing throat and gave her water and benadryl 25 mg PO for itching. Patient noted that her throat was starting to feel funny like it might be closing up and her tongue felt like it was swelling. Epinephrine 0.3mg IM administered immediately after identifying these symptoms and patient wheeled down to ER for evaluation. Patient received IV benadryl in ER and famotidine. Observed for a couple of hours and then released. The outcome of the events was unknown.; Sender's Comments: A causal relationship between BNT162B2 and the reported events swollen tongue, pruritus and throat irritation cannot be excluded based on temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate .
1247913	4/23/2021	WY	47	M	3/24/2021	4/1/2021	Suffered severe anaphylaxis 4 days later with no known history of allergy

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1247009	4/23/2021	WI	68	F	4/5/2021	4/5/2021	Patient was aware she might have a reaction to the covid vaccine as she reports a reaction to influenza and tetanus vaccines in the past. Patient received Janssen vaccine today. Patient brought along her own EpiPen and Benadryl as a precaution. Pharmacist advised patient to wait in the observation area for atleast 30 minutes to monitor for signs of an allergy. Patient's appointment was for 1355 and after vaccination around 1410 patient complained of a mild rash insides of both arms. Pharmacist advised her to take a Benadryl and continued to monitor for signs of anaphylaxis. After 20 minutes, patient left with no additional harm. Mild rash was still present but patient felt ok to leave home.
1249360	4/23/2021	CO	59	M	4/20/2021	4/22/2021	On 4/22/21, approximately 36 hours after Moderna dose 2, Patient started having hives at his worksite in the morning. Paramedics were called at treated him on site, then took him home. about 20 minutes later he called his girlfriend, and said his lips and throat were swelling. She sent paramedics to him and he was taken to the emergency department, and then transferred to ICU were he was diagnosed and treated for anaphylaxis overnight. He was released from the hospital on 4/23/21 and was reportedly doing much better, albeit with a rash still. All reporting was done by patient's girlfriend to me.
1246111	4/23/2021	LA	37	F	4/20/2021	4/21/2021	Systemic: Allergic: Anaphylaxis-Medium, Additional Details: Pt reports swelling of face that is getting worse. Does not indicate difficulty swallowing. At time of call pt hadn't taken anything. Advised to take Benadryl around the clock. If symptoms worsen, advised to see MD.

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1249629	4/23/2021	NY	55	F	4/17/2021	4/1/2021	<p>Doctor felt it was an anaphylaxis reaction; Cough; Left arm is still so sore she can not lift it; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of ANAPHYLACTIC REACTION (Doctor felt it was an anaphylaxis reaction) in a 55-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 040B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). Concomitant products included CETIRIZINE HYDROCHLORIDE (ZYRTEC [CETIRIZINE HYDROCHLORIDE]) for an unknown indication. On 17-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. In April 2021, the patient experienced COUGH (Cough) and VACCINATION SITE PAIN (Left arm is still so sore she can not lift it). On 17-Apr-2021, the patient experienced ANAPHYLACTIC REACTION (Doctor felt it was an anaphylaxis reaction) (seriousness criterion medically significant). At the time of the report, ANAPHYLACTIC REACTION (Doctor felt it was an anaphylaxis reaction) outcome was unknown and COUGH (Cough) and VACCINATION SITE PAIN (Left arm is still so sore she can not lift it) had not resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. The patient was treated with antihistamine for tingling in her lips and whole face became swollen and her lips were huge and it started to go away. On 18-APR-2021, it started again so patient had seen her physician on 19-APR-2021 who referred her to a specialist. The patient was tested for an allergy to the vaccine. The doctor felt it was an anaphylaxis reaction. The reporter did not provide an assessment for the events. Company Comment - Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

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1243584	4/22/2021	TX	37	F	3/6/2021	3/25/2021	Within 10 minutes after my vaccine, the roof of my mouth began to itch, and 3 days after my vaccine, I developed hives across my abdomen that started at 5am and did not subside until I was able to take a Benedryl before bedtime. Three weeks after my vaccination, my shot site began to hurt and then I started to exhibit an allergic reaction to foods I had never been allergic to previously. First it was ground turkey, and then two days later, I had an allergic reaction (hives, itchy mouth, and anaphylaxis) to chicken. A few days later I developed the same reaction to beef, and now I have the same reaction to berries and vegetables. My body seems to be attacking everything I eat.
1240179	4/22/2021	IL	20	F	4/21/2021	4/21/2021	anaphylaxis, hives, hypotension, tachycardia, facial swelling
1237204	4/21/2021	CO	28	F	4/2/2021	4/2/2021	Anaphylaxis

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1235689	4/21/2021	OR	40	F	4/15/2021	4/15/2021	Feeling dizzy and bad; Thought her blood sugar was dropping; Lips started tingling; Started sweating; Felt weak; Felt pressure on chest; Muscles started twitching/legs started twitching; Had difficulty breathing; Anaphylaxis Shock; When the Benadryl wears off I start shaking; When the Benadryl wears off I have shallow breathing; When the Benadryl wears off throat starts tightening; This spontaneous case was reported by a consumer and describes the occurrence of DIZZINESS (Feeling dizzy and bad), BLOOD GLUCOSE DECREASED (Thought her blood sugar was dropping), PARAESTHESIA ORAL (Lips started tingling), HYPERHIDROSIS (Started sweating), ASTHENIA (Felt weak), CHEST DISCOMFORT (Felt pressure on chest), MUSCLE TWITCHING (Muscles started twitching/legs started twitching), DYSPNOEA (Had difficulty breathing) and ANAPHYLACTIC SHOCK (Anaphylaxis Shock) in a 40-year-old female patient who received mRNA-1273 (batch no. 027B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Fruit allergy. On 15-Apr-2021, the patient received first dose of mRNA-1273 (Intramuscular) 1 dosage form. On 15-Apr-2021, the patient experienced DIZZINESS (Feeling dizzy and bad) (seriousness criteria hospitalization and life threatening), BLOOD GLUCOSE DECREASED (Thought her blood sugar was dropping) (seriousness criteria hospitalization and life threatening), PARAESTHESIA ORAL (Lips started tingling) (seriousness criteria hospitalization and life threatening), HYPERHIDROSIS (Started sweating) (seriousness criteria hospitalization and life threatening), ASTHENIA (Felt weak) (seriousness criteria hospitalization and life threatening), CHEST DISCOMFORT (Felt pressure on chest) (seriousness criteria hospitalization and life threatening), MUSCLE TWITCHING (Muscles started twitching/legs started twitching) (seriousness criteria hospitalization and life threatening), DYSPNOEA (Had difficulty breathing) (seriousness criteria hospitalization and life threatening), ANAPHYLACTIC SHOCK (Anaphylaxis Shock) (seriousness criteria hospitalization, medically significant and life threatening), TREMOR (When the Benadryl wears off I start shaking), HYPOPNOEA (When the Benadryl wears off I have shallow breathing) and THROAT TIGHTNESS (When the

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Benadryl wears off throat starts tightening). The patient was hospitalized from 15-Apr-2021 to 15-Apr-2021 due to ANAPHYLACTIC SHOCK, ASTHENIA, BLOOD GLUCOSE DECREASED, CHEST DISCOMFORT, DIZZINESS, DYSPNOEA, HYPERHIDROSIS, MUSCLE TWITCHING and PARAESTHESIA ORAL. On 15-Apr-2021, DIZZINESS (Feeling dizzy and bad), BLOOD GLUCOSE DECREASED (Thought her blood sugar was dropping), HYPERHIDROSIS (Started sweating), ASTHENIA (Felt weak), CHEST DISCOMFORT (Felt pressure on chest), DYSPNOEA (Had difficulty breathing) and ANAPHYLACTIC SHOCK (Anaphylaxis Shock) had resolved, MUSCLE TWITCHING (Muscles started twitching/legs started twitching) had not resolved. At the time of the report, PARAESTHESIA ORAL (Lips started tingling) had not resolved and TREMOR (When the Benadryl wears off I start shaking), HYPOPNOEA (When the Benadryl wears off I have shallow breathing) and THROAT TIGHTNESS (When the Benadryl wears off throat starts tightening) outcome was unknown. Not Provided The action taken with mRNA-1273 (Intramuscular) was unknown. The patient was treated at the closest hospital with epinephrine (epi pen), IV diphenhydramine, and IV Famotidine. The patient was having anaphylaxis shock (confirmed by Emergency Department). She stated epinephrine made her heart beat so fast that it was going to collapse. She was discharged 3 hours later from the hospital with epi pen (emergency use), diphenhydramine(as needed), Famotidine (as needed). Consumer stated that when the Benadryl weaned off she felt tingling of lips, starts shaking, muscles start twitching, throat tightening, and has shallow breathing. Company comment: Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, excluding other etiologies causal relationship cannot be excluded. Anaphylaxis is consistent with the product known safety profile.; Sender's Comments: Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, excluding other etiologies causal relationship cannot be excluded. Anaphylaxis is consistent with the product known safety profile.

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1236114	4/21/2021	GA	67	F	2/20/2021	2/20/2021	Anaphylaxis or anaphylactic shock Treatment: Epinephrine, Benadryl and steroids
1236707	4/21/2021	PA	32	M	4/5/2021	4/5/2021	while in waiting area post vaccination pt started exhibiting sx of anaphylaxis. he was treated by EMTs onsite with Epi and transported to a local healthcare facility.
1236966	4/21/2021	WA	64	F	4/9/2021	4/18/2021	This is probably coincidental but it's a hell of a coincidence. First Pfizer shot on 4/9, on 4/18 I had an anaphylactic shock reaction to eating a banana. I've never had a food allergy in my life. Had all the symptoms of anaphylaxis except for hives and my throat closing up. It was quite scary and very painful. I did not call an ambulance or go to the hospital.
1237146	4/21/2021	NH	24	M	4/21/2021	4/21/2021	Patient developed nausea and dizziness. He then had a witnessed syncopal event. HR was noted to be in the 50s. BP was noted to be 60 systolic initially. He denied any skin issues, mouth swelling, SOB or any other signs to suggest anaphylaxis. After several minutes, patient improved. Repeat BP 100/60, HR 56, SP02 99%. He recovered completely and elected to go home with family. Symptoms likely consistent with a vasovagal response to the injection.

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1237273	4/21/2021		25	M	4/20/2021	4/20/2021	<p>Patient is a 25 year-old Male with past medical history of nothing. Patient presented to the Center vaccination site for their first Pfizer vaccination. Patient received vaccination at 11:02. Approximately 10 minutes after receiving vaccination patient began experiencing Dizziness. Patient did not lose consciousness. Patient did not fall, hit their head or sustain any injuries. On exam patient GENERAL: Does not appear to be in distress, is alert and fully oriented, following commands. RESP: Speaking in full sentences, no cough, no signs of respiratory distress, no audible wheezing SKIN: No visible rash or lesion. SKIN: Positive for: moist. Patient had no urticaria, angioedema, or other signs of severe allergic reaction/anaphylaxis. Patient was brought to vaccination observation area and vitals were as follows Blood pressure 95/59 initial and now 102/64 Heart rate 69 bpm now 80 O2 saturation 100 % on room air Respiratory Rate 12 Patient was placed in supine position and legs were elevated. Patient showed rapid improvement towards complete resolution of symptoms. Patient was able to tolerate p.o. Patient was observed for at least 15 minutes after onset of symptoms. Patient reported significant improvement and was able to ambulate with steady gait. Patient requesting to return home. Patient is well appearing and repeat vital signs at time of discharge were stable.</p>

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1239968	4/21/2021	NY	32	F	4/18/2021	4/19/2021	On Sunday, 04/18, I went and received my second dose of the Pfizer vaccine at 12:30 pm on my left arm. It hurt much sooner than the first, within a couple hours. It hurt worse as well. The next morning was Monday. My arm was super sore. I work from home and went by my normal routine. Oatmeal with raspberries and blueberries. I eat this every day. I started work at 9 AM. Around 9:30 Am or so, I started having sneezing fits. Which I thought was annoying more than anything, but didn't think anything of it, until the fits developed into my hands itching, burning, turning red. I looked at my face and noticed it was red and swelling. I've had skin allergies before, but nothing outside of hives and maybe a little skin swelling. I have an allergy to bees. Worse that ever occurred was hives. This instance did not produce hives but a very beet red rash and swelling. Then very quickly after, my tongue started swelling and my throat started tightening. I called my mother as I noted this was life threatening and went to the ER. I was informed I had experienced anaphylaxis. My heart rate going in to the ER was 166. I have never experienced this in the 32 years I've lived before. I was administered an Epi and steroids. As soon as I realized what it was, even in my panic, I was lucky to make a judgment call to save my life. The doctor said to throw out the berries just in case. The odd thing is, I eat this every day...no issues. I realize it is rare for reactions to be delayed, but was made aware it is possible. I was not stung by anything to make this occur.

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1237969	4/21/2021	MA	33	M	4/21/2021	4/21/2021	PATIENT WAS GIVEN HIS FIRST DOSE OF MODERNA VACCINE ON 4/21/21 AT 11:00AM. NO KNOWN SEVERE ALLERGIES TO MEDICATIONS, OR VACCINES (HAS SEAFOOD ALLERGY BUT NEVER WENT INTO ANAPHYLAXIS). PATIENT STARTED FEELING DIZZY A FEW MINUTES AFTER AND STARTED SWEATING. NO SIGNS OF SWELLING OR REDNESS AROUND THE INJECTION SITE. HAD PATIENT LIE DOWN ON FLOOR WITH FEET ELEVATED. PATIENT'S RECOVERED WITHIN A MINUTE, NO LONGER DIZZY OR SWEATING WITH BLOOD PRESSURE AT 112/76. PATIENT WAS OBSERVED UNTIL 11:30 AM, CONDITION STAYED STABLE, AND THEN LEFT WITH HIS FAMILY MEMBER.
1238773	4/21/2021	CA	48	F	12/29/2020	12/29/2020	Patient had PM H of anaphylactic reaction to fish with last episode 2 years ago, carries a epipen since haveing 4 prior episodes. Patient presented to ED 20 after COVID 19 Moderna vaccine. Patient given dose and sent to the ED and was evaluated for vaccine reaction. Patient initially had sudden onset of dizziness, lightheadedness and chest tightness and right arm droop. Evaluated for CODE stroke initially but had NIH score of 0 and these initial symptoms resolved. Patient then developed shortness of breath, dyspnea, tachycardia and chest tightness as well as abrupt nausea and wheezing which was more concerning for anaphylaxis. Patient treated with epi, solumedrol, pepcid and benadryl. Patient was admitted from ED to inpatient bed for observation.
1237015	4/21/2021	IL	46	M	4/14/2021	4/19/2021	Started with dizziness then anaphylaxis like symptoms and lymph node symptoms of tingling lockjaw hard to swallow very difficult to breathe a little bit of chest pains, called EMS and paramedics to took blood oxygen levels, blood pressure which were all normal by then the symptoms had started to subside

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1234456	4/20/2021	CA	15	F	4/17/2021	4/17/2021	On 4/17/2021 1630, RN Lead vaccinator was notified by, RN Vaccinator at Community Center that she had vaccinated a client under the age of 16 years old with a Pfizer covid-19 vaccine at approximately 1421 on 4/17/2021. Patient's name is (unlisted). RN went on to share the details of the event as follows: RN delegated the task of verifying the patient's age to her ancillary staff RN explained the procedure to the patient, asked the screening questions, and under aseptic technique administered 0.3 mL of the Pfizer Covid-19 Vaccine (LOT #EW0171) to the patient's left deltoid. Per RN, patient tolerated the vaccine well, patient was negative for s/s of anaphylaxis and denied pain or discomfort. Pt was observed for 15 minutes in the observation area by the EMT's and was ambulated to the car with her mother, as patient was not displaying any signs or symptoms of anaphylaxis/adverse reactions or distress.
1232803	4/20/2021	NJ	31	M	3/27/2021	4/3/2021	Rashes and hives on my hands, then feet then legs exactly 1 week after my vaccination. Itching started on the back of my hands and then progressed to the tops of my feet and rose up my legs, I took 2 Benadryl and went to urgent care. The Benadryl started working within a half hour of taking it. The itching started as o laid in bed where the only food or liquid I consumed before getting out of bed was a bottled water. The doctor stated that I may be allergic to the pba?s in the water bottle. I have never been allergic to this before I was given this vaccine. Intense itching and hives have been occurring ever since that day and without taking Claritin or Benadryl daily the itching and hives takes over my whole body. I fear I could go into anaphylaxis if I do not take this medication. I have cut out several different foods and different liquids including bottled water and have fasted yet still am getting a allergic reaction. I saw my family dr and he said it?s likely due to the Johnson and Johnson covid 19 vaccine and I believe that to be true. Other symptoms include facial flushing and upset stomach

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1235173	4/20/2021	LA	39	F	4/14/2021	4/14/2021	Got vaccine and less than an hour later when driving down the road I had this strange sensation like something was stuck in my throat. I tried to cough to clear it multiple times and drank water with no result. Of note that I had not and was not eating. I then started to feel like my throat was closing up and it was hard to swallow. I have had anaphylaxis in the past from taking Bactrim, so I was very familiar with the feeling in my throat. I drove straight to the emergency room where I was given IV Benadryl and Pepcid. They watched me for a few hours and sent me home on Benadryl for 5 days. The doctor did say that my cervical lymph nodes were swollen as well. I had COVID in November. I did get pretty sick with the first and second shot. No allergic reaction to first shot. It almost seems as if it put me back into a spiral of fatigue, shortness of breath, headaches and dry cough. I have been struggling with being dizzy, weak and fatigued again since vaccines.
1234215	4/20/2021	NH	41	F	4/20/2021	4/20/2021	Pt developed throat tightness shortly after vaccination. Symptoms were mild. Pt was observed for over a half hour. No signs/symptoms to suggest anaphylaxis. HR 84, BP 110/82, SP02 97%. Pt elected to drive home and did not want to stay for further evaluation or possible treatment.
1233755	4/20/2021	FL	55	M	3/25/2021	3/30/2021	rcvd shot 3/25/2021, symptoms started 2 days after ... two days later swollen neck glands , higher bp than usual, numb face...Mar 30 th 6:am facial numbness, thick tongue, anaphylaxis went to ER, could not breathe , trouble speaking...by the time got to er BP diastolic was about 200. discharged after 4 hrs. Multiple body symptoms since include all over numbness, balance, Balance issues, fatigue, loss of taste, Heat spikes, myoclonus and stare seizures, sense of Euphoria, infusion, many more symptoms, contact me
1232870	4/20/2021	NH	48	F	4/20/2021	4/20/2021	Pt developed nausea, and dizziness shortly after injection. She was noted to be pale and diaphoretic. She denied any other symptoms. Initial BP 60/40, HR 65, SP02: 99%. Pt improved over the course of 20-30 minutes. Repeat BP 100/80. No signs/symptoms to suggest anaphylaxis. Her symptoms completely resolved and she elected to drive home.

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1232827	4/20/2021	NH	41	F	4/20/2021	4/20/2021	Pt developed lightheadedness, and diaphoresis shortly after vaccination. She has a history of similar reactions with injections in the past. HR72, BP 110/80, SP02: 98%. Pt improved without intervention. No signs to suggest anaphylaxis. Pt elected to drive home.
1232744	4/20/2021	IN	39	F	4/20/2021	4/20/2021	Patient given Moderna vaccine at 4:40pm in L deltoid. Pt c/o tightness in chest, mouth, and throat at 5:00pm. V/S 164/98, 76, 16, o2 93%. O2 applied at 2L per NC. Patient developing rash on neck and chest with dry cough present. Patient has hx of anaphylaxis x2. Patient given 0.5mg Epinephrine IM in the R deltoid. V/S at 5:10 158/86, 76, 16, O2 97%. Ems called. Patient transported to hospital via EMS at 5:23 pm.
1232619	4/20/2021	WA	61	F	3/28/2021	4/3/2021	Six days after my 2nd vaccine I had an anaphylaxis reaction. Out of the blue while I was driving my face started to burn like acid was rubbed on it. It got really hot and turned very bright red. Then my lips began to feel like they had been sunburned badly. Then my forearms both started burning and also turned bright red. I was very anxious. Had two bouts of diarrhea. All this occurred within about a 20 minute time-frame. I chewed up 4 children's Benadryl (50mg) and the redness, burning and anxiousness subsided mostly. My heart rate was still over 100 bpm even after 6 hours. (Usually my HR is 68-70 bpm). I slept for 12 hours and the next day seemed fine. This has occurred two more times since that first time. The 2nd reaction being 5 days after that first one and the 3rd reaction being 5 days after that. Same reaction, same treatment and same outcome.

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1232481	4/20/2021	GA	35	F	4/11/2021	4/11/2021	I recieved the vaccine on 04/11/2021 at Pharmcy in the left arm and started having numbness/tingling in my extremities 72 hours later. I had fever chills and aches within the first 24 hours after the vaccine. The body aches were there till Thursday. Once the body aches started subsiding, I felt the numbness and tingling in the legs on Thursday. Then it spread to my arms. Stays in the legs. Then I started feeling in back of arms and upper back. Certain things make it worse, laying and sitting is worse. Standing helps it. I have no swelling. I have never had a reaction before to a vaccine. No problems ambulating, no breathing problems, no wheezing. I would also like a refill of my headache medication and inhaler today. The patient is a 35 year old female who presents with a complaint of COVID vaccine reaction. COVID Janssen J&J vaccine recieved on 04/11/2021 at Pharmacy, IM in left deltoid. Several hours later I had fever/chills/body aches/ racing heart which lasted 24 hours. The body aches lasted for 72 hours. I began noticing numbness and tingling in my extremities as well as in my upper back. The numbness and tingling worsens when I sit and lay down. No bowel/ bladder problems. I also have Raynaud's and I do not know if that ties in to my symptoms at all. My nipples have also been abnormally hard and sensitive. Note: hx of raynauds denies cp/sob/rash/abdominal pain/n/v/bowel or bladder incontinence/seziures/syncope. symptoms are constant. no fam hx of neurological conditions. no injury and no fall. able to walk okay. no muscle weakness. no rashes. pt denies anaphylaxis

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1232329	4/20/2021		45	F	3/17/2021	3/17/2021	~~Pt received vaccine at 11:57 - pt started to c/o tongue felt metallic taste and felt numb at 12:06. Pt c/o slight sweating. Pt did not eat breakfast and states this has not happened to him before. Pt denies cp, sob, tongue swelling, trouble swallowing, dizziness. Pt requesting some water. Initial vitals 142/76 99% RA. Hr 76. RR 20. 12:24 - pt still c/o sweating, funny taste in Mouth. Pt repeat vitals 142/82 100% RA HR 85. RR 20. Feel pt needs further evaluation. No rash, cp, sob, trouble swallowing. Pt still diaphoretic. Note from ED: 46yoM with possible allergic reaction after Moderna vaccine. VS wnl, OP exam wnl, no signs of anaphylaxis or airway compromise. Monitored here in the ED and did well with symptom resolution. Advised on current CDC recommendations to avoid 2nd injection, as well as potential for rebound allergic reaction, with good return to ED instructions. Pt indicated understanding. No evidence of anaphylaxis or airway compromise. Discussed rebound potential; feel home observation reasonable. Instructed on antigen avoidance. ~~
1232240	4/20/2021	GA	64	M	4/20/2021	4/20/2021	Anaphylaxis (SOB, throat closing, wheezing, tachycardia, change in mentation over 10 minutes) Given Epi-Pen and Benadryl, Transported via EMT to ER
1231718	4/20/2021	KS	31	F	4/19/2021	4/19/2021	Site: Pain at Injection Site-Mild, Site: Redness at Injection Site-Mild, Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Headache-Severe, Systemic: Hyperventilation-Severe, Systemic: Seizure-Medium, Systemic: Shakiness-Severe, Additional Details: Patient was given Moderna Covid Vaccine in Right Deltoid at 10:50. About 30 seconds later patient slid down from sitting position and was shaking uncontrollably and reported difficulty in breathing. Patient was given Epi 0.3mg pen IM in right outer thigh and 911 was called.

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1232837	4/20/2021	OK	53	M	4/20/2021	4/20/2021	Code Cowboy called around 1610. Went to the parking lot to assess the patient after having a request for help as physician on call for code cowboy was assisting another patient. Patient wheeled inside to collect vitals. He reported that he was having chest tightness and some shortness of breath. Has never had an allergic reaction to anything but latex, and it was not anaphylaxis. Denied swelling of his lips, tongue, throat and trouble swallowing. Denied rash or itching. Patient's BP was 151/75, HR 100. Physical exam: mildly tachycardic, no murmurs. Lungs, CTA bilaterally. No swelling of lips, tongue, face noted. No rashes. EMSA arrived shortly after vitals were taken and he was assessed. He refused to go to the ER via ambulance, but agreed to let his wife take him for evaluation. No medications were given before he left. No major progression of symptoms before he left with wife in car.
1228787	4/19/2021		20	F	4/9/2021	4/9/2021	Rash - both arms, redness to cheeks, history a anaphylaxis. Complaint of difficulty breathing. Hydrocortisone cream applied bilateral arms. Patient took Benadryl 50mg tablet. Onset of symptoms was observed within 60 minutes of vaccine injection. Symptoms improved within 45 minutes.
1231102	4/19/2021	GA	40	F	4/14/2021	4/14/2021	Feels "woozy" and light headed, shaky per patient. VS stable. Unable to obtain Pulse Ox due to patient's nail polish. Observed until 1718pm and wants to go home after something to drink. VS continue stable. No symptoms of anaphylaxis.

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1229958	4/19/2021	ID	60	M	4/16/2021	4/16/2021	Face and arms visibly flushed. HX hypertension. No difficulty breathing or tightness in throat. Vital Signs: BP 150/80 HR 72 O2Sat 97% Skin Signs: Warm and dry, Other - Very red and flushed warm to touch Circulation: Cap refill <2sec Respiratory: Breath sound clear bilaterally No increased res. effort Initial treatment: Continue observation. Patient observed to be flushed prior to vaccination. HX of rosacea. Patient states HX of sun exposure prior to clinic. 11:13 AM Vital Signs: BP 138/74 HR 76 Resp. 16-18 O2Sat 95% Possible irregular HR noted while getting BP Skin Signs: Other - Flushed A/Ox4 Circulation: Cap refill >2sec Respiratory: Breath sound clear bilaterally Follow up Treatment: Observation. No increased res. effort. Neg S/S anaphylaxis. 11:19 AM Vital Signs: BP 122/80 HR 78 Resp 14-16 O2Sat: 95% Skin Signs: Warm and dry, Other - Flushed A/Ox4 Circulation: Cap refill <2sec Respiratory: Breath sound clear bilaterally Notes: Vitals at 11:32 AM BP 130/72 HR 81 O2Sat 94% Lung sounds clear bilaterally Resp 16 Patient states no dyspnea upon sitting. Cap refill <1sec No nausea Patient instructed to update son. Released home by self.
1229945	4/19/2021	NJ	38	F	4/10/2021	4/13/2021	3 days after receiving my 2nd Moderna vaccine I went into anaphylaxis. My throat felt like it was closing, tongue swelled up and could barely speak. My hands swelled and very extremely itchy. I developed hives all over my upper body including my head. This has Never happened before.
1229687	4/19/2021	MN	64	M	4/19/2021	4/19/2021	24 minutes after vaccination the patient began to "feel tingly all over". Patient's vital signs remained stable throughout the episode. Patient insisted upon taking his own 50 mg of Benadryl. EMS called patient wished to be transferred to the Emergency Room. The patient has a history of several episodes of anaphylaxis with varying medications.
1229433	4/19/2021	OH	18	F	4/17/2021	4/17/2021	Patient had anaphylaxis reaction. Tongue swelling, SOB, rash, Given benadryl. Taken to ED for observation. Epi pen, benadryl, pepcid, and solumedrol administered.

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1228505	4/19/2021	IN	40	M	4/16/2021	4/16/2021	ER Nursing Intervention/Reassessment [Charted Location: EMR-Emergency Rm Service] [Authored: 04/16/2021 15:18]- for Visit: 004092726008, Complete, Revised, Signed in Full, General IV: IV Intervention: ? IV IV INTERVENTION/REASSESSMENT ? IV 1 Date 04/16/2021 ? IV 1 Time 14:25 ? IV IV 1 ? IV 1 Size 20G ? IV 1 Type peripheral iv ? IV 1 Inserted By inserted per RN ? IV 1 Side right ? IV 1 Right antecubital ? IV 1 Actions flushes easily labs obtained ? IV 1 Dressing needleless valve placed, catheter secured, transparent dressing applied with date/time/initials transparent semi-permeable dressing applied ? IV 1 Response pt. tolerated well pt instructed to call RN for problems ? IV 1 Total Attempts 1 COVID Screening Questions: COVID Screening Questions: ? Have you had a COVID-19 vaccine in the last 7 days? Yes (1) ? Was this COVID-19 vaccine your: First dose (1) Assessment Date / Time: ? Date/Time 04/16/2021 14:25 History of Present Illness: Chief Complaint: ? History of Present Illness allergic reaction ? Onset Time/Last Seen Normal 04/16/2021 13:15 Skin Assessment: Skin Assessment: ? Skin cool diaphoretic ? Mucous Membranes moist intact COVID Screening Questions: COVID Screening Questions: ? Have you had a COVID-19 vaccine in the last 7 days? Yes ? Was this COVID-19 vaccine your: First dose ER Triage Note: ? Triage Date/Time 04/16/2021 14:21 ? Triage Chief Complaint medical, Allergic Reaction to Covid Vaccine ? Additional Triage Comments Pt states he went home after receiving his Covid Vaccine (Pfizer) when he noticed he was itching on his back. Pt arrived to ED with generalized erythema, skin cool and clammy, and wheezing. Pt denies contact with chemicals or anything else. ? Have you been sexually assaulted? no ? Stroke Screening no ? Pregnant/Could be pregnant not applicable ? LMP not applicable ? Tetanus <5 years ago ? Immunization up to date yes ? CDC Early Warning Symptoms None Identified ? CDC Precautions standard precautions mask applied Infectious Disease: Infectious Disease: ? Have you traveled recently? No ? Do you have any of the following symptoms? none Mode of Arrival: ? Mode of Arrival private auto Height/Length - Weight for Calculation: Weight for Med Calculation: ? Height (ft) 6 Feet ? Height (remainder in inches) 0 Inch ? Height (cm) 182.8 cm ? Body Measurements stated ? Weight for

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Calculation (kg) 108 Kg ? Weight Method stated ? BSA (m2) 2.29 M2 ? BMI (kg/m2) 32.3 kg/m2 Triage Vital Signs: ? Temp (degrees F) 97.1 degrees F ? Temp (degrees C) 36.1 degrees C ? Method skin/temporal ? Heart Rate (beats/min) 118 bpm ? Respiration (breaths/min) 18 ? BP Systolic (mm Hg) 156 mm Hg ? BP Diastolic (mm Hg) 103 mm Hg ? Sitting BP right upper arm ? SpO2 Patient On room air ? SpO2 (%) 98 % Treatment Prior to Arrival: ? Treatment Prior to Arrival none Allergies: Allergies/Intolerances: Allergies: ?? Pfizer-BioNTech COVID-19 Vaccine: Anaphylaxis ?? tramadol: Hives Home Medications - OMR: Home Medications - OMR: * Patient Currently Takes Medications as of 04/16/2021 15:11 documented in Structured Notes ?? losartan 50 mg oral tablet: None, 1 tab(s) orally once a day, Hx, Status: Active, Quantity: 0, Refills: None, Last Dose Taken: ?? Albuterol (Eqv-ProAir HFA) 90 mcg/inh inhalation aerosol: None, 2 puff(s) inhaled every 6 hours, Hx, Status: Active, Quantity: 0, Refills: None, Last Dose Taken: Patient Seen Time: ? Patient Seen Time 04/16/2021 14:21 ? LMP not applicable ? Tetanus <5 years ago ? Immunization up to date yes Triage Vital Signs: ? Temp (degrees F) 97.1 degrees F ? Temp (degrees C) 36.1 degrees C ? Method skin/temporal ? Heart Rate (beats/min) 118 bpm ? Respiration (breaths/min) 18 ? BP Systolic (mm Hg) 156 mm Hg ? BP Diastolic (mm Hg) 103 mm Hg ? Sitting BP right upper arm ? SpO2 Patient On Pulseox: 98 % on RA @ bedside monitor -- normal ? SpO2 (%) 98 % ? Acuity Level 3 Preferred Pain Scale: Preferred Pain Scale Numeric Pain Scale@ Numeric Pain Score - Rest@ 0 - No Pain Numeric Pain Score - Activity@ 0 - No Pain Treatment Prior to Arrival: ? Treatment Prior to Arrival none Nursing Documentation Review: ? Triage Review I have reviewed the above Vital Signs, Nursing Documentation and Triage Assessment. Arrived From: ? Arrived From home home after leaving vaccination clinic HPI: ? HPI CC: rash/itching HPI: history from patient He describes Covid just after receiving the Pfizer vaccine, his initial dose. By the time that he returned home he had opened up a soft drink was having some slight cough, trouble swallowing and had sensation of itching on his back. He asked his mother to check his back and it was discovered that he was starting to have rash over his

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body. This seemed to be persistent and he returned to ER for further evaluation/treatment. He has not had reaction to vaccination in the past. He does have allergy to tramadol. He denies having any allergy to soap, detergent, or other chemicals. He denies having exposure to any chemical, fume, dust, plant material after receiving the vaccination. He denies having any new foods or drinks recently. He is not having any nausea or vomiting. He has felt somewhat sweaty. Allergy: tramadol H/O LE muscle weakness/atrophy, COPD ROS Const: No fever, chills, sweats. No unusual weakness (he does note "my leg is atrophying" when he is speaking about his LLE) HEENT: No runny nose, congestion, ear ache. Perhaps some odd sensation in the throat due to swollen uvula. CV: No chest pain, palpitations. No unusual shortness of breath. No edema to the ankles / legs. No pain with breathing. Abdom: No nausea, vomiting, diarrhea, or constipation. No abdominal pain. Lymph: No swelling to glands. Physical Exam: ? Physical Exam A&O, nontoxic. Pleasant. No pain distress. Mild physiologic distress. Appears to be overweight adult with component of chronic illness and with acute allergic reaction/process. Eyes: EOMI, nonicteric, conjunctiva clear. Throat: Moist mucous membranes. Symmetric rise of palate. No pharynx erythema. Tonsils normal size and without erythema or exudate. His uvula is moderately edematous and elongated. He is managing his secretions well. There is no angioedema of the tongue, soft palate, lips. No stridor. No blood in the oropharynx. No rhinitis/runny nose. Neck: supple, normal ROM, nontender. trachea midline. No cervical or supraclavicular lymphadenopathy. Thyroid nontender and normal size. Back: No pain on percussion. No muscle spasm. Nontender palpation. No kyphosis. Lungs: fair to good air movement with quiet, fine primarily inspiratory wheezes in the mid to lower lung fields. No effort, no rales, crackles, rhonchi. Normal resonance on percussion. Cough clear. Cardiac: borderline tachy RRR S1, S2, without murmur or rub. Posterior tibial, Pedal pulses 2/4 bilaterally. No ankle or pretibial edema. Skin: cool & dry extremities. cool & moist (not diaphoretic) back skin. Normal turgor. He does have confluent macular rash to the neck, (somewhat on face), arms, back/chest/abdomen. Some mild hyperemia to the legs/ankles. No urticaria. The right

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deltoid injection site is involved with the hyperemia/macular rash but no urticaria at this location right now Abdom: Bowel sounds present x 4 Quadrants. Normal tympany to percussion. Soft. Non-distended. Nontender. Nonsurgical. Good muscle tone and moves all extremities. He notes he has his chronic weakness in his left lower extremity. Medical Decision Making: ? Discussed with another healthcare provider Discussed case with another healthcare provider ? Consultation Consultation 1, Consultation 2 ? Consultation 1 04/16/2021 15:54 ? Consultation 1 Comments discussed with RPh. He will come to ER to obtain additional information from patient. This is the hospital's first presumptive Pfizer vaccine reaction. ? Consultation 2 04/16/2021 15:41 ? Consultation 2 Comments discussed with Dr. we discuss presentation. he agrees pt will need monitoring with the persisting symptom/findings and the H/O COPD. 1617 Dr has been to ER and completed eval. pt to be placed on 2nd floor med/tele for additional monitoring and treatment. pt did have labs yesterday. ? Decision to Admit Based On 1446 Based on his symptoms and presentation presumptive acute anaphylaxis to component of the Pfizer Covid vaccine. We will begin treatment with 0.3 mg epinephrine IM once as well as dexamethasone, famotidine, diphenhydramine IV. We will continue to monitor with cardiac telemetry and pulse oximetry. He does have slight wheezing but this may be related to his chronic COPD. No respiratory distress at this time, but his symptoms seem to have been mildly progressive over the past hour (per his report). I believe inclusion of the epi to be prudent based on his presentation. Additionally, I will inform the vaccination clinic of this reaction. he agrees pt will benefit from continued monitoring and repeated IV antihistamine and IV steroid treatment. Pt will need IV fluid for hydration as well. Recheck: ? Recheck Recheck 1, Recheck 2, Recheck 3 ? Time 14:55 ? Recheck patient stable patient improving with treatment ? Comments He is improving. His skin is now warm and moist (not sweaty, not diaphoretic). The rash is receding from the arms. Good coloration to the legs/ankles. Back & torso rash starting to recede. no nausea/vomiting. no difficulty breathing. still with fading macular rash on the torso and upper back. Lungs: improved air movement compared to the initial exam, nl

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effort, no rales, crackles, rhonchi. He has lower field (only) quiet fine inspiratory wheezes. Normal resonance on percussion. Cough mildly wheeze @ bases, with improved airflow. Cardiac: borderline tachy RRR S1, S2, without murmur or rub. Posterior tibial, pedal pulses 2/4 bilaterally. No ankle or pretibial edema. ? Time #2 15:05 ? Recheck #2 patient stable patient improving with treatment ? Comments #2 man from pharmacy is here and recognizes patient from the vaccination clinic. Patient rash has faded from his extremities fully and appears to have faded from his abdomen still somewhat at the malar area of the cheeks as well as the neck and torso portion of the chest. His pulse is 98?99 continues to have elevated blood pressure. Pulse oximetry 98-100% on room air, normal. Pharmacist will enter the reaction into the CDC/FDA/Pfizer database. Overall pt notes he feels tired (probably related to hydration & benadryl). He notes he has returned to home about 2 weeks ago after spending some time on the road in mountains playing guitar / touring with a small band , playing music. ? Time #3 15:37 ? Recheck #3 patient stable ? Comments #3 He has been resting. No respiratory distress. His blood pressure and pulse and pulse oximetry are reviewed at bedside and they are nonfocal at this time. Overall he is improving. He notes he still has malaise and feels about the same with itching in his back and the sensation in his throat. When I evaluate his back there is hyperemia/some macular rash that is in approximately the distribution of the trapezius muscle of the back this is where he notes he has the itching. Additionally when I evaluate his throat there is still some presence of uvula edema. There is no other angioedema. Perhaps he does have some mild hyperemia to the uvula and soft palate at this time. He is clinically improving but his symptoms have not resolved fully. Skin warm and dry normal turgor. No diaphoresis Lungs initially some coarseness/mucousy breath sounds to the mid lower fields but this clears after he coughs. Good air exchange at this time. No rales rhonchi wheezes or crackles. Cough initially mucousy then clear. managing secretions well. no stridor. no respiratory distress. Critical Care Times: ? Critical Care Time of minutes excluding, separately billable procedures 35 Disposition Summary: Arrival 04/16/2021 14:21 Disposition to be admitted Disposition Decision

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1228359 4/19/2021 RI

46 F

4/10/2021

4/10/2021

Date/Time 04/16/2021 15:54 Does an Emergency Medical Condition Exist at the time of D/C? yes Condition at Disposition Stable Alert and Oriented Guarded Emergency Diagnosis: ?? History of COPD (Z87.09): Entered Date: 04/16/2021 15:59, ICD-10: Z87.09 ?? Anaphylaxis due to immunization (T80.52XA): Entered Date: 04/16/2021 15:59, ICD-10: T80.52XA ?? Drug reaction, initial encounter (T50.905A): Entered Date: 04/16/2021 15:59, ICD-10: T50.905A PCP Summary: ? PCP , ? Select Follow-up Physician Follow Up Physician #1 Follow Up Physician #2 ? Follow-Up MD ? Group Name Primary Care ? Specialty ? Follow-Up MD ? Fax Number ? Follow Up In 04 days Instructions: ? Other Instructions Return to ER for worsening symptoms or other concerns ? Additional Instructions Patient has had clinical improvement and stabilization although he is not fully resolved of his symptoms. He is placed into the hospital for further evaluation and management under Dr. Note Complete: Note Complete This document is complete. Affix my electronic signature. Last Updated: 04/16/2021 16:19 by (MD) References: 1. Data Referenced From "ER MD Exam and Disposition" 04/04/2021 17:40 2. Data Referenced From "1. Vital Signs - Adult" 04/16/2021 14:30

- 1-2 minutes after the moderna vaccine on 4/10, felt a shock in her head and then her eyes went blurry. Face felt hot. Then it came down to her throat and she felt like there was something big stuck in her throat. It was hard to talk. Husband was there also and noted that Pt had trouble speaking. Felt faint but did not faint. The thing that was stuck in her throat came down to her chest and felt chest tightness. Then a few minutes later, that sensation went away. Ears felt hot and red. - Pt was monitored following vaccination and BP was taken and was 140s (higher than normal). - Pt then decided to go to the ED and be monitored. ED provider thought reaction was due to anxiety as symptoms were not classic for an allergic reaction/anaphylaxis and Pt improved without intervention/symptoms resolved. Pt denies anxiety and feels reaction was an AE.

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1227981	4/19/2021	NJ	61	F	3/27/2021	3/27/2021	anaphylaxis/anaphylactic condition; abnormal heart problems; vocal cord dyskinesia; SOB; extremely red all over body; Abnormal liver enzymes; Hr became Brady with widening if qtinterval; leg cramps; neuro s/s migraine severe; throat closed; Weight gain 15+ lbs on body non pitting edema; non pitting edema; extreme leg pain; breathing problems; This is a spontaneous report from a contactable consumer (patient). A 61-year-old female patient received first dose of bnt162b2 via an unspecified route of administration in right arm on 27Mar2021 16:45 (Lot Number: er8733, expiration date was unknown) as single dose for covid-19 immunisation. Medical history included asthma, brain disorder, arthritis, vertigo. Patient had known allergies. It was unknown if patient had COVID prior vaccination. She was not pregnant at the time of vaccination. Patient did not have other vaccine in four weeks. She used other medications in two weeks. The patient experienced anaphylaxis within 5 minutes went home extreme leg pain. Her throat closed and she had short of breath (SOB). She had extremely red all over body. She went back to emergency department (ED). Electrocardiogram (EKG), X-ray and blood work were done. She had c/o leg cramps. Her weight gain more than 15 lbs on body with non-pitting edema. She received treatment for events. She had abnormal liver enzymes, abnormal heart problems and breathing problems. Anaphylactic condition was to step down was on bipap epi (Epinephrine injection) Benadryl 50 mg every 4 hours and intravenous steroids along with fluids. Renal replacement therapy (RRT) called the next day. Patient didn't remember exact cause. Neuro s/s migraine severe Ajovy taken Uberlvy and not else remembered (as reported). Heart issues maintained and pulmonary showed improvement. Ear, nose, and throat (ENT) consult with scope done showing vocal cord dyskinesia. Heart rate became brady with widening if qt interval. She transferred to telemetry 2 d and echo done. Monitor patient for low heart rate 24 hours. Patient released from hospital on 06Apr2021 evening. At home patient continue to have organs change every 24- 36 hours keeping video monitoring and pictures. All events occurred on 27Mar2021 16:45 and resulted doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization/Prolongation of existing hospitalization

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							(vaccine received during existing hospitalization), Life threatening illness (immediate risk of death from the event). The duration of hospitalization was 6 days. Patient tested COVID-19 via nasal swab on 01Apr2021 with negative result. Benadryl 50 mg she had around the clock, steroids and epi used as treatment. The outcome of all events was not recovered. No follow up attempts are possible. No further information is expected.
1227971	4/19/2021	PA	24	F	4/12/2021	4/12/2021	Anaphylaxis; Lightheaded/Dizziness; Throat Swelling; Scratchy Throat; This is a spontaneous report from a contactable consumer (patient). A 24-year-old female patient (not pregnant) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EP6955), via an unspecified route of administration, administered in left arm on 12Apr2021 at 09:30 (at 24-year-old, not pregnant at the time of vaccination) at single dose for COVID-19 immunisation. Medical history included known allergies: tree nuts. The patient had Covid-19 prior vaccination. The patient's concomitant medications were not reported. No other vaccine was received in four weeks. No other medications were received in two weeks. On 12Apr2021 at 10:00 AM, the patient experienced anaphylaxis; lightheaded/dizziness; scratchy throat; throat swelling. The events resulted in emergency room/department or urgent care, life threatening illness (immediate risk of death from the event). Therapeutic measures were taken as a result of the events included epinephrine and steroids to prevent swelling. The outcome of the events was recovered on an unspecified date in Apr2021. The patient did not have covid test post vaccination.

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1229892	4/19/2021	MD	63	F	3/30/2021	3/30/2021	I'm very worried my reaction could be worse after the 2nd shot-----+++In the past Ive had anaphylaxis to Cat Scan Dye- symptoms were immediate nose, ear blockages, hoarse voice, felt like breathing through a straw, chest tightness. ***on day of 1st shot I waited for 30 mins, felt fine. Within 2hrs of shot, while I was home I experienced throat tickling/itchiness, one side of my nose felt the same, and the other side ear felt stuffy I took a benadryl and used my inhaler, while I have prednisone I didn't think I was suppose to take it after the vaccine, so I did not. The symptoms didn't get worse Spoke with my dr., we did a conference call with cdc, they couldn't tell me to get the 2nd or not, said to contact VAERS
1229275	4/19/2021	CA	45	F	4/19/2021	4/19/2021	Reported raid heartrate 5 minutes after vaccine. Heartrate 132-144 on initial assessment, BP 128/78, RR18, o2 sat 99 on RA. Had patient lie down and heartrate decreased every 5 inutes- 99/84/88/75. BP stable 120's/80's. No signs of anaphylaxis. No CP or SOB. Reports some nervousness with injections and vaccine.

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1224682	4/18/2021	CO	66	F	4/2/2021	4/2/2021	Anaphylaxis; This is a spontaneous report from a contactable consumer (patient). A 66-year-old female patient received first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiration date unspecified), via an unspecified route of administration, administered in left arm on 02Apr2021 09:45 as single dose for COVID-19 immunisation. Medical history included type 2 diabetes, hypothyroidism, and allergy to: shellfish, penicillin, all narcotics, mold, catfish, vaccinium berries, peaches, somegrass and trees. Concomitant medications included levothyroxine sodium (SYNTHROID), cholecalciferol (D3), famotidine (PEPCID AC), biotin, and salbutamol sulfate (VENTOLIN ACCUHALER). On 02Apr2021 10:00, the patient experienced anaphylaxis. Treatment for the event included Ventolin, steroids antihistamines and nebulizer. The event result in Emergency room/department or urgent care. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. Outcome of event was recovering. Information about lot/batch number has been requested.; Sender's Comments: Due to a strong drug-event temporal relationship the company deems there is a reasonable possibility that the reported anaphylaxis is related to BNT162b2.

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1224197	4/18/2021	NJ	68	F	3/29/2021	3/29/2021	feels tired; She did have palpitations overnight that woke her up in her sleep for 15 minutes; head feels tight, like there is a band around it/head feels tight, like there is a band around it; Nausea; severely lightheaded; her limbs felt heavy; her blood pressure went way up and lasted a good 7 hours/blood pressure at this time was elevated to 190/86; it was hard to lift her arms; This is a spontaneous report received from a contactable two nurses (one nurse reported for herself). This 68-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EN6205 and expiration date: 30Jun2021), via an unspecified route of administration right arm on 29Mar2021 at 10:15 as single dose for COVID-19 immunization. Medical history included anaphylaxis (recovering), hypertension ongoing, gastroesophageal reflux disease (GERD), anemia (her hemoglobin dropped to 6.9 and ferritin was low), hiatal hernia surgery (had mesh), a latex allergy (her lips would start swelling) and food allergy (tuna fish). Family history included lung disease (her dad was diagnosed). Concomitant medications included hydrochlorothiazide (HCTZ) 25 mg, daily (been on it for 10 years) taken for high blood pressure from an unspecified start date and ongoing; losartan 100 mg, daily (for about 10 years) taken for hypertension from an unspecified start date and ongoing; iron (Tablet) 65 mg, daily (about 10 years) taken for anaemia, cetirizine hydrochloride (ZYRTEC) taken for an unspecified indication; The patient previously took cefalexin (KEFLEX) and experienced swelling on face and mouth, epipen, acetylsalicylic acid (ASPIRIN) (6 years ago aspirin sensitivity took place) and experienced haematuria, tolectin as nonsteroidal anti-inflammatory drug (NSAIDS) (about 30 years ago (received steroids, breathing treatments and benadryl) and experienced anaphylactic reaction, flu vaccine taken for flu (at 19 years old). The patient got first vaccine on 29Mar2021 and had an event. On the same day, she was severely light headed and her limbs felt heavy and her blood pressure went way up and lasted a good 7 hours. They had her in the emergency room. She did have palpitations overnight that woke her up in her sleep for 15 minutes but she had no chest pain or shortness of breath and then it went away. At first, she didn't feel anything, but then as soon as she got up to go to the sitting area

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where she was supposed to wait for 15 minutes, she became very very light headed, almost like there was a band around your head. there was no dizziness, but she was lightheaded and all four of her limbs felt really heavy, it was hard for her to move her limbs, she experienced nausea while sitting in the waiting area as well. She did not throw up and it started about an hour after the vaccine and describes the nausea as fleeting and states it lasted about a couple of hours, but not as long as the light headedness and heavy limbs. her blood pressure at this time was elevated to 190/86. the doctor there told them to send her to the ER. The reporter stated that the vaccine was given at the hospital, so they just wheeled her to the emergency department within the hospital, the doctor in the emergency room told her they didn't think it was an allergic reaction. after about 6 hours around 1600 her blood pressure finally came down to 141/67. She was discharged from the emergency room around 16:00 on 29Mar2021. At the time of discharge, the heaviness of limbs and light headedness had went away, but when she was walking to get to her car in the parking lot the lightheadedness and heaviness of her limbs returned. it was hard to lift her arms. she went home and went to bed, the lightheadedness and heaviness of her limbs went away after she was able to lay down and rest. Last night around 2:30 or 3:00am she woke up with heart palpitations. Caller states that these palpitations went away after 15 min and that she hasn't had this experience in years since hiatal hernia surgery. she felt much better next day, the only thing she felt today was tightness in her head but not a headache and just felt tired. The outcome of the events severely lightheaded, her limbs felt heavy, her blood pressure went way up and lasted a good 7 hours/blood pressure at this time was elevated to 190/86 and head feels tight, like there is a band around it were recovered in 2021; nausea was recovered on 29Mar2021; palpitations was recovered on 30Mar2021 and other events were unknown. As reported causality : Feeling light headed; Limbs felt really heavy; high blood pressure Related; head feels tight, like there is a band around it; heart palpitations Related. Information on Lot/Batch number was available. Additional information has been requested.; Sender's Comments: Based on the reasonable temporal association, the Company cannot completely exclude the

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possible causality between the reported events and the administration of the suspect COVID19 vaccine, BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

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3/20/2021

3/20/2021

Itching all over, coughing, asthma, anaphylaxis; Itching all over, coughing, asthma, anaphylaxis; Itching all over, coughing, asthma, anaphylaxis; This is a spontaneous report from a contactable consumer (reporting for herself). A 44-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Right on 20Mar2021 (Batch/Lot Number: Ep-7534) as single dose for COVID-19 immunization. Medical history included seasonal allergy, asthma, and known allergies: penicillin. Concomitant medication included fexofenadine hydrochloride (ALLEGRA); montelukast sodium (SINGULAIR); amlodipine. all taken for an unspecified indication, start and stop date were not reported. The patient previously took grastek for immunomodulatory therapy and experienced drug allergy; bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: En-6198) on 27Feb2021 for COVID-19 immunization. On unspecified date the patient experienced itching all over, coughing, asthma, anaphylaxis. The patient received 2 doses of epinephrine, 100 ml benedryl, and h1h2 bloc. The outcome of the events was recovering. The patient was not tested post vaccination and did not has COVID prior to vaccination.

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1224374	4/18/2021	GA		M			dry throat; itching; This is a spontaneous report from a contactable nurse. A 22-year-old male patient received bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced multiple spots where he was itching and reported a "dry throat or something like that." The patient's vital signs did not change and did not have any other anaphylaxis reaction. The outcome was unknown. No follow-up attempts are possible, information about batch number cannot be obtained.

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1224391	4/18/2021	KY	57	M	3/1/2021	3/29/2021	<p>small peripheral right lower lobe pulmonary embolism; anaphylaxis; whole body rash and erythema; whole body rash and erythema; This is a spontaneous report received from a contactable physician. A 57-year-old male patient received BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration on 01Mar2021 (at the age of 57-year-old) as single dose for COVID-19 immunization. Medical history included joint pain and ongoing 45-packs per year smoker. The patient did not have any allergies to medications, food, or other products. Concomitant medications included salbutamol (ALBUTEROL), hydroxyzine (manufacturer unknown) and diclofenac sodium (manufacturer unknown). The patient did not receive any other vaccines within four weeks prior to the vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The physician reported, "patient had anaphylaxis and whole-body rash and erythema on separate hospitalization (I was not involved for this but reviewed photos and this was reportedly attributed to the vaccine; I'm uncertain if that event was reported). On hospitalization, the patient was with small peripheral right lower lobe pulmonary embolism on a CT PE (CT scan for Pulmonary Embolus). Patient is an active smoker. No other obvious cause." As a result of the adverse events (unspecified), the patient was hospitalized for one day. The start date of the events was on 29Mar2021. The patient was treated with apixaban (for pulmonary embolism). The clinical outcome of "anaphylaxis and whole-body rash and erythema" and "small peripheral right lower lobe pulmonary embolism" was resolving. The lot number for the vaccine, BNT162b2, was not provided and will be requested during follow-up.;</p> <p>Sender's Comments: Based on temporal association, a possible contributory role of BNT162B2 cannot be excluded for events pulmonary embolism, anaphylactic reaction and associated generalized rash and generalized erythema. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will</p>

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be promptly notified to Regulatory Authorities, Ethics
Committees and Investigators, as appropriate.

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1224495	4/18/2021	NJ	37	F	3/31/2021	3/31/2021	anaphylactic shock; chest pains; tingling in extremities; shortness of breath/couldn't breath; wheezing; Throat closed; chest tightened; burning in arms that traveled down my arms then into my torso and legs/Scalp and ears also burning/still feeling the burning; Scalp and ears also burning; ears also burning; Itchy throat all days; couldn't breath or talk; This is a spontaneous report from contactable consumers. A 37-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 31Mar2021 13:30 (Lot Number: EW0151) as SINGLE DOSE for COVID-19 immunisation. The patient was not pregnant at time of vaccination. Medical history included fish, tree nuts, peanuts allergy, in-door & outdoor environmental allergies, pet dander allergy, rheumatoid arthritis, asthma, GERD, chronic dry eye and ADHD; all from an unknown date and unknown if ongoing. Concomitant medications included albuterol, lifitegrast (XIIDRA), amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL), prednisone, cetirizine hydrochloride (ZYRTEC) and etanercept (ENBREL); all taken for an unspecified indication, start and stop date were not reported. The facility where the most recent COVID-19 vaccine was administered was in the hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. On 31Mar2021 13:45, the patient began with chest pains, then tingling in extremities, then shortness of breath & wheezing. Suddenly, was in anaphylactic shock. The patient experienced throat closed, chest tightened, couldn't breath or talk. Same symptoms came back on 01Apr2021. The patient went to emergency room/department or urgent care. The patient stated, "I went into anaphylactic shock again and back to hospital. The following day, anaphylaxis re-turned, but no anaphylactic shock. Shortness of breath, burning in arms that traveled down my arms then into my torso and legs. Itchy throat all days. Scalp and ears also burning. Today, on day 4, still feeling the burning and trouble breathing. Every time the Benadryl wears off, it feels like it's still attacking my body". Treatment for the events was

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1224515	4/18/2021			F			<p>received such as 3 epi-pen injections, EKG, IV of Benadryl and IV of steroids. The outcome of the event "burning in arms that traveled down my arms then into my torso and legs/Scalp and ears also burning/still feeling the burning" was unknown and the outcome of the rest of the events was not recovered. The patient was hospitalized due to event anaphylactic shock that was also reported as life threatening.</p> <p>angioedema; This is a spontaneous report from a contactable nurse. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on an unspecified date (batch/Lot number was not reported) as single dose for COVID-19 immunisation. Medical history included anaphylaxis to NSIADs. The patient's concomitant medications were not reported. The patient experienced angioedema after 1st dose of vaccine and an epinephrine (EPIPEN) was administered. She subsequently was tested for a Miralax allergy which was negative. Outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: A causal association between administration of BNT162B2 and the onset of angioedema cannot be excluded, considering the temporal association and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.</p>

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1224647	4/18/2021	TX	39	F	3/19/2021	3/19/2021	Mild anaphylaxis--tongue swelling as well as occlusion of airway; This is a spontaneous report received from a non-contactable other healthcare professional. A 39-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot was unknown due to not available/provided to reporter at the time of report completion) via an unspecified route of administration on 19Mar2021 at age of 39-year-old at single dose for COVID-19 immunisation. Medical history included eczema, known allergies: Food sensitives including gluten and dairy. Rashes with prolonged skin contact with metals or adhesives. The patient's concomitant medications were not reported. No COVID prior vaccination. COVID was not tested post vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not receive any other medications within 2 weeks of vaccination. The patient experienced mild anaphylaxis-tongue swelling as well as occlusion of airway on 19Mar2021. Started about 2min after shot. Occlusion lasted for 7minutes. EMS said vitals were normal. Swollen tongue lasted 24 hours. Have never had an allergic response to any vaccine before. The events were non-serious. No treatment was received for the events. The outcome of anaphylaxis was recovered in 2021, of tongue swelling was recovered on 20Mar2021, of occlusion of airway was recovered on 19Mar2021. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event anaphylaxis cannot be totally excluded.

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1224070	4/18/2021	GA	57	F	3/13/2021	3/13/2021	anaphylaxis, requiring 3 epi pins, emergency transport, ER and inpatient treatment, 2 days hospitalization, pcp followup.; A 57-years-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EL9266), via an unspecified route of administration, administered in Arm Left on 13Mar2021 10:00 as SINGLE DOSE for covid-19 immunisation. Medical history included asthma and thyroid disorder. Concomitant medications included fluticasone; sodium propionate (PROPIONATE) and levothyroxine sodium. The patient previously took alatrofloxacin, pencillin, bactrim, levaquin and sulfa and experienced known allergies. The patient experienced anaphylaxis, requiring 3 epi pins, emergency transport, er and inpatient treatment, 2 days hospitalization, pcp followup on 13Mar2021 10:15. The patient was hospitalized for for 2 days on an unspecified date. Therapeutic measures were taken as a result of anaphylaxis included epinephrine, breathing treatments, speech therapy. Outcome of the event was unknown.

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1224806	4/18/2021	MI	49	F	3/10/2021	3/10/2021	anaphylaxis; sneezing; throat swelling; Continued having breathing difficulty; coughing; This is a spontaneous report from a contactable consumer (patient). A 49-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), (Batch/Lot Number: OCDPH) via an unspecified route of administration, administered in the left arm on 10Mar2021 16:15 (at the age of 49 years-old) as SINGLE DOSE for covid-19 immunisation. Medical history included Crohn's Disease and chronic Migraines. Patient has allergies to medications, food, or other products such as Milk Protein and Compazine. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hasn't been tested for COVID-19. Concomitant medications included midodrine taken for an unspecified indication, start and stop date were not reported; and rizatriptan benzoate (MAXALT) taken for an unspecified indication, start and stop date were not reported. On 10Mar2021 16:30 (as reported), patient was sneezing within 5-10 minutes of receiving dose, had anaphylaxis within 15-20 minutes of receiving dose. She continued having breathing difficulty, sneezing, coughing and throat swelling for 5 days which was treated with Benadryl. Second dose of EpiPen was required 20 hrs. later and continued use of Benadryl, Allegra and inhaler for 4-6 days. Continued issues with over stimulation of allergic reaction to other known allergies continues. The outcome of events was reported as recovered with sequelae. The events required emergency room and physician's office visit. Therapeutic measures taken as a result of the events included EpiPen, Steroid, Benadryl and inhaler (unspecified). The events were assessed as serious, life threatening illness (immediate risk of death from the event). Follow-up attempts are completed. The information on the batch/lot number has already been obtained.

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1224840	4/18/2021	MN	55	M	12/5/2020	3/18/2021	anaphylaxis; This is a spontaneous report from a contactable healthcare professional (patient). A 55-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiration date unspecified), via an unspecified route of administration, administered in left arm on 05Dec2020 11:00 as single dose for COVID-19 immunisation; and amoxicillin, clavulanic acid (AUGMENTIN), via an unspecified route of administration from 18Mar2021 at unspecified dose for an unspecified indication. Medical history included myocardial infarction (MI), coronary artery bypass grafting (CABG), AV Nodal block, and pacemaker. The patient's concomitant medications were not reported. On 18Mar2021 20:00, the patient experienced anaphylaxis. The patient was hospitalized for 2 days on an unspecified date due to the event. The patient reported that he was on augmentin on and off for years and when he got his first vaccine. And on 18Mar2021, he began augmentin again and had anaphylaxis requiring hospitalization. The patient was asking if this was related to the vaccine, but seems to be a possibility. The event resulted in emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event). The event was treated with epinephrine, steroids, benadryl, and fluids. There was no other vaccine in 4 weeks and patient had not had Covid prior vaccination and was not Covid tested post vaccination. The action taken in response to the event for amoxicillin, clavulanic acid was unknown. Outcome of event was recovered in 2021. Information on batch/lot number was requested.; Sender's Comments: Based on available information, the event anaphylaxis is assessed as unrelated to BNT162B2. The event occurred more than 3 months after the administration of vaccine and can be attributed to augmentin based on provided information, including close temporal relationship and positive rechallenge.

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1226241	4/18/2021	CT	26	M	4/18/2021	4/18/2021	Patient received dose 1 of Moderna COVID-19 vaccine. Approximately 5-10 minutes after administration, the patient's mother alerted me that the patient was feeling faint and sweaty. I came to check on the patient. He appeared pale and diaphoretic. Patient said his vision was narrowing and he subsequently lost consciousness for approximately 10-20 seconds. I checked the patient's blood pressure and initial result was 88/64. Upon regaining consciousness, patient reported immediately feeling better. His blood pressure was still low at 94/70. He remained seated and drank some cold water and a cool compress was applied to his forehead. I questioned the patient to determine if he was experiencing any other symptoms that may indicate anaphylaxis (skin itchiness, tight throat, stomach upset) and he denied any other symptoms. I continued to monitor the patient for approximately 30 minutes. During monitoring, the patient told me he is nervous of needles, and has fainted trying to give blood in the past. After 30 minutes of monitoring, diaphoresis had resolved, color returned to patient's face, blood pressure recheck was 116/84, and patient self-reported feeling fine. He was escorted home by his mother.

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1226328	4/18/2021	CA	26	F	4/17/2021	4/17/2021	Received the 1st COVID vaccine Pfizer EW0171 Expiration date 04/17/21 at 5:51pm. Client reported to EMT that she was experiencing "pins and needles sensation throughout her entire body" at 12:43pm. RN responded. Client sitting in chair complaining of "pins and needles sensation in her legs and arms". Client denies experiencing itchiness, shortness of breath, flushing of face, head, palms, hives, pruritus of legs/hand/arms/or palms, urticaria, dizziness, GI symptoms, swelling, or chest pain at this time. Client reports she began to experience the pins and needles sensation about 1 minutes after receiving the vaccine, but decided not to say anything during her 30 min observation period until 2 minutes prior to her 30 min observation period ending. She reports experiencing a non-radiating left sided chest tightness which lasted one minute which occurred a few minutes after receiving the vaccine. Client reports medical history Raynaud's Syndrome. Client reports receiving approval from PCP to receive this vaccine. Client reports history of intermittent chest pains/tightness which has been evaluated multiple times. Client report this incident of chest pain felt similar. Client notes she was prescribed Aspirin 81 mg by her Rheumatologist and she usually takes the Aspirin when she has chest pains or arm pains. Per Client, she has experienced pins and needles sensation in the past. She reports the last time she experienced a pins and needles sensation was after drinking. She denies similar incident with other vaccines. Client was placed in semi-fowlers position, offered water. Client is a/o x4. RN offered client activation of 911. Client denied. RN gave pt strong recommendation for activation of 911 or further evaluation given symptoms reported. Client verbalized understanding and reported she does not want activation of 911. Client was observed for an additional 45 minutes. VS at 1244 BP 11/78 HR 82 RR18, VS at 1255 BP 114/76 HR 76 RR 14, VS at 1303 116/74 HR 72 RR 14, VS 1315 BP 114/72 HR 76 RR 15, VS 1335 BP 116/76 HR 74 RR 14. Symptoms resolved at 1328. Client notes Fiance is driving client home. At this time, RN offered EMS activation for transport to the hospital x2. Client denied. bRN provided client with ER precautions. RN walked client to Fiance's car. Client walking with steady gait. No additional concerns reported. RN provided client with education on F/U with PCP regarding current

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1226771	4/18/2021	TX	41	M	4/16/2021	4/16/2021	<p>situation provided, importance of reporting symptoms as soon as they occur, and s/s concerning symptoms of anaphylaxis and allergic reaction. Client verbalized understanding. No further RN interventions required at this time. RN</p> <p>Anaphylaxis treated with EpiPen, Steroids & Benadryl. It began as a hives on 04/16 around 8 PM, the morning of 04/17 I had swelling in my eyes, lips and tongue, Along with difficulty swallowing. I was treated with epinephrine on 04/17 around 1 pm and then again on 0/18 around 11 am.</p>

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1224599	4/18/2021	CO		F	3/20/2021		breathing/unresponsive; seizures; blood sugar was 35/Blood sugar dropped into the 60's again; This is a spontaneous report from a contactable reporter. A 75-year-old female patient (reporter's mother) received second dose of bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 20Mar2021 at single dose for covid-19 immunisation. Medical history included parkinson's disease from 2018 to an unknown date, the progressive type, covid-19 from Nov2020 to an unknown date (She had mild case of covid in November), she was not symptomatic, rheumatoid arthritis from 2018 to an unknown date, Heart failure from 2018 to an unknown date(which she was diagnosed in 2018 with and was being managed appropriately), spinal operation from an unknown date and unknown if ongoing PRESS (Posterior reversible encephalopathy syndrome) Complication, posterior reversible encephalopathy syndrome from an unknown date and unknown if ongoing (Complication after Back surgery). The patient's concomitant medications were not reported. The patient had the first dose of dose of bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 VACCINE) on 27Feb2021 for covid-19 immunisation. The patient experienced breathing/unresponsive but breathing on her bi-pap (hospitalization) on an unspecified date with outcome of unknown, seizures (hospitalization) on an unspecified date with outcome of recovered, blood sugar was 35/blood sugar dropped into the 60's again, blood sugar low (hospitalization) on an unspecified date with outcome of unknown. The patient underwent lab tests and procedures which included lumbar puncture: proteins and white blood cells on unknown date, Presence of proteins and white blood cells, magnetic resonance imaging(MRI): something that happened with brain on unknown date, assault from something that happened with brain, white blood cell count: nothing crazy on unknown date. Therapeutic measures were taken as a result of seizures, blood sugar was 35/blood sugar dropped into the 60's again. The clinical course was reported as follows: She states, "Her mother was in a rehab facility up until the 26Mar2021, the CNA came in at noon and her mom wanted to keep sleeping. Thursday afternoon was the last time she got to talk to her. PT/OT came in at noon on Friday - found to be breathing/unresponsive. blood sugar

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was 35, gave her glucose, came up to 111. Still not responsive but breathing. Sent her to ER, she was breathing but still not responsive, then started she started having seizures. Blood sugar dropped into the 60's again, having seizures from Friday until Monday. managed it with Keppra and another seizure medicine and now she is in ICU. Her mother is 75 years old with degenerative Parkinson's Disease, wheelchair bound, and a history of PRES (Posterior reversible encephalopathy syndrome). She was about to be discharged but then all of this happened. The only thing that was really different is the vaccine that she received. She had mild case of covid in November, she was not symptomatic. Waited 3 months to get the covid vaccine after she had covid. The caller states that her mother received the first dose of the Pfizer COVID-19 vaccine on 27Feb2021 and the second dose on 20Mar2021. The caller would like to know if there have been any reports of low blood sugar associated with receiving the Pfizer COVID-19 vaccine. The caller wants to know if anyone has reported seizures as a side effect from receiving the Pfizer COVID-19 vaccine. Responded per page 23 of the attached EUA Prescribing Information LAB-1457-6.0 Revised: 25Feb2021: "Throughout the safety follow-up period to date, Bell's palsy (facial paralysis) was reported by four participants in the Pfizer-BioNTech COVID-19 Vaccine group. Onset of facial paralysis was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of Bell's palsy were reported in the placebo group. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic or neuroinflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine. 6.2 Post Authorization Experience: The following adverse reactions have been identified during post authorization use of Pfizer-BioNTech COVID-19 Vaccine. Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. Immune System Disorders: severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria,

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angioedema)". The caller has her best friend on the line with her in case the caller forgets something. The caller's is calling on behalf of her mother who had both doses of the covid vaccine. The patient is currently in the Intensive Care Unit. The patient was supposed to go home from a rehabilitation facility on 27Mar2021 and staff found the patient on 26Feb2021 unresponsive but breathing on her bi-pap. Prior to the patient being found like this she was tired at noon and asked the staff to hold her lunch for her because she was tired and wanted to lay down because she had been up late the previous night. When physical therapy and occupational therapy came in a couple of hours later to do therapy they found the patient unresponsive and the patient's blood sugar was 35 so they gave her glucose and the blood sugar came up to 111. Emergency medical services came and took the patient to the emergency room and then she was put in the Intensive Care Unit, this was all within 30 minutes. The glucose dropped one more time and she started having seizures. The medical staff stabilized the patient with Keppra and another seizure medicine that starts with a V on a drip. The patient has been off her sedatives since Tuesday and she has eye movement under the eyes, she withdraws from pain, and when (name withheld) was talking to the patient on speakerphone the patient moved her head towards the phone. The caller mentions that the patient was not protecting her airway when the emergency medical service showed up and so the staff placed a king airway and then the patient moved to a normal ventilator. Wednesday the patient was being weaned on the ventilator and was able to breathe on her own for 7 hours. The caller was only able to breathe on her own on the ventilator for 2 hours yesterday, split up into 2 different trials. The medical team is pressuring the caller talking about tracheostomy and peg tubes and the medical staff wants to talk about that next week if the patient is not coming around. Investigations: MRI showed basically an assault from something that happened with the brain from having a low blood sugar. The patient has no history with diabetes or low blood sugars. Maybe the patient had a seizure prior? The patient had signs of infections, her white blood cell count is nothing crazy. The patient's lumbar puncture showed proteins and white blood cells present. The caller is trying to figure out what may have caused this incident. The patient had 4 strokes

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on her left side and has come back from that and has been driving and fine after. The patient's outpatient neuro person said it is from the seizures. The caller is trying to rule out if there is anything weird with this vaccine that may have caused this or been reported? PRESS is a rare complication after back surgery and the patient had that. If something is super weird and rare then the patient usually has it, she usually gets weird things. Is this related to the vaccine? The caller knows it may not be likely but it was the only thing she hadn't looked into yet. Information on the lot/batch number has been requested.

PATIENT STARTED OUT BEING NERVOUS ABOUT THE VACCINE. I CALMED HER DOWN AND ADMINISTERED VACCINE. I INFORMED PATIENT TO WAIT FOR 15 MIN. I CHECKED ON HER IN A FEW MINUTES AND SHE SAID SHE HAD NAUSEA. I GAVE HER A PLASTIC BAG TO BARF IN IF NEEDED AND I RAN TO THE FRONT OF STORE TO GET A BOTTLE OF WATER. MANAGER SENT ME TO BREAK ROOM TO GRAB A BOTTLE OF WATER. AS I WAS RUNNING BACK, I OBSERVED PATIENT PASSED OUT ON THE FLOOR WITH BLOOD AROUND, NOT RESPONDING. I CHECKED PULSE (LOW) AND ASSUMED SHE HAD AN ANAPHYLAXIS REACTION TO THE VACCINE, SO I ADMINISTERED EPIPEN 0.3 MG AND PATIENT WOK UP. SHE HAD BLOOD NEAR HER MOUTH AND BLOOD ON THE FLOOR. WE CALLED 911 AND THEY ARRIVED WITHIN MINUTES AND TOOK HER IN THE AMBULANCE. I HAVE NO FURTHER INFORMATION ON THE PATIENT.

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1223586	4/17/2021	CA	54	F	4/17/2021	4/17/2021	<p>Patient presents following administration of the second dose of Moderna COVID19 vaccine in the left deltoid. Patient stated that 20 minutes following administration of the vaccine, the patient started to experience an itching sensation in her left shoulder, neck, and right shoulder. She denies decrease in muscle strength or difficulty swallowing. She relates that a similar experience also happened following administration of the first dose of Moderna vaccine. She related that it lasted for about 2 hours and went away without intervention. She did not seek medical attention. She denies allergies to medication, vaccines, and food. She denies a past medical history. She does not take medication on a regular basis. She denies chest pain, difficulty breathing, swelling of the face/lips/tongue/throat, skin rash/itching, cramping abdominal pain, nausea, and vomiting. Exam (update as needed): GEN: Alert and oriented x 4, NAD. HEAD: NCAT EYES: PERRL, EOMI ENT: Ears normal, Nose normal, OP normal, no evidence of angioedema NECK: Supple, without LAD. CV: RRR, no m/r/g PULM: Clear to auscultation bilaterally, no accessory muscle use ABD: Soft, no tenderness. SKIN: No rashes, skin warm and dry. No erythema or edema of the injection site. MSK: FROM, MS 5/5 NEURO: Alert and oriented x 4, CN 2-12 grossly intact, no ataxia, gait steady Clinical Impression/Field Tx: Paresthesias related to vaccination. No acute skin manifestations or anaphylactic manifestations that require emergent intervention. Vitals signs stable. Symptoms are stable. Patient was driven to the site by significant other and stated they would take PO Benadryl once they arrive at home. They do not intend to operate heavy machinery for the remainder of the day. Further instructed patient about what vaccine side effects to expect following second dose administration and appropriate interventions/at home care. Instructed patient to consult their PCP regarding the post-vaccination reaction. Patient instructed to go to emergency department should they develop chest pain, difficulty breathing, swelling of the face/lips/mouth/tongue/throat, or cramping abdominal pain with nausea/vomiting, as these are signs of possible anaphylaxis that requires immediate intervention. Medications administered: None Disposition: Home</p>

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1223263	4/17/2021	CA	57	F	4/17/2021	4/17/2021	At 0902, RRT activated when client (57 y/o F) called recovery nurse c/o feeling itchiness all over her body, and she started turning red all throughout her upper extremities including face. Teary eyed and redness in eyes noted. Vaccinated at 0839 on the L arm. Has had severe anaphylaxis in the past for PCN. BP ? 140/80, HR ? 82, RR ? 22, Pain ? 0/0. Head to toe assessment completed. No PMH. Did not take any medications today. During monitoring period, client?s condition improved. Stated ?feeling much better? after 5 minutes, redness and tearing of eyes subsided. At the end of observation period, client was not experiencing what was experienced initially. Client remained in the post-vaccination area an extra 15 minutes per client?s request. She left the vaccination clinic at 0930 ambulatory, in stable condition.
1223090	4/17/2021	RI	57	F	4/17/2021	4/17/2021	Pt presented to EMS with a complaint of dizziness and heart palpitations. Pt states she has no past medical and no known drug allergies. She was taken into the hallway where she stated she was already feeling better. She was given water, and vitals were obtained. First set: BP136/78 right arm HR100 SPO2-100% Second set: BP102/79 left arm HR96 SPO2-100% Pt is boreline tachy, she is concerned about her blood pressure being higher than normal. Blood pressure was taken on both arms so she can see that the BP can differ depending on which arm its taken on. No signs or symptoms of an allergic reaction or anaphylaxis noted. Pt was cleared from EMS and she stated she was good to go. She was assisted to the exit.

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1223085	4/17/2021	VA	19	F	4/16/2021	4/16/2021	During 15 min waiting period patient developed lightheadedness and dizziness with heart racing. No chest pain or chest tightness. She felt weak and unable to walk. At first was thought to be a vasovagal reaction and she was given po fluids and monitored. Vitals were stable. HR was in the 70s with a baseline of 50s. She began to feel somewhat better in terms of the lightheadedness and dizziness and was able to walk to "clinic" area at the vaccination event. Her heart rate was fluctuating between 50 and 107 and otherwise vitals remained normal. Blood pressure up a bit more than likely due to anxiety. BP 132/90; HR 50 - 107; Rep 20; P.O. 98%; denied pain. She was given 25mg diphenhydramine IM. No complaint of throat closing, no anaphylaxis. She continued to feel waves of tachycardia. Rescue squad dispatched for further management and observation to make sure no delayed anaphylactic reaction. Her course at the ED was benign. No further management other than fluids. Urine pregnancy test was negative. No bloodwork completed. Patient observed four hours with no adverse event and left ED feeling her normal self. At no time had anaphylactic reaction.
1222620	4/17/2021	MA	56	F	4/17/2021	4/17/2021	Before vaccination patient stated she had allergies to iron and epinephrine that caused anaphylaxis. Pt appeared anxious. Asked pt if she would like to receive vaccination in a quiet area w/ observation by EMTs, patient stated yes. Post-vaccination, pt complained of SOB, dizziness, lightheadedness, nausea, tingling to mouth. Patient appeared lethargic. Responded appropriately to questions from on-site EMTs. VS taken - HR 108, RR 24, BP 180/120, SPO2 99% RA. Pt was asked if she would like to be taken to ED for additional assessment, patient stated yes. Pt transported to ED by ambulance for further assessment.

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1222191	4/17/2021	NV	59	F	4/16/2021	4/16/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Systemic: Allergic: Itch (specify: facial area, extremities)-Medium, Systemic: Allergic: Itch Generalized-Medium, Systemic: Allergic: Rash (specify: facial area, extremities)-Medium, Systemic: Allergic: Rash Generalized-Medium, Systemic: Allergic: Swelling of Face / Eyes / Mouth / Tongue-Medium, Systemic: Abdominal Pain-Mild, Systemic: Confusion-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hyperventilation-Severe, Systemic: Shakiness-Severe, Systemic: Tingling (specify: facial area, extremities)-Medium, Systemic: Weakness-Medium, Additional Details: Patient waited in the observation area after getting vaccinated for 15 minutes, went home and started feeling anaphylactic symptoms around 30 minutes after and drove back to the pharmacy to seek medical attention. She was panicked and hyperventilating upon arrival and I had the patient sit down and to take deep breaths. I was about to give her benadryl but she complained of swollen throat and having a hard time breathing. I injected her with epi-pen and within 5 minutes she was better.

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1221918	4/17/2021		66	F	1/11/2021	1/11/2021	Died; The initial case was missing the following minimum criteria: Reporter with no first-hand knowledge. Upon receipt of follow-up information on 13Apr2021, this case now contains all required information to be considered valid. This is a spontaneous report from a Pfizer-sponsored program. A non-contactable consumer reported that a 66-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 11Jan2021 (at the age of 66-year-old) (Batch/Lot number was not reported) as single dose for COVID-19 immunisation. Relevant medical history and concomitant medications were not reported. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 21Dec2020 for COVID-19 immunisation. The patient died on 11Jan2021; the cause of death was unknown. On 11Jan2021, the patient experienced cardiac arrest and breathless with outcome unknown. The patient was found pulseless and breathless 20 minutes following the vaccine administration. MD found no signs of anaphylaxis. It was not reported if an autopsy was performed. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Died
1223654	4/17/2021		22	M	4/16/2021	4/16/2021	pt had face rash , we gave him IM benadryl , he was fine, no anaphylaxis
1224153	4/17/2021	AZ	66	F	4/17/2021	4/17/2021	Pt showed signs of anxiety including hyperventilation. EMS evaluated and watched her 40 min. Vital signs remained stable 122/88, 79, 98%. However, her end total CO2 would drop to 19-22 until paramedics calmed her down and she was free to go home. Patient gave us an extensive list of over 50 allergens and her reactions, including abx, pain meds, methadone, fire retardant, Tylenol and Advil. However, she states that she refuses to carry an epipen even though she claims to have experienced anaphylaxis over 20 times. Pt also refused transport for further observation.

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1219125	4/16/2021		17	F	4/12/2021	4/12/2021	Patient had anaphylaxis with recorded trigger (Pfizer COVID vaccine). She received epinephrine onsite, and then an additional dose of 0.3mg in ED. She however, required two more doses of 0.5mg epinephrine and racemic epi neb. She was admitted for further observation given need for multiple doses of epinephrine. At approximately 9:00 am (~18 hours post vaccine) a rapid response was called on 4/13 and patient was transferred to the PICU for further treatment. Patient also received the last dose of epinephrine 0.5mg at approximately 9:00 am (~18 hours post vaccine). Patient received famotidine 20mg IV x1 and methylprednisolone 90mg IV x2 in the PICU. Patient was discharged on 4/14 at 8:00 am from the PICU, approximately 41 hours post vaccine administration. Received a total of epinephrine x7 doses during the hospitalization.
1219557	4/16/2021	NY	44	F	3/11/2021	3/20/2021	Came to the ED for shortness of breath for the past 3 days; also claims was treated for anaphylaxis at other institution after receiving the vaccine (patient has schizoaffective disorder). Patient tested positive for COVID-19 on 3/20/21 and treated with remdesivir and convalescent plasma
1219544	4/16/2021	MI	26	F	4/8/2021	4/8/2021	While at pharmacy my lips started feeling tingly and itchy, thought it was just from mask. After 15 minutes I was told I was fine to leave, so I left and headed home. Almost halfway home my throat began to feel swollen and tighter, like a rock was in it. My lips and face continued to itch and tingle. My face also was bright red. I have experienced anaphylaxis before, and was on Bactrim for days before I had the reaction. I waited it out to see if I needed to go to the hospital, but felt I was okay. The next couple days however I still felt like there was a rock in my throat and it was still a little tight, but no longer itchy or feeling hard to swallow so I didn't take myself in.
1219368	4/16/2021	FL	41	F	4/14/2021	4/14/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe

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1215766	4/16/2021	NY	42	F		4/3/2021	<p>FEELING COLD; PAIN IN LEFT ARMPIT; PAIN IN LEFT SIDE OF NECK; BODY ACHE; PAIN IN THE INJECTED ARM (LEFT SIDE); ANAPHYLAXIS; This spontaneous report received from a patient concerned a 42 year old female. The patient's height, and weight were not reported. The patient's past medical history included covid-19 infection on an unspecified date in MAY-2020. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, frequency 1 total, administered on 03-APR-2021 around 11:00 a.m. on left arm for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date in MAY-2020, Laboratory data included: COVID-19 antibody test (NR: not provided) positive, (3.72). On an unspecified date in 2021, Laboratory data included: COVID-19 antibody test (NR: not provided) level of 0.2. On 03-APR-2021, the patient experienced anaphylaxis. It was reported that within 5 minutes after vaccination patient experienced tongue was swollen, throat started closing, throat breaking in hives. The pharmacy called the emergency service, and the consumer was taken to the hospital. On 04-APR-2021, the patient experienced feeling cold, pain in left armpit, pain in left side of neck, body ache and pain in the injected arm (left side). She was treated with routine treatment for anaphylaxis, and she was put on prednisone and Benadryl. It was reported that, the treatment was still on. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from anaphylaxis, and had not recovered from feeling cold, pain in the injected arm (left side), pain in left armpit, body ache, and pain in left side of neck. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to AER20210409478.; Sender's Comments: V0 20210410075-Covid-19 vaccine ad26.cov2.s Anaphylaxis. This event(s) is considered related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and is scientifically plausible. There is no information on any other factors potentially associated with the event(s).</p>

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1217053	4/16/2021	CA	30	M	4/15/2021	4/15/2021	<p>Client was vaccinated with the Pfizer Covid vaccine with lot #EW0162 at 11:59am on 04/15/2021. EMT observed client standing at the facility exit speaking to the interpreter. EMT noted upon approach client appeared alert, tracking with his eyes, in no apparent distress. Client had a chief complaint of numbness at his injection site. Client stated that he had completed his 15 minutes and had exited the site but began to experience numbness at his injection site while exiting. This was the client's first dose of the Pfizer vaccine. Client states he has a history of a deep vein thrombosis and hypertension. Client is not on any medications and denies any known allergies. Assessment revealed that client's left arm/injection site was clean, dry and bandage remained intact. Client was negative for hives, swelling, severe sweating, shortness of breath or other signs of anaphylaxis. Client was alert and oriented to person, place, date, and event; and airway, breathing and circulation were intact. Client had full range of motion of his arm and denied any tingling. Client denied any pain upon palpation of the injection site and stated that his numbness was strictly localized to injection site and did not spread to rest of arm. Client's vital signs upon entering EMT station for further evaluation revealed: blood pressure 180/140, respirations 18, pulse 68, 98% on room air; lung sounds clear bilaterally, temp 98 degrees F, eyes remained equal, round, and reactive to light at 5 mm. Client stated that he had his blood pressure taken last week and that his systolic was approximately 160. Client agreed to remain for an additional 30 minutes of monitoring per site lead nurse and was stable throughout observation. Vital signs at 1220: blood pressure of 180/140, respiratory rate of 18, heart rate of 68, and oxygen saturation of 98% on room air. Vital signs at 1235: blood pressure of 160/124, respiratory rate of 18, heart rate of 76, and oxygen saturation of 99% on room air. Vital signs at 1250: blood pressure of 158/118, respiratory rate of 18, heart rate of 76, and oxygen saturation of 99% on room air. At the completion of the client's observation, client stated that numbness was "better" and stated that it was "almost gone." Client's blood pressure improved upon reassessments, and all other vitals were remained within normal limits. Client was provided with vaccine information packets and encouraged to seek follow-up</p>

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care or emergency care if symptoms become more severe later in the evening. EMS was denied by client, no medication or other interventions were indicated or administered. Client departed facility by ambulation to private care at 1253 in positive disposition. EMT reported to lead nurse about client's status after client left facility already. Lead nurse educated EMT regarding high blood pressure referral to EMS. But EMT stated client denied EMS.

1217483 4/16/2021 NC

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4/8/2021 ANAPHYLAXIS; HYPOTENSION; VOMITING; This spontaneous report received from a pharmacist concerned multiple patients (4 patients). The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose was not reported, 1 total administered on 08-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 08-APR-2021, upon the vaccination patients had string of events among which the one patient experienced anaphylaxis, three patients have experienced hypotension and vomiting. And seven patients were taken for further review. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the anaphylaxis, hypotension and vomiting was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210416852-Covid-19 vaccine ad26.cov2.s-anaphylaxis. This event is considered related. The event has a compatible/suggestive temporal relationship, is unlabeled, and is scientifically plausible. There is no information on any other factors potentially associated with the event.

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1217560	4/16/2021	MA	50	F		4/11/2021	BODY ACHES; FREEZING COLD; NAUSEA; TIREDNESS; DIZZINESS; This spontaneous report received from a patient concerned a 50 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included food allergy, anaphylaxis to allergens, metal allergy, environmental allergy, non smoker, and alcohol use, and other pre-existing medical conditions included the patient had no history of drug abuse or illicit drug use. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 206A21A, expiry: UNKNOWN) dose was not reported, administered on 11-APR-2021 12:45 for prophylactic vaccination. No concomitant medications were reported. On 11-APR-2021, treatment medications included: ibuprofen. On 11-APR-2021 12:45, the subject experienced dizziness. On 11-APR-2021 12:45, the subject experienced nausea. On 11-APR-2021 12:45, the subject experienced tiredness. On 11-APR-2021 22:30, the subject experienced body aches. On 11-APR-2021 22:30, the subject experienced freezing cold. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from dizziness, body aches, freezing cold, nausea, and tiredness on 12-APR-2021. This report was non-serious.
1217605	4/16/2021	GA	31	F	4/4/2021	4/10/2021	Site: Itching at Injection Site-Severe, Site: Redness at Injection Site-Medium, Site: Swelling at Injection Site-Medium, Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Rash Generalized-Medium, Additional Details: pcp. it was the weekend after her vaccine she got \"hives all over body and itchy!\" We recommended she take bendryl and head to the emergency room after she reported to us.
1217939	4/16/2021	NC	55	F	4/15/2021	4/15/2021	Anaphylaxis - throat swelling

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1220336	4/16/2021	AL	47	F	4/16/2021	4/16/2021	about 30 minutes after receiving the covid vaccine pt reported feeling dizzy and tightness in her chest. She was coughing occasionally when talking. EMS was immediately called and vital signs were as follows 160/100 HR 83 RR 24 O2sat 99, pt reported having "locked jaw" which is consistent with her previous allergic reactions. At 1008 pt given one dose of epipen in right leg, she reported some relief after 3 min. and refused Benadryl. EMS arrived at 1013 report given to them, o2 applied by nasal canula and EMS requested second dose of epipen to be given. at 1014 second dose of epipen given in left leg. pt was able to move with assistance to stretcher, pt's family notified and pt transported to hospital by EMS. pt's belongings given to pt. Pt denied any anaphylaxis to any injectable medication prior to vaccine administration. Plan to contact pt for outcome of incident.
1219939	4/16/2021	GA	65	F	2/10/2021	2/10/2021	Pt vaccinated at 11:30 am with COVID-19 Moderna, 1st dose. While waiting in her car at the observation station of the drive-thru site for 30 minutes due to hx of anaphylaxis to an unknown substance, pt began to feel like her nose and lips/mouth were itching at 11:54. Alert and talking, no distress noted. Pt given benadryl 25 mg tab at 11:56 am. Pt remained on site another 30 minutes. No worsening of symptoms and reported improvement. Pt was discharged to home via her own car with husband driving at 12:30 pm. Called the next day to check on pt. She took another benadryl that night. No further problems.
1217878	4/16/2021	ME	37	M	4/15/2021	4/15/2021	Patient started to feel nauseas after vaccine. When asked if having other sxs patient unable to express. Vitals taken and provider came to assess patient. Patient complained of nausea and arm burning, but unable to answer questions well. Not able to tell us if mouth felt swollen. Due to patient unable to express sxs, provider had us call EMS, as could not tell if patient would or would not have anaphylaxis reaction. Patient brought to hospital/ER for further evaluation.

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1220477	4/16/2021	NC	19	M	4/16/2021	4/16/2021	Patient experienced loss of consciousness after administration of vaccine. This happened within 45 seconds of administration. This happened 3 separate times within a 5-10 minute time frame. No signs of anaphylaxis were identified during this time. Patient would "faint" briefly (approximately 10 seconds) and then regain consciousness and confirm that he had no symptoms of anaphylaxis. Symptoms observed were loss of color of the face and lips and some diaphoresis. The patient was monitored for any changes and EMS was called. The patient refused EMS service or hospital service. He stated that the "fainting" happened to him regularly whenever he received a vaccine. The total time of the event was approximately 30 minutes and the patient was advised to stay longer for monitoring if he would refuse EMS service, which he did. The patient has since been called and is currently feeling "normal except for being somewhat tired". He has been advised to follow up with his primary care.
1219679	4/16/2021	OK	40	F	3/31/2021	4/1/2021	Severe hives all over and anaphylaxis reaction

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1219813	4/16/2021	CO	35	F	4/15/2021	4/15/2021	Pt presented to clinic for 2nd Moderna Vaccination today. Patient reported to vaccinating RN Hx of anaphylaxis to NSAIDs, Hx of covid infection resulting in multi-week hospitalization in December 2020, reports that she is a "covid long hauler." Additionally, pt reported that she experienced "throat scratchiness/tickle" and "dry throat" immediately following Moderna vaccine dose #1 on 3/16/2021, which resolved after drinking water. Pt was instructed by her physician to bring her personal epi-pen with her when receiving 2nd dose of Moderna. 2nd dose vaccination administered today, with pt agreeing to stay in observation for 30 minutes. 10 minutes post vaccination at 10:24am, Pt reported that she was getting the same scratchy tickle in throat she experienced following 1st dose. RNs brought pt into clinic room five for closer observation. 10:33am, Pt reported feeling dizzy, was visibly shaking, and reported tightening in her chest. At 10:33am, pt was laid down on floormat, and 0.5L Oxygen was administered via mask. 10:35am, HR 77, RR 24, Oxygen was increased to 1.0L. 10:36am, pt reported decreased chest pressure, decreased dizziness, stated "this feels better." 10:40am, pt reported tightness in chest had resolved completely, denied dizziness, denied itching, however, throat still "tickles." 10:48am, patient remained supine, O2 at 1L, B/P 138/90- pt reports resolved throat itching, states she feels "much better." 10:52am, RNs assisted pt to sitting position, pt states she feels "way better," denied tight chest, dizziness, throat tickle. 10:55am- HR 66, pt given water. 11:00- pt moved to standing position then sitting position in chair, and O2 was removed. 11:10- pt reported breathing and throat feel normal, denied dizziness. 11:16am, pt walked to observation to wait for daughter to pick her up and drive her home. 11:38am, patient's daughter arrived at clinic to drive her home. RN provided education on s/s of anaphylaxis reaction vs expected s/s following vaccination to patient and daughter. RN instructed patient not to drive today and have someone remain with her for at least 4 hours. Instructed not to take benadryl as it may mask symptoms of anaphylaxis. Instructed to go to ED if she experiences difficulty breathing, rapid onset of symptoms such as tight chest, SOB, throat swelling & dizziness. Both patient & daughter verbalized understanding before leaving clinic.

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1220462	4/16/2021	CA	70	F	3/16/2021	3/16/2021	Pt returned to vaccine site today on 4/16/2021 for her second dose but wanted to speak with a provider prior to her second dose. Pt reports after her first dose of Moderna on 3/16/21 she went home after waiting for 30 minutes and noticed red lines by her nose when she got into her car but thought it was nothing and did not mention it to any staff members/providers. Per the patient, went to bed that night and her throat got tight and her tongue swelled up so she called her PCP and he advised her to take 'medication' and she said symptoms improved. Pt notes for a few days she had to take these 'medications' because her throat was still a bit tight. Pt denies ever going to the ER. Pt reports symptoms have resolved completely. *I did not vaccinate this patient. This pt did not report any reactions while being monitored for 30 minutes by a provider on 3/16/21. I am currently seeing regular office visits today and the patient asked to speak with a provider prior to her second dose she was scheduled to come have done today. This patient is brand new to me and new to clinic and has never been seen before aside from getting her first Moderna vaccine here. I advised she cannot get her second dose of Moderna and she agreed. I also advised that she report the adverse reaction herself and she agreed. STRICT ER precautions were advised and pt was recommended to follow up with her PCP. Pt verbalized understanding and agreed and her second dose of her Moderna COVID vaccine was cancelled and I wrote on her vaccine card she cannot receive her second dose due to anaphylaxis.

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1220872	4/16/2021	MD		F	2/12/2021	2/13/2021	wiped out; dizziness; problems with ears; This spontaneous case was reported by a consumer and describes the occurrence of FATIGUE (wiped out) in a 74-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 011M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Bee sting hypersensitivity (anaphylaxis after bee stings). Concomitant products included METOPROLOL, BUDESONIDE (PULMICORT) and ZOLPIDEM for an unknown indication. On 12-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Feb-2021, the patient experienced FATIGUE (wiped out) (seriousness criterion medically significant), DIZZINESS (dizziness) and EAR DISORDER (problems with ears). At the time of the report, FATIGUE (wiped out), DIZZINESS (dizziness) and EAR DISORDER (problems with ears) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to MOD-2021-065503 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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1221003	4/16/2021	CA	49	F	4/10/2021	4/10/2021	Tachycardia, facial flushing, dizziness, and back/neck pain within five minutes of vaccine injection. Because I've had anaphylaxis several times in the past, I know these are warning signs that my reaction is heading toward anaphylaxis. Rite Aid called 911 and EMT came ten minutes later. I took Benadryl and Advil immediately after my tachycardia started. My heart rate went back to normal by the time the EMT arrived because my Benadryl had started working. I was still flushed and dizzy with pain in my back and neck. I did not go the hospital or use epinephrine. For the next 12 hours at home, I took Benadryl and Advil every time my heart started racing. 12 hours after my allergic reaction started, all symptoms had stopped. I will not be getting a second dose of ANY Covid-19 vaccine.
1221229	4/16/2021	PA	43	F	4/16/2021	4/16/2021	I waited the recommended 15 mins as having no prior issue with anaphylaxis. 20 mins after the vaccine, I was driving and started itching on the left side of my neck. I didn't notice any face, lip or throat swelling and continued to pick up my child from school. An hour after the injection, the itching was felt all over my body not localized. I called my doctor to ask if I could take Benadryl. He agreed. The itching continued and red blotchy skin could be observed all over body. About 4 hours after injection, I experienced body aches that lasted an hour and then subsided. 8 hours after my injection, most of the itching and blotchy skin had subsided
1221244	4/16/2021	CA	51	F	4/3/2021	4/3/2021	About 10 minutes after the vaccine I began feeling dizzy. I called the nurse over to my car. She shared it was a side effect some people felt. I stayed for about 50 minutes total and left as I did not feel an anaphylaxis response. I then experienced vertigo that day and the next. By the evening of the next day I felt the dizziness and vertigo relief.

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1221369	4/16/2021	FL	74	F	2/8/2021	2/8/2021	started to itch; Scratchy throat; Mental confusion; tightness in throat; Her throat tightening made her anxious and her respiratory status worse; Her throat tightening made her anxious and her respiratory status worse; This is a spontaneous report from a contactable consumer. A 74-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: EL9262), via an unspecified route of administration, at the age of 74 years, administered on the left arm on 08Feb2021 12:45 at a SINGLE DOSE for covid-19 immunisation. Medical history included ongoing hypersensitivity. Additional Information for Other Conditions: medications, cloves, spices, MSG, processed foods and she can't take any antibiotics. There were no concomitant medications. The patient wanted to report a less severe reaction she experienced within 10 minutes of the first dose 08Feb2021. After her vaccine within 10 minutes, she started to itch. The patient had a scratchy throat, mental confusion, tightness in her throat. The tightness in her throat she usually experiences with clove, food allergies and antibiotics. She was familiar with what was happening. The side effects did go away. They asked her to stay 30 minutes. As soon as she left, she took one Benadryl and 10 min later she took a second one. Then, it subsided. Her itching did go into the next day. Her throat tightening made her anxious and her respiratory status worse. It happened so quick. Her first concern was conflicting facts sheets in regards to taking the second dose. The patient wanted to know what was recommended. Should she take the second dose. She has never had anaphylaxis so she doesn't have an EpiPen. She can take Benadryl which has gotten her out of more severe responses before. Therapeutic measures (Benadryl) were taken as a result of the events. The outcome of the event itch was recovered on 09Feb2021 while other events were recovered on 08Feb2021.
1221457	4/16/2021	SC	38	F	4/16/2021	4/16/2021	Anaphylaxis, tongue tingling and swelling, lip tingling and swelling, facial tingling and swelling, difficulty breathing, nausea

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1220302	4/16/2021	CA	61	F	4/12/2021	4/12/2021	Patient received first Pfizer Covid-19 immunization on 4/12/2021. The shot was administered at 11:01 am into the left upper deltoid. Approximately 3 minutes later patient complained of faintness and experienced syncope. Patient was able to lie on the ground without assistance and her legs were elevated. Emergency services were placed on standby, and a first responder from the fire department was on hand. Patient was responsive and alert, citing tingling in her left arm and an irritated, scratchy throat. Diaphoresis, but no signs of dyspnea or acute anaphylaxis. Blood pressure elevated. Supine position with elevated legs maintained for about 30 minutes. Patient declined EMT evaluation and was able to leave without assistance.
1220084	4/16/2021	RI	24	F	4/16/2021	4/16/2021	Patient began to feel nauseated at 1555, while sitting in observation approximately 5-10 minutes after receiving the Pfizer COVID-19 vaccine IM. Patient was brought to the EMS room at the vaccination clinic. Patients vital signs: BP 148/100; PR 125; RR 24; SpO2 100% r/a. Patient was treated with IV in right a/c. Patient began to have full uncontrollable body shaking, remained conscious, alert, and oriented throughout event. Patient did not complain of difficulty breathing or other anaphylaxis symptoms. Patient was transported to Hospital.

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1214618	4/15/2021	WA	52	M	4/12/2021	4/13/2021	Medical Decision Making 52-year-old male with past medical history of HIV, fibromyalgia, status post VP shunt, presenting to the emergency room with chief complaint of fever, headache, nausea, generalized malaise and body pain after receiving the 2nd Kaiser COVID vaccine yesterday morning. Patient is hemodynamically stable on arrival and afebrile. He is well appearing on examination without any acute neurovascular deficits on examination. He is placed on cardiac monitor and IV access was established. He was given symptomatic treatment with IV fluids Toradol and Zofran as well as a 25 mg IV dose of Benadryl. No evidence of anaphylaxis or concerning vaccine reaction, likely side effect. EKG was reviewed and grossly unremarkable. Patient was signed out to oncoming ED physician Dr. pending reassessment for symptom control. No further interventions while under my care in the emergency room. Patient was in agreement with plan of care and all questions and concerns were answered best my ability.
1213024	4/15/2021	TX	64	F	4/10/2021	4/10/2021	Call rec'd from pt; she wants to report a reaction to the J & J vaccine which she got this past Saturday 4/10 at 10am; her symptoms began that night at 9pm , primarily nausea and vomiting. she could not keep anything down, finally she remembered a past txment from her childhood, pepto bismol and milk; (she had IBS as a child); her sxs persisted for about 3 days, finally on Wednesday she felt better and has been tolerating a bland diet; she is better now; pt feels that there is a strong correlation between her diabetes and the vaccine; she is asking that this be reported via the VAERS system; pt did not experience anaphylaxis nor rashes/urticaria, nor any classic blood clot sxs; rn

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1211835	4/15/2021	TX	47	M	4/14/2021	4/14/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Medium, Systemic: Allergic: Itch (specify: facial area, extremities)-Mild, Systemic: Allergic: Itch Generalized-Mild, Systemic: Allergic: Rash (specify: facial area, extremities)-Medium, Systemic: Allergic: Rash Generalized-Medium, Systemic: Allergic: Swelling of Face / Eyes / Mouth / Tongue-Medium, Systemic: Abdominal Pain-Medium, Systemic: Chest Tightness / Heaviness / Pain-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Headache-Medium, Systemic: Visual Changes/Disturbances-Medium, Additional Details: complained of heart burn and blood pressure rose
1212204	4/15/2021	OH	66	F	4/14/2021	4/14/2021	Patient tolerated the vaccine administration with no problems in the left deltoid. I had plans to monitor her for thirty minutes as she had anaphylaxis to a penicillin injection as a child. She was walked to the waiting room at which time she felt completely well. After five minutes she felt comfortable, but at the ten minute marker she stated that she felt dizzy. I instructed her to remain seated and rest. At the thirty minute mark she said she still felt dizzy which I then led her to a room for her to lay down with her feet up. While walking down the hall she felt dizzy, but made it to the room. After laying down for 30 minutes she felt better and was able to walk down the hall several times without difficulty.
1212266	4/15/2021		60	F	4/12/2021	4/12/2021	throat numb; coughing, clearing throat; HX seasonal allergies- take zyrtec and allegra; no HX: anaphylaxis

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1212484	4/15/2021	TX	61	F	4/15/2021	4/15/2021	8:48 AM- Patient complains of dizziness/chest tightness and SOB after second dose of moderna covid vaccine. States she experiences SOB sometimes but this time feels different. States she takes BP medication and has a hx of high bp. Denies throat swelling, assessed and all appeared normal. Vital signs at 8:51 AM- 118/88, 98%, 60. Assisted patient and husband to private room and assessed stomach, back and arm for rash and/or hives; none apparent. Patient states she is feeling better and not having difficulty breathing. Vital signs at 9:00 AM- 108/82, 96%, 58. Assessed throat for swelling, none apparent. Vital signs at 0905- 118/79, 98%, 60. Patient states she is feeling completely better and sob and chest tightness went away. Also had patient walk in hallway and states she is no longer dizzy. Advised patient and husband that all vital signs are normal and no other apparent signs of anaphylaxis, however if she still felt dizzy or any other symptoms she could stay as long as needed. Patient denies having any remaining symptoms and states she is ready to go home. Advised patient that if she experienced any other symptoms after leaving clinic such as sob, chest pain, rash/hives to contact emergency services. Patient and husband verbalize understanding. RN
1212805	4/15/2021	AZ	50	F	4/11/2021	4/11/2021	First Vaccine: Symptoms of only left arm local errythemia and itchy, flu like symptoms x 48 hours. Second Vaccine: Delayed anaphylaxis beginning slowly 20 min after injection with SOB/Wheezing without relief using rescue inhaler 4x in 2 hours. Progressed to full waist, chest, arm, face rash/hives with significant SOB, Progressed to full A-fib. Symptoms self treated at home with Benadryl and Prednisone. No epi-pen used. Continued self treatment on 4/11, 4/12 and had follow up with Asthma/Allergy specialist due to not resolving. Added steroids and anti-histamine for rest of this week.

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1211826	4/15/2021	GA	52	F	4/14/2021	4/14/2021	Patient received 2nd Pfizer dose at 10:00 am. She left the facility after 15 minute wait time. Within the next 5 - 10 minutes she became SOB with respirations 40 per minute. She was taken to Medical Center and seen by 10:45 - 11:00 am. She was treated for anaphylaxis and was worked up for any other underlying problems. She had to be put on the vent due to acute respiratory failure. She was negative for COVID, pulmonary emboli and pneumonia. As her status declined, ED felt she needed higher acuity care. She was over the weight limit to be airlifted so she was transported by critical care ambulance to hospital where she is in ICU and on ventilator.
1212907	4/15/2021	CA	31	M	3/8/2021	3/15/2021	swollen mass in left axila. started feeling anaphylaxis-like symptoms, including swollen throat, face/jaw numbness, inner ear swelling. the symptoms appear random with varying intensities, no apparent trigger
1211828	4/15/2021	DC	54	F	4/14/2021	4/14/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Shakiness-Mild, Systemic: Tachycardia-Medium, Additional Details: temp within normal range, BP 149, 146, then 161. had a fast heartbeat so drink 2 small water bottle and shaking hands a liitle.\r\npharmay monitored her more than 1 hour and 30 minutes. she is ok to go home. (previous event happened on last december d/t epinephrine inj at dental office)

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1213141	4/15/2021	WI	80	F	3/23/2021	3/24/2021	She got her vaccine, and started with her arm hurting that evening. The next morning it was itching, and then blotchy. She then started scratching her arms, shoulders, back, chest, and there were little clusters of measles like areas. She scratched on her wrist that had fluid in it. She had them in both of her eyes, and has been horrid, and they jump all over and now she has clusters of scabs that are itching as well. She went to the doctor and they gave her steroids which did not help much, but was given Benadryl also which has helped some. She also saw her cardiologist who told her she could take up to 4 Benadryl a day. She was fine last night, and this morning she had the itching and scratching again in the same areas as before. No fevers and no other reactions other than the itching rash. She also had swelling of the palms of her hands and itching, which is the reaction she gets when she gets anaphylaxis. She said that they are all over her back, all over her chest. She said that yesterday it seemed to be calming down. She was told not to get her vaccine on the 20th, but to wait until things settled down a bit.
1214200	4/15/2021	IL	36	F	4/15/2021	4/15/2021	Pfizer-BioNTech COVID-19 Vaccine EUA. About ten minutes after receiving her first covid-19 vaccine, pt experience dizziness, weakness and nausea while in observation area. Pt was observed for an additional 15 min (a total of 30min) and reported feeling better. At 30 mins pt still reported dizziness. We offered to call an ambulance and pt refused. Pt had a family member pick her up from pharmacy as to not drive. Counseled pt to be aware of any additional symptoms and to have family member continue monitoring her as needed depending on symptoms. Pt was also told if got worse or symptoms related to anaphylaxis developed to call 911
1214575	4/15/2021	OK	49	F	4/15/2021	4/15/2021	nausea PT felt better after she was given fluids orally and something to eat and to lie down no evidence of anaphylaxis; pt was watched for 15-20min post vaccination; she was discharge instruction to eat breakfast and rtn if n/v or abd pain, fever or sob , cough or chest pain-DR VU

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1214633	4/15/2021	CA	58	M	4/12/2021	4/12/2021	Anaphylaxis x- scratchy throat at +10 mins x- swollen tonsils at +15 mins x- difficulty swallowing at +20 mins x- voice changed noticeably at +30 mins, subsequently lost x- Some heart palpitations and chest tension at +45 mins x- Angiodema of right eye +90 mins
1214661	4/15/2021		43	F	4/14/2021	4/14/2021	At 1535 nurses in observation noted that patient was itching. Pt reported she had long-standing untreated hypertension and did not take medication for it. Pt reported anaphylaxis to PCN in the past. Pt reported itching in arm and throat. No respiratory distress noted at this time. VS: 170/147, 103, 98%, 16. Pt reports 170-200 systolic is baseline BP and that she did not feel sick or any other symptoms at this time. Pt declined any emergency services to be called at this time. Continued to monitor patient closely. No further escalation of itching or other sx's were reported. Vitals taken again at 1600 before patient was released from 30 min observation time. VS: 173/118, 91, 100%, 16. Pt was educated on blood pressure management and encouraged to follow up with PCP. No further adverse effects noted. Pt remained in the facility until staff departure at 1645.
1215125	4/15/2021	NY	27	F	3/17/2021	3/17/2021	Anaphylaxis (nausea, dizziness, lost vision, muffled hearing, difficulty breathing, swollen-feeling throat, blue under fingernails). Nausea began < 5 min after vaccine; everything else began within 10 min of vaccination. Was treated with epinephrine, water, and Benadryl. Most symptoms subsided within a minutes. Breathing ease returned to normal within 5-10(?) minutes. Was only monitored for 30 min or so after epinephrine. No EMS called; was not advised to go to hospital.

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1215535	4/15/2021	CA	56	F	4/15/2021	4/15/2021	@1515 pt came to clinic reporting tightness to throat. Pt stated she felt throat tightness five min after being vaccinated at 0800 am.. She did not report it to the observing nurse. Pt went home, had to come back for covid test routine for work per patient. Pt attempted to call call center, was put on hold, so she decided to come to vaccination clinic to report symptoms. Pt was awake, alert, speaking full clear sentences, breathing easy non labored, HR 86, sat 99%. No coughing, no drooling noted. Pt transferred to ED via wheelchair accompanied by RN and Mia LVN, RN carried Anaphylaxis kit. SBAR handoff given to RN in ED triage area. Opened chart for RN note.

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1216453	4/15/2021	CA	35	F	4/12/2021	4/12/2021	<p>Client had a chief complaint of chest pain. Client stated that she began feeling chest pain several minutes after the start of her observation. Client has a history of depression and other unspecified psychiatric illnesses. Client stated that she takes sertraline daily and has a history of taking Risperdal. Client stated that she regularly sees a Psychiatrist. Client denied any allergies or other underlying medical illnesses. Assessment revealed chest pain located in the center of the patient's chest. Client pointed to her sternum to indicate the exact location and stated that her arms felt "heavy." Client's airway, breathing and circulation were intact, however, client complained of shortness of breath. Client was alert and oriented to person, place, date and event while appearing slightly distractible. O2 saturation 100%. Client was negative for redness, swelling, hives, severe sweating or other signs or symptoms of anaphylaxis. Client denied any increase in chest pain or shortness of breath when breathing in or out and did not state any additional pain throughout her body. Client then added that she felt "anxious" after receiving her shot and stated some reluctance with even receiving the shot prior to her arrival. Client's mother was present and stated that client had been reading the Pfizer fact sheet she was given and had been focusing on the side effects portion before signaling for assistance. Client's initial vitals were as follows: Blood pressure:138/88, Pulse 76, Respirations 20, O2 sat 100%, Eyes equal and reactive to light, Lung sounds clear bilaterally. Client initially consented to staying an additional 30 minutes. She began to become anxious and impatient with her additional observation time. After 10 minutes of sitting the client began stating that she was afraid that her "heart would become too fast" when she got home if she "didn't throw it away." After some encouragement, the client was able to clarify "it" as "meth" which she had hidden at home. Client stated some reluctance to go home stating that if she smoked her "meth" that her heart rate would become too "fast." Client then asked EMT if he was willing to come home with her to help her "throw it away." All staff present praised the client for sharing this information and after discussing her concerns further, client became much calmer and stated that she felt much safer and that her chest pain, shortness of breath and anxiety had subsided. Client then stated that she wanted to go home</p>

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							but consented to a second set of vitals before leaving. All of the client's vitals improved: blood pressure 132/88, pulse 68, respirations 16, O2 sat 98%. 1636 - 138/88, 76, 20, 100% 1651 - 132/88, 68, 16, 98%. Client was encouraged to discuss the incident with her psychiatrist and to seek further counseling. Client was also instructed to seek further medical care or the emergency room if symptoms returned. No medications were administered.
1214567	4/15/2021	CA	64	M	4/5/2021	4/5/2021	Patient received first dose of pfizer (lot # ER8729)at 11:17AM. Individual complained of sick feeling. EMT found no abnormalities, EMT assessment: BP-110/60, RR-16, HR-66, A&Ox4, PERRLA, skin warm and dry, lung sounds clear to auscultate. EMT notified RN of Individual complaints. When RN first arrived on scene individual was sitting in chair erect. Client appeared sweaty having labored breathing. Client state "I am feeling tightness on my chest. EMT took individuals vitals (BP 110/80, HR 90, RR 16, SPO2 98). Individual was found to have a history of high blood pressure and diabetes. Currently taking metformin and medication for high blood pressure but denies taking the diabetes medication this morning. Additionally individual was alert and oriented times three and had clear lung fields as assessed by the EMT. Despite no change in vitals, 911 was called at 11:35 by lead ancillary. During which time the individual stated "I'm starting to feel drowsy and sleepy." Paramedics arrived on scene at 11:40 at which time the EMT and RN transferred care. The individual refused ambulance transportation and signed waiver. Individual was asked if symptoms had improved or if they were the same and he stated "I feel the same." Upon giving this answer, the signed the AMA, the last assessment: client breath sounds were assessed to be clear to auscultate, speaking in full sentences without shortness of breath, was A&OX4, skin was warm and dry and not showing signs of anaphylaxis. At 11:40AM and upon completion of the last assessment, the individual departed the facility without any assistance with a steady gait.

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1210290	4/14/2021	NM	36	F	4/8/2021	4/8/2021	<p>Covid-19 Vaccine Clinic I was notified by EMT that they had given Benadryl IM to this patient. I went to evaluate patient who was sitting in a quiet corner attended by EMT and her husband. BP 150s/104, O2 100% RA Patient reported that about 5 mins after 2nd MODOerna vaccine today, she felt itchy eyes and noticed that her eyes were swollen and she notified EMT on site. They had given her Benadryl IM. She reports that she has h/o Anaphylaxis reaction to PCN. 3/12/21 Moderna 1st vaccine- given, patient noted getting tongue swelling and onsite EMT at BTR gave her Benadryl IM. Pt observed 30mins, Doctors note stated pt did not have throat/tongue swelling lung exams clear. He observed her during the episode and checked on her 3hrs later and pt noted to be felt fine. She reports that a week later, she had tongue swelling, went to ER where she was given Epi pen and admitted to ICU for 2 days. No intubation. Sent home on Prednisone taper- dosage unknown but she reports she is still taking 2 tabs daily. She reports she was told by her Hospitalist that she could go ahead for her 2nd Moderna vaccine dose. Gen: watery eyes, eyelids slightly swollen, very obese Throat: no tongue swelling, tonsils enlarged touching her palate Mallampati-Class III Pulm ctab no c,w,r Breathing comfortable, speech coherent, normal CV rrr About 10 mins of observation by this MD, I had consulted with our other on-site providers and we all agreed to give her Epi injection due to her prior history and current eye swelling immediately after vaccine was administered from EMS. Patient noted she felt shaky but denies sob/chest pain/throat pain/tongue swelling. She was not coughing. I accompanied patient to womens restroom for patient to void. EMS officer called EMS who came to pickup patient. Patient requested to be taken to Hospital ER. During the entire stay, patient denied feeling short of breath/chest pain/throat swelling. Treated in ER: IV Decadron/Benadryl/Famotidine and discharged in few hrs with discharge meds: Prednisone taper, Famotidine and Epi pen prescription 4/14/21 Called to check on patient and she reports took 2 days to settle down to feel normal but no throat swelling or any allergic reactions. States she is feeling well now. She followed up with her PCP (who is not from our facility).</p>

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1211375	4/14/2021	VA	32	F	4/5/2021	4/5/2021	Anaphylaxis - swollen tongue, swollen lips, difficulty breathing, body numbness and tingling
1211279	4/14/2021	SC	34	F	4/14/2021	4/14/2021	anaphylaxis: throat closing
1211228	4/14/2021		51	M	3/5/2021	3/5/2021	Anaphylaxis.
1211136	4/14/2021	WI	33	F	4/6/2021	4/6/2021	Client started out with anxiety following IM injection. Indicated that she had some tingling in her hands and feet. Visually upset. Within the course of staff evaluating client, client indicated that numbness and tingling spread to both hands and feet (worse on left side) and left side of face. Client with significant left sided weakness and favoring that side of body. Evaluation by Fire Department and onsite nurse showed no sign of anaphylaxis or stroke. B/P elevated to 148/96 at 18:03, 152/100 at 18:13, and 138/103 at 18:17. SpO2 remained at 100%. PR 94, 105, and 103 at respective times. Staff convinced client to go in for evaluation. Client was evaluated at Hospital in and diagnosed with idiosyncratic reaction to the vaccine. EKG was mildly abnormal but not out of concern. Potassium was low which physician attributed to the hyperventilation and panic attack. CT an all other lab work unremarkable.
1211105	4/14/2021	MD	38	F	4/14/2021	4/14/2021	Anaphylaxis and swelling of the lips - administered benadryl and patient felt better
1207777	4/14/2021	OR	56	F	4/12/2021	4/12/2021	Significant fatigue, muscle ache, headache, and periorbital edema following second vaccine dose. No evidence of anaphylaxis. Pt w/history of sig seasonal allergies that are particularly bad at the moment. S/s developed 6-12 hours after the 2nd dose. She rested and hydrated. She took a single OTC Claritin. Pt instructed to rest, use IBU 600mg q6h and continue Claritin. Follow up outlined.

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1210302	4/14/2021	CA	24	F	4/14/2021	4/14/2021	<p>Patient Allergies: NKA 14:53 patient received the covid vaccine Pfizer Lot:EW0162 Expiration:7/21 dose 0.3ml in left deltoid, then slid off the chair, nurse caught her and slid her to the ground provided support for her head, ensure the area was clear, she went unconscious for 15 seconds then regain conscious, vitals were taken, BP-133/89, Pulse-81, SPO2 97%, numeric pain scale 0/10. Patient was A &O x 4 person, time, place, and situation-----RN 14:56 reassessed vitals BP-131/68, Pulse- 71, R-16 even and unlabored, Spo2 98%, numeric pain scale 0/10, she was A&O x 4 person, person, place and situation, patient denies chest pain, denies shortness of breath, denies hx of going unconscious, she was moved to a chair for observation, will continue to monitor-----RN 15:07 contacted to alert her of the situation and to follow next step of protocol, will continue to monitor the patient-----RN 15:15 patient denies any chest pain, denies shortness of breath, denies dizziness, A&Ox4 person, place, time, and situation-----RN 15:24 reassessed the patient vitals BP-108/63, Pulse-70, SPO2-99% , numeric pain scale 0/10, denies chest pain, denies shortness of breath, denies dizziness, A&Ox4 person, place, time, and situation, had patient raise for chair slowly reported no dizziness, had patient walk back and forth w/ no assistance, observed a steady and even gait, patient denies any dizziness, provided education to follow up with primary care or head to urgent care, if patient starts to experience shortness of breath or anaphylaxis to call 911, both patient and partner verbalized understanding, the partner verbalized that he would be driving the patient home-----</p>

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1210345	4/14/2021	CA	63	F	4/12/2021	4/12/2021	Client was complaining of a tingling sensation on the same side as her vaccine administration. Client stated that she began experiencing the tingling sensation several minutes after beginning her observation. Client denied any major medical history, past allergies or history of any previous vaccinations. Assessment revealed no bleeding, bruising, swelling or other signs of trauma on her left side vaccine site. Bandage was clean dry and intact. Client complained of tingling sensation that began behind her neck that was painless. Clients airway, breathing and circulation were intact. She was alert and oriented to person, place, time and event. Client was negative for hives, redness, severe sweating, shortness of breath or other signs of anaphylaxis. : Blood pressure 150/78, Pulse 66, O2 sat 100% room air, respirations were 16 and regular, eyes equal and reactive to light, Temperature 97.8° f and lung sounds clear bilaterally. She was given Oral Benadryl 50mg, water and observed for an additional 30mins.Vitals were taken every 5mins. After 30mins of observation client stated that her tingling sensation was improving but still remained. She was offered to be transported to the hospital via ambulance for further observation or go home and continue observation and contact her primary Dr for further evaluation. She decided to go home to continue observation. She was recommended to make a follow up appointment with Dr. or seek emergency care if needed. She verbalized understanding. Left with husband.
1206950	4/14/2021	VA	42	F	4/14/2021	4/14/2021	Moderate Anaphylaxis. Treated with Epinephrine, Diphenhydramine and Solumedrol. Symptoms mostly resolved within 30 minutes and stable for 4 hours.
1207005	4/14/2021	PA	39	F	4/12/2021	4/12/2021	Anaphylaxis approximately 18 min after vaccine injection. Received epinephrin through epi pen. Transported to hospital via ambulance. Received IV steroids at hospital and monitored for 4 hours.

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1207728	4/14/2021	MA	43	F	4/14/2021	4/14/2021	Pt with known anaphylaxis to various things presented for 1st Pfizer with the advise of her physician. Pre-medicated herself (also with MD advise) with 50mg Benadryl, took additional 50mg post vaccine (again at MD advise). within 5 min post vaccine became symptomatic with lips puffiness, throat itch. 5 min later administered Epi pen and called 911. Airway remained patent, some scratchiness but trach sounds clear. Sats wnl--left site on stretcher, airway intact to local ED
1207883	4/14/2021	NV	27	F	4/12/2021	4/12/2021	Minor anaphylaxis and hives/heat rash behind underarms near shoulder blades. Sensitivity to sunlight. Minor anaphylaxis-started about 2 hours after injection and lasted approximately 8 hours. Resolved fully by next morning. Hives/heat rash behind underarms near shoulder blades-started about 3 hours after injection. Was made worse during sunlight exposure. Are minorly itchy. Sunlight Sensitivity lasted for about 24-48 hours. Seems to have resolved.
1207946	4/14/2021	NC	73	F	4/3/2021	4/3/2021	Pt c/o abdominal pain that began 5 min after vaccine administration, per pt's son. Pt main complaint in the ED was abdominal pain. On exam pt's abdomen was tender diffusely. Within minutes of initial evaluation the pt lost consciousness. Minutes later the pt was apneic and pulseless. Resuscitative efforts were initiated per ACLS protocol. During resuscitative efforts the pt received several rounds of code-dosed epinephrine. In addition, the pt received 1 dose of IV Benadryl in addition to medications standard for ACLS protocol. Benadryl was administered specifically to treat the possibility of anaphylaxis.

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1208286	4/14/2021	OH	36	F	4/1/2021	4/7/2021	Initial injection site soreness, red, itchy, heat approx 3 inch in diam for 3 days. Delayed reaction on 4/7 heat, hard lumps, red, itchy. Consistently growing daily several inches. Currently 8 inches by 10 inches. Morning lighter and blotches, 2 hours later very red and solid, growth occurring in afternoon with increase of pain and itch, evenings uncomfortable and causing movement restriction. Swelling of arm, fingers lymph nodes next to left neck and part of neck. Attempts at ice packs, over the counter cortisone creams and Benadryl resulting in little to no relief. Doctor prescribed prednisone course to be started today 4/14 and recommends discontinuing vaccine course, concerned about anaphylaxis if shot 2 is administered.
1208546	4/14/2021	TN	74	F	4/6/2021	4/6/2021	Client describes nausea initially which went away without intervention. Three to four hours after the injection, the right side of her tongue began to swell and eventually swelled to the roof of her mouth. This made swallowing difficult, but breathing was OK. Swelling persisted until 4/8 - it began to diminish and then she experienced right jaw and neck soreness along with a tender lymph node. On Monday, 4/12, she had an appointment for a regular physical with her doctor. She mentioned this experience to him and he strongly urged her not to get the second shot because this was anaphylaxis and she would likely die . Today, she is feeling pretty normal.
1208865	4/14/2021	TX	39	F	4/12/2021	4/12/2021	Pt experienced anaphylaxis with 1st dose of Pfizer cov19 vaccine, but patient wanted to be fully vaccinated due to losing a family member to Cov19. Patient was instructed by her Md to get the Janssen vaccine instead of the 2nd dose of Pfizer vaccine that was due on 3/28. A few minutes after the injection, the patient became itchy and had increased respiratory rate. Despite using her inhaler and receiving a dose of liquid Benadryl, the patients breathing worsened, and I injected the patient with an EpiPen. Patients breathing improved and we monitored her for an hour before releasing her. A follow-up call was made on 4/13 to confirm the patient was stable.

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1209672	4/14/2021	TX	33	F	3/10/2021	3/10/2021	Patient came to get 2nd dose of Moderna COVID-19 vaccine but stated that she had allergic reaction after the 1st dose. She had swelling on her throat, lips and tongue one hour after her 1 dose so she went to the PCP where she was treated with oral antihistamine but was not given EpiPen. Patient did not report to pharmacy about the adverse reaction. She came to receive her 2nd dose at pharmacy with an EpiPen in her bag as advised by her doctor but pharmacist advised to hold on to 2nd dose as recommended by CDC guidelines as she had an anaphylaxis reaction after 1st dose and consult back her doctor or take 2nd dose at doctor's office
1207510	4/14/2021	MA	42	M	2/19/2021	2/19/2021	anaphylaxis. throat closing, tongue tingling, couldn't breathe within a few minutes of injection epiPen and Benadryl given on site, sent to hospital for observation, treatment with allergy medications and steroids for five days after. Observed in hospital for four hours. Advised by primary care doctor not to get second dose or any other covid vaccines due to reaction.
1210082	4/14/2021	MA	65	F	4/1/2021	4/1/2021	anaphylaxis, severe face swelling, throat closing, arm swelling, headaches, ongoing dizziness, equilibrium issues, aches, stomach issues, rash on face, neck, torso and both legs, nausea ongoing, tingling sensations. 8 benadryl in first 30 min. kept me there for one hour - almost two weeks out and still not fully resolved (very dizzy, severe headaches, some swelling remains)
1208916	4/14/2021	CA	59	F	4/14/2021	4/14/2021	Approximately 10 minutes after administration of Moderna vaccine (second dose) patient complained of onset of throat swelling, shortness of breath and dry cough. Epinephrine 0.3mg IM was given due to concern for early anaphylaxis

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1209904	4/14/2021	MI	69	F	4/14/2021	4/14/2021	Pt reported for second dose of Moderna COVID-19 vaccine. Pt stated to vaccination nurse of reaction (shortness of breath, warmth in her lips) following first vaccine Pt denied throat/tongue swelling, and did not require treatment, symptoms/reaction resolved on its own. Pt received second dose vaccine at 3:21 PM and was advised to remain in observation for 30 mins. At 3:30 PM pt reported an onset of "swollen lips and a scratchy throat". This RN assessed pt and noticed slightly swollen and red right upper lip and pt reported her throat felt scratchy. Pt denied any throat or tongue swelling. Pulse ox 97% no difficulty breathing noted. At 3:50 PM pt reported an increase in lip swelling and scratchy throat. 25 mg of Benadryl was administered IM in R deltoid at 3:50 PM. No throat/tongue swelling; no other symptoms of anaphylaxis noted at this time. RN came in at 3:55 PM and took pt vital signs BP: 118/80, O2: 95% Pulse: 82 RR: 20. Pt reported no increase in lip swelling and noted an improvement from throat scratching. At 4:20 PM this RN retook pt vital signs, BP: 120/60, O2: 95%, Pulse: 77, RR: 18. At 4:20 PM pt reported a decrease in lip swelling and a decrease in throat scratching, pt states she is comfortable to go home, husband outside waiting in car and will be with her through the night. Pt advised if symptoms worsen to call EMS. Pt verbalized understanding.
1209849	4/14/2021	NH	27	M	4/14/2021	4/14/2021	Pt developed nausea and dizziness shortly after vaccination. He had a similar reaction with a blood draw in the past. He was noted to be visibly pale. HR 90, SP02 98%, BP 100/60. Pt improved with observation only. No signs to suggest anaphylaxis. Family drove him home.

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1209319	4/14/2021	CA	46	F	4/14/2021	4/14/2021	<p>HPI: Patient reports mild substernal nonradiating, non-positional chest discomfort/pain and dizziness that started 10 minutes after receiving 2nd dose of Pfizer (at 11:30 AM). Denies worsening of pain with upper extremity movement or when presses on it. Reports she has never had these symptoms before and did fine with first dose. Pt denies swelling of the face, throat tightness, difficulty swallowing, itching of the skin, SOB, or CP. Pt denies n/v, HA, changes in vision, slurred speech, n/t/weakness in extremities. Patient reports h/o hypothyroidism, depression, migraines, and duodenitis. She takes Synthroid QD, Effexor QD, Sumatriptan PRN, and unspecified antacid or PPI PRN (no flares > 6 months). H/o facial/body swelling w/ PCN and Vancomycin (last reaction 11/2018 during labor). Denies h/o COVID-19 infection. Exam: GEN: Alert and oriented x 4, in NAD HEAD: NCAT EYES: PERRL, EOMI ENT: Ears normal, Nose normal, OP normal, no evidence of angioedema NECK: Supple, without LAD. CV: RRR, no m/r/g PULM: Clear to auscultation bilaterally, no accessory muscle use ABD: deferred SKIN: vaccine site at left deltoid without edema, erythema, bleeding, or discharge. No rashes, skin warm and dry MSK: FROM, MS 5/5 NEURO: Alert and oriented x 4, CN 2-12 grossly intact, no facial droop, normal speech, NVID, strength 5/5 in bilateral UE, no ataxia, gait steady Clinical Impression/Field Tx: Suspicion for anaphylaxis low due to no face/lips/eye swelling, no SOB or difficulty swallowing, and no rash/itching of the skin. No hemodynamic instability seen as patient?s vital signs were WNL. Patient given water and grape Jolly Rancher sucker at and felt 40-50% better (in regards to chest pain and dizziness) at 12:15 PM. EMS called due to concerns about chest pain and arrived at 12:16 PM. Medications administered: None Disposition: Following over 30 minutes of observation, patient?s symptoms improved. Patient evaluated by EMS in ambulance - EKG and further exam normal. Per EMS, patient left AMA - husband drove her home in their car. Pt was advised to drink plenty of water, eat a substantial meal, and take it easy for the rest of the day. She was also instructed to visit the ER if she felt SOB, swelling of the face/lips/eyes, throat tightness, difficulty swallowing, itching of the skin, vision changes, onset of severe headache, or any other concerning symptoms. Pt indicated understanding of</p>

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							instructions.
1209122	4/14/2021	TX	29	F	4/9/2021	4/10/2021	<p>Provider's Notes for 4-10-2021 visit: 29 y/o F presents to Urgent Care with c/o possible side effects after receiving 1st dose of Pfizer BioNtech COVID-19 vaccine yesterday evening. Reports to feeling pruritis in R arm at time of vaccine administration but this resolved within few minutes. However, pt admits to waking up with headache and R sided body pain. Husband noted erythematous rash behind pt's ear; pt denies warmth, pruritis or tenderness at rash site. Symptoms of generalized body aches and chills have developed in the last few hours (similar to symptoms of cold). Took excedrin with relief to headache and myalgias. Denies recent use of antihistamine but adds that she was prescribed cetirizine and diphenhydramine by PCP for hx of random rashes that occur after being outdoors. Pt also states that she was recently prescribed cyclobenzaprine, meloxicam and norco for R "trapezius" pain. She was referred to physical therapy by specialist recently. Last use of pain medication was 1 week ago. Denies arthralgias, numbness, tingling, rash or pruritis at injection site (does have soreness), fever, sore throat, dysphagia, facial/neck swelling, chest pain, SOB, nausea, vomiting, diarrhea, inner or external ear pain, discharge from ear, rhinorrhea, post nasal drip, persisting headache, hx of anaphylactic reaction to meds or vaccine in past. Adverse reaction to vaccine product Due to acute onset of symptoms after recent vaccine administration (onset within 12hrs), pt's symptoms of myalgias, acute onset rash, chills are likely mild adverse reaction to the recent COVID-19 vaccine. No current signs of anaphylaxis and pt was reassured. She opted to take cetirizine while at clinic. PO or IM steroids will be avoided to reduce risk of suppressing intended immune response to vaccine. May apply topical hydrocortisone or topical benadryl if rash becomes pruritic. RTC if symptoms worsen or persist. ER precautions discussed for acute worsening. Pt and her husband voiced understanding. Start cetirizine 10 mg tablet 1 tablet as needed On examination - erythematous rash See above recs. Cellulitis is low in ddx due to acute onset of symptoms, bilateral distribution, and lack of tenderness. Monitor closely. Muscle pain Can continue acetaminophen or NSAIDs with food as needed. RTC if symptoms worsen or persist.</p>

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1209066	4/14/2021	CT	36	F	4/14/2021	4/14/2021	Patient felt dizzy/faint after receiving first dose of Pfizer covid vaccine. Pharmacist went out to her, she took a few sips of water and vomited into the garbage from the pharmacy. She didn't appear to be having an allergic reaction or signs of anaphylaxis, so no epipen or Benadryl was administered. She stated she never had a reaction to a vaccine before. She felt weak so I stayed with her, asked he if she wanted an ambulance. Patient refuse medical treatment and she just wanted me to call her sister which I did. Patient started to feel better as we waited for her sister.
1208931	4/14/2021		73	U	3/8/2021	3/8/2021	Anaphylaxis; Difficulty breathing; Shortness of breath; Swollen lips, tongue, eyes, or face.
1208923	4/14/2021	PA	49	F	4/9/2021	4/9/2021	I was monitored for 15 minutes after the shot and felt fine, so I left. Within about 5 minutes of leaving Pharmacy, my face became extremely flushed, hot and red. I thought my car was hot, so I turned on the air conditioning, but it didn't subside. No hives or any other reaction. When I got home, I called Pharmacy and was told it could be an allergic reaction and to take Benadryl and monitor for Anaphylaxis (go to ER if that happens). The Benadryl worked and I had no further symptoms. I was perfectly fine by that evening and into the next day.
1199683	4/13/2021		22	M	4/7/2021	4/9/2021	c/o subjective fever, chills, H/A, sweating, rhinorrhea, and nausea since receiving COVID vaccine Wednesday evening around 1800. Symptoms have improved, per pt, but have not subsided completely. Has tylenol and ibuprofen at home but has not taken it. HPI: 22yo AD M presents to ED for above symptoms that began shortly after receiving the J&J COVID vaccine 3 days ago. He has no focal neuro symptoms, no LE swelling, no pleurisy or dyspnea. No URI/LRI symptoms. No rash. L deltoid vaccination site. Pt has generalized malaise after vaccine. No red flags for HA, no acute abdominal symptoms/signs, unlikely PE or DVT, unlikely CVA. Unlikely anaphylaxis. F/u and return precautions discussed. Stable for D/C.

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1199686	4/13/2021		32	M	4/8/2021	4/9/2021	c/o subjective fever, N/V, h/a, chills, and generalized body aches after receiving 2nd dose of Moderna COVID vaccine yesterday AM. HPI: 32yo M presenting to ED for generalized malaise and HA. He received MODERNA COVID #2 vaccine yesterday. HA is not first/worst/max at onset, no chest pain or dyspnea, no focal neuro deficits. Pt has no acute neuro findings- unlikely CVA. Not likely PE/DVT, no evidence of dysrhythmias, unlikely anaphylaxis. F/u and return precautions discussed.
1202467	4/13/2021	NJ	57	F	4/11/2021	4/12/2021	2nd dose - In addition to the flu like symptoms routinely reported I had also had anaphylaxis approx. 24 hours after the shot. It happened between 6-11 pm on 4/12 (the day after receiving the vaccine at 6 pm on 4/11). It did not impact my breathing, but I had itchy welts and hives over most of my trunk and arms and upper legs. I took a Claritin and it helped relieve the symptoms. After the 1st dose on 3/20/2021 I also experienced mild rash like symptoms and hives for several weeks following the vaccine.
1203261	4/13/2021	GA	24	M	4/7/2021	4/7/2021	3 minutes post vaccine with syncopal episode. Diaphoretic and pale and cool to the touch. BP 98/68, 69bpm, 96% RA, No signs of anaphylaxis. Patient awake alert oriented but slow to answer. Given juice po. No hx of DM. Hx of COVID with increasing exertional SOB according to girlfriend not reported before vaccine. Discussed patient history and ongoing VS including O2 sat that falls into the 80s when resting and returns to 90s when reminded to take a deep breath. Discussed with Dr. (Name). EMS called on his advice. Arrived 533pm. Patient refuses to go to the Medical Center. Signed refusal forms and will seek PCP care. Released to girlfriend by EMS.
1202720	4/13/2021	CA	40	F	4/9/2021	4/9/2021	Patient complained of a headache, nausea, clamminess, feeling warm and sweaty. Vitals stable. Laid patient down in Trendelenburg position. Symptoms improved, headache became less severe. Nausea returned when patient sat up. No symptoms of anaphylaxis.

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1203667	4/13/2021	MI	25	F	2/18/2021	2/19/2021	Vomiting, hives, swelling of face lips thoart and closing of airways. Causing anaphylaxis shock, was in hospital 6 different times. Still having sever reactions 3 months after. Still causing airways to close and swelling of lips thoart eyes and neck was admitted to hospital and them not being able to stop the reaction after 4 shots of epi april 11 2021 I was admitted
1202459	4/13/2021	TX	36	F	4/12/2021	4/12/2021	around 15 minutes post-imz, pt reports dizziness and difficulty breathing due to palpitations. sat pt on the floor and gave her cold compress. had epipen readily available but determined difficulty breathing was due to increased HR/anxiety. second rph came into clinic, took pts temp (WNL), blood sugar (was 122) and BP which was 157/103, HR 83. BP concerned pt so she stayed longer, called pts husband so she wouldn't be driving home. we rechecked 15 minutes later and BP check was 168/109, HR 89. pts breathing was rapid and shallow but no facial swelling or other signs of anaphylaxis. pt did not want us to call EMS at this time. another 25 minutes later, BP recheck was 147/104 HR 82. Determined husband would take her to urgent care. Upon helping her get up and out to the car, pt became closer to passing out, she fell limp and started gasping for air. At this time I called EMS and paramedics arrived on scene to assess her further and took her to the ER, Follow up with pt about 2 hours later, she was still in the ER with her BP being monitored
1202134	4/13/2021	CO	52	F	4/3/2021	4/11/2021	MDM: Apparent large localized reaction to moderna vaccine for Covid infection 8 days ago. In review of the literature this has been reported elsewhere. No evidence of cellulitis and no systemic symptoms. At this time would have her treat this locally with some hydrocortisone and ice packing. It is advised that she does receive her second dose as scheduled. No evidence of anaphylaxis.
1201890	4/13/2021	CA	66	M	4/10/2021	4/10/2021	anaphylaxis; treated with an epipen; extreme swelling of tongue and parts of mouth.
1201581	4/13/2021	FL	60	M	4/8/2021	4/8/2021	anaphylaxis requiring intubation, stable after extubation and discharged from hospital intubation required the morning after he got the vaccine at around 11am the previous day

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1200488	4/13/2021	IL	25	M	4/12/2021	4/12/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Medium, Systemic: Allergic: Itch Generalized-Mild, Systemic: Allergic: Swelling of Face / Eyes / Mouth / Tongue-Mild, Systemic: Chest Tightness / Heaviness / Pain-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Tachycardia-Medium, Additional Details: Patient reported a shell fish allergy that produces similar reactions. Patient has not taken Benadryl before and dose not own an Epi-pen.
1203719	4/13/2021	PA	60	F	4/13/2021	4/13/2021	pt states after receiving vaccine about one minute after pt states she felt arm tingling and pins and needles feeling in left arm and metallic taste in mouth, and very anxious pt shaking and was unable to sit still in stretcher, refused wheelchair to observation area and ambulated self without difficulty. pt also very guarded and did not want to talk about health history or meds upon assessment. pt state feeling hot and cold chills as well. pt anxious about previous anaphylaxis had in past with darvocet. denies feeling symptoms of anaphylaxis, site of injection healthy no observed hives or redness in area. vs as noted, pt feeling better and wanting to be sent home pt ambulated to exit with husband at 1438 vs: 1410 bp123/81 hr 84 rr 18 o2 97 1415 bp 140/96 rr 18 hr 78 o2 98 1420 bp 137/80 hr 80 rr 18 o298 1425 131/89 hr 80 rr 18 o2 99

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1203716	4/13/2021	MA	38	F	4/7/2021	4/8/2021	<p>Situation Patient called the COVID-19 Nurse Hotline with post-dose vaccine related symptoms/guidance. Pt called PCP office after hearing several news regarding J & J Vaccine/side effects. Pt was advised to call Nurse Hotline. Noted from pt's PCP notes from today 4/13/21: "has some anxiety at baseline." Background Patient received her J & J on 3/7/21 on the left arm. Number of days post vaccine (today's date minus vaccine date): 6 Initial reaction was noted on : 1 day post vaccine: 3/8/21 around 8 or 9 am. Symptom Screening c/o Bilateral leg "achiness." Pt rated pain 5 out of 10 on the pain scale. Pt denies any hives, itchiness, wheezing, swollen lips, tongue, eyes, difficulty breathing. Chest tightness/pain. Denies any swelling, redness, or itchiness to the both injection sites and to BLE. Pt denies numbness and tingling on the bilateral toes. Pt denies bilateral calf pain. Pt was able to ambulate without any difficulties. Medication: Pt took one dose of OTC Aleve at 5pm at 3/8 with a good effect. Pt back to baseline until today. Pt denies any unusual changes. No distress noted. ALLERGIC Reaction Did potential immediate allergic reaction (less than 4 hours after receiving vaccine) or anaphylaxis to first dose of the COVID vaccine occur? No Within 24 hours of vaccine administration, did patient experience symptoms of a severe allergic reaction? No Assessment/Action Patient experienced a MOD reaction to the vaccine. Symptom relieved with over the counter medications. Patient answered NO to any of the Allergic Reaction questions. Patient referred to allergy:Yes Placed a referral for now for the further evaluation if needed VAERS Complete: Yes Patient experiencing any COVID-19 Symptoms AND >3 days post vaccine? No Response/Recommendation . Teaching -Provided education to patients as appropriate to the patient's clinical presentation. -Provided home remedies/OTC medication use. -Educated the reasons to call the Nurse hotline, PCP office and the reasons go to the nearest ED if symptoms change or worsen. - Informed to make sure to call in advance if seeking medical care so sites can be prepared to receive the case. Good verbal return and agreed with the plan.</p>

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1200629	4/13/2021	ME	71	F	4/3/2021	4/3/2021	Allergic reaction with mild-mod facial flushing, tongue tingling, no anaphylaxis Diphenhydramine given, no epinephrine, sent to ED, reaction resolved, pt reported similar reaction for for 1st dose
1205686	4/13/2021	PA	26	M	4/13/2021	4/13/2021	Patient noted on form that he had a severe reaction to peanuts which causes him to have anaphylaxis. He stated that he does carry an EpiPen and any time anything with peanuts touches his mouth/lips he immediately notices his throat starting to close. He also is allergic to cats. Before administering the vaccine, the patient noted that he does not like needles and was not going to look. I administered the vaccine and the patient and I exited the vaccination room. I explained that he should sit in the waiting area for about 30 minutes due to his severe allergic reaction in the past. By the time that I walked back into the pharmacy, the patient's wife shouted "He's not breathing!". My technicians called 911 while I grabbed an EpiPen and rushed to the patient. I immediately administered a 0.3 mg dose of epinephrine and observed that the patient had passed out, was not breathing, but had a pulse. A few seconds later he regained consciousness and his breathing was erratic. I gave him water and he stated that he felt very lightheaded and dizzy. I instructed him to remain seated. He also noted that his vision was blurry and he saw a black dot. His wife was fanning him to cool him down while I tried to obtain the patient's blood pressure, but could not get a reading. The paramedics came and evaluated him thoroughly. His blood pressure, heart rate, EKG, and blood sugar were all within normal limits. They determined that the syncope was most likely due to the patient not eating during the day and not liking needles. The patient was feeling much better and declined further medical treatment, including going to the hospital. He was instructed to go home and relax.
1203472	4/13/2021	CA	44	F	2/6/2021	2/6/2021	ANAPHYLAXIS; SWELLING OF FACE

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1203763	4/13/2021	ID	42	F	4/9/2021	4/9/2021	Prior Hx of anaphylaxis. Tingly feeling bilateral of face/jaw described as moving up and down. Patient visibly anxious before and after vaccine administration. Vital Signs: BP 151/121 HR 93 Resp 18 O2Sat 94 Skin Signs: Other - flush A/Ox4 Circulation: Cap refill <2sec Respiratory: Diminished bilateral Initial Treatment: Observation. Family doctor: Dr. (local) 1:19 PM Vital Signs: BP 136/90 HR 98 Resp 12 O2sat 96 Skin Signs: Other - flush, dry Circulation: Cap refill <2sec Respiratory: Breath sound clear bilaterally Follow up Treatment: Continue observation. Patient visibly more calm. Hx of hives with influenza vaccine. A/Ox4. No obvious distress, No increased resp effort. Advised patient to have discussion with family doctor before second dose. Tingling reduced by 1:28 PM. 1:31 PM Vital Signs: BP 132/102 HR 88 Resp 12 O2Sat 96 Skin Signs: Warm and dry Respiratory: Breath sound clear bilaterally Follow up Treatment: 'Tingly' feeling moved to lower jaw and decreased in intensity at 1:34 PM. Notes: 1:43 PM call placed to Dr. - Related patients vitals to RN. 1:48 PM patient denies 'tingly' feeling. No SOB or difficulty swallowing. Stated she feels 'normal again'. Disposition: Home with husband at 1:57 PM.
1206005	4/13/2021	PA	24	F	1/25/2021	1/25/2021	24 yo female who presents to the ED for concern for anaphylaxis after receiving her second dose of the COVID-19 vaccine. Patients presents as a rapid response after receiving Epi pen to her thigh at 11:18AM. She reports that after getting the vaccine, she was sitting in the monitoring area. At the 10 min mark she noted that she had a slight cough and some eye tearing. She went to the bathroom and noticed that her eyes were swollen and she could barely open them. Someone told her that her lip looked swollen but she did not look at it in the bathroom. She also felt some throat tightness but no wheezing. She had nausea prior to vaccine, no vomiting. She had no lightheadedness or palpitations and no itching or rash anywhere. She got an EpiPen at 11:18AM. A rapid response was called and she was brought to the ED. She has no personal or family history of allergic reactions and no known allergies.

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1205379	4/13/2021	FL	60	F	4/13/2021	4/13/2021	Administration was administered at the correct location. When observing the administration site, there was a small lump with bruising around the injection area. The patient did state when I followed up on the phone an hour after administration that the lump is still there with bruising. Pt did state there is no pain or irritation. Pt has stated no issues with breathing, or anaphylaxis type reactions.

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1205290	4/13/2021		29	F	3/29/2021	4/5/2021	<p>Patient is a 29 y/o F w no sig past medical history who now presents with a maculopapular rash around her injection site 1 week after Moderna mRNA covid vaccine that then spread to her trunk/chest. Initially pt was advised to pretreat before her second dose, but a web-based consult was done in the interim with the following advice: This doesn't appear to be an immediate type allergic reaction. Benadryl would not be expected to prevent a reaction. I do have some concern about a second dose having the potential to induce a much more intense reaction. This one is very atypical but doesn't appear to be insignificant. Unless the patient has very significant risk factors for a severe case of COVID, I would refrain from a second dose. There is nothing wrong in continuing cetirizine if it helps with current itching. A second opinion on the web-based eConsult service yielded the following: Having a delayed reaction is not a contraindication toward getting the 2nd dose. However, I see 1 vesicular/bullous lesion on her rash, which is concerning as the next dose may develop into bullous dermatitis or SJS. In this case, I would definitely encourage patient getting the J&J vaccine given that patient had reaction towards mRNA one. If patient does get the 2nd dose of mRNA vaccine, I would recommend it on the other arm. I would tell her to start taking cetirizine 1 tablet twice daily for 1-2 weeks, and I would also prescribe her topical Triamcinolone twice daily to put on when rash erupts. Having anaphylaxis would be unlikely, but I would still prescribe her an epinephrine autoinjector to be on the cautious side since some people have mixed drug reactions (both type 1 and type 4). I would wait until her symptoms fully resolve before she gets the J&J vaccine. Given that she had a reaction to a prior COVID vaccine, I would prescribe epipen just in case even if she gets J&J. Again, highly unlikely she would react with anaphylaxis but it's always good to be safe. will send pt epipen and give counseling as above. Allergist #1 response: I think above is reasonable. Reasonable regarding giving J&J. I would not give second dose of Moderna.</p>

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1205076	4/13/2021	CT	32	F	4/11/2021	4/12/2021	Rash and itching developed within 10 minutes; administered oral Benadryl. Anaphylaxis at 45 minutes; administered 1 EpiPen at 45 minutes, 1 EpiPen at 50 minutes. Anaphylaxis subsided until 2 hours post-vaccination; administered an additional 2 EpiPens and an additional dose of oral Benadryl. Anaphylaxis did not return. Rash and itching were gone by hour 6 post-vaccine. Fever, chills, sore throat, anorexia, and lethargy developed 12-16 hours post-vaccine. Changes in sense of taste and smell developed 36 hours post-vaccine (could be related to seasonal allergies).
1204565	4/13/2021	CA	22	F	4/13/2021	4/13/2021	22 yo female without pmh, presented to USC vaccine site for 2nd dose of Moderna covid vaccine today. She arrived with boyfriend feeling well. Shortly after administration of vaccine, pt felt lightheaded and nauseated and passed out. Syncope was witnessed by medical staff. Pt was sitting in chair at the time and lowered carefully to the ground in supine position with legs elevated. She responded to name and sternal rub within seconds. Now feels sleepy. Denies SOB, CP, HA, numbness/tingling, pruritus or rash, abd pain. Nausea improving. No hx of syncopal reaction to vaccines or other. Denies being pregnant, not on menses. No meds pta. Vitals BP 110/70, HR 59bpm, RR 14, SpO2 100% ra, no thermometer available Heart and lung sounds normal, oropharynx benign, abd non-tender, no obvious rash or swelling or angioedema. No signs of anaphylaxis. Appears vasovagal. Within minutes, pt improving, skin color returning to normal. Able to respond verbally with understanding. A&Ox4. Sxs improved. Monitored full 30 minutes. Able to go home with boyfriend, educated on precautions, recommended rest and hydration.
1204562	4/13/2021		65	F	4/13/2021	4/13/2021	Patient stated that "I feel funny. I feel shaky and my fingers are all tingly." Pt's vitals were taken and they were stable, pt was observed for 30 more minutes and was educated on the signs and symptoms of anaphylaxis and the symptoms happen. Upon discharge from the clinic, the pt stated that she was feeling better.

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1204466	4/13/2021	CO	31	F	4/12/2021	4/12/2021	Pfizer-BioNTech COVID-19 Vaccine EUA: soon after vaccination patient reported throat itching. Paramedic administered oral diphenhydramine twice at vaccination site. Patient then reported chest pain, shortness of breath, urticaria, and increased throat scratching. Paramedics administered epinephrine twice and methylprednisolone and transported to emergency department (ED). On arrival to the ED patient still reported chest tightness, numbness, and was tachycardic (pulse 122 beats per minute), tachypneic (26 breaths per minute), and hypertensive (blood pressure 139/85). In the ED patient experienced more difficulty breathing and epinephrine continuous infusion was started. Laryngoscopy did not document evidence of airway compromise. Patient diagnosed with possible anaphylaxis and admitted (currently still hospitalized).
1204144	4/13/2021	CO	21	F	4/13/2021	4/13/2021	Patient in clinic to receive first dose of COVID-19 Vaccine. Per vaccinator patient oriented/alert, behaving and talking normally prior to vaccine administration. Pfizer dose administered in left deltoid, patient completed 30 minute observation period due to her medical history and previous allergic reactions (swelling after pain medication at dentist, anaphylaxis with carbonated drink and tuna). Per patient's report: was getting in to her vehicle ready to leave and vision in right eye became blurry, came back to clinic. Patient reports this is not the first time the blurred vision has occurred, reports blurry vision to right eye occurs anytime she is stressed or tired and typically lasts about 20 minutes.

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1203823	4/13/2021	MN	38	F	4/13/2021	4/13/2021	Suspected anaphylaxis: Client vaccinated at 10:48am. Sat in wait room area for brief time, then out to car in parking lot. Client experienced dry mouth, raspy voice, cough & continued clearing of throat. Sat and drank water in car for 40 minutes. Came back into clinic at 11:35 to report symptoms. No SOB noted; regular respirations; mild anxiety noted. VS @ 1143am: BP 138/98, P 68, R 16. Client continually observed. No improvement in dry mouth, raspy voice, cough & continued clearing of throat. Client continually observed. EMS called at 1210p for further assessment of possible anaphylaxis. VS @ 1215p: BP 150/100, P 70, R 18. EMS arrived and recommended transport to local ED for further assessment. Client transported at 1225pm from clinic.
1204916	4/13/2021	CA	61	F	4/13/2021	4/13/2021	Patient developed chest pain, palpitations, SOB and "feeling like throat closing" approximately 10 minutes after receiving vaccine. Hx of anaphylaxis from penicillin and cipro. Pt was given oxygen via non rebreather mask, EpiPen and transported to ED via paramedics.

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1206044	4/13/2021	WA	39	F	4/13/2021	4/13/2021	39 y.o. female with history of asthma but no previous anaphylaxis to vaccines received covid-19 vaccine (Moderna) at 4:15pm today and within a few minutes developed tachycardia, nausea and vomiting. No shortness of breath, no wheezing, speaking in full sentences. No chest pain. She has a history of asthma and hives to terbutaline, and anxiety reaction to gabapentin. No history of intubation or serious reaction from asthma. Transferred to the procedure room by RN with my assistance. Blood pressure 132/82, pulse of 135, O2 sat 100% on RA, speaking full sentences, stating she had some chills, lungs clear, tachycardic, and moving air well, no wheezing. Patient stated said she had to the bathroom right away, was going to have diarrhea. Said she could walk, and was walked across hall with assistance to bathroom, where I stayed with patient. I accompanied patient to bathroom, she had one episode of diarrhea, and dry heaving, returned to procedure room, lied supine, IV started, NS bag hung. RN present, additional ARNP present, staff aware, anaphylaxis kit present. Patient tachycardic and continued with normal O2 sat and good air movement, EMS with request for ALS activated due to reaction to vaccine. I made decision to give epinephrine with her tachycardia and continued nausea with diagnosis of anaphylaxis, and as preparing epinephrine, patient stated she started to feel tight in chest, epinephrine given 0.3mg of 1:1000 IM. Lungs notable for reduced air movement lung bases. Patient denied throat tightening, rash, lip swelling, but she continued to have dry heaves, and stated she had a "sore throat". EMS had already been activated before first epinephrine dose. Awaiting medics, patient given Solumedrol 125mg IV, benadryl 50mg IV, and zofran 4mg IV. Patient also given four puffs of albuterol MDI with spacer. Medics arrived, patient still feeling tight in chest, blood pressure 125/70, O2 sat 100%, lungs still tight with reduced air movement. Patient given second dose of epinephrine 0.3mg, 1:1000 IM, approximately 7-8 min after the first dose. EMS transferred patient to gurney with transport to PEMC. Patient alert during entire reaction. PEMC notified. To ED via ALS. PEMC notified. Timeline of anaphylactic reaction: 1615: Covid Moderna 2nd injection given. RN notified of patient feeling rapid heart rate and nausea. Patient pulled back to procedure room. 1631: Vitals: BP 132/82, HR 135,

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							Temp 97.1, O2 sat 100% 1637: IV start in LAC, NS running 1645: 0.3 mg IM Epi - administered by RN 1648: 4 mg IV Zofran - administered by ARNP 1650: 4 puff Albuterol sulfate 90 mcg given via spacer - administered by MD 1651: 50 mg IV Benadryl - administered by ARNP 1652: 125 mg IV Solumedrol - administered by ARNP 1653: 0.3 mg IM Epi - administered by RN
1203928	4/13/2021	PA	44	F	3/31/2021	3/31/2021	Note that this patient is an employee of the facility where the vaccine was administered. Five minutes after injection on 3/31/2021, c/o chest tightness followed by nausea and heaving. Treated for anaphylaxis, transferred by ambulance to Medical Center; and discharged to home later that afternoon. The employee worked her regular schedule 4/2/21 and 4/5/21 with no stated complaints. On 4/6/21, received notification from the Employee that she was to be off work through 4/12/21 as her physician feels that the vaccine has damaged her heart. She states she has a heart rate down to 38 BPM, experiences black outs, has left sided head pain and weakness. Her personal physician is scheduling her for Holter Monitor and Echocardiogram. Her physician has now stated she cannot work through 4/16/21. I have no supporting written documentation from the physician for these medical concerns.
1196110	4/12/2021	GA	36	M	4/7/2021	4/7/2021	Patient received first dose at the Vaccine Drive-Through. Patient appeared curious and asked multiple questions regarding the vaccine. However, the decision was made by the patient to proceed to receive the first dose of Pfizer vaccine. Patient received vaccine at approximately 02:00 pm. Shortly after administration of the vaccine and while in the reaction waiting area, he experienced ?dizziness and difficulty breathing? and requested assistance. Onsite medics state patient leaned his head back and his eyes rolled back in his head. No sign of swelling, itchy, or rash. Vital signs were within normal limit. Paramedic was immediately called at 02:08 pm. EMS arrived at 02:15 pm and departed at 02:20 pm. Paramedics transported non-emergent patient to ED. ED DX: vasovagal syncope; no signs of anaphylaxis or severe vaccine reaction. Patient released from emergency department at 03:15 pm with without activity restrictions.

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1197352	4/12/2021	MA	17	F	4/5/2021	4/5/2021	Reportedly had some redness and blotchiness at the time but currently no signs of anaphylaxis with no urticaria, no respiratory involvement, no intraoral swelling or voice changes, no GI symptoms. He is warm and well-perfused although is slightly tachycardic but appears anxious. His reported inability to move her arms and legs does not seem consistent with a neurologic etiology of this complaint and more likely consistent with anxiety/conversion reaction in the setting of a vasovagal episode. Will give zyrtec at mother and patient's request, PO challenge and reassess.
1196824	4/12/2021	FL	66	F	3/30/2021	3/30/2021	When I checked into Walgreens I was asked if I had had any reaction to any vaccines. I said no. This was my first shot. I am scheduled for the 2nd shot on the 27th of April. I was not asked if I had had a severe allergic reaction to anything else. I had my shot, not monitored. Just called the next patient in, and I walked out the door to drive home. Within ten minutes, I started having tingling on the top of my ears, cheeks, inside my mouth, top of my head and down the back of my neck. I was itchy all over. My head, back of my neck, arms, all over. I have had an anaphylaxis reaction to bee stings and fire ants many years ago, so I recognized the feeling. I drove home and took some over the counter allergy medicine and laid down. I did not have trouble breathing, but the tingling lasted for a few hours.
1196716	4/12/2021		28	F	4/10/2021	4/10/2021	dyskinesia and anaphylaxis
1196702	4/12/2021	IN	28	F	3/18/2021	3/18/2021	dyskinesia and anaphylaxis

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1196385	4/12/2021		61	F	4/7/2021	4/7/2021	Received vaccine on 04/07/2021 at 07:47 AM; Presented at ED on 4/08/2021 at 8:29 am and received prednisone 60 mg and diphenhydramine HCl 50 mg; chest tightness and throat swelling that began yesterday afternoon. She explains that she has h/o anaphylaxis to flu vaccine. She got the first dose of Covid19 vaccine yesterday, she did premedicate with benadryl. She was monitored on site for an hour and felt some left neck pain and jolt of pain down left arm, but it resolved and she went home. Shortly after, she began feeling like she was having asthma attack, wheezing, chest pressure and throat swelling. She used inhaler and took benadryl. Last dose of benadryl at midnight, took Zyrtec D at 7am this morning, last nebulizer and symbicort at 6:30am. She states she still feels chest tightness and throat swelling. She feels like her tongue was very swollen but improved after benadryl. States her voice is different. Feels a little harder to swallow but she is able to drink fluids. She took pantoprazole this morning. States this does not feel like her usual asthma. Rates chest tightness a 4/10 on pain scale, states it feels like something is sitting on chest or squeezing chest. States it does feel a little better in anterior chest now, but she feels it on lateral lower chest still. Denies h/o cardiac issues. Denies h/o MI. No jaw or arm pain at this time. Discharged from ED at 9:27 am and reported to ED at 10:03am on 4/08/2021. Received famotidine 20 mg and discharged home at 1206pm on 4/08/2021 with prednisone, Pepcid, EpiPen

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1195524	4/12/2021	WI	51	F	4/10/2021	4/10/2021	Anaphylaxis reaction which began immediately upon injection at 2:45Pm (roughly) into arm with wide spread hives covering the entire right arm and spread to left arm right leg. Head and neck, face became numb and I felt like I was going to pass out. Neck numbness/swelling moved to front of neck within five minutes. Itching of left leg. Was able to maintain consciousness but was very out of it. Possibly from lack of oxygen when neck and head swelled. Began to lose ability to recite address or remember address by the time was placed in paramedic van. Paramedic put IV in hand. Paramedics administered ephedrine, Benadryl, prednisone and reaction subsided. Was taken directly to hospital arrived there for monitoring by 3:15 Pm . Felt much better at hospital. Had one wave/head rush where it felt like the reaction was starting again and may pass out but that subsided and they continued to monitor. Had a few waves of nausea which did not last long. The IV placed in hand by paramedic was infiltrated so attempts at giving fluids failed and it was never corrected at hospital. After 2 hours of monitoring I was told to go home and given a prescription for steroids. I was asked to monitor for the remainder of the night for any trouble breathing. Night sleep was not good waking often with one occasion of wheezing which subsided after taking Benadryl. Continue to monitor.

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1197486	4/12/2021		54	U			ANAPHYLAXIS; COVID LIKE SYMPTOMS; FLAT OUT; This spontaneous report received from a patient via a company representative concerned a 54 year old of unspecified sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. It was reported that the health care professional (HCP) did the stress full immunity after three four weeks with vaccine. They caught anaphylaxis quickly. The patient was expecting to have a reaction as the patient was vaccine sensitive. It took about 8 minutes post jab. The HCP was on it very quickly, but it was severe. The patient clarified that it was full anaphylaxis. On an unspecified date the patient was flat out. The patient might have been exposed to emergency room (ER). The patient was having COVID like symptoms so would get a test on Monday. The patient was still recovering. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from anaphylaxis, flat out, and COVID like symptoms. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: 20210409239-JANSSEN COVID-19 VACCINE Ad26.COV2.S-Anaphylaxis. This event is considered related. The event has a compatible/suggestive temporal relationship, is unlabeled, and is scientifically plausible. There are no other factors more likely to be associated with the event than the drug.
1198690	4/12/2021	RI	19	M	4/10/2021	4/10/2021	Anaphylaxis. Turned gray, diaphoretic, blurred vision, difficulty hearing. Blood pressure quickly dropped to 66/31. Perfusion was 5 seconds. Received EpiPen (0.3mg Epinephrine) x1. BP better but slow to return to baseline. To Emergency Room for 4 hours observation. While in ED, received IV Benadryl and IV Zofran. Condition improved by the end of 4 hour observation so discharged with an EpiPen.

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1196657	4/12/2021		47	F	4/9/2021	4/9/2021	<p>~~1423 History of present illness-patient is a 47-year-old female with a significant past medical history presenting to the emergency department with large reaction. Patient received the Pfizer colored vaccination approximately 45 minutes prior to ED arrival. Patient had hives, throat swelling. EpiPen and Benadryl were administered. Patient has had significant improvement in her symptoms. Currently note throat swelling or shortness of breath. Hives markedly improved. [SM] 1425 Medical decision making-47-year-old female presenting to the emergency department with allergic reaction. Likely anaphylaxis given airway involvement. Covid vaccination was likely trigger. Will administer Pepcid and prednisone. [SM] 1426 Patient has been improving throughout the 2-hour ED stay. Will discharge with prescription for prednisone as well as EpiPen. Patient instructed to follow-up with PMD. She expresses a full understanding of the plan and is amenable to it. Strict return precautions given. All questions answered. ~~</p>

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1197645	4/12/2021	CA	25	F	4/10/2021	4/10/2021	<p>HPI: Patient is a * year old * who presents following administration of a single dose of J&J COVID19 vaccine in the left deltoid. Patient states she started to experience ocular burning and tearing about 20 minutes following administration of the vaccine. She denies ocular pain. Patient denies wearing contacts, eye makeup, and face products at this time. She relates that she spent most of her day outside in the sun today but has never experienced these symptoms in the past. She reports an allergy to amoxicillin and numerous food sensitivities. She has never required epinephrine for treatment of aforementioned allergies. She denies a history of seasonal allergies. She relates that she has a past medical history of PCOS. She does not take medication on a daily basis. She denies chest pain, difficulty breathing, swelling of the face/lips/tongue/throat, skin rash/itching, cramping abdominal pain, nausea, and vomiting. Exam (update as needed): GEN: Alert and oriented x 4, NAD. HEAD: NCAT EYES: Conjunctival injection bilaterally. Tearing noted in the bilateral eyes. No purulence noted. No foreign body noted. Surrounding tissue nonedematous. Visual acuity grossly intact. PERRL, EOMI ENT: Ears normal, Nose normal, OP normal, no evidence of angioedema NECK: Supple, without LAD. CV: RRR, no m/r/g PULM: Clear to auscultation bilaterally, no accessory muscle use ABD: Soft, no tenderness. SKIN: No rashes, skin warm and dry. No erythema or edema of the injection site. MSK: FROM, MS 5/5 NEURO: Alert and oriented x 4, CN 2-12 grossly intact, no ataxia, gait steady Clinical Impression/Field Tx: Possible allergic conjunctivitis, bilateral eyes. Patient not displaying active signs or symptoms of anaphylaxis, to include facial edema and patient demonstrated ability to control airway. No foreign body was noted in the orbi to explain symptomst, nor was purulence noted, thus decreasing likelihood of infection origin. Visual acuity was not compromised at the time of exam. Conjunctival injection and epiphora, in addition to consistent sun and wind exposure, makes an allergic conjunctivitis more likely. Instructed patient to consult their PCP or follow up with urgent care regarding the post-vaccination reaction. Also instructed patient to consult an ophthalmologist if they are able to should the eye symptoms not improve. Recommended patient utilize visine or other normal saline eye drops for burning</p>

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							sensation relief, in addition to OTC antihistamine medication per package directions.. Patient instructed to go to emergency department should they develop chest pain, difficulty breathing, swelling of the face/lips/mouth/tongue/throat, or cramping abdominal pain with nausea/vomiting, as these are signs of possible anaphylaxis that requires immediate intervention. Medications administered: None Disposition: Home
1197931	4/12/2021	AZ	27	F	4/5/2021	4/5/2021	Anaphylaxis approx. 5 minutes after injection, recieved Epi Pen injection, Benadryl injection, rescue inhaler used, symptoms resolved after 5-10 minutes
1198068	4/12/2021	IN	23	M	4/12/2021	4/12/2021	The patient reported feeling like his throat was closing up 15 minutes after receiving the vaccine. Reports he has h/o anaphylaxis to oysters in past 4 different times with h/o anaphylaxis. Pt refused epi-pen multiple times. He asked for oral medication. Reviewed risks/benefits. Vitals were stable with BP 150/84, Pulse-99, O2-97%. Pt without any swelling, SOB, chest pain, no rash, no tongue or lip swelling, no respiratory distress. He was given 25 mg Benadryl per pt request - reviewed risks. States that it was helping. Was taken by EMS to hospital via ambulance - pt was able to walk with them without issues. Was taken for observation.
1198445	4/12/2021	WI	74	M	3/30/2021	4/9/2021	He tested positive for COVID-19 on April 7 2021. He qualified for monoclonal antibody therapy and presented for that therapy 4/9/2021. After starting the infusion he developed sudden onset shortness of breath. He is noted to be wheezing. He was given Solu-Medrol and benadryl prior to transfer to ED. Acute hypoxic respiratory failure in patient with recent Covid diagnosis with sudden worsening during monoclonal antibody infusion. Differential includes allergic reaction/anaphylaxis, flash pulmonary edema, worsening Covid. Given the wheezing he was given a DuoNeb with no significant improvement but may be slightly decreased wheezing. Patient was placed on BiPAP given concern for pulmonary edema and increased work of breathing. We were able to titrate down the FiO2 to 40%. He was transitioned to high flow nasal cannula. Will admit to the hospital for further supportive cares given Covid and hypoxic respiratory failure.

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1198675	4/12/2021	NC	17	F	4/12/2021	4/12/2021	Anaphylaxis (hives, oropharyngeal swelling, cough, shortness of breath) 20 mins following vaccine administration. Patient given epinephrine at vaccine site 20min after symptom onset with significant improvement in symptoms including improved pharyngeal swelling and resolution of hives. Patient presented to the emergency department 1.5 hours following onset of anaphylaxis with mild cough and mild pharyngeal swelling for observation.
1198812	4/12/2021	CT	43	F	4/12/2021	4/12/2021	Anaphylaxis, acute respiratory distress, mild tongue edema
1198855	4/12/2021	TN	29	F	4/12/2021	4/12/2021	Patient states at 10 min mark post vaccination (around 17:15 PM) that she developed sweats/clammy, some lightheadedness while waiting her 15 minutes in the lobby post vaccination injection. There was no rash, throat swelling, dysphagia, drooling, angioedema, rashes, etc in clinic. Vitals were taken in clinic which were WNL (O2 -98%, RR-16, temp- 98.6, BP - 100/60 (this is Normal for her), and HR -74). Patient states this has happened to her previously receiving injections and has had vagal responses. A cold pack was given to patient to place on head and Patient was monitored for an additional 20 minutes in exam room/clinic without complication. No epi/Benadryl was given/needed and I felt patient was stable/safe for discharge home. No signs of anaphylaxis. However, strict ED precautions given to patient. Patient was in right mind state and capable of making proper decision making.
1199345	4/12/2021	CA	35	F	4/10/2021	4/10/2021	35 y/o reservist on drill weekend presents to ED 40 mins after receiving 2nd dose of moderna SARS-CoV-2 vaccination with c/o redness of upper r forehead and mild sensation of tightness in her throat, face and tongue itchy and tingly. No prior vax reactions or h/o anaphylaxis. Pt was given 50mg benadryl which resolved her Sx within 20 min. No e/o anaphylaxis was noted but given pt's complaints of tightening throat she was observed for 4 hrs in ED. She had no worsening of sx over this time.
1199488	4/12/2021	MA	30	F	4/12/2021	4/12/2021	Mild anaphylaxis

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1198621	4/12/2021		39	F	4/9/2021	4/9/2021	Patient arrived after 3 minutes c/o dizziness. VS = 113/79, HR - 86, RA 100. Pt fully examined s/s of stroke or anaphylaxis, patient observed for another 5 minutes and began c/o itching to neck and throat. Pt developed a cough. O2 sat remain 100% RA. Pt accompanied to ER by RN.
1193580	4/11/2021		42	F	2/24/2021	2/24/2021	7 125/97 108, 98% 20 RR. 1630 136/91 108 24 98% 1628 911 arrived. 1634 Discharged to ER. Patient fiance made aware per patient request. ,Patient arrived to observation with NKDA, no history of hives or anaphylaxis. Placed on 15 minute observation. AtVasovagal response
1195021	4/11/2021	TX	39	F	3/22/2021	3/22/2021	Pt received shot at 1626. At 1637, pt reported that her lower lip felt itchy, cheeks were red. Pt has hx anaphylaxis to multiple food allergies and carries epi pen with her. At 1638, VS: BP 168/112, P 86, O2 100% RA.Lungs clear bilaterally. Pt then reported that her tongue felt ?numb? and ?pins and needles? sensations. Recheck BP is 200/130 at 1644. Pt is awake, alert, oriented. She states that when she has anaphylaxis in the past, this is how it initially presents. Dr called at 1645 and notified of pt condition and advises to give epi and benadryl and call ems. EMS called at 1650 by RN. Pt requested to wait until EMS is closer to take epi as she said that it can make her blood pressure raise. At 1653, pt willing to take epi. Pt?s seat reclined. Epi pen 0.3mg given at 1653, Benadryl 50mg liquid given at 1654 by RN. EMS on site to take over care at 1655. Pt remains A&OX4 at this time. No difficulty breathing at this time. Pt remains fully conscious. Pt transferred to hospital in EMS. Pt notified that due to her having anaphylactic reaction to vaccine, she will not be able to receive another vaccine. Pt advised to follow up with PCP.

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1194231	4/11/2021			F			Tingling in her throat; mild swelling in the face; This is a spontaneous report from a contactable pharmacist. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration on an unspecified date (Batch/Lot Number: Unknown) as single dose for covid-19 immunisation. Medical history included ongoing skin itching. Concomitant medication included loratadine (CLARITINE) taken for skin itching, start and stop date were not reported. The patient received the vaccine first dose in morning and in the afternoon reported mild swelling in the face and tingling in her throat on an unspecified date. She happened to go to the dentist that afternoon. The dentist referred patient to local ER. By time she got to the ER and had the examination the doctor did not notice any anaphylaxis reaction, no bradycardia symptoms so he sent her home and gave her Benadryl and after that was fine. Reporter's concern is with second dose of Pfizer-BioNTech COVID-19 Vaccine the doctor is concerned about possible anaphylaxis that has been reported. The patient recovered from the events on an unspecified date. Information on the lot/batch number has been requested.; Sender's Comments: The reported pharyngeal paraesthesia and swelling face were likely causally related to the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), due to plausible temporal relationship, and the clinical course of the events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.
1193816	4/11/2021	KS	52	F	4/10/2021	4/10/2021	Systemic: Allergic: Anaphylaxis-Severe

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1193096	4/11/2021	GA	23	F	4/7/2021	4/7/2021	Within 30 seconds of the injection of my second dose of Moderna, I experienced extreme nausea unlike any that I have experienced before. Within 1 minute of the injection, my face, arms, chest, and neck flushed and I turned completely red. I felt hot and started to sweat. At the same time, I began having trouble breathing with the sensation that my throat was beginning to close. My eyes filled with tears and I was not able to talk to communicate what was happening. My mom, who was with me at the time of vaccination, asked the administering pharmacist if I could remove my mask because I was having trouble breathing. Throughout this reaction, the pharmacist froze and was visibly in shock of what was happening. Because of this, my mom began asking me questions to figure out what else I was experiencing. Once I was able to remove the mask and breathe deeply, the reaction subsided after two minutes. The pharmacist, after my reaction began to subside, stated that they had an epipen ready to administer if needed. I was never administered the epipen. The pharmacist asked me to wait 30 minutes instead of the general 15 minutes before leaving the site. Because the symptoms went away and did not return within the 30 minutes, I left the site. After the vaccination, I experienced a low-grade fever for 79 hours, chills, a headache, muscle aches, and extreme fatigue. After realizing my reaction was not considered ?normal,? I began to research and realized these symptoms align with anaphylaxis, even though they subsided quickly after experiencing them.
1192928	4/11/2021	IL	36	F	4/9/2021	4/9/2021	Site: Pain at Injection Site-Mild, Systemic: Allergic: Anaphylaxis-Mild, Systemic: Chest Tightness / Heaviness / Pain-Mild, Systemic: Dizziness / Lightheadness-Mild
1189958	4/10/2021	TN	50	F	4/10/2021	4/10/2021	Patient is complaining of ringing in her ears since vaccine and tightness in her throat (not anaphylaxis type tightness)

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1192543	4/10/2021	MO	28	F	4/10/2021	4/10/2021	Patient received second dose of Pfizer-BioNtech Covid-19 vaccine today and after 5-7 minutes reported to a pharmacy technician she was feeling nauseous. Patient wanted to keep her head down because she experienced light sensitivity; I placed cold compresses on her neck. Patient worsened over the next 10 minutes, complaining of feeling dizzy, anxious, intense headache. At this time, 15 minutes after being vaccinated, I (the vaccinating pharmacist) moved the patient to a private booth to have her lie down on the floor with her feet elevated. The patient was able to communicate the entire time and called her relatives to come pick her up from work. Emergency services were called as the patient was not experiencing anaphylaxis, but was increasingly more anxious and was afraid she'd fall or faint. Emergency medical services arrived after the patient had been laying down with feet elevated for almost 30 minutes. Patient did not complain of trouble breathing but did request use of her inhaler. Patient did not state on her patient questionnaire and consent form that she has asthma; she mentioned this during her episode. Patient was taking to a local hospital.

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1188844	4/10/2021			U			Signs of early anaphylaxis; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a physician assistant and describes the occurrence of ANAPHYLACTIC REACTION (Signs of early anaphylaxis) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included No adverse event (No reported medical history). On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced ANAPHYLACTIC REACTION (Signs of early anaphylaxis) (seriousness criterion medically significant). At the time of the report, ANAPHYLACTIC REACTION (Signs of early anaphylaxis) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported treatment information was not provided by reporter Very limited information regarding this event has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.
1189558	4/10/2021	CA	45	F	4/9/2021	4/9/2021	Systemic: Allergic: Anaphylaxis-Mild, Systemic: Abdominal Pain-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Headache-Mild, Additional Details: Pt fainted 1 to 2 minutes after getting vaccinated and regained consciousness immediately. Her BP was normal - 108/80 and HR was 86. Pt's breathing was normal. She felt mild stomach pain and headache after gaining consciousness.
1189760	4/10/2021	MD	46	F	4/9/2021	4/9/2021	Was taken by ambulance diagnoses anaphylaxis Throat swelling itching you get swelling was released after 4 hours with meds given iv steroids iv Benadryl

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1190487	4/10/2021	CA	38	F	4/8/2021	4/8/2021	Received vaccine at 4:10pm on Thursday 4/8/21. 2 hours later, at 6:15pm, I noticed mild tongue swelling which slowly continued to worsen. I pulled out my EpiPen but was not having any difficulties breathing and my tongue was only mildly swollen still, so I took Zyrtec at 8pm (which I usually do), and continued to monitor. Zyrtec seemed to slow the progression of tongue swelling slightly but at 10pm, I started having a dry cough and wheezing. I took Albuterol and Benadryl and that worked to stop the tongue swelling. Please note, the reason I don't use Epi immediately is because I have Reynaud's and it is contraindicated. So I use other rescue meds first if I can. My O2 sats remained above 95%, so I was not in full anaphylaxis. I did not eat anything or come in contact with anything within those 2 hours that would have caused the allergic reaction, so I am positive it was the vaccine. I also have a red, raised itchy bump at the site.
1190497	4/10/2021	VA	57	F	3/20/2021	3/20/2021	17 minutes after injection, I experienced Nausea, Sweats, Dizziness, Lightheadness, and Fainting occurred. BP dropped to 80/39 per EMT arriving at Pharmacy site. Did EKG, Sugar Level, and administered fluids. EMTs took me to the hospital for treatment. ER staff noted vitals and bloodwork were alright and could not determine if Anaphylaxis reaction. ER Doctor ruled it a Vaso Vagal Syncope suspected response to vaccine as body saw it as foreign substance that rejected and severe reaction response occurred after 15 minutes.

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1190527	4/10/2021	GA	44	F	4/9/2021	4/9/2021	<p>We had a member come back for her second dose of the Moderna vaccine. It was administered and she was given a timer to wait her 15 minutes. She turned in her timer at the end of the 15 minutes and told us she was leaving. A few minutes later she came back and stated that she was not feeling well. I told her to have a seat and went to check on her. She stated that she was having pain down her arm where she was given the vaccine and down her left side. Then she stated she was itching. I could see her starting to turn red with hives/rash on her left arm where we administered the vaccine. stayed with the patient in front of the pharmacy while I ran into the pharmacy and got the blood pressure machine, Benadryl, EpiPen, adverse reaction chart, and cold pack. I asked to grab pen and paper and take notes as we ran back out. Her itching was becoming more severe, and she stated she was feeling lightheaded. We immediately began checking her blood pressure (which was extremely high at 187/120) and administered 50 mg of Benadryl. We applied a cold pack to her neck as it appeared she was sweating and then applied a cold pack to the injection site. She continued to progress with the itching moving to other sites on her body. I asked one of the technicians to get the other pharmacist to call 911 and a code white was called. She was in a chair without arms, and I needed to have her lay down. I also had five more people waiting for vaccine administration, so we moved her to the break room. We continued to monitor her blood pressure, which was dropping, and watch for signs of anaphylaxis. She stated she was feeling really tired and began closing her eyes. We continued to have her talk with us and not go to sleep. We had EpiPen's ready for administration if needed. The EMS arrived as we were checking her BP once again and they took over. She was placed on a stretcher and taken into the ambulance. Assistant had a curbside delivery a little while after the incident, at this point the EMS decided that her blood pressure had normalized, and the Benadryl was enough to control her allergic reaction and she was released to go home.</p>

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1191493	4/10/2021	MD	17	M	4/9/2021	4/9/2021	The individual starts to show signs of anaphylaxis reaction some minutes after vaccination by the nurse. Said "I am not feeling good." Upon assessment, the individual is leaning his head backwards, unable to read how many fingers I held up; complained "can't see"; slow in responding. The individual appears to be losing consciousness; eyes closed. Color of face pale. HR: 47; Pulse Ox 95%. RR:16. BP 112/64. Epipen 1 dose administered L leg IM. 911 was called. Continue to monitor and check vital signs. BP 143/75, HR: 54 and pulse ox: 94%. At 0850:EMS arrived. VS remain stable. HR: 62; Pulse Ox 94%. The individual starts to open up his eyes and responding. Parents at his side. He is taken to the ER. Followed up with the patient's parent, mom and is stable and doing better.
1190579	4/10/2021			U			Patient was observed for 30 minutes post vaccination (drank Gatorade and water while waiting) and left facility. She reported feeling baseline and went shopping and ate a meal which included chicken. Several hours after vaccination she reported feeling some tightness in her throat and itching on arms/ chest and noted rash on arms. She was driven by partner back to the vaccine administration facility and was immediately assessed by EMS on site. Rash on arms was noted. Vital signs per paramedics were not out of normal ranges. Due to airway concerns reported ongoing, rash, and prior anaphylaxis history, she was given epinephrine. She received a second dose of epinephrine. She was monitored ongoing until transferred to the ambulance for transit to the hospital.

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1190597	4/10/2021	IN	42	F	4/8/2021	4/8/2021	Felt tightening in left arm from wrist to shoulder in the first five minutes. Lost sensation in first three fingers of left hand within ten minutes, however I've experienced this with previous vaccinations (usually the next day) and did not consider it to be an immediate concern. Waited the required fifteen minutes and then proceeded to leave the vaccination area to do some shopping. As I was looking for an item, I began to notice a tightening in my chest and in my throat. I waited several minutes to confirm that it tightening in my throat still was a problem and proceeded back to the front of the store to let the pharmacist know. We then took my blood pressure - it was 163/85. I typically have low blood pressure in the low 90s over high 50s (asymptomatic), so this caused immediate concern. Even in more stressful scenarios in which I've felt extremely anxious (rushing to doctor's appts with young children in tow, having a ruptured ovarian cyst and experiencing high levels of pain), my blood pressure has never exceeded 128/70. This reading was the exception and not the norm. EMTs confirmed that I was not in anaphylaxis, but I was picked up in an ambulance and taken to the ER. After my blood pressure decreased, my initial symptoms resolved. The next day I experienced more typical vaccine reactions - aching, fatigue, soreness, tingly of hand/fingers, headache - but those are what I experience with many other vaccines and they raised no cause for concern. The high blood pressure and immediate tightness in arm, chest, and throat from Covid vaccine was new.

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1190877	4/10/2021	CA	60	F	3/15/2021	3/18/2021	Went to bed and woke up at 4 am to pee. Afterwards I blacked out and work up on the bathroom floor; Anaphylaxis; chest hurt to breathe; Itching in my arms and chest in the evening.; rash; This is a spontaneous report from a contactable healthcare professional (patient). A 60-years-old non-pregnant female patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration, administered in Left arm on 15Mar2021 at 17:00 (Batch/Lot Number: EP8534) as SINGLE DOSE for covid-19 immunisation. Medical history included Only occasional migraines. Never anything like this and known allergies: Some grasses. The patient was not diagnosed with COVID-19 prior to vaccination. Concomitant medications included probiotics (PROBIOTICS) taken for an unspecified indication, start and stop date were not reported; betaine hydrochloride, bromelains, cellulase, pancreatin, papain (DIGESTIVE ENZYMES) taken for an unspecified indication, start and stop date were not reported. On 18Mar2021, at 8pm, the patient reported that "3 days after 2nd shot I started itching in my arms and chest in the evening. Went to bed and woke up at 4 am to pee. Afterwards I blacked out and work up on the bathroom floor. My rash was worse and spreading and chest hurt to breathe and I had bumps on head so we called # and nurse and my husband drove me to (Name). They gave me an IV and epinephrine shot and Pepcid and did CT scan of head and blood work. Diagnosed Anaphylaxis. They sent me home a couple hours later with prescription for Epi pens Zyrtec and Famotidine. Over the course of Friday my rash/hives got worse and spread over my body and my lips /mouth started to swell. I called the nurse who suggested I come back in and they checked by throat to ensure it wasn't closing up and gave me ibuprofen and Benadryl and sent me home. Rash/hives worse and spread all over body and face when I woke up Saturday morning (today). Plan to see specialist Sunday or Monday." The outcome of the events was not recovered. The patient was not tested for COVID-19 after vaccination.

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1191286	4/10/2021		38	F	4/10/2021	4/10/2021	1317: Patient vaccinated with 2nd dose by RN Received at 30 min obs by RN per previous reaction to 1st dose and anaphylaxis to amoxicillin/latex. 1325: Patient C/O throat numbness and ear tingling. VSS, NAD, A&OX4. Airway patent. Speech clear and logical. States "25mg Benadryl worked last time." 1328: Benadryl 25mg IM given VSS, NAD, A&OX4. Airway patent. Speech clear and logical. 1345: Patient feels relieved by Benadryl 25mg VSS, NAD, A&OX4. Airway patent. Speech clear and logical. Denies pain, throat numbness, ear tingling, SOB, and nausea. 1400: Patient left stadium with SO. Patient declined further intervention/hospitalization. Patient states "I feel okay to go home." VSS, NAD, A&OX4. Airway patent. Speech clear and logical. Denies pain, throat numbness, ear tingling, SOB, and nausea. No longer providing direct care after 4/10/2021 @ 1400
1191481	4/10/2021	IL	70	M	4/9/2021	4/9/2021	PATIENT SUFFERED ANAPHYLAXIS 40 MINUTES POST DOSE. WAS FINE AFTER 30 MINUTES, THEN LEFT FOR THE BUS STOP AND FELT HIS THROAT CLOSING UP. HE HAD AN EPI-PEN ON HIM DUE TO HIS DRUG ALLERGIES, AND WAS ABLE TO ADMINISTER AND THEN GO STRAIGHT TO MD OFFICE.

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1190573	4/10/2021	CA	22	F	4/10/2021	4/10/2021	<p>HPI: Patient is a * year old * who presents following administration of a single dose of J&J COVID19 vaccine in the left deltoid. About 20 minutes following administration of the vaccine, the patient started to experience numbness in the left shoulder to the left neck and post auricular region. Patient denies allergies to medication, food, and other vaccines. She states she has never had a similar experience. She declares a past medical history of asthma that is controlled with rescue inhaler and oral medication. She has not taken the medication for the past week and uses her rescue inhaler 2-3 times per week, particularly when she exercises or coughs too much. She affirms numbness of the left neck, left shoulder, She denies chest pain, difficulty breathing, swelling of the face/lips/tongue/throat, skin rash/itching, cramping abdominal pain, nausea, and vomiting.</p> <p>Exam (update as needed): GEN: Alert and oriented x 4, NAD. HEAD: NCAT EYES: PERRL, EOMI ENT: Decreased touch sensation in the left post auricular region and left posterior neck region. Normal ROM and 5/5 strength of the neck. Right ear normal, Nose normal, OP normal, no evidence of angioedema NECK: Supple, without LAD. CV: RRR, no m/r/g PULM: Clear to auscultation bilaterally, no accessory muscle use ABD: Soft, no tenderness. SKIN: No rashes, skin warm and dry. No erythema or edema of the injection site. MSK: FROM of the bilateral upper extremities and neck, MS 5/5 bilaterally NEURO: Alert and oriented x 4, CN 2-12 grossly intact, no ataxia, gait steady. Decreased sensation of the left post auricular region, left posterior neck region, left shoulder, left bicep compared to the contralateral side. Clinical Impression/Field Tx: Possible peripheral nerve injury secondary to vaccine administration. Patient not displaying active signs and symptoms of anaphylaxis. Patient demonstrated ability to adequately control airway and secretions. The patient was experiencing decreased sensation on the ipsilateral side of the vaccine site compared to the contralateral side. Muscle strength was 5/5 bilaterally. CN II-XII were grossly intact. Patient offered further evaluation by EMS, however, patient declined as she has an appointment with her PCP on Monday and would prefer to address it there. Instructed patient to consult their PCP regarding the post-vaccination reaction. Patient states she has an appointment on Monday. Patient instructed to go to</p>

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							emergency department should the area of decreased sensation increase in size or if they develop chest pain, difficulty breathing, difficulty swallowing, swelling of the face/lips/mouth/tongue/throat, or cramping abdominal pain with nausea/vomiting, as these are signs of possible anaphylaxis that requires immediate intervention. Medications administered: None Disposition: Home
1189736	4/10/2021	PA	54	F	3/21/2021	3/21/2021	Anaphylaxis - hives, sensation of throat tightness, shortness of breath, sweating, hypertension, tachycardia Treated immediately at vaccine site with epi-pen, Benadryl 50mg with improvement in symptoms. Transported to the ER where symptoms subjectively were returning and treated with famotidine 30mg and IV Solumedrol 125mg. Monitored for 3 hours further in the ER and discharged home with prednisone taper and prescription for Epi-pen.
1192187	4/10/2021	CT	40	F	4/10/2021	4/10/2021	First shot: mild fever diarrhea, arm pain, headache, fatigue, lethargy Anaphylaxis- swelling of lips, mouth, tongue, face, coughing, wheezing, closed airway, dry heaving, increased heart rate
1186959	4/9/2021	UT	25	F	4/9/2021	4/9/2021	Dizziness, Lightheadedness, right throat started after 2 minutes and continued to get worse. Altered consciousness began. Anaphylaxis started approximately 25 minutes after vaccine.
1186783	4/9/2021	CA	52	F	4/9/2021	4/9/2021	At roughly 5 minutes post vaccination client C/O feeling lightheaded and just not feeling well. Skin pale and diaphoretic. Client with positive loss of consciousness. Client assisted to floor and placed in shock position with legs elevated. At which point client regained consciousness. BP 80/40 HR 55 RR 18, A&O x4. Client stated she had only a "smoothy for breakfast" No S&S of anaphylaxis no SOB, no swelling of tongue or face. 911 notified. At 15 minutes post vaccination client stated still feeling lightheaded and shaky client states no allergies to food - given small piece of chocolate, client was able to sit up and drink water.

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1186765	4/9/2021	VA	27	F	3/30/2021	3/30/2021	Patient had swelling of lips and tongue within 15 minutes of vaccination. Given Benedryl and epi and transported to ER by EMS. Report from ER: She had anaphylaxis with progressive tongue swelling despite multiple doses of IM epi and an epi drip. She was ultimately intubated to secure her airway in the face of potential airway compromise.
1186700	4/9/2021	CA	59	F	4/9/2021	4/9/2021	At 5 minutes post vaccination client C/O feeling nauseous and dizzy. Skin pale and diaphoretic. Assisted to supine position with legs elevated. BP 90/40 HR 56 RR 18, A&O x4, no other signs or symptoms. Client stated she had the same reactions when donating blood and had to stop for that reason. 911 notified. At 15 minutes post vaccination client stated feeling better BP 120/70 HR 70 RR 18. EMS on scene. Client refused transport or follow up in ER with symptom resolution at 12:50. No symptoms consistent with anaphylaxis were observed or reported.
1186698	4/9/2021	NM	35	F	4/8/2021	4/8/2021	Patient was seen at offsite UNM-Gallup COVID vaccine event today 4/8/21. At ~1305, provider was asked to assess this 35yo who had received her 2nd dose of Pfizer COVID vaccine at 1247, with complaint of itchy rash to neck and throat "tightening." She has a hx of multiple drug allergies and is on multiple medications as below for seizure disorder and other comorbidities. She had reported a hives rash after her first dose of COVID vaccine 3wks ago. As such, she had taken 50mg benadryl at ~1200 today to attempt to prevent a reaction. On limited evaluation, her oral airway was clear without obvious angioedema. She did have hives to her neck and was quite pruritic. Her lungs were clear and she was moving air without wheeze. She began slurring her speech and seemed confused, which her family member reported is how she becomes before seizures. With concern for anaphylaxis, gave a dose of 0.3mg IM epinephrine. EMS was called to transfer patient to ED. Dose epi given at 1320, with almost immediate improvement in hives, pruritus and notable improvement in mentation and slurring of speech. EMS arrived at ~1325, patient found to have HR 106, BP 180/84 after epi. She was transferred in stable but acute condition.

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1186663	4/9/2021	NY	27	M	4/9/2021	4/9/2021	Vasovagal event with lightheadedness, diaphoresis, blurry vision. No CP, SOB, palp. No s/sx anaphylaxis: no hives/rash, wheezing, stridor, throat closing, tongue swelling/itching, N/V/D. VS: BP 95/50s, HR 50s, SaO2 99% RA, afebrile. Pt clammy, bradycardic. Lung clear, abd soft, no edema. No focal neuro deficits, A&Ox3. Pt laid down on the floor with legs elevated with improvement in symptoms, and BP up to 120s/70s, HR 70s. After ten minutes, felt well enough to sit up, repeat BP while sitting 120/70s, HR 70s. Given water/juice and a snack. After another ten minutes, felt well enough to stand, repeat BP unchanged. Pt monitored for another 30 minute without recurrence of sxs. Pt went home without issue.
1186459	4/9/2021	MN	16	F	4/9/2021	4/9/2021	Pt was vaccinated. She said she felt fine. Pt walked 15 feet then fainted. Her mom was able to catch her. We moved her to a cot. She slowly regained consciousness. She had no signs of anaphylaxis. She was breathing fine. Her mother states she has fainted during blood draws in the past and her daughter hadn't eaten this morning. We monitored pt for 30 minutes. Her color and smile came back. Pt was able to walk out on her own. Her mother will monitor her today.
1187012	4/9/2021	OH	67	F	4/8/2021	4/8/2021	Hospital said: Acute allergic reaction, initial encounters, allergic reaction Anaphylaxis; swollen Vocal cords; loss of voice; bad cough; & headache Reaction Started 20 minutes after shot; cough was about 30 minutes later; headache started about 3 hours after shot
1187988	4/9/2021	WV	43	F	3/20/2021	3/20/2021	No issues during the 15 minutes at pharmacy, went back to work and about 45 min later went into anaphylaxis. Called 911 and went to emergency room

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1186529	4/9/2021	MN	42	F	4/8/2021	4/8/2021	<p>Pt received the 1st dose of Pfizer COVID-19 vaccine on 4/8/21. Prior to administration, pt reported to vaccinator that she has a hx of allergic reactions (no anaphylaxis) and sees an allergist. Pt reports that her allergist has her come to the Allergy Clinic for the flu vaccines and to be monitored. Vaccinator escorted pt to check-out and reported to me that pt should remain for 30 minutes of observation d/t reported hx. Pt sat in observation for about 10 minutes and began to feel very warm. Volunteer from Observation group alerted RN who was volunteering as a vaccinator. Staff notified me and I joined in the recovery room with the pt. Pt appeared very flushed and we observed redness and some red bumps on her face and neck, Pt chest appeared red, as well. Hx of allergies to shellfish, cats, seasonal and others yet unidentified. Applied cool cloth to back of neck, and gave juice and crackers. Vitals: 12:10pm--P-98, BP-120/88, O2-98% on RA 12:25pm--P-98, BP-131/91, O2-98% on RA Due to slight increase in BP and not seeing resolution to the flushing, it was determined to give Benadryl. 25 Mg Benadryl, PO @ 12:30pm Vitals @ 12:45pm: P-84, BP-91/56, O2-99% on RA Flushing resolved and pt reported she felt well enough to go home. Discussed plan to get to urgent care STAT is she experienced worsening symptoms, especially difficulty swallowing and/or facial swelling. Pt informed that a VAERS report would be filed and she may be contacted by this agency as they collect data on immunization reactions. Pt is agreeable. Compass-Safety report will also be filed.</p>

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1187061	4/9/2021	CA	35	M	4/9/2021	4/9/2021	<p>HPI: Patient is a 35 year old male who presents following administration of a single dose of J&J COVID19 vaccine in the left deltoid. Patient started to feel light headed and nauseous while walking to his car. About 20 minutes following vaccination, a vaccinator had walked passed his vehicle and noted that he was unconscious. Patient was still unconscious upon medical response team arrival and unresponsive to stimuli. Once the patient awoke about 30 seconds later, he continued to state that he was nauseated and "did not feel good." Patient was unaware that he had lost consciousness. He further disclosed that he had been working in the sun planting trees all day and had not consumed any food or beverage. He denied allergies to medication, food, and other vaccines. He relayed that he had passed out from vaccinations in the past as a child. He affirms lightheadedness and nausea. He denies chest pain, difficulty breathing, swelling of the face/lips/tongue/throat, skin rash/itching, cramping abdominal pain, and vomiting. Exam (update as needed): GEN: Upon arrival, patient unconscious and not responsive to stimuli HEAD: NCAT EYES: pupils unreactive and mydriatic ENT: Ears normal, Nose normal, OP normal, no evidence of angioedema NECK: Supple, without LAD. CV: RRR, no m/r/g, palpable strong radial pulse PULM: Clear to auscultation bilaterally, no accessory muscle use ABD: Soft, no tenderness. SKIN: Skin pale, cool, and clammy. No rashes. No erythema or edema of the injection site. MSK: FROM, MS 5/5 NEURO: Patient unconscious upon arrival. CN 2-12 grossly intact, no ataxia, gait steady Clinical Impression/Field Tx: Vasovagal syncope. EMS called immediately to respond to the site for further evaluation. Patient placed into a reclined position. Patient not displaying active signs or symptoms of anaphylaxis. Upon regaining consciousness, patient was alert and oriented x4. Once the patient demonstrated ability to control airway, he was given candy and water. EMS arrived and an EKG and BGL were performed, both of which were normal. Vital signs were stable. Instructed patient to consult their PCP regarding the post-vaccination reaction. Patient instructed to go to emergency department should they develop chest pain, difficulty breathing, swelling of the face/lips/mouth/tongue/throat, or cramping abdominal pain with nausea/vomiting, as these are signs of possible</p>

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anaphylaxis that requires immediate intervention.
Medications administered: None Disposition: FD EMS
called to the scene for further evaluation. Patient elected
to go home after evaluation by EMS.

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1187311	4/9/2021	FL	34	F	4/9/2021	4/9/2021	<p>Patient presented at clinic for COVID19 Vaccine administration on 04/09/2021 at 1:26 pm. Upon checking in for her appointment, she was provided with clinic's COVID19 vaccine screening and consent form in which she denied the following: ? Having allergies and reactions to any medication, foods, vaccines, or latex. ? Carrying an Epi-pen for emergency treatment of anaphylaxis. ? Having had a severe reaction to previous dose of this vaccine or to any of the ingredients of this vaccine. After the vaccine administration, patient was guided to the observation area for a 15-minute observatory period. At approximately 2:00 pm- while in the observation area, approximately 5 minutes from vaccine administration, patient, expressed to the clinical staff member monitoring the observation area, Medical Assistant, that she felt lightheaded and the clinical alert team was activated. While sitting, patient stated that she was feeling dizzy, she leaned forward and at this time patient was lowered to the floor; a pillow was placed under her head and her feet were elevated. Vitals reported were taken in the presence of ARNP while patient was laying on the floor. 2:00 pm Vitals ? Blood pressure 60/40 ? Oxygen saturation level 99% 2:01 pm- Paramedics were called by Lead Medical Assistant ARNP reports that patient was laying on the floor, alert, oriented to place, time and person. Patient never lost consciousness. At this time, patient was asked the following series of questions: ? How do you feel? As per patient, she felt bilateral ear pressure without losing ability to hear were she was dizzy weak, and nervous. ? Are you allergic to any medications or have you had any allergic reactions to a vaccine? Patient denied having had a history of any adverse or allergic reaction to any medication or vaccines in the past. 2:09 pm- Blood pressure: 60/50 2:13 pm-Blood pressure 95/60 2:14 pm -Paramedics arrived. 2:16 pm- Blood Pressure taken by paramedics 104/68 2:22 pm- Patient asked for water. Water bottle was supplied, and Patient began to take sips of water. 2:30 pm-Patient fully functional, blood pressure stable. Patient was walking, drinking water, and utilizing her cell phone. At 5:00 pm- Staff , (Center Administration) called Patient, she stated that she felt fine and that she had had something to eat. No other symptoms reported.</p>

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1187344	4/9/2021	FL	36	F	4/9/2021	4/9/2021	<p>Patient presented at Hospital for COVID19 Vaccine administration on 04/09/2021 at 1:21 pm. Upon checking in for her appointment, she was provided with COVID19 vaccine screening and consent form in which she denied the following: ? Having allergies and reactions to any medication, foods, vaccines, or latex. ? Carrying an Epi-pen for emergency treatment of anaphylaxis. ? Having had a severe reaction to previous dose of this vaccine or to any of the ingredients of this vaccine. After the vaccine administration, Patient was guided to the observation area for a 15-minute observatory period. At approximately 2:00 pm- while in the observation area, approximately 15 minutes from vaccine administration, Patient, began to feel faint after family member was being treated by our medical alert team and sat down while hyper ventilating triggering a panic attack. At this time husband, also in the observation area, was asked by our medical team if patient had a history of panic attacks where he preceded to confirm that patient indeed has a history of panic attacks. Vitals were taken while patient was sitting in the presence of a nurse. 2:02 pm Vitals ? Blood pressure 130/80 ? Oxygen saturation level 98% ? Pulse 83 2:04 pm-Paramedics were called by Lead Medical Assistant 2:14 pm -Paramedics arrived. While the paramedic team assessed patient, EKG normal, vital signs normal. Patient was hyperventilating, became rigid, unable to open eyes with a locked jaw while grinding her teeth. Patient never lost consciousness. At this time, patient?s husband and paramedic began speaking to her, comforting her, and assisting her with breathing exercises. Patient?s husband confirmed that was she was experiencing was one of her usual panic attacks that usually can last 30-45 minutes. As a precaution, paramedics offered to transport patient to the nearest hospital to which the patient refused. 2:30 pm- patient was fully recovered and deemed stable by the paramedics? team. At 5:00 pm- Center Administration called patient, she stated that she felt fine. No other symptoms reported.</p>

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1187421	4/9/2021	IL	62	F	4/9/2021	4/9/2021	Pt is here today for COVID-19 immunization per federal guidelines/written order. See immunization activity for details. Pt was observed post-immunization for a minimum of 15 minutes with evidence of dizziness and nausea, heart palpitations. Anaphylaxis Management Standing Order protocol initiated. Physician/APP notified of patient condition. Additional orders received: none per Dr. COVID-19 (MRNA) VACCINE Allergen added to patient's Allergies. VAERS reporting completed as appropriate. 1640: At end of 15 minute observation, patient complained of sudden onset dizziness, flushing, palpitations and nausea. Immediately brought to exam room and patient began to dry heave (no actual emesis). Cool cloth applied to neck. VITALS: BP 153/81, Pulse "166" via dynamap, but manual recheck was 84. Patient stated symptoms starting to resolve. 1645: Dr. came up from office to evaluate patient. Manual pulse check 80. No shortness of breath or throat tightening. No chest tightness, no rash, no itching. Patient states symptoms much improved. Per Dr. , no additional orders, but observe for 30 additional minutes. 1655: VITALS: BP 161/77, Pulse 67 via dynamap. Patient states she feels much better. Discussed precautions prior to next vaccine (eating and drinking) and consideration of taking oral Benadryl prior to next vaccine (using caution if driving). Also advised she can take a dose of oral Benadryl this evening (has history of bee sting allergy and carries Epi Pens). Verbalized understanding. Patient going home from clinic and accompanied by mom. 1705: Patient states she feels "100% better," and would like to leave. Has been 25 minutes since reaction started. Patient discharged ambulatory. VAERS submitted. COVID-19 post-vaccination Patient Instructions added to After Visit Summary for patient to review in her MyChart account.
1187450	4/9/2021	RI	35	F	4/9/2021	4/9/2021	pt arrived approx. 30min after vaccine adminstartion with complaints of congestion. pt denied any complaints of throat swelling sob, nausea vomiting head ache chest pain. pt vitals were taken multiple times. pt bp 130/93 hr 96 spo2 100%ra rr 18. pt wanted to be reevaluted just to "make sure I am ok". pt appeared to be stable and not suffering from any anaphylaxis. pt refused treatment and transport. pt report can be found through agency pcr

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1187775	4/9/2021	CA	33	F	4/6/2021	4/6/2021	Patient completed 47-minute observation period with flushed face and itchiness to face and body. Patient's mother brought pt Benadryl and patient willingly took the medication. Pt had relief of itchiness and redness 15 minutes after taking medication. Pt stated that she felt better and left with mother. Allergist entered"Ok to premedicate with Zyrtec 10mg twice daily 3 days prior to, on day of, and 3 days after Covid vaccine. Make patient aware that risks of true anaphylaxis is rare (5 in 1 million) and benefits of Covid vaccine outweigh risks at this point. Hoping moving forward they let the PCPs know that Dr. Advices are being sent on their behalf and nurses provide actual clinical history of reactions." in the patient's medical record
1187828	4/9/2021	NY	24	F	4/9/2021	4/9/2021	PT WEEPING 10 MINUTES AFTER SHOT. CALLED 911 AT HER REQUEST. NO SYMPTOMS OF ANAPHYLAXIS. PT STATES SHE FELT COLD AND HANDS FELT STRANGE AS WELL AS MIDSECTION
1187926	4/9/2021	NE	49	F	4/9/2021	4/9/2021	Patient felt funny after getting vaccination, I directed her to wait 30 minutes at the pharmacy. At the end of 30 minutes, she said she felt like she wanted to take a Benadryl tab that she had in her purse and she said that she had an EpiPen as well. Her husband accompanied her and she said that she was going to leave. I counseled her to watch for signs of anaphylaxis and she left. After she left, on the drive home she felt like she was having trouble breathing, so she went the ER. At the ER they gave her some steroids and she felt better.

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1187971	4/9/2021	CA	23	F	4/9/2021	4/9/2021	23 yo FM who received first dose of Pfizer vaccine and then was noted to have shortness of breath and complaining tongue closing sensation immediately after at Vaccine Clinic --I was called to evaluate the patient. When I arrived patient was laying down on a chair with a friend, shaking with seizure like activity but alert and oriented to person place and time. Upon my arrival she was shaking, vomited x 1 and then complained about chest pain. Vitals upon my arrival: HR 58, o2 100% RR appeared to be around 22-24 (hyperventilating) BP 88 systolic (manual)--repeated by medics upon arrival minutes later 110/72. Given throat closing sensation, vomiting, shortness of breath I advised to call 911 and ordered Epinephrine x 1 which was given by RN immediately. Pt was then placed on the grown chin up, she continued to shake throughout entire body but continued to be alert and oriented. Medics then arrived on scene, started an IV, glucose by medics 84, IVF started by medics. Pt was transported to ER via medics. Pt is not a patient, last visit 2017. Pt did state she has hx of POTS and DRESS syndrome to Lamictal. Reports taking cetirizine this AM, Zofran and Oxycodone and Baclofen (prescribed by external PCP?). Prior to transport to ER pt continued to be alert oriented, but shaking and twitching throughout her body. MD verbally communicated to patient to not receive the 2nd dose given her severe anaphylaxis like reaction to the first dose of the vaccine. Pt can be referred to allergist after ER follow up by PCP. Denied pregnancy.

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1186259	4/9/2021		47	F	4/9/2021	4/9/2021	1230 sitting in general observation area and is itching right arm. States she did not have any problems with the first dose. States she has her EPI pen with her for anaphylaxis reaction to bee stings. States she is not having any trouble breathing. Tongue examined and not swollen. Taken to private observation area. Noted red blotchy flat rash on right arm, neck, and front of chest. Itching constantly. 1232 gave Benadryl 25 mg, two tablets by mouth for itching. Husband is present. 1235 noting rash is progressing to left arm. 1240 HR 91, BP 166/88; O2 sat 99% on room air. Denies throat discomfort or itching in throat. Drinking water without difficulty. 1245 gave ice for itching. Mild redness noted bilateral thighs. 1255 BP 162/93; HR 72. No throat or tongue swelling. Respiration even/ regular. Redness of rash subsiding, still itching but less. States she is anxious as well and thinks her BP may be from anxiety. Husband present and will be driving. Patient states this is nothing like her anaphylaxis and feels well enough to go home. Ambulated without difficulty to POV Rash redness subsiding
1187959	4/9/2021		42	F	3/29/2021	3/29/2021	Per ED report, patient went to Pharmacy to get her 2nd COVID 19 vaccine on 3/29/2021 ~ 1 pm. She first felt fine, but ~ 2 pm she started having breakout of her rash, a dry cough and slightly raspy throat as well as facial swelling. She came to the Outpatient Center where she usually receives Xolair for her idiopathic anaphylaxis q 2 weeks, where she received a total of 300 mg of IV diphenhydramine and 40 mg of IV famotidine, after which they sent her to the ED for further observation and medication administration. Per ED note, allergic reaction/early anaphylaxis after 2nd COVID 19 vaccine, but no severe anaphylaxis or hypotension noted; no evidence of acute pharyngeal edema. In the ED pt was given 2 doses of epinephrine IM and further diphenhydramine. Later she was admitted for observation and further epinephrine and diphenhydramine administrations. She was discharged on 4/1/2021 in stable condition.

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1184295	4/9/2021		40	F	4/6/2021	4/6/2021	Patient received Pfizer COVID-19 vaccine on 4/6/2021. Patient reports the following adverse reactions: facial swelling, lips swelling, redness, small hives. Patient was given 25mg Benadryl PO per protocol. Dr was made aware. Monitored patient. Patient started to experience some throat tightness but no shortness of breath or difficulty breathing. Spoke with Dr again and gave patient 0.3mg Epinephrine in right deltoid. Dr came down to clinic as patient was going to ED per car with her sister driving. In the ED, patient was treated for anaphylaxis at hospital and stayed overnight (epinephrine, solumedrol, pepcid x2). After discharge on prednisone 40mg daily x5 days, patient came back with hives and was readmitted and treated overnight with pepcid/benadryl expect to be discharged again today.
1186299	4/9/2021	TX	49	F	4/9/2021	4/9/2021	Onset of anaphylaxis (tightening of the chest). Mild symptoms. Self-treatment with Epipen, followed by liquid Benadryl.
1186297	4/9/2021	NC	34	F	4/7/2021	4/7/2021	34yr old female with shellfish allergy (reaction: anaphylaxis), exercise induced asthma, previous issues with injections/blood draws (reaction: dizziness) and other comorbidities presented for COVID-19 J&J vaccine on 4/7/21. CMA administered the JANSSEN COVID19 VACC (LOT # 043A21A, exp 6/21/21) IM in patient's left deltoid at 1318. Within 2 minutes of administration, patient became lightheaded and shortly after passed out. Patient had one convulsion (arching back, tense limbs) lasting 5-6 seconds. Once relaxed, patient was arousable. Patient denied hives, shortness of breath, throat swelling, or chest pain. At 1325, BP 48/31, MAP 76, HR 79. Patient assisted to Trendelenburg position and remained lying for 20m. Patient developed chills and tremors during this time stating she was cold. At unknown time later, patient endorsed feeling better and was lifted to sitting position and allowed to sit for another 10minutes. At 1346, final BP 105/58, HR 73. Patient endorsed feeling back at baseline. Provider released patient and patient discharged. Of note, provider notes patient with vasovagal syncope and convulsions after receiving J&J COVID vaccine. Patient has history of vasovagal reactions.

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1183598	4/9/2021		35	F	4/8/2021	4/8/2021	Moderna, second dose, anaphylaxis
1184213	4/9/2021	NC	28	M	4/7/2021	4/7/2021	On 04/07/21, 28 yo presented to clinic for immunization. Pt's documented allergies include codeine (rxn: rash; severity: low) since 02/06/2018. Pt had no previously documented encounters. Pt was seen at another institution on 02/06/18 for Generalized Anxiety Disorder and was prescribed sertraline 25 mg PO daily. Unknown if pt continues on this medication. On 04/07/21 at 1141, pt was administered COVID-19 J&J (Janssen) Vaccine 0.5 mL in left deltoid (Lot #043A21A; Exp: 6/21/2021; NDC #59676-580-15). Immediately after injection, pt became lightheaded, dizzy, diaphoretic and "felt like his vision was closing in". Vitals assessed at 1145 were BP: 94/55, P: 42, O2 sats: 98%. Pt placed in Trendelenburg position with vitals BP: 116/75, HR: 43, O2 sats: 98%. Pt denied any chest pain, shortness of breath, throat swelling, skin itching or hives. Pt reported no previous reactions to vaccines and no h/o anaphylaxis. Pt did report a similar event during a previous blood draw. Pt remained in Trendelenburg x 10 minutes. At 1159, pt was repositioned to sitting with BP: 120/80, HR: 48. Pt reported a low baseline HR. After a total observation of ~20 minutes, pt was reassessed by MD and permitted to leave. Event noted as "Symptoms are most consistent with a vasovagal reaction after J&J Covid vaccine.~~
1184283	4/9/2021	ME	46	F	4/8/2021	4/8/2021	Delayed anaphylaxis. Treated with diphenhydramine and albuterol at 90 minutes post vaccination, epinephrine at 125 minutes post vaccination. Patient release from ER after 4.5 hours, discharged home.

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1184475	4/9/2021	SC	64	F	3/29/2021	3/31/2021	Within approximately 48 hours, I started breaking out in hives on the back of my head and then within 2 more days, it spread to my backside, buttocks and upper back. I did not exhibit any signs of anaphylaxis; only hives. Seven days after the vaccine, I went to an urgent treatment care center as the hives were continuing to spread . I requested an injection of 10 mg dexamethasone instead of a prednisone dose pack because of prior experiences (minor side effects). The hives were mostly resolved when I woke up 12 hours later but returned 2 days later, even with taking my Zyrtec BID instead of once daily as recommended by Physician. Today, April 9th, I started a prednisone 4mg dose pack after notifying my Physician's office again yesterday.
1184662	4/9/2021	FL	46	F	4/9/2021	4/9/2021	Pt received 2nd dose Moderna COVID-19 vaccine this morning at 0805. At 0820 she complained of feeling hot and nauseous and was given a bottle of water. Then complained of feeling itchy all over. She stated she was very itchy and nauseous after 1st COVID vaccine but that this happened about 24 hours after her injection last time. She reported she did not take any medicine so far today. Was given diphenhydramine 50mg po at 0824. At 0829 Pt stated her throat felt like it was tightening and 911 was called. She then began coughing and self-administered albuterol inhaler x 2 puffs (Hx of asthma) while waiting for EMS. She was transported by fire to hospital for possible anaphylaxis. Pt was stable and responsive with open airway at time of transport.
1184841	4/9/2021	OH	18	M	4/9/2021	4/9/2021	anaphylaxis
1186075	4/9/2021	VA	30	M	4/1/2021	4/1/2021	Client received Johnson & Johnson vaccine and during the 15 minutes post vaccination waiting period, he complained of lightheadedness and nausea. Client denies all symptoms of anaphylaxis. Client indicates that he has a shellfish allergy. Client was evaluated by paramedic on site and medic 209. Client was moved to the ambulance from the POD for further evaluation.

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1184279	4/9/2021	CA	25	M	4/8/2021	4/8/2021	Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Hypertension-Mild, Additional Details: 12:20pm\r\n24/Male fainted after administration of Janssen vaccine. No other symptoms noted. Had patient sit on the floor and elevate legs. Assessed for anaphylaxis, epinephrine was not indicated.\r\n12:24pm BP 140/75 (unsure of patients baseline, no diagnosis of hypertension). Ambulance was called. When ambulance arrived patient felt better. May have just been nervous due to needle itself, not COVID vaccine. followed up with patient 4:20pm and he states he feels perfectly normal now.

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1186145	4/9/2021	IL	45	M	4/8/2021	4/8/2021	Pt. received the vaccine at approximately 2:44pm. Before I could hand him his card, his hands began trembling and he looked pale. I asked how he was feeling. He reported feeling shaky, dizzy, and very hot. I asked him if he was having any difficulty breathing, had tightness in his throat/airways, or even felt a tingle. He said no. Noting the time, I asked if he had eaten lunch. I asked if he has ever felt this way before. He said he had when he gets a "hypoglycemic attack." While not diabetic nor on any medications, he said he will occasionally get very low blood sugar. He said he had not eaten since early that morning. Another employee brought some juice I requested. I again asked him about symptoms related to anaphylaxis, to which was not an indication of an anaphylactic reaction. I gave him the juice to sip. I asked him again about symptoms. Because he was still dizzy, I took his blood pressure/heart rate. His BP was 160/119 and heart rate 96bpm. His color became more gray over the next several minutes. He was still too dizzy to stand, felt hot, shaky, and now nauseous. He handed over the juice and was given a receptacle if he vomited. We suspected a vasovagal response, but was still symptomatic after 10 minutes. Meanwhile, the other pharmacist tried to call his doctor's office. We learned his doctor had moved away and he had not yet come in nor selected a new provider. We asked him if he felt he needed to be seen by a doctor. He said he did and agreed to us calling an ambulance. The ambulance arrived around 3:10. The EMTs took his BP. It had come down, but he could not stand up without his knees buckling. The EMTs got him on the stretcher and took him to the hospital.
1184847	4/9/2021	VA	16	F	4/9/2021	4/9/2021	Pt received first dose pfizer covid vaccine. Approx 1-3 min later pt lost consciousness and experienced upper extremity myoclonic jerks for approx 5-7 seconds before regaining consciousness with fists clenched. Upon regaining consciousness, pt was A&Ox4, reported slight lightheadedness; denied CP, SOB, or cutaneous sx suggestive of anaphylaxis. Pt denies anything like this in the past, denies family hx of seizures, and denies needle phobia. Pt instructed to recline supine in car seat with legs elevated on dashboard, and soon reported feeling better, less lightheadedness.

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1186063	4/9/2021	IA	52	F	4/3/2021	4/3/2021	Anaphylaxis fast heart beat sob like being on fast treadmill tongue swelling super high blood pressure the next two days after I had really bad migraine and high fever of 102.3° with bad fatigue for 4 days.
1185983	4/9/2021	WA	61	F	4/8/2021	4/8/2021	Anaphylaxis leading to intubation and hospitalization
1185910	4/9/2021	NC	43	F	4/7/2021	4/7/2021	PER PATIENT: APPROXIMATELY 1 HOUR POST-VACCINATION, A.C. STARTED TO EXPERIENCE NAUSEA, NUMBNESS AND TINGLY SENSATIONS, RASH ON ARMS, LEGS, SWELLING IN ELBOWS, KNEES, CHEST PAIN, CHILLS, SLIGHT SHORTNESS OF BREATH. THESE SIDE EFFECTS PROGRESSED AND WERE WORSE 4 HOURS POST-VACCINATION. THE DAY AFTER VACCINATION, AFTER REGISTERING WITH V-SAFE, A REPRESENTATIVE CALLED A.C. AND TOLD HER TO TAKE 75 MG DIPHENHYDRAMINE. THE REPRESENTATIVE STATED THAT A.C. WAS HAVING A MODERATE REACTION TO THE VACCINE (A.C. DID NOT EXPERIENCE ANAPHYLAXIS). MOST OF THESE ADVERSE REACTIONS IMPROVED AFTER TAKING THE DIPHENHYDRAMINE. TODAY, 2 DAYS POST-VACCINATION, A.C. IS NO LONGER HAVING ANY SIDE EFFECTS AND IS RECOVERED.

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1185132	4/9/2021	XB	51	F	3/30/2021	3/30/2021	ABOUT hour after injection started with itchy throat, progressed within 5 to 10 minutes to dry cough, the persistent dry cough, about 20 minutes after symptoms started 1 puff from inhaler, coughing increased to non stop unable to breath, co worker (LVN) called a code, code team arrived within 2 minutes continued trouble breathing, coughing, given 2nd puff from inhaler, put on oxygen transported to emergency room treatment started with breathing treatment, steroids, started experiencing chest pressure, right arm tingling and numbness, face numb and mouth monitored for couple hours, EKG, labs, blood work, x ray's done, then IV's started notified transferring to an adult hospital due to cardiac concerns. Transferred by Ambulance Hospital, triaged labs, EKG, X-Rays, seen by Cardiac Doctor on call advised being admitted for Anaphylaxis to Moderna injection. Monitored and treatment then released on 04/01/2021. Discharge medications prescribed and advised to follow up with medical doctor.
1184950	4/9/2021	IL	38	F	4/8/2021	4/9/2021	8 minutes after shot in Left Deltoid, pt developed scratchy throat, dry cough, dry cough got worse after 2 minutes and pt reported throat felt funny, appeared pale and states throat felt really strange. Epi 0.3ml was given due to complaint of throat tightness, scratchy throat, and dry cough; classic signs of anaphylaxis. Pt also received 50 mg Benadryl IM. After Epi pt reported throat tightness improved. Pt was then transferred to ER for observation after EPI.

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1181699	4/8/2021		46	F	4/3/2021	4/3/2021	After receiving dose of COVID vaccine, patient reported difficulty breathing and became shaky. Patient was transferred to wheelchair, given water and ice and was transferred by an RN to the ED. Per ED MD, patient developed throat tightness, nausea, fluctuance a shin after COVID vaccine. Concern this could represent of a allergic reaction. Less likely vasovagal reaction as throat tightening would be very atypical. There were no signs of any angioedema, she has no rash, no wheezing, no chest pain. At this time she does not have signs of anaphylaxis. Patient's symptoms have completely resolved by the time of evaluation. Per MD, this could have been allergic reaction to the vaccine and therefore would not recommend that she received a 2nd dose. She is recommend to follow up with her primary care physician for re-evaluation and to discuss other options for vaccine.

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1183092	4/8/2021	WI	49	F	4/8/2021	4/8/2021	The patient received a Janssen COVID vaccine on 4/8/21 at around 5:00 pm. The patient was nervous during the administration and reported never receiving a flu vaccine in the past. The common side and serious side effects were discussed with the patient. The vaccine was administered to the patient without issue. The patient and husband instructed to wait 15 minutes after the administration of the vaccine as is the recommendation per the CDC. About 5 minutes after the administration of the vaccine, the patient's husband notified the pharmacy staff that his wife was not feeling well. Pharmacist responded to the patient. The patient reported shortness of breath and feeling hot and stated she was about to pass out. Pharmacist was instructed to retrieve the Epi-Pen from the immunization cart and assist. Code White was called and Division 1 staff responded and assisted. The patient was lowered to the ground and her feet were elevated. It was at this point that it was determined that the patient was not experiencing anaphylaxis based on the symptoms she was reporting and exhibiting. The patient was instructed to remove mask to help obtain better breaths and remove the patient from hyperventilation. An icepack was obtained and placed on the patients neck once she was able to sit up. The patient's symptoms improved to the point of moving to a chair. The patient sipped water and continued deep breathing. The patient's symptoms continued to improve and she was able to leave.
1179350	4/8/2021	CO	32	F	4/7/2021	4/7/2021	Systemic: Allergic: Anaphylaxis-Mild, Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Systemic: Allergic: Swelling of Face / Eyes / Mouth / Tongue-Severe
1180552	4/8/2021	CO	20	F	4/6/2021	4/7/2021	Flulike symptoms -- fever, body aches, chills, abdominal pain, fatigue, headache; onset 6 hours after receiving vaccine, resolved 24 hours after receiving vaccine. HIVES without anaphylaxis -- developed 12 hours after receiving vaccine, still progressing 40 hours after receiving vaccine

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1181275	4/8/2021	MI	64	F	4/8/2021	4/8/2021	Patient was feeling light headed, shaky and started to sweat. She then fainted and was caught by myself. We immediately called 911 , her blood pressure was taken and it was within normal limits. She did not have any difficulty breathing, swelling of the tongue or other side effects that were showing signs of anaphylaxis. Patient received water and started to feel cooler and less shaky. Once the paramedics arrived, she was assessed and was monitored for at least 25 minutes by myself and the paramedics. Patient was not disoriented and was given the OK to go home by the paramedics. Patients husband was contacted to come and drive her home.
1181329	4/8/2021	GA	36	M	4/7/2021	4/7/2021	EE attended a vaccine event at plant T1 and obtained his first dose of Pfizer COVID-19 vaccine at 3:35 pm. EE was instructed to wait for 30 minutes in the post vaccine observation area due to previous anaphylaxis response, to a medication as a child. EE was eating a snack when at 3:45 pm, he became light headed and stated "I feel like I am going to pass out." EE became pale and Diaphoretic with an altered level of consciousness. EE was lower to a supine position on the floor and an ice pack was applied to head/ chest. EE states it is a little more difficult to breath, but I do not feel like my airway is closing up. No hives or reaction noted at injection site. At 3:45 pm airway was clear with no adventitious sounds noted. PERRLA with Oxygen level of 98% RA. Pulse 47. 3:50 pm EE unable to take Benadryl due to altered level of consciousness. BP: 80/60, Pulse: 69 and O2: 86% RA. EPI pen(Amneal 0.3 Mg, IM to the left thigh) administered per protocol and EMS was contacted. 3:52 pm BP: 95/70, pulse 82 and O2: 94% RA. Benadryl 25 mg administered orally per protocol. 3:54 pm BP: 100/85, O2:99% RA. Skin pink. EE states " I am feeling much better and do not need to go via EMS. EMS arrived at 4:00 pm and informed of care provided. EE was instructed that he needs continued monitoring due to EPI administration. EE was educated that he would not be able to obtain the second dose of Pfizer due to his reaction.

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1181355	4/8/2021	CT	33	F	4/8/2021	4/8/2021	Approximately 13 minutes after the vaccine was administered patient reported feeling faint. She was sweaty, shaky, hyperventilating, tingling in her fingers and reported a rapid heart rate. Patient was able to speak in full sentences and answer questions. The pharmacy team immediately called 911. The pharmacist assessed the patients symptoms and determined the patient was not experiencing anaphylaxis as she was not experiencing swelling or throat closure. No emergency medications were administered. The patient layed down on her back and elevated her feet. The EMT arrived within 5 minutes and assessed the patient. Patient was taken to the emergency department.
1181489	4/8/2021	TX	72	F	2/21/2021	3/1/2021	patient reports developing a rash on her right breast on the same side that she received her second dose of the COVID vaccine occurring approximately 8 days after the 2nd dose of the COVID vaccine. she reports that she developed a rash on her left arm after her 1st moderna covid vaccine at the site of injection. she denies any shortness of breath or anaphylaxis. both rashes spontaneously resolved.
1181537	4/8/2021	FL	38	M	4/6/2021	4/6/2021	Within 1-minute of vaccination, the patient reported tongue swelling, hives, shortness of breath, tongue tingling, and chest tightness. EMS evaluated the patient on-site. The patient was hypertensive (165/95). EMS administered 50mg IM Benadryl and 0.3mg of Epinephrine. EMS transported the patient to Hospital Emergency Department. In the ED, the patient presented with presumed anaphylactic event. On arrival, patient was hypertensive (166/91). The patient reported lightheadedness, tachycardia, chest discomfort, hives along his trunk, and tingling to his tongue after vaccination. Patient denied tongue swelling or difficulty breathing and swallowing. The patient reported improvement and was discharged with diagnosis of Anaphylaxis secondary to COVID vaccine. Physician prescribed 4-days of Benadryl 25mg PO q6-8h, Pepcid 20mg PO BID, Prednisone 20mg PO BID, and an Epinephrine 0.3mg IM injectable kit.

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1179826	4/8/2021	ME	69	F	4/2/2021	4/7/2021	Pt called into our PCP office to report to the nurse that she developed a trunkal and peritoneal rash with red raised hives 6 days after her first covid pfizer vaccine. Pt denies exposure to any recent exposure to known allergens. Pt sought care at ED where she was prescribed a Prednisone taper, zyrtec, benadryl and pepcid to manage her rash, which then became generalized. Pt did not report s/s of anaphylaxis and is managing s/s at home withb meds Rx'd by the ED.
1181945	4/8/2021	NV	71	F	4/8/2021	4/8/2021	Patient received her Moderna vaccine. She waited the 15 minutes and went around the store to shop. She then started to feel sharp chest pain and shortness of breath and returned to pharmacy. Patient did not report swelling in the airways, was able to breathe however with some difficulty. Patient reported having history of asthma and high cholesterol when asked. With patients consent, took patients blood pressure and the reading was 130/87. Told daughter what was going on, most likely not an allergic reaction/anaphylaxis. Patient then started to have "pseudo-seizures." Asked daughter and patient if we can call ambulance, and they both agreed. Stood by patient in post-vaccination area waiting for ambulance. Patient was still able to breath and her chest pain has decreased per patient - said pain lessened when sitting down. Ambulance arrived and took patient away. Both daughter and patient thanked pharmacy for helping and taking care of patient.

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1182257	4/8/2021	TX	43	M	4/5/2021	4/5/2021	Reported onset of frontal headache before leaving vaccination observation area on 5 April; headache later resolved after taking Naproxen and has not returned. Patient also experienced feeling sweaty and clammy evening of vaccine receipt; did not measure temperature; no chills; symptoms did not interfere with sleep and were resolved upon awakening on 6 Apr.. On evening of 5 Apr and on 6 Apr, patient reported generalized achiness diminished after taking Naproxen; aching did not change much between 5 and 6 Apr (no worsening); no joint swelling, warmth, or redness. Also noted "rash" within 2-3 hours of vaccine receipt - not pruritic and only located in antecubital area of left (vaccinated) arm (review of photo showed round/oval, erythematous patch about 3x3, possibly Herald patch); no significant local vaccination site reaction of left upper extremity or axillary tenderness and swelling. Denied symptoms c/w immediate allergic reaction [any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration. On 8 Apr, patient reports all symptoms gone except red area on left antecubital, which seems to be getting better
1182609	4/8/2021	FL	31	M	4/8/2021	4/8/2021	Administered Janssen COVID-19 vaccine to pt and had him sit in designated chairs for monitoring. A couple of minutes later he said he was feeling light-headed. We had him stay seated in the chair and I went and got the BP machine. I had the technician taking notes. Checked BP and it was 67/35 pulse 75. I advised him that we will have him lie down and elevate his feet to help increase his BP but he declined and stated that this usually happens with needles. I checked his BP again and it was 79/28 pulse 71. We gave him a bottle of water and very shortly after he expressed he was feeling much better. At no point did the patient have trouble breathing or was experiencing any symptoms of allergic reaction/anaphylaxis. I had patient stay seating for another 10 minutes and checked his BP one last time and it had come up to 110/77 pulse 79 and he expressed he was feeling back to normal.
1182619	4/8/2021	OH	45	F	4/2/2021	4/3/2021	Anaphylaxis with throat swelling and hives.

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1182645	4/8/2021	DE	55	F	4/7/2021	4/7/2021	Patient experienced anaphylaxis with second dose of vaccine, epinephrine 0.3mg IM (as EpiPen) was administered, and patient went to hospital via ambulance.
1182777	4/8/2021	MD	36	F	4/8/2021	4/8/2021	Patient felt itchiness and throat discomfort. No respiratory distress. Patient stated it felt like throat was tightening. She brought her own Epi Pen (Seafood anaphylaxis) and was instructed to self administer. 911 / EMS took her to nearest hospital
1182969	4/8/2021	MO	60	F	4/8/2021	4/8/2021	anaphylaxis with stridor and diffuse wheezes. No rash, GI symptoms. Received epinephrine, bronchodilators, IV steroids, histamine blockers, epinephrine drip. ICU admission
1183059	4/8/2021	HI	20	M	4/8/2021	4/8/2021	Patient briefly fainted after covid vaccination administered by pharmacy technician. Patient was sitting down. EMT arrive but patient refused ambulance transport to hospital. No anaphylaxis or other symptoms.

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1179915	4/8/2021	FL	29	M	4/5/2021	4/5/2021	<p>Patient presented himself for COVID19 Vaccine administration on 04/05/2021 at 4:10pm. Upon checking in for his appointment, he was provided with Conviva's COVID19 vaccine screening and consent form in which he denied the following: ? Having allergies and reactions to any medication, foods, vaccines, or latex. ? Carrying an Epi-pen for emergency treatment of anaphylaxis. ? Having had a severe reaction to previous dose of this vaccine or to any of the ingredients of this vaccine. After the vaccine administration, patient was guided to the observation area for a 15-minute observatory period. At approximately 4:25 pm- patient, while in the observation area, expressed to the clinical staff member monitoring the area, that he felt lightheaded and needed to lay down, he leaned forward, and the clinical alert team was activated. Patient was lowered to the floor; a pillow was placed under his head and his feet were elevated. Vitals reported were taken in the presence of registered nurse while patient was laying on the floor. Vitals ? Glucose 97 ? Blood pressure 120/77 ? Oxygen saturation level 97% ? Pulse 72 Register nurse reports that patient was laying on the floor, alert, oriented to place, time and person. Patient never lost consciousness and within approximately 5-7 minutes he was sitting up, drinking water. At this time, patient was asked the following series of questions: ? How do you feel? As per patient, he was feeling nauseous, dizzy, and anxious. ? Are you allergic to any medications or have you had any allergic reactions to a vaccine? Patient denied having had a history of any adverse or allergic reaction to any medication or vaccines in the past. Several minutes later patient stated that he was feeling better and he was assisted to sit up. Patient stated that he was feeling fine, and able to drive. Patient was kept in the observation area an additional 15 minutes. At approximately 4:40 pm- After patient was considered stable by doctor, he was checked out. Patient was given phone numbers in case he had any clinical or general questions. At 6:00 pm- (Center Administration) called patient, he stated that he was still driving and felt fine. At 6:21 pm- Patient sent a text to Center Administrator, stating the had arrived home and was feeling fine.</p>

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1182980	4/8/2021	NC	28	M	4/8/2021	4/8/2021	The patient had symptoms of light-headedness, diaphoresis, and was pale approximately 8 minutes after administration. No signs or symptoms of anaphylaxis were identified so the patient was observed and monitored. The patient then became unconscious for approximately 10-15 seconds with small jerking movements identified during this time. 911 was called and the patient was monitored until EMS arrived. Epinephrine was prepared and ready during this whole time but was not administered because the patient didn't show symptoms of anaphylaxis (trouble breathing or talking, trouble swallowing, hives, flushing etc). The time from vaccine administration to EMS arrival was approximately 20-25 minutes. The patient was able to talk and communicate clearly the entire time except during the brief unconscious period.
1179449	4/8/2021	MA	41	F	4/5/2021	4/5/2021	Systemic: Allergic: Anaphylaxis-Mild, Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Mild, Systemic: Allergic: Itch (specify: facial area, extremities)-Mild, Systemic: Allergic: Swelling of Face / Eyes / Mouth / Tongue-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Tachycardia-Mild

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1177962	4/7/2021	IL	63	F	3/31/2021		<p>DIZZINESS; FACE SWELLED; THROAT CLOSING; CHEST TIGHTNESS; ITCH IN EAR; HEART BEAT RACING; WHEEZING; WEAKNESS; This spontaneous report received from a patient concerned a 63 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included non-smoker, non alcoholic, penicillin allergy, and sulfonamide allergy, and other pre-existing medical conditions included the patient had anaphylaxis with tetanus booster shot 4 years ago. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808980, expiry: unknown) dose was not reported, administered on 31-MAR-2021 at 12:18 p.m. vaccinated on left arm for prophylactic vaccination. Concomitant medications included cetirizine hydrochloride for allergy, and fluticasone propionate for allergy. On 31-MAR-2021, the subject experienced dizziness. On 31-MAR-2021, the subject experienced face swelled. On 31-MAR-2021, the subject experienced throat closing. On 31-MAR-2021, the subject experienced chest tightness. On 31-MAR-2021, the subject experienced itch in ear. On 31-MAR-2021, the subject experienced heart beat racing. On 31-MAR-2021, the subject experienced wheezing. On 31-MAR-2021, the subject experienced weakness. Laboratory data included: Blood pressure (NR: not provided) Unknown. Treatment medications (dates unspecified) included: diphenhydramine hydrochloride. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from dizziness, face swelled, throat closing, chest tightness, heart beat racing, wheezing, and weakness on 31-MAR-2021, and had not recovered from itch in ear. This report was non-serious.; Sender's Comments: V0: Medical Assessment comment not required as per standard procedure as the case assessed as non-serious</p>

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1174294	4/7/2021	AZ	62	M	3/19/2021	3/19/2021	'blood pressure had been up to 180/increase in blood pressure'; he was freezing; he was cold; "he is usually up at work every day and he hasn't been able to work the last few days"; feels like he can't think", "tired; "he may be getting in for breathing treatments today"; so sick; feels like he can't think", "tired; Feeling lousy; Lethargic; Running temperature; Chills; Hives; Anaphylaxis; fell asleep for 16 hours. Caller reported that he doesn't normally sleep for 16 hours; Throat scratching; Eye itching; Bags under eyes; This is a spontaneous report received from a contactable consumer (patient). A 62-year-old male received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Solution for injection, Batch/Lot number: EN6207), via unspecified route of administration on right arm on 19Mar2021 13:09 as a single dose, for COVID-19 immunization. The patient medical history included Ongoing COPD (about 5 years ago), high blood pressure (about 10 years ago and still ongoing) extensive allergies to food and insect bites. The patient was diagnosed with the allergies when he was a little kid, allergic to penicillin ongoing. Concomitant medications included lisinopril at 20 mg once daily in the morning for high blood pressure and albuterol at 2 pumps in AM and 2 in PM before going to bed for COPD (Chronic obstructive pulmonary disease). The patient previously took historical vaccine ampicillin for infection. On 19Mar2021, the patient experienced, ended up feeling really sick right after the shot. He has a lot of allergies and he was advised to take his Epi-Pen kit and stay an additional 30 minutes past the recommended waiting time after receiving his vaccine. His throat began scratching after getting the shot and lasted for about 3 to 4 hours for which the patient received Benadryl and resolved completely. His eyes were itching and lasted for 24 hours, and bags started to form under his eyes like anaphylactic shock. It was reported that the bags under his eyes would normally stay after anaphylaxis for a day or two. His eyes were still a little puffy at the bottom. He did not see a rash but started to get hives, the paramedics were called and monitored him for another 30 minutes. The paramedics administered a shot of Benadryl. After the Benadryl was administered, his body and blood pressure started to come down. The paramedics reported that his blood pressure had been up to 180. It was reported that on 19Mar2021, afternoon,

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when the patient got home, he was sick, laid down and fell asleep for 16 hours. He does not normally sleep for 16 hours. He was unsure if his eyes were itchy in his sleep. Later in the call it was clarified that this might have only lasted 3-4 hours, he was so tired he just went to sleep. It was reported that he was not a sleeper, that he was usually up at work every day and he had not been able to work the last few days. It was reported that he started feeling the side effects of the Covid-19 vaccine at 13:20 on 19Mar2021. On 20Mar2021, he felt lousy ever since he received the COVID-19 vaccine. On the same day, his wife took his temperature, and his temperature was hovering around 100-100.9. He felt lethargic, running a temperature between 100.5 and 100.9 pretty consistent every day. On an unspecified date, his wife took his temperature, and it was 99.9. He felt like his mind was in a fog, intoxicated and he had not felt good since receiving the first dose of the Covid-19 vaccine. It was reported that the mental fog made him felt like he cannot think. The paramedics gave him a test and asked him to add 5+7. The patient answered 14, even though he knew that the answer is 12because he could not think, and he felt punch drunk. He reported that he can concentrate a little more, but he still felt drunk, this was hanging around the same now. It was reported that the paramedics were asking him questions and gave him things to do, addition and subtraction formulas, to keep his mind. He could not finish those formulas and that he told the paramedics that he felt foggy or punch drunk. He spoke with his health care provider at the VA and the provider advised him not to get the second dose of the Covid-19 vaccine. It was reported that the patient was inquired if he had any immunity to Covid-19 without taking the second shot and if he was protected with just the one dose of the Covid-19 vaccine. It was also reported that, the reporter also looked through the list of side effects for Covid-19 vaccine and it was like patient had all of them. The patient experienced chills, he was freezing, and he was cold. The patient had the whole list of them. It reported that he had doctor appointment on Monday, 29Mar2021, and that he may be getting in for breathing treatments today. He was waiting for his insurance to finalize the approval for the breathing treatments in the evening. The outcome of the events throat scratching and eye itching was recovered on

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							19Mar2021, Outcome of the events bags under eyes and blood pressure had been up to 180/increase in blood pressure were recovering. The outcome of the events feeling lousy, lethargic, running temperature and chills were not recovered. Outcome of the other events was unknown. Information on the lot/batch number has been requested. Information on the lot/batch number has been requested.
1175375	4/7/2021	VA	44	F	4/7/2021	4/7/2021	Vaccine administered around 0850, approximately at 0854 patient notified provider with symptoms of anaphylaxis reaction. Patient brought to private room, notice symptoms of generalize rash. Vital signs taken at 0902 BP: 142/82 HR:102 O2: 100%. Administered Benadryl 50mg/mL at 0902 Lot number: 6020111 Exp: 07/21. Patient expressed tightness of throat with audible wheezing, immediately administer EPI Pen 0.3 mg/mL Lot number: 0FN1407 Exp: FEB2022 on the left thigh. Patient improving symptoms. FED FIRE was called at 0901, arrived at 0908, transported at the Hospital at 0912.
1175377	4/7/2021		24	F	4/6/2021	4/6/2021	Dizziness, Lightheadedness, Loss of Consciousness, Weakness "Approximately 10 minutes after receiving first COVID-19 vaccine, patient reported she felt lightheaded. Denies CP, SOB, throat swelling. Denies any hx of severe allergic reaction or anaphylaxis. Reports hx of similar reactions after receiving the flu shot. On initial evaluation: BP 126/69 HR 68 RR 16 O2 sat 97% ORA After sitting in a wheelchair for approximately 15 minutes she reports symptoms had resolved other than a very mild headache. No signs of anaphylaxis or severe allergy Patient released after monitoring. State she feels comfortable driving home.~~

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1175497	4/7/2021	NY	33	F	3/10/2021	3/10/2021	My right hand started hurting, then started tingling and it radiated up my arm. I had a heavy wave of dizziness, my chest started feeling weird and I started having a little trouble swallowing. I alerted a pharmacist, who sat with me with an EpiPen, but I wasn't sure what was happening so I didn't want it. My hands started shaking, I got dizzy, had a headache, felt nauseous, my arm started hurting more and I could feel my throat getting tighter. I started panicking when I couldn't feel much air coming out of my throat, started feeling confused and so the pharmacist administered the EpiPen. Within a minute or so, I was able to breathe a little better and within 15-30 minutes, I was able to breathe normally. At the hospital, my potassium levels crashed to a critical level and I had a potassium transfusion, which normalized my levels. I felt better the next day. It's almost a month later and my right hand/arm is still having issues, which was determined to be an Ulnar Nerve Entrapment...most likely caused by the anaphylaxis since my arm tightened up. I have an EMG test this week for it.
1175556	4/7/2021	NJ	47	U	4/6/2021	4/6/2021	Patient experienced lightheadedness, tingling in lips and redness in face x 5-8 minutes of moderna vaccine. shot 2. shot 1, had no symptoms except for soreness on arm. hx of cyclic neutropenia and migraines. no hx of allergies or anaphylaxis. no SOB. no itching. no N/V stomach pain. no other rash/ redness except for face. swallowing is normal. no throat or tongue or lips swelling. Patient was monitored until symptoms resolved, no additional medications administered.

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1175622	4/7/2021	MA	26	F	4/6/2021	4/6/2021	Pt reported feeling faint and nauseous to administering RN immediately after vaccination. Pt was still seated at vaxxing table. Pt vomited x 1 mod amt, x1 sm amt into basket provided by nurse. Her appearance was pale and she was visibly shaky and reported feeling weak. Pt did not lose consciousness and denied SOB. Pt was advised by nurse to stay seated w/ head down. An ice pack was applied to the back of pt's neck. Pt reported having similar syncopal episodes when she gets blood drawn. She was transferred to wheelchair with assistance frm administering nurse and on-site EMT team and moved to a quiet observation area. Pt was observed for 30 min while on continuous VS monitoring - all were stable and WNL. Pt's color returned and she stopped shaking w/in 10 min. Pt drank some water and had a hard candy. After 30 min pt reported feeling "fine", was up and ambulatory, alert and oriented, and stated she felt fine to drive home. Charge nurse and EMTs felt comfortable that pt was back to baseline and able to drive herself. Pt was advised to seek emergent care if sx returned/worsened, if she experienced any s/s of anaphylaxis or for any other concerning sx.

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1177058	4/7/2021	MT	27	F	4/1/2021	4/2/2021	Family reports that patient had her 2nd dose of COVID-19 vaccine on 4/1, approximately 3 weeks after her first dose. Patient had one week history of "allergy type" symptoms. Evening of 4/1 developed "GI symptoms and diarrhea". Morning of 4/2 her "neighbor came by to check on her and she stated that she was not feeling very well last night but thought she just needed some Gatorade of something...He stated that as he gave her the alka-Seltzer he told her that there was aspirin in it which apparently she has an allergy to. He stated that her response was I should be fine I do not think I'm that allergic to aspirin...5 to 10 minutes later she started to have some issues...Patient stated to her neighbor that she was having a hard time breathing and thought she needed to go to the hospital, and that maybe she was more allergic to the aspirin than she had thought...Over the 15 miles between her house and the hospital patient condition deteriorated to the point where they arrived at the hospital she is in full cardiac arrest...given ACLS protocol including epinephrine and was intubated." "They achieved ROSC after approximately 10 minutes." Patient was then flown, MT emergency department to Hospital. Patient was cared for in the ICU. Patient herniated her brain the night of 4/5-4/6. "After meeting the clinical and imaging criteria at 1605 on 4/6/2021 she was declared brain dead. Medical team suggests that patient had Samter's Triad/Triad Asthma with history of asthma, nasal polyps and allergy to aspirin. Anaphylaxis secondary to ingestion of aspirin via Alka-Seltzer.
1178900	4/7/2021	CA	28	M	4/6/2021	4/6/2021	While waiting in observation my chest began to feel tight and in pain. The symptom lasted around 5 minutes and did not impede my ability to breathe. This concerns me since one of the allergic responses is anaphylaxis and I will need a second vaccination. Additionally, that night at 8:30 and the following day I have developed a minor headache (5), feel fatigued and tired, slight nausea, and slight aching in my body (3)

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1177641	4/7/2021	CO	40	M	4/7/2021	4/7/2021	Patient recieved the vaccine in the left arm and was asked to wait in the pharamcy waiting area for observation for 15 minutes (no previous hx of anaphylaxis). Upon returning to the main pharmacy floor a few minutes later one of the technicians alerted me to the patient had returned to the counter and was "feeling something". He was visibly struggling to maintain balance and I asked patient to take a seat to prevent any risk of falls and motioned to a chair. He took a seat on the floor next to the pharmacy counter and I rushed over to him to tend to him. I asked him if was having any other symptoms and he noted he was feeling lightheaded and having chills all over his body. His body was cold and clammy to the touch and had a difficult time locatiing a pulse on the radial artery. While talking to him his responses were shorter and he seemed like was starting to almost lose conciousness. Management had already called 911 and we offered water to the patient while we waited. Prior to the paramedics arriving I was able to get a pulse using a cuff and it was around 53bpm, the patient also seemed hypotensive.

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1178233	4/7/2021	OR	30	F	3/17/2021	3/1/2021	severe allergic reaction/anaphylaxis; hallucinations; accidentally given a 3 ml dose of the Moderna Covid-19 vaccine instead of 0.5 ml; nightly terrors; fear of dying; intermittent delusions that children were taken away; intermittent delusions that the vaccine was inside her and crawling through her skin; This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 17-Mar-2021 and was forwarded to Moderna on 17-Mar-2021. This spontaneous case was reported by a pharmacist and describes the occurrence of HALLUCINATION (hallucinations) and ANAPHYLACTIC REACTION (severe allergic reaction/anaphylaxis) in a 30-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (Medical history was not provided). On 17-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 3 milliliter. In March 2021, the patient experienced SLEEP TERROR (nightly terrors), FEAR OF DEATH (fear of dying), DELUSION (intermittent delusions that children were taken away) and FORMICATION (intermittent delusions that the vaccine was inside her and crawling through her skin). On 17-Mar-2021, the patient experienced ANAPHYLACTIC REACTION (severe allergic reaction/anaphylaxis) (seriousness criterion hospitalization) and ACCIDENTAL OVERDOSE (accidentally given a 3 ml dose of the Moderna Covid-19 vaccine instead of 0.5 ml). On 24-Mar-2021, the patient experienced HALLUCINATION (hallucinations) (seriousness criterion medically significant). The patient was hospitalized from 17-Mar-2021 to 18-Mar-2021 due to ANAPHYLACTIC REACTION. In March 2021, ANAPHYLACTIC REACTION (severe allergic reaction/anaphylaxis) had resolved. On 17-Mar-2021, ACCIDENTAL OVERDOSE (accidentally given a 3 ml dose of the Moderna Covid-19 vaccine instead of 0.5 ml) had resolved. At the time of the report, HALLUCINATION (hallucinations), SLEEP TERROR (nightly terrors), FEAR OF DEATH (fear of dying), DELUSION (intermittent delusions that children were taken away) and FORMICATION (intermittent delusions that the vaccine was inside her and crawling

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through her skin) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient did not have any psychological history; this was the first time she experienced hallucinations. Treatment for the severe allergic reaction/anaphylaxis included intravenous steroids and hydrocortisone. Treatment for hallucinations included droperidol and lorazepam. Based on the current available information and temporal association between the use of the product and the start date of the event (anaphylactic reaction), a causal relationship cannot be excluded. Very limited information regarding the events (Hallucination, anaphylactic reaction, sleep terror, fear of death, delusion, and formication) has been provided at this time. This report refers to a case of (accidental overdose) for mRNA-1273, lot # 031A21A. Further information has been requested. Most recent FOLLOW-UP information incorporated above includes: On 24-Mar-2021: Significant Follow up appended; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event (anaphylactic reaction), a causal relationship cannot be excluded. Very limited information regarding the events (Hallucination, anaphylactic reaction, sleep terror, fear of death, delusion, and formication) has been provided at this time. This report refers to a case of (accidental overdose) for mRNA-1273, lot # 031A21A. Further information has been requested.

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1178271	4/7/2021	FL	53	F	3/24/2021	3/24/2021	This is a spontaneous report received from a contactable Consumer, the patient. A 53-years-old non-pregnant female patient received first dose of BNT162B2 (BNT162B2, Solution for injection, lot number, expiration date: not available) via an unspecified route of administration on left arm on 24Mar2021 09:15 at single dose for COVID-19 immunisation. The patient's medical history included Gastroparesis, allergies to medications, food, or other products: latex, yeast, wheat, guaifanisen and Dextromethorphan. Concomitant medications were not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 24Mar2021 09:15 AM, patient experienced anaphylaxis within minutes of having the injection and began to feel flushing down throat, then down to chest. That was concerning but when suddenly, patient got really hot, ripped her mask off, and she realized that she was having difficulty breathing and it got worse as time went on, it was resulted in Emergency room/department or urgent care. Patient received Epi-pen, Benedryl, fluids as the treatment for the events. The outcome for the events was recovered on an unspecified date. Information on the lot/batch number has been requested.
1178316	4/7/2021	NV	49	F	4/4/2021	4/4/2021	Within 30-60 seconds of receiving the vaccine my heart started racing. No other symptoms. I alerted the nurse - she took my blood pressure and it was very high (XXX/110). EMTs were called in case I was having an allergic reaction, but I did not have any other symptoms of allergies, just a very high BP and heart rate. At this point I'm sure anxiety drove my BP higher, on top of the reaction, since I was concerned I was going to go into anaphylaxis, but the original racing heart started within one minute of the injection while I was beginning my 15 minute wait time near the injection station. I worked on regulating my breathing and with the EMTs monitoring, my BP down to a manageable but still elevated rate after about 20 minutes. I did not go to the hospital. Once I was resting at home it took about 4 hours before I felt my heart rate was at a normal level and the feeling of racing was gone. I did not have any other adverse reactions until 4/7/2021 which is the first day that the injection site (upper L arm) started aching.

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1178397	4/7/2021	CA	45	F	3/20/2021	3/20/2021	Pt requested medical consultation and I and paramedics arrived to assess. Pt has hx mast cell activation, in consultation with allergist took Benadryl, cromolyn sodium and Pepcid 1 hour prior to vaccination. 20 minutes after vaccination had pink puffiness of lower eyelids bilat and had GI bloating, no SOB/wheeze/tongue or throat swelling but elected to self-administer own Epi-Pen to prevent progression to anaphylaxis that has started with similar sx's in past. Exam: CV RRR no M slight tachycardia, bp 150/73 HR 107 RR 99. Pt observed for 10 minutes with no progression of sx's and advised to wait additional 15 minutes to ensure she was feeling well enough to drive home.
1178413	4/7/2021	CA	32	F	3/20/2021	3/20/2021	Patient was vaccinated at 1125 on 03/20/2021, in the left bicep. Presented to the observation area at 1135 with progressively worsening throat and ear discomfort described as "itching." EMTs immediately placed patient on the monitor and collected a set of vital signs. Patient denies having LOC, syncopal episode, confusion, visual changes, generalized weakness, n/v, lightheadedness, dizziness, changes in vision, respiratory distress, sob, abdominal pain, n/v/d, swelling to the tongue or throat, feeling clammy or other associated symptoms at this time. Patient reported history of IV benadryl anaphylaxis. Provider administered 50 mg of Benadryl, by mouth, with water, at 1148. Patient tolerated medication well. Sister at bedside. Paramedics notified at 1145 and arrived at patient's bedside at 1158. Patient left at 1215 on stretcher with all personal belongings.
1178499	4/7/2021	OR	67	F	4/5/2021	4/5/2021	S. In monitoring area, patient complained of a feeling of swelling and tingling in the lips. She denied shortness of breath, pruritus, or light headedness. History of multiple drug allergies reviewed O. BP 166/77 P84 R14 SPO2 95% Repeat. 159/76 81 14 96% No rash. No visible facial swelling No respiratory distress or stridor Diphenhydramine 50 mg PO given Symptoms resolved over 15 minutes A. Possible hyperventilation v. allergic response. Rapid resolution rules out anaphylaxis or serious allergy. P. After 10 more minutes of observation, symptoms resolved. Discharged in personal vehicle.

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1178514	4/7/2021	OR	19	F	4/5/2021	4/5/2021	S: Patient began to develop petechiae within about 10 minutes of her vaccination today. She felt well, without respiratory distress or urticaria. Later on, she developed some tingling in the right palm and part of her forearm. Her vaccination was on the left side. There were no visible changes associated with these symptoms. O: I personally witnessed the spontaneous appearance of small petechiae on patient's forearm. She had about 10 of them on either forearm and a couple on her shoulders. No erythema, rash, wheals. BP128/66 P 70 sPO2 100% RR 12 A: I was unsure regarding the importance of this finding, so I called emergency department and conferred with one of the MDs there. We felt that, since the patient was in no distress, and this condition was not getting worse, we would allow her to head home. After a total of an hour of monitoring, no signs or symptoms consistent with anaphylaxis or respiratory distress of any sort had emerged.
1178598	4/7/2021	MI		U			Patient received vaccine at approximately 5:07 pm on 04/07/2021 and started experiencing a swollen lower lip at 5:32 pm. 911 was called and the paramedics at the scene determined it was an allergic reaction but not anaphylaxis and instructed patient to take benadryl. Patient went home after the paramedics left a little after 6 pm.
1177621	4/7/2021	NY	38	F	4/7/2021	4/7/2021	Ten minutes after vaccination patient experience lightheadedness, diaphoresis, and brief syncope at the pharmacy counter. Pharmacist assisted patient to a chair. Patient was responsive but sweating profusely, experiencing tremors, and appeared lethargic. No signs of anaphylaxis, however upon checking patients vitals - heart rate and blood pressure were below normal for patient. Paramedics arrived and monitored vitals for about 20 minutes. Patients condition appeared to improve and walked out of the pharmacy with the paramedic personnel. Patient was not taken to the hospital.
1173415	4/6/2021	TX	59	F	3/28/2021	3/28/2021	anaphylaxis response Swelling of neck/face/eyes, difficulty in breathing

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1174131	4/6/2021	WA	17	F	4/6/2021	4/6/2021	Pt had itching about 50 minutes after getting the Pfizer covid vaccine. Pt waited the time requested and was thankfully still shopping with her mother and brother in the store when the reaction developed. Pt was given 50mg of liquid diphenhydramine. I discussed calling 911 with the family and they said they would prefer we did not if possible. She has food allergies, which were discussed before giving the vaccine and she is used to having reactions, she also knows what anaphylaxis feels like and could tell that was not the reaction she was having. After discussing with the family and consulting with my market direction I decided to not call 911 immediately but let them know that if the diphenhydramine was not helping quickly I would make the call. I observed the patient for 30+ minutes with an EpiPen on my person in case she showed any signs of worsening. She improved visibly while getting drowsy from the antihistamine. After she had stabilized for some time and the patient and her family was also comfortable with her improvement I allowed her to depart the pharmacy with a request to keep her EpiPen close and call 911 if things worsen or the EpiPen became necessary.
1173409	4/6/2021	CO	20	F	4/1/2021	4/2/2021	Awoke in the middle of the night to mild/moderate anaphylaxis - tingling throat and tongue, swelling of throat and tongue, difficulty breathing, nausea, gagging, diarrhea - lasting for about 30 minutes - all symptoms occurred at the same time

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1172944	4/6/2021	TX	47	M	4/1/2021	4/6/2021	Client received his first dose of Covid vaccine in the clinic on 4/1/2021 at approximately 10:25 a.m. Client was walked to the courtroom for observation for 15 minutes post-vaccination. This is standard procedure. When his 15 minutes was up, Nurse informed him that his time was up and he was free to go, and signed him out. As she was speaking with him, she noticed he was disoriented. She asked if he was all right and fanned his face for a few seconds. 2nd nurse came by at that time, and the women helped pt. back to the clinic and onto a pad on the floor in a nurse?s office. Third person was called. Vitals were taken several successive times (BP ranged from 148/99 to 155/104), Temp was normal and in 97.5 to 98.4 range. Resp 16-18. Pulse was between 78 and 93. Client was disoriented, could not state his name and could not name anyone for us to call. Ammonia salts were employed with no effect. All emergency meds, oral airways, and AED were gathered in case they were needed. No other meds or equipment were used. By standard called for the clerk, and By standard, to call paramedics. She called 911 x 2 and when put through to EMS, was given a disconnect notice. She ran down the hall to the constable?s offices, who placed the call and had paramedics on their way. Then two constables (male and an unknown female constable) came to the Health Dept. Third person got the client to answer with whom to call. Third person called the client?s mother-in-law and employer. Both arrived after the client was transferred via ambulance and left to join him immediately at the hospital. As all this was happening, Nurse, 2nd Nurse, third person, and Bystander were attempting to ensure pt. airway and breathing were patent. He never had difficulty breathing and never had wheezing. There were no other visible signs of anaphylaxis. His color was pale, then improved, but became pallid again at about the time the paramedics arrived. He was never alert or oriented throughout the event. Paramedics arrived at approximately 11:00 a.m. They did an initial assessment and received report on what had occurred and data gathered. They then had to lift pt. onto the stretcher. He was then transported to Hospital.

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1171865	4/6/2021	PA	26	M	4/1/2021	4/2/2021	Patient presented to ED after 2 days of rash with no relief of symptoms from Benadryl. Received full treatment for anaphylaxis including: Epi-Pen, Solumedrol, Benadryl, Pepcid.
1171452	4/6/2021	PA	50	M	3/23/2021	4/2/2021	Patient presented to ED with two day history of hives over body. Received treatment for anaphylaxis in ED including Epi-Pen, Pepcid, Benadryl, and Solumedrol. Patient initially hypotensive.
1171167	4/6/2021	MA	49	F	4/5/2021	4/5/2021	hx OF ANAPHYLAXIS TO MMR; PATIENT EXPERIENCING TONGUETHICKNESS AND ITCHING5-7 MIN POST INJECTION. VITAL SIGN 130/78-78-100%.NO TONGUE SWELLING VISIBLEPATIENT TALKININ FULL SENTENCES. USED INHALER. PLACED ON STRETCHER 0915 EPIPEN ADMIN TO LEFT QUAD.; MD IN TO EVALPATIENT TRANSFERRED TO ER FOR EVAL AT 0935.
1171162	4/6/2021	MA	47	F	4/3/2021	4/3/2021	PATIENT HAS ANAPHYLAXIS TO BEE STINGS AFTER 20 MINPT C/O PHLEGMY FEELING IN BACK OF THROAT AND HER MOUTH FELT WEIRD. PT WAS OBSERVED BP 145/88 O2 100%HR 81 SHE RESTED ON STRETCHER AT 1:40PM REPORTED FEELING 90% BETTER AND SHE WENT HOME IF SX CHANGE OR GET WORSE WILL GO TO ER CALL MD
1173836	4/6/2021	CA	35	F	3/11/2021	3/11/2021	Anaphylaxis, rash, hives, 15 minutes after vaccine. Given EpiPen, Benadryl 50 mg IM.
1174028	4/6/2021		21	F	4/7/2021	4/7/2021	21 year old female patient ambulated to Hospital with complaints of abrupt urticaria 2 hours after receiving first Covid-19 Moderna vaccine. Patient vital signs within normal limits. Physical examination was conducted with no signs of anaphylaxis. Patient was prescribed diphenhydramine 25mg capsules, taken 2 tabs by mouth under direct observation. She was monitored for an additional 40 minutes, with vital signs retaken and within normal limits. She was placed Sick In Quarters x 24 hours, and instructed to follow up with her DR should symptoms not improve.

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1170112	4/5/2021	TX	39	F	3/22/2021	3/22/2021	Pt received shot at 1626. At 1637, pt reported that her lower lip felt itchy, cheeks were red. Pt has hx anaphylaxis to multiple food allergies and carries epi pen with her. At 1638, VS: BP 168/112, P 86, O2 100% RA. Lungs clear bilaterally. Pt then reported that her tongue felt ?numb? and ?pins and needles? sensations. Recheck BP is 200/130 at 1644. Pt is awake, alert, oriented. She states that when she has anaphylaxis in the past, this is how it initially presents. Dr. called at 1645 and notified of pt condition and advises to give epi and benadryl and call ems. EMS called at 1650 by RN. Pt requested to wait until EMS is closer to take epi as she said that it can make her blood pressure raise. At 1653, pt willing to take epi. Pt?s seat reclined. Epi pen 0.3mg given at 1653, Benadryl 50mg liquid given at 1654 by RN. EMS on site to take over care at 1655. Pt remains A&OX4 at this time. No difficulty breathing at this time. Pt remains fully conscious. Pt transferred to hospital in EMS. Pt notified that due to her having anaphylactic reaction to vaccine, she will not be able to receive another vaccine. Pt advised to follow up with PCP. RN
1167502	4/5/2021	TX	31	M	4/4/2021	4/4/2021	Site: Bruising at Injection Site-Mild, Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Mild, Systemic: unconscious not responsive-Severe, Systemic: Shakiness-Mild, Additional Details: Pt. unconscious, not responsive fell off his seat on face

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1167534	4/5/2021	NC	40	F	4/2/2021	4/2/2021	Experienced brief, minor dizziness about 10 minutes after the shot. On my drive home about 15-20 min. after the shot, I experienced more severe symptoms of anaphylaxis. I was able to breathe but my airway was constricted and swollen. After arriving home, I called pharmacy but their pharmacists were out on lunch. My primary care doctor was closed (Good Friday). I waited until the pharmacist was back from lunch and they advised Benadryl (I took 50 g at 2pm) and to have someone with me for the next 24 hours. Symptoms improved some but by 5pm I still couldn't take a deep breath normally and was concerned about eating food. I went to the ER where they admitted me and administered Pepcid and dexamethasone at 6:22pm. After about an hour and a half, I felt better and was released. Once home, I ate food and that irritated my throat again so I kept an EpiPen nearby that evening just in case. The next morning I felt 100% with no side effects.

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1167725	4/5/2021	IN	76	F	3/27/2021	3/30/2021	76-year-old female presents to the emergency department complaints of a rash. The rash is red, seems to be worsening daily, very painful, constant. She has been taking prednisone, that does not seem to help. She developed a rash after the initial Moderna COVID immunization, and then it went away. When she got her 2nd immunization on 03/27, a couple days later she developed the same type of rash, only significantly worse. She denies any difficulty with breathing, swelling of the tongue. There is no rash throughout the rest of the body, she did get the shot in the left shoulder. She has not had any fevers. No difficulty breathing. This rash is consistent with that of shingles. It occurred on the left shoulder, where the COVID vaccine was given. She initially developed a rash after the 1st 1, then again after the 2nd shot. This has pain consistent with that of shingles. Unlikely allergic reaction, but possible. She is currently on prednisone she will continue that. She was given acyclovir and gabapentin. One dose was given here in the ER. No swelling of the tongue, no evidence of anaphylaxis. The rash does not go beyond the left shoulder region. Patient appears otherwise stable, normal vital signs besides hypertension. The primary encounter diagnosis was Herpes zoster without complication. A diagnosis of Rash was also pertinent to this visit.
1168141	4/5/2021	MD	62	F	3/30/2021	3/30/2021	Anaphylaxis flushing, warm, unable to breath, chest pain.
1168152	4/5/2021	TN	35	F	3/31/2021	3/31/2021	started having itchy throat and strange taste in mouth about one hour after vaccination. Voice became hoarse, had some wheezing the following morning. Had some breaking out on her face along with small amount of injection site pain. Hasn't had any reactions in the past. Discussed based on timing and symptoms, likely was reaction to COVID vaccine. Little chance of anaphylaxis at this point but call 911 if this happens. Steroids and hydroxyzine prescribed.

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1168912	4/5/2021	MA	68	F	3/13/2021		ITCHY SKIN ALL OVER THE BODY; NUMBNESS IN TONGUE; This spontaneous report received from a patient concerned a 68 year old female. The patient's weight was 200 pounds, and height was 63 inches. The patient's concurrent conditions included hyperactive immune system, environmental allergy, food allergy, pharmaceutical allergy, alcohol user, non smoker, inflammation, hiatal hernia, seasonal allergies, and insulin resistance, and other pre-existing medical conditions included there is no history of drug abuse or illicit drug use. The patient experienced 2 anaphylactic events when treated with urethane. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805031, and batch number: 1805031 expiry: UNKNOWN) dose was not reported, 1 total, administered on 13-MAR-2021 13:00 for prophylactic vaccination. Concomitant medications included famotidine for hiatal hernia, metformin for insulin resistance, and levocetirizine dihydrochloride for seasonal allergies. On 13-MAR-2021, the subject experienced itchy skin all over the body. On 13-MAR-2021, the subject experienced numbness in tongue. Treatment medications included: diphenhydramine hydrochloride. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from itchy skin all over the body, and numbness in tongue on 14-MAR-2021. This report was non-serious. Additional information was received from patient on 29-MAR-2021. Following information was updated and incorporated into the case narrative: other reference numbers, onset date for event numbness in tongue updated, Vaccination time updated. Upon review, following correction was performed in the case: Anaphylaxis to urethane coded as past event past drug format.

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1169095	4/5/2021	WI	53	F	4/1/2021	4/1/2021	Pt reported feeling her hands suddenly "swollen, tight, and tingling" 15-20 minutes after vaccine administration. RN noted some mild bilateral edema in pt hands. RN took pt to observation at 3:25 PM and advised administration of oral diphenhydramine; pt consented to medication, and RN offered 50 mg of oral diphenhydramine, which pt swallowed at 3:25 PM. Pt denied all other s/s of allergic reaction. RN continued to monitor pt, completing BP, HR, and SpO2 assessment q 5 minutes; all vitals remained WNL. Pt reported no worsening or new onset of symptoms. No signs of anaphylaxis developed, so RN released pt to home at 3:55 PM. Advised pt to contact her PCP the same day for further evaluation/instruction.
1169506	4/5/2021	CO	34	F	4/2/2021	4/2/2021	Patient came in to the pharmacy to receive second dose of the covid-19 vaccine around 1230pm on 4-2-2021. She stated that after she left from her first dose her jaw felt slightly weird but nothing more than that and it went away after a short while. It was determined to give her the second dose but to monitor her for any reactions/anaphylaxis. She received the vaccine around 1:00pm from a pharmacy tech, and within 5ish minutes told my tech that her jaw line was tingling and her lips felt swollen. Pharmacist on duty, took the e-kit and went to check on her. She seemed to be talking fine and stated she wasn't having a hard time breathing. Pharmacist made the decision with the patient's consent to call 911 to be on the safe side. No meds were administered. Paramedics showed up, evaluated patient, and with the patient's consent, took her to the ER. The pharmacy followed up with the patient on 4-5-2021 to make sure she was okay. She said she was doing fine and that on 4-2-2021 her throat started to get prickly when she got to the ER so they administered bendadryl which helped.

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1170080	4/5/2021	WA	43	F	4/5/2021	4/5/2021	Patient presented for COVID vaccine and indicated that she has had anaphylaxis but only to allergy shots in the past, not to other vaccines. Our immunizing technician gave the patient her first COVID vaccine between 2:45 and 3pm. She sat down for observation with her daughter beside her. About 10 to 15 minutes later the patient began coughing more and more profusely. She expressed chest tightness and became flush in her face and upper chest. She stated she was going to use her EpiPen that she carried with her. An in-date EpiPen from the pharmacy was provided instead and the patient self-injected in the right thigh as she was familiar with its use. She was monitored after and she continued to cough along with having some jittery feelings from the EpiPen. This continued for about 3 minutes with her still straining to cough. She wanted to hold off on the second dose of the EpiPen as she was still jittery but the paramedics were called for her. The paramedics arrived and they took over the scene and took her to the emergency room at 3:25pm.

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1170290	4/5/2021	FL	54	F	4/5/2021	4/5/2021	Administered vaccine at 12:40pm Pt during administration of vaccine started to pull away but full dose was administered, pt was nervous about the needle. After instructing pt to sit in the post vaccine chair for 15 minutes I noticed visible distress at around 12:50pm. I rushed to her aid and asked her how she was feeling and she reported feeling dizzy. I then helped her out of her chair onto the floor to ensure she would not fall and hit her head - told her to lay supine. I then asked my technician to give me the bp monitor. I then checked her bp and it was below 80/60. I informed her this could be contributing to her dizziness and then asked for consent to help raise her bp. She consented and then I told her I would be lifting her legs in the air to raise her BP. I held her legs in the air for 10 minutes or so and then reassessed her BP and it was 110/48. She started to feel better but reported feeling as if ants were all over her left arm which is where I gave her the vaccine. I assessed once again for angioedema, anaphylaxis, hives, redness, swelling, but didnt see anything. Since the pt was dizzy I did not offer her benadryl liquid but instead offered clairitin. The pt was merely having a panic attack post immunization and said she could swallow tablets and was feeling better. I gave her one clairitn tablet etc. She wanted to sit up so I assisted her to a sitting position while she was on the floor. She sat there for additional ten minutes then moved into a chair and was brought food by her husband because he said she did not have breakfast and thought that could be why she was dizzy. She was not a diabetic so I was not concerned about her BG. She said that this never happened in the past when I reviewed her PCQF form prior to giving her the vaccine. She has had zero history of syncope so this was rare for her. After an additional 10 minutes she had a bp reading of 98/60 and left the store feeling much better
1169249	4/5/2021	WI	64	F	4/5/2021	4/5/2021	Patient received the Covid-19 vaccine. She reports symptoms of Other: difficulty swallowing similar to shell fish reaction, but no difficulty breathing. No Hx of anaphylaxis and does not have epi pen I have observed at 1350 P ox 97%, HR 85, B/P 150/82, RR 24 At 1400 Pox 97% HR 77, B/P 132/78, RR 16 Treatment/intervention Benadryl oral 25mg at 1353 VAERS report submitted: Yes NO

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1169841	4/5/2021	VA	29	F	4/2/2021	4/2/2021	Anaphylaxis 30 minutes after injection. Lasted 2 minutes. Came back 20 minutes later for 1 minute. Went away on it's own both times. Currently pregnant, due November 10.

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1168959	4/5/2021	MO	66	F	3/24/2021		<p>BOTH EYES WERE IRRITATED; BOTH EYES WERE RED; DIZZINESS; FELL AGAINST SINK; FEELING VERY BAD; HEADACHE RADIATING TO SHOULDER AND NECK; TEMPERATURE 101.4 F; MUSCLE ACHES TO BILATERAL BUTTOCKS AND BILATERAL THIGHS; LEFT ARM PAIN ALL THE WAY TO THE BACK OF THE SHOULDER; VERY BAD HEADACHE; NOSE SWELLING; LIP SWELLING; LEFT EYE SWELLING; FEELS NASAL PASSAGE CLOSED; LEFT EYE NOT OPENING COMPLETELY; LEFT EYE TEARING; This spontaneous report received from a patient concerned a 66 year old female. The patient's weight was 218 pounds, and height was 62 inches. The patient's past medical history included anaphylaxis (closed throat) to sulfa, and concurrent conditions included asthma, sulfa allergy, corn allergy, non-alcoholic, smoker, hypothyroidism, seasonal allergies, and allergy to pcn, and other pre-existing medical conditions included the patient have allergy to caines. the patient did not have any drug abuse/illicit drug use. The patient was previously treated with epinephrine for anaphylaxis (closed throat) to sulfa. The patient received covid-19 vaccine (suspension for injection, route of admin not reported, batch number: 1805018 and expiry: unknown) dose was not reported, administered on left arm on 24-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 24-MAR-2021, the subject experienced left arm pain all the way to the back of the shoulder. On 24-MAR-2021, the subject experienced very bad headache. On 24-MAR-2021, the subject experienced nose swelling. On 24-MAR-2021, the subject experienced lip swelling. On 24-MAR-2021, the subject experienced left eye swelling. On 24-MAR-2021, the subject experienced left eye not opening completely. On 24-MAR-2021, the subject experienced left eye tearing. On 24-MAR-2021, the subject experienced feels nasal passage closed. On 25-MAR-2021, the subject experienced both eyes were irritated. On 25-MAR-2021, the subject experienced both eyes were red. On 25-MAR-2021, the subject experienced dizziness. On 25-MAR-2021, the subject experienced feeling very bad. On 25-MAR-2021, the subject experienced temperature 101.4 f. On 25-MAR-2021, the subject experienced muscle aches to bilateral buttocks and bilateral thighs. On 25-MAR-2021, the subject</p>

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							experienced fell against sink. On 25-MAR-2021, the subject experienced headache radiating to shoulder and neck. Laboratory data included: Body temperature (NR: not provided) 101.4 F. The action taken with covid-19 vaccine was not applicable. The patient was recovering from dizziness, had not recovered from nose swelling, lip swelling, temperature 101.4 f, left arm pain all the way to the back of the shoulder, very bad headache, left eye swelling, both eyes were irritated, left eye tearing, muscle aches to bilateral buttocks and bilateral thighs, both eyes were red, and left eye not opening completely, and the outcome of feeling very bad, feels nasal passage closed, fell against sink and headache radiating to shoulder and neck was not reported. This report was non-serious.; Sender's Comments: V0: Medical Assessment comment was not required as per standard procedure as the case assessed as non-serious.
1166919	4/4/2021	TX	33	F	3/24/2021	3/24/2021	Initially complained of dizziness, onset within minutes of receiving the vaccination. Within 5 minutes complained of chest pain. Stated she had a history of angina at the initial assessment. BP: 145/100. P: 83. O2 sat: 98%. Anaphylaxis ruled out by medical director. Pt was advised to have further evaluation for chest pain; chest pain was located in center of chest, described feeling as "a punch in the chest". Pulse increased to 100, BP remained elevated. EMS activated. Pt then recanted statement; said it was her sister that had angina. Pt continued to have dizziness and chest pain. Ambulance arrived at 4:13. Pt care transferred to EMS service for evaluation and possible transport to local emergency department.

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1166444	4/4/2021	CA	55	F	4/2/2021	4/2/2021	<p>HPI: Patient is a * year old * who received a single dose of J&J COVID19 vaccine in the left deltoid. About 5 minutes following administration of the vaccine, patient started to develop a red and pruritic rash on the left forearm and left hand. Patient related that she has an alcohol sensitivity where she develops red and itchy skin following consumption of alcoholic beverages. She relates she also experiences cold urticaria where she develops a red, itchy rash following submersion in cold water. When this occurs, she typically takes Benadryl or Zyrtec/Claritin (depending on the time of day), of which resolves the itching and the rash subsides. She has an allergy to Bactrim. She relates a past medical history of asthma, which she takes a daily inhaler, as well as uses her rescue inhaler twice a week. She has not seen her PCP in about 1 year. She denies chest pain/tightness, shortness of breath, difficulty breathing, swelling of the face/lips/tongue/throat, skin rash/itching, cramping abdominal pain, nausea, and vomiting. Exam (update as needed): GEN: Alert and oriented x 4, in NAD HEAD: NCAT EYES: PERRL, EOMI ENT: Ears normal, Nose normal, OP normal, no evidence of angioedema NECK: Supple, without LAD. CV: RRR, no m/r/g PULM: Clear to auscultation bilaterally, no accessory muscle use ABD: Soft, no tenderness. SKIN: Erythematous, coalescing raised papules in the distribution of the left forearm and left dorsal hand. Small, erythematous wheal on the dorsum of the left shoulder. No erythema or edema of the injection site. Skin warm and dry MSK: FROM, MS 5/5 NEURO: Alert and oriented x 4, CN 2-12 grossly intact, no ataxia, gait steady Clinical Impression/Field Tx: Urticarial rash. Patient was observed for 15 minutes following 30 minute observation period. During that time, the skin manifestations stabilized. Patient did not display signs/symptoms of anaphylaxis. Vital signs were stable. Patient offered evaluation by EMS, however, patient denied evaluation and preferred to go home. Patient was driven to site by significant other and self-administered OTC Benadryl. Patient asked to follow up with PCP/allergist and to inform them of the post-vaccination reaction, as well as to further discuss asthma/urticaria management. Patient instructed to go to the emergency department should she develop chest pain, shortness of breath, and swelling of the face/lips/mouth/tongue/throat, as these could be possible signs of anaphylaxis that</p>

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							require immediate attention. Medications administered: None. Patient self-administered OTC benadryl Disposition: Home
1165996	4/4/2021	NY	17	M	3/17/2021	3/1/2021	multi-phase anaphylaxis/several anaphylactic reactions; This is a spontaneous report from a contactable consumer (parent) from a Pfizer-sponsored program. A 17-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly in the right arm, on 17Mar2021 at 12:45 (at the age of 17-years-old) as a single dose for COVID-19 immunization. Medical history included allergies to sticking plaster (adhesive) and diabetes type 1. Family history included allergies to some antibiotics in the mother. The patient had no concomitant medications. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced multi-phase anaphylaxis/several anaphylactic reactions in Mar2021, which caused hospitalization and was reported as an important medical event and life-threatening. The clinical course was reported as follows: The patient had multi-phase anaphylaxis following his first dose of vaccination. He went to three different hospitals and was in the pediatric intensive care unit (PICU) at the time of reporting. The patient was heavily sedated, intubated, and on a ventilator for 3 days. The clinical outcome of multi-phase anaphylaxis/several anaphylactic reactions was unknown. Follow-up attempts are completed. No further information expected.

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1165894	4/4/2021	CA	49	U	3/17/2021	3/17/2021	anaphylaxis; This is a spontaneous report from a contactable consumer (patient). A 49-year-old patient of an unspecified gender received the first dose of bnt162b2 (BNT162B2) reported as PFIZER BIONTECH COVID-19 VACCINE), via an unspecified route of administration in the left arm on 17Mar2021 09:30 (lot number: EN6208) as a single dose for covid-19 immunisation. Medical history included covid-19 prior vaccination. The patient has known allergies. The patient did not receive other vaccine in four weeks. There were no concomitant medications. On 17Mar2021 09:30, the patient had anaphylaxis which resulted in a doctor or other healthcare professional office/clinic visit. The adverse event required treatment which included diphenhydramine (BENADRYL). The patient has not been COVID tested post vaccination. The outcome of the event was recovered in Mar2021.
1165881	4/4/2021			F			anaphylaxis reaction to the COVID vaccine; This is a spontaneous report from a contactable consumer reported that a female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date as a single dose for covid-19 immunisation. Medical history included asthma from an unknown date. The patient's concomitant medications were not reported. On an unspecified date, the patient had an anaphylaxis reaction to the COVID vaccine. The reported symptoms were itchy, throat hot and swollen, high heart rate, red hives in throat, trouble breathing and drop in blood pressure. The provider gave her Benadryl and also administered an Epi Pen. She was taken to the ER by ambulance. The outcome of the events was unknown. Information about lot/batch number has been requested.

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1165572	4/4/2021			U			<p>ANAPHYLAXIS DESCRIBED AS SEVERE REACTIONS; This solicited report received from a patient via social media account concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient initiated treatment with covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient experienced anaphylaxis described as severe reactions. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of anaphylaxis described as severe reactions was not reported. The reporter considered the causality between covid-19 vaccine ad26.cov2.s, and anaphylaxis described as severe reactions as related. The company causality between covid-19 vaccine ad26.cov2.s, and anaphylaxis described as severe reactions as related. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 20210356466-Covid-19 vaccine ad26.cov2.s Anaphylaxis. This event is considered related. The event has an unknown/unclear temporal relationship, is unlabeled, and is scientifically plausible. There is no information on any other factors potentially associated with the event(s).</p>

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1167240	4/4/2021	DE	21	M	3/12/2021	3/13/2021	My left arm was sore starting a few minutes after the vaccine. This soreness last through that night. When I woke up the next day, my arm was extremely sore and I was very dizzy. Additionally, my pulse felt fast but my heartbeat seemed to have less strength. My breathing felt more shallow like I wasn't getting as much oxygen from the air that I breathed in as I should. For the first two weeks, the dizziness was very strong. Now, at the three-week mark, it is more manageable and life is somewhat returning to normal. I visited an ENT doctor and their diagnosis was that my dizziness was not being caused by a preexisting medical condition. Their prediction was that I would be fine, though looking back, I downplayed the severity of my vertigo. At its worst, I felt that, when I went for a walk outside, the surface was the Earth was violently spinning through space, with me stuck to the surface. It felt paralyzing. My body felt almost stuck in shock. I was afraid I would be stuck with this dizziness for the rest of my life since it was so long-lasting. Now, I am taking ginger pills and am watching my sodium intake. I feel better but am extra vigilant about taking ginger and not stressing myself too much. I do not plan on getting a second shot since some of my symptoms mirror those of anaphylaxis.

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1164475	4/3/2021	CA	44	F	4/3/2021	4/3/2021	Patient is a * year old * who received a single dose of J&J COVID 19 vaccine in the right deltoid. Immediately following administration of the vaccine, patient began experiencing the sensation of heart racing, difficulty breathing, and feelings of anxiety. Patient relates this has happened with vaccines received in the past, as she has postural orthostatic tachycardic syndrome (POTS). She feels as if this is an aggravation of her POTS. Patient states she has allergies/sensitivities to ciprofloxacin, bactrim, and sulfa drugs, but she has never needed to use epinephrine. She denies chest pain/tightness, wheezing, swelling of the face/lips/mouth/tongue/throat, skin rash/itching, cramping abdominal pain, nausea, and vomiting. She does not take any medications on a daily basis. POTS aggravation. Patient was not displaying active signs and symptoms of anaphylaxis. Patient's heart rate and breathing continued to slow down once patient was brought to a quiet place and started to enact breathing techniques. Vital signs continued to improve as patient sat. Patient encouraged to consult her PCP and inform them of their post-vaccination reaction. She was instructed to go to the emergency department if she should develop chest pain, difficulty breathing, swelling of the face/lips/airway, cramping abdominal pain with nausea and vomiting. Patient discharged to home
1164868	4/3/2021	IL	37	F	4/3/2021	4/3/2021	I went to a community event (held at a church) for the COVID vaccine. After the vaccine, I wanted the 15 minutes and felt ok - just hot. I went out to my car and over the next few minutes - I was getting hotter - My face was extremely hot and flushed, and hives started developing on my arms and chest. They were burning and itching; my skin was hot to the touch. My chest felt tight and my throat felt swollen, but I was able to breathe (breathe felt a little short, but I was able to take a full breathe). I was also dizzy and felt nauseous. I went to the ER, where they treated me for anaphylaxis with Benadryl, Pepcid, Breathing treatment, and a steroid. After about an hour or so I felt fine, and the dr gave me some medications to take over the next few days.
1164802	4/3/2021	MN	25	F	3/26/2021	3/26/2021	Patient was dizzy, lightheaded, and had tachycardia. They had tingling in hands and feet. No anaphylaxis noted. They were transported by EMS.

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1164480	4/3/2021	CA	62	F	4/3/2021	4/3/2021	The Pt presents with swelling of her lips 20 minutes following injection of 1 dose Janssen vaccine to the left deltoid. The Pt states that she has had anaphylaxis in the past to Macrobid, Sulfa, Amoxicillin. She has an EpiPen at home but states that she has never had to use it because her symptoms develop slowly. In the past she has driven herself to the ER where she has received breathing treatments and observation. Pt denies swelling of the eyes, tongue, throat tightness, difficulty swallowing, itching of the skin, SOB, CP, nausea or vomiting. She also denies dizziness, lightheadedness, or vision changes. The Pt also has a Hx of meningioma and SVT s/p ablation. Suspicion for anaphylaxis high due to lip swelling, wheezing, and previous episodes of delayed onset anaphylaxis. Pt drove herself today so IM injection of diphenhydramine was delayed. Upon recheck Pt's wheezing was unchanged and lip swelling had not progressed further. Due to past episodes of SVT and no progression of current symptoms, epinephrine was on stand by but not administered. Care was transferred to EMS. Care was transferred to EMS and Pt was transported to the hospital.
1164265	4/3/2021		49	F	4/2/2021	4/2/2021	Scratchy throat, no complaints of shortness of breath or difficulty. No swelling. No skin redness or hives. Benadryl (25mg) solution administered with improvement after 15 minutes of observation. Educated regarding anaphylaxis. Patient left in stable condition. Confirmed she understood signs/symptoms of allergic reaction.
1164304	4/3/2021	FL	32	F	4/1/2021	4/1/2021	Systemic: Allergic: Anaphylaxis-Mild, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Vomiting-Mild

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1164029	4/3/2021	CA	26	F	4/3/2021	4/3/2021	Patient is a 26 year old female who presents immediately following administration of a single dose of J&J COVID19 vaccine in the left deltoid. Patient was walking with her mother to their vehicle when she lost consciousness. Per patient's mother, the patient has a developmental delay and can be a poor historian. Patient states that she has never experienced syncope. She denies allergies to medications and foods. She has never had a vaccine in the past. Patient denies a medical history. Patient states that she takes Concerta and Lexapro on a daily basis. She denies chest pain/tightness, shortness of breath, wheezing, swelling of the face/lips/mouth/tongue/throat, skin rash/itching, cramping abdominal pain, nausea, and vomiting. Vasovagal syncope with loss of consciousness. Patient not displaying active signs and symptoms of anaphylaxis. Patient was transferred to a cot and very quickly regained consciousness. Patient was A&O x 4 and in NAD. EMS was called to the scene for further evaluation due to limited resources. EMS called to the site for further evaluation due to vasovagal syncope with loss of consciousness. EMS related patient was experiencing orthostatic hypotension. EKD and blood sugar levels were within normal limits. Patient transported to ER.
1163813	4/3/2021	MD	36	F	4/2/2021	4/2/2021	Anaphylaxis to Moderna Covid Vaccine
1163697	4/3/2021	NH	67	F	4/3/2021	4/3/2021	Shortly after vaccination, pt developed nausea and dry heaves. Symptoms lasted appx. 10 minutes before improving. She denied any SOB, tongue/throat swelling, dizziness or other symptoms. HR 78, BP 158/90, SP02: 99%. No signs to suggest anaphylaxis. EMS services and ER evaluation were offered but pt declined. She elected to drive home with her husband.
1163264	4/3/2021	MD	31	F	4/2/2021	4/2/2021	Systemic: Allergic: Anaphylaxis-Mild, Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Allergic: Itch (specify: facial area, extremities)-Mild, Systemic: Allergic: Itch Generalized-Mild, Systemic: Allergic: Rash (specify: facial area, extremities)-Mild, Systemic: Abdominal Pain-Mild, Systemic: Nausea-Mild, Systemic: Tachycardia-Mild, Additional Details: patient also experienced runny nose and congestion

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1163188	4/3/2021	NJ	71	F	3/19/2021	3/19/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe

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1162504	4/3/2021			F	3/15/2021	3/1/2021	full on hives; bad body rash; underarm pain; armpit swelling; Exhaustion; This is a spontaneous report received from a contactable consumer (patient) via Medical Information Team. A female patient of an unspecified age received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on 15Mar2021 as SINGLE DOSE for covid-19 immunisation. The patient medical history and concomitant medications were not reported. Patient previously took BNT162B2 (first dose) for COVID-19 immunisation. The patient experienced underarm pain on Mar2021, armpit swelling on Mar2021, exhaustion on Mar2021, full on hives on 18Mar2021, bad body rash on 18Mar2021; all (non-serious). The caller stated that she received her second dose of the Pfizer COVID-19 vaccine on 15Mar2021 and she had the "basic" side effects of "underarm pain, armpit swelling and exhaustion." She stated that 3 days after her second dose she experienced "full on hives, a bad body rash." She stated that did not experience any throat swelling or difficulty breathing, no anaphylaxis. She did go to the hospital to be evaluated due to the severity of the rash and hives and out of fear that it may get worse and turn into anaphylaxis. She was not admitted to the hospital but she was kept for observation and treated with steroids which did help improve her symptoms. She is still currently on a course of steroids now. Her doctor told her to report this reaction to Pfizer. She stated that she gone online and reported her side effects and spoken with someone at Pfizer and filed a report regarding her symptoms. She would like to know if her experience is common and if it has been previously reported. She stated that she did not have any side effects at all after her first dose of the Pfizer COVID-19 vaccine. Response: The following adverse reactions have been identified during post authorization use of Pfizer-BioNTech COVID-19 Vaccine. Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. Immune System Disorders: severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema). Also let the caller know that we would refer her back to HCP regarding any future doses of the Pfizer

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1162498	4/3/2021	AK		U	3/20/2021	3/20/2021	COVID-19 vaccine based on her reaction to the second dose. For event, underarm pain, outcome was unknown, for armpit swelling, outcome was unknown, for exhaustion, outcome was unknown; for full on hives, outcome was recovering, for bad body rash, outcome was recovering. Information about batch/lot number has been requested.
							presumably anaphylaxis.; baby broke out in hives; course cough; wheezing; she breastfed her 12 month-old infant shortly thereafter without problem. around 1215 baby was getting fussy and breastfed for ab; she breastfed her 12 month-old infant shortly thereafter without problem. around 1215 baby was getting fussy and breastfed for ab; This is a spontaneous report from a contactable pharmacist. This pharmacist reported information for both mother and baby. This is a baby report. A 12-month-old patient of an unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) dose 1 via transmammary on 20Mar2021 as a single dose for Covid-19 immunization.The medical history and concomitant medication not reported.The patient mother received first in series covid vaccine on 20Mar2021 09:15 and she breastfed her 12-month-old infant shortly thereafter without problem. On 20Mar2021, around 12:15, patient was getting fussy and breastfed for about 5 minutes before baby broke out in hives. EMS was called and epinephrine/diphenhydramine (Benadryl) administered for course cough/wheezing, presumably anaphylaxis. Other foods consumed by patient on same day included banana, kids fig newton bar, dried apples, meat from frozen meal, and two piece of 'Trix' cereal (new to baby). ER course required 4 hours of monitoring. The events result in emergency room/department or urgent care. The outcome of the events was recovered in Mar2021.; Sender's Comments: Based on the temporal association, there is a reasonable possibility that the administration of vaccine with BNT162B2 in the mother played a contributory role in triggering the onset of the events in the infant exposed to the suspect product via breast milk. ,Linked Report(s) : US-PFIZER INC-2021305721 mom/baby

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1164794	4/3/2021	NH	26	M	4/3/2021	4/3/2021	Shortly after injection, pt developed dizziness/near syncope. He was noted to be very pale and was reclined in his chair. He improved after appx. 5 minutes and symptoms resolved. BP 110/80, HR 72, 99%. No signs to suggest anaphylaxis. He felt completely back to normal when he drove home. Symptoms likely consistent with vasovagal response from injection. Pt notes he did not eat much during the day
1164007	4/3/2021	MD	74	F	4/1/2021	4/2/2021	Redness, heat, pain and swelling at injection site, spreading over a 48 hour period. 1st noted at 1300 4/2/21, 24 hrs post injection 2 (019B21A). Doubled in size over the next 24 hours. No systemic fever. Developed a systemic rash during the night of 4/2/21. No signs or symptoms of anaphylaxis. Takes 80 mg Pepcid BID and Extra Strength Tylenol BID, added 25 mg Benadryl QID

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1160173	4/2/2021	TX	57	F	3/30/2021	3/30/2021	ASSESSMENT: 57 y.o. female with PMHx of HTN who presented today to the Vaccine site for her second COVID vaccine. She c/o only a sore arm for 1-2 days after her first vaccine but otherwise tolerated it well. NKDA. She states that about 5-10 min after the vaccine she developed rhinorrhea so she went to the bathroom and blew her nose and it improved some but did not resolve. She did not inform us of this until her 15 min timer went off so I completed an evaluation. I am the physician assistant on site at the vaccine clinic who monitors the patients and is there for emergencies. If a patient feels they are having a reaction I complete an exam on the patient. She states the rhinorrhea was still there but was better than it was. Associated with a sensation of "oil in my throat, like eating some butter" but denies throat itching or tightness. Associated with intermittent dry cough and throat clearing. Denies difficulty breathing, wheezing, tongue/lip swelling, mucosal or skin itching, hives, palpitations, lightheadedness, dizziness, SOB, headache, nausea, vomiting, diarrhea, abdominal pain. She has experienced similar rhinorrhea and dry cough in the past with certain medical masks like the one we provided her today. She also experiences this with her seasonal allergies. Her allergies have not been flaring up the last 2 weeks or so but they were before that. She states she has dry mouth and has to drink a lot of water or she will develop a dry cough and throat clearing like she has today. Reports she has never had an allergy to any vaccine or injectable medication in the past. ROS: Constitutional: Negative for chills, fatigue, fever, diaphoresis and weakness. Eyes: Negative for blurred vision, photophobia, vision loss and visual disturbance. E/N/T: Positive for rhinorrhea. Negative for hearing loss, ENT Pain, ear pain, nasal pain, sore throat and hoarseness. Cardiovascular: Negative for chest pain, palpitations, tachycardia, edema, dyspnea on exertion, irregular heartbeat and near-syncope. Respiratory: Positive for cough (dry, intermittent, associated with PND). Negative for shortness of breath, wheezing and sputum production. Gastrointestinal: Negative for abdominal pain, diarrhea, stool changes, nausea and vomiting. Musculoskeletal: Negative for myalgias. Integumentary: Negative for pruritus, rashes, color change and flushing. Neurological: Negative for

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dizziness, headaches, paresthesias, weakness, difficulty with concentration, disturbances in coordination, focal weakness, light-headedness, loss of balance and vertigo. Allergic/Immunologic: Positive for allergies and environmental allergies. Negative for frequent illnesses, urticaria, hives and persistent infections. Psychiatric/Behavioral: Negative for anxiety and depression. OBJECTIVE: Vitals: 15 min after vaccination B/P: 140/88 Pulse: 70 Temp: 98.2 Resp: 12 SpO2: 99% Vitals: 25 min after vaccination B/P: 148/90 Pulse: 68 Resp: 14 SpO2: 98% Vitals: 40 min after vaccination B/P: 150/92 Pulse: 67 Resp: 12 SpO2: 99% Vitals: 70 min after vaccination B/P: 142/82 Pulse: 70 Resp: 12 SpO2: 99% PHYSICAL EXAM CONSTITUTIONAL Vitals reviewed. GENERAL APPEARANCE: Well-developed. GROOMING: Well groomed. LEVEL OF DISTRESS: The patient is not distressed, nervous/anxious, diaphoretic or tearful. She appears to be well. The patient is not lethargic or toxic. The patient does not appear tired. EYES: LIDS/CONJUNCTIVA: Lids and conjunctiva are normal. PUPILS/IRIS: extraocular movement intact. ENT EXTERNAL EARS/NOSE: External ears and nose are normal. SEPTUM/MUCOSA: Negative for sinus tenderness. LIPS/TEETH/GUMS: Normal lips, teeth and gums. No lip edema. OROPHARYNX:Mucosa: Mucosa appears normal. No edema of lips, face, tongue, oropharynx or posterior pharynx NECK: Neck normal. RESPIRATORY EFFORT AND PATTERN: Effort normal. No tachypnea, intercostal retractions, accessory muscle usage, hypopnea and irregular rate. AUSCULTATION: Normal breath sounds with no rales, rhonchi, wheezes or rubs. No coarse breath sounds or decreased breath sounds. CARDIOVASCULAR AUSCULTATION: Rate: Is normal. Rhythm: regular. Heart sounds: S1 is normal. S2 is normal. S3/S4 not present. With no murmurs heard. EDEMA/VARICOSITIES: No edema or varicosities. RADIAL: radial pulses normal bilaterally PEDAL PULSE: Normal bilateral posterior tibial pulses. LYMPHATIC OTHER NODES: No neck adenopathy. MUSCULOSKELETAL STABILITY: Normal stability. INTEGUMENTARY SKIN INSPECTION: Normal. PALPATION: Normal. No diaphoresis, no flushing, no urticaria Injection site is unremarkable, no swelling or erythema NEUROLOGICAL GAIT, COORDINATION,

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REFLEXES Gait: normal PSYCHIATRIC
 ORIENTATION: She is alert and oriented to person,
 place and time. MOOD/AFFECT: Normal mood and
 affect. INSIGHT/JUDGEMENT: Normal
 insight/judgement. The patient has good insight with
 good judgment. ASSESSMENT/PLAN:
 Rhinorrhea - Airway remained clear, breathing was
 normal, circulation was good and mentation was good. -
 She was monitored for 60 min after the rhinorrhea began,
 vitals remained stable and WNL (despite slightly elevated
 BP). She drank 1.5 bottles of water which improved her
 dry cough. She stated she was feeling back to normal
 before she left the clinic. - Warned her that she likely
 was having a mild allergic reaction to the vaccine and
 warned that it is possible for allergic reactions to worsen.
 Reviewed signs and symptoms of anaphylaxis in detail
 and gave strict ER warnings if any develop, especially
 difficulty breathing, throat/facial swelling or any
 worsening symptoms occur. Warned her while driving to
 work (15 min drive) she keep an eye on her symptoms
 and pull over and call 911 if any signs or symptoms of
 anaphylaxis develop. - Advised she take a non-sedating
 antihistamine like Claritin on her way to work. I advised
 she let her colleagues at work now to keep a close eye
 on her at work. - She expressed understanding and
 stated she was feeling well and wanted to go to work - All
 questions were answered. I informed her PCP and sent
 them my note. I called 4 hours after the vaccine to follow
 up but had to leave a voicemail,. I spoke with her the
 following day on 3/31/21 and she stated she felt great
 besides localized soreness at the injection site.
 Otherwise she felt well. The rhinorrhea, cough and throat
 clearing had completely resolved after taking 1 claritin.
 Denied shortness of breath, difficulty breathing,
 wheezing, fever, chills, n/v/d, chest pain, hives, itching,
 palpitations, dizziness, syncope, near syncope or
 headache. She did not require any further treatment and
 did not need to have a visit with her PCP and did not
 need to go to the ER or hospital.

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1161238	4/2/2021	SC	52	F	4/2/2021	4/2/2021	Patient developed swelling and redness from the injection site down to the wrist of the left arm. This occurred within 10 minutes of injection and was resolved with 50 mg of benadryl within 12 minutes after administration. All symptoms resolved and patient was counseled on signs of anaphylaxis. Patient was observed for 15 additional minutes prior to being dismissed with husband.
1161064	4/2/2021	NY	62	F	4/2/2021	4/2/2021	Patient received vaccine and immediately began to feel sweaty and light-headed. She did not faint or lose consciousness. Patient received an ice pack and some cold water and began to feel better. Her blood pressure was normal and after about 10 minutes she began to feel like herself again. There was no sign of anaphylaxis or further respiratory distress.
1160940	4/2/2021	WA	51	M	3/31/2021	4/1/2021	Approximately 16 hours after receiving his first Moderna COVID 19 vaccine the patient developed chest tightness and wheezing, relieved by administration of albuterol by nebulizer given at home. He had no systemic anaphylaxis reaction.
1160827	4/2/2021	OH	73	F	3/26/2021	3/26/2021	Anaphylaxis reaction involving closing throat, numbness of lips, and redness of hands. Occurred 20 minutes after injection. Treated with Epinephrine IM self administered and 2 ounces Benadryl oral self administered. Overt symptoms abated within 15 minutes. Transported via emergency squad to local hospital 20 minutes after onset of symptoms. Administered prednisone and pepcid at hospital. Held for observation for 2 hours before discharge. Lingering symptoms included thickness of throat and numbness of lips for approximately 7 days. No further symptoms after 7 days.

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1160487	4/2/2021	TX	53	F	3/30/2021	3/30/2021	Patient filled out vaccine consent form stating no to all questions (denying anything that might exclude her from receiving the vaccine), fever was taken (non-feverish), and signed under the bolded statement stating the patient is to wait in the pharmacy at least 15-20 minutes after receiving vaccination. Patient was then given the J&J covid-19 vaccine in left deltoid and told that it is recommended by CDC to wait in the pharmacy for 15-20 minutes after vaccination. However, the patient immediately proceeded to leave. Patient states upon getting to her car in the parking lot, she started noticing signs of anaphylaxis such as throat swelling, however patient did not come back into the pharmacy and left the premises. Patient did not report seeking any sort of treatment for her anaphylaxis side effects. Patient received vaccine on 3/30/21, did not report this event to the pharmacy until 4/2/21. Patient also states she is a registered nurse.

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1162123	4/2/2021			F			<p>it felt like she was having a heart attack; anaphylaxis; her blood pressure was 160/110; she had a rash on her neck and chest; chest pain; heart palpitations; chest pressure; her arm was numb; her heartbeat was ridiculous/heartrate went over 150; dizziness could be a symptoms of this type of reaction and she stated she was dizzy; She swelled up the first time but yesterday it felt like she was having a heart attack; She swelled up the first time but yesterday it felt like she was having a heart attack; she got the shakes; This is a spontaneous report from a contactable consumer (patient). A female patient of unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, batch/Lot number was not reported) via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunisation. The patient medical history included Drug allergy (had lot of drug allergies) and anaphylaxis (it was different than what she experienced yesterday). The concomitant medication was not reported. The caller stated she had the first dose of the vaccine and was in the emergency room with chest pain, heart palpitations, and her blood pressure was 160/110 all day. They gave her nitroglycerin and Benadryl because she had a rash on her neck and chest, had chest pressure, her arm was numb, and her heartbeat was ridiculous. They got it under control, and she was sent home. She stated she read that if you have had a severe allergic reaction you should not get the second dose and saw that dizziness could be a symptom of this type of reaction and she stated she was dizzy. She asked what would be considered a severe allergic reaction. she was scared about getting her second dose. She asked how many other people have had a rapid heartbeat, dizziness and a rash and still got their second dose? Is there treatment if you get the second dose and have a reaction? How many got the second dose with these symptoms and survived? How does she know she will live through it if she gets the second dose. It was also reported that patient experienced anaphylaxis. She swelled up the first time but yesterday it felt like she was having a heart attack. She stated the HCP wants her to go to an allergist. She said when they gave her Benadryl she got the shakes and her heartrate went over 150 with this medication. She asked if the second was worse than the</p>

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							first dose. Therapeutic measures were taken for the events it felt like she was having a heart attack, anaphylaxis, her blood pressure was 160/110, she had a rash on her neck and chest, chest pain, heart palpitations, chest pressure, her arm was numb, her heartbeat was ridiculous/heart rate went over 150, dizziness could be a symptom of this type of reaction and she stated she was dizzy, She swelled up the first time but yesterday it felt like she was having a heart attack. The outcome of the events was unknown Information on the lot/batch number has been requested
1160189	4/2/2021	AZ	29	F	3/27/2021	3/27/2021	2:50pm started with chest pressure and heaviness. 2:52pm shortness of breathe, honked and there was a delay of paramedics. Took 2 pumps of inhaler. Did not work. EMT loaded me on the stretcher out of my car in the ambulance. Gave albuterol mix in nebulizer. Went into full anaphylaxis on the way to ER. 4 epi in the arm did not help 2 benedrylshits to the arm did not help. I was on 5L oxygen until the epi was mixed with albuterol to pen airways. Anaphylactic episodes continued every 5 hours for 2 days, then became every 12 hours, then 24 hours, then 12 hours. Steroids, Claritin, antacid, albuterol epi mix have helped managed episodes. Still currently in the hospital.
1161142	4/2/2021	NY	58	F	1/11/2021	1/11/2021	About 35-40 minutes after injection started feeling like had to clear throat. Went back into Urgent Care and was told to keep an eye on it. Went home and within another 20 minutes had completely lost voice. Went back to Urgent Care. Was told again to keep an eye on it or go to ER. They didn't even look at me. My own Doctor was down the street so I went right to her office. My doctor was not in, so another doctor came right out to look at me. She checked my breathing and it was okay but I could not speak at all. She put me on prednisone and Benadryl for several days. Eventually felt better after meds. Made appointment with allergist, for follow-up. He said it was an anaphylaxis reaction. Was told to not get second dose of Moderna shot. I have since had the J&J vaccine on 3/30/2021 with no immediate adverse reaction, just side effects (chills, severe headache, fatigue, sore arm).

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1159983	4/2/2021	MT	47	F	4/1/2021	4/1/2021	Patient presented back to clinic approximately 1.5hrs post second vaccine complaining of full body rash with pruritus. No signs of anaphylaxis or airway distress. She was evaluated and cleared with return precautions.
1159943	4/2/2021	KY	49	F	1/8/2021	1/8/2021	Patient reported hives on arms along with rednes @ 1215s. Diphenhydramine 50 mg PO was given to patient @ 1218. At 1225 patient reported facial swelling and redness with edema noted. Patient declined a rapid response team be called (to escort to emergency department) and declined IM epinephrine. She reported that she has had anaphylactic reactions and she knows that she needs steroids. Patient was escorted to the emergency department @ 1228. ED MD noted no hives on arms and no rash but several scatted hives on back. No symptoms consistent with anaphylaxis noted and patient improved with oral diphenhydramine and was ultimately discharged from the ED.
1159578	4/2/2021		51	F	3/29/2021	3/29/2021	Anaphylaxis Pt was seen in the office 3/29/21 for follow up and elected to receive covid vaccine after counseling with PCP. Pt has been working from home and isolating from others. She has been tested multiple times and all were negative. Pt had strong desire protect herself and others so considered getting it. Pt has a history of idiopathic angioedema and multiple allergic reactions to medications.. Pt states she felt like vaccine would cause a reaction but she sustained close COVID loses and felt a stronger desire to get the vaccine and risk reaction. 10 minutes after receiving the vaccine she developed lip swelling and SOB. Emergency response was activated. She received epi and benadryl in the office. Pt went to ED, monitored, and received steroid taper and H2 blocker. she did not require supplemental O2 or airway interventions. She was stable for discharge to home.
1159266	4/2/2021	MD	61	F	4/2/2021	4/2/2021	Scratchy throat, feels like throat closing up, coughing to clear airway. Voice hoarse and feels like she is having anaphylaxis as she has had in past

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1158850	4/2/2021	CA	46	F	3/31/2021	3/31/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Medium, Systemic: Hyperventilation-Medium, Systemic: Tingling (specify: facial area, extremities)-Medium, Additional Details: Patient presented with soariness in throat a couple of hours after administration. SHe was taken to the fire department (Uncertain about what treatment was conducted here). Next day, and patient is still not fully recovered. Still has scrachthy throat and soreness in her throat.

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1158690	4/2/2021	PA	63	F	3/11/2021	3/11/2021	rash that was all over her body; Extremely red sunburn rash- really bad sunburn, most of it on torso, had it on legs/face was so red like the rough sunburn feeling; Eyelids red, itchy, and swollen; Eyelids red, itchy, and swollen; Eyelids red, itchy, and swollen; Felt dizzy and weak/had less energy today; Dizziness and lightheadedness /felt dizzy and weak; Worst and really sharp Charlie horse between ankle and calf- took forever to walk; Extremely dehydrated, kidneys were showing some damage, creatinine level was really off.; Extremely dehydrated, kidneys were showing some damage, creatinine level was really off.; Extremely dehydrated, kidneys were showing some damage, creatinine level was really off.; Anaphylaxis due to vaccination; Vomited; Major diarrhea; She was so cold that her toes were purple; Blood Pressure so low: 58, couldn't find a bottom number at first but then at the hospital it was 58/38; Face was extremely pale; could not function- she was beyond cold; felt like she was in a bad dream and couldn't wake up, couldn't walk. Feeling like she was getting the flu; could not function- she was beyond cold; felt like she was in a bad dream and couldn't wake up, couldn't walk. Feeling like she was getting the flu; could not function- she was beyond cold; felt like she was in a bad dream and couldn't wake up, couldn't walk. Feeling like she was getting the flu; Too cold to function or do anything; Nauseated- almost like morning sickness/Extremely nauseated/queasy feeling; Nauseated- almost like morning sickness; very extremely tired; creatinine /it was still high; sick; body temperature was low; She thought she was going to die because of the purple toes; but it seems like her nose won't stop running ever since she got it, sore from blowing- looks like Rudolph.; but it seems like her nose won't stop running ever since she got it, sore from blowing- looks like Rudolph.; her body catching up on sleep or she's just tired; This is a spontaneous report from a contactable consumer (patient herself). A 63-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot Number: EN6206), via an unspecified route of administration, on 11Mar2021 as single dose in left arm for COVID-19 immunisation. Medical history included ongoing High Blood Pressure (It's under control now, fairly healthy; diagnosed probably when she started menopause in early 50s), ongoing

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Anxiety (Diagnosed probably when she started menopause in early 50s), ongoing Sinus headache (Worst sinuses; Takes Excedrin because Tylenol does not have an effect on her), ongoing smoker (Pack a day, but smoking about only about half of it each time. started when she was a teenager. She was without a cigarette for 3 days in the hospital, but when she came home she had to start again), menopause (in early 50s), shoulder-torn rotator cuff-operated in 2018. Family history included cardiac and heart disease, Parkinson's and Frontal lobe dementia (husband). Concomitant medication included colecalciferol (VITAMIN D3) 1000 IU, once a day, by mouth (Taken these for as long as she can remember, they kept advising it, husband takes it for Parkinson's so she just throws one in for her), calcium ascorbate (VITAMIN C) 1000 IU, once a day, by mouth (Started at least 2 years ago, doesn't drink enough orange juice, doesn't do fruits, doesn't get enough Vitamin C), linum usitatissimum seed oil (FLAXSEED OIL) 1000 IU, once a day, by mouth (Started at least 2 years ago, family history of cardiac and heart disease, takes as preventative) for cardiac and heart disease, takes as preventative, fish oil 1000 IU, once a day, by mouth (Started at least 2 years ago, family history of cardiac and heart disease, takes as preventative) for family history of cardiac and heart disease, takes as preventative, hydrochlorothiazide, lisinopril 20/12.5 mg, once a day, by mouth (She has been taking this medication for years, under control with this medication) for High Blood Pressure, lansoprazole from 2020 30 mg, once a day, by mouth (Started years ago) for Stomach pill for acid reflux, duloxetine hydrochloride 60 mg, once at bedtime, by mouth (Started forever ago) for just being achy and anxiety, lorazepam .05 mg, 1 tablet 3 times a day, takes one tablet a day at bedtime, by mouth for Anxiety (Started this a while back-with the heart disease and everything else, gave this to help with menopause symptoms too), meloxicam 15 mg, at bedtime as needed from 2017 for back issues- really sore at times, takes if really stressed or she overdoes it. Patient previously took Tylenol for sinus headache and does not have an effect on her. After the first dose of the vaccine the patient reported that she was extremely tired on 11Mar2021. She was completely nauseated most of the day on the second day. On Saturday, she was extremely nauseated (12Mar2021) with vomiting and

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major diarrhea on 13Mar2021. By 4 PM that afternoon (12Mar2021), she could not function because she was so cold; she felt like she was in a really bad dream and couldn't wake up. She called on 13Mar2021, her blood pressure was so low-they got 58 for the top number, they were unable to pull up bottom number at that point. patient reported that when the ambulance arrived, they described her face as extremely pale on 13Mar2021; her major complaint was that she was so cold- she has never been that cold in her life. When she got to the ER- they had to use the old blood pressure cuff to get her blood pressure because it wasn't coming up on the machine- the kind where you pump it up and watch the needle, they said it was 58/38. patient states that they asked her about the rash that was all over her body in 2021; caller reports that she did not have a rash when she called at 4 PM. patient describes the rash as an extremely red sunburn rash- like you got really bad sunburn, most of it was on her torso, she also had it on legs on 13Mar2021. patient mentioned she remembers them taking off sock and her toes were purple on 13Mar2021. She also had a red on her eyelids- she described as itchy and swollen on 13Mar2021. patient mentions that unbelievably as sick as she was in 2021, she could understand everything that they were telling her. Treatment was given as they prescribed her Prednisone and Benadryl; she was also hooked up to an IV, and they were trying to warm up her body because body temperature was low in 2021. Discharge paper reads as anaphylaxis due to vaccination on 13Mar2021. patient states that she came home from hospital on Monday, 15Mar2021. patient reports she started a diet. 2nd day (12Mar2021)- From the time she got up, she was too cold to do anything; she couldn't walk and she was feeling like she was getting the flu. Saturday (13Mar2021)- She woke up and had the worst Charlie horse between ankle and calf- took forever to walk Charlie horse off. Really sharp Charlie horse. Even had less energy today. Really nauseated. patient reports that yesterday and today, she is just tired. She doesn't know if it's just her body catching up on sleep or she's just tired; she will find out today when she goes to doctor. Caller mentions that she is normally more active than she feels right now. patient reports her eyes have been itchy and she has a rash on her eyelids. patient doesn't know if it's from the shot; patient mentions that she decided on

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01Mar2021 she would start a diet, get healthy, and see a nutritionist. patient reports that initially she didn't think her symptoms were from the vaccine and thought it was that she wasn't eating enough food on Friday. She got in touch with the dietitian. patient reiterated she did not attribute this to shot right away. patient reports that she was wondering if she had asymptomatic covid, and it would have been within a 3-month period that she reacted to the shot. She was not sick if she did have asymptomatic covid. There still trying to figure out why her body had this reaction. patient states that every now and then she was still cold, but she doesn't know if its her imagination and plus it is cold outside where she is. She is still on the cuff on that one. patient describes the nausea she first felt as almost felt like morning sickness on 12Mar2021-that's why she attributed it to her diet. patient mentions that the day she started feeling better, late Sunday afternoon, she wanted salty foods. Anything salty, chips, she just really wanted salty stuff. She was not normally a salt person, but the saltier it was, the better it was. patient reports that when she was vomiting with diarrhea and laying down, she would be throwing up in a towel because she couldn't make it to the bathroom when she was laying, it would just gush. patient describes it felt like her body was going to be locked into the position it was in, she doesn't know how to describe it. patient states that she had vomit on her clothes when she called. patient reports the nausea stopped late Monday and the queasy feeling went away. patient reports she stopped vomiting when they gave her Zofran-they had to give her a couple because she didn't stop throwing up right away. patient reports she was extremely dehydrated and her kidneys were showing some damage; her creatinine level was really off on 13Mar2021. The diarrhea was gone, but now she has a mixture of soft stools and semi formed. It is trying to improve but hasn't yet. patient states that because of her creatinine level, they did want her to drink and she might have soft stools because she was drinking so much. patient reports she knows when her husband put the shirt on her she did not have the rash, but when the ambulance arrived, they said she had the rash. Upon discharge, they told her not to receive any further covid vaccines- she cannot get her second one which was scheduled for 01Apr2021. She started experiencing the

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really cold feeling on 12Mar2021 after receiving the vaccine. She went to bed at 7, that's not like her, she was usually up all hours of the night. symptoms she was experiencing were beyond typical. patient reports she also felt dizzy and weak on 13Mar2021. She thought she was going to die because of the purple toes in 2021- she knew that was a sign of her body shutting down and she got the most scared. patient mentions she is experiencing a residual side effect from the covid and influenza tests-both were negative on 13Mar2021, but it seems like her nose won't stop running ever since she got it, sore from blowing- looks like Rudolph in 2021. patient reports she feels human today, but she is still sleepy in 2021. She thinks she would feel a whole lot better if her nose stopped running. The tiredness might be from nose blowing and stuff. patient remembers the nurse was thrilled that her toes weren't purple anymore. It started going away when her blood pressure and everything came back up. patient states that she was so scared that she was dying so she remembers everything that happened. patient remembers she was in the ER still when her blood pressure improved. Treatment for her face was so red like the rough sunburn feeling and putting moisturizer on the dried cheeks. patient reports that she doesn't see any patches of red on her. Part of her has a fear that the stuff is not totally out of her system and it will happen again. patient mentions she has heard comments that this was not a typical reaction from the first one and wants to know if it is typical to be that sick from the first dose. patient reports that now her eyes just feel like she's allergic to something. She doesn't know if the redness is from crying now- it was improving, but was still there. Husband has Parkinson's and Frontal lobe dementia and she is his caregiver, she cannot afford to get Covid, she wants to get back to normal. patient reports that she did not take any of her prescriptions the day of the vaccine, she did not want to get a reaction. patient reports she had her shoulder- torn rotator cuff- operated on in 2018. If nose is really stuffed up or allergies, or Fluticasone nasal spray- she can take it 2 times a day, 2 squirts in each nostril, take it as needed. patient reports that she has the worst sinuses- when it gets too bad, she'll go to the doctor and she'll prescribe Flonase, take Metamucil or whatever she thinks will help with sinuses. she still wants to get the second vaccine.

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patient reports her creatinine came down well enough that she could come home from the hospital, it was still high on 15Mar2021 so they told her to drink lots of water so she does not get dehydrated. Patient was hospitalized from 13Mar2021 to 15Mar2021 for Anaphylaxis, Tiredness, Nauseated, Morning sickness, Vomited, Activities of daily living impaired, Walking difficulty, Flu like symptoms, Pale, Photosensitive rash, Asthenia, Dizziness, Charley horse, Dehydration, Renal disorder, Creatinine low, Cold, Diarrhea, Purple toes syndrome, Blood pressure low, Redness of eyelid, Eyelids itchy sensation of, Swollen eyelid. For rash also patient was hospitalised. The outcome of Vomited, Pale, Photosensitive rash, Dizziness, Asthenia recovered on 13Mar2021, Nauseated, Morning sickness recovered on 15Mar2021, Activities of daily living impaired, Walking difficulty, Flu like symptoms recovered on 17Mar2021, Diarrhea, Cold, Blood pressure low, Purple toes syndrome, Redness of eyelid, Eyelids itchy sensation of, Swollen eyelid were recovering, Tiredness and Creatinine high were not recovered, while remaining events were unknown. No follow-up attempts are possible. No further information is expected.

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1158366	4/2/2021	CA	38	F	4/1/2021	4/1/2021	<p>On Thursday, 4/1/2021, client received her first dose of Pfizer COVID vaccine (LOT # EW0150, EXP 7/2021) at approximately 10:07 am by vaccinator RN. RN instructed client to self-monitored at the observation area. EMT found this 38 years old female in an observation chair sitting upright and requesting assistance. Due to the client needing translator, site manager present provided translation. lead RN came to assist EMT as needed. EMT reported client had a chief complaint of lightheadedness. Client stated that she felt like her head was "big" but that she did not feel like fainting. Client stated she had a history of high blood pressure and diabetes type 2 but did not take diabetes medication. Instead, she stated that she managed it strictly with her diet. Client had no known allergies. Assessment revealed no redness, hives, swelling, shortness of breath, chest pain or other signs of anaphylaxis throughout her body. Client denied having a headache but stated that she felt "hot" and that the heat was rising to her head. Client denied having a meal before her vaccination. Initial vitals were as follows: Alert and oriented x 4, Eyes were PERL (Pupils Equal and Reactive to Light) at 4 mm, pulse - 74, regular and strong at radial, O2 - 99%, blood pressure 160/98, Temperature 97 F, Respirations 20 and regular. Skins were warm and mildly sweaty. Client consented to staying present for an extra 30 minutes after incident onset. Staff present verified that client had no food allergies and was provided food to eat while under observation. Client's vitals were monitored at 5 minutes intervals after the onset of the incident as follow: 10:18 am: 160/98 (Blood Pressure) , 74 (Heart Rate) , 99% (Oxygen), 20 (Respiration), 97 F (Temperature); 10:23 am: 162/98 , 68 , 99% , 18; 1028 : 162/98 , 68 , 99% , 18; 1033 : 162/98 , 72 , 99% , 18; 10:38 am: 162/98 , 72 , 99% , 18 , 98 F; 10:48 am: 162/98, 72, 99%, 18. Client reported at the end of her observation that she no longer felt hot and her head sensation was gone. Client's temperature improved from 97 degrees Fahrenheit to 98 degrees Fahrenheit and she ceased sweating at the end of her observation period. Client's husband was present and both were provided a Pfizer vaccine fact sheet and instructed to seek out medical advice or emergency care if a severe allergic reaction occurs later in the evening. Client left with husband in no apparent distress at 10:48 am with husband stating he would drive them home.</p>

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1160192	4/2/2021	IN	54	F	3/31/2021	3/31/2021	Patient received her second dose of the COVID 19 vaccine today. She has had anaphylaxis to allergy shots in the past, but did not have reaction to first dose COVID 19 vaccine. Patient received second shot and started coughing, felt throat closing. Benadryl 50 mg PO was given to her prior to being transferred to ED around 1300. Blood pressure was 207/100, chest x-ray and EKG negative. Patient also received albuterol puffs various times. She was monitored for almost 2.5 hours prior to being discharged to home.
1161017	4/2/2021	MT	40	F	3/23/2021	3/23/2021	Signs/Symptoms: severe dyspnea, wheezing, anaphylaxis Treatment: Epi Pen (Left Anterior Thigh) and EMT Called/Transported to Hospital Emergency Department.
1153980	4/1/2021	ND		U			anaphylaxis; A Spontaneous report was received from a nurse concerning unknown patient who received Modern's COVID-19 vaccine (mRNA-1273) and experienced Anaphylactic reaction. The patient's medical history was unknown. Concomitant medications are not reported. On unknown date prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On an unknown date the patient experienced Anaphylactic reactions. The event is considered as medically significant. No treatment was given. No lab details are provided. No Action taken with mRNA-1273 in response to the events was not reported. At the time of this report, the outcome of the events were unknown.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.

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1154048	4/1/2021	CA	39	F	3/5/2021	3/5/2021	Anaphylaxis; swelling of face, eyes, mouth, tongue.; swelling of face, eyes, mouth, tongue.; swelling of face, eyes, mouth, tongue.; This is a spontaneous report from a contactable consumer (patient). A 39-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot: EN6205), via an unspecified route of administration on 05Mar2021 08:45 (at the age of 39-years-old) as single dose for covid-19 immunisation. The patient was not pregnant at the time of vaccination. Medical history included possible Covid one year ago (in 2020) and known allergies: mild shellfish allergy. Concomitant medication included ibuprofen in two weeks. On 05Mar2021 at 16:00, the patient experienced anaphylaxis, swelling of face, eyes, mouth, tongue that resulted in emergency room/department or urgent care. Treatment included epinephrine, steroids and diphenhydramine hydrochloride (BENADRYL). It was unknown if with covid prior vaccination. Not covid tested post vaccination. The patient had no other vaccine in four weeks. The outcome of the events was recovered in Mar2021.

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1153976	4/1/2021	CO	39	M	3/11/2021	3/11/2021	<p>Extreme itchiness; Numbness of lips; Closing of throat; Extremely high blood pressure 180/111mmHg; Anaphylaxis; Numbness; Numbness of tongue; Shortness of Breath; The patient's O2 sat would drop as well, O2 levels were reported to be 88%; 135bpm resting heart rate; Tachycardia; Sleepiness; Swollen eyes; A Spontaneous report was received from a Healthcare professional , concerning a male patient of 39 age , who received Moderna's COVID-19 vaccine experienced Anaphylactic reaction/Anaphylaxis, Hypoaesthesia/Numbness, Eye swelling/Swollen eyes, Hypoaesthesia oral/ Numbness of tongue, Hypoaesthesia oral/ Numbness of lips, Oropharyngeal discomfort/ Closing of throat, Blood pressure increased/Extremely high blood pressure 180/111mmHg, Somnolence/Sleepiness, Pruritus/ Extreme itchiness, Heart rate increased / 35bpm resting heart rate, Dyspnoea/Shortness of Breath, the patient's O2 sat would drop as well, O2 levels were reported to be 88%/and Tachycardia /Tachycardia. The patient had a medical history of celiac disease and is a kidney patient (other kidney surgically removed). The reporter states that Patient's concomitant medications are gabapentin and duloxetine hydrochloride for chronic back pain. On 11 Mar 2021, prior to the onset of events, the patient received his first of two planned doses of mRNA-1273 (unknown lot number) via intramuscular route on left arm for COVID-19 infection prophylaxis. On 11 Mar 2021, anaphylaxis 3 minutes post receiving the first dose of vaccine the patient developed numbness and his eyes became swollen, then numbness of the tongue, lips and closing of the throat, which all happened at the vaccination site. The attending EMT provided 3 pills of oral 50mg Benadryl (diphenhydramine) and did not apply an EpiPen. Patient's blood pressure went extremely high (180/111mmHg) instead of dropping. At that moment, it was decided to contact 911. The paramedics placed the patient on a stretcher and loaded him onto the emergency vehicle to be rushed to the hospital. On the way, the patient was given an EpiPen. While in the hospital, the patient was given more diphenhydramine and injected with methylprednisolone. Patient was in observation for 4 hours and then released with a prescription of an EpiPen. It was reported that the patient was extremely sleepy due to the medications given.</p>

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When the patient arrived home, he went straight to bed. The patient was hospitalized on 11 Mar 2021 for Anaphylactic reaction, Hypoaesthesia, Eye swelling, Hypoaesthesia oral, Hypoaesthesia oral, Oropharyngeal discomfort, Blood pressure increased, Pruritus and released on same day after 4 hours. The next day, Friday (12 Mar 2021) the patient got up around 10:00am. Then at 10:05am, the symptoms began to reoccur with numbness of the lips, tongue, closing of throat and extreme itchiness. As soon as patient's husband noticed, he did not apply EpiPen and drove the patient to the emergency room. The emergency room followed the same protocol with methyprednisolone steroid, EpiPen and diphenhydramine. On Saturday (13 Mar 2021) and Sunday (14 Mar 2021), the doctor was seen and the patient was advised to take diphenhydramine every 4 hours. Then this past Monday (15 Mar 2021), patient started developing shortness of breath and a resting heart rate of 135bpm. That day, the patient was taken to urgent care. There he was administered diphenhydramine and the patient's heart was checked. Urgent care agreed that his heart was acting up and his blood pressure was acting up for an unknown reason. Reporter states that the patient had been developing tachycardia for no reason for a week now. Since the tachycardia had occurred, reporter would check patient's oxygen (O2) levels. When the tachycardia had started, the patient's oxygen saturation (O2 sat) would drop as well. O2 levels were reported to be 88% and resting heart rate of 103bpm. The reporter would let 5 minutes pass, recheck, and everything would return to normal. On Monday (22 Mar 2021), patient is scheduled to see a cardiologist who will place the patient on a machine to check his heart rate for 3 days to see what is going on. Follow-up with various health care providers was scheduled for the rest of the week. Nephrologist will be seen on Monday, Neurologist will be seen on Tuesday, and Kaiser will be visited on Wednesday. Reporter stated that even though asked to run bloodwork and images, the emergency room did not do it. Lab work was performed on Monday (15 Mar 2021) which came back normal. A check for blockage of the heart, also had looked fine. Action taken with mRNA-1273 in response to the event Anaphylactic reaction, Hypoaesthesia, Eye swelling, Hypoaesthesia oral, Hypoaesthesia oral,

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Oropharyngeal discomfort, Blood pressure increased, Somnolence, Pruritus, Hypoaesthesia oral, Oropharyngeal discomfort, Blood pressure increased, Somnolence, Pruritus, Tachycardia, Heart rate increased, and Dyspnoea was unknown. The outcome of the event Anaphylactic reaction, Hypoaesthesia, Eye swelling, Hypoaesthesia oral, Hypoaesthesia oral, Oropharyngeal discomfort, Blood pressure increased, Somnolence, Pruritus, Hypoaesthesia oral, Oropharyngeal discomfort, Blood pressure increased, Somnolence, Pruritus, Tachycardia, Heart rate increased, Dyspnoea, and the patient's O2 sat would drop as well, O2 levels were reported to be 88% was considered to be unknown at the time of this report. The treatment medications diphenhydramine, EpiPen injection x 2, and Methylprednisolone steroid injection x 2 was reported to be taken by the patient. The events Anaphylactic reaction, Anaphylactic reaction/Anaphylaxis, Hypoaesthesia/Numbness, Eye swelling/Swollen eyes, Hypoaesthesia oral/ Numbness of tongue, Hypoaesthesia oral/ Numbness of lips, Oropharyngeal discomfort/ Closing of throat, Blood pressure increased/Extremely high blood pressure 180/111mmHg, Pruritus/ Extreme itchiness were considered meet seriousness criteria of hospitalization, life threatening, and medically important.. The events Somnolence/Sleepiness, Pruritus/ Extreme itchiness, Heart rate increased / 35bpm resting heart rate, Dyspnoea/Shortness of Breath, and Tachycardia /Tachycardia were considered medically important. The causality per reporter was not provided.; Reporter's Comments: This case concerns a 39 Y/O M hospitalized with a serious expected anaphylactic reaction and unexpected BP increased, oropharyngeal discomfort, eye swelling, hypoaesthesia, pruritus, and NS unexpected somnolence, tachycardia, heart rate increased, and dyspnea with O2 saturation decreased. Event onset 3 minutes after first dose mRNA-1273. Based on current available information and temporal association between use of the product and start date of the event, a causal relationship cannot be excluded

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1158181	4/1/2021	NY	54	F	3/31/2021	3/31/2021	March 31 - received vaccine and immediately within 2-3 minutes experience moderate anaphylaxis: Throat constricted, rapid heartbeat, hot flash, tingly face. But breathing was normal throughout. Within minutes was given EpiPen, followed by intravenous Benadryl. Then taken to ER to later receive steroids. Was observed in ER for 4 hours, with no reoccurrence of symptoms. Prescription for Prednazone (3 day course) and Benadryl (as needed). Epi Pen if needed. April 1 - Next day, felt totally normal. Slight soreness in arm, and very minor fatigue. was able to work, drive, and go about normal activities.
1158022	4/1/2021	NJ	52	F	4/1/2021	4/1/2021	as per notes of vaccinating nurse: 1:53pm 2nd vaccine, Pt mentioned she had swallowing and breathing issue at home after 1st dose. nurse asked Pt to stay f/30min post vaccine. RN educated Pt on anaphylaxis protocol care. RN reassured Pt to return to RN if breathing or swallowing issues occur. 225pm Pt returns to RN c/o tightness in neckand throat, problems swallowing and breathing. 911 called. epi administered. 3 min Pt states not better, 2nd epi administered. waited 2 min, 3rd epi administered. 245pm EMS arrived. 250pm Pt transported by EMS to hospital to higher level of care.

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1157994	4/1/2021	CA	56	F	3/30/2021	3/30/2021	The patient was screened and was found to have multiple medical allergies but no allergies to any of the components to the Janssen vaccine. As a precaution, the nurses advised a 30 minute observation. She received the vaccine without complication and then was being observed and they called me over and the paramedics were also with the patient. About 17 minutes into observation, the patient started developing chest pressure (4/10), lightheadedness, and nausea. No shortness of breath, stridor, diaphoresis, back pain, abdominal pain, vomiting, neurologic changes, and any signs or symptoms of anaphylaxis. She was very anxious. Further history revealed that the patient had been discharged from the hospital 6 week prior. She initially went in for an abdominal laproscopic surgery and woke up to having 32 staples closing an abdominal incision. They had to change from a laproscopic approach to an open abdomen approach due to complications. She ended up with sepsis and a colostomy and was hospitalized for 2 weeks getting antibiotics. She lives by herself and was overwhelmed before coming into the clinic for her vaccine. The paramedics did a 12-lead ECG that showed sinus rhythm. Vital signs and blood glucose were within normal limits. The paramedics recommended that she go to the hospital to be checked out but she was very resistant and was tearful because she was traumatized from her previous hospitalization. After some time, the paramedics convinced her to go to the hospital. The paramedics hung around the emergency department and then came back once they found out that she was fine.
1157862	4/1/2021	MO	47	F	4/1/2021	4/1/2021	Pt called at 6:30 stating that they had developed hives post their first administration of the covid vaccine, no other issues than a bilat. rash (hives) on upper arms. pt took benedryl before calling and stated no signs of anaphylaxis and will follow up with their dr in the am
1157846	4/1/2021	OH	38	F	4/1/2021	4/1/2021	Face tingling, lips swelling, throat tightening, tongue swelling (moderate anaphylaxis reaction) and rash on neck, chest and abdomen.

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1157791	4/1/2021	CA	26	F	3/26/2021	3/26/2021	<p>S:The pt walked in, patient is a 26 year old female C/O dizzy after 1st Covid-19 Moderna Vaccine O: Appearance: alert, well appearing, and in mild distress and oriented to person, place, and time. A: Pt received 1st Covid-19 Moderna Vaccine about 1440, at 1458 pt stated she felt dizzy after getting the vaccine, stated she also felt like something was stuck in her throat and chest pressure that lasted for 2 minutes and subsided, no other complaints. The patient is in need of an appointment for medical evaluation. Pt transferred via wheel chair from Covid-19 Vaccine area to 2nd floor MD area. P: The patient was given an appointment which pt accepted. Appointment with Dr. scheduled for today Electronically signed by: RN 3/26/2021 3:46 PM Start Time 3/26/2021 3:34 PM Filed at 3/26/2021 10:51 PM Status: Signed I have reviewed the Chief Complaints and Vital Signs for this encounter as entered by the nurse. Chief Complaint Patient presents with ? DIZZY Patient received Covid 19 vaccine today ? CHEST PRESSURE SUBJECTIVE: Patient is a 26 year old female Complains of of feeling her head warmth, lightheadedness, nausea, like something stuck on her throat and chest pressure after receiving COVID vaccine today. Symptoms lasted about 20 minutes, feeling well now, symptoms resolved. Patient with history of anxiety and panic attacks, states she nervous with coming to the clinic for vaccine. Past Medical History: Anxiety Social History Tobacco Use Smoking Status Never Smoker Smokeless Tobacco Never Used Current medication list was reviewed in detail with the patient. No outpatient medications have been marked as taking for the 3/26/21 encounter (Office Visit) with, M.D.. OBJECTIVE: The most recent lab test results were reviewed in detail. HGA1C (%) Date Value 02/23/2021 5.4 ALT (U/L) Date Value 02/23/2021 16 CR (mg/dL) Date Value 02/23/2021 0.57 Review of Systems Constitutional: Negative for chills, fever, malaise/fatigue and weight loss. HENT: Negative for sore throat. Cardiovascular: Negative for palpitations and leg swelling. Respiratory: Negative for cough and shortness of breath. Gastrointestinal: Negative for abdominal pain, heartburn and vomiting. Genitourinary: Negative for dysuria. BP 119/67 (BP Location: LA-LEFT ARM, BP Patient Position: SITTING, Cuff Size: Large Adult) Pulse 82 SpO2 99% Physical Exam</p>

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Constitutional: She is well-developed, well-nourished, and in no distress. HENT: Mouth/Throat: no lip swelling, no tongue swelling, no uvular swelling, moist mucous membranes. Tonsils slight enlarged R>L, no erythema, no exudate. Cardiovascular: Normal rate and regular rhythm. Pulmonary/Chest: Effort normal and breath sounds normal. No respiratory distress.

Musculoskeletal: General: No edema. Neurological: She is alert. Nursing note and vitals reviewed.

ASSESSMENT F41.9 ANXIETY (primary encounter diagnosis) Z23 VACCINATION FOR SARS-COV-2

Comments: no signs of anaphylaxis. Lungs clear, no wheezing, no swelling, no respiratory distress. No rash. Most likely anxiety/panic attack. Patient was observed for a while. Symptoms resolved. Red flag signs given. PLAN: advised patient to find ways to cope with stress Follow up with PCP Please see the orders, patient instructions and follow-up plans for this visit. CURES reviewed when necessary. The patient was advised on the nature and expected course of this condition. Patient was advised to call, return to clinic or go to UC or emergency room if symptoms persist or worsen. Pt voiced understanding. Electronically signed by: MD Department of Family Medicine Medical Office Building 3/26/2021

ANGIOEDEMA (primary encounter diagnosis) Plan: METHYLPREDNISOLONE SODIUM SUCC 125 MG/2 ML INJ RECON SOLN PREDNISONE 5 MG ORAL DOSE PK TAB FAMOTIDINE 20 MG ORAL TAB DIPHENHYDRAMINE HCL 25 MG ORAL CAP Discontinue ace-I, benadryl q-4 hrs prn, pepcid and f/u with pcpr, if any swelling of throat, DIB or SOB to ED immediately. PE: Mouth/Throat: edema of lower lip and chin, no tongue swelling, no uvular swelling or pharyngeal swelling, moist mucous membranes, no erythema, no exudate S: presents with swelling of lower lip since last night. Per grand-daughter pt's L lower lip was swollen in similar fashion a few months, back, yesterday started again and now spread to entire lower lip and chin. Pt denies any swelling of tongue, throat, no DIB/SOB/CP. Pt is on lisinopril, no new medications.

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1157783	4/1/2021	AL	61	F	3/31/2021	4/1/2021	Patient had generalized itching all over her body, not just in the injection site. No rash and no anaphylaxis symptoms are present. Patient had immunization on 3/31/21 at 1:31pm and onset of itching was at approximately 9 am the following morning. She also had light nausea and light fatigue and a sore arm but it wasn't severe. Patient did not seek medical treatment at time of reporting and was planning to manage itching with benadryl.
1154100	4/1/2021	PA	31	F	3/17/2021	3/17/2021	Anaphylaxis; Swelling/tightness of the throat and chest; Swelling/tightness of the throat and chest; Swelling of the tongue; numbness of the tongue; persistent disorientation; confusion; Rapid heartbeat; This is a spontaneous report from a contactable consumer (patient herself). A 31-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6207), via an unspecified route of administration in left arm on 17Mar2021 as a single dose for COVID-19 immunisation. Medical history included rheumatoid arthritis (RA) and asthma. The patient had no known medical allergens. Concomitant medications in two weeks included amoxicillin, clavulanic acid (AMOXCLAV 875-125 MG) and cetirizine hydrochloride (ZYRTEC 10 MG). The patient did not receive other vaccines in four weeks. The patient was not pregnant and was not diagnosed with COVID prior to vaccination. On 17Mar2021 12:15 PM, the patient experienced anaphylaxis, swelling/tightness of the throat and chest, swelling of the tongue, numbness of the tongue, persistent disorientation and confusion, and rapid heartbeat. The events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, life threatening illness (immediate risk of death from the event). Treatment included 2 Epipens, Benadryl 25 mg, and intravenous Benadryl. Outcome of the events was not recovered. The patient was not tested for COVID post vaccination.

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1157514	4/1/2021	LA		F	3/24/2021		ANAPHYLAXIS (SEVERE HEADACHE, NAUSEA, COUGHING, RAPID INCREASING SHORTNESS OF BREATH LEADING TO RESTRICTION OF BREATHING, PALE, DIAPHORETIC); This spontaneous report received from a health care professional concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's concurrent conditions included penicillin allergy. The patient experienced drug allergy when treated with tetanus vaccine for prophylactic vaccination. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805018 expiry: UNKNOWN) dose was not reported, administered on 24-MAR-2021 for prophylactic vaccination on left arm. No concomitant medications were reported. On 24-MAR-2021 at 10:31, the patient experienced Anaphylaxis (severe headache, nausea, coughing, rapid increasing shortness of breath leading to restriction of breathing, pale, diaphoretic). On 24-MAR-2021 at 10:40 epinephrine was administered. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from Anaphylaxis (severe headache, nausea, coughing, rapid increasing shortness of breath leading to restriction of breathing, pale, diaphoretic). This report was serious (Other Medically Important Condition).; Sender's Comments: V0:20210350143-COVID-19 VACCINE AD26.COV2.S-Anaphylaxis. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and is scientifically plausible. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY, UNDERLYING DISEASE.

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1154953	4/1/2021	CA	28	F	3/31/2021	3/31/2021	On Wednesday, March 31, 2021 client (DOB 4/30/1992) received her first dose of Pfizer COVID vaccine (LOT # EW0150, EXP 7/2021) at approximately 11:50 am by vaccinator RN. RN instructed client to self-monitored at the observation area. EMTs found a 28 years old female sitting up while leaning forward and waving for assistance in an observation chair. Client had a chief complaint of dizziness. Client reported dizziness and fatigue to EMTs present after having sat in the observation area for approximately 10 minutes. Client had no known allergies or major medical history. Client denied pregnancy. Client agreed to be assisted walking up to the front EMT station so that she may be assessed more closely and with greater privacy. While walking over to the EMT station, the client experienced sudden loss in weight bearing and was prevented from falling by EMT present. EMT promptly came over to assist with transferring the patient to a chair for safety. Client was kept safe in her chair by EMT. It was at this point client experienced syncope. Client was then transferred to the gravity bed and laid supine until she became more alert. Client was then transferred to sitting semi-fowlers at 45 degrees once she was alert and tracking. lead RN came to assist EMTs as needed. Assessment revealed no hives, swelling, redness, difficulty breathing, wheezing or pain throughout her body. Client's skin was free of any signs of anaphylaxis throughout her body. Client's first set of vitals at 11:50 am was as follows: blood pressure 100 / 64, O2 - 99% on room air, pulse was 64 and regular at radial, respirations was 20 and regular. Client was fully alert and oriented x 4 (person, place, time, situation) and eyes were equal and reactive to light. Client stated that she had breakfast and denied any pain throughout her body. Client agreed to stay in the observation area for another 30 minutes after the onset of the incident per lead nurse's instruction to EMT. Client's vitals were reassessed at 5 minutes intervals as follows: 11:50 am- 110/64 (BP), 20 (respirations), 64 (pulse), 99% (O2); 11:55 am- 102/64, 18, 64, 99%; 12:00 pm - 104/ 68, 72, 18, 99%; 12:05 pm - 118/ 72, 72, 16, 100%; 12:10 pm - 118/ 78, 99%, 16, 78; 12:15 pm - 118/ 78, 100%, 16, 78; 12:20 pm - 118/80, 100%, 16, 78. After approximately 10 minutes, the client was asked to sit up so that her orthostatic vitals could be reassessed. Throughout her observation, client's vitals slowly returning to normal with

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							a blood pressure - 118/ 80, pulse 78, respirations 16 and 02 100% on room air. Client was provided with a fact sheet and pertinent areas of interest were highlighted for convenience. Client stated that she felt safe going home and ordered a ride sharing service. Client was encouraged to follow up with her primary and to seek medical care or the emergency room if a severe incident occurs. At 12:35 pm, the client departed the facility in a ride sharing service in no apparent distress and with all relevant information in her purse.
1154204	4/1/2021	CT	27	F	3/30/2021	3/30/2021	Patient reported tingling of the tongue 10 minutes after 2nd dose of Moderna vaccination. No swelling/ redness/ hives noted. 25mg Benadryl PO administered. Vital signs stable throughout observation. Reports hx. of anaphylaxis from iodine. 11:56a.m. Tingling in tongue improved, no further symptoms. 12:00pm Discharged from clinic with instructions to go to ED / call 911 if symptoms persist or worsen.
1153898	4/1/2021			U			ANAPHYLAXIS; This spontaneous report received from a patient via a company representative concerned a patient of unspecified age and sex. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included no known drug abuse or illicit drug usage. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: UNKNOWN expiry date: UNKNOWN) dose, 1 total administered, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient had anaphylaxis post vaccination. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of anaphylaxis was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: 20210335633-Covid-19 vaccine ad26.cov2.s-Anaphylaxis. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and is scientifically plausible. There is no information on any other factors potentially associated with the event(s).

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1155004	4/1/2021	NY	65	M	3/31/2021	3/31/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Medium, Systemic: Chest Tightness / Heaviness / Pain-Mild, Systemic: Flushed / Sweating-Medium
1155183	4/1/2021	SC	49	F	3/25/2021	3/25/2021	reported to onsite medical clinic at 11:30am after taking 2 puffs of albuterol, c/o HA/lightheaded/dizzy, VSS, developed mild SOB/clammy/groggy, sent to Emergency Room for evaluation and treatment where it was documented that she had an anaphylaxis reaction to the vaccine administered at 0800 on the same day at a community vaccination event
1155273	4/1/2021	MN	43	F	3/31/2021	3/31/2021	Immediately after receiving the injection she became dizzy and lightheaded. She decided to drive home and on her way her face began to tingle and her nose became stuffy. She drove the rest of the way home and after 30-60 minutes her throat became thick and it started to become difficult to breathe. She called 911 and administered an epi pen that she had at home due to anaphylaxis in 2015. She was treated by the paramedics and declined going to the ER. She has more tingling in her face when she was getting ready for bed but this subsided on it's own.
1155950	4/1/2021	TN	50	F	4/1/2021	4/1/2021	following vaccination patient c/o sudden HA with 3/10 pain level. Writer assessed patient. Denies shortness of breath, denies tongue tingling/swelling. Denies itching. Denies nausea or symptoms of anaphylaxis. Patient declined further medical attention offered. VS 118/78, 88, 20, 98% RA. After waiting 30 minutes patient reports HA now 1/10 and she feels ok to leave site.
1155975	4/1/2021	PA	55	F	4/1/2021	4/1/2021	anaphylaxis approx. 25 minutes after injection - took 50mg benedryl and recovered within 90 minutes of injection

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1156230	4/1/2021	WA	55	F	4/1/2021	4/1/2021	Client received to post vaccination observation with hx of anaphylaxis with influenza and pneumonia vaccination when administered together. Guest accompanied by husband. Husband states he is a medic with the fire department. Client has brought Epi-Pen with her today given her previous experiences. Client is seated in observation area with complaint of dry mouth. Pt given water. Client is visibly anxious and it was decided to take a set of vitals to help reassure and calm the client. VSS. Client was visibly relieved when given vitals were normal. Client continued to wait 30 min observation time without incident. Client discharged with her husband.
1157242	4/1/2021	IL	53	F	4/1/2021	4/1/2021	After waiting 15 minutes after vaccine administration, pt states she felt very warm and stopped by the bathroom that is when she noticed her face was very red. Patient was examined and had a red rash on her cheeks, nose, and chest. Patients vitals were obtained BP 110/70, HR 66 and O2 sat 98. Emergency anaphylaxis kit was obtained and pt was given 50mg IM Benadryl per protocol. Patient was observed for an additional 30 minutes. Rash had lightened in color. Patient left facility and drove herself home.
1152590	3/31/2021	FL	42	F	1/20/2021	1/20/2021	Anaphylaxis
1151684	3/31/2021	PA	50	F	3/31/2021	3/31/2021	Pt developed symptoms of anaphylaxis. Two doses of IM epinephrine were administered. 911 was called. The patient was taken to the hospital via ambulance.

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1152294	3/31/2021	IL	64	F	3/23/2021	3/23/2021	Patient required to stay 30 minutes for monitoring due to previous reactions: tetanus (reported dizziness, no anaphylaxis or treatment needed) and Norco in which anaphylaxis was reported. Patient stated she has had flu shots and pneumonia vaccinations in past. Approximately 15 - 20 minutes into monitoring patient reported headache and feelings of throat spasm. She took diphenhydramine that she had with her because of her past experience with anaphylaxis. At the end of the 30 minute monitoring period she said the throat spasm was not any worse and did not report any new symptoms, but an ambulance was contacted to take her to the local ER as a precaution. According to patient, she was monitored in the ER and given iv medications and sent home later in the afternoon. The patient stated she believes she was given a steroid medication and anti-nausea medication to fill at an outpatient pharmacy (unknown, uses other pharmacy).
1152230	3/31/2021		62	F	3/10/2021	3/10/2021	fever 102.6, chills, headache lasted 36 hours. started around 4-6 hours after her shot. no anaphylaxis. patient does not want to experience this again and refuses second shot.
1152170	3/31/2021		49	F	3/31/2021	3/31/2021	Initial transient nausea. In parking lot she had a headache and numbness in her ears. No s/s of anaphylaxis or other more serious reaction.

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1152122	3/31/2021	CT	43	M	3/3/2021	3/3/2021	Received his 1st dose of the Moderna vaccine on 3/3/2021 Lot # 002A21A PCP: Dr. (name) Employee was alerted to the pt's condition on 3/31/2021. Employee placed call to patient for further information. On the same day of the vaccine the pt reported nausea and vertigo for about 7 days. Pt reports on day 4 his legs were hurting him. Day 10 his legs became weak and numb, day 17 pt reports losing all sensation in legs and losing sensation in his hands and arms. Trouble throwing a ball, using a toothbrush, etc. Pt went to the ED. Pt had a normal CT scan and MRI of brain and neck. Pt stated he recently started having some intermittent issues with swallowing, feeling like there was a lump in the back of his throat. Pt states his PCP is fully aware of all of his symptoms. Pt is scheduled to see a neurologist at next week. Pt notes he experienced anaphylaxis to sulfa for the first time this past summer that required the use of an epi pen. Pt states he has a lung issue but otherwise is healthy. Pt reports no neurological symptoms prior to the vaccine. Patient was advised to continue to monitor his symptoms and keep his PCP up to date. Discussed precautions in great detail. Pt does not feel like he needs to seek emergency care again at this time.

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1152103	3/31/2021	CT	43	M	3/3/2021	3/3/2021	Received his 1st dose of the Moderna vaccine on 3/3/2021 Lot # 002A21A PCP: Dr. (name) Employee was alerted to the pt?s condition on 3/31/2021. Employee placed call for further information. On the same day of the vaccine the pt reported nausea and vertigo for about 7 days. Pt reports on day 4 his legs were hurting him. Day 10 his legs became weak and numb, day 17 pt reports losing all sensation in legs and losing sensation in his hands and arms. Trouble throwing a ball, using a toothbrush, etc. Pt went to the ED. Pt had a normal CT scan and MRI of brain and neck. Pt stated he recently started having some intermittent issues with swallowing, feeling like there was a lump in the back of his throat. Pt states his PCP is fully aware of all of his symptoms. Pt is scheduled to see a neurologist next week. Pt notes he experienced anaphylaxis to sulfa for the first time this past summer that required the use of an epi pen. Pt states he has a lung issue but otherwise is healthy. Pt reports no neurological symptoms prior to the vaccine. Patient was advised to continue to monitor his symptoms and keep his PCP up to date. Discussed precautions in great detail. Pt does not feel like he needs to seek emergency care again at this time.
1152432	3/31/2021	MA	42	F	3/31/2021	3/31/2021	42 yo female with c/o itching to neck/throat, sensation of throat swelling/SOB, dizziness ~1:43 pm. She has prior h/o anaphylaxis to IV contrast and appeared to be very anxious. Pt was given Benadryl 25 mg PO, water, and rested in a recliner. BP 140/80, HR 88, o2 sat 100%. 911 was called as pt's symptoms were not improving and she had travelled to vaccination clinic alone by bus. She remained A&Ox3, was speaking in full sentences, and no swelling or erythema to throat visualized.

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1152033	3/31/2021	AZ	69	F	3/23/2021	3/29/2021	<p>Patient is a 69-year-old female who reports a history of hayfever who is coming in today after recent Covid vaccination with concerns of facial swelling also complaining of the rash and itching to her chest. On exam the patient has obvious facial swelling. She has what appears to be an urticarial rash on her chest. While she does have swelling around her lips and face otherwise she does not appear to have any obvious signs of airway involvement with no swelling of her tongue or uvula, she has good phonation with normal respirations without difficulty. Does not appear to be having reactive airway disease exacerbation at this time. Does not appear to have impending respiratory distress. She otherwise does have some skin changes in her bilateral lower extremities that she reports is baseline with her history of eczema. Primary concern at this time is for possible allergic reaction. Patient appears to have angioedema. Does not appear to have anaphylaxis. Other abnormalities are considered. Patient will be connected to cardiac and respiratory monitors. IV access will be obtained. The patient will be given a 1 L IV fluid bolus. She will be given Benadryl, Solu-Medrol, and famotidine. Patient be monitored for response. Labs have been ordered to evaluate. EKG as well as chest x-ray will be obtained. We will file VARES report. Chest x-ray obtained. There is no acute cardiac no acute pulmonary pathology on my interpretation. Laboratory evaluation has returned. The patient's CBC is reassuring. CMP shows a glucose of 78, otherwise reassuring without significant abnormality. Troponin within normal limits. Covid, influenza, RSV testing is negative. On repeat evaluation the patient is resting comfortably. She reports that the itching has resolved. Her face feels less uncomfortable. She has had no progression of the swelling. On repeat examination she continues to have facial swelling as well as swelling around her lips however she has no tongue swelling, no swelling within her posterior oropharynx, and her phonation continues to be normal. She and her friend were informed of the initial findings. Plan at this time is to admit for further evaluation and treatment.</p>
1151941	3/31/2021	TX	36	M	1/28/2021	3/31/2021	No adverse reactions; no anaphylaxis

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1153229	3/31/2021	IL	55	F	2/19/2021	2/19/2021	Anaphylaxis, confirmed by ER; This is a spontaneous report from a contactable other healthcare professional (HCP). A 55-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number: EN6200, expiration date was unknown), intramuscularly, administered in the left arm on 19Feb2021 at 12:15 PM as a single dose for COVID-19 immunization. The vaccination facility type was reported as the hospital. The patient's medical history and concomitant medications were not reported. The patient previously took codeine and hydrocodone bitartrate, paracetamol (VICODIN), from which she had known allergies. The patient was not pregnant at the time of vaccination. The patient had no other vaccine in four weeks. The patient had no COVID prior vaccination. She was not tested for COVID post vaccination. On 19Feb2021 at 12:15 PM, the patient experienced anaphylaxis, confirmed by emergency room (ER). The adverse event (AE) resulted in a doctor or other HCP office/clinic visit and emergency room/department or urgent care visit. Therapeutic measures were taken as a result of anaphylaxis, confirmed by ER, which included epinephrine, steroids, and antihistamines. The patient recovered from the event on an unspecified date.; Sender's Comments: Based on known drug safety profile and temporal association, the causal relationship between bnt162b2 and the event anaphylactic reaction cannot be excluded.
1151889	3/31/2021	CA	59	F	3/31/2021	3/31/2021	10:10 am - 15 minutes post vaccine, patient felt dizzy and light headed with tingling at the back of her neck. BP 128/84, P 78, R 14. No headache, no chest pain, no s/s of anaphylaxis. 10:40 am - Patient recovered, symptoms resolved.
1153467	3/31/2021	CA	39	F	3/31/2021	3/31/2021	AT 1040 AM PT RECEIVED VACCINE, APPROXIMATELY 15 MINUTES LATER PATIENT COMPLAINED OF TROUBLE SWALLOWING SIMILAR REACTION TO WHEN SHE HAD BEESTINGS WHEN YOUNGER. PT DIDN'T STATE SHE HAD ANAPHYLAXIS PREVIOUSLY. WE HAD THE EMT FROM FIRE DEPARTMENT EVALUATE PATIENT AND THEY RELEASED HER FROM CARE SAYING SHE SHOULD BE OK IN 30 MINUTES . NO MED WAS ADMINISTERED.

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1151648	3/31/2021	OH	44	F	3/31/2021	3/31/2021	44yo F with PMH of anaphylaxis on multiple medications who developed subjective symptoms of her throat becoming tight, dry, and scratchy. Pt became tachypnic and tachycardia to 110s, 100% saturation. Pt was evaluated by medical staff and ems, given oral hydration and 60mg fexofenadine. Pt was monitored with symptomatic improvement after 45min. She was cleared and discharged with instruction to not receive second pfizer dose.
1151416	3/31/2021	CA		F	1/31/2021		had a "bad reaction"; wants to know the definition of anaphylaxis as that may be what happened; This is a spontaneous report. A contactable consumer (patient herself) reported that a female patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number and Expiration date were unknown), via an unspecified route of administration on 31Jan2021 as a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that, caller received first dose on 31Jan2021 and, on an unspecified date in 2021, the patient had a "bad reaction"; wants to know the definition of anaphylaxis as that may be what happened. Feels she was unable to get second shot because of reaction to the first. The outcome of the event was unknown. Information on the lot/batch number has been requested.

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1151386	3/31/2021	OK	38	U	1/11/2021	1/11/2021	Anaphylaxis; This is a spontaneous report from a contactable consumer (patient). A 38-year-old patient of an unspecified gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose at the age of 38-years-old, via an unspecified route of administration on 11Jan2021 (lot number: EL1283, expiry date not reported) as single dose for covid-19 immunisation. Medical history included allergy from an unknown date and unknown if ongoing and supplement from an unknown date and unknown if ongoing. Concomitant medications included iron (IRON) taken for an unspecified indication, start and stop date were not reported; rosa canina, tanacetum vulgare, urtica dioica (NEUROTEC) taken for hypersensitivity, start and stop date were not reported; ashwagandha taken for supplementation therapy, start and stop date were not reported. The patient received bnt162b2 (PFIZER-BIONTECH COVID-19), first dose at the age of 38-years-old on 21Dec2020 (lot number: EK5730, expiry date not reported) for covid-19 immunization and experienced a mild reaction. The patient experienced anaphylaxis on 11Jan2021. The patient underwent lab tests and procedures which included blood test: unknown result on an unspecified date, cardiac stress test: unknown result (I had a perfusion like "stress pass" (not clarified)) on an unspecified date, echocardiogram: unknown result on an unspecified date. The outcome of the event was unknown.

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1150933	3/31/2021	IL	44	F	3/12/2021	3/12/2021	Anaphylaxis; This is a spontaneous report from a two contactable consumer (patient and office assistant). A 44-year-old non-pregnant female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: EN6208), via an unspecified route of administration in left arm on 12Mar2021 at 18:30 as a single dose for COVID-19 immunization. Medical history included hypothyroidism, bipolar and high blood pressure. The patient did not receive any other vaccines within four weeks prior to the COVID vaccine. It was unknown if patient had covid prior vaccination. Concomitant medication included lamotrigine (LAMICTAL), levothyroxine (MANUFACTURER UNKNOWN), amlodipine (MANUFACTURER UNKNOWN) and glucosamine (MANUFACTURER UNKNOWN). On 12Mar2021 at 18:45, the patient experienced anaphylaxis. It was reported that patient visited emergency room/department or urgent care. The patient took Benadryl and 2 epinephrine shots as a treatment. It was reported that COVID test was not done after post vaccination. The outcome of the event was resolved on Mar2021.

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1151938	3/31/2021	CO	68	F	3/19/2021	3/19/2021	Got the vaccine and they had her pull over as she had already had a reaction to the first one. All of a sudden she felt like her lip was swelling, and her tongue swelling, her face was a little red. She then had trouble breathing, and thought it may have been anxiety. She also has had headaches which have lasted for about 11 days, and depression. Her breathing was getting worse and the nurse came over and told her that she was having problems breathing and started coughing. She had Benadryl with her and she was advised to take that, and took 2 puffs of her inhaler. She stopped coughing as much, and was able to drive home within 10 minutes. She went home and realized that she was hyper, advised to take more Benadryl. It did not make her sleepy and did help with the allergic reaction. A friend saw her and told her that she was wired. She keeps having the coughing fits and breathing problems, and was thinking she was going into anaphylaxis. She also has had some confusion. She then went to the doctor on 3/25/21 due to urinary symptoms and had a UTI. Within the first couple of days she was having coughing bouts and was wondering if she should go the UC or not, wheezy type feeling. Her doctor gave her antibiotics and told her to use inhalers. She went back to the doctor on Monday 3/29/21, did a chest x-ray which was clear. She still thought that she was wheezy and ordered a new inhaler which she has been using, and still having coughing fits even today. She has been taking Benadryl every night since the vaccine which has not made her sleepy. The antibiotics seem to have helped the chest symptoms, but she is still coughing.

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1150930	3/31/2021			F			serious reaction and is on disability. She described it as continuous anaphylaxis; This is a spontaneous report received from a non-contactable consumer. An unspecified aged female patient received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Solution for injection, Lot Number: unknown) via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient medical history was not provided. Concomitant medications were reported as none. On an unspecified date patient was reported as she received her first Pfizer COVID vaccine and had a serious reaction and is on disability. She described it as continuous anaphylaxis. It was unknown if the patient received any treatment. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

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1150230	3/31/2021	OK	37	F	3/30/2021	3/30/2021	<p>Patient described having lightheadedness, the began to experience dyspnea saying her breathing felt strange. This began approximately 5 minutes after her dose was administered. We had her sit down in our injection room and began to monitor her symptoms. I immediately got out our protocol for Treatment of an Allergic Reaction as part of our vaccination program protocol. the patient remained conscious and responsive throughout the encounter. A pulse oximeter was placed on her left pointer finger. Her heart rate fluctuated in the 110s to 130s during the encounter. Her pulse ox remained 97% throughout the encounter. Patient reported having a history of hypertension treated with lisinopril. We placed a blood pressure monitor on her left wrist to take her blood pressure. Her initial blood pressure was 164/105, which she reported was "just a little bit over normal" for her. After taking the initial blood pressure, she described that her symptoms were beginning to subside a bit. We discussed the signs/symptoms that we would be looking for in an anaphylaxis type reaction, some of which were present (i.e. tachycardia, dyspnea) and some of which were not (i.e. hives, swelling of the face/lips, throat, etc.). We then began to take her blood pressure again. The second blood pressure measurement was 156/104. Shortly after taking the second blood pressure, she described having feelings of dyspnea again. At that time, I notified another staff member to contact EMS/call 911 and let them know we potentially had an allergic reaction to the second dose of Moderna COVID-19 vaccine. When the symptoms came back for the second time, I got out the Epipen Two Pack in the case that we would need to administer a dose. We continued to monitor her symptoms and kept her responsive over the next few minutes, until the first set of EMS arrived from the local fire department. The EMS staff began taking her vitals and took over care of that patient at that point. Patient was still responsive and describing only dyspnea and having clinical symptoms of tachycardia and hypertension. Patient got nauseated around 10 minutes after the first set of EMS arrived, and experienced a bit of vomiting. About 10-15 minutes after the first set of EMS arrived and took over care of the patient, the ambulance and second set of EMS arrived and took over care. They began monitoring the patients symptoms and placed an IV line. The patient was then transported to the local</p>

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1149838	3/31/2021		40	F	3/2/2021	3/2/2021	<p>Emergency Department. At around 5PM, the patient called the pharmacy to report that the physicians at the emergency department had ruled that she had experienced an allergic, non-anaphylactic reaction to the dose of Moderna COVID-19 vaccine.</p> <p>Anaphylaxis 40 y.o. female with multiple environmental allergies, migraines, asthma, mild OSA, and anxiety presents to the emergency department from the vaccine clinic with syncope and allergic reaction. She says shortly after getting her COVID-19 vaccine, she felt lightheaded, had near syncope. Per bystanders at the clinic, she had a brief episode of unresponsiveness and then spontaneously returned. She was conversant with multiple members of the code and rapid response team at the bedside. Did initially have some labored breathing but significantly improved. She had no vomiting but had mild nausea also significant improvement. In the field, IV was established and 125 mg of Solu-Medrol was administered. She was also given 1 IM dose of epinephrine. Her symptoms resolved she is at her baseline. Medically stable for discharge. Discharge home with short course of steroid, H2 blocker and Benadryl as needed. Advised patient to follow-up with PCP post discharge. Resume other home medicationS as listed. Of note, the patient had a similar reaction with influenza vaccine.</p>

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1149818	3/31/2021	NH	56	F	3/31/2021	3/31/2021	Shortly after vaccine administration, the pt honked her car horn for help and was noted to be minimally responsive. Initial BP was noted to be 60/palp. She was promptly given a dose of epi (epipen) at appx. 0830. She did not improve immediately and required a second dose of epi. Prior to transport by EMS, she improved slightly and denied any respiratory symptoms or skin involvement. She complained of feeling weak and tired only. SP02 was 89% and HR was in the 70s and regular. 02 was administered by EMS and she was given a dose of Benadryl, 25mg as well. While EMS was still on scene with the pt, BP improved to 130 systolic and she was noted to be significantly improved. She had a significant period of hypotension for appx. 20 minutes however (prior to improvement). Unclear if she had a prolonged vasovagal response or possibly anaphylaxis. She did not have clear mucosal, respiratory or GI involvement to suggest a definite diagnosis of anaphylaxis. She was transported to local ER by EMS in improved condition.
1149659	3/31/2021		25	F	3/30/2021	3/30/2021	Anaphylaxis, Urticaria Patient was transferred to the Emergency Room @ 14:14 via EMS, After 1st vaccination patient experienced tingling of the tongue. After 3 mins of observation patient began to have hives around her neck. Epi was given 14:07 lot# 9fm640. Exp apr 2021 Vital Anaphylaxis
1149509	3/31/2021	MI	35	M	3/29/2021	3/29/2021	1:58pm vaccine administered in left deltoid, immediately after shot patient said "I feel dizzy" then became pale, diaphoretic, and hard to rouse. Help called. RN's NP. Blood pressure taken 76/35, heart rate 46 b/m. EMS notified, patient protected from falls and head held stable, nausea and then patient vomited. Oxygen placed on pt. Patient air way assessed and patent, no sign of anaphylaxis, patient appears to be experience an vasovagal event related to vaccine administration. Blood glucose monitored with vitals every 3 to 5 minutes. 2:20 pm EMS arrived and patient transferred to their care.

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1149388	3/31/2021	CA	52	M	3/30/2021	3/30/2021	Systemic: Allergic: Anaphylaxis-Mild, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Additional Details: Patient had shortness of breath, chest tightness and throat swelling (uncomfortable feeling described by patient). Paramedics took the patient with them. Patient came to the pharmacy 3 hrs later and informed us that he was doing okay and his breathing was better.
1149304	3/31/2021	CA	44	F	3/20/2021	3/20/2021	20 minutes after injection, started feeling itchy all over. Began coughing and having asthma, used inhaler twice with no relief, was taken from coliseum by ambulance to ER. Enroute given epinephrine and 50 ml of benadryl. At ER repeat epinephrine and benadryl, H1/H2 blockers given. Released after three hour observation. Diagnosis of anaphylaxis.

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1153302	3/31/2021	VA	68	F	3/6/2021	3/6/2021	<p>blood pressure was checked and it had skyrocketed to 204/110; blood pressure had dropped to 95/58; she was lightheaded; feel chest pressure; facial flushing and warmth; facial flushing and warmth; redness on her neck and chest; This is a spontaneous report from a contactable retired registered nurse (patient). A 68-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration, administered in right deltoid on 06Mar2021 10:09 (Batch/Lot Number: EN6198) at single dose for COVID-19 immunisation. Medical history included hypertension. Concomitant medications included fexofenadine hydrochloride (ALLEGRA) taken for anaphylaxis prophylaxis; famotidine (PEPCID) taken for anaphylaxis prophylaxis; cetirizine hydrochloride (ZYRTEC) taken for anaphylaxis prophylaxis; methylprednisolone acetate (MEDROL) taken for anaphylaxis prophylaxis. The patient previously received H1N1 vaccine (Sanofi Pasteur, lot number: UP006AA, expiry date: 15Mar2011) on 27Oct2009 and experienced anaphylaxis. Patient had no other vaccines on the same day as the suspect product. The patient experienced blood pressure was checked and it had skyrocketed to 204/110 (hospitalization (from 06Mar2021 to 08Mar2021)) on 06Mar2021, felt chest pressure on 06Mar2021 10:29, facial flushing and warmth on 06Mar2021 10:29, redness on her neck and chest on 06Mar2021 10:29, she was lightheaded on 08Mar2021, blood pressure had dropped to 95/58 on 08Mar2021 21:43. Clinical course: Caller states that she received her first dose of the product on 06Mar at 10:09am. Caller states that to provide some history, in Oct2009, she had anaphylaxis from the H1N1 Vaccine and in 2017, she finally found an allergist who specialized in medication allergies. Caller states that since then, any time she takes the Flu Vaccine, she pre medicates with a combination of antihistamines and a proton pump inhibitor. Caller states that in preparation of the COVID vaccine, her allergist prescribed her a Medro Dose pack and antihistamines and a proton pump inhibitor for preparation, starting three days prior to the vaccine, in order to prevent anaphylaxis. Caller states that 20 minutes post receiving the vaccine, she started to feel chest pressure, she had facial flushing and warmth, and redness on her neck and chest. Caller states that her</p>

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blood pressure was checked and it had skyrocketed to 204/110. Caller states that she did not have anaphylaxis though. Caller reports that with her blood pressure being so high, they had to call paramedics, and the caller went via ambulance to the ER at about 1130am on 06Mar2021. Caller states that she spent 6 hours in the ER, and then she was put in the hospital for the next two days. Caller reports she was admitted to the hospital for her blood pressure because the ER could not get it below 185 systolic. Caller states that all her labs were negative for everything, and they checked heart attack markers that were all negative. Caller had an EKG and a stress test and those were both negative as well. Caller had blood work done, EKG and stress test that were all normal. But caller states that it took a while to get her blood pressure down. Caller states that she was talking with her allergist and he said that if she gets the second dose of the vaccine, it would need to be in a hospital setting, with an IV already in place, and caller does not think insurance will cover all that. Caller states that she did speak with an Infectious Disease doctor, who told the caller that she needs to get the second dose of the product for COVID coverage, but how would the caller move forward with getting the second dose, following what happened to her? Caller is wondering how much protection the vaccine provides after just one dose? Caller is also wondering, the hospital gave her at least two or three doses of Solu-Medrol, and caller is wondering if having received steroids in the hospital would reduce the efficacy of the COVID vaccine, and if so, by how much? Event Details: Caller had the vaccine, and the reaction started on 06Mar2021, and she was admitted on the same day. Caller was discharged from the hospital on 08Mar2021 around 330pm. Caller reports that the morning of her discharge from the hospital, her blood pressure had gotten back to 135 systolic, but before it was time for her to go down for the stress test, it was back to 159, and down while she was in nuclear medicine, it got to 160 systolic. Caller reports that the day she was discharged, she went home and got settled in, and she took her blood pressure and it was down to 128/78, but then that evening, things got spinning around her, and lights were flickering in her head, and she was lightheaded, and her blood pressure was 110/63 at 9pm and by 9:43pm, her blood pressure had dropped to

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95/58. Caller states that it has not been a fun trip. Caller reports that the next morning, her blood pressure was back up to 139/78, but then later in the day she was lightheaded again, and by 9am her blood pressure was 111/69. Caller states that since then, her systolic blood pressure has been between 110 and 126. Caller states that there is nothing else she can think of. Caller states that she felt fine the morning of getting the COVID vaccine, she was looking forward to getting it, and she got herself on the list and made sure to consult with her allergist so that she would have prophylactic medications ready to go. Caller states that she does have a history of hypertension, but her blood pressure was 128/72 the morning of getting the COVID vaccine. The outcome of the events Blood pressure high and Blood pressure dropped was recovering, of the other events was unknown. The reporter considered the event blood pressure had skyrocketed to 204/110 was related to the suspect vaccine.; Sender's Comments: Based on the temporal association and known drug safety profile, a possible contributory role of vaccination with BNT162B2 to the reported event blood pressure increased cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

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1148731	3/31/2021	OK	50	F	3/18/2021	3/18/2021	Stroke; Anaphylactic shock; High blood pressure; A spontaneous report was received from a pharmacist concerning a 50-years-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced anaphylactic shock, stroke/cerebrovascular accident and high blood pressure/hypertension. The patient's medical history was not reported. The relevant concomitant medications were not reported. On 18 Mar 2021, approximately five minutes prior to onset of the events, the patient received their first of two planned doses of mRNA-1273 (batch number: 032M20A) via unknown route for prophylaxis of COVID-19 infection. On 18 Mar 2021, five minutes after vaccination the patient experienced anaphylactic shock, stroke and was subsequently hospitalised. The patient also had high blood pressure. The events anaphylactic shock and stroke was life threatening. Treatment for the events included steroids, diphenhydramine and epinephrine. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events anaphylactic shock, stroke and high blood pressure was not reported.; Reporter's Comments: This is a case of Anaphylaxis and Stroke in a 50-years-old female patient with no medical hx provided who was hospitalized immediately after receiving first dose of vaccine. Very limited information has been provided at this time. Further information is expected

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1150486	3/31/2021	FL	77	F	3/8/2021		allergic anaphylaxis; A spontaneous report was received from a consumer, concerning herself a 77 years old female patient, who received Moderna's COVID-19 vaccine and experienced allergic anaphylaxis reaction in which the throat is swollen and could not eat and drink liquids. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 08 MAR 2021 prior to the onset of events, the patient received their first of two planned doses of mRNA-1273 (Batch Number: 030A21A) via Intramuscular route for COVID-19 infection prophylaxis. On unknown date, she experienced allergic anaphylactic reactions which the throat was swollen and could not eat and drink liquids. She took Benadryl (diphenhydramine) as the treatment. Action taken with mRNA-1273 in response to the event was unknown. The outcome of the event was considered to be unknown at the time of this report.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported event, a causal relationship cannot be excluded.

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1150913	3/31/2021	FL	65	F	3/4/2021	3/4/2021	<p>Gasping for air; Tongue swelling; Swollen lips; Throat closing/restriction in her throat; tickle in the throat; Headache; Dizzy; couldn't think clearly/her thinking wasn't clear; Confused; sensation in her chest; weak; fatigued; she had a full tongue which effecting her talking; tingling in her lips; anaphylactic reaction; This is a spontaneous report from a contactable consumer (patient). A 65-year-old female patient received the 1st dose of bnt162b2 (BNT162B2, Lot Number: EN6198; Expiration Date: Jun2021), as single dose in left shoulder on 04Mar2021 at noon for COVID-19 immunisation. Medical history included Hashimoto's disease from May2012 and ongoing (autoimmune condition), ongoing undifferentiated connective tissue disease (UCTD) (autoimmune condition, unsure when diagnosed, started with polymyalgia rheumatica, then it went to rheumatoid arthritis (RA), then it went between Lupus and undifferentiated connective tissue disease), hospitalization: she had to go hospital twice in last 4 months, one was for Amlodipine which has polyethylene glycol and another time for Lisinopril as another blood pressure medication, she had 2 mild anaphylactic reactions in the last 4 months from amlodipine and Lisinopril, patient thought they all have PEG in the ingredients; underwent colonoscopy unknown results. There were no concomitant medications. On 04Mar2021 the patient experienced anaphylactic reaction, gasping for air, headache, dizzy, could not think clearly/her thinking was not clear, tongue swelling, swollen lips, throat closing/restriction in her throat, confused , sensation in her chest, weak, fatigued, she had a full tongue which effecting her talking, tickle in the throat, tingling in her lips. Course of events was as follows: The patient drove two hours to get the vaccine. The patient was vaccinated on 04Mar2021 at noon. The reaction started immediately, the caller had a severe headache within seconds, a little bit of sensation in her chest. The patient's thoughts were getting mixed up, she was not thinking clearly. This was one of first things that happened. The patient stumbled a little bit and the nurses were there around her and said she better sit down now. Then the sensation in her throat was starting to feel like it was closing up, her lips were swollen; so she would say she was a little bit confused. The patient started getting dizzy and her thinking was not clear, her</p>

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tongue swelled, she had a full tongue which effecting her talking, she was gasping for air, she needed a moment to regulate her breathing. In regards to swollen lips she added at first she had a tickle in the throat, tingling in her lips, restriction in her throat, then she started slurring her words before the ambulance got there. On site they responded and watched her because she did not know if the symptoms were going to get worse. The paramedics gave the caller oxygen and an IV, since she had a mild experience she wanted to see what she did not take any medications before taking the vaccine so she could see what it would do, she did not take an ibuprofen or Tylenol. Patient commented, she knew it was not recommended, but some people do it. The patient mentioned started speaking very badly and very fast, she started gulping for air, and was informed the histamines are hitting her. She felt like she was going to faint, she thought if she was able to count back from ten she was going to be knocked out. Once she counted back she started to feel better. Like she would not faint. She did not faint often. She mentioned counting backwards from ten when getting a colonoscopy or something like don't get passed five and then knocked out, so she knows the sensation that can occur. After 1.5 hours they decided to call the emergency number and that was when the ambulance came. The ambulance service was the one who did everything for the patient. Because the patient got in the ambulance, they required her to go to the hospital, she was in a bed in the hall, by the time her doctor had looked at her, her throat had opened up and was feeling reasonably well after an hour and half. Confirmed she was not admitted just in the Emergency Room. On 04Mar202 the patient was at the hospital and was gasping for breath. The patient was on an IV and they gave her 125 mg of Solu-Medrol, 50 mg of Benadryl, and 5 mg of nausea medicine, phedrol the caller thought it was called. They did a good job and that helped the patient down from the most severe symptoms and she wanted to report her symptoms. The patient has been looking around and she thought this reaction it was from the polyethylene glycol. She mentioned historically she had a minor reaction. She had to go hospital twice in last four months. One was for Amlodipine which has polyethylene glycol and another time for Lisinopril which is another blood pressure medication. She confirmed she

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visited the emergency room for all 3 of these cases. The patient was still very confused on 09Mar2021 and over the weekend, she had to rest, she was weak and fatigued. On 09Mar2021 it was first real day she went back to work. She worked and asked her brother to watch out for her. On 10Mar2021 she was starting to feel a little bit better as regarded anaphylactic reaction, she has recovered with residual effects from the anaphylactic reaction. Confusion was improved but still a concern. The outcome of anaphylactic reaction was recovered with sequelae, of headache, swollen lips, confused was recovering, of gasping for air, dizzy, could not think clearly/her thinking was not clear, tongue swelling, throat closing/restriction in her throat, sensation in her chest, weak, fatigued, she had a full tongue which effecting her talking, tickle in the throat, tingling in her lips was unknown. Patient asked if there was a conclusion about the PEG and her anaphylactic reaction. Her second dose was scheduled on 25Mar2021. Patient stated that her PCP and the CDC recommend to not get the second dose. Caller wanted to know if the anaphylaxis could be worse in the second dose. The patient wanted to know if she should she get the next dose. She was very concerned about COVID as well but did not know if it's worth her risking her life. Patient wanted to know if she can get the Johnson and Johnson vaccine after a certain amount of time after receiving the Pfizer COVID 19 vaccine, caller cannot get the second dose of the Pfizer COVID vaccine due to a reaction. As of 12Mar2021 patient stated she does not wish to be contacted any further. A Product Complaint was filed.

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1154397	3/31/2021	NC	52	F	3/30/2021	3/30/2021	After 1hour / 1 1/2hour from injection start tingling left side of tongue, lip, swelling the throat After 2hours find a red burning rash under breast/torax.Called health clinic, the Triage nurse directed me to hospital.Went to the Emergency room. Main Hospital Team Dr. Diagnose:allergic reatcion+Yeast infection. 7:28PM gave 3 pills prednisone. Prescription for Prednisone 20mg 3for4days, nyastatin podwder for rush, epinephrine injection in case of anaphylaxis, benadryl as needed.While I was at ER, the tingling/swelling expand my entire body left side. This night I had to remove wedding ring, today the face still swelling/warming+almost same/little bit worsening simptoms
1154351	3/31/2021	VA	33	F	3/30/2021	3/30/2021	pt has idiopathic anaphylaxis, stayed at pharmacy for 30 minutes for first dose and planned to stay longer for the second dose. after 15-20 minutes after vaccination was administered she felt her lungs were itching and she had a bit of a cough, no difficulty breathing. Pt had brought Benadryl and took 50mg of that, then she used her albuterol inhaler and stayed in the pharmacy area for monitoring. about 5-10 minutes later she was having difficulty breathing, based on discussion with paramedics EpiPen was administered by the patient (personal prescription that she has with her). less than 5 minutes after EpiPen was administered the paramedics arrived. She was assessed by paramedics taken to the hospital but released the same day. She stopped back by the pharmacy later on to let us know she was ok. She was treated by the ED with Medrol and monitoring.

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1153493	3/31/2021	NJ		F			generalized rash; This is spontaneous report from contactable healthcare professional. A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, batch/lot number and expiration date were not reported), via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced generalized rash (not just at injection site, as reported) without anaphylaxis on unspecified date and with outcome of unknown. The reporter was trying to clarify if it was safe for the patient to get the second shot. Information on the lot/batch number has been requested.
1153373	3/31/2021	WA	51	F	2/26/2021	3/15/2021	Had first Moderna Covid vaccine dose on 2/26. Rash appeared on 3/15 on starting on her neck and spreading to her arms and shoulders; denies rash on her abdomen, torso, back, face and legs. Rash composed of maculopapular fixed lesions that are itchy; she did scratch and has secondary scabbing from inflicted skin damage. Itchiness worsened during warm shower. She took oral benadryl and OTC hydrocortisone which helped lessen the itchiness. She saw her PCP clinic 3/29 and was given a medrol dosepak; she took her first day yesterday and feels better-wants to stop. Denies history of adverse reaction to injected medications/therapies/vaccines. No historical allergies, anaphylaxis. At no time did she experience fevers, chills, conjunctivitis, congestion, shortness of breath, wheezing, swelling, urticaria, open lesions, blistering rash.

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1153297	3/31/2021			F			Anaphylaxis; hypersensitivity reactions; Injection site reactions; headache; feeling tired; This is a spontaneous case received from a contactable consumer (patient). A female patient of unspecified age received first dose of BNT162B2 (PFIZER BIONTECH COVID 19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The relevant medical history and concomitant medications were not reported. The patient experienced small rash after the first dose didn't itch, headache and feeling tired on an unspecified date. She treated her symptoms by taking 2 Tylenol. Spoke from fact sheet Adverse Reactions in Post Authorization Experience: Severe allergic reactions including anaphylaxis and other hypersensitivity reactions (e.g rash pruritus urticaria angioedema) had been reported following administration of the Pfizer BioNTech COVID 19 Vaccine during mass vaccination outside of clinical trials. Injection site reactions duration was 2.5 days. The outcome of the events headache, fatigue was recovered on an unspecified date, while other events were unknown. Information on the lot/batch number has been requested.
1153246	3/31/2021	FL	38	F	3/10/2021	3/10/2021	Emergency room for emergent treatment of anaphylaxis; This is a spontaneous report from a contactable physician. A 38-years-old non-pregnant female patient (nurse) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: Not Reported), intramuscular, administered in Leg Left on 10Mar2021 at 18:00as a single dose, for COVID-19 vaccination. Medical history included hysterectomy. There were no concomitant medications. No other vaccines were given within 4 weeks. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination the patient had not been tested for COVID-19 The patient previously took cephalexin [cefalexin] and experienced drug hypersensitivity. On 10Mar2021 at 20:00, The patient went to the emergency room for emergent treatment of anaphylaxis (medically significant). Treatment included' Epi/Decadron/Benadryl/Pepcid IV'. The clinical outcome of the event anaphylaxis was recovered. Information on the lot/batch number has been requested.

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1153230	3/31/2021	NC	74	F	2/25/2021	2/27/2021	Chills; Irritation in throat; Swelling of tongue; Unable to swallow solids; This is a spontaneous report from a contactable nurse (patient). A 74-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EN6202), dose 2 via an unspecified route of administration, administered in the right arm on 25Feb2021 for covid-19 immunization. The patient's medical history was not reported; She takes other unspecified medications, though declined to provide details. The patient previously took BNT162B2 (Lot EM9809) on 04Feb2021 as first single dose for covid-19 immunization and hydrochlorothiazide and experienced anaphylactic reaction on an unspecified date (reported as years ago). The patient experienced the following medically significant events: irritation in throat on 27Feb2021 with outcome of recovered; swelling of tongue on 27Feb2021 with outcome of not recovered; unable to swallow solids on 27Feb2021 with outcome of not recovered; chills on an unspecified date with outcome of unknown. Details were as follows: the reporting nurse received both doses of the Covid-19 vaccine. She received the first dose on 04Feb2021. She received the second dose on 25Feb2021. 48 hours after the second dose she developed a really sore throat way down in the back of her throat. Her tongue also started swelling. She took diphenhydramine (ASSURED) 50mg. Her tongue was swollen the next day and she was unable to swallow solids. She went to a Covid clinic and was prescribed a diphenhydramine mouthwash. She was still unable to swallow. She has been taking diphenhydramine and Ibuprofen. It waxes and wanes. She had to take diphenhydramine to go to sleep. She thinks it is a reaction to the vaccine. She read about the ingredients and is not allergic to anything in the vaccine. She clarified that she did not have a sore throat. Her throat was irritated. It felt like pop rocks in the back of her throat. She saw a provider on 01Mar2021. She thinks her histamine level is too high. She also had chills last night, date unspecified. She had them once since 27Feb2021 and again last night. She was unable to confirm if they are ongoing or resolved. She had to turn up her electric blanket to 8. She was not shaking but just had chills. Years ago she had an anaphylactic reaction to hydrochlorothiazide. This felt similar to that. She was walking around fine and then started having swelling.

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							<p>She did not have difficulty breathing. She hoped it was not anaphylaxis. The diphenhydramine mouthwash was a compound of lidocaine, diphenhydramine and Maalox. The ratio was 1:1:1. The diphenhydramine 50 mg was a liquid children's allergy relief medication. Therapeutic measures were taken as a result of the events as aforementioned. Relatedness of drug to reaction for irritation in throat, swelling of tongue, unable to swallow solids and chills per primary source reporter of assessment was reported as related. The outcome of irritation in throat was recovered on 28Feb2021; the outcome of swelling of tongue and unable to swallow solids was not recovered; the outcome of chills was unknown.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of irritation in throat, swelling of tongue, unable to swallow solids due to temporal relationship and the known product safety profile. The clinical presentation is suggestive of a severe allergic reaction, involving the tongue and throat. There is limited information provided in this report. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>
1149300	3/31/2021	VA	23	F	3/24/2021	3/28/2021	<p>Patient presented for swelling of her lips with associated burning/pain 4 days after first dose of Pfizer Covid vaccination. No strong clinical correlation of symptom onset and vaccination, however unable to completely r/o as a cause. Patient also reported onset of abdominal pain, diarrhea, and nausea after lip swelling started. Treated for angioedema vs allergic dermatitis and monitored on outpatient basis. No signs of anaphylaxis or airway compromise. No other systemic rash or signs of allergic reaction noted.</p>

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1150875	3/31/2021	CA	27	F	3/4/2021	3/4/2021	anaphylaxis; throat tightness; shortness of breath; lip swelling; throat swelling; This is a spontaneous report from a contactable nurse. A 27-year-old female patient received the first dose of bnt162b2 (lot number EN6199) via intramuscular on 04Mar2021 at 13:45 PM at single dose in left arm for COVID-19 immunisation. The patient had no COVID prior vaccination. The patient's medical history included ADHD, obesity, anxiety, history anaphylaxis to peanuts and allergies: peanuts. The patient's concomitant medications included amphetamine aspartate, amphetamine sulfate, dexamphetamine saccharate, dexamphetamine sulfate (ADDERRAL), diphenhydramine hydrochloride (BENADRYL). "5 min after injection", the patient developed throat tightness, shortness of breath, lip and throat swelling consistent with anaphylaxis. Events onset date reported as 04Mar2021 at 13:45 PM. Events resulted in emergency room/department or urgent care. The patient received epinephrine as treatment. The outcome of events was unknown. It is unknown if COVID tested post vaccination.; Sender's Comments: Based on temporal association and known drug profile the reported anaphylaxis with throat tightness, shortness of breath, lip and throat swelling are assessed as due to bnt162b2. Case will be reassessed if additional information is received.

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1151384	3/31/2021	NC	55	F	2/19/2021	2/19/2021	hands got very swollen and rash and itchy beyond itch; hands got very swollen and rash and itchy beyond itch; Anaphylaxis; Double vision; Right eye is going cross eyed/Left eye is dropping; Right wrist pain increased dramatically after the vaccine; Throat starting to close/Throat started tightening; severe rash- latus stranding, purple dots, and hives from face all the way down to toes; severe rash- latus stranding, purple dots, and hives from face all the way down to toes; This is a spontaneous report from a contactable consumer (the patient). A 55-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 intramuscular, administered in arm left on 19Feb2021 10:00 (Batch/Lot Number: EN6201), at the age of 55 years, as single dose for covid-19 immunisation. Medical history included ongoing asthma diagnosed 3 years ago, ongoing gastroesophageal reflux disease diagnosed 4 years ago, ongoing hypertension diagnosed 4 years ago, ongoing food allergy: allergic to eggs, shellfish, dairy/lactose intolerant, ongoing allergies to environmental: standard- hay fever, dust, mold, ongoing allergies to dogs and cats, contrast media reaction (IV contrast CT scan dye- respiratory distress, throat tightens), urticaria, pruritus. She had Covid on 18Dec2020 and "Covid rash it attached her muscular system. She had muscular pain in the wrist and hip on the right side and mild double vision." The patient previously took vitamin k 2 and experienced anaphylactic reaction, Toradol and experienced urticaria, influenza vaccine and experienced rash at the injection site, at the age of 34 years (because she's allergic to eggs). The patient received the first dose of bnt162b2 on 29Jan2021 Lot: EL3247; 9:30 AM; Right arm for covid-19 immunisation and she did not have any symptoms whatsoever with the first shot. The patient did not receive any recent vaccines for any other conditions prior to the event being reported. Vaccination Facility Type: Hospital. Concomitant medications included omeprazole taken for gastroesophageal reflux disease; lisinopril taken for hypertension; montelukast sodium (SINGULAIR) taken for asthma; salbutamol sulfate (INHALERIN) taken for asthma; start and stop date were not reported for all. The patient experienced anaphylaxis on 26Feb2021 with outcome of unknown, throat starting to close/throat started tightening on 19Feb2021 with outcome of

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recovered, severe rash- latus stranding, purple dots, and hives from face all the way down to toes on 19Feb2021 with outcome of not recovered, double vision on 20Feb2021 with outcome of not recovered, right eye is going cross eyed/left eye is dropping on 20Feb2021 with outcome of not recovered, right wrist pain increased dramatically after the vaccine on 20Feb2021 with outcome of not recovered, hands got very swollen and rash and itchy beyond itch on an unspecified date with outcome of unknown for Hand swelling and recovered for Localised itching. Therapeutic measures were taken as a result of the events: Benadryl, Zyrtec, Pepcid, New glasses for double vision, Prednisone 7 day ween. The patient underwent lab tests which included Hematology test on unknown date with unknown results; Immune markers on 11Mar2021 with unknown results. Clinical course: The patient received the vaccine on 19Feb2021at 10:00 AM and five minutes after, her throat started tightening and they put her in observation for another hour and then her throat felt fine and they let her go. Caller confirmed she was not referring to this occurrence as anaphylaxis. The anaphylactic reaction occurred days later. She mentioned from 19Feb2021- 26Feb2021, her symptoms were progressing and then on 26Feb2021, it was full blown out; the actual anaphylaxis was 26Feb2021. Between this, she had severe double vision, severe rash from face all the way down to toes, one eye going cross eyed (right eye), left eye is still drooping. On 20Feb2021, she started having double vision that started with the sunlight and fluorescent lights and the next day she couldn't see anything without double vision, and her eye started going cross eyed. She still cannot see normally now. She is under eye doctor care for that too. The patient was treated with Epi-Pen into leg and then into the Emergency Room. She received 50 mgs of Benadryl and 125 mg of Solu-Medrol IM injection, but still have to give Epi because her throat was still closing. Her airway was intact and no nebulizer treatment needed. The patient reported also that her hands got very swollen and rash and itchy beyond itch. The patient reported that her weight at that point was 204, the she had been on Prednisone for a week, and her weight has gone up to 210 now. After her throat closed on the 26Feb2021, caller reports she gained 7 pounds while on it for one week. Caller stated she was

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also put on prednisone when she got diagnosed with asthma, reactive airway. She confirmed her throat stop closing immediately after the Epi. The patient was also treated with 25 mgs of Benadryl, Zyrtec, and Pepcid a day. Outcome for throat closing was improved with medication. Outcome for rash was not improved and she is taking medicine to counteract it; itch went away when she took the Zyrtec. Regarding right wrist pain, it increased dramatically after the vaccine. Caller reports it felt like a spiral fracture down the ulna and it started to ache on 20Feb2021, by the next day it hurt a 5 out of 10. By 22Feb2021, she was wearing a splint, it was 8 out of 10, and she felt like she fractured it and it was swollen on the ulnar side. Regarding eye disorder, she is now under the care of an eye doctor for her severe double vision, eye crossing, and eye drooping. The blurred eyes give bad balance and that kind of stuff. The cross eyedness gives her poor peripheral vision and also her depth perception has now been compromised. They say the glasses will fix it. As of 22Feb2021, a new pair of special lenses with prisms were ordered for her. The patient was not hospitalized.

1150898 3/31/2021 TX

70 F

1/16/2021

1/22/2021

Delusions; wandering (attempting to leave the home with no purpose); This is a spontaneous report from a contactable consumer. A 70-year-old female patient (not pregnant) received the first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EL3249), via an unspecified route of administration in left arm on 16Jan2021 at 11:30 AM (at the age of 70-years-old) at single dose for covid-19 immunisation. The patient had a history of Early-onset Alzheimer's, high blood pressure and allergy to fire ants (Allergy to insect sting resulted in anaphylaxis). Relevant concomitant medications included memantine hydrochloride (NAMENDA), amlodipine, clopidogrel and atorvastatin. On 22Jan2021 the patient experienced delusions. Believing that people are trying to get into home. Belief that people on TV are in her home and speaking with her. Frequency and severity have increased since second dose. Also wandering (attempting to leave the home with no purpose), patient has dementia. Clinical outcome of the events was not recovered.

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1148544	3/30/2021	AZ	24	M	3/28/2021	3/29/2021	got up about 5:15AM to use the restroom, parents heard a huge crash and we came running - he had collapsed and fainted in the bathroom, against the toilet, (with shelves and glass crashing down him - he grabbed the shelves and had a few cuts and bruises), was unresponsive, no color in his face, could not stand or move, could barely speak - slumped against the toilet. Parents called 911 and tried to get him to respond, he was listless but opened his eyes - we lifted him and moved him to recliner in living room. Fire Dept./EMT's arrived within a few minutes, blood pressure was 87/43, glucose was normal. EMT's determined it was a reaction to the vaccine and asked if he wanted an ambulance or if parents should drive him for further care - he opted for us to drive him (his Mom called the Dr. on staff first - Dr. said it was a reaction to the vaccine and he should not get a 2nd dose). Patient's Dad took him to Urgent Care - they ran an EKG (normal), and stayed there until his blood pressure showed (although still low) normal/acceptable again. I looked at the CDC website for covid anaphylaxis and it appears it was an allergic reaction (cardiovascular), on the site, he had these symptoms: "Cardiovascular: fainting; hypotension (abnormally low blood pressure); pallor. ... Symptoms of anaphylaxis often occur within 15-30 minutes of vaccination, though it can sometimes take several hours for symptoms to appear.~~
1147639	3/30/2021		54	F	1/8/2021	1/8/2021	Reaction: Anaphylaxis Severity: High ED Note: 54-year-old female presents throat swelling, cough after receiving a vaccine. On exam patient appears distressed with persistent dry cough. Patient's posterior oropharynx is mildly erythematous. No wheezing or stridor. Given patient's persistent coughing and subjective throat swelling will treat with IM epinephrine, Benadryl, Pepcid, prednisone. Will observe in the emergency department. On reevaluation symptoms improved patient still complaining of throat tightness. Will treat with albuterol nebs. Reassess. Symptoms resolved on reevaluation. Patient observed for 2 hours emergency department with no rebound of symptoms. Patient stable for discharge. Will write for EpiPen. Return precautions discussed.

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1147590	3/30/2021	MA	48	M	3/27/2021	3/28/2021	Vomiting. 24hrs Diarrhea 30 hrs Headache Muscle Ache Chills Hives (severe) Nausea Stomach pain Anaphylaxis
1147424	3/30/2021	RI	32	F	3/22/2021	3/29/2021	Exactly one week after first dose my arm started to itch, a huge lump quickly formed, the morning after it formed it became hot to the touch. Day 2- still hot to the touch, hard lump on injection site arm. History of a anaphylaxis to Zithromax has me worried about second dose or any long term effects.
1147330	3/30/2021	NY	48	M	3/23/2021	3/23/2021	Anaphylaxis - Benadryl, Epinephrine, Prednisone
1147846	3/30/2021	MN	64	M	3/26/2021	3/26/2021	Patient reports itchy rash all over upper torso that started about 6 hours after receiving vaccine. Patient denies swelling, difficulty breathing, or signs/symptoms of anaphylaxis. Patient took an antihistamine (does not remember which one, but not Benadryl), and the condition began to improve, yet not fully resolved as of 4 days after vaccination. Patient was instructed to inform primary care physician of reaction and to sign up for the V-Safe program to report the reaction to the CDC as well.
1148312	3/30/2021	NC	60	F	3/12/2021	3/13/2021	She developed dyspnea while out of state the day after vaccine administration. She went to the ER, was observed, not felt to have anaphylaxis, administered oxygen, then released. She was told to get her second vaccine.

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1147314	3/30/2021		51	F	3/29/2021	3/29/2021	Angioedema, shortness of breath Patient administered 50mg IM Benadryl and 0.3mg Epinephrine IM on site. Ambulance transported stable patient to ED for further evaluation ED Note: 51 y.o. female with past medical history of DM, GERD, TIA, HTN, migraine, PUD, angioedema, and anaphylaxis to multiple agents who presents with complaints of tongue and throat swelling following first Moderna vaccine. Patient already received epinephrine and Benadryl at clinic, is having improvement in her symptoms with only slight voice change now, no residual shortness of breath or visualizable swelling. Patient states she is feeling better. Patient was provided with Pepcid and corticosteroids, was observed in the department for greater than 4 hours. Patient had full resolution of her voice change. Recommended that she follow-up with her primary care doctor, likely should not receive a second Covid shot but she discussed this with them. Did discharge her on Medrol Dosepak. Also recommended to the patient that she carry her EpiPen's at all times.
1148902	3/30/2021	CO	39	F	3/30/2021	3/30/2021	After administration, pt presented with itchy/ numb tongue . Patient took benadryl first , after 40 minutes, patient complained of trouble swallowing. At this time, an ambulance was called to evaluate the patient for anaphylaxis. She was fine after an hour and EMT sent patient home.
1149007	3/30/2021	MN	61	M	3/30/2021	3/30/2021	Anaphylaxis
1149076	3/30/2021	VA	31	F	3/30/2021	3/30/2021	Client reported hx of anaphylaxis to flu vaccine. Vaccine administered with client in supine position on a cot. EMS present. Approx 3-5 minutes post 1st dose Pfizer vaccine client reported feeling pressure in her chest, tiredness, vertigo, itching in her throat. vitals WNL. Client reported symptoms worsening. EMS present entire time. On-site medic called. Decision to call for Medic, Benadryl given by EMS team 50mg, PO, at 12:00. Decision to transfer client to ED.
1149254	3/30/2021		57	F	3/29/2021	3/29/2021	Patient complained of itching, said previous anaphylaxis started with a deep itch. Vitals stable and no shortness of breath. Patient had pre medicated with prednisone and Benadryl. As itching continued urgent care MD ordered epinephrine to be administered

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1147166	3/30/2021	OK	43	F	3/26/2021	3/26/2021	Client received Pfizer for first dose on 3/4/21 and Moderna for second dose on 3/26/21. Client was monitored for 30 minutes with no initial reactions. Client was given Departments number if she experienced any reactions and told to call 911 for any s/s of anaphylaxis.
1147004	3/30/2021		40	F	3/24/2021	3/26/2021	Two days after vaccination patient developed new onset itchy, raised rash over the left arm, chest, face and neck. Clinical signs consistent with eczema/contact dermatitis/atopic dermatitis, but patient does not have a history of these disorders. No shortness of breath, diarrhea, fever, vomiting or other signs of anaphylaxis.
1146291	3/30/2021	CA	33	M	3/29/2021	3/29/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: SEVERE DROP IN BP TO 90/52 AND EXCESSIVE SWEATING - TSHIRT SOAKED WITHIN A FEW MINUTES INTENSE THIRST-Severe, Systemic: Flushed / Sweating-Severe, Systemic: Hypotension-Severe, Systemic: Shakiness-Mild, Additional Details: PATIENT HAD IMMEDIATE DROP IN BP , EXCESSIVE SWEATING, EXCESSIVE THIRST AND SLIGHT SHAKING.
1148009	3/30/2021	CA	48	F	3/12/2021	3/12/2021	Pt presented to health center for Covid-19 vaccine #1. During check-in, verbalized an allergy to PCN-anaphylaxis reaction and current back pain. Due to prior allergy, determined we will watch her for 30 min post injection. Injection given without incidence and patient brought to recovery area. Approximately 5 mins later, RN came and asked for assistance. States patient was exhibiting stridor breathing. Epi-Pen injected at 9:04am to left thigh, BP=173/109 by electronic BP machine. 9:06am- O2 at 10L paced via non-rebreather mask and 911 called. 9:08am BP=166/83. P=120. Pt remained alert and oriented. Reclined to approximately 45 degree angle due to complaints of back pain. 9:09am IV line started in L antecubital, normal saline wide open. 9:11am PB=171/97. 9:16am BP=105/79 P=119. rescue arrived. Pt ambulated with minimal assistance to gurney for hospital transfer for evaluation.

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1147830	3/30/2021	CA	31	M	3/30/2021	3/30/2021	At approximately 1238 patient was noted to be on floor, experienced fall from chair. 911 called. came to patient. Pt placed in recumbent position. noted to be having seizure regained consciousness. Airway not obstructed no s/s if respiratory distress noted. Regain consciousness after 2 seconds. Vs bp130/82, O298% on RA, HR 72, RR 28. Denies pain or discomfort. Pt alert and oriented able to state his name date location. Mae x34 I neurologically intact. did not give Epi . No s/s of anaphylaxis noted. please patient and become a position. Ambulance and fire department on site at this time.
1144834	3/29/2021	NJ	65	F	3/26/2021	3/29/2021	RASH ON RIGHT ARM, AROUND SITE AREA. NO ANAPHYLAXIS OR HIVES. PATIENT CONTACTED MD AND BENADRYL WAS NOT NECESSARY AT THIS POINT

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1145302	3/29/2021	CT	51	F	3/10/2021	3/10/2021	After administration of COVID-19 vaccine patient complained of chest tightness 2/10 radiating to left arm. Complaining of tongue swelling, nothing observed and airway visibly clear at this time, no rash/urticaria. SBP has increased to >140s, note that she held her beta blocker and has recently diagnosed hypertension. Lungs CTA b/l. We discussed that without decreased blood pressure and wheezing at this time and given her chest pressure we will hold off on epinephrine for now as this is not consistent with suspected anaphylactic reaction but given her hypertension history and chest tightness patient been sent to urgent care at this time. We are giving cetirizine 10 mg and discussed that if objective signs of anaphylaxis clearly epinephrine will be given but with current signs/symptoms further observation where EKG may be done is warranted .Pt in NAD. Appears well, Nontoxic. No respiratory distress at rest, with conversation, or on ambulation. Alert and Oriented times three. Mental Status clear and coherent. Normal conversation. Mucous Membranes moist THROAT: No perioral or oral edema noted. Tolerating all secretions. Voice clear NECK: supple, no lymphadenopathy LUNGS: CTA. Good air movement COR: RRR without murmur No axillary adenopathy No chest wall tenderness to palpation. Procedures/ EKG EKG: NSR . No ischemic changes. NSTWAs Compared with EKG 12/7/20: No significant change. Slight difference in T wave morphology isolated to V1 (nonspecific)
1143715	3/29/2021	MD	45	F	3/29/2021	3/29/2021	Anaphylaxis type reaction with chest tightness and throat fullness. Pt had reaction first dose with Benadryl IM used with a lot of anxiety . Second dose very anxious gave Epi x 2 and Benadryl with pt going out via 911. Pt was awake and talking BP 175/106, P81 O2sat 98%

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1143814	3/29/2021	CA	71	F	3/12/2021	3/1/2021	Anaphylaxis; Respiratory distress; Sensation of throat closure; trouble breathing; Upper airway swelling; Tachycardia; Her tongue started symptomatic; sweating; Generalized erythema; general feeling of unwellness; energy is still very low; Generalized prickle sensation; Nausea; This is a spontaneous report from a contactable consumer (Patient) via telephone. A 71-year-old female patient (non-pregnant) received second dose BNT162B2 (Pfizer, Formulation: Solution for injection, Lot Number: EN9808) administered in Left Arm via an unspecified route of administration on 12Mar2021 at 13:30 at a single dose for COVID-19 immunization. Medical history included Cancer survivor, High BP, Allergies: Shell fish, Allergies: Latex, Allergies: Iodine, urticaria and insect bite/sting allergy, GI sensitivity to all antibiotic, Allergy: surgical scrubs, intestinal reaction to Pneumonia In 2017, (patient had intestinal reaction to Pneumonia Vaccine by (Name) for which she was administered antihistamine, IV Benadryl and Oral Benadryl). On 19Feb2021, patient took historical vaccine BNT162B2 (COVID 19, brand=Pfizer, Lot Number: EN6201) as 1st dose at 12:30 PM on left arm for Covid-19 Immunization and not received any vaccines for SARS-CoV2 other than Pfizer-BioNTech COVID-19 Vaccine prior to the event being reported. Patient did not receive any recent vaccines for any other conditions prior to the event being reported. Concomitant medication included hydrochlorothiazide taken for BP medication. The patient was not received any vaccine in four weeks. On 12Mar2021, patient experienced anaphylaxis 5 minutes after the vaccine 2nd dose which resulted to visit emergency room and was treated with EPI, Benadryl, Zophylin, DEX and Pepcid. Started with general feeling of unwellness. Her tongue started symptomatic, sweating, trouble breathing, they took BP they injected 1st dose of Epipen which had no improvement, however after 5 minutes given the 2nd dose and body reacted to Epinephrine. Then given Benadryl injection and transported to a different hospital. Corticosteriod DEX was administered. Patient was under ER observation for 5-6 Hours. On an unknown date in Mar2021, patient also experienced upper airway swelling, respiratory distress, difficulty breathing (without wheeze or stridor), energy was still very low, general feeling of unwellness, sensation of throat closure, her tongue started symptomatic, sweating, trouble breathing,

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							tachycardia, generalized erythema, generalized prickle sensation and nausea. Therapeutic measures were taken as a result of anaphylaxis, respiratory distress, general feeling of unwellness, her tongue started symptomatic, sweating, trouble breathing. The outcome of all the events reported as recovering.
1143823	3/29/2021	NY	57	M	3/29/2021	3/29/2021	Patient had Moderna Vaccine Dose #1. He started to feel light headed. He fell from chair to floor. He was unconscious when first found approx 950 am. Nurse administered Chest compressions. Patient regained consciousness. EMS was called 9:52 am by clinical staff. At same time vitals were stable 129/62, oxygen sat at 95%, pulse 77. No supplemental oxygen or medications were administered. Vitals at 10:02am 130/74 pulse 78 oxygen sat 95%. Vitals at 10:07 were 113/76 oxygen sat 98% pulse 79. EMS was on scene at 10:08am. Patient stated he has a history of vasovagal syncope. He denies any current medications, medical history, or allergies. He refused EMS services to be transported to hospital stating he was "fine" and he "usually has these reactions". He denied any difficulty breathing, shortness or breath, chest pain, palpitations, or any symptoms pertaining to an anaphylaxis reaction.
1144123	3/29/2021	MI	42	F	3/19/2021	3/19/2021	Numbness on left side of face, cheek, chin, ear, behind ear, upper neck. Tingly lips, slight difficulty swallowing. Was NOT in anaphylaxis.
1143560	3/29/2021	MI	54	F	3/26/2021	3/26/2021	Acute anaphylaxis - throat closing. Given Benadryl.
1144754	3/29/2021	WI	64	M	3/25/2021	3/25/2021	Anaphylaxis, dizziness, flush, itching, nausea, headache, heart racing, difficulty breathing. Gave me EpiPen. Was in ER for 4 hours after. Took antihistamine every 6 hours for 3 days.

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1143281	3/29/2021	ME	65	F	3/29/2021	3/29/2021	30 min post vaccine, patient developed slight dry cough and feeling of tightness in back of throat. Noted hoarseness of her voice. Brought to medical area where she then noted flushing, warmth of skin on face, neck, upper arms and chest. Slight nausea. On exam, no abnormalities except flushed skin. Vitals remained normal and stable. Monitored vital signs, had epi pen ready and elected to send her to ED via EMS for further monitoring, esp given her long hx of anaphylaxis. No other tx provided at site.
1145022	3/29/2021	WI	43	F	3/19/2021	3/19/2021	43 year old female with a past medical history significant for asthma, anxiety, DM, migraines, thyroid papillary carcinoma who is presenting to the ED with an allergic reaction. She received her COVID vaccination at 1700. At approximately 1715 she felt a lump in her throat. Shortly after she felt as if her tongue/lips were tingling/becoming swollen and then she developed nausea. No rash or abdominal pain. No dyspnea or chest pain. All symptoms are consistent with prior episodes of anaphylaxis. She has had anaphylaxis to vaccinations in the past but was advised by her allergist to get the COVID vaccine today. On arrival patient is quite anxious. Vital signs are stable. Her tongue is enlarged/mildly edematous, additionally appreciated mild lip/perioral swelling. There is no stridor or wheezing, no evidence of respiratory distress. Given examination findings, symptom description, findings concerning for anaphylaxis. As such, epinephrine promptly administered as well as solumedrol, famotidine, and benadryl. Shortly after the epinephrine she endorsed improvement in her swelling, though during benadryl administration she endorsed a sudden onset of subjective throat swelling/felt as if she could not breathe. Patient was reassessed, no change in initial examination findings, within a few minutes she felt her symptoms improve without intervention. A short while later she again felt as if her throat swelling was worsening, as such epinephrine dose re administered. Following a 2.5 hour period of observation she endorsed continued improvement in her allergic symptoms, requested discharge home though continued observation offered. A course of prednisone prescribed, patient already with epi pen. Patient discharged home.

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1145080	3/29/2021	MD	26	M	2/13/2021	2/13/2021	5 minutes after getting shot, started to feel same effects of Tree nut allergy anaphylaxis. Did not need an EpiPen, but still had trouble breathing for the day.
1145214	3/29/2021	SC	45	F	3/29/2021	3/29/2021	patient developed severe pruritis almost immediately after vaccination then came to our clinic. no hives, no signs of symptoms of anaphylaxis. controlled with high doses of antihistamines.
1146084	3/29/2021	OR	51	F	3/28/2021	3/28/2021	I had the first dose of the Pfizer vaccine last night (6 p.m.). Within 15 minutes my left hand and left arm started to itch. I saw the medical folks on location but since there were no hives or anaphylaxis, I was told "it must be eczema" (which I do not have. The itching continued to get worse and spread to under my eyelids, inside my ears, and "under" the surface of my skin - mostly on my face, skull, neck, behind my knees. I called the advice nurse at 7:30 but there was still no hives, visible rash, or breathing issues. I started taking 10 ml of Benadryl every four hours but the itching was awful and the Benadryl only "took the edge off" and the itching persists enough I could not sleep last night (3/28). There is still no visible rash or breathing issues but the itch is awful. I reached out to my primary care Dr and I was instructed to take Zyrtec in addition to the Benadryl. It helps but makes it slightly tolerable, it does not stop the itching. As of right now (7:36 p.m. the day after the shot), I am still experiencing itch...but it is less than it was this time last night (however, I am taking both Zyrtec and Benadryl).
1145960	3/29/2021	WA	30	M	3/29/2021	3/29/2021	Experienced anaphylaxis. Similar to what I experience for peanuts. Symptoms: Difficulty swallowing, indigestion, high pulse

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1145381	3/29/2021	MI	45	F	3/26/2021	3/26/2021	<p>HPI: Patient is a 45-year-old female who presents for evaluation after COVID-19 vaccine reaction. Patient just received 1st vaccine this morning. She was being observed in the vaccine clinic when she started to experience numbness all over her body and hives over the upper chest. She was brought immediately to the emergency department for treatment. Upon assessment, she is lying flat in the bed. States she feels weird. No difficulty swallowing, no difficulty breathing. She is not itching. She has no known allergies. MEDICAL DECISION MAKING Upon arrival to the emergency department patient was immediately assessed at the bedside. She was lying in the bed, eyes closed, appeared somnolent with answering questions. She did have urticaria on the upper chest. She was also tachycardic. IV was established, she was treated with intramuscular epinephrine, IV Benadryl, famotidine, and Solu-Medrol. Patient was observed in our emergency department for 3 hours and had complete resolution in her symptoms. She was reassessed on multiple occasions during her emergency department stay and continued to show signs of improvement. I do feel that she is safe for discharge home. Recommend not getting COVID-19 vaccine in the future given her allergic reaction today. Patient is in agreement with this plan, she was discharged home in improved condition. Medications EPINEPHrine anaphylaxis kit 0.3 mg (0.3 mg Intramuscular Given 3/26/21 0814) methylPREDNISolone sodium succinate (SOLU-Medrol) injection 125 mg (125 mg Intravenous Given 3/26/21 0818) famotidine (PEPCID) injection 20 mg (20 mg Intravenous Given 3/26/21 0818) diphenhydrAMINE (BENADRYL) injection 50 mg (50 mg Intravenous Given 3/26/21 0816) sodium chloride 0.9% bolus injection 1,000 mL (0 mL Intravenous Stopped 3/26/21 0948) broke out in hives, heart started racing, went to ED where they treated her. Patient got home a couple hours ago and back of neck is breaking out again and says throat feels funny.</p>

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1145339	3/29/2021	NC	58	F	3/18/2021	3/18/2021	Pt. informed nurse of anaphylaxis to flu vaccine approximately ten years ago. Her personal MD, advised her to have COVID-19 vaccine and to have Benadryl and EPI-Pen in purse. Pt. monitored for 30 minutes instead of usual 15 minutes. Twenty-five minutes post-vaccination, pt. developed rash on wrists and shortness of breath. Five minutes later O2 Sat. 97% on RA and rash spread up arms and around lips. Reported feeling clammy. Pt. took 25 mg of personal Benadryl by mouth and declined further Benadryl as it would "make me too sleepy to drive". Six minutes later O2 Sat. 85% on RA and rash on trunk, lips and face. EMS was dispatched, and pt. transferred to ER via EMS.
1144731	3/29/2021	PA	56	F	3/28/2021	3/28/2021	Immediately after injection (within 5 minutes) I was shaky and short of breath. I recovered within few minutes. Minor Anaphylaxis?
1142761	3/29/2021	MN	45	M	3/28/2021	3/28/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Medium, Systemic: Fainting / Unresponsive-Medium
1143623	3/29/2021	MN	54	M	3/24/2021	4/17/2021	15 minutes after receiving vaccine, patient report left ear turning red. Patient waited in the clinic an additional 30 minutes. Left ear was red and patient report left arm and neck felt warm. Patient was seen by a provider who recommended she take an oral Benadryl and report to the ER if any other anaphylaxis reactions.
1142017	3/28/2021	NC	52	F	3/26/2021	3/26/2021	Right arm swelling, pain Patient also reports intermittent tongue tingling and scratchy throat, no sign of anaphylaxis on exam, neuro exam is normal. This exam occurred 2 days after her vaccine
1141898	3/28/2021	MA	72	M	3/11/2021	3/11/2021	4-5 hours after vaccination he developed swelling in the back of his throat and a sensation of his throat closing. He had a change in character of his voice with hoarseness. He developed chest tightness and difficulty swallowing saliva. His uvula was edematous. He had severe throat discomfort. He was evaluated and hospitalized and required treatment for anaphylaxis with epinephrine, famotidine , IV methylprednisolone and diphenhydramine.

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1141870	3/28/2021	MS	25	F	3/10/2021	3/10/2021	C/O Heaviness in her chest and difficulty breathing with tingling to her lips. B/P 108/68; Pulse 82. R 20. Recovered. States did not know what anaphylaxis meant but knew she was allergic to PNC & Benadryl. Advised to receive next dose at MD Office. Recovered.
1141049	3/28/2021	CA	43	F	2/27/2021	2/27/2021	Patient described slight warmth on her chest after vaccination. She said the sensation was similar to many months ago when she received her lidocaine/hydrocortisone shot. After 30 minute of observation, patient says feeling has dissipated. No signs & symptoms of anaphylaxis. Counseled patient about calling 911. Mentioned all the symptoms to watch out for on Moderna's EUA. I spoke to patient a week later and she said the "warmth" dissipated in about 8 hours. She said she could smell & taste the vaccine. I encouraged her to see her PCP for evaluation. She has an appointment in 1 week. She will talk about whether to receive a 2nd dose.
1141130	3/28/2021	SC	22	F	3/27/2021	3/27/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Medium, Systemic: Allergic: Itch (specify: facial area, extremities)-Medium
1141033	3/28/2021	CA	33	F	3/12/2021	3/12/2021	Patient report that she was a bit "dizzy" and loopy. I told her that her symptoms were a bit worrisome. She presented with no other signs & symptoms of anaphylaxis. I told her if any symptoms (written on the EUA were present) she needed to go to ER ASAP. She said her dad was driving her home, and she would be family all night. I spoke to her again and she said she's feeling better. She was lightheaded & had a headache for 3 days.
1141139	3/28/2021	CA	33	F	3/26/2021	3/26/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Fainting / Unresponsive-Medium, Additional Details: Pt fainted 2-3 minutes after getting vaccinated with the first dose of moderna covid vaccine. She recovered immediately but had her front teeth bent from falling forward. Pt was talking as usual after regaining consciousness and her bp was within normal range.

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1141039	3/28/2021	CA	88	F	2/23/2021	2/23/2021	Patient said she was "tired, [nauseous], and couldn't eat for 3 days" after 1st dose. Then, a week later she had "chicken bites" on her arms and legs. All of the symptoms have been resolved. No sign & symptoms of anaphylaxis after 2nd dose.
1140307	3/27/2021	WA	61	M	3/26/2021	3/26/2021	Immunization was administered at 1pm, and patient started to go into anaphylaxis at 10:00pm. He swelled up, and had trouble breathing. He received epinephrine, steroids and breathing treatments in the ER.
1139281	3/27/2021	FL	59	F	3/26/2021	3/26/2021	Site: Bruising at Injection Site-Mild, Systemic: Allergic: Anaphylaxis-Mild, Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Medium, Systemic: Allergic: Itch (specify: facial area, extremities)-Medium, Systemic: Allergic: Rash (specify: facial area, extremities)-Mild, Systemic: Allergic: Rash Generalized-Mild, Systemic: Allergic: Swelling of Face / Eyes / Mouth / Tongue-Medium, Systemic: Body Aches Generalized-Mild, Systemic: Chest Tightness / Heaviness / Pain-Mild, Systemic: Confusion-Mild, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Mild, Systemic: Headache-Mild, Systemic: Hypertension-Medium, Systemic: Nausea-Medium, Systemic: Shakiness-Medium, Systemic: Visual Changes/Disturbances-Severe, Systemic: Weakness-Medium, Additional Details: Eye ball rotating
1139313	3/27/2021	CA	22	F	3/26/2021	3/26/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Systemic: Allergic: Itch Generalized-Severe, Systemic: Allergic: Rash Generalized-Severe, Systemic: Dizziness / Lightheadness-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Shakiness-Severe, Additional Details: Patient had her own Epipen with her since she has many allergies and just had anaphylactic reaction as recently as Monday. She began to feel itchy and had redness, rash after shot during the 30 minute observation period. Epipen was self-administered and emergency services called.

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1140050	3/27/2021	UT	82	M	2/3/2021	2/6/2021	Patient received his first dose of Pfizer COVID-19 vaccine on 02/03/2021. He has significant medical history, but presented to the hospital on afternoon of 02/08/2021 with report of three days of nausea and vomiting. He thought this attributed to a new cholesterol medication. He also reported some shortness of breath, mild cough, no fever. reported some epigastrium pain the day prior but since resolved. Significant other reported some significant swelling and that pt complained of feeling like he had a "blockage in his throat". Workup showed concerns of pneumonia so pt was started on antibiotics and Vitamin K. Shortly after meds started pt started complaining of itching arm and trouble breathing. He became bradycardic and lost consciousness. Resuscitative efforts initiated but unsuccessful. Time of death called on 02/08/2021 at 1737. Hospital notes report "cause of death is anaphylaxis", and pt would be an OME case.
1140451	3/27/2021	VA	55	F	3/27/2021	3/27/2021	POSSIBLE ANAPHYLAXIS, DIFFICULTY SWALLOWING, BREATHING, THEN SPEAKING. 911 CALLED. TRANSPORTED VIA EMS
1141017	3/27/2021	CA	54	F	2/22/2021	2/22/2021	After 2nd dose immunization by my tech, I asked patient if she had significant side effect after first dose. She said she had palpitations for an entire month. She was seen by her prescriber, Dr, and she was told to continue with her 2nd dose. She reports no heart palpitations or signs & symptoms of anaphylaxis after her 2nd dose.
1139417	3/27/2021	NY	31	M	3/25/2021	3/26/2021	Anaphylaxis and Angioedema
1136419	3/26/2021	NC	54	F	3/25/2021	3/25/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Medium, Systemic: Allergic: Itch (specify: facial area, extremities)-Medium, Systemic: Dizziness / Lightheadness-Medium

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1137813	3/26/2021	CA	21	M	3/26/2021	3/26/2021	pt experienced syncope post injection, reported that he could not hear or speak for a moment. Benadryl and Epipen were present, but pharmacist on site performed blood pressure reading, and did not believe it was anaphylaxis. Paramedics arrived and patient tried to refuse medical care, but paramedics convinced patient to go with them to the ambulance so that they can monitor blood pressure, heart, and blood glucose.
1138662	3/26/2021	MO	23	F	3/26/2021	3/26/2021	Itchy skin and mouth/throat, but no anaphylaxis, benadryl given
1138932	3/26/2021	CA	37	F	3/26/2021	3/26/2021	The Pt presents complaining of throat tightness, cough, and dysphagia 10 minutes following 2nd dose of Pfizer vaccine to left deltoid. Pt has a Hx of UC, endometriosis, and seasonal allergies for which she takes 1600mg BID Mesalamine, Vyfemla 0.425mg QD, and 180mg Allegra. Pt states that she took Allegra prior to her vaccine. She reports allergy to hydrocodone and confirms skin rash as the reaction to that medication. Currently she denies any itching of the skin or swelling of the lips/face/eyes. She also denies dizziness, numbness, tingling, or nausea. Epinephrine dose prepped and ready should condition worsen or anaphylaxis develop. Upon observation and oral rehydration Pt's condition remained unchanged with persistent cough and throat tightness. EMS was called and care was transferred to fire and rescue. Pt was transferred to the hospital.

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1139132	3/26/2021	NY	36	F	3/24/2021	3/24/2021	Received the vaccine at 10:40am on 3/24/2021 and felt normal. At 1:20pm anaphylaxis set in - experienced tingling then tightness in throat, tongue swelled, swallowing would cause me to choke and tongue would get stuck blocking air passage. Hyperventilating began as I could not get enough air into my lungs. For 15 minutes tried drinking water and laying down to help open airways. Breathing slightly eased for 2-4 minutes and then the anaphylaxis would spike again. This happened 3x getting worse, I called my Primary Care Physician's office and was advised to go to the ER immediately. At 2:15pm I arrived at the ER and at 2:30pm I was given a 1mg shot of EPINEPHrine, and intravenous shots of diphenhydrAMINE, methylPREDNISolone, and famotidine along with oxygen. Anaphylaxis finally dissipated around 3:30pm and by 5pm I was breathing more normally. I was discharged at 7:00pm, and was feeling very energized. I was also given a prescription for an epipen incase I should have any further issues. The next morning, 3/25/2021 I woke up after 5 hours of sleep feeling extremely energized. I had a virtual doctor's appointment with my allergist, Dr. at 12:00pm. My doctor was surprised at how well I seemed to be doing and we made arrangements to do further allergy tests in 2 weeks. We came to the conclusion that I am most likely allergic to POLYETHYLENE GLYCOL. This ingredient is also in a cold medicine that I was taking in January and I was experiencing minor anaphylaxis (which I thought was due to the extreme congestion I was experiencing with the cold). It is also an ingredient (aka PEG) in an eye cream that caused a severe eczema patch under my eye in January. After my appt, at 1:30pm I went into anaphylaxis again. My throat got tingley and began to close, my tongue swelled and again was getting stuck in my throat when I attempted to swallow. I laid down and tried to get in deep breaths. My husband bought children's BENADRYL, which does not have polyethylene glycol in it, and gave me 15ml at 2:15pm. I reached out to my allergist, Dr. and updated him. He advised that I immediately take an additional 5ml of the BENADRYL. Dr. prescribed me 60mg/day Prednisone for 2 days followed by 40mg/day of Prednisone for 4 days, 40mg/day Famotidine for 2 weeks, 10mg/day antihistamine (I chose loratadine) for 2 weeks. Dr. also shared that I should have been prescribed steroids when

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							I was discharged from the hospital, but my energetic state gave the impression I was OK. My manic energy was a result of the epinephrine, which had finally worn off 23 hours later, causing my body to begin the allergic reaction all over again. The evening of 3/25/2021 (after the first dose of 60mg prednisone, 40mg famotidine, and 10mg loratadine) and all three meals on 3/26/2021 I experienced minor anaphylaxis when I began to eat. Tightness in throat throughout the meal and lasting an additional 20 minutes following the meal. My throat has reopened after each incident on 3/26/2021 and I was able to breathe normally again.
1138513	3/26/2021	WI	73	F	3/26/2021	3/26/2021	With both COVID vaccines pt experienced raspy voice, hoarseness, funny feeling in bronchial tubes. Pt denies SOB, CP or anaphylaxis. Her symptoms started approximately 1 hour after admin and resolved within 3 hours of onset.
1138503	3/26/2021	CA	67	F	3/15/2021	3/15/2021	Client complained of pain on the left side of her head. She stated began having a headache five mins after receiving vaccine. Assessment revealed no hives, no rashes, and no difficulty breathing, no chest pain or other signs of anaphylaxis. Client reported a 7/10 pain on the left temporal region. She denied pain or swelling upon palpation. She denied any allergies and has a history of hypertension with prescribed meds. Client declined any other pain throughout her body. She was given water, and vitals were taken at 5mins intervals. She was observed for an additional 30mins. After 20 mins she reported that she "much better" and her headache was gone. She decided to leave 10mins before her 30mins of observation were completed. She was in no apparent distress when leaving. She was given ER precautions. Pfizer fact sheet was provided.

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1138017	3/26/2021	WI	20	M	3/22/2021	3/22/2021	ED COURSE & MEDICAL DECISION MAKING Patient is a 20 y.o. male who presents emergency department for evaluation of fevers, chills, nausea, and shortness of breath. Symptoms occurred approximately 3 to 4 hours after his Covid vaccination today. He has not felt symptomatic for symptoms related to COVID-19 prior to his vaccination. Nausea was noted without vomiting and he was given Zofran prior to arrival. No objective evidence of anaphylaxis or angioedema was noted at urgent care nor was this noted on physical examination. He does have a fever on arrival with Tylenol taken a little more than an hour prior to arrival. Chest x-ray negative for findings of COVID-19. There was no evidence of pneumonia. His blood counts were otherwise reasonable though he did have relative lymphopenia that can be described in COVID-19 infection. Metabolic profile was otherwise benign. Differential diagnosis of his fever include the possibility of a vaccine reaction though the timing is rather quick for this reaction. Certainly this remains in his differential. His he has history of asthma and felt short of breath he was given Solu-Medrol. He was given Toradol with improvement of symptoms as well as IV fluid. With differential diagnostic considerations that he may have Covid, he was swabbed and tested at bedside. With his well appearance he was ambulatory in the emergency department. He was discharged stable condition with recommendations for Tylenol and ibuprofen in the short-term. Procedures MDM CHIEF COMPLAINT Fever and Chills HPI The history is provided by the patient, medical records and the EMS personnel. Patient is a 20 y.o. male who presents emergency department with fevers, nausea, and shortness of breath. He has generally not felt well over the course of the last 8 hours after receiving his first Covid vaccination this morning at 9 AM. Fevers have been noted. He took Tylenol with 2 tablets an hour prior to arrival. He has had shortness of breath with a history of asthma. He denies productive cough, or chest pain. He denies abdominal pain, or diarrhea. He denies dysuria or frequency or hematuria. Seasonal allergies are noted without significant medication allergies. He denies a sensation of throat closing. He denies tongue or lip swelling. He was seen in urgent care and sent to the emergency department for further evaluation.

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1138002	3/26/2021		33	M	3/22/2021	3/23/2021	Patient received the J&J COVID vaccine around 10:00 a.m. In the evening began experiencing subjective fevers, chills, nausea, headache. He took ibuprofen around 4:45 a.m. in the morning and went to work. Symptoms do not improve and patient presented to ED for evaluation. Patient denies chest pain, shortness of breath, vomiting, diarrhea, dysuria. No Hx anaphylaxis. Denies sensation of upper airway stridor or other respiratory symptoms. Past medical history is unremarkable. He is not on home medications. Denies smoking or illicit drug use. Patient was given 1 gm Tylenol, 10 mg metoclopramide, and 1 L NS. Patient improved, and was discharged
1137893	3/26/2021	WA	44	F	3/25/2021	3/25/2021	Anaphylaxis: Shortness of breath, chest tightness, itching, muscle spasm
1136537	3/26/2021	RI	74	F	3/23/2021	3/23/2021	Pt entered the monitoring area of the high-risk anaphylaxis clinic at noon for her 30 minutes of monitoring. At 12:30pm when her 30 minutes had passed and the patient was ready to leave, patient reported to RN that her tongue felt itchy and mild tingling. Evaluation of her tongue revealed no redness or swelling. Pt states she is allergic to dogs, latex, codeine, and Augmentin (severe reaction). She does have a dog at home and reacts to his dander for which she take a Benadryl nightly. Pt was given diphenhydramine 25mg PO x 1. VS = 78, 148/85, 98% O2 sat. Pt reported resolution of tongue symptoms at 12:56pm. VS 71, 159/65, 98% O2 sat. Pt discharged home in no apparent distress at 1:05pm.

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1137874	3/26/2021	CA	61	F	3/26/2021	3/26/2021	Pasting clinicians note below: Patient is 61 year old female with hx of anaphylaxis presenting for Covid-19 vaccine, Dose #1. She developed itching in there throat within 30 minute waiting period. She was taken to Rapid Response Room. Symptoms progressed from itchy throat, to congestion in throat/upper chest, clearing her throat, watery eyes. Then dry cough. No nausea, no vomiting, no light headed feeling. No facial swelling No hives. OBJECTIVE: Vitals - 154/97, 105, 100%RA Neck - Supraclavicular mild retractions, end inspiratory stridor CV: tachy, regular, no murmur pulm - diminished breathe sounds throughout, no wheezing. Speaking full sentences. Assessment/ Plan: Anaphylaxis to Covid-19 Vaccine: - emergency responders - epi 0.3 mg IM administered to L mid outer thigh at 9:35 am by me - epi 0.3 mg IM administered to R mid outer thigh at 9:41 am because symptoms not subsiding by me -benadryl 50 mg IM x 1 L deltoid by RN 9:45 am - Itching in throat subsided but still retracting and clearing throat so albuterol 3 puffs given at 9:50 am Vitals stable entire time (see midas report) EMS arrived to transport to local hospital.
1136952	3/26/2021	NH	70	M	3/24/2021	3/24/2021	On 3/24 by 9:25 PM I had mild shakes. At about 10:00 PM my lips stared to tingle and become numb. Subsequently I began to have difficulty swallowing as well as experiencing some sub sternal pain. Went to get my EpiPen and put it beside me in bed. Difficulty swallowing got a bit worse but as I was not experiencing shortness of breath I held off the Epinephrine injection. (What on earth was I thinking?!)The "semi anaphylaxis" was self limiting and by 11:00 PM symptoms had subsided completely. But by approximately 11:30 MP I had severe rigors lasting about 3 - 5 minutes. On 3/25 I developed a severe headache and a low grade T (T-max 99.9). Took Tylenol 825mg with good effect. The following night I had severe night sweats, drenching 3 sets of pajamas. Today, on 3/26 I have been experiencing several cold sweats and I am altogether feeling "strange" (can't put my finger on it - maybe dehydration?). Have vegan to aggressively hydrate. Notified my Primary Care Physician's office. Agreed to "ride it out" for now. Shall see my PPP on

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1137492	3/26/2021	ID	54	F	3/24/2021	3/24/2021	Anaphylaxis
1137488	3/26/2021		58	F	3/19/2021	3/19/2021	58 y/o F with history of drug allergy (anaphylaxis from penicillin, facial swelling/diarrhea from doxycycline), seasonal allergy, mild intermittent seasonal asthma developed facial angioedema, erythematous, non-pruritic macules on her face/chest, and a "tiny bit" of chest tightness 5 hours after Pfizer vaccine. Responded to benadryl. 24 hours later facial swelling returned. On 3rd day after vaccination, swelling had fully resolved. No history of dermal fillers. No history of miralax use. Has tolerated influenza vaccine. No recent other vaccines. Skin testing to miralax, methylprednisolone and triamcinolone was negative. I advised her to avoid second dose of Pfizer vaccine.
1137266	3/26/2021	MD	25	M	3/26/2021	3/26/2021	0927 vaccine dose 0947 reported diffuse itching and "felling like I do when I eat nuts" 0950 BP 120/74, HR 100, SpO2 99% (CTAB, no SOB, no rash or oral swelling) 0952 reported he felt his "throat closing" the same as prior episodes of anaphylaxis so epi 0.3mg given by me via auto injector IM right vastus lateralis and called 911 0954 BP 124/71, HR 84, RR 18, 99% RA 0956 50mg IM Benadryl right deltoid 1001 EMS arrived and patient transferred to ED
1137239	3/26/2021	MI	37	M	3/26/2021	3/26/2021	Received injection at approx. 10:30am. Waited at vaccination site for approx. 30 minutes with no reaction. At approx. 11:10am (40 minutes after injection) I started to feel tightness in my chest and developed moderate wheezing. I immediately took two puffs of my albuterol sulfate HFA inhaler. The wheezing stopped after I used the inhaler. I did not need to use my epi injector but it was definitely anaphylaxis based on prior experience. I did not report this to the vaccination site as I had already left. It is now 12:45pm and I feel fine.
1137233	3/26/2021	NY	43	M	3/13/2021	3/13/2021	Anaphylaxis at half hour after second shot , had allergic symptoms on following Thursday 3/18 and Thurs 3/25

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1138597	3/26/2021	IA	34	F	3/23/2021	3/23/2021	Pfizer COVID-19 Vaccine EUA Patient upon receiving vaccine 2 mins began feel nauseated and hot- provided ice pack wheelchair and got her to the provider where she was placed on gurney.vitals were taken please see chart. Epi pen was given when patient's lips started to turn red cough and stridor noted please see the notes. Ambulance was call and patient was taken to the hospital see chart. At approximately 0903 peri oral erythema was noted and patient reported chest tightness. Stridor was noted. SpO2 remained stable at 97-98% on RA. EpiPen administered, 911 contacted for transport to ED. 0909 patient reports improved chest tightness, peri-oral erythema improving stridor. EMS transported patient to ED for further evaluation and treatment. ED - does not have chart access. 3/25: ED 3/23/21 Anaphylaxis after receiving Covid vaccine: chest tight, hot, and dizzy. Patient received epi at clinic and epi and benadryl in ambulance. Patient advised not to get 2nd dose. Patient states she picked up epi pens that were prescribed. She reports better. She is tired and has headache, her arm is red and bruised but it looks better. Patient states she will not be getting second dose.
1136515	3/26/2021	RI	70	F	3/23/2021	3/23/2021	Pt received Pfizer COVID vaccine in left arm at 0828 at our high-risk anaphylaxis clinic. After receiving the shot she then proceeded to our monitoring area for 30 minutes. At 0836 pt c/o of mild pain in her left deltoid. RN observed the injection area to be slightly red. Pt no c/o of itchiness or SOB. RN provided the pt with an ice pack. VS 162/110 and pulse ox of 97-99%. At 0855 left arm redness notably decreased. At 0905 pt c/o of feeling SOB. O2 sat of 99% with HR of 114. Pt taken into exam area in back of clinic and put on a stretcher. Now c/o of left shoulder and neck pain. Area tender to touch. Pt placed in 2 liters nasal O2. Rapid response was called at 0915. Team arrived, evaluated pt, and then transported pt to ER for further eval and tx.

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1136993	3/26/2021	NY	55	F	3/24/2021	3/24/2021	pt stated that she felt a little funny and lightheaded after taking the covid vax. Her skin started feeling a little prickly and she developed rash on her extremities and upper chest. She started having trouble speaking, her voice got hoarse and she started coughing. She had an intense headache, fatigue and could barely speak. She was taken to the UrgentCare . She was given EPI pen and steroids injections. Paramedics were called and she was taken to a hospital, where she was monitored after getting those injections and given Pepcid and IV fluids. She was diagnosed w/ Anaphylaxis from adverse reaction to vaccine. She discharged and sent home to FU w/PCP. Her appt w/ her PCP on 3/25/2021 she was taken next door by wheelchair to all allergist Dr. She noticed that her respiratory symptoms were improving while she was there as her Pepcid medication was wearing off. Pt is convinced that she is allergic to the ingredient Polyethylene Glycol. She is still taking prednisone medication and continuing to improve.
1132329	3/25/2021	WI	45	F	2/23/2021	3/2/2021	Pt received 1st COVID vaccine on 2/23/21. Returned to clinic on 3/17/21 for 2nd dose. Reports "being itchy without any rash on various parts of the body" about a week after injection. Also reported no appetite and a dry mouth along with being weak and tired. Denied any dyspnea, rash, or other s/s allergic reaction or anaphylaxis. States s/s resolved after 1-1.5 weeks. Did not seek medical care. States "she thinks it may have been pre- or post- menstrual issues and/or supplements". Also states she had had rash in December 2020 of unknown cause. Reports she used "allergy cream then and was sick to her stomach" and was resolved before first dose.
1135910	3/25/2021	VA	51	F	2/26/2021	3/7/2021	Severe allergic reaction including throat swelling, hives, burning /itching skin (head to toe), swelling of hands and feet. Over a thirty minute span, the reactions started to the time I made it to the ER. They got progressively worse during that 30 minute span. Required a shot of epinephrine due to anaphylaxis.

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1131201	3/25/2021	PA	23	F	3/5/2021	3/10/2021	Anaphylaxis; Rash all across her leg; Swelling; Itching; Red; Hot; A spontaneous report was received from a consumer concerning a 22-years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events anaphylaxis, rash all across her leg/rash, swelling, itching./pruritus, red/erythema, hot/feeling hot. The patient's medical history was not provided. No relevant concomitant medications were reported. On 05 Mar 2021, prior to the onset of the events the patient received first of two planned doses of mRNA-1273 (lot/batch: 030M20A) Intramuscularly on right leg for prophylaxis of COVID-19 infection. On 10 Mar 2021, the patient experienced the event(s) anaphylaxis symptoms of swelling, itching, rash all across her leg. It was red, and hot.S he was a very fragile person with many syndromes and so they took her to the doctor. She was feeling better on 14 Mar 2021. Treatment for the events were none. Action taken with mRNA-1273 in response to the events was not reported. The outcome of event(s), anaphylaxis, rash all across her leg, swelling, itching, red, hot were reported as recovering on 14 Mar 2021...; Reporter's Comments: This case concerns a 23-year-old female who experienced a serious expected event of anaphylactic reaction along with unexpected rash, erythema, pruritus, swelling, and feeling hot. Event onset occurred on Day 6 after the first dose of mRNA-1273. Treatment not reported. Events resolving. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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1135301	3/25/2021	TN	53	M	3/11/2021	3/11/2021	<p>Patient report to have been in A-fib for three days after receiving first dose of vaccine; Throat closure; Felt like anaphylaxis; A spontaneous report was received from a consumer who was a 53-year-old, male patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and who developed atrial fibrillation and an anaphylactic reaction. The patient's medical history included heart failure and allergies to butter and NSAIDS. Products known to have been used by the patient, within two weeks prior to the event, included metoprolol, diltiazem, apixaban, lisinopril and loratadine. The patient received their first of two planned doses of mRNA-1273 (Batch number: 040A21A) on 11 Mar 2021 in the left arm for prophylaxis of COVID-19 infection. On 11 Mar 2021, the patient reported that he experienced a moderate reaction; throat closure (not complete). He stated that it felt like anaphylaxis. He also reported having a numb tongue. He reported that the reaction was not immediate and that it started about four hours after the vaccine. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the event, atrial fibrillation, was considered recovered/resolved. The outcome of the event, anaphylactic reaction, was considered recovering/resolving.; Reporter's Comments: This case concerns a 53-year-old male who experienced a serious anaphylactic reaction with serious unexpected event of atrial fibrillation and throat closure. Event onset occurred the same day as the first dose of mRNA-1273. Treatment not reported. Atrial fibrillation resolved, and anaphylaxis resolving. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p>
1135429	3/25/2021	IN	81	F	3/25/2021	3/25/2021	tongue and lip swelling concerning for anaphylaxis
1135431	3/25/2021	IL	50	F	3/25/2021	3/25/2021	<p>Allergic reaction. Hives/redness on injection site (arm). Hives/redness, mottled skin on chest and abdomen. Patient has had anaphylaxis to shellfish stated it felt the same as before.</p>

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1135540	3/25/2021	IL	39	F	3/25/2021	3/25/2021	Scratch in throat. Patient has history of anxiety and anaphylaxis. Patient states she feels nothing like previous allergic reactions. Patient is speaking in full sentences, no signs of swelling/rash.
1135849	3/25/2021	MA	40	F	3/24/2021	3/24/2021	Received vaccine at 7:31a, and at 7:37a I started to feel a mild swelling in throat. It did not get worse after being there under observation for 35 more minutes. I was able to swallow and breathe ok, nurse checked on me every 10 minutes or so. No need to take any medication as it was slight and I wasn't sure if it was anxiety or the start of an anaphylaxis reaction. The swelling was gone by 9:30a, and then it reappeared that evening and was more intense, around 4:40p. It did not get worse, and was gone by 5:30a the next morning (3/25/2021).
1132483	3/25/2021			F			she became very ill with Viral Meningitis and Vertigo and has been in the hospital for a month now; she became very ill with Viral Meningitis and Vertigo and has been in the hospital for a month now; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot#: UNKNOWN), via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. It was reported that the patient became very ill with viral meningitis and vertigo and had been in the hospital for a month now. The events was reported as non-serious. The consumer wanted to know if there had been any reports of serious side effects or serious illnesses after receiving a dose of the Pfizer Covid Vaccine other than the ones that is listed which is anaphylaxis. Stated that she is asking about this since her sister had a Pfizer Vaccine and 2 1/2 weeks later she became very ill with Viral Meningitis and Vertigo and has been in the hospital for a month now. The clinical outcome of the event became very ill with viral meningitis and vertigo unknown. Information on the lot number has been requested.

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1135909	3/25/2021	ME	65	M	3/23/2021	3/23/2021	After about 5 min of receiving his second Pfizer vaccine, pt suddenly developed generalized raise erythematous rash on arms legs, back . Hx: In anticipation onset of anaphylaxis, after appearance of rash on lt arm, pt put on stretcher , undressed immediately, and generalized rash noted. none pruritic. v/s and sat NORMAL. airway NORMAL. lungs clear. given pt's very concerning rash but lack of indication of impending anaphylaxis, given 50mg po benadryl. rescue called for trans and observation in ER where given 30mg prednisone po and monitored. was observed in ER and discharged after 2 hrs observation. 24 hrs later, pt continues to do well. Dx : acute allergic reaction to pfizer vaccine.
1131978	3/25/2021	FL	50	F	3/23/2021	3/23/2021	evening around 4p.m. after the vaccine Adverse effect- lethargy, sleepy 03/23/21 felt cold, swollen lip and face, lethargy, sleepy Ever have a reaction to a previous vaccine? If yes, what? no- usually gets 3 vaccines each month for allergies she didnt take the third dose this month because she was getting the COVID vaccine, area of injection usually gets swollen when she gets these vaccines and it goes away within a few hours Recommendations: please contact your PCP for recommendations since he has your medical records available, see what he recommends for you to take whether it be your prescribed allergy medication or any OTC items. If you are currently experiencing any Shortness of breath please visit your nearest Emergency Department, otherwise inform your PCP that you are experiencing swelling on your lips and that you experienced a swollen face that subsided. Consult with him on whether you should or shouldn't get the second dose vaccine, one of the contraindications for the vaccine is anaphylaxis so its better to take precaution.

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1134890	3/25/2021	NY	29	F	3/24/2021	3/24/2021	<p>Patient previously had an adverse reaction of throat tightness to the first dose of the Moderna covid vaccine. She had been counseled to discuss with her doctor about getting a second dose, and if cleared, to receive the second dose at a hospital facility. Patient reports that she discussed with her doctor, who advised her to wait for allergy testing, however the patient chose not to wait for the shipment and decided to proceed with receiving the second dose at the same location as the first dose. Per patient, had taken two puffs of QVAR prior to second dose vaccination. 11:30am Time of administration of second dose 11:40am Adverse reaction began. Patient reports throat tightness, lightheadedness, foggy. Denies trouble breathing, itching. Reports had breakfast. Two areas of erythema noted on her neck. No erythema on chest/trunk/arms/face/ears. 11:50pm BP 147/92, HR 91, O2 sat 99% 12:01pm Administered two tablets of 25mg diphenhydramine. 12:03pm O2 sat 99%, HR 112. Appears teary-eyed, distressed about circumstances. Lungs clear to auscultation bilaterally, no stridor or use of accessory muscles. 12:08pm Neck erythema resolving. 12:11pm O2 sat 99%, HR 92, BP 143/97. Reports throat tightness feels the same, but not worse. 12:19pm O2 sat 99%, HR 94 12:28pm Reports throat still tight, but feeling much better. Affect and appearance much improved, no acute distress, lucid and conversational. No erythema on neck/chest/trunk/arms/face/ears. 12:35pm Patient declined offer to consider EMS if throat tightness not resolving. Patient has her own epi-pen. Provided counseling on s/s of anaphylaxis, training husband on use of epi-pen. Instructed to call 911 if symptoms worsen or have difficulty breathing. 12:45pm BP 145/88, HR 89, O2 sat 99% 12:49pm Discharged home.</p>
1136086	3/25/2021	WA	18	F	3/25/2021	3/25/2021	<p>Patient received vaccine at noon on 3/25/21 and left the pharmacy after waiting 15min with no side effects. Patient called pharmacy at 4:10pm reporting hives, swelling, pruritus on both arms. Patient denied shortness of breath and dizziness. Advised to take benadryl 25mg stat. and to seek emergency care if developing signs of anaphylaxis or if hives/swelling worsens. Followed up with patient at 6:14pm and patient reported a positive response to benadryl (reduced swelling, no more pruritus).</p>

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1136141	3/25/2021	CA	35	F	3/24/2021	3/24/2021	Immediately after receiving vaccine, patient began to experience skin and throat itchiness. Given 25mg oral Benadryl and sent to Urgent Care clinic. At clinic, patient received 50mg Bendryl IM and 125mg Solu-Medrol IM. No anaphylaxis. Patient refused to wait 30 minutes for observation following injections. Patient educated about risks and signed AMA. Patient stated understanding of strict ER precautions and of Epi-pen prescription. Patient returned as advised to clinic following day for follow-up appointment. Symptoms improved but not resolved. Patient received another 50mg injection of Benadryl IM; again declined 30 min wait. Patient agreed to start oral Bendaryl and prednisone burst tomorrow. Aware of Epen prescription and use.
1136178	3/25/2021	CA	57	F	3/25/2021	3/25/2021	Pt received vaccine at clinic at 5pm 3/25/21. During screening process, pt was asked about hx of allergic reaction. Pt reported history of anaphylactic reaction to penicillin in the past. Pt was informed to wait for at least 30 minutes after the vaccination due to potential of anaphylaxis to the COVID19 vaccine. Shortly after patient received the vaccine, pt stated she she felt symptoms at around 5:08-5:15PM and alerted the staff at around 5:20PM. Pt reported swelling of the throat and was given 1st dose of EpiPen 0.3mg at 5:24PM. Campus safety was notified at the same time.. Pt reported improvement in symptoms after the first injection. Pt was monitored by pharmacy staff and was given a 2nd injection of EpiPen 0.3mg at 5:47PM due to symptoms not being completely alleviated with 1st dose (per anaphylaxis action procedure). Pt reported improvement of symptoms and denied any wheezing, chest or throat tightness, or lip/tongue swelling. Pt refused further medical care from EMT/ambulance to the campus safety officer on site. Pt blood pressure of monitored every 2 minutes from 5:26 to 5:54PM and left the vaccination site with public health staff. Pt was instructed to follow up with PCP and seek emergency help if symptoms worsen or development after she leaves clinic site.

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1134827	3/25/2021	MN	39	F	3/25/2021	3/25/2021	Patient received her 1st Pfizer vaccination dose at 12:37PM. Patient was seated in the vaccination waiting area for her 15 minutes observation window. About 5 minutes after vaccination the patient fainted and fell out of her chair on to the ground. She hit her head on the wall behind her, and ground when falling. Pharmacy staff immediately went to check on patient. She was found to be breathing, but unresponsive for about 20 seconds. 911 was called immediately by another employee. She was positioned lying on the ground with her feet up and came to consciousness quickly. Once awake patient was alert, verbal, and seemed to have a normal mental status. She reported no respiratory issues, no throat or lip symptoms, and no itching or hives. She states that she felt fine other than her head hurting from the fall. She reported no symptoms prior to waking up on the ground. She was speaking in full sentences, responsive, and had a strong, steady pulse at 98 bpm and a normal respiratory rate. No hives, swelling were observed. Patient reported she was a type 1 diabetic and her blood sugar was found to be normal (approx. 145) after she was able to sit. No medications were administered on site as she did not report any additional symptoms indicative of anaphylaxis. The ambulance and local PD arrived quickly. She was walked outside for observation and appeared to be taken away in the ambulance. The patient was not reached for a follow-up call to check in on her later the same afternoon.
1134752	3/25/2021	WA	78	F	3/25/2021	3/25/2021	25 minutes after administering the 2nd moderna vaccine. , patient started complain of tongue swelling . BP 183/101 , Pulse 81. symptom wasn't getting worse . Called 911. they evaluate patient. Bp was still high, There are no signs of anaphylaxis. Recommend to go to hospital for follow up . Patient stayed in the pharmacy for 20 minutes after 911 left and felt good and left home.

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1135883	3/25/2021	CA	58	F	3/25/2021	3/25/2021	<p>Situation: Pt here for covid vaccine #2. After vaccination pt experienced reaction. Background: @ 0815 TEAM ALERT was called to covid vaccine clinic. This RN arrived @ 0818 to find pt sitting in chair in observation room. Received report from RN, pt received covid vaccine #2 and began experiencing cough, clearing throat, runny nose, and chills. Benadryl 25mg PO given @ 0810. Overall discomfort 1/10. 0818: VS: BP 132/98. HR 63. R 14. O2 Sat 98%. Pt c/o clearing throat, chills, coughing, itchy throat, itchy chest. Pt alert & oriented. 0820: overall discomfort 3/10. 0828: VS: BP 124/92. HR 63. O2 Sat 100%. Still experiencing above symptoms plus dizziness, lip numbness and discomfort in diaphragm region. "feels like it won't go down. Like something is stuck there." pt moved to gurney in hallway. 0842: VS: BP 122/86. HR 63. O2 Sat 100%. Pt still feeling diaphragm discomfort. States other symptoms are resolving. Noted pt no longer clearing throat. States lip numbness improved and diaphragm discomfort improving. Pt alert & oriented. 0855: Manager, spoke to pt. Advised pt she may go home when she feels okay. Pt states she feels well enough to go home. This RN advised pt to go home and relax for the remainder of the day, benadryl will make her feel sleepy. Advised pt to watch for symptoms of shortness of breath, difficulty breathing, and chest pain and go to ED if she experiences any of those symptoms. Pt verbalized understanding. VS: BP 118/72. HR 63. O2 Sat 100%. 0857: Pt left covid vaccine clinic ambulatory in stable condition. COVID Vaccine Worksheet 1. Did the patient have an immediate allergic reaction of any severity such as urticaria, angioedema, respiratory distress, or anaphylaxis (<4 hours following administration of the COVID vaccine)? Yes 2. Did the patient previously have an immediate allergic reaction of any severity to polysorbate or polyethylene glycol? No 3. Has the patient had prior anaphylactic reactions from another vaccine, medication or any other cause? No 4. Did the patient have an allergic reaction >4 hours after administration? OR have an expected side effect of the COVID vaccine? No Assessment: Pt had reaction to covid vaccine. Pt reported previous reaction to first dose with similar symptoms. After close observation and benadryl 25mg PO pt symptoms resolved and pt was able to leave clinic ambulatory in stable condition.</p>

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1133021	3/25/2021	FL	54	F	2/23/2021	2/23/2021	severe fatigued/fatigue; red eyes; fever; Darkened skin in face; Itchy scalp and subsequent hair; hair loss; headaches; Anaphylaxis; hives; itching breathing, lips, throat impacted; itching breathing, lips, throat impacted; This is a spontaneous report from a contactable consumer (patient). A 54-year-old female patient not pregnant received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Left arm on 23Feb2021 at 01:00 PM (at age of 54-year-old) as SINGLE DOSE for covid-19 immunisation, Lot Number: EN6198. First vaccine dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) was administered on 03Feb2021 in Left arm for COVID-19 immunisation, Lot number: EL8982. Medical history was not reported. Patient did not receive any other medications within two weeks prior to the vaccination. Patient did not receive other vaccine in four weeks prior to the COVID vaccine. Patient had no COVID prior vaccination. Patient was not tested for Covid post vaccination. On 23Feb2021 within 20 mins patient experienced anaphylaxis, hives, itching breathing, lips, throat impacted. On 23Feb2021 at 02:00 PM (also reported as over next week) patient experienced severe fatigued; red eyes; fever; darkened skin in face; subsequent results, Itchy scalp and subsequent hair; seeing hair loss continuing and fatigue, headaches ongoing thus far. Events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. Treatments received included Anaphylaxis medicine, intravenous (Iv) administration; prescript. Patient had not recovered from the events, at the time of the report.
1134495	3/25/2021		52	F	3/25/2021	3/25/2021	itchy-redness on arms, throat clear, allergic to ASA only= anaphylaxis history, positive NSAIDs, negative dysphagia, negative airway or oropharynx component, admin 50 mg benadryl PO 12:45, admin famotidine 20 mg PO 1300, BP 130/80; HR 98; O2 sat 98% R.A., pharmacist monitored over time, pharmacist gave PO meds for home zyrtec and famotidine

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1134490	3/25/2021	MN	65	F	3/24/2021	3/24/2021	(note I had half the dose in each arm because my first shot had caused reactions of rash, lightheadness and swelling tongue). This time I am having more effects. Immediately I had blurred vision in my right eye and facial muscle tightening. Upon arriving home I became severely fatigued and and still am 24 hours later. As of 16 hours later I developed severe pain in the right arm only, body aches, loss of taste and various facial tightening sensations and swelling tongue (I took Zyrtec for the latter and that helps). NO anaphylaxis. These may go away in the next day or so but that is as yet unknown.
1134337	3/25/2021	CA	51	F	3/25/2021	3/25/2021	Approximately 5 minutes post injection, patient reported feeling flush, overheated, and promptly vomited. Patient was observed for s/sx of anaphylaxis. Patient was given 25mg diphenhydramine, temperature checked (temp had elevated ~2 degrees from time of injection), pulse and breathing function. Pt was visibly flushed in the face. Patient was given a cool rag as well. Patient was A&Ox3. Pt did not report any immediate issues of breathing issues, cardiac abnormalities, etc. Injection site was unremarkable. Pt reported feeling a bit better after the medication. About 7 minutes later, patient began to complain of scratchy throat and minor difficulty breathing. Patient does have a history of atopic reactions and has noted this sensation in the past when experiencing allergic reactions. Observed patient tongue and mild signs of angioedema were noted. Patient given second dose of diphenhydramine and water. Epipen was on site. Patient was observed and monitored for 25 minutes further. After approx. 5 more minutes, patient reported feeling better and looked visibly less flushed and the swelling of the tongue had diminished. Approx 5-10 min later patient was walking around, talking normally, and showed no signs of distress or reaction.
1134280	3/25/2021	OH	31	F	3/11/2021	3/11/2021	Metal taste in mouth within 3 minutes of receiving the vaccine. Metal taste lingered in mouth for several hours after receiving the vaccine. Metal taste had disappeared completely after approximately 6 hours post vaccine administration. No anaphylaxis or allergic effects. Patient did not need medical treatment. Patient intends to receive the second dose on schedule.

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1134163	3/25/2021	WY	41	F	3/17/2021	3/17/2021	03/18/21- ct called-reports developed fever (103 F) evening post vaccination, this am developed angioedema-self tx w/ Claritin, midday feeling much better, -PCP aware of s/s, no further tx at this time, - day 2 evening- low grade fever, slept 11 hrs, feeling 'great today'. Hx anaphylaxis x2, 6-7th grade r/t aspirin, dx salicylate allergy, has epipen. Hx chronic hives/angioedema that can last 5-7yrs, tx w/ steroids. 3/19/21- PCP aware of s/s, no further tx at this time, last evening (day 2) low grade fever, slept 11 hrs, feeling 'great today'
1133685	3/25/2021	PA	42	F	3/17/2021	3/17/2021	patient fainted from seated position in recovery waiting room. she was attended by Dr. for supportive care. paramedics were summoned and transported patient to medical center for further treatment. Symptoms were not anaphylaxis; most likely vasovagal response.
1131802	3/25/2021	NY	55	F	3/24/2021	3/24/2021	Pt seen at ED for anaphylaxis after Moderna Vaccine pt received 1st Moderna COVID19 vaccine at pharmacy today, within 2 mins felt throat closing, itching, SOB. had slight hives on abdomen. received epi-pen and po benadryl at pharmacy. was given additional epi-pen , iv solumedrol, iv benadryl in ED. discharged after improvement and 6 hr observation

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1134661	3/25/2021	MI	45	F	3/24/2021	3/24/2021	Requested to check on pt due to her feeling her HR was elevated after vaccine. Approx 5 min after vaccine, she felt a "rush" and then a warm/flushed feeling, followed by the elevated HR that she checked on her Apple watch of 117bpm. Assessed pt approx 5 min after that, she was stable and felt better. See ROS, PE, and VS info for more data. patient also states she is allergic to bees (anaphylaxis to bee sting) which was not indicated on her consent checklists prior to vaccine. Additional post-vaccine screening: pt states (after VS checked) that she has history of elevated BP in the past, with systolic as high as 170s, however has not been dx formally with hypertension or been put on meds. Observed pt for 20 more minutes (total of 35 minutes) and her HR remained in the 80s and no further sx's. Released to go back to work, where she has a number of co-workers. Advised to observe that would prompt to go to ER or UC in the coming hours or days. Ok to receive the next dose of covid vaccine and would need a 30 minute observation due to history of allergy to bee stings. Patient verbalizes understanding and agreement with plan of care. Also advised pt to f/u with her provider regarding the history of elevated BP with BP also elevated today
1131919	3/25/2021	WI	56	F	2/24/2021	2/24/2021	Pt received 1st dose COVID vaccine on 2/24/21. When she returned for 2nd dose on 3/17/21, reported that she had "fatigue for 3 days afterward, but also worked long hours those 3 days". Reported "swollen glands in throat and neck" on the 3rd day "that lasted about 8 hours". Reported "she could breathe fine through nose" and denied any other difficulties breathing. Stated her grandson "said she didn't sound right when she was sleeping" but pt denied any difficulty breathing or sleeping. Denied any rash, itching, or other s/s allergic rxn/anaphylaxis. Did not seek medical care.

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1132854	3/25/2021	MA	53	F	3/25/2021	3/25/2021	<p>Patient received COVID-19 Pfizer vaccine today. She has a hx of allergies and was being monitored for 30 minutes. She alerted staff after approx 25 min that she was feeling unwell. Reported that she developed generalized headache, ear fullness and tingling in the upper lip soon after receiving vaccine. Denied symptoms of anaphylaxis. She was brought into the triage area. She appeared well, in no distress, no evidence of angioedema or hives. VS were taken: BP 114/70, HR 87 bpm, SpO2 97%. She was given zyrtec 10 mg PO once. After approx 10 minutes she reported that she was experiencing new mild itching in the roof of her mouth and back of throat. She was then given benadryl 25 mg PO once. VS taken again: BP 112/74, HR 86 BPM, SpO2 98%. Continued to appear well. There was no observed difficulty breathing. No hives or evidence of angioedema. After approx 10-15 minutes she reported significant improvement of symptoms. She reported resolution of headache, ear fullness, tingling of the upper lip, and 90% resolution of itching of roof of mouth and back of throat. She denied feelings of swelling of tongue or lips, tightness in throat, difficulty breathing, hoarseness, dyspnea, wheezing, CP, chest tightness, abd pain, N/V, dizziness, lightheadedness. She was monitored for an additional 30 minutes after reporting feeling improved. During that time she reported resolution of symptoms. She continued to appear well. Prior to leaving she was counseled that should she develop any recurrent tingling in the lip, itching in the throat/mouth, feeling of swelling of tongue or lips, tightness in throat, difficulty breathing, hoarseness, dyspnea, wheezing, CP, chest tightness, abd pain, N/V, dizziness, lightheadedness she should seek urgent medical attention. Her daughter is waiting outside and will escort her home. Encouraged her to call with questions or concerns. She verbalized understanding of and agreement with plan</p>

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1132711	3/25/2021	FL	34	F	3/1/2021	3/5/2021	Background 1: Anaphylaxis (previously reported) - within 30m of administration of vaccine I experienced a severe anaphylactic reaction impacting multiple body systems - diagnosed by PCP and allergy specialist. Background 2 (not reported previously): Side effects from insert -The day after vaccine I developed a fever (>100f) which persisted for 8 days (>99.5) in addition to substantial mental fog, aches and pain, diarrhea and vomiting, severe nausea, food aversions and altered sense of taste, 5lb weight loss, and general feeling of unwellness. Adverse event (not reported previously): Anemia symptoms became so severe that my physician recommended that I avoid driving and either seek emergency treatment or schedule iron infusion within 3 days. I became extremely dizzy and short of breath with visual disturbances. My doctor hypothesized that my reaction to the vaccine had caused this rapid deterioration in my health.
1132457	3/25/2021	WI	65	F	2/23/2021	2/23/2021	Patient received 1st dose COVID vaccine on 2/23/21. Presented at clinic for 2nd dose on 3/16/21. Reported "swollen glands that were achy in neck area and a sinus headache" after the first dose. Denied any rash, dyspnea, or other s/s allergic reaction or anaphylaxis. Clinic staff discussed with medical advisor before giving 2nd dose. Medical advisor recommended continuing with 2nd dose, as swelling was likely immune response and patient did not have any breathing difficulties. Patient agreeable and received 2nd dose.

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1132150	3/25/2021	IL	39	F	3/24/2021	3/24/2021	Lead RN was notified about a patient being ill in the parking lot after her vaccination. 3 RN's met the patient in the parking. The Site Officer was with the patient and called EMS. The patient stated she was nauseous and dizzy. She stated she "threw up" and she had a smoothie for breakfast. The patient vitals were stable but her B/P was elevated. Vital Signs: B/P 146/102, Pulse 88, Temp 97, RR 16. The EMS suggested to take her to the ER, but the patient refused. After assessing the patient, she refused to go to the ER and stated she is fine now. Also, she stated she became anxious and now she's calm now. No anaphylaxis was noted and no respiratory distress. EMS had the patient sign a "Against Medical Advice" refusal because she did not want to go to the ER. Lead RN informed the patient to call her PCP about her blood pressure
1132142	3/25/2021	FL	49	F	3/15/2021	3/15/2021	After receiving Moderna covid-19 vaccine (first dose), patient was experiencing some itching on body, primarily on trunk, arms, and head. No rash visible. Blood pressure elevated at 154/118-has a history of hypertension and reports that she just took her blood pressure medications about 1 hour ago. Pulse within normal range in 70s. Denied any respiratory issues, itching/swelling of tongue/mouth/throat, or nausea/vomiting. Patient stayed her 30 minutes and left at 12:52 p.m. Advised her to seek emergent care should those signs of anaphylaxis occur. Patient verbalized understanding. Medications ordered and administered: Benadryl 25 mg capsule - TAKE 2 CAPSULES BY MOUTH NOW FOR ONE DOSE FOR ITCHING. Qty: 2 capsule(s)
1134534	3/25/2021	IN	58	M	3/25/2021	3/25/2021	After his injection, the patient was in the waiting area and described a new taste in his mouth. He described it as a "medicine" taste. He said it wasn't there until he received the vaccine. I examined his arm for redness, swelling, signs of a reaction. There was none. I also screened him for symptoms of anaphylaxis and he had none. I checked on him several times and before he left, he said the taste was "better" and said he had no other symptoms.

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1133663	3/25/2021		45	F	3/25/2021	3/25/2021	Face tingling, lightheadedness. History of childhood anaphylaxis with nuts, carries epi pen and benadryl. Sx onset within 15 minutes of first dose of pfizer vaccine administration. Tx: recline in car seat, lower extremety elevation. Pt given 25mg PO diphenhydramine upon pt request. Approximately ten minutes later pt states facial tingling and lightheadedness subsiding. Pt then had son (vaccinated at same time) drive them home.
1130098	3/24/2021	PA	55	F	3/19/2021	3/22/2021	I started developing hives first down my right leg, then on my stomach and on my tailbone starting 4 days after receiving the vaccine. So far, I continue to develop them slowly. No anaphylaxis, but a strange systemic reaction.
1128520	3/24/2021		43	M	3/23/2021	3/23/2021	Dry mouth, "feels like a knot in my throat" ED Note: 43 y.o. male with a history of hypertension and eosinophilic esophagitis presenting s/p allergic reaction. Patient received his first dose of the Pfizer COVID vaccine around 17:30 today and states that he developed hives down his left arm and was having difficulty swallowing. He does have a known egg allergy and states that he has had prior anaphylaxis reactions to the flu vaccine. Patient was given PO Benadryl with complete relief of his symptoms. He has no complaints at this time and states that he feels "perfectly fine". At bedside for initial evaluation. Discussed plan for continued Benadryl throughout tomorrow and follow-up with his PCP. Patient is agreeable. Plan for discharge. The patient is comfortable with further observation of his symptoms at home. I discussed our workup, answered all questions and made sure there were no other concerns. I provided counseling about standard home and self-care measures and advised on standard return precautions including new, persistent, or worsening / concerning symptoms.
1130840	3/24/2021	FL	40	F	3/23/2021	3/23/2021	Anaphylaxia, breathing trouble

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1130622	3/24/2021	NY	48	F	3/24/2021	3/24/2021	Patient reported at about 25 minutes after 1st dose of pfizer covid vaccine she began to feel facial itching and flushing, similar to what she felt with previous anaphylaxis due to allergy immunotherapy. She was brought to the medical tent and given 50mg benadryl po and observed x 1 hour. No progression of sympoms, vitals stable. No angioedema, throat or tongue swelling, difficulty breathing or speaking, sob, or wheezing. Symptoms had completely resolved prior to discharge. She was driven home by her husband.
1131344	3/24/2021	MO	80	F	3/24/2021	3/24/2021	PATIENT HAD ANAPHYLAXIS. IT PRESENTED AS A LIGHT COUGH THAT GOT WORSE AND BEGAN PROGRESSING TO SHORTNESS OF BREATH . THIS HAPPENED APPROXIMATELY 15 MINUTES AFTER SHE RECEIVED THE VACCINE. I ADMINISTERED AN EPIPEN THAT IMPROVED SYMPTOMS FOR ABOUT 5 MINUTES. THE EMT'S ARRIVED AT THAT TIME AND TOOK OVER CARE.
1128364	3/24/2021		38	F	3/23/2021	3/23/2021	she complained that her throat began to swell to the paramedic caring for at that time whom alerted this writer. Another provider was alerted to call 911. While I went to assess the patient. Patient stated that her throat was starting to felt swollen Anaphylaxis, dizziness, shortness of breath,
1131609	3/24/2021	MO	66	F	3/24/2021	3/24/2021	Pt has PMH of anaphylaxis to PO sulfa drugs, red-syndrome to IV vancomycin and multiple food and environmental allergies. Physician and patient underwent shared decision making process in regards to getting vaccination. - 13:10, pt received shot. - 13:20, pt reports L orbital swelling and numbness/tingling in L upper lip. Given 50mg diphenhydramine. Lungs CTAB. Airway non-edematous. No visible abnormalities or facial edema. O2 sat 98%. HR 77. - 13:30, pt states that tingling has not subsided. Reports that symptoms are mild compared to historical allergic reactions. - 13:35 - pt discharged with instructions to take diphenhydramine Q 4-6 hours for 24 hours and to discuss reaction with PCP (pt already had appt scheduled on same day).

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1129781	3/24/2021	MA	30	F	3/22/2021	3/22/2021	Patient sent to emergency department from nearby vaccine clinic with tachycardia (HR 138). She received her second dose of the Pfizer vaccine approximately 45 minutes prior to arrival to ED. On arrival to ED she also had abnormal sensation in the back of her throat, change in her voice, and a new rash which developed few minutes prior to arrival. At this point, with signs and symptoms c/w anaphylaxis, she was given IM epinephrine, solumedrol, Benadryl, and famotidine. Symptoms improved entirely after 3-hour observation period and she was discharged home on EpiPen, prednisone, Benadryl, and famotidine.
1129803	3/24/2021	MA	41	F	3/24/2021	3/24/2021	Patient was given her first dose of the Moderna vaccine 3/24/21. Patient was directed to the observation room for monitoring and asked to wait 30min due to anaphylaxis allergy to peanuts and angioedema reaction to shellfish. Pt explained her throat was "scratchy" and "feeling funny, like I ate something I wasn't supposed to." Pt was alert and oriented. Denied SOB/chest pain. Reports slight wheezing. Vitals WNL-see below. ED rapid response was called. Vitals @ 0900 BP 110/80 HR 96 O2 sat 96% on room air Patient declined receiving epinephrine pens and requested diphenhydramine which she received when she was taken to ED for observation. Patient was discharged an hour later

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1129871	3/24/2021	WI	60	F	3/24/2021	3/24/2021	Patient received the Covid-19 vaccine. She reports symptoms of Anaphylaxis Patient was dizzy, light-headed, and BUE tingling @1111. At this time denies shortness of breath and difficulty breathing. Patient was given juice, water, and granola bar. No difficulty swallowing noted. 1116: Patient noted that she was feeling worse with throat tightness without difficulty breathing. Vital signs stable with 100% O2 saturation. 1118: Rapid response called. Patient reports throat feels tighter and difficulty swallowing noted. Lungs clear, HR regular both radial and apical. I have observed for 40 minutes. Treatment/intervention: Patient observed. Taking given water, juice, and granola bar. Vital signs taken every 5 minutes per protocol. 1120: rapid response team arrived. 1111 98.9 82 128/73 16-18/100% 1116 93 148/86 16-18/100% 1120 95 164/95 16-18/100% Patient took 2 puffs of her personal albuterol inhaler 1127 Care transferred to rapid response team. Patient transported to ER via cart.
1129876	3/24/2021	CT	42	F	3/24/2021	3/24/2021	1st dose, 12:10 pm pt c/o feeling flushed, rapid pulse, cold legs and body, funny taste in mouth, light headed, and nauseous. BP 140/80 HT 84 O2Sat 99% , Repeat VS 140/80 HR 72 O2sat 98%. Pt reports history of allergy to Augmentin, with hives. Denies anaphylaxis. 12:15 PM pt reported feeling a little better. Pt declined EMS evaluated that was offered. Pt signed Chesprocott refusal form and was given ED precautions. Pt was advised to contact her PCP this afternoon. Pt's husband who was present the entire time will drive the pt home.
1130388	3/24/2021	IL	70	F	3/19/2021	3/19/2021	beginning 20 minutes after the vaccine, patient had near syncope and shortness of breath. no hives or flushing. fatigue persisted several days after, along with chest discomfort, worrisome for anaphylaxis reaction.
1130629	3/24/2021	OH	40	M	3/24/2021	3/24/2021	Within one minute of receiving the vaccination, he developed lightheadedness. He single pies from the sitting position and struck the left side of his forehead. He was taken to a private section of the arena and monitored. Initial blood pressure was 75/50s, and subsequent monitoring show that his blood pressure was in the 136/85. No itching, rashes, shortness of breath, facial swelling, tongue swelling, or anaphylaxis.

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1130652	3/24/2021	NY	48	F	3/24/2021	3/24/2021	About 25 minutes after 1st dose of Pfizer covid vaccination the patient noted facial itching and flushing and this was similar to previous anaphylaxis she had from allergy immunotherapy. No angioedema, throat swelling, tongue swelling, sob, wheezing, difficulty speaking or swallowing. She was brought to the medical tent and given benadryl 50mg po and observed x 1 hour. Symptoms completely resolved. She was discharged home with her husband.
1130766	3/24/2021	MD	30	F	3/19/2021	3/19/2021	Anaphylaxis, hives
1125268	3/23/2021	MA	21	F	3/19/2021	3/19/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Medium
1126685	3/23/2021	FL	40	F	3/22/2021	3/22/2021	Patient stated she felt her throat tightening and had trouble swallowing within 5 min or so of vaccination. History of shrimp anaphylaxis.
1125346	3/23/2021	MT	43	F	3/20/2021	3/20/2021	5 minutes after shor, experienced lip swelling and went into anaphylaxis
1125442	3/23/2021	IN	66	F	3/23/2021	3/23/2021	Patient had her shot at 7:23am. She said she didn't feel well and her tongue felt funny. She stated similar issues with shot 1. She reports hx of anaphylaxis to penicillin. I gave benadryl 50mg po at 7:47am. Her bp was 137/85, pulse 67, and pulse ox was 98%. Patient left at 7:58. She states she just wanted to go home.
1125608	3/23/2021		37	M	3/19/2021	3/19/2021	After receiving his vaccine client stated his throat felt "Itchy" and he was "light headed". Reclined in car seat and seen by EMS and Dr on site. Client reports he does carry and Epi Pen for a shell fish allergy that causes anaphylaxis. Blood pressure 132/88 Pulse 80 and oxygen saturation 100%. Released by Dr once feeling better, Advised to seek medical attention later if needed. Client verbalized understanding
1125952	3/23/2021		32	F	3/1/2021	3/1/2021	Pfizer vaccine- unknown lot number and dose number Reaction documented: anaphylaxis, high

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1126088	3/23/2021	MO	28	F	3/22/2021	3/22/2021	I went to the medical facility for a covid vaccine today. I received the Pfizer vaccine. I started to have a reaction to it and was instructed by the physician on site to use my epi pen. Symptoms resolved within 5-10 minutes of using my epi pen. The on site MD called EMS and I was transported to ED for obs. I was discharged shortly thereafter. I have a hx of anaphylaxis both idiopathic and to iron dextran and basil.
1125330	3/23/2021	OH	38	F	3/19/2021	3/19/2021	PATIENT PRESENTED FOR 1ST DOSE OF COVID19 VACCINE, DISCLOSED TO US THAT SHE HAD MCAS, BUT WANTED TO GO AHEAD WITH VACCINE WEIGHING RISK/BENEFITS. SO POSSIBILITY OF ANAPHYLAXIS WAS PRESENT AHEAD OF TIME. PATIENT RECEIVED DOSE, THEN SAT DOWN FOR 30 MINUTES, DURING THAT TIME SHE STARTED FEELING FLUSHED, HOT, TONGUE STARTED SWELLING. RPH ON CLINIC PROCEEDED TO GIVE ONE DOSE OF EPI INTRAMUSCULAR THEN WE CONTACTED 911 FOR SQUAD TO COME TAKE CARE OF PATIENT. SQUAD PICKED UP PATIENT AND TRANSPORTED TO HOSPITAL FOLLOWING REACTION.
1126999	3/23/2021	CA	22	F	3/23/2021	3/23/2021	allergy: nuts, dairy - anaphylaxis Hx: asthma Not pregnant Patient was found sitting on ground with swollen face, lips, and hives on bilateral arms, back, chest and abdomen. Patient is aox4. Patient already took 50mg PO Benadryl and used her albuterol. Partner at side. Patient stated she had a sandwich about an hour and a half before that might've cause allergic reaction. Patient does carry an epi pen, but not today. 1230 bp 100/60 hr 97 o2sat 99%. 50mg IM benadryl administered to left arm at 1230. 1240 hr 120, o2 sat 99%> No relief and now patient is coughing, 0.5 mg epi im to left arm. Laid patient down. Ems called. Patient remains conscious and alert. Noted she was feeling better before EMS arrived.
1127090	3/23/2021	FL	34	F	3/22/2021	3/22/2021	Anaphylaxis.

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1127158	3/23/2021	CA	32	F	3/22/2021	3/22/2021	Between 45minutes to 1 hour following injection of the vaccine, I experienced a tightness in the jaw and an extremely fast heartbeat lasting roughly 10-15minutes. As I had left the vaccination facility and was on my way home I was prepared to inject an epipen sensing an anaphylaxis reaction, however my heartbeat went back to normal at around the 15 minute mark. During these 10-15minutes, I felt that there were a couple of times where I might lose consciousness, but did not. Prior to leaving the vaccination center, I placed an ice pack on the injection site for roughly 45 minutes, only removing for my drive home. There was no redness or apparent swelling at the injection site.
1127432	3/23/2021	CA	55	M	3/22/2021	3/22/2021	Approximately 10 minutes after 1st dose of Pfizer vaccination. Pt. was fanning himself, appeared diaphoretic with mask down. He flagged down nurse and reported feeling hot/lightheaded. NP asked for BP machine, instructed patient to take slow deep breaths. Pt. reported he felt like he may lose consciousness. His eyes rolled and he became white/pale and appeared to stop breathing. Code assist called; didn't respond to sternal rub, but raspy breathing, weak/rapid pulse palpated; immediately transferred to the ground level without falling, 2 person assist. 9-1-1 called, BP machine didn't immediately work. As soon as his head was low, his face became bright red and he regained consciousness. He was disoriented briefly but then able to answer questions/oriented. BP elevated, HR 80s. BS 257. No s/s anaphylaxis. Hx of syncope r/t blood draw. Wife present and report hx of DM, HTN, Palpitations. He denied CP/SOB or palpitations. He had eaten and took regular medicine the morning. Paramedic arrived and patient was transported to the nearest ER. Pt. was later discharged.

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1127554	3/23/2021	CA	49	F	3/23/2021	3/23/2021	Patient received vaccine around 2:45 pm. At 2:52 pm while in observation area, patient reported feeling her "heart racing." Patient was seated in a comfortable position and assessed for other symptoms of possible allergic reaction. No other symptoms reported and no signs of anaphylaxis noted (no SOB or rashes, etc). Denied any history of anxiety. At 2:55 pm, BP was 154/84 and HR was 60. Patient was provided emotional support, encouraged to take slow, deep breaths, and asked to stay for monitoring for an additional 15 mins. Patient later disclosed a history of panic attacks and reports being hypertensive during doctor visits. At 3:15 pm, patient's BP/HR were reassessed: BP 146/72/HR 62; patient reported the "heart racing" sensation had resolved and denied any other symptoms.
1127619	3/23/2021	CA	34	M	3/23/2021	3/23/2021	13:45 patient received first Pfizer covid vaccine. Began to complain of throat dryness and extremity tingling shortly after while in observation post vaccine. Patient taken to private room and evaluated by MD. BP 150's/90's,HR slightly tachy with normal rhythm, o2 @100%RA. Patient continued to express dryness of throat and tongue and feeling swollen, also continues to mention tingling of body. Patient with hx of and also verbalized anxiety, @ 14:35 25mg of oral diphenhydramine was administered to patient, patient reported feeling better soon after. Bp lowered to 140's/80's and pulse to 70's-80's, and O2 remained at 100%RA. @15:07 patient expressed feeling back to normal, clinician gave home precautions and patient proceeded to go home. MD reported this as "mild anaphylaxis", patient will not be receiving 2nd dose

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1127826	3/23/2021	CA	67	F	3/13/2021	3/22/2021	The only issue post vaccine was a sore arm equivalent to a flu shot. Nine days later (yesterday) I developed an itchy red rash at the vaccine site. Today is about the same but the itching subsided quite a bit this afternoon. Still red, a little bit raised and feels hot to the touch. I realize this reaction is called "Covid Arm" or "Vaccine Arm" and harmless, and I will still have my second injection on April 11th. Just reporting it to you so you know it's probably more widespread than actually reported. Just a note: I had a much worse reaction to pneumovax 23 last October, with swelling and erythema of my upper arm, creeping down my arm to past the elbow over several days, and a low grade fever. Had anaphylaxis in 1982 or so with a Gamma Globin injection. Was a medical assistant, cut myself on a surgical blade, patient had left and no record of her hepatitis history so the doc I worked for gave me the injection.
1127335	3/23/2021	IL	35	F	3/23/2021	3/23/2021	Patient was administered the 1st dose of COVID at 4:12, reported SOB at 4:20pm. PA on site assessed patient, all vitals normal (1220/70, Pulse 67, initial O2 94%, final O2 99%). PA administered 2 puffs of albuterol. PA administered 2 puffs of albuterol. Patient was observed for 15 additional minutes. PA provided education on possible delayed anaphylaxis reaction and gave Epi pen to take home as preventive measure. VAERS report was completed.
1127293	3/23/2021	MO	28	F	3/22/2021	3/22/2021	Anaphylaxis
1124474	3/22/2021	AK	1	M	3/20/2021	3/20/2021	MOTHER OF 12 MONTH OLD BOY RECEIVED FIRST DOSE OF COVID 19 VACCINE AT 9:15 AM SHE BREASTFED HER 12 MONTH OLD SON 3 HOURS LATER AND WHILE BREASTFEEDING THE CHILD DEVELOPED ACUTE ANAPHYLAXIS. TO BE CLEAR: MOTHER HAD THE VACCINE AND THE CHILD HAD THE REACTION

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1123251	3/22/2021	MO	56	F	3/22/2021	3/22/2021	Vaccine given at 11:58am. Patient started showing symptoms of anaphylaxis at 12:02pm. Patient was barely able to communicate, said she was having trouble breathing and wheezing. Pharmacist gave EpiPen 0.3mg IM at 12:04pm while manager called 911. This seemed to give some relief. Fire department and ambulance arrived shortly after. They took blood pressure and oxygen was checked. Patient put on oxygen and taken to hospital.
1124651	3/22/2021	CA	46	F	3/19/2021	3/19/2021	Within 10 minutes of receiving injection in right arm I felt a BOOM flush all over my body like I just had an IV Contrast. Then I became dizzy, my heart started racing, I started cold sweats and felt tightness in my mid upper chest to the base of my throat. The ED RN on site took my BP and HR and had me lie down because I felt that I couldn't breathe. She called paramedics who took my BP and HR, then did a 12 lead EKG. They transported me to the ED. I was worked up for cardiac, lung, chemistry. My troponin-HS was slightly elevated and a cardiologist was called. He did an echo on my heart, liver and right kidney -- normal. Chest X-ray was normal. A second 12 lead EKG was done, normal sinus. Hematology, Chemistry was normal. Was in the ED from 11:30 to 4:00 p.m. Advised by ED Doctor, and Cardiologist, that it seems the stress of the anaphylaxis reaction stressed the heart which caused the spill of troponin. Advised to see my cardiologist and get a stress test. I have already informed my Primary Care Doctor and he has prescribed me an EPI-PEN to carry. I have no history of allergic reactions/anaphylaxis reactions to vaccines. I am up to date with all other vaccines and just had my yearly flu shot in November 2020. This was my first allergic reaction/anaphylaxis reaction to a vaccine.
1124508	3/22/2021	NM	55	F	3/18/2021	3/18/2021	Anaphylaxis (tongue swelling, loss of airway, required oxygen)

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1123551	3/22/2021	OK	18	F	3/17/2021	3/17/2021	Client received first dose of Moderna Vaccine at 15:31. 15:32--sat down in observation area F. Without warning, client lost consciousness, fell from chair and hit head/left side on concrete floor. Was unresponsive x 1min. Used Syncope protocol. APRNs assessed client and local on-site paramedics notified. Client denied difficulty breathing, or any other symptoms typically associated with anaphylaxis. 15:36: BP 87/57, pulse 67 15:37--client awake and talking. Complaining top of head hurts. Client reports she has not eaten today, as she indicated she was very anxious about getting the covid immunization and reports she did not sleep last night. Next page15:39: BP 110/65, pulse 87 15:41: BP 119/77, pulse 91 15:47: BP 110/77, pulse 88 15:50--paramedics started IV and checked blood sugar at 103. Client very anxious, but agreed to be transported to ER due to hit to head. Local transport unit called. 16:01: BP 98/64, pulse 76. 16:03: EMS transport unit arrived/transported to Emergency Room.
1122240	3/22/2021	MI	79	F	3/20/2021	3/22/2021	Patient became short of breath and felt flushed within 5 minutes after dose administration. Pulse ox recorded at 92 and pulse of 99. Blood pressure 160/110. EMS was called and vitals had stabilized to pulse ox of 98-99 and systolic BP of 140s. Patient remained short of breath, has a cardiac history but as baseline status was unknown and husband was a poor historian we sent her to the ER for workup. Did not endorse symptoms of anaphylaxis. Unknown h/o COPD or other chronic lung conditions.

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1122572	3/22/2021	PA	76	F	3/19/2021	3/19/2021	<p>Patient was in the office on 3/19/21 for her first dose of Moderna COVID vaccine. 15 minutes after administration of vaccine, patient expressed she was feeling hypertensive and her hands were feeling cold. Patient was taken to an exam room for evaluation with assistance of language interpreter and RN. BP of 220/120 with symptoms of headache and blurry vision. No chest pain. No signs of anaphylaxis. Patient stated she was feeling slightly better after 3 minutes. Repeat vitals of BP 180/94, pulse 80, RR 32, O2 sat 98%. Patient did take BP meds as prescribed. Plan to go to the ED was communicated to patient and her brother in law to which they agreed. Patient requested that her brother-in-law drive her to the ED instead of activated EMS. Report was called to the hospital ED receiving provider by myself with diagnosis of hypertensive emergency.</p>

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1123110	3/22/2021	CA	26	F	2/19/2021	2/19/2021	tingling in her mouth and lips; lump in throat; dizziness; tunnel vision; shaking; headache; anaphylaxis; A spontaneous report was received from a physician concerning a 26-year-old female patient who received Moderna (mRNA-1273) vaccine and experienced Anaphylactic reaction, having tingling in patient's mouth and lips and a lump in their throat, very bad headache, dizziness, tunnel vision and shakiness. The patient's medical history included: allergy to azithromycin and penicillin. Concomitant product use was not provided by the reporter. On 19 Feb 2021, approximately four minutes prior to the onset of the symptoms, the patient received their second of two planned doses of mRNA-1273 (Batch number: 031L20A) for prophylaxis of COVID-19 infection. On 19 Feb 2021 at 14.09, the patient had tingling in their mouth and lips and a lump in their throat. The patient's heart rate noted was 130s. The patient also reported very bad headache dizziness and tunnel vision. The patient developed shakiness which was noted on exam. The reporter reported for an anaphylaxis reaction. The patient's Blood pressure reported was 156/80. At 14.29, the patient's Blood pressure reported was 176/87. Treatment information provided included EpiPen (0.3mg) given Intramuscularly to right thigh at 14.22 and supplemental O2 provided. The reporter stated ambulance was called, husband of the patient was called. Reports were given to ambulance services. The systolic BP upon transport was 168. Action taken with mRNA-1273 in response to the event(s) was Not applicable. On 19 Feb 2021, the outcome of the events, having tingling in patient's mouth and lips and a lump in their throat, very bad headache, dizziness and tunnel vision were considered resolved and the outcome of the event, shakiness was considered not resolved. On an unknown date, the outcome of the event, Anaphylactic reaction was considered unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the se events, a causal relationship cannot be excluded.

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1121847	3/22/2021	NY	39	F			<p>Kidneys and liver shutting down; Kidneys and liver shutting down; Heart started racing 3 days later; Vomiting; A spontaneous report was received from a consumer concerning a 39-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced heart racing, kidney failure, liver failure, vomiting and death. The patient's medical history included Sjogren's syndrome, Hashimoto's, inflammatory joint disease, osteoporosis, osteoarthritis. She has history of fractured tail bone and leg in three places. Concomitant medications included D3 2 pills a day, folic acid, B12, and calcium citrate. She was allergic to 15 different antibiotics two of which she had anaphylaxis; had huge autoimmune issues; had had reaction to Pneumovax vaccine. On an unown date ,prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. Approximately after three days of receiving second dose vaccine patient experienced heart racing and went to the emergency room .The patient started vomiting and developed a kidney and liver failure. And on the next day she died. Autopsy is doing and the results are not available at the time of report. Action taken with mRNA-1273 in response to the events was reported as not applicable. The events heart racing, kidney failure, liver failure and death were considered serious and medically significant. The outcome of the events renal failure, hepatic failure, palpitations and vomiting was considered as Fatal.; Reporter's Comments: This is a case of death in a 39year-old female subject with unknown medical history of anaphylactic reactions, allergic reactions to pneumovax vaccine, Sjogren's syndrome, Hashimoto's, inflammatory joint disease, osteoporosis, osteoarthritis, who died 4 days after receiving second dose of vaccine. Very limited information has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Renal failure; Hepatic failure</p>

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1123114	3/22/2021	GA		M		12/1/2020	Severe allergic reaction;anaphylaxis; Dizzy; Shortness of breath; Numbness; A spontaneous report was received from a consumer concerning a male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced dizziness, severe allergic reaction, shortness of breath, numbness, anaphylaxis. The patient's medical history was not provided. No relevant concomitant medications were reported. On unknown date, prior to the onset of the events the patient received a dose of mRNA-1273 (Lot number: unknown) intramuscularly for prophylaxis of COVID-19 infection. On an unspecified date in Dec-2020 the patient felt dizzy, had severe allergic reaction, shortness of breath, numbness, and anaphylaxis. Treatment details included diphenhydramine and immune medications. Action taken with mRNA-1273 in response to the events was unknown. The outcome of events, dizzy, severe allergic reaction, shortness of breath, numbness, anaphylaxis, was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
1123197	3/22/2021		44	F	3/12/2021	3/12/2021	The patient had an anaphylactic reaction. The patient experienced angioedema and could not speak. The patient presented with difficulty swallowing, shortness of breath, wheezing, and was unable to talk. As a result to the reaction the patient had to be intubated. However, the patient has a history of excessive anaphylaxis with multiple intubations.
1123545	3/22/2021	OK	21	F	3/17/2021	3/17/2021	Client received first dose of Moderna Vaccine at 14:57 pm. Sat in observation for 15 mins. 15: 12--Reported to Observer that her right arm felt numb, however received immunization in left arm. 15: 20: APRNs assessed client and local on-site paramedics notified. Client denied difficulty breathing, or any symptoms typically associated with anaphylaxis. 15:21--BP 148/94, pulse 102 15:26--BP 136/84, pulse 96, O2 saturation @ 99% 15:31--BP 128/97, pulse 94, O2 saturation @ 98% Client able to move arm and vocalized feeling in arm/hands/fingers. EMS offered to take client to ER; client declined transport. 3/18/21 client reports she is feeling well

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1123530	3/22/2021	CT	54	F	3/22/2021	3/22/2021	The patient received the vaccine and when she went to her car she was feeling short of breath. When the EMT arrived they gave her an epi-pen. We called and checked on the patient. She stated that they did not believe it was anaphylaxis but they gave her an EpiPen as a precaution. The patient is doing well.
1124435	3/22/2021	PA	37	F	3/14/2021	3/14/2021	Per pt "Within moments of vaccine I developed a headache, felt like my heart was racing / pounding out of my chest. Quickly became short of breath, cough, nauseous and dizzy. I reported my symptoms to the RN in the observation room and took Benadryl. My HR was in the 130s at that time. I then used my EpiPen. They gave me 2 puffs of an albuterol inhaler and a 2nd EpiPen before taking me to the ER where IV allergic reaction protocol was initiated (famotidine, iv fluids, solumedrol) and a 3rd EpiPen was given along with a duoneb and iv lorazepam. My symptoms improved after the 3rd EpiPen and seems to slowly resolve over the next 48 hours. " Per ED note Patient is a 37 y.o. female presenting to the ED with shortness of breath and throat tightness. Immediately after getting a COVID vaccine today, patient developed sudden onset of shortness of breath, voice hoarseness and throat tightness. She gave herself IM epinephrine, Benadryl, and albuterol puffs through the inhaler prior to arrival. She was in her normal state of health prior to today. Patient has hx of vocal cord dysfunction, mast cell activation syndrome, and anaphylaxis, and has required epinephrine drips in the past with ICU hospitalizations. Has also needed intubation in the past. Initial evaluation reveals patient to be tachypneic, tachycardic and anxious. +stridor and hoarse voice. Patient gave herself IM epinephrine prior to arrival along w Benadryl and albuterol puffs. Says her symptoms feel similar to what she has had before w anaphylaxis. Patient was given additional IV methylprednisolone, pepcid, Duonebs, and ativan. She was monitored and her work of breathing improved. No additional epinephrine was needed and patient was monitored in the ED for a few hours.~~

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1123673	3/22/2021	TX	37	F	3/12/2021	3/14/2021	Patient has experienced worsening generalized urticaria and arthralgias, fatigue 48 hours after her vaccination. This is a chronic longstanding issue for her already but has worsened, and patient is unsure if she should get the second dose of pfizer. She did not experience any anaphylaxis symptoms.
1123736	3/22/2021	NE	49	F	3/7/2021		Day 1 Sweats, Severe Headache, Fatigue and aches Day 2 Headaches and Sweats Day 3 Profuse sweating, fatigue, headache and aches Day 4 Sweats, Headache Day 5 HIVES, Headache Day 6 HIVES, ANAPHYLAXIC Swelling in hands, feet, tongue & throat. Had to go to the ER! Day 7 Swelling, hives Day 8 Hives Day 9 Hives Day 10 Hives Day 11 Hives Day 12 started to subside
1123759	3/22/2021		41	F	3/17/2021	3/17/2021	Anaphylaxis.
1124030	3/22/2021	VA	28	M	3/18/2021	3/18/2021	Anaphylaxis
1124345	3/22/2021	OR	30	F	3/17/2021	3/17/2021	HPI: patient is a 30 y.o. female with various medical conditions and various allergies who presents to the emergency department secondary to an allergic reaction following her first COVID-19 vaccination. This morning patient went to have her first Moderna COVID-19 vaccination. She was accidentally given and 3 mL instead of 0.5 mL of this vaccine. She was monitored following administration of this vaccine. Patient apparently did well and she went home. Then around 1030 she started having diffuse body itching and felt that her throat was tight. She has an epinephrine pen at home and administer this medication to herself over concerns of potential anaphylaxis. She contacted EMS who transported her to the ER. EMS gave her 25 mg of Benadryl in route. On arrival patient reports that she still feels itchy but she is no longer having any tightness in her throat. She reports that she is feeling better. Patient denies any lip swelling, tongue swelling, throat tightness, difficulty breathing, difficulty swallowing, and other related symptoms not mentioned above.

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1124409	3/22/2021	IN	49	F	3/18/2021	3/18/2021	About 1 minute after the patient's vaccine she said she felt badly. We took her back to the bed. She said she has a hx of anaphylaxis to allergy shots 3 times. She reports no history of hypertension. Her BP was 131/94, pulse 65, oxygen 99. Patient reported throat was getting tight. I gave 50mg of benadryl.
1124073	3/22/2021		27	M	3/20/2021	3/20/2021	Client complained of feeling dizzy and light headed after receiving the vaccine, He reports an allergy to Bananas which causes anaphylaxis. He does not carry an Epi Pen. Vasovagal event with no syncope. Blood pressure 87/41 pulse 78 with O2 saturation 96%. Se4cond set of vitals in 5 minutes was blood pressure 116/70 with pulse 75 and o2 saturation 98% . Released by Dr after second vitals by EMS on site. Advised to seek medical attention later if needed. Client stated understanding.
1123837	3/22/2021	MI	58	F	3/22/2021	3/22/2021	Patient stated she had tingling in her face 10-15 minutes after receiving the vaccine. She thought maybe it was just her mask, but wasn't sure. She stayed an additional 15 minutes for a total of 30 minutes and at that time said it was better but still existent. She went home with understanding to call 9-1-1 if any symptoms of anaphylaxis.
1120956	3/21/2021	CA	37	F	3/18/2021	3/18/2021	Mast cell degranulation/anaphylaxis. I pre-dosed with my normal antihistamines and mast cell inhibitors, as well as an additional dose of Benadryl. As soon as I got the shot I could feel a degranulation and tightening in my throat, but I did not need to use my epi-pen. I did use my inhaler. After about 15 minutes the allergic reaction subsided, and after 30 minutes I felt well enough to go home.
1120928	3/21/2021	CA	47	F	3/19/2021	3/19/2021	Prior to the shot, my idiopathic anaphylaxis has been in remission. Since the shot, my throat and tongue have been swollen. I cannot be around certain smells because my tongue and throat start to swell.

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1120869	3/21/2021	CA	33	F	3/16/2021	3/16/2021	Patient reports feeling flushed and having increased chest redness 5 minutes after taking her first dose of the Moderna COVID-19 vaccine. She denies swelling, itchiness, shortness of breath, or chest pain. Her vital signs were stable (BP 122/89, HR 71, RR 16, SaO2 99%RA). She self administered her own hydroxyzine 50mg and symptoms resolved. She was monitored for a total of 49 minutes. She was educated on angioedema and anaphylaxis symptoms. She was also given go to ER precautions if symptoms return or worsen.
1120784	3/21/2021	NY	39	F	3/21/2021	3/21/2021	FOLLOWING ADMINISTRATION OF PFIZER VACCINE PT DEVELOPED SWOLLEN TONGUE. HX MULTIPLE ALLERGIES AND MULTIPLE INCIDENTS OF ANAPHYLAXIS. CARRIED EPIPEN. EPI-AUTO INJECTOR 0.3MG IM X 1. TRANSFERRED TO HOSPITAL ED IN THE BUILDING FOR EMERGENCY MEDICAL ASSESSMENT. NO SOB OR DIFFICULTY BREATHING. NO ITCHING OR RASH. PT CALM.
1120660	3/21/2021	OH	57	F	3/21/2021	3/21/2021	Five minutes after receiving the vaccination on her left deltoid, she developed tingling over her left arm as well as her left lower s and her left hand, primarily over the dorsum of the second through fifth digits. Denies any shortness of breath, itching, counseling, facial swelling, no evidence of anaphylaxis.
1120534	3/21/2021		56	F	3/21/2021	3/21/2021	56 year old F with hx/ of multiple autoimmune conditions and hx/anaphylaxis to multiple agents presented with generalized pruritis 10 minutes after receiving first dose of Pfizer COVID-19 vaccine. Denied lip swelling, tongue swelling, or throat swelling, and had absence of urticaria. Received 50 mg of PO Benadryl with some improvement in her symptoms prior to leaving facility. Advised of CDC Recommendation to avoid second shot with any allergic reaction to the first dose. Counseled to discuss with her allergy/immunology physician prior to making a decision about whether to return for a second dose.

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1120283	3/21/2021	MD	23	F	3/19/2021	3/20/2021	I received the Pfizer vaccine on Friday afternoon, and the rash presented on the face (both cheeks and forehead), chest, and both arms on Saturday morning. I also woke up with puffy cheeks, and the swelling is now gone. The facial rash is itchy, and there is tiny pustules present?however, no shortness of breath, sore throat, fever, anaphylaxis, or other severe symptoms.
1121333	3/21/2021	IL	57	F	3/20/2021	3/20/2021	At about 23 minutes broke out in a cold sweat. At 26 minutes, became hoarse (always my first symptom of anaphylaxis). Progressed to coughing and feeling a lump in my throat and then tightness in my chest. My blood pressure elevated to 152/100. At that point I self administered epi pen and paramedics called 911. This provided relief but after about 5 to 10 minutes the tightness in my chest and the feeling I couldn't get a deep breath began to return and the paramedics administered two puffs of an albuteral inhaler and transported me to the hospital. At the ER, they did an EKG, started an IV and administered fluids, prednisone and Benadryl. I was discharged about 90 -120 minutes later with a prescription for 3 days of prednisone (50mg) and instructions to continue to take 25 mg oral Benadryl every 4 hours. The next morning my face and chest were red and looked like I was sunburned. My face was also swollen.
1117682	3/20/2021	CA	43	F	3/19/2021	3/19/2021	Patient felt nauseous within 5 minutes of receiving the Moderna COVID vaccine. Patient had no anaphylaxis reaction- we made sure. Patient vomited right before the paramedics had arrived. Paramedics stated her vitals were all normal. Patient was suffering from anxiety. Patient stated she felt better after vomiting. Paramedics did take her with them. No further information was given by the paramedics.

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1117764	3/20/2021	NC	32	M	3/19/2021	3/19/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Hypotension-Medium, Systemic: Seizure-Severe, Additional Details: Approx. 15 minutes after getting his COVID vaccine pt. notified clinic staff that he was feeling unwell and his heartbeat was irregular. Pt. then started to collapse and after being assisted to the ground had a seizure lasting approx. 10 seconds. After waking back up from seizure pt. had trouble breathing. Clinic staff notified me and I immediately administered 0.3 mg of epinephrine via an auto-injector. 911 was called and Pt. was able to sit back up while he waited for EMS.
1118436	3/20/2021	MD	37	M	3/20/2021	3/20/2021	Pt with chest tightness after vaccine with throat itching and fullness. Gave Benadryl IM with symptoms not getting better with pt looking pale . Gave Epinephrine IM with 911 called . Anaphylaxis like reaction
1118733	3/20/2021	NY	55	F	3/20/2021	3/20/2021	Patient reports feeling unwell, collapsed on floor, skin tone became grey, 911 called, epinephrine 0.3 mg IM autoinjector administered, patient put in recovery position, BP monitored, vomitted X 3 or 4, EMT's arrived and transported patient to Hospital. Call from MD at hospital confirming anaphylaxis and patient recovery. Spoke with patient at 15:50 and confirmed recovery.
1119088	3/20/2021	AK	35	F	3/20/2021	3/20/2021	Patient received 1st in series covid vaccine at approximately 915... she breastfed her 12 month-old infant shortly thereafter without problem. around 1215 baby was getting fussy and breastfed for about 5 minutes before baby broke out in hives. EMS was called and epinephrine/diphenhydramine administered for course cough/wheezing, presumably anaphylaxis. Other foods consumed by baby on same day included banana, kids ?g newton bar, dried apples, meat from frozen meal, and two piece of cereal (new to baby). ER course required 4 hours of monitoring but no other medical interventions.

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1119213	3/20/2021	CO	33	F	3/20/2021	3/20/2021	33 yr.. female AAO x4, CC possible allergic reaction. Pt. had Pfizer Covid-19 vaccination (lot EP6955 exp 06/31/21) and started to experience some tightness in her throat. Paramedics on site evaluated and of medical site lead a decision was made to activate EMS due to pt. advising her bottom lip was swelling a little and her voice was changing slightly. Crew showed up scene, evaluated pt. and got an AMA release with the caveat that her mom would drive her direct to the hospital. On site paramedics also advised pt. Had wheezing in upper R lobe, which resolved upon arrival. Pt. has medical hx of anaphylaxis to peanuts (carries EpiPen) and bipolar type ii disorder, medications of Lamictal and bupropion. Tx: pt was administered 25 mg Benadryl PO . Pt was further evaluated with course listed as above. Vitals were BP 110/72, P 90 R 16 97% on RA Pox. Follow-up: pt went, was seen in ED and was given diphenhydramine, Pepcid and a steroid. Pt. discharged to home with no further incident. Pt. advised to advise vaccination staff of reactions she had for second appointment.
1119250	3/20/2021	IN	48	F	3/19/2021	3/19/2021	Patient was received her covid vaccine and sat for her observation period. When driving home she noticed her throat was itching and feeling tight. She returned to the clinic. At 3:50 pm patient's symptoms progressed (throat itching, uvula swelling, and pt developed a migraine) and Dr. administered Epi .03 ml IM in right anteriolateral thigh. Patient diagnosed with anaphylaxis/angioedema, hyperventilation, and right side migraine. Paramedics dispatched. Patient transported to Hospital. Dr called report to ER.

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1118894	3/20/2021	CA	40	F	3/20/2021	3/20/2021	<p>PI: The pt is a 40 year old female who presents with syncope 20 minutes post Moderna dose #1 vaccination to the left deltoid. Pt syncopized from a seated position, falling forward and catching herself with her arms outstretched. +LOC before immediately regaining consciousness. No head or neck injury, +abrasion to the left elbow. Pt notes similar episode following an influenza vaccine 15 years ago. Pt denies any medical Hx, daily medications, or Hx of anaphylaxis. Pt denies swelling or itching of the lips, eyes, or face. She also denies any swelling of throat, difficulty breathing, or SOB. Exam (update as needed): GEN: Alert and oriented x 3 upon immediate evaluation, HEAD: NCAT EYES: PERRL, EOMI ENT: Ears normal, Nose normal, OP normal, no evidence of angioedema NECK: Supple, without LAD. CV: RRR,+Bradycardic, +hypotensive, no m/r/g PULM: Clear to auscultation bilaterally, no accessory muscle use ABD: Soft, no tenderness. SKIN: +pale, +diaphoretic, +1cm circular abrasion to left elbow, No rashea MSK: FROM, MS 5/5 NEURO: Alert and oriented x 4, CN 2-12 grossly intact, no ataxia Clinical Impression/Field Tx: Syncope post moderna does #1 vaccination. Impression supported by clinical scenario, vital signs, and Pt?s endorsement of similar incident in the past, Suspicion for anaphylaxis low due to no signs of angioedema, no SOB, and no complaints of itching. Pt also denied any Hx of anaphylaxis or allergic reaction. Vital signs stabilized in the field and pt reported improvement following 30 minutes of repositioning and observation. Because of limited resources on site, the Pt was evaluated by EMS where repeat vital signs, blood glucose, and EKG were obtained. Medications administered: None Disposition: Pt was evaluated by EMS and transported to the Hospital.</p>
1116081	3/19/2021	NY	41	F	3/18/2021	3/18/2021	<p>several hours, 8, after getting the COVIDvaccine, my throat began to feel tight and my chest began to feel tight as well. I began to wheeze and notice that my breathing had changed and it was not normal. symptoms similar to anaphylaxis of when I was given Rocephin in my teen years and had anaphylaxis within a minute of receiving that medication.</p>

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1116217	3/19/2021	KS	70	F	3/16/2021	3/16/2021	Progress Notes (Nurse Practitioner) ? ? Cosigned by: MD at 3/18/2021 2:57 PM Expand AllCollapse All COVID VACCINE CLINIC 3/16/2021 Date: 3/16/2021 Subjective Patient is a 70 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She was given the Pfizer vaccination in the left deltoid muscle in the medical bay by staff given prior allergic rxn to unspecified eye gtt. During her 30 minute waiting period after the injection, the patient began to experience headache. She denied rash or SOA This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to red flag findings. PMH anaphylaxis to unspecified eye gtss, prompting vaccine to be given under observation in medical bay. During 30" observation period, pt developed mild headache. Pt treated with Tylenol 500 mg tab x 2. ALLERGY REVIEW OF SYSTEMS: Patient complains of headaches Mild headache during 30" observation period: CONT negative HENT negative Eyes negative Respiratory negative Skin negative GI negative Musculo negative Previous Reactions: anaphylaxis to an unspecified eye gtt as a teenager Objective Vitals Vitals: 03/16/21 1522 BP: 110/68 Pulse: 55 Physical Exam Constitutional: Appearance: Normal appearance. HENT: Head: Normocephalic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: No oropharyngeal exudate. Eyes: Pupils: Pupils are equal, round, and reactive to light. Cardiovascular: Rate and Rhythm: Normal rate. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Skin: General: Skin is warm and dry. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Behavior: Behavior normal. Clinically, pt developed a mild headache during 30" observation. She was administered her vaccine Dose #1 of 2 in the medical bay after reporting having anaphylaxis to an unspecified eye gtt as a teenager. Assessment/Plan Treatment included: observation, Tylenol, snacks Follow up response to treatment: excellent. Patient discharge: Stable to go home and follow up with PCP. Differential Diagnosis: Vaccine-Related Anxiety (include misc mental

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							health) Electronically Signed 3/16/2021 3:23 PM
1115454	3/19/2021	FL	71	F	3/19/2021	3/19/2021	Patient reports history of seafood allergy; within 10 minutes of administration of vaccine, began to develop dryness in throat leading to persistent coughing, was closely monitored and began to develop some difficulty breathing. Was given 50mg of Benadryl at first, coughing became more severe, epinephrine injection was administered on right thigh and paramedics were contacted as administration took place. As a result, patient was still responsive but continued to show symptoms of anaphylaxis, paramedics arrived and escorted patient to the nearest hospital in which patient complied. Paramedics were also provided with information of what to place and what was given to the patient as a result of the anaphylactic episode.
1115632	3/19/2021	OH	59	F	3/19/2021	3/19/2021	26 minutes after receiving the vaccination, the patient developed over her left forearm, right shoulder, posterior neck, and left scalp. Upon evaluation, she had no hives or rashes. Lungs were clear on auscultation bilaterally. No shortness of breath, nausea, respiratory distress, anaphylaxis. She was given Allegra 60 mg PO times one. Her blood pressure, taking by machine, was 205/117. No dizziness, chest pain, headaches, or vision changes. Subsequent manual recheck of her blood pressure were in the 160s to 180/ 100s, and after possibly 30 minutes of monitoring with serial your blood pressure checks, her blood pressure was 172/94 manually. Her itching resolved, and she developed no other symptoms.
1115788	3/19/2021	NY	20	F	3/11/2021	3/11/2021	Hives which started within 1 hour after the first dose of the COVID-19 Pfizer-BioTech vaccine was administered. Hives started on left arm and then spread throughout body, mostly on upper and lower extremities and trunk. Was seen and evaluated by a medical provider (nurse practitioner) 3/16/2021. Patient was diagnosed with urticarial rash (hives) and given prescription for cetirizine 10 mg 1 tab twice per day and Epipen to use in case of anaphylaxis. There were no signs of anaphylaxis at time of exam on 3/16/2021.

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1115852	3/19/2021	WI	66	F	3/19/2021	3/19/2021	Patient was observed for 30 minutes and she left. She returned a short time later and reported feeling flush and a bit of chest and throat tightness. Stated having many trips to the ER in the past for anaphylaxis, she no reaction to her first dose and says her allergist told her she was safe to receive the second dose. We sent her to the ER following her elevated blood pressure and assessment of her swollen hard/red injection spot.
1117274	3/19/2021	CA	88	F	3/17/2021	3/17/2021	1538- pt in vaccine observation area after receiving Moderna vaccine dose 2. 1539-Pt was minimally responsive and diaphoretic in her sit/walker. BP not reading , perhaps too low, pulse 70, R20,O2 sat 99% RA, No obvious sign of anaphylaxis. Family reported same symptoms previously, last on 3/12/21 and was eval in outside ED for syncope. 1540-Pt now less responsive but responds to simple commands, BP 63/45,P64,R16, O2sat 98% RA, cold compress applied to forehead. 1546- transferred to gurney in Trendelenburg & decision made to call ambulance. 1550- 911 called. Pt was transferred to ED
1116808	3/19/2021		39	F	3/13/2021	3/13/2021	No symptoms reported. Found dead seated on couch the day after vaccination (3/14/2021). Autopsy performed on 3/15/2021 showed no evidence of anaphylaxis. Cause of death = Cardiomyopathy of Obesity.
1116847	3/19/2021	TX	20	F	3/16/2021	3/18/2021	Patient called pharmacy complaining of tight throat, hives, and itching. All occurred about 36 hours after vaccination. Advised patient to take 50mg of Benadryl 4 hours apart then 25mg every 4 to 6 hours. Patient described a close form of anaphylaxis. Advised patient to proceed to ER if difficulty breathing or symptoms progress. Also advised patient to follow up with PCP if symptoms continue for another 24-48 hours.

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1117101	3/19/2021	IN	30	F	3/18/2021	3/18/2021	1022 - Patient received her 1st Pfizer vaccine by RN. She noted a history of vasovagal syncope to needles in the past (did not seem like it was complete syncope to all needle sticks per RN). RN offered for her to lie down, but she said she felt ok sitting. She did not endorse any history of severe allergies or reactions to injectables in the past; she was asked the necessary questions prior to vaccination. We later learned she has Crohn?s and is on immunosuppressant Imuran for this disorder. 1023ish ? walked to checkout area 1025 - While sitting at the checkout registering for her second shot she started to feel faint and checkout staff called for help 1026 - RNs were getting the BP cuff on her. She appeared obtunded and slouching in her chair- eyes closed. Gentle sternal rub and she was able to open her eyes and tell us what her name was and ask to call her dad. BP 90/58. Cold cloths placed on her neck. Continuous pulse ox monitor placed, showing 99%. 1030 - Still drowsy and diaphoretic. Able to tell us that "she passes out when she gets shots" C/O nausea and vomited. Still in and out of awareness. NP is site coordinator is now present and suggests taking patient by wheelchair to safer and more private area for evaluation in SR Room. Patient able to stand and transfer to wheelchair, which we did slowly and carefully. 1034 ? Now in safer and more private area SR room with NP and RN and Dr. Firemen are here and assessing the scene with medic assessing patient. Ambulance in route, about 5 - 10 minutes out per radio communication. Checking BP every 2 minutes. Now is 68/44. C/O nausea and vomited. Pulse ox won?t pick up. Patient with decreasing LOC, eyes rolling back in head, unable to maintain posture seated, and not able to describe symptoms to us (unknown if she felt itchy but no obvious cutaneous manifestations). Unable to visualize oropharynx. 1037- BP 57/40. NP administered Epi pen 0.3 mg dose to L lateral thigh due to s/s of systemic allergic reaction/anaphylaxis including 3 known body systems: hypotension (cardiovascular), vomiting (GI), and decreased LOC (neuro). No IV fluids immediately available but were preparing to obtain. Staff getting cot for patient to lie down. Provider spoke with her mom on the phone and informed her of event. Mom confirmed that she has often before passed out with vaccines and blood draws. Dad was on his way to center and rerouted to ER. 1038 - BP 68/45 Talking to medics and able to tell

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							<p>them she ate breakfast and that she has a hx of Crohn's and takes a monthly injection. Informed provider that her dad was on his way. EMS team here to transport to ER. We were preparing to put her on a cot so help with her blood pressure/blood flow when she started to stabilize and EMS arrived with stretcher. 1040 - BP 97/53. Patient is now alert and talking to us. Says she has had syncope in the past ?but never anything like this.? 1041 - BP 115/53. Patient still alert and talking. Oriented x 3. 1042 - Transported to ER by EMS ambulance on stretcher. DEBRIEF: Somewhat atypical (no obvious cutaneous manifestations) and rapid, severe reaction. Ddx vasovagal vs anaphylaxis. Response to epi consistent with anaphylaxis reversal. Perhaps immunosuppressant medication contributed to severity and rapidity of reaction.</p>
1117117	3/19/2021	OR	74	F	3/19/2021	3/19/2021	Tongue Swelling, Dizziness, Upset Stomach, Anaphylaxis
1117120	3/19/2021	DE	50	F	3/19/2021	3/19/2021	Was waiting 30 minutes due to previous anaphylaxis and tongue started to feel tingly, we administered 50mg of benadryl generic and held for 2 hour observation. No sequelae.
1115909	3/19/2021	NC	51	F	3/18/2021	3/18/2021	Anaphylaxis. Five minutes after vaccination felt itching. Mouth, tongue, throat began swelling 10 minutes after vaccination. Received Benadryl, then treated with treated with epinephrine or EpiPen. Transported by EMS to hospital where she received IV famotidine and methylprednisolone sodium succinate.
1116803	3/19/2021		66	M	2/15/2021	2/15/2021	<p>Appeared unwell after vaccination. After returning home, sat down in chair and became unresponsive. Resuscitation unsuccessful. Autopsy performed 2/17/2021 showed severe hypertensive and coronary heart disease with congestive heart failure and no signs of anaphylaxis (postmortem serum tryptase = 9.2 mcg/L; RR <= 10.9).</p>

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1111735	3/18/2021	OR	57	F	3/16/2021	3/16/2021	Pt was at outside public health vaccination clinic- but was deemed high risk and was brought to the hospital to administer it. ER nurse gave vaccine and 10-15 mins after vaccine pt started to feel dry mouth and felt her throat closing off. She stated she had had anaphylaxis in the past and this was very similar. Pt was given EpiPen and admitted to the ER for further treatment. Pt's symptoms slowly resolved. Pt was started on IV and given Benadryl 25mg IV and solumedrol 125mg IV. She was observed for 2 hours and had stable vitals and symptoms didn't return. She received 1 liter of fluids.
1111653	3/18/2021	IL	68	F	3/18/2021	3/18/2021	Patient in the observation area post vaccination c/o "hot feeling" tightness in her throat. The patient admits to having had anaphylaxis reactions in the past to latex, penicillin and clindamycin. Patient states this feeling is similar to what happens when anaphylaxis is pending. Patient was transported to the ER for observation.
1111497	3/18/2021		66	F	3/1/2021	3/1/2021	Anaphylaxis
1111361	3/18/2021	SC	67	F	2/16/2021	2/16/2021	My face went numb; Headache; This is a spontaneous report from a contactable consumer. A 67-years-old non-pregnant female patient received BNT162b2 (Pfizer-BIONTECH Covid-19 Vaccine), via an unspecified route of administration, in the left arm, on 16Feb2021 at 10:15 (at the age of 67 years-old) as a single dose for covid-19 immunisation. Medical history included headache, anaphylaxis reactions to food allergies, Spinich, cabbage, sulfa based drugs diabetes, and asthma. The patient had not received any other vaccinations within 4 weeks and was not diagnosed with COVID-19. Concomitant medication included diabetes meds and insulin glargine (BASAGLAR). The patient reported on 16Feb2021, at 10:45 after waiting 30 as instructed, I had a reaction 5 - 10 minutes later. My face went numb, and then a headache started. I have had only 1 headache in my life prior to this. The patient was not hospitalized for the events nor was treatment received. The clinical outcome of the event was recovered
1111884	3/18/2021	TX	59	F	3/16/2021	3/16/2021	Anaphylaxis - Difficulty breathing, chest heaviness, wheezing Reaction began 1:05 pm, Admitted to ER at 1:52, Released at 4:00 pm

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1110939	3/18/2021	WI	37	F	3/12/2021	3/12/2021	<p>Patient with past medical history significant for multiple sclerosis arrives at emergency department for concern for allergic reaction after receiving the Moderna COVID-19 vaccine 3/12/21. Patient describes that soon after receiving the vaccine yesterday, she has felt swelling over her face and hands, and felt somewhat dizzy. This morning, patient with shortness of breath, wheezes, continued facial swelling, abdominal pain, nausea, vomiting. Also reports left upper and lower extremity weakness, typical of patient's recent MS flares. 911 was called, on arrival EMS administered Benadryl 25 mg, famotidine, and methylprednisolone, then transported patient to this emergency department. On arrival to this emergency department, patient describes that she is still only slightly nauseous, however patient does feel chest tightness, shortness of breath, and a strange feeling in her throat. After arriving a diagnosis of anaphylaxis on rooming of patient, IM epinephrine ordered and administered with significant improvement in shortness of breath and expected increase in heart rate. Provided racemic epinephrine nebulizer as well. Deferred Benadryl, steroids, histamine blockers as these have been given in route by EMS. After these treatments as above, patient felt better, and over the next 5 hours slowly returned to baseline without any recurrence of significant shortness of breath, nausea, vomiting. Patient discharged home. Next day, patient awoke with recurrence of facial swelling after sleeping, as well as redness, initially without chest tightness or shortness of breath, which then developed over the course of the day. Patient states that she used her IM epinephrine approximately an hour prior to presentation due to concerns for worsening chest tightness. Returned to emergency department. Observed and was later discharged with steroids, antihistamines and albuterol nebulizer.</p>

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1112578	3/18/2021	CA	18	M	3/18/2021	3/18/2021	Received first dose of Moderna vaccine today around 2:30 pm. Reports 2 minutes later, felt left side of throat "swell" and was uncomfortable. Also felt mild chest discomfort. Symptoms resolved after about 3 minutes, so he finished his 15 minute observation time, and left the clinic. He returned approximately 15 mins later, and informed the ER MD here in the clinic that his throat swelling and tightness had returned and that he now had and some difficulty breathing. He was answering questions appropriately, appeared in no distress. At 1510 VS taken: BP 122/74, O2 sat 100%, P 73, RR 18. Skin color pink/normal. ER MD advised patient be taken to ER and he called report there. Patient was taken via WC right away to ER with MD, and RN and myself. Anaphylaxis kit brought. But not used. He was stable during transport. In ER he c/o more throat tightness, and it appeared that the left side of his neck was mildly swollen. He then c/o bilateral pedal numbness and also some difficulty breathing. Care was assumed by RN and report was given to her. He was able to call his parents prior and remained stable at the time we departed the ER. NP
1110900	3/18/2021	MD	55	F	3/11/2021	3/11/2021	full anaphylaxis including tongue and throat swelling, elevated heart rate, elevated blood pressure, delirium, face slightly swollen, shortness of breath, dizziness

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1111305	3/18/2021	SC	71	M	1/22/2021	1/23/2021	<p>suspect anaphylaxis; passed out while driving.; entire body itching; vision issue; This is a spontaneous report from a contactable physician. A 71-years-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular Right arm on 22Jan2021 11:00 at single dose for covid-19 immunisation. Medical history included diabetes mellitus (DM), hypertension (HTN), hypercholesterolaemia. No other vaccine in four weeks. There were other medications in two weeks. No covid prior vaccination. Clinical course reported as: Patient got vaccine with no issues. 36 hours later he developed entire body itching. He then developed vision issues and passed out while driving. He was hospitalized and no cardiac or neurologic issues were found. The reporting physician suspected anaphylaxis since patient had severe itching with the event. There were no other likely triggers found during history other than the vaccine. Events onset date reported as 23Jan2021. Events resulted in Emergency Room Visit and Physician Office Visit. Covid test type post vaccination: Nasal Swab on 06Feb2021 result: Negative. Treatment received for the events. Outcome of events was Recovered/Resolved with Sequel. Information on the lot/batch number has been requested.; Sender's Comments: A causal relationship between the events suspect anaphylaxis, passed out while driving, entire body itching, and vision issue and suspect product bnt162b2 is possible based on the information provided, drug profile and a temporal association in this 71-year-old male patient. This case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.</p>

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1112017	3/18/2021	KS	48	F	3/17/2021	3/17/2021	<p>Progress Notes Nurse Practitioner COVID VACCINE CLINIC Subjective Patient is a 48 y.o. female who was seen at SVH COVID Vaccine Clinic today for her second dose of the COVID 19 vaccination. She was given the Pfizer vaccination in the left deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience difficulty breathing, and chest tightness and phlegmy throat. . She denied rash, hives, welts, difficulty swallowing, wheezing, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to abdominal pain, blood pressure abnormality , collapse, drooling, hypotension, increased swelling, rapid progression of symptoms, respiratory distress, skin changes, tongue swelling and vomiting. ALLERGY REVIEW OF SYSTEMS: Patient complains of frequent throat clearing, chest tightness and shortness of breath Previous Reactions: Covid shot : Muscle ache and headaches for 2 days. Objective Vitals Vitals: 03/17/21 1603 03/17/21 1639 03/17/21 1650 BP: 109/88 (!) 146/104 Pulse: (!) 117 (!) 107 SpO2: 99% 97% 99% Physical Exam Constitutional: Appearance: Normal appearance. She is well-developed. HENT: Head: Normocephalic. Right Ear: Hearing normal. Left Ear: Hearing normal. Nose: Nose normal. Mouth/Throat: Lips: Pink. Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Uvula midline. Eyes: General: Vision grossly intact. Pupils: Pupils are equal, round, and reactive to light. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Decreased air movement present. Examination of the right-upper field reveals decreased breath sounds and wheezing. Examination of the left-upper field reveals decreased breath sounds and wheezing. Decreased breath sounds and wheezing present. No rhonchi or rales. Comments: Tight wheeze in lungs Cleared after 2 puffs of albuterol inhaler, symptoms reoccurred within 10 min of use. Neurological: Mental Status: She is alert. Psychiatric: Behavior: Behavior is cooperative. Pt was given albuterol inhaler 2</p>

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							<p>puffs, Pepcid, Benadryl IM and Solumedrol 125 mg IM. Pt initially clears for about 10 minutes, then airways tighten up again after inhaler use. Epinephrine 0.3 given and pt sent by AMR to hospital. O2 started at 2L at 4:50. Assessment/Plan Treatment included: albuterol, antihistamines, oral steroids, water and pepcid Follow up response to treatment: poor. Patient discharge: Transported to ED by ambulance. Differential Diagnosis: Anaphylaxis (dyspnea, stridor, drooling, tongue swelling) and Red flag symptoms (CP, SOB, NVD, Visual/Neuro concerns) 5:05 left for ER. Update given to AMR and SV ER. Electronically Signed 3/17/2021 4:56 PM</p>
1112021	3/18/2021	MN	25	F	3/10/2021	3/10/2021	<p>Client received Moderna second dose vaccine at 2:10 pm. Stated no problems with first dose. Had a history of numerous allergies including anaphylaxis to mold but no injectables. instructed to wait 30 minutes. After about 10 minutes, client complained of trouble breathing, dizzy and itchy mouth. Nurses noted extreme trouble breathing . EPI 0.5 ml given SQ in left leg. Blood pressure 189/90, P 138 O2 sat 99%. No wheezing noted. Skin clammy. 911 called. BP better at 130/82 P 110 and O2 sat 100%. Clients breathing improved. Cool compress applied to head and elevated legs. Client was alert. EMS arrived at 2:35 pm and transported client to ER.</p>

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1112133	3/18/2021		30	F	3/17/2021	3/17/2021	C/o Generalized itchiness. No rash visible. VSS 123/84 HR 74 100% on RA RR 16. No tongue, lip swelling, no hives. No chest pain, sob. No hx of prior vaccine reaction. Hx of allergies to strawberries with anaphalaxis. Vaccine received at 0925. Pt still c/o itchnng at 10:05. Will send to ER for further monitoring as may need antihistamines, steroids, h2 blockers. No signs of anaphalaxis. Will need further monitoring. ED Note: This is a well-appearing and pleasant 30-year-old female who presented to the emergency department for generalized body itching following getting the first dose of Pfizer COVID-19 vaccine at approximately 930 this morning. On presentation patient is well-appearing, respirations are even and nonlabored, she is speaking in complete sentences with normal work of breathing. She denies any symptoms other than itching currently on her upper arms and upper back. She notes that the itching is already starting to resolve and has lessened. There is no rash present on exam, no hives. Airway is clear, uvula midline, patient is tolerating secretions well with no drooling or voice changes and there is no mouth or tongue swelling present. Neck is supple without lymphadenopathy. Patient was observed close to an hour and a half and she remained stable with no changes. At time of discharge patient with no skin reaction, facial, mouth, or tongue swelling. She is speaking in complete sentences with normal work of breathing, respirations even and nonlabored. She appears well and appropriate for discharge. I had an in-depth discussion with her regarding monitoring her symptoms at home seeking emergent care if she has any compromise. We discussed all signs and symptoms that she should look for that would be concerning and need emergent intervention. She indicated that she understood all instructions. Patient was given the opportunity to ask questions. All questions and concerns were thoroughly addressed. Patient indicated she understood all instructions was comfortable with this plan of care. No evidence of Stevens-Johnson syndrome, anaphylaxis, cellulitis, or systemic compromise. Feel supportive care and symptomatic treatment reasonable. I reviewed recent and relevant Chart Entries, Previous Notes, Previous Labs, Previous Radiology studies. Patient ambulated out of the emergency department with a steady gait. Received benadryl and famotidine in the ED and take

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1112347	3/18/2021	CA	35	M	3/18/2021	3/18/2021	home prescriptions for famotidine and hydroxyzine. The first dose of the vaccine was given on 2/16/21 - he vomited at clinic, felt lightheaded, and was brought to the urgent care and observed, given 50mg IM diphenhydramine. all sx resolved. No sx airway swelling or respiratory sx. VS wnl. He was discharged and given PO benedryl TID for 48h. Since pt had reaction but was not clearly allergy/anaphylaxis, recommended ok to give second dose - but to give in urgent care in monitored setting. Second dose given 3/18/21. within 5-10 min of vaccine administration, patient began vomiting. He was treated with 4mg IM Zofran, then another 4mg IM Zofran (8mg total) and 50mg IM diphenhydramine. All sx resolved. No airway swelling or respiratory sx. VS wnl. Pt was stable, discharged from urgent care. Gave 50mg PO diphenhydramine x 24h.

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1112584	3/18/2021	CA	48	F	3/18/2021	3/18/2021	Adverse reaction after receiving the COVID-19 vaccine in Vaccine Clinic. Medications: Fludrocortisone 0.1mg (pt took med prior to vaccine) No current outpatient medications on file. Allergies: Pt reports anaphylaxis x2 as a child after receiving vaccine (varicella and MMR) Not on File Medical history: "low blood pressure" per pt No past medical history on file. This was vaccine dose 0.3ml Pfizer Lot# ER2613 given @ 2:55pm Describe adverse reaction: Per pt "itchy throat" and "knot in my throat" Tachycardia to 110's Hypertension 120-150/80' Employee was monitored for 30minutes. Vaccine @ 1455 and pt started to c/o "itchy throat" @ 1515. Pt requested water and was able to swallow w/o difficulty. C/o feeling dizzy and warm. VS continued to be taken while pt sat on gurney. MERT called @ 1527 and arrived @ 1534. Pt taken to ED. AOD present @ 1530 and escorted pt via gurney to ED w/ MERT @ 1540. A/O x3, following commands, RR 20's. No difficulty breathing. 15:21 128/86 100% RA HR107 RR20 15:27 157/84 100% RA HR100 RR20 15:33 125/85 100%RA HR114 RR20 Anaphylaxis symptoms: Per pt "itchy throat" and "knot in my throat" Tachycardia to 110's Hypertension 120-150/80' Anaphylaxis plan: Anaphylaxis kit within reach. Pt also brought her own Epi pen. Not used. MERT called. Vasovagal symptoms: Dizziness Vasovagal plan: Pt remained seated and gurney brought to clinic. Administration error: NONE MERT called YES @ 1527 Transferred to ED VAERS report number: Email sent to OHS and patient documented in adverse reaction log.
1112667	3/18/2021	MD	67	F	3/17/2021	3/17/2021	Patient received her first covid vaccine at approximately 9:05 am, walked over to the observation area and after sitting down reported to the post observation nurse that she felt dizzy and nauseous. Vital signs measured, wnl and pt. without s/s of anaphylaxis. She reports eating breakfast, history of motion sickness. She was helped to lie down and monitored for 25 minutes without incident. Water given. Dizziness/nausea slowly resolved. EMS offered, declined. Wheeled to car by staff and driven home by family member.

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1112729	3/18/2021	CA	55	F	3/18/2021	3/18/2021	55 y/o F with hx of HTN and allergies who complained of mild erythematous papules (b/l forearms) and mild forehead pruritis. Exam with stable VS. No evidence of respiratory distress, urticaria, abdominal pain, nausea. No evidence of anaphylaxis. Pt observed for 60 minutes. Recv'd benadryl 25 mg PO. Discussed options for care and pt opted to return to work. She recv'd anticipatory guidance and precautions for what symptoms should prompt an ED visit. Pt stable and well appearing on d/c from the vaccination clinic.
1113604	3/18/2021	MD	66	F	3/11/2021	3/11/2021	anaphylaxis, asthma attack, heart racing, dizziness, severe headache, pain in left side from shoulder to waist, numbness in both hands, pain in right arm from shoulder to hand with numbness and tingling sensation. Inability to walk or stand, red eyes, swollen faces, shortness of breath, weakness in legs, rise in blood sugar levels, feeling light headness, fever, sore throat, chills.
1110078	3/18/2021	TX	71	F	3/17/2021	3/17/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Confusion-Severe, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Severe, Systemic: Shakiness-Severe, Systemic: Weakness-Medium

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1112154	3/18/2021		72	F	3/17/2021	3/17/2021	Pt received vaccine at 09:52. 10:22 pt started to itching on arms and back. No visible rash. No chest pain, stridor, sob, tongue or lip swelling. Hx of allergies to pcn, iodine, sulfa, latex. Hx of rash and itching with pneumonia shot. No hx of anaphalxis to vaccines or meds - just itching and rash. VSS . 98 % RA 68. BP 177/84 (pt did not take her BP medication as of this mornig). Pt states she feels well but still itching as of 10:41. Pt appears to have the ability to make her own decisions and would like to talk to husband about going to ER. If pt still itching, recommend pt be evaluated. Pt would like d/w husband and physician prior to going to ER. EMS crew on standby. Note from ED: This is a well-appearing and pleasant 72-year-old female who presented via ambulance for itching response after receiving the Pfizer COVID-19 vaccine today. Patient is very well-appearing. Skin is normal and well-appearing there is no rash or erythema. Patient is speaking in complete sentences with normal work of breathing. Respirations are even and nonlabored. Lung fields are clear to auscultation bilaterally throughout patient denies any shortness of breath or breathing issues, cough or itchy throat. Airway is clear with no tongue or mouth swelling, floor mouth is soft and not elevated mandible is easily palpated, throat is nontender, neck is supple. Heart rate is within normal limits with regular rhythm. She was provided with Benadryl and famotidine as treatment for her itching. Patient was observed for greater than 2-1/2 hours in the emergency department. Patient noted that itching markedly reduced with use of Benadryl I felt patient was appropriate and stable for discharge. I had an in-depth discussion with her regarding she monitor her symptoms closely at home we discussed all symptoms that she should look for that would be concerning and she should make sure to seek emergent care. She was given the opportunity ask questions. All question concerns were thoroughly addressed. Patient indicated she felt good with her care here today with discharge and would monitor herself at home. She was picked up by her husband would also be home to monitor her. Advised her to follow-up with her primary care provider regarding recommendations for whether she should receive her second dose of the vaccine. Provided her with CDC printed out recommendations for vaccine allergic reaction. She was given the opportunity ask questions. All questions and

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							concerns were addressed and answered to the best of my ability. No evidence of Stevens-Johnson syndrome, anaphylaxis, cellulitis, or systemic compromise. Feel supportive care and symptomatic treatment reasonable. Urged dermatologic follow up. At time of discharge patient remained well-appearing not in any type of acute distress. She ambulated out of the emergency department with a steady gait. I reviewed recent and relevant Chart Entries, Previous Notes, Previous Labs, Previous Radiology studies.
1110294	3/18/2021	NY	17	M	3/17/2021	3/17/2021	Approximately 15 minutes after vaccination, recipient developed tightness in throat. Taken into ambulance by EMTs. Seen by doctor at 20 minutes post vaccine. Patient developed stridor and shortness of breath. Treated for anaphylaxis- IM epinephrine x2, IV dexamethasone, 250 mL normal saline bolus. Transported to emergency department by EMS.
1110016	3/18/2021		28	M	3/17/2021	3/17/2021	Received vaccine at 0900. At 2100, chills, body aches. At 2300, itching left elbow that progressed. Seen at 0600 next day and diagnosed with hives. No anaphylaxis. However, as precaution he was given epi, solumedrol iv, and Benadryl po. Patient discharged to room. He is in setting overseas.
1109964	3/18/2021	TN	48	F	3/17/2021	3/17/2021	10 minutes after shot first noticed increased pulse, then lips and tongue tingling/slight swelling. Throat tight. Some dizziness. Some chest pain. Some itching (especially scalp and sole of feet and then some on arms). Stayed where medical professionals could see me for about 2 hours. Took Benadryl about 3 hours later (after shot) and lingering symptoms mostly cleared up. 8 hours later still some itching and lips feel a little "off" still. Arm is normal vaccine sore. I have a strong history of repeated anaphylaxis (from MCAS) and this didn't get too serious compared to previous reactions I had to be hospitalized for.

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1110614	3/18/2021	VA	33	M	3/13/2021	3/13/2021	<p>Progress Notes R.N. (REGISTERED NURSE) ? ?</p> <p>Urology Patient is a 33 yr old male on 03/13/21 approximately 17:35 PM for 1st covid Pfizer vaccine Reviewed allergies and vaccine covid vaccine information provided to member. Allergies: Seafood, general rash, itchy and hives . 1st dose Pfizer given IM at 17:42 PM via left deltoid 5 minutes later started itching, redness bilateral hands Gen: Alert nontoxic No chest pain or dyspnea Pt denies Resp Distress Wheezing: no No SOB,tongue or Throat Swelling: no At :17:43 PM; 25 mg/10 ml liquid Benadryl given PO NDC # 0121-0978-10 Lot # 4EF Expired Date: 11/21 At 17:45 PM second dosef 25 mg /10 ml liquid Benadryl given PO Lot # C4EF EXP: 11/21 Blood pressure : 151/101, sat 98%, RR 16. (left arm) At 18:00 PM; Blood pressure 144/104, hr 79, rr 16. Sat 97%. Right arm blood pressure 140/94 No sob or wheezing, no chest pain No Throat swelling At 18:15 PM: developed macular/Papular rash through out upper and lower ext, with severe itching At 18:25 PM, Accompanied member to ER, report given to ER charge nurse Pt registered via call center staff at PM. Pt in room 7,ER waiting to be seen per ER provider Approximately 19:15 PM Report given to ER provider. Approximately 19:45 PM member moved to room 8, resting,on cardiac monitor, states feeling sleepy now. Mother and sister waiting in the waiting area in ER, they both were made awarded. Completed by: RN, March 14, 2021, 12:46 PM 20:00 PM Primary Director was informed Completed by: March 14, 2021, 12:48 PM Allergic Reaction</p> <p>SUBJECTIVE Patient is a 33 yr old male presenting with allergic reaction for approximately 30 min. Accompanied by nurse upstairs that administered vaccine and gave 50 mg of benadryl as well. o Associated sx: rash o SOB, Tongue or Throat Swelling: No o Exposure/Trigger: covid vaccine 5 minutes later started itching and with rash o Any treatment prior to arrival: antihistamines Relevant medical history reviewed/updated. ROS All other aspects of the 10 point ROS performed and negative other than the pertinent positives and negatives listed below and in the HPI GENERAL No fever, weight loss CARD No chest pain or dyspnea on exertion PHYSICAL EXAM Vitals: BP (!) 148/96 Pulse 83 Temp 98.8 °F (37.1 °C) (Tympanic) Resp 16 Ht 5' 6" (1.676 m) Wt 182 lb (82.6 kg) SpO2 98% BMI 29.38 kg/m² GEN Alert, nontoxic EYES PERRL, EOMI,</p>

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anicteric HEENT Lingual edema: No Hydropic Uvula:
 No Airway Patent: Yes Mucosal Lesions: No NECK
 Supple, FROM CARD RRR, No murmurs RESP RR nl,
 No Resp Distress Wheezing: none EXT Well perfused,
 no deformity NEURO A&Ox3, moving all ext SKIN
 Rash: Macular/Papular through out upper and lower ext
 Skin Desquamation: No ASSESSMENT/PLAN
 Evaluation most supportive of allergic reaction. o
 Evidence of anaphylaxis, respiratory distress or airway
 compromise: No o Concern for Stevens-Johnson
 Syndrome or Erythema Multiforme Major No Tx/Plan:
 o Benadryl 50 mg given immediately after vaccine
 administration o Solumedrol given here with
 improvement in rash and redness after 1 hour o
 Discussed taking prednisone for the next 5 days and
 benadryl q6 at home. o Do not get second
 vaccine. 03/13/21 2025 Other Notes All
 notes ED Notes from L.P.N. (Hematology and
 Oncology) ED Notes from L.P.N. (Hematology and
 Oncology) ED Notes from R.N. (z Urgent Care Facility)
 ED Notes from L.P.N. (Hematology and Oncology) ED
 Notes from L.P.N. (Hematology and Oncology)
 Additional Orders and Documentation Results Meds
 Orders Procedures Flowsheets Encounter Info:
 Detailed Report, History, Allergies, AVS, Mark As
 Reviewed This Encounter Vitals Recorded in This
 Encounter 3/13/2021 1824 3/13/2021 1825 3/13/2021
 1917 3/13/2021 1952 3/13/2021 1953 BP:
 163/102Abnormal 148/96Abnormal 138/88
 133/91Abnormal ? Pulse: 83 ? 62 69 ? Resp: 16 ? 18
 22Abnormal 21Abnormal Temp: 98.8 °F (37.1 °C) ? ? ?
 ? Temp src: Tympanic ? ? ? SpO2: 98 % ? 100 % 98 %
 ? Weight: 182 lb (82.6 kg) ? ? ? Height: 5' 6" (1.676 m)
 ? ? ? ? All Flowsheet Templates (all recorded)
 Acuity/Destination Custom Formula Data ED Assess ED
 Reassessment MD Initial Contact Neurologic
 Respiratory Assessments ER All Flowsheet Data ER All
 Flowsheet Data Results for all Tests ordered in this
 Encounter Results for all Tests ordered

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1107854	3/17/2021	NH	57	F	3/17/2021	3/17/2021	Pt has history of mast cell disease and has numerous medication, food and environmental allergies. She also develops histamine related reactions to stress. She has a history of recurrent anaphylaxis and carries an epipen. She notes that she felt anxious prior to the shot and developed lightheadedness several minutes after injection. Symptoms were mild to moderate but did not resolve. The pt declined EMS services and decided to go home after approximately 40 minutes. She is aware of the risks. BP 140/90, SP02: 98%, HR: 80
1107209	3/17/2021		77	F			Anaphylaxis reaction; A spontaneous report was received from a consumer concerning a 77 year old, female patient who developed Anaphylaxis reaction. The patient's medical history included allergies. Concomitant product use was not provided by the reporter. Vaccination details are not provided by the reporter. After she received vaccine developed Anaphylaxis reaction. Treatment for the event included steroid shot. Now her doctor says the shot is ineffective and she can't get the second shot. She wants to know whether that information true and she is willing to take second shot despite her doctors advice. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the event Anaphylaxis reaction was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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1107266	3/17/2021	MA	68	F	3/6/2021	3/6/2021	she was so tired; Rash on both arms and inside arms/Rash on Face/rash on front and back of knees; burning and itching with bleeding; swelling in lips; Blood in stool/she had blood in her stool, leaking blood around rectum and it had like a burning itch; Blood leaking around rectum/she had blood in her stool, leaking blood around rectum and it had like a burning itch; Face and Neck Burning/hot face and neck was flushed; hot face and neck was flushed; Tingling in tongue, lips, face; Tingling in tongue, lips, face; throat felt tight; lips were puffy; thought she was starting to shake; anaphylactic event; severe allergic reaction; This is a spontaneous report from a contactable consumer (patient) via Medical Information Team. A 68-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EN6199), via an unspecified route of administration in left arm (left shoulder area) on 06Mar2021 17:45 at SINGLE DOSE for COVID-19 immunisation. The patient had no additional vaccines administered on same date of the Pfizer vaccine. The patient had no prior vaccination within 4 weeks. Medical history included upset stomach after eating banana's last year (2020). There were no concomitant medications. The patient had no family medical history relevant to events. The patient previously took bactrim and pneumonia vaccine and experienced anaphylactic reaction to both. On 06Mar2021, the patient experienced anaphylactic event, allergic reaction, face and neck burning, hot face and neck was flushed, tingling in tongue, lips, face, swelling lips, throat felt tight, and lips were puffy. On 07Mar2021, the patient experienced rash, blood in stool, blood leaking around rectum, burning and itching with bleeding. The patient further reported that she had a 'serious life threatening event' after first dose of the Pfizer Covid 19 vaccine on 06Mar2021. Hospital papers say 'anaphylactic event.' Tingling in lips tongue and face, hot face and neck after vaccine, swelling in lips, rash started yesterday evening (07Mar2021), bloody stools for a few hours yesterday evening (07Mar2021) but has resolved. The patient was seen in emergency room (ER) via ambulance. The patient asked if there was a chance the preservative in the vaccine caused her reaction and if the potassium in the vaccine causing her anaphylactic reaction. Additionally, the patient reported that she had a severe allergic reaction this past Saturday

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to the Covid Vaccine, stated the nurse sent her back to the pharmacist who told her she was having an allergic reaction to the vaccine. The patient reported having a hot face and neck was flushed, after the vaccine, she stated she had tingling in her tongue, lips, and face. And she stated her throat felt tight also, her lips were puffy, and a lot of heat of neck and face, thought she was starting to shake. The patient reported the pharmacist gave EpiPen in thigh and 20 mg tablet of Benadryl and called 911, and took her to the local hospital. Patient also reported that she has not seen this doctor yet she asked to see her and has an appointment with her. The patient also stated that her new PCP was not aware of the reaction to the vaccine at this time. The patient further mentioned that she was still having a rash that broke out. She reported that her tongue was tingling and she still has some swelling in her lips. Patient continues to clarify she still has swelling and some tingling on the tip of tongue and half back on her tongue. She stated that the swelling was persisting and that Benadryl or Prednisone does give some relief but it comes back. Patient mentioned being on a 4 day cycle of Prednisone, takes two in the morning with food. The patient clarified the location of the rash as a rash on both arms that was inside of both of the arms, like a pink rash, she states it was on face and on knees around the front and back of her knees like a red rash. She continues it was on the neck down to the collar bone around the back of her neck, like if she was a bust statue it would be all in that area from the collar bones at that point up and around the back of the shoulder blades. It goes all the way around face and neck. Patient also further reported that she had a scary reaction last night (07Mar2021), she said she had blood in her stool, leaking blood around rectum and it had like a burning itch, when she wiped it was blood, she continued to say when she wiped it was like 'giblets.' She stated was stool, blood, and giblets. Patient stated this lasted for about an hour and half or 2 hours until the stool stopped and it was about 1:30 am before she finally went to sleep, she was so tired on an unspecified date. She stated she took Benadryl right away. She continued to report the bleeding has resolved completely as of this point and reported a regular bowel movement today (08Mar2021). She has two Epi Pens from the drug store that was prescribed but she was afraid to use it, and she thought to see what

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happens if she uses the Benadryl. She received the Epi shot at the drug store, at (pharmacy), when her reaction broke out, on 06Mar2021, in her thigh, for the allergic reaction. This was her first time ever receiving EpiPen (Lot 029F20AA, expiration Mar2022, and NDC is 0093-5986-27). The ER doctor prescribed her 0.3 mg every 5-15 minutes as needed for anaphylaxis, and not to exceed 3 doses. She received the Benadryl at the drug store, 120mg tablet, first dose was given at drug store. Patient reported she was given prednisone IV in hand through IV at ER, she doesn't know how much that was, then was given Prednisone to go home with- 20mg tablets take 2 a day for 4 days, which she started Sunday morning, 07Mar2021. She was told she experienced a life threatening allergic reaction. Patient was taken to the ER in the ambulance, the paramedic who was with her said she was his first COVID reaction patient. ER doctor told her not to take the second dose of Pfizer vaccine, and to be cautious if taking the EpiPen, she states her heart was racing because of the EpiPen and was told it was because she was not younger that her body did not handle the Epi like younger people do and was told she could have a heart attack from the EpiPen. She was scared because she was not covered fully, since she can't get the second shot of Pfizer, and she was afraid of the Epi Pen, so she was really in a tough spot. ER doctor stated she may be able to take the Johnson and Johnson vaccine, as the second, but she needs to talk to her Primary care about that. The ER doctor continued to tell her it would have to be a special case where she was in a hospital setting in case she has another serious reaction, she was concerned for not receiving the second dose because that means she was not completely covered with one vaccine. She was afraid of the Epi-Pen since she can get a heart attack from it because of her age. The patient mentioned she was tested in Oct (clarified as 14Oct2020) for Covid due to having a viral infection at that time but was negative. Added the ER paper work says ED anaphylaxis. The patient wanted to ask about finding out the ingredients in Pfizer vaccine and the ingredients in the Johnson and Johnson vaccine. She saw the list on the fact sheet of Pfizer's ingredients and in a few places it says Potassium, 3 different ingredients, and several months ago, she quit eating bananas, bananas have potassium, and they were giving

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							her stomach upset, diarrhea, she used to eat them all her life, she noticed that there was a lot of potassium in the medicine. Doctor wanted to know if she would be able to take the Johnson and Johnson vaccine. He said if she got the second shot, of the Johnson and Johnson, that it would have to be a special case, like in a hospital setting, and there would have to be medical people in a medical center, to take care of her was she has a reaction to it as well. He advised that she take the Johnson and Johnson than not taking it, because by not taking it, she was very vulnerable to catching COVID 19. And patient wanted to know was it a preservative that was causing the reaction. It was reported that rash began around 10PM, bloody stool began between 11 PM and 12:30 AM, all other symptoms within 15-20 minutes, it began around 6PM, maybe sooner 5:55 PM, she was in denial, it felt like tongue and lips tingling, she did have a reaction before to a different shot. The anaphylactic reaction required emergency room visit. Patient was not hospitalized and was in observation in ER. On 08Mar2021, the patient recovered from blood in stool, rectal bleeding, and burning and itching with bleeding. The patient had not yet recovered from severe allergic reaction, hot face and neck was flushed, tingling in tongue, lips, face; lips were puffy, and rash. The outcome of throat felt tight, thought she was starting to shake, she was so tired, and swelling in lips was unknown.
1107612	3/17/2021	NY	45	M	3/16/2021	3/16/2021	Pt started to feel slightly lightheaded about 10 minutes after vaccination, then started to have some tingling in his face. He received 25 mg of oral diphenhydramine with good results within 30 minutes. Pt has a h/o anaphylaxis to allergy shots as a child one time, but then never had a reaction again.
1107806	3/17/2021	MO	64	F	2/22/2021	2/25/2021	3 DAYS AFTER SHOT, LIP SWELL- NORMALLY FIRST STAGE FOR ANAPHYLAXIS SHOT. TREATED WITH CLARITIN TO REMOVE SWELLING. HAD PREVIOUS REACTION BEFORE. STILL UNDETERMINED WHY I STILL GET THAT REACTION AFTER NOT TAKING LISINAPRIL FOR MANY YEARS. 6 DAYS AFTER- TONGUE SWOLLEN ON LEFT SIDE ONLY- TREATED WITH CLARITIN TO STOP SWELLING

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1107943	3/17/2021	NC	33	M	3/11/2021	3/11/2021	2005: pt self reported new onset of visible rash - both arms. More pronounced on R side. Pt reports history of serious anaphylaxis to latex - resulting in intubation. Benadryl 25 mg offered. Pt Education brochure offered. No change in color, respirations. Pt reports felling well otherwise. Pt encouraged to remain an additional 30 min. 2014: no change in status. Pt stable. 2024: No change in status. Pt stable. No further progression of rash. 2040: Pt stable, no further progression of rash. Pt self discharged from OBS to home, stated feels fine.
1108043	3/17/2021	NY	18	F	3/11/2021	3/13/2021	Patient developed urticarial rash on 3/13/21 which began on her lower extremities and progressed to most of her body by the following day. She was seen on 3/15/21, and had no other symptoms besides the rash and was treated with zyrtec and benadryl but prescribed an EpiPen (Auvi-Q) in case of worsening. The next day, 3/16/21 she awoke with swelling in her mouth and worse rash, used her Auvi-Q and called 911 and was taken to ER where she was treated for anaphylaxis with IV solumedrol,, IV fluids and IV benadryl and was sent home on Prednisone and benadryl and Pepcid.

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1108431	3/17/2021	CA	43	F	2/11/2021	2/11/2021	After the first injection, I noticed mild mouth tingling, but nothing else, did not report as it was so mild and it was more notable in retrospect. A week after the first injection developed vertigo for the first time in my life. This lasted about a week had mostly resolved when I got the second dose. Immediately upon receiving the second dose I felt faint. I went to the observation area and when the feeling got stronger, reported it. My blood pressure was taken and although I always have normal blood pressure, it was extremely high - 195/100. My heart was racing. I was observed for longer because of this, and was asked to lie down. The faint feeling and high blood pressure lasted 30 min, at which time it started to improve and was sent home. I persisted in having bouts of feeling faint (but never fainting) in the days and weeks following, joined with shortness of breath which started the second day after the second injection. I also had the normal fever, aches and pains for 4 days. It is now a month after the second injection, and while the faintness and vertigo are mostly gone, I have persistent shortness of breath. Prior to the vaccine I had an albuterol inhaler that I would use 1-5 times a year for allergies. Almost never used it. I began having to use it multiple times daily after the second dose of the vaccine. I am not on a steroid inhaler. I have never had shortness of breath like this before. I was examined at the doctors office, not much can be seen that is wrong. An allergist believes that I did not have an allergy because my blood pressure was high instead of low as in anaphylaxis.

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1108768	3/17/2021		37	F	3/17/2021	3/17/2021	PT RECEIVED FIRST DOSE OF PFIZER COVID-19 VACCINE (LOT NO. EN6207, EXP 07/2021). FIVE MINUTES AFTER RECEIVING DOSE, PT COMPLAINED OF FEELING HOT, DIFFICULTY SWALLOWING, AND DIFFICULTY BREATHING. HX OF ANAPHYLAXIS AND CARRIES AN EPIPEN AROUND. PT RECEIVED ONE DOSE OF EPIPEN (LOT NO. 0FM407, EXP 02/2022). NO OTHER VACCINES RECEIVED WITHIN THE LAST 14 DAYS ON PATIENT'S RECORD. TRANSPORTED TO EMERGENCY DEPARTMENT FOR FURTHER EVALUATION. EMERGENCY DEPARTMENT VISIT TIME SEEN BY PROVIDER: 0958, 17 MAR 2021. CHIEF COMPLAINT: ALLERGIC REACTION. NO SKIN RASH, DIZZINESS, OR FAINTING EPISODE. HAD DIFFICULTY BREATHING BUT NOT HAD ITCHING OR SWELLING. SYMPTOMS STARTED PRIOR TO ARRIVAL AND IS STILL PRESENT BUT IMPROVING. VAERS REPORT: . PATIENT DISCHARGED FROM THE EMERGENCY DEPARTMENT AT 1143, 17 MAR 2021. CONDITION: STABLE. CLINICAL IMPRESSION: ANAPHYLAXIS DUE TO A DRUG.
1109226	3/17/2021	DC	46	F	3/14/2021	3/14/2021	I received my vaccine and then was told to go sit in the waiting area. After 5 minutes or so I noticed my throat feeling thick like it was swelling. I turned my head from side to side to make sure my throat was swelling (I've had anaphylaxis before). I got up and went to one of the people in the vests and they took me to the medical tent. They took my oxygen rate, blood pressure, and checked my heart rate. I was given (2) 25 mg of Diphen(Benadryl) . I was monitored till 4 pm when I was released.

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1109594	3/17/2021	OR	40	F	3/7/2021	3/7/2021	Called over to patient's car after vaccination where patient reported feeling flushed and with itchy hives over anterior neck. Denied SOB, throat scratching or closing, cough, chest pain/pressure, palpitations, or any other complaints. Reports feeling well and in usual state of health prior to vaccination. PMH significant for asthma and prior allergic reaction requiring epinephrine. No medications Allergies reviewed HR 94 with strong radial pulses RR 16 Alert and oriented, Pink warm dry - Mild raised erythematous wheals just inferior to bilateral earlobes. Nothing over anterior neck. No chest or back involvement. RRR with normal S1 and S2 Lungs CTAB Likely mild allergic reaction. Patient requested to take own Benadryl, and took 25 mg PO Benadryl. She was observed for an additional 20 minutes with improving symptoms and no further progression of rash. Patient reported feeling much better, and was accompanied by both parents (both RNs). She also was in possession of her Epi-Pen. Reviewed the signs and symptoms of anaphylaxis. Reviewed the indications for taking Epi-Pen. Reminded the patient that if she used her Epi-Pen OR if she was feeling worse in any way, I would strongly recommend evaluation in the Emergency Department. Reviewed that if she needed Epi-Pen, she should call 9-1-1 for immediate care and transport. Patient and parents expressed verbal understanding and agreement prior to leaving the vaccination site at patient request. (Patient was not the vehicle driver.)
1107682	3/17/2021	FL	76	M	2/27/2021	2/27/2021	Anaphylaxis Pulmonary embolism
1105254	3/16/2021	SC	42	F	3/9/2021	3/9/2021	Itchy red bumpy Rash (hives) on cheeks, ears, necks started 10 hours post vaccination, being treated with Benadryl (oral antihistamine), still present 7 days later but less intense, no signs of anaphylaxis Also, Sore arm within an hour, lasted for 36 hours

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1105532	3/16/2021	NM	41	F	3/13/2021	3/13/2021	Anaphylaxis. Initially, pt experienced palpitations and tightness in throat after vaccination and wasn't sure if she was experiencing swelling in her arms. BP was 130/79 and HR 93 initially. Pt started to feel better without intervention but given diphenhydramine as a precaution while we continued to monitor her. 10 mins later she started to have tingling in lips and tongue and visible lip swelling in addition to palpitations. Immediately administered Epipen (0.3mg) x 1. EMS was called. No worsening but not improvement after 5 mins so a second dose of Epipen (0.3mg) was administered. By the time EMS arrived (9 mins after first epipen dose) pt was feeling better, swelling had resolved, no throat tightness. Pt was transported to local hospital by EMS for monitoring.

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1103796	3/16/2021	MN	36	F	3/11/2021	3/11/2021	Allergic Reaction to first COVID shot, manufacturer unknown, given with public health, required field to pick a manufacture. 36-year-old female that is in the emergency room for concerns of reaction to COVID vaccine. At 11:00 a.m. this morning she received her 1st dose of the COVID vaccine and began to feel her throat closing. Immediately she received 1 dose of IM epinephrine. Approximately 15 minutes after that she received a 2nd dose of epinephrine by IM. EMS was activated and she was brought to the emergency room. She was stable and received 50 mg of Benadryl by IV during transport. She denies shortness of breath or nausea. was rather concerning that her chest pressure began after the administration of the epinephrine. She denies shortness of breath, nausea, or other concerning findings for anaphylaxis minus the throat swelling. It is unclear whether this was truly anaphylaxis or other. Upon arrival to the emergency room she was rather stable and a thorough workup was initiated. With her reports of the chest pressure I felt that a cardiac workup was indicated with concerns that the epinephrine may have caused her a cardiac event. Initial troponin was negative, and a 2 hour troponin was warranted as her symptoms were less than an hour prior to arrival to the emergency room. The 2 hour troponin did show a delta of 16 and changing. At this time I informed the patient of the results and recommended a 6 hour troponin. She was understandable and willing to comply. She did have a low potassium at 2.9 and received to 40 mEq doses of oral potassium replacement. Her magnesium is 1.6, and a corrected magnesium was calculated at 1.78 with her albumin at 4.4. The patient was stable and comfortable throughout the evaluation in the emergency room. She did not exhibit hypotension, nausea, vomiting or other concerning findings for anaphylaxis. She did receive Solu-Medrol, and Pepcid while in the emergency room. I did consider administering Benadryl, but she did receive 50 mg of IV Benadryl in the ambulance on the way to the emergency room. The 6 hour troponin was reassuring and unchanging. The patient was then discharged home with follow-up precautions and instructions follow-up with a primary care provider.

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1104297	3/16/2021	CT	62	F	3/15/2021	3/15/2021	Allergic-Anaphylaxis Itching 17 min after administration, redness, rash, chest pressure under heart. Facility called 911 administered Benadryl via IV transported to ER Once in ED given EpiPen at 2:21 and Decadron @ 6:05, discharged at 6:00 pm
1104811	3/16/2021	FL	47	M	3/16/2021	3/16/2021	On 3/16/21 at approximately 12PM a middle-aged male patient came in to get his first dose of Moderna vaccine. I took in this patient into the IMZ room to give his vaccination and reviewed his form he filled out. On the question related to "have you ever had a reaction to a vaccine (fainting/dizzy)" the patient answered "No". The patient walked outside to the waiting area and sat down to begin his 15mins, at that point another customer yelled for medical attention for him because he passed out in the chair. I ran out with an EpiPen in case it was anaphylaxis. After I got outside the patient regained consciousness in the matter of seconds but was still dazed/confused and I applied a cold compress to the back of his neck and gave the patient some water to drink while feeling for his pulse in the wrist. He began to lose his color/pallor in his face again for a second time at that point I told my technician to call 911, after we dialed them, the patient came back to fully again this time and all color was restored to his face and he was fully conscious this time and able to speak in complete sentences. He wanted me to cancel the 911 call and since he came back to consciousness again in the matter of seconds so we canceled it. I made the patient wait an extra 30 minutes to observe him and he was fine from there on out, his wife was accompanying him and stated he has done this in the past for vaccines (despite answering no in the assessment form) and said she will be driving him home and checking in with his doctor later.
1103680	3/16/2021		51	F	3/15/2021	3/15/2021	Anaphylaxis; Severe Angioedema of lips, tongue, eyelids. Hypoxemic Respiratory Distress, O2 88-89% on presentation. Chest pain/tightness. Epi pen, IM, minimally responsive. Epi gtt, IV steroid, dual histamine block. IVF bolus x2L. HF O2 support, via non RB. Pt with slow response to above intervention, but remained hemodynamically stable and with improvement to respiration/oxygenation and angioedema over about 1 hour. while patient prepared for transfer to higher level of care.

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1105870	3/16/2021	PA	30	F	3/13/2021	3/13/2021	Pt had itchy throat, tight throat, sense of doom at 30 min obs mark. Was given EPI and transferred to local ED. Had rebound anaphylaxis days later (3 days after) resulting in 2nd ED trip.
1106166	3/16/2021	LA	70	F	2/24/2021	2/1/2021	Blood pressure up and down; Vaccine was purple and not clear in vial; A spontaneous report, was received from a consumer (patient), a 70 years-old female patient, unknown race and ethnicity, who was administered Moderna's COVID-19 vaccine (mRNA-1273), and experienced blood pressure up and down (blood pressure fluctuation), and vaccine was purple and not clear in vial (product colour issue). The patient's current conditions included allergy to dye and anaphylaxis. Concomitant medications were not reported. On 24 Feb 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Batch number: 012M20A) intramuscularly for the prophylaxis of COVID-19 infection. On an unknown date in Feb 2021, after receiving the vaccine, the patient had her blood pressure up and down. The patient stated that the vaccine was purple and not clear in the vial on 24 Feb 2021, and still the pharmacist gave her. The patient was hospitalized for her blood pressure fluctuations. Treatment information was not provided. Action taken with second dose of mRNA-1273 in response to the events was not provided. The outcome of the event, blood pressure up and down was not reported and that of event vaccine was purple and not clear in vial was recovered on 24 Feb 2021. Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start of the event, a causal relationship cannot be excluded. Further information has been requested.

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1106405	3/16/2021	AK	55	F	3/16/2021	3/16/2021	After the patient's 15 minute wait, she left the facility, only to feel like her legs were "weak." She was brought back to the facility to sit down and recover. After several minutes, the patient stated that he throat felt itchy, and she began to cough and described dyspnea. She also developed nausea. She denied cutaneous symptoms, but with her multiple symptoms that were consistent with anaphylaxis, the patient was administered an EpiPen. Her symptoms did not improve, and 16 minutes later she was administered another EpiPen (as well as 25 mg of diphenhydramine). She was transported via EMS to the base ER for further treatment and evaluation.
1106764	3/16/2021		23	F	3/16/2021	3/16/2021	23 yo F with h/o POTS who was feeling fine until about 25 minutes after the vaccine at which time she developed shortness of breath, chest tightness, flushing sensation, lightheadedness with sense of impending doom and abdominal cramping. Reported she felt similar to when her POTS flares up, but that only occurs with standing which she hadn't done. HR 126 and BP 174/93 and repeat was 132 and 152/113. Oropharynx appeared normal but she appeared pale and very weak, and slumped over in the seat of the car. 911 called and EpiPen and IM Benadryl given with some improvement of symptoms. BP continued to be hypertensive and HR tachycardic. O2 sats remained stable at 99%. With her overall symptoms, concern for anaphylaxis, although her symptoms were likely multifactorial - POTS, anxiety.
1107295	3/16/2021	MN	68	F	3/16/2021	3/16/2021	within several minutes of receiving Moderna, pt c/o coughing spells and SOB, no angioedema or hives. Self-administered albuterol neb she had brought with at 3:30. Some improvement, benadryl 50mg given at 3:38. Pt initially continued to improve and was monitored. At 3:48 writer entered the room to find pt bent over stating "I can't breath", was pale. EpiPen administered. Within minutes pt had improved, breathing easier, lungs clear, there was never any oral swelling. EMS arrived and transported pt to ER. of note, pt was given red liquid benadryl as it was all we had; she stated she had a history of sensitivity to red dye but not anaphylaxis, just will "feel sick" the next day

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1104396	3/16/2021	MA	54	F	3/11/2021	3/11/2021	<p>Background Patient received her 1st dose of Moderna: 2/11/21 2nd dose of Moderna: 3/11/21 Number of days post vaccine (today's date minus vaccine date): 5days Initial reaction was noted on 2/11/21 Symptom Screening Local Reaction S/p 1st dose: 2/11/21: Pt noticed redness, "looks like hives." on the left arm (on the injection site) and disappeared on its own 2 days later. Denies any SOB, breathing issues, lips or eyes swelling or any other concerning s/sx. "I felt fine."</p> <p>Systematic Reaction: S/P 2nd dose: Sxs Onset 3/11/21: Low grade fever: 99.8, headache, fatigue," jittering feeling." Pt stated. "All the symptoms went away on its own on 3/12/21 around 2 pm except the "jittery feeling." Today on day 5 S/P2nd dose: Pt still continues to feel "jittery and hyper at times." Denies any anaphylactic reaction, dizziness, headache, fever, chills, breathing issues or any chest pain/discomfort. Denies any other unusual S/SXs. Pt was able to speak clearly in full sentences. No distress noted. Pt is at work right now.</p> <p>ALLERGIC Reaction Did potential immediate allergic reaction (less than 4 hours after receiving vaccine) or anaphylaxis to first dose of the COVID vaccine occur? "Not exactly sure. Pt unable to express if it was an actual hives or just redness at the injection site." Within 24 hours of vaccine administration, did patient experience symptoms of a severe allergic reaction? "Not exactly sure. Pt unable to express if it was an actual hives or just redness at the injection site." Assessment/Action Patient experienced a Moderate reaction to the vaccine. Symptoms relieved with over the counter medications. No medication needed. Sxs resolved on its own expect the "Jittery and hyper feelings." Patient answered YES to mild-mod Allergic Reaction questions. Patient was referred to allergy clinic for further evaluation. VAERS Complete: Yes. Patient experiencing any COVID-19 Symptoms AND >3 days post vaccine? NO</p> <p>Response/Recommendation Teaching -Provided education to patients per DPH guidelines as appropriate to the patient's clinical presentation. -Educated the reasons to call the MGB Nurse hotline, PCP office and the reasons go to the nearest ED if symptoms change or worsen. -Informed to make sure to call in advance if seeking medical care so sites can be prepared to receive the case. -Good verbal return and agreed with the plan.</p>

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1105557	3/16/2021	KS	36	F	3/16/2021	3/16/2021	<p>Progress Notes APRN (Nurse Practitioner) Family Medicine COVID VACCINE CLINIC 3/16/2021</p> <p>Subjective Patient is a 36 y.o. female who was seen at COVID Vaccine Clinic today for her second dose of the COVID 19 vaccination. She was given the Pfizer vaccination in the right deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience lightheadedness. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, dizziness, facial swelling, lip swelling and tongue swelling. This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to blood pressure abnormality, chest pain, collapse, rapid progression of symptoms, respiratory distress and skin changes. PMH includes asthma (on Symbicort and albuterol). Takes zyrtec daily for seasonal allergies and on Wellbutrin for mood stabilizing. She did not eat or drink anything today other than coffee. She has not taken her zyrtec or albuterol dose today. ALLERGY REVIEW OF SYSTEMS: Patient denies chills, fever, malaise/fatigue, facial swelling, sore throat, frequent throat clearing, eyes watering, eyes itching, cough, chest tightness, shortness of breath, wheezing, rash, hives, itching of skin, vomiting, abdominal pain, muscle aches, joint pain, dizziness and headaches Previous Reactions: none to vaccines. Hx of anaphylaxis to sulfa and cephalosporins.</p> <p>Objective Vitals Vitals: 03/16/21 0955 03/16/21 1015 BP: 127/73 127/64 Pulse: (!) 101 80 SpO2: 100% 100% Physical Exam Constitutional: General: She is not in acute distress. Appearance: Normal appearance. She is well-developed. She is not diaphoretic. HENT: Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Eyes: Extraocular Movements: Extraocular movements intact. Conjunctiva/sclera: Conjunctivae normal. Pupils: Pupils are equal, round, and reactive to light. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. No respiratory distress. Breath sounds: Normal breath sounds. No wheezing. Skin: General: Skin is warm and dry. Neurological:</p>

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							General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Gait: Gait normal. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. Thought Content: Thought content normal. Judgment: Judgment normal. Assessment/Plan Treatment included: water and snacks Follow up response to treatment: excellent. Patient discharge: Stable to go home and follow up with PCP. Differential Diagnosis: Red flag symptoms (CP, SOB, NVD, Visual/Neuro concerns) Lightheadedness R/t probably not having breakfast this am along with stress response of vaccine. Recommend rest, continue to hydrate today and eat well. Follow up with pcp as needed. APRN Electronically Signed 03/16/2021 10:03 AM
1102055	3/15/2021		23	F	3/15/2021	3/15/2021	23 y/o female presents with nausea, vomiting, and shortness of breath since just after lunch time. SM reports 3 episodes of emesis, she ate fish for lunch. +wheezing/shortness of breath. Pt received Janssen COVID vaccine at around 0900 hours this morning. She did experience some fatigue a couple hours after vaccine. No other medications or allergies. PE pertinent for wheezing b/l on lung exam. VS normal. Due to current presentation and history suspect anaphylaxis 2/2 COVID vaccination. Pt given Epinephrine auto-injector in clinic, after which she reported resolution of wheezing and improved ability to take a full breath. Heart rate elevated to 124 BPM with BP of 142/95 and SPO2 stable at 100%, these VS subsequently normalized. Pt also given 125mg solumedrol and 50mg Benadryl both IV. Due to concern for progressive deterioration will transfer Pt to ER for improved monitoring and potential for other emergent treatment.

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1100309	3/15/2021	MA	28	F	1/9/2021	1/10/2021	Swelling and pain of left supraclavicular lymph node approximately 18 hours after second dose/left axillary node temporarily swollen; Swelling and pain of left supraclavicular lymph node approximately 18 hours after second dose; Left supraclavicular node is no longer painful, but still swollen and palpable (moveable); This is a spontaneous report from a contactable other hcp (patient). A 28-year-old non-pregnant female patient received 2nd dose of bnt162b2 (lot number: EK4176), via an unspecified route of administration in the left arm on 09Jan2021 11:45 at a single dose for COVID-19 immunization. Medical history included allergies: shellfish- severe GI response (not anaphylaxis) from an unknown date and unknown if ongoing. Concomitant medication included desogestrel, ethinylestradiol (APRI), colecalciferol (D3), paracetamol (TYLENOL) and unspecified multi vitamin. The patient did not receive other vaccine in four weeks. The patient previously received 1st dose of bnt162b2 (lot number: EH9899) on 19Dec2020 11:30 AM in the left arm for COVID-19 immunization. On 10Jan2021 06:00, patient experienced swelling and pain of left supraclavicular lymph node approximately 18 hours after second dose. Also left axillary node temporarily swollen. Left supraclavicular node is no longer painful, but still swollen and palpable (moveable). Outcome of events was recovering. The patient underwent lab tests and procedures which included Nasal Swab: negative on 15Jan2021. The events resulted in: Doctor or other healthcare professional office/clinic visit. No treatment was given for events. The patient was not diagnosed of covid prior vaccination.

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1100482	3/15/2021	MD	46	F	2/13/2021	2/13/2021	Throat swelling; severe allergic reaction to the Pfizer vaccine; chills; sweats; nausea; This is a spontaneous report from two contactable physicians. A 46-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9267), via an unspecified route of administration on 13Feb2021 at a single dose in left arm for COVID-19 immunization. Medical history included herpes Simplex I, back pain, SI joint dysfunction, difficulty sleeping and allergy to raw tomatoes. The patient's concomitant medications were not reported. On 13Feb2021, the patient experienced throat swelling, severe allergic reaction to the Pfizer vaccine, chills, sweats, nausea, the seriousness of throat swelling, severe allergic reaction was reported as hospitalization, seriousness of the other events was reported as medically significant. Under anaphylaxis that the patient has EpiPen at home for raw tomatoes Clinical course: she had a severe reaction to the first shot presenting the following side effects: chills, sweats and nausea within 5 minutes and then developed throat swelling within 10 minutes, the patient was administered with an EpiPen, Benadryl and was sent to the ER where she received Benadryl IV monitored, eventually her symptoms diminished from 10 of 10 to a 6 in a scale of 10, the patient also received Prednisone 40 mg everyday for 4 days. She did have nausea and sweats. It was six out of ten in the ER. Then it went to four or five out of ten. It took four to five days to get back to normal. By five days after the vaccination she was back to normal. She had a virtual visit with a patient who apparently had a severe reaction after the first vaccine. It was set up in physical therapy office. HCP wants to know if it is safe for the patient to receive the second dose of the vaccine. HCP mentioned that this is her first patient who has a severe allergic reaction to the Pfizer vaccine. She was feeling better. She was told to call her doctor about getting the second shot. The bottom line is if they acted as severely as they did she would think the answer would be not to get the second. She was better. She felt fine. She has an allergy to raw tomatoes. She knows she is not supposed to have raw tomatoes. A couple of days ago she had a dressing that must have had raw tomatoes in it because she had throat swelling. The patient said what happened with Pfizer was more. She knew it when it was happening because it has happened before. She

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had no hypoxia. The patient reported that her pulse ox was checked and was in the high 90's. The patient was able to swallow. No drooling. She did have nausea and sweats. It was six out of ten in the ER. Then it went to four or five out of ten. It took four to five days to get back to normal. By five days after the vaccination she was back to normal. On 23Nov2020, the patient weighed 150 pounds and her height was 66 inches. The outcome of events was recovering. There is a causality, because it happened with 5 to 10 minutes after receiving the vaccination. She had to wait for 15 minutes. The patient had chills, sweats, and nausea within 5 minutes. She felt fine upon immediately receiving and then within 5 minutes she had chills, sweat, nausea, headache. Then within 5 to 10 minutes throat swelling. There is a causality, because it happened with 5 to 10 minutes after receiving the vaccination. She had to wait for 15 minutes. The patient had chills, sweats, and nausea within 5 minutes. She felt fine upon immediately receiving and then within 5 minutes she had chills, sweat, nausea, headache. Then within 5 to 10 minutes throat swelling.;

Sender's Comments: Based on known safety profile and temporal association, the contribution of the suspect drug to the onset of events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

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1100877	3/15/2021	VA	42	F	3/10/2021	3/10/2021	Patient reported arms and legs being itchy approx. 10 min post-injection. Administered 50mg Benadryl orally. Patient also complained of tightness in throat, which improved after Benadryl. Vitals did not indicate anaphylaxis, continued to monitor BP over course of symptom reporting. Also applied ice pack to left forearm and back of neck. EMTs arrived to check vitals and reported no signs of anaphylaxis, inquired if patient wanted to return home or wanted to get higher level of care, and she chose to go to the hospital. There, the providers found no emergent medical issues. Nurse called and checked on patient 4pm same day, the patient reported no issues and all concerns were resolved.
1101660	3/15/2021	CA	71	F	3/9/2021	3/9/2021	moderate anaphylaxis - body shaking, rapid heart beat, high and fluctuating blood pressure, immediate dry throat and feeling of dehydration, stomach cramps followed by diarrhea about half hour after onset. Symptoms eased after 30-40 minutes so that I could get home and then diarrhea and weakness and shakiness for 3-4 hours. No epi pen administered because breathing was ok
1101760	3/15/2021	NC	36	F	3/10/2021	3/10/2021	Patient with anaphylaxis to COVID-19 vaccine. Onset of symptoms occurred five minutes after receiving vaccine. Urticarial rash occurred on chest and abdomen. Shortly after, she developed a wheeze. EMS was onsite so they administered methylprednisolone, diphenhydramine, Zofran, Phenergran and epinephrine IM. Second and third dose of epinephrine was administered due to partial response from previous doses. Patient was taken to Health care hospital for further evaluation and treatment.
1102236	3/15/2021	SC	55	F	12/26/2020	12/26/2020	Immediate tachycardia, tingling in throat and mouth, hypertension. Treatment in ER. Anaphylaxis protocol. Days later nausea w dizziness. By day 6 sudden onset of vertigo, diagnosed as vestibular neuritis. PT, supportive meds, continued dizziness.
1102479	3/15/2021	GA	28	M	3/10/2021	3/10/2021	About 40 mins after I felt my throat closing and felt like I couldn't breathe. Since then I have had several other instances of feeling similar (though none of them went to full anaphylaxis. I went to the ER Saturday and my PCP today, still for shortness of breath.

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1103262	3/15/2021		38	M	3/10/2021	3/12/2021	allergic reaction. Rash, itchy to BLE and BUEs x 2 days with swelling; pt reports mainly in joint areas, getting worse today and spreading; received J&J vaccine on 10MAR21. Rash with redness and itchiness to BUEs/BLEs; no pain; patent airway. MDM: Pt does not have anaphylaxis. The temporal relationship to COVID vaccine is suspicious. Will treat as allergic reaction. F/u and return precautions discussed.
1103663	3/15/2021	OR	43	F	3/13/2021	3/13/2021	Anaphylaxis: Closing throat, swollen mouth, sore throat, difficulty swallowing, difficulty breathing deeply, itchiness in mouth, blotching of skin

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1104431	3/15/2021		83	M	1/19/2021	1/20/2021	Cardiac arrest Narrative: An 82 year old, male, resident of a facility, received his first dose of the Pfizer COVID vaccine on 12/30/20 (time of dose not known). On 12/31/20, patient was reported to be febrile with increased lethargy and UTI was suspected so patient received a dose of ceftriaxone and levofloxacin. Within 30 minutes he became wheezy and short of breath, developed hives and tongue swelling. He required intubation and admission for treatment of acute respiratory failure, acute kidney injury and significant lactic acidosis. Treatment included epinephrine, H1 and H2 blockers, and steroids. He recovered and was extubated on 1/3/21 and discharged back to the facility on 1/6/21. Attending physician noted that antibiotics were most likely contributor to event, but recommended that patient not receive the 2nd COVID vaccine dose. Patient was referred to an allergist to assess this event, with an outpatient visit on 1/14/21. Patient expressed interest in receiving the 2nd dose. Allergist determined that the antibiotics were the cause of anaphylaxis, and recommended skin testing to take place 6 weeks after his reaction. Allergist determined the reaction was not due to the COVID vaccine and advised patient that he could receive the 2nd dose. Patient received the 2nd dose of the Pfizer COVID vaccine on 1/9/21 (time not known). Notes from the facility indicate patient was lethargic and running a fever the morning of 1/20/21. At 1500 on 1/20/21 patient was noted to be lying supine in bed, visiting with aides. At 1508 nurse entered room and noted patient to be lying on floor supine and nurse was unable to get patient to respond to shaking or calling his name. Breathing was noted to be labored, and nurse was unable to detect a pulse. At 1509, 911 was called and CPR initiated. Spontaneous pulse and breathes resumed just before ambulance arrived at 1522. On arrival at the ED patient was responsive and breathing spontaneously, however, hemodynamically unstable. Patient went into cardiac arrest and code blue called at 1535. Received treatment with epinephrine, methylprednisolone, diphenhydramine, amiodarone, atropine. Patient was intubated. EKG obtained and showed acute MI. At 1622 he again went into cardiac arrest and time of death was called.

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1101682	3/15/2021		65	F	3/4/2021	3/4/2021	Full anaphylaxis, Vertigo, Blood Pressure spike to 200 and it lingered there. Sent immediately to Hospital. Was administered IV Benadryl and Prednisone. Slept for three hours. BP dropped to 165 and was released with Benadryl and Prednisone to take for the next four days. Next several days of nausea, diarrhea, fever, weakness, shakes. No energy. Not feeling well until March 14th.
1099093	3/14/2021	WV	41	F	3/11/2021	3/12/2021	On Saturday 03/13/2021 the patient's mother contacted me. Due to the patient having a mental disability, the mother described the event. She stated the patient's arm became very red, swollen, hot, and painful the day after vaccination. I asked if the patient was having any trouble breathing other signs of anaphylaxis to which the mother responded "no." I instructed the mother to give the patient Benadryl and to use a cold compress to help with the reaction. I also told the mother if the patient's condition worsened, showed signs of anaphylaxis, or didn't improve within 3 days to go to her doctor. On Sunday 03/14/2021 the patient and her mother came to the store and the mother asked me to examine the patient's arm. There was a noticeable rash 6 inches in diameter. I felt the arm in comparison to the other arm but did not notice any hardening or warmth. The mother stated the patient's arm seemed to be improving from the previous day, but that the arm was still red and painful. At this time, I advised the mother to draw a line around the rash; if it got bigger, she needed to go to the hospital, but if it got smaller that was a good sign that the condition was improving. I instructed the mother to continue giving the patient Benadryl and using a cold compress. I also advised that the patient should still receive the second dose of the series, because this was not an anaphylactic reaction. I also advised the patient to pre-medicate with Benadryl before the second dose. I told the patient I was going to follow up with them in a few days.

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1099155	3/14/2021	PA	58	F	3/14/2021	3/14/2021	While patient was sitting in chair waiting her 15 minute monitoring period in post- immunization waiting area patient fainted. Patient did not fall down or was she injured by fainting. Patient slowly rolled off chair and patients friend helped lower her to floor where patient regained her awareness . Pharmacist raced quickly to be by patient's side to monitor her vitals and to see if an allergic/ anaphylactic reaction had occurred. No symptoms of an allergic reaction or anaphylaxis was observed by pharmacist. Patient quickly regained her awareness and stated that fainting is common to her when routine blood work, injections, giving blood, etc.. Patient stated that fainting is something that has occurred several times in her past. No signs of allergic reaction, redness, hives, facial swelling, cardiovascular collapse were observed by pharmacist while closely monitoring her vitals after 911 was called. EMTs and paramedics arrived quickly and after closely examining patient and talking with her it was decided by Paramedics that patient fainted due to an emotional response by patient and there was no allergic reaction or anaphylaxis to report, nor any injury sustained by patient after fainting. Patient was quickly back to normal, and she verbally declined ambulance. Patient stated that she felt fine and that she was going to do some shopping and return home to relax.
1098907	3/14/2021	NE	44	F	3/12/2021	3/12/2021	Patient received vaccine and after checking on her in about 10 minutes, she reported that her tongue felt weird, kind of tingly. I said I wanted to give her benadryl and patient refused. Sat with patient and she reported no changes, just felt different and tingled a little. Patient stated that it did not feel like allergic reactions she has had in the past. Checked tongue and lips for swelling, no sign of anything like that or other signs of anaphylaxis. By the end of allotted 30 min waiting period, patient said she felt normal again. She stayed in the store for another 30 minutes and reported back that she was fine.

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1098606	3/14/2021	CT	55	M	3/14/2021	3/14/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Medium, Systemic: Chills-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Fainting / Unresponsive-Medium, Systemic: Shakiness-Medium, Systemic: Weakness-Severe, Additional Details: note: pt stated no allergies on form and when asked verbally by immunizer. at the 7 minute mark he began to exhibit weakness and started falling off his chair. seemed like he was going to pass out. his breathing seemed labored. we position pt on floor, rph admin epipen to left outer thigh. 911 called. ems responded. pt felt better after epipen. bp, hr normal. pt taken to er by ems
1098051	3/14/2021	NY	71	F	3/13/2021	3/13/2021	Patient experienced shortness of breath and anxiety within 15 minutes of vaccine administration. No indications of anaphylaxis. EMS assessed client and released to home.
1098011	3/14/2021	VA	49	F	3/13/2021	3/13/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: Numbness (specify: facial area, extremities)-Medium
1097962	3/14/2021	SC	24	F	3/13/2021	3/13/2021	Patient developed shortness of breath, tachycardia, epigastric and chest pain. A thorough workup was performed to search for other causes and none was found, ultimately patient was treated as moderate anaphylaxis, symptoms improved with fluids, steroids, benedryl, and she was discharged with strict return precautions and outpatient followup.

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1097912	3/14/2021	TX	28	F	3/8/2021	3/8/2021	<p>Symptoms: Fainting, Unconsciousness (repeatedly), Profusive Sweating, Low Blood Pressure (60 over unknown number), Nausea, Dizziness, Unable to stabilize quickly, not able to get an IV, extreme thirst</p> <p>Signs: Immediately felt unwell within 5 minutes of the vaccine. Time Course: Injection (1st dose - Pfizer) at 4:00pm. Adverse Reaction at 4:05/4:10 (est.) Released at 5:00pm (est.) Description of Incident: On March 8th, at 4:00 pm, I received my first dose of the covid vaccine. Within 5 to 7 minutes, I felt unwell while sitting in the waiting area. I walked towards a worker to inform them that I was feeling unwell and that I was going to pass out. I became unresponsive and laid on the ground. My husband was with me at the time. I was unconscious for a bit and when I regained consciousness, my legs were being raised. I regained consciousness and was able to recall my name, DOB, and address. After I was done recalling my information, I began to lose consciousness again. They brought a wheelchair and took me to the medical room. As I moved from the wheelchair to the bed, I began to lose consciousness again. They told me to lay down. I overheard a woman ask my husband if I had diabetes or heart problems. He answered "No.". She explained to him that my body did not know how to accept the vaccine and was trying to regulate back to normal. She explained that my body was going through "homeostasis" (?). While I laid on the bed, some workers took my blood pressure and tried to start an IV. One of them made a comment and said I was extremely dehydrated. This was odd to hear because I normally drink 3 to 4 liters of water daily. During this entire medical event, I felt the water pushing out through my pores. I was drenched in sweat. He tried to start an IV on my left arm and was unsuccessful. He tried to start an IV on my right hand, which was also unsuccessful. He stated they were unable to start IV liquids because my veins kept popping/collapsing. My blood pressure was reading 60. They checked it again, still at 60. I laid in the bed and basically waited it out. After a few minutes, they checked my blood pressure at it was at 120. They said that was good and I was good to go. No report was given to me nor my husband about the event that occurred. Even after they agreed to let me use a wheelchair (due to feeling weak), one was not provided to me. They basically stated that I was "good to go", after doing a</p>

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							series of hand squeezes and walking a few steps upright. I am currently trying to obtain a copy of the report I saw the gentleman fill out at the time. I was given Zofran to help with my nausea, it was placed under my tongue. After going home, I felt weak, tired and somewhat lightheaded. My husband drove me home and I got some rest. I set an appointment with my doctor on Friday March 12th to determine what happened to me during my vaccine and to record the incident. After describing the incident, she determined that it was anaphylaxis. She recommended for me not to get my second dose due to the anaphylactic shock I experienced with the first dose. She was shocked to learn that they did not transport me to the hospital or provided an Epi Pen injection. When asked why I didn't drive myself to the hospital, I let her know that they told me I was 'good?'. They did not explain what had occurred to me, no mention of anaphylaxis was explained. I was not aware that is what had occurred. The incident occurred from 4:00pm (injection time) to 5:00pm (left location).
1098608	3/14/2021	FL	50	F	3/14/2021	3/14/2021	Systemic: Allergic: Anaphylaxis-Medium
1097100	3/13/2021	TX	28	M	3/12/2021	3/12/2021	Anaphylaxis. High temp, swollen face, throat, eyes, chills, Required ER visit
1097835	3/13/2021	IL	44	F	3/12/2021	3/12/2021	Pt walked up to staff c/o itchy & swelling to throat & tongue. Staff assessed pt & vitals. Pt presents with anaphylaxis & hypertension. Staff gave ALS care and administered 50mg Benadryl IM & EPI 0.3 mg IM. Due to no improvement, staff gave O2 prior to 2nd EPI dose. Staff transported pt to Hospital. EOR.
1097070	3/13/2021	IA	53	M	3/10/2021	3/10/2021	Patient had 1st dose of pfizer and 45-60 minutes later had anaphylaxis in which an epipen was administered. Patient was taken via ambulance to The hospital
1097122	3/13/2021	IA	50	M	3/10/2021	3/10/2021	Patient had anaphylaxis to first dose of Pfizer vaccine - Epipen used
1097361	3/13/2021	CA	71	F	3/12/2021	3/12/2021	Anaphylaxis within 5 min of injection. Treated with 2 doses Epi pen, IM Benadryl 50. Transferred via ambulance to ED. More drugs Decameron, Pepcid. Observed 6 hours. Discharged to home with instructions and meds Benadryl and Pepcid. Recovering at home.

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1097625	3/13/2021	VA	33	F	3/13/2021	3/13/2021	Patient immediately developed respiratory distress and wheezing concerning for anaphylaxis. Was given an IM injection of epinephrine alone with albuterol nebs which didn't improve her symptoms. She was not responsive to 4 albuterol nebs and an epinephrine drip and ultimately require intubation and mechanical ventilation. She stabilized on the ventilator but required a MEDEVAC to a civilian hospital for ongoing care.
1097761	3/13/2021	WA	49	F	3/13/2021	3/13/2021	Patient has prior allergies to other medications, never had to use epinephrine. Past allergies include: Percocet, tramadol, Toradol and latex tape. Patient stated she has some full budding numbing experience but no anaphylaxis. We gave her the J&J covid 19 vaccine and asked her to wait 30 minutes to be monitored due to her past allergies. Around 20 minutes patient let one of the pharmacist know she was feeling very flushed and dizzy. We brought her over to the side to be monitored more closely. We had patient elevate her feet to help with faint feeling and drink some water. Within 5 to 10 minutes her symptoms started worsening. Tingling sensation started going up her side of head and neck. It started moving to the front of her face. Once that happened I asked how her breathing was and she was starting to get short of breath. Soon after patients throat started to close. We administer 0.3 m of epinephrine and called 911. Pt was able to breathe a little better but within 5 minutes she was back to gasping for air, we administered another 0.3 mg of epinephrine and the paramedics arrived.
1097803	3/13/2021	CO	39	F	3/12/2021	3/12/2021	throat and tongue swelling 5 minutes after vaccine. Hard time swallowing. Sat at the facility for 1 hour under observation, then went to the ER. by the time I got to ER, I was short on breath. Doctors immediately gave epi and steroids. Was diagnosed with anaphylaxis.

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1096819	3/13/2021	PA	61	M	3/13/2021	3/13/2021	patient was given 1st injection and about 5 minutes afterward @ 1205 he started to feel like a warm flushing feeling, and feeling a little fuzzy in the head, heart rate 64bpm, patient blood pressure on the monitor did not appear to be accurate indicating 180/118 and this was also tried on the right wrist. Patient did not have any complaints with the elevated with this blood pressure, patient was conversing and without headache, patient denied any itching or signs of anaphylaxis. patient was monitored for a total of 55 minutes before being released. Patient was instructed to call 911 with signs of anaphylactic reaction and to call his provider with any other symptoms that he was concerned with.
1096131	3/12/2021	PA	47	F	3/12/2021	3/12/2021	Pt complaint of numbness and tingling to upper lip area 30minutes after vaccine given. Pt did complete 15+ minutes of observation in the waiting area at the vaccine site. Pt did go to her car then came back into the vaccine site to report her symptoms. O2 @ 2L/min applied. Deep breathing encouraged. No s/s of anaphylaxis occurred. Respirations easy, skin warm and dry. Pt did present with increased anxiety prior to receiving the injection. No worsening of symptoms. Family on site to transport patient home. EMS was on site. No transport to local ER needed.
1095193	3/12/2021	NV	24	F	2/19/2021	2/19/2021	Anaphylaxis - Throat swelled almost completely closed, wheezing, lightheadedness (nearly passed out), throat/neck and injection site were very itchy and swollen, face/eyes swelled up, turned very pale all over, heart palpitations, etc. The next day - severe, horribly painful burning sensation all throughout my body. Even clothing lightly touching my skin felt like hot razors cutting in to me. Residual swelling of the face/ arm. Migraine. For two weeks after - Very large, hard lump under my skin at the injection site. It was about the size of my hand and was very painful. After a few weeks it went away. Treatment-large amounts of benadryl. The pharmacist wanted to use an epipen and send me to the hospital, but I refused because I could still get some air in (doctor later told me that my reaction was so severe I should have gone to the hospital). I had to keep taking large amounts of benadryl for the next few days to keep the reaction down a bit.

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1094218	3/12/2021	CO	67	M	3/7/2021	3/8/2021	Vaccine shot at 10:20 am Sunday. Severe swelling of lips, face and around eyes at 6:00 pm on Monday. Several days for swelling to go down. Not anaphylaxis. No swelling of tongue or throat. No trouble breathing. Exactly the same reaction and time line after first shot, 2/14/2021. I reported first event as well.
1094804	3/12/2021		39	M	3/3/2021	3/3/2021	Patient reports body aches since having Moderna vaccine on 03/03/2021, taking hydrocodone 10/acetaminophen 325mg, lyrica. Patient rates pain at 9/10 today. Patient reports "knot" at injection site. NO fever, chills, diaphoresis, SOB, anaphylaxis reported. Describes pain as soreness after a workout.
1095026	3/12/2021		61	F	3/12/2021	3/12/2021	patient bring observed for 30 minutes post vaccine. hx of seizures and has service dog hx of anaphylaxis to bee stings and antibiotics. uses epi pen ,not available with patient 10 minutes post vaccine sudden onset cough and c/o itching throat, followed by wheezing nurse stat called. patient stated feels like passing out, within 1 minute started having seizures. was conscious but not responding patient lowered to floor stat team present eejrosepatient lifted to stretched, 100% NRB applied. patient taken to ER. patient conscious and responding
1095027	3/12/2021	NC	26	M	3/11/2021	3/11/2021	Pt is here with c/o diffuse redness and itching rash which started last night; he took the J&J COVID vaccine around noon yesterday from facility; he denies any wheezing, dyspnea or SOB; denies any prior allergic reaction; no h/o anaphylaxis; Pt stated he was not provided with a hotline to call to reports vaccine reactions. Solu-Cortef 100 mg IM x1 given in the office today; will also place him on prednisone taper which he will start tomorrow morning; Zyrtec 10 mg qd also started today; pt is advised to call 911 or go to the nearest ER should he developed wheezing, SOB and difficulty breathing; he agrees with plan and voices understanding. Incident about the vaccine reported to VAERS.

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1095077	3/12/2021	NJ	59	F	3/11/2021	3/11/2021	59-year-old female with possible history of SJS, diabetes, hypertension presents ED 20 minutes after receiving Covid vaccine for concern for anaphylaxis. Initially in the ED, patient is afebrile, with normal heart rate, respiratory rate, blood pressure; nonhypoxic on room air at 100%. No stridor or adventitious lung sounds appreciated. Normal rate. Clear to auscultation bilaterally. Patient is nontoxic in appearing. Exam unremarkable. Patient was given Benadryl and Decadron. She was watched for approximately 30 to 45 minutes in the ED. She had no further concerns after this observation. Patient was discharged home with a prescription for epinephrine pen. Recommendation to follow-up with her primary doctor and also with an allergist. Patient was comfortable this plan. At time of discharge, patient is hemodynamic stable.
1095272	3/12/2021		68	F	3/12/2021	3/12/2021	Within minutes of receiving the Janssen vaccine, patient c/o dizziness, difficulty breathing, and feeling like her throat was closing. Her breathing was labored, shallow and fast RR high 30s, 93% RA, HR 120s. Lungs sounds with poor air entry, no wheezing. No rash, injection site unremarkable. Pt disclosed extensive history of allergies and h/o anaphylaxis needing Epi. States that current symptoms feel like previous anaphylaxis events. Called Code. Administered Epinephrine IM L thigh and within 2 minutes patient felt better, vital signs improved to HR 121, 99% RA, 170/86 speaking in full sentences. Allergy fellow and ED team arrived and patient was transported to ED alert and responsive in NAD.
1095345	3/12/2021	CA	25	M	3/12/2021	3/12/2021	Pt was in seated position in a chair and slumped over to right side and fell to floor. Pt appeared to twitch slowly for about 20 seconds. Pt was brought to seated position on floor. Appeared pale and diaphoretic. Pt verbalized he did not realize he fainted and loss consciousness for about 20-50 seconds. BP: 67/27. HR: 36. MDP doctor called over to assess situation. 2nd set of vitals taken. BP 51/27. HR 41. Pt given water. States he feels dizzy and light headed. Vision is "weird." Sees colors more vibrantly. The Dr. recommends pt go to ED. Pt transported via wheelchair by the Dr and clinic NP with Anaphylaxis kit. In ED, pt's BP was 86/60. Blood Sugar 91. Pt admitted for fluid hydration and monitoring.

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1095733	3/12/2021	OK	49	M	3/12/2021	3/12/2021	Pt developed symptoms of anaphylaxis: nausea, anxiety, chest tightness, throat tightness about 13 minutes after injection. Was given 0.3 mg epinephrine and sent by ambulance to ER.
1095760	3/12/2021	OK	40	M	3/10/2021	3/10/2021	Medical staff was called for patient distress. Upon getting to the car that the pt was in, he reported trouble focusing, left sided chest pain, and sweating. Gen: Awake, Alert, Moderate Distress, diaphoretic Cardio: RRR w/o m/g/r Resp: LCAT in all fields, mildly increased work of breathing Skin: no rashes noted, no edema noted of the face or angioedema noted of the lips Psych: anxious Neuro: able to answer questions appropriately, able to follow instructions, CN 2-12 grossly intact Pt instructed that his symptoms were not necessarily consistent with anaphylaxis but with diaphoresis and left sided CP I recommended that he be evaluated in the Emergency Department. Pt agreed to this. Transport to ED via EMS was offered and pt declined as he had a driver. Informed pt that I could not make him go via EMS but I did recommend it. Pt expressed understanding but thought that he would be fine with it being as close as it is and him being the passenger, so he again declined transport via EMS. They were instructed to proceed directly to the ED for further Eval.
1095813	3/12/2021	OK	49	F	3/12/2021	3/12/2021	Received phone call at 2:30pm. Patient stated she felt flushed. Had BP 140/90. Pulse 68. Respirations 14. Lungs were CTA B, No wheezing, stridor, or respiratory distress, No Hives but did have erythema about bilateral cheeks. No murmurs noted and normal pulse rate on exam. Given 20mg pepcid and 25mg benadryl. Monitored for 30 minutes. Symptoms resolved. Repeat exam normal. Told to monitor symptoms for 24 hours and call 911 if any chest pain, SOB, or other signs of anaphylaxis discussed with patient.
1093788	3/12/2021	TX	55	M	2/1/2021	2/1/2021	One day after patient's 2nd covid-19 Pfizer vaccine, he experienced generalized urticaria lasting for approximately 3-4 weeks. I evaluated the patient 5 weeks after his 2nd dose, and the urticaria has since subsided. He never had a hive at site of vaccination, never had anaphylaxis, and never had any severe allergic manifestations, only itchy urticaria.

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1096144	3/12/2021	PA	61	F	3/12/2021	3/12/2021	Patient reported prior to administration of vaccine significant history of syncope episodes with previous vaccine injections. Placed in wheelchair prior to administration of vaccine. After vaccine given patient experienced lightheadedness and feeling hot within 1 to 2 minutes placed on cot no respiratory distress or anaphylaxis occurred symptoms persisted EMS on site now feeling better EMS recalled back to site and transported to local hospital.
1095805	3/12/2021	OK	45	F	3/12/2021	3/12/2021	Code called at 3:00pm. Patient stated she felt flushed. Had BP 172/100. Pulse 68. Respirations 14. Lungs were CTA B, No wheezing, stridor, or respiratory distress, No flushing seen, no rash or Hives. No murmurs noted and normal pulse rate on exam. Given 20mg pepcid and 25mg benadryl. Monitored for 30 minutes. Symptoms resolved. Repeat exam normal. Told to monitor symptoms for 24 hours and call 911 if any chest pain, SOB, or other signs of anaphylaxis discussed with patient.
1093786	3/12/2021	IL	57	F	3/11/2021	3/11/2021	Patient received 2nd dose of Moderna. 15 minutes after the shot patient said she was feeling dizzy. We gave her some water and took her blood pressure. She sat and we observed her. As time progressed, she started to get itchy, her hands and then the soles of her feet. We gave her 50mg of Benadryl and kept watching the patient. She did not have any shortness of breath or anaphylaxis. We kept observing the patient, and she continued to improve. We informed her to keep taking Benadryl 50mg every 4-6 hours and to call 911 if anything gets worse.
1093616	3/12/2021	CO	41	F	3/11/2021	3/11/2021	Anaphylaxis, swollen throat, itchy lips, hives.
1093559	3/12/2021		33	F	3/11/2021	3/11/2021	Anaphylaxis, lightheadedness 33F with hx epilepsy, asthma, and multiple food and drug allergies who reported that she was experiencing chest pain/heaviness as well as feeling warm and throat tightness shortly after receiving her first COVID vaccine.
1094183	3/12/2021	CO	67	M	2/14/2021	2/15/2021	Vaccine shot at 10:20 am Sunday. Severe swelling of lips, face and around eyes starting at 6:00 pm on Monday. Several days for swelling to go down. Not anaphylaxis. No swelling of tongue or throat. No trouble breathing. Exactly the same reaction and time line after second shot, 3/7/2021.

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1094209	3/12/2021	MI	45	F	2/2/2021	2/2/2021	While patient was shopping after receiving her vaccine she started feeling "pressure"/"tightening" in the left chest/shoulder area and then in the front and back of upper torso. She stated it continued to increase and became painful. Her respirations increased and she felt like she was panting. She states it didn't feel like her previous anaphylaxis where her throat "felt like a rubber chicken" and she was unable to speak and had swelling in her throat.
1092052	3/11/2021	CO	45	F	3/10/2021	3/10/2021	11 minutes after injection, the patient reported her tongue and throat "felt funny". She did not have SOB, difficulty breathing, hives, dizziness, light-headedness, or closing up of the airways and thus anaphylaxis was excluded. She was given water and the option to take a dose of benedryl which she did. Symptoms resolved and following up later that day she reported being fine.
1090382	3/11/2021	MA	78	M	3/10/2021	3/10/2021	Patient came to emergency department after receiving second dose of COVID-19 vaccine, unknown which manufacturer as occurred prior to emergency department visit, with worsening neck pain. Wound up being treated for possible anaphylaxis and intubated. He was intubated around 12 hours after the vaccine.

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1090800	3/11/2021	TX	30	F	3/10/2021	3/10/2021	PT C/O DIZZINESS, SOB, TIREDNESS, AND FACIAL FLUSHING. SHE STATES THAT THESE SYMPTOMS STARTED ABOUT FIVE MIN AFTER RECEIVING HER VACCINE. AFTER 10-15 MINUTES HER EYES STARTED TO FEEL HEAVY AND SHE NOTICED SHE WAS SQUINTING MORE. SHE HAS A Hx OF ANAPHYLAXIS AND BROUGHT HER EPI PENS IN CASE SHE NEEDED THEM, BUT THIS REACTION WAS NOT AN EARLY SIGN OF HER NORMAL ANAPHYLAXIS. SHE MENTIONED THAT SHE CONSUMED A MONSTER ENERGY DRINK THIS AM AND A PIECE OF TOAST. PT DENIED CP OR CHEST PRESSURE. BP 134/92 AND 138/93 SpO2 100% HR 71 AND 67 PT APPEARED IN MILD DISTRESS DUE TO A SENSE OF TIGHTENING WITHIN HER CHEST AND FATIGUE. AFTER ALLOWING PATIENT TO SIT IN HER CAR FOR AN ADDITIONAL 15 MIN , GIVING HER COOL WATER, AND A SNACK , THE PATIENTS BREATHING IMPROVED 100% AND HER DIZZINESS/FATIGUE IMPROVED 70%. AT THIS TIME PT WAS STABLE TO TRAVEL HOME (15 MIN) AND INSTRUCTED TO EAT AND REST FOR THE DAY. PT WAS NOT GIVEN MEDICATION.

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1090935	3/11/2021	ND	74	F	2/26/2021	2/27/2021	22 hours after vaccination and one hour after taking morning pills, patient developed full body rash and itching. Morning meds she consumed were: Losartan, amlodipine, pravastatin, escitalopram, baby aspirin, vitamin D3. Episode of rash and itching improved with oral Benadryl 50 mg. The next day patient took her meds same time and one hour later developed rash. Took Benadryl and rash resolved. Patient then stopped medications for 1 week and had no occurrences of rash. Restarted medications morning of 3/10/21 and developed full body rash with itching and early anaphylaxis, one hour after medication consumed. It should be noted, patient has been on these medications for several years without reaction. Reaction started after she had received the Moderna COVID19 vaccination. On 3/10/21 when she had full body rash with anaphylaxis, patient presented to our clinic and was given 2 rounds of IM epinephrine, IM Benadryl 50 mg, IM Solu-Medrol 125 mg, and oral Zyrtec. Episode took 2.5 hours to resolve. Patient prescribed tapering course of prednisone, Zyrtec once daily, famotidine 20 mg once daily for the next 7 days, outpatient. We will be restarting one medication at a time to assess for medication reaction.
1090937	3/11/2021	IN	62	M	3/9/2021	3/9/2021	Slight lump in throat, of the kind experienced with previous anaphylaxis episodes, that developed a couple of hours after vaccination, and is continuing.

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1091427	3/11/2021	NJ		F	2/23/2021	2/23/2021	felt like she was having a "heart attack"; extremely nauseous and dizzy; extremely nauseous and dizzy; reported stiffness in both legs and could not walk; reported stiffness in both legs and could not walk; This is a spontaneous report from a contactable pharmacist. An elderly (65+ Years) female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on 23Feb2021 at SINGLE DOSE for covid-19 immunisation. The patient was not Pregnant at Time of Vaccination. Facility type vaccine was Public Health Clinic/Administration facility. The patient medical history and the concomitant medications were not reported. The patient previously received first dose of bnt162b2 intramuscular on unknown date at SINGLE DOSE for covid-19 immunisation. After 2nd dose on 23Feb2021, the patient felt extremely nauseous and dizzy, felt like she was having a "heart attack" though no reported difficulty breathing or anaphylaxis. The patient also reported stiffness in both legs and could not walk and do could not reach phone to call anyone. No treatment received. The outcome was unknown. No covid prior vaccination. Information about lot/batch number has been requested.; Sender's Comments: Based on temporal relationship, the causal association between BNT162B2 and the reported "felt like having a heart attack" cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.
1091640	3/11/2021	NY	45	F	1/15/2021	1/15/2021	Add:Hx of anaphylaxis. Reported hives and nausea after first shot. Did not receive 2nd shot. Unknown referral plan.

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1091805	3/11/2021	NY	21	F	3/11/2021	3/11/2021	5 mins post 1st dose vaccination patient began feeling nauseous, throat felt tight with mild pain when swallowing, tingling sensation from the chest down to her toes, facial flushing, and dizziness. She states these symptoms are common due to her history of EDS but today they are slightly worse since she got the vaccine. She was brought to the medical evaluation area via wheelchair and evaluated by us and EMS. Patient was administered Benardyl 50mg and provided orange juice and water. Vitals taken throughout and were slightly high in the beginning and then stabilized. Patient states her throat felt better and the tingling localized to her hands after 5 mins. Patient was monitored for over 45 mins. She was instructed to contact her PCP and her allergist to be cleared for her second vaccine dose. She was informed her 2nd dose should be administered at a facility where she can be observed closely. She declined transport to the hospital but agreed to follow up to the ER with any worsening signs of anaphylaxis. The nausea resolved and she felt less groggy upon leaving with her boyfriend.
1091813	3/11/2021	OH	62	F	3/10/2021	3/10/2021	Patient arrived to the outpatient vaccine clinic for her scheduled appointment. Immediately after receiving the vaccine, the patient felt chest pain, dizziness, and passed out. She had swelling of the tongue, lips, eyes, and throat. Patient was admitted to the hospital and treated for anaphylaxis with epinephrine, benadryl, famotidine, methylprednisolone, Duoneb and tylenol. Patient is currently still in the hospital but her condition is stable.
1091814	3/11/2021	MI	72	F	3/10/2021	3/10/2021	Patient was monitored and at 30 minutes, patient stated feeling itchy with slight rash/redness developing on neck/chest area. Patient stated feeling increased heartrate, however heart rate and spO2 were check twice and at normal levels. Administration of benadryl 50 mg was given. Patient did not have any signs of anaphylaxis , after 1 hour patient still had itchy feeling/rash but no other issues. Patient was recommended to seek medical attention. Contacted later and patient was doing ok with no other symptoms besides tiredness/fatigue from vaccine.

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1091931	3/11/2021		24	M	3/11/2021	3/11/2021	24 Y/O M reports "scratchy throat" and onset of cough. Hx of anaphylaxis 2yrs ago. Stated symptoms similar to previous episode. PT given 50mg Benadryl w/out resolution of symptoms. EMS called. Sent to ED.
1092096	3/11/2021	PA	73	F	3/10/2021	3/10/2021	Vague chest tightness and tickle in her throat. Improved with albuterol treatment. Hx of nausea with PEG - no anaphylaxis with PEG.
1092326	3/11/2021	UT	51	F	3/10/2021	3/10/2021	chest tightness, throat tightness, itching, headache, and nausea, which are consistent with her usual anaphylaxis symptoms with first COVID-19 mRNA vaccine IM. Called RRT. Taken to ED. Took diphenhydramine 50 mg PO. Patient had an EpiPen, but wanted to wait to see if diphenhydramine worked. Symptoms improved over 20 minutes. Observed patient until fully resolved. Instructed patient to return to ED if symptoms worsened or returned.
1092356	3/11/2021	LA	34	M	3/11/2021	3/11/2021	Racing heart rate 30-45 minutes after injection. Also mild facial numbness on upper neck and jawline to ears. No difficult breathing at any point. Called 911 and pulled over. Evaluated by Fire/EMS and found no evidence of severe anaphylaxis. All vitals (except elevated heart rate) were normal.
1092476	3/11/2021	MT	16	M	3/10/2021	3/10/2021	0930 red, puffy, tingling hands 0945 cough 0948 benadryl 50 mg administered by medic. pt hx of anaphylactic reactions to nuts. mom stated she did not have pt's epi pen with her. pt stated these same symptoms happen with anaphylaxis prior. mom/pt wanted transport via ambulance vs POV for peace of mind in case any symptoms worsened. to ED.

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1092507	3/11/2021	MA	51	F	3/11/2021	3/11/2021	<p>Vax Clinic note: Approximately 10 minutes after receiving J&J vaccine c/o lips tingling and tongue feeling thick. Medicated with 10 MG cetirizine. VS o2Sat 97%, Pulse 84, BP 146/74. Pt states has had allergic reactions to IV contrast that involved tongue swelling. staets this feels similar but not as bad. o2Sat continues at 97%, Pulse 58, BP 128/68, pt trying to relax, c/o slight headache. Swellig has spread to her lips, and cheeks feeling heavy, O2Sat 97%, Pulse 75, medicated with 50mg benadryl. 911 called to transfer pt to ED for further eval. States throat is feeling tighter. And unable to swallow Epi given 11:18, daughter aware and will meet her at ED. BP 148/82, PULse 75, O2Stat 97% swelling in tongue decreasing, throat n o longer tight, tongue still feels thick, has some hives between her eyes, and forehead. Pt transported via EMS to ED Intake ED note: 51 y.o. F here after getting J&J vaccine and 10 min. After she c/o her tongue feeling thick and lips tingling Pt given zertec Then 15 min later pt felt lips swelling and had hives around eyes and forehead Pt c/o difficulty swallowing and was rx'd with epi pen Pt has no stridor, or resp issues on arrival, able to speak in full sentences. Pt denies COVID sx 2nd ED note: Pt arrived to ED via EMS from community health center S/P Covid vaccination. About 15 minutes after receiving vaccine - felt nausea and smelled "medicine" followed with upper lip swelling and numbness to tongue associated with difficulty swallowing and redness to forehead. Pt alert and oriented at this time. Speaking in full sentence, drinking bottled water without any difficulty. No drooling noted. Denies SOB, chills or fever. Emergency Department Attending Attestation Note See resident/PA/student note for further details of HPI, history, exam, ED course, and diagnoses. Briefly, this is a 51 y.o. female with PMH reviewed in chart and w/ patient notable for insulin dependent diabetes, depression, prothrombin mutation, migraine, p/w concern for allergic reaction. Emesis or change in Covid vaccine today. 10 minutes after receiving the vaccine, patient reports feeling thick in her tongue with tingling in her lips. Patient was given Zertec. The minutes later, her lips began to swell up and was also noted to have new erythematous rash between her eyes and forehead. Patient was given 50 mg of Benadryl. Patient felt like she could not swallow with worsening lip swelling. She was given EpiPen and 911</p>

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was called. No stridors. No wheezing. Reports continued tingling and the numbness in her mouth but no lip swelling or tongue swelling. Denies any difficulty swallowing at this time. No wheezing. No abdominal pain or nausea. No rash at this time. Of note, patient also notes left-sided facial, arm, and leg numbness starting about 10 minutes prior to arrival to the emergency department. She reports that she has had recurrent numbness on the left side in the past, which was thought to be due to migraine versus TIA. She has had extensive work-up and multiple hospitalization for this symptom. She reports that she is allergic to iodine and gadolinium containing contrast. Denies any headache at this time though she had a mild headache after receiving the vaccine. Denies any blurry vision. Denies any weakness in her bilateral upper and lower extremities. Assessment and Plan: Vital signs notable for O2 sat of 96 to 98% on room air without tachypnea. Patient is mildly hypertensive. Patient is well-appearing speaking full sentences without any dysarthria. Pupils are equal and reactive to light. Extraocular movement intact. She notes diminished sensation to her left face, left upper extremity, and left lower extremity. Tongue is midline. Hearing is intact bilaterally. No facial droop. She has 5 out of 5 strength in bilateral upper and lower extremities. No pronator drift. Normal gait. No tongue swelling or lip swelling. No stridors. No uvula swelling. No pharyngeal or erythema. Lungs are clear to auscultation bilaterally without wheezing or rhonchi. Cardiac exam without murmurs rubs or gallops. Regular rhythm. No abdominal distention or tenderness on palpation. No CVA tenderness. 51-year-old female who is presenting to the emergency department with improving lip swelling and numbness in her mouth, raising a concern for anaphylaxis related to her Covid vaccine. Reassuringly, status post EpiPen, her symptoms are improving. However, she has new onset left-sided numbness, with without any headache. She reports that she has had this numbness in the past the last time she had the numbness on the left side was approximately 10 years ago. Her neurologic exam is only notable for diffuse numbness on her left side including her face. Differential diagnosis include migraine headache and TIA. Stroke is possible though less likely given the patient has had the same symptoms in the past

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							with negative work-up. Will defer code stroke at this time but will emergently consult neurology. Will get labs including BMP and CBC. We will continue to monitor her from the anaphylaxis perspective. We will also give her a dose of steroid. Prednisone 60 mg by mouth given 12:29 PM NEUROLOGY CONSULT NOTE Assessment: Formulation- Diagnosis is guarded. Localization structurally would suggest subcortical (thalamic) or small brain-stem in a sensory territory on the right. Etiologies could be stroke given her vascular risk factors but seems unlikely given there is stereotypy of earlier symptomatology. Demyelinating would be another possibility as well, but again, the stereotype. Seizure unlikely because of the timing of rash from toes to body was minutes and duration of some occasions being days. Complicated migraine possible, has some risk factors, but should be treated as dx of exclusion. She does make complaint of headache, which could support. Some FND elaboration on her anxiety-ridden allergic reaction is also possible, but no objective non-structural signs to support.
1092877	3/11/2021	IL	32	M	1/12/2021	1/14/2021	2 days later began having rash on trunk and spreading to neck/face, began taking antihistamines, following day (3 days later) had rapid heartbeat and trouble breathing and treated at hospital for possible/probable anaphylaxis per treating physician. Also followed up with allergy center, continued taking steroids and antihistamines for 1 week to keep reaction under control. Was cleared by allergy office to get dose #2 and has similar rash appear around 20-24 hours after receiving dose 2, spreading to neck and face within a few hours despite antihistamine use, needing to be treated with course of steroids again.

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1091628	3/11/2021	NY	41	F	3/11/2021	3/11/2021	ITCHING ALL OVER, SCRATCHY THROAT, ANAPHYLAXIS PT PREMEDICATED WITH BENADRYL 50MG PO AT HOME PRIOR TO COMING FOR SECOND VACCINATION AT 1125 12:57 PT STATES S/S OF ANAPHYLACTIC REACTION, SCRATCHY THROAT, TONGUE SWELLING, HIVES, ITCHING VS TAKEN: HR 120,RR 20,BP 150/78, SPO2 100% RA 1258: EPI PEN GIVEN X 1 IM TO LEFT VASTUS LATERALIS, PT TOLERATED WELL. 1259: SQUAD AND ER NOTIFIED FOR NEED OF TRANSPORT TO CPH. 1301:DEXAMETHASONE10 MG IM IN RT LETOID GIVEN X 1, PT TOLERATED WELL. 1305: 20 GUAGE SL PLACED TO RT WRIST. PT TOLERATED WELL. 1315: REPEAT VS TAKEN AND STABLE HR 95, RR 20, BP 140/74, SPO2 100% RA. 1315 RESCUE ARRIVED AND TRANSFERED TO CPH
1091848	3/11/2021	MA	67	F	3/11/2021	3/11/2021	increased cough, difficulty breathing, anaphylaxis; received IM EpiPen, IM Benadryl, and IV Solumedrol 125mg Symptoms improved; did not need repeat Epi dosing. did not receive Famotidine because has documented allergy to Ranitidine.
1091125	3/11/2021	AZ	68	F	3/11/2021	3/11/2021	patient developed coughing, shortness of breath, lip swelling, hoarse voice, and tightness in throat. She became diaphoretic and pale. Symptoms worsened and progressed to anaphylaxis without shock. EpiPen was given and placed immediately on oxygen. EMS/911 called. Patient was given nebulized albuterol and placed on exam table. Normal saline drip via IV given. Patient stated allergy to Benadryl so not given. Within 5 minutes color improved, diaphoresis resolved, and hoarseness/shortness of breath resolved. Lips swelling improved. Patient transported in guarded condition by ambulance by to Clinic.

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1086858	3/10/2021	FL	39	U	1/27/2021	1/27/2021	Anaphylaxis; low blood pressure; experienced flushing; nausea; A spontaneous report was received from a consumer concerning a 39-years-old patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events anaphylaxis, flushing, nausea, and low blood pressure. The patient's medical history included allergy to medications (information not reported). Concomittent meds included Xyrem (for narcolepsy/cataplexy) and Adderall (narcolepsy) On 27 Jan 2021, prior to the onset of the events the patient received their first of two planned doses of mRNA-1273 (lot/batch: 012M20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 27 Jan 2021, 20 minutes after the vaccine the patient experienced flushing, nausea, low blood pressure (reading unknown). Patient was premedicated with Benadryl and Xyzal because of known history of allergy to medications. Treatment details were not reported. Action taken with mRNA-1273 in response to the events was not reported. The outcome of events were reported as resolved.; Reporter's Comments: Very limited information regarding this events has been provided at this time. Further information has been requested.
1089675	3/10/2021	CO	50	F	3/10/2021	3/10/2021	Anaphylaxis - rash, SOB, lip swelling. Body aches. Symptoms started within 1 hr of getting vaccine.
1089507	3/10/2021	MD	64	F	2/24/2021	2/26/2021	48 hours (Feb 26) after receiving the shot, I had anaphylaxis symptoms... red blotches around mouth, swelling face, swelling lips, ants-crawling feeling on face, neck and scalp. Went to Urgent Care, given benadryl and steroid shot. Rx Prednisone 20 mg x2, 5 days. Anaphylaxis happened again the next day (Feb 27) just prior to taking the first prednisone. Went back to Urgent Care, another shot. Meds kept full on allergic reactions at bay on Monday and Tuesday. Had swelling face, lips and tongue happen in Primary Care office on March 3, received another shot and increased prednisone rx to 30 mg x2, with taper. On March 5, happened again, went to ER, where doc changed timing of prednisone to 60 mg all in one dose. All in conjunction with hydroxyzine 25 mg every 12 hours and 50 mg of benadryl every six hours. Situation continues with mild swelling, itchy sensations happening just before it is time to take new meds .

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1089384	3/10/2021	ID	58	F	3/10/2021	3/10/2021	Dizzy/ Lightheaded Vitals: B/P: 140/70 HR: 77 Resp.: 14 O2Sat: 99% Skin signs: Warm and dry Circulation: Cap refill <2sec Treatment: Pt placed in supine. States she still feels dizzy but room not spinning. Had patient sit up, no noted increase or decrease in symptoms. LOI 2 hours. Toast with peanut butter. No Hx of anaphylaxis. @ 11:30 pt states she feels "jittery" Repeat Assessment @11:32 Vitals: B/P: 134/70 HR: 68 Resp.: 14 O2sat: 98 % Skin signs: Cool/ dry Resp.: No noted increase in effort AOx4 Cap refill <2sec Treatment Pt remained supine. Pt states gradual return to normal. Vitals stable. Repeat Assessment @11:47 Vitals: B/P: 121/82 HR: 69 O2sat: 97%
1089381	3/10/2021	WY	54	M	3/10/2021	3/10/2021	Patient came back to our office about 1 hour and 45 minutes after having his first Moderna shot saying that his throat was feeling a little bit itchy. 25 mg of Benadryl was given, patient waited in clinic for 30 minutes and reported that itching had resolved. Patient was encouraged to seek medical care if he had any other problems. Sign and symptoms of anaphylaxis were reviewed and pt was advised to call emergency responders if he had any symptoms. Patient has a appointment scheduled with his primary care doctor tomorrow morning, and will also follow up with patient tomorrow,.

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1089219	3/10/2021	KS	78	M	3/8/2021	3/8/2021	<p>Progress Notes APRN (Nurse Practitioner) ? ? Family Medicine Cosigned by: MD at 3/9/2021 9:00 AM Expand AllCollapse All COVID VACCINE CLINIC 3/8/2021 Patient: Date: 3/8/2021</p> <p>MRN: 9750775 Subjective Patient is a 78 y.o. male who was seen at COVID Vaccine Clinic today for his first dose of the COVID 19 vaccination. He was given the Pfizer vaccination in the left deltoid muscle. During his 30 minute waiting period after the injection, the patient began to experience itching. He denied rash, difficulty breathing, difficulty swallowing, wheezing, throat tightness, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. This provider was notified of patient reaction and he was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to rapid progression of symptoms and skin changes. PMH: idiopathic anaphylaxis in 1995. Hx of copd, a-fib (on eliquis) and hypothyroidism. ALLERGY REVIEW OF SYSTEMS: Patient complains of itching of skin Patient denies chills, fever, malaise/fatigue, facial swelling, sore throat, frequent throat clearing, cough, chest tightness, shortness of breath, wheezing, rash, hives, eczema, dizziness and headaches Previous Reactions: none to vaccines. Unknown cause of his anaphylaxis in 1995. At that time he developed rash/hives and it progresses quickly. He's had itching off/on chronically. He doesn't think the itching today changed from baseline. His wife would like him to be checked out. Objective Vitals Vitals: 03/08/21 0338 03/08/21 1555 BP: (!) 133/93 Pulse: 93 73 SpO2: 99% 99% Physical Exam Vitals reviewed. Constitutional: General: He is not in acute distress. Appearance: He is not ill-appearing or diaphoretic. HENT: Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Eyes: Conjunctiva/sclera: Conjunctivae normal. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds and air entry. Skin: General: Skin is warm. Coloration: Skin is not pale. Findings: No rash (visual exam of abdomen, chest, back and groin and upper extremities w/o evidence of rash/hives.). Neurological: General: No</p>

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1088791	3/10/2021	OK	64	F	3/10/2021	3/10/2021	<p>focal deficit present. Mental Status: He is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. Thought Content: Thought content normal. Judgment: Judgment normal. Assessment/Plan Treatment included: antihistamines benadryl Follow up response to treatment: excellent. Patient discharge: Stable to go home and follow up with PCP. Differential Diagnosis: Systemic reaction (hypoglycemia, hypotension, generalized rash) Itching. Chronic vs new itching. He reports immediately upon getting back to the bay that he doesn't think it's anything but his chronic itching that he gets. He declines feeling like this is an allergic response like he's had in the past. Benadryl given as requested by pt's wife for comfort measures. This request was reasonable. Pt's wife will be driving. They both are aware of what to monitor for and when to call 911. Pt's exam is unremarkable. VS stable. Follow up with pcp otherwise. APRN Electronically Signed 3/8/2021 3:48 PM</p> <p>Was in 30 minute monitoring d/t hx of anaphylaxis to wasp sting. At 20 minutes post injection, developed tight cough and wheezing. States it felt like a film in her throat and her tongue felt "weird." Placed on O2, administered 0.3 mg Epi pen to right VL and 50 mg Benadryl IM to RD. Began improving immediately. States she always has a low BP and pulse. Medical hx includes liver disease, bipolar, dementia, arthritis. Accompanied by son.</p>

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1088623	3/10/2021	KS	74	F	3/4/2021	3/4/2021	<p>Called patient to follow up on her reaction to the COVID vaccine administered on 3/4/21. She was transported by EMS to the ER after having anaphylaxis to her second Pfizer vaccine. She states she was hospitalized in the ICU overnight and was discharged home this afternoon. Patient feels she is doing much better. She does note feeling very tired from all the medications they gave her. She plans to call her PCP on Monday to schedule an appointment and has follow up scheduled with allergy specialist. She denies any further questions or concerns. Patient is appreciative of phone call. Progress Notes: 3/4/2021 Subjective Patient is a 74-year-old female who was seen at COVID Vaccine Clinic today for her second dose of the COVID 19 vaccination. She was given the Pfizer vaccination in the left deltoid muscle. During her 30-minute waiting period after the injection, the patient began to experience hoarse voice. She denied rash, difficulty breathing, difficulty swallowing, dizziness, facial swelling, lip swelling and tongue swelling. This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to rapid progression of symptoms. PMH of anaphylaxis x 3, with one hospitalization. ALLERGY REVIEW OF SYSTEMS: Patient complains of chest tightness (she later developed chest tightness when she was in the bay prior to epi-pen administration.) Patient denies chills, fever, malaise/fatigue, facial swelling, cough, shortness of breath, wheezing, rash, hives, eczema, itching of skin and abdominal pain Hoarse voice.: Negative for nausea: + lightheaded.: Previous Reactions: anaphylaxis to medications. Never to vaccines. Pt's husband with her today. He states she progresses rapidly with her anaphylaxis and wishes for her to get epi pen now based on her symptoms. She typically starts out this way. Vitals: 03/04/21 1135 03/04/21 1140 BP: (!) 187/100 (!) 163/95 Pulse: 93 95 Resp: 18 16 SpO2: 100% 100% Physical Exam Constitutional: Appearance: She is well-developed. She is not toxic-appearing or diaphoretic. Comments: flushed HENT: Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Comments: Clear airway. Voice is hoarse. Eyes: Extraocular Movements: Extraocular movements intact.</p>

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							<p>Conjunctiva/sclera: Conjunctivae normal. Pupils: Pupils are equal, round, and reactive to light.</p> <p>Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. No respiratory distress. Breath sounds: Normal breath sounds. No wheezing. Skin: General: Skin is warm and dry. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Gait: Gait normal. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. Thought Content: Thought content normal. Judgment: Judgment normal. Assessment/Plan Treatment included: benadryl 50 mg IM R leg antihistamines and epinephrine x 1 at 1136 in L leg Follow up response to treatment: good. She started to have return of symptoms when AMR was leaving with her. Patient discharge: Transported to ED by ambulance. Differential Diagnosis: Anaphylaxis (dyspnea, stridor, drooling, tongue swelling) Pt with early onset of presumed anaphylaxis that responded well to epi-pen. Pt sent to ED for closer observation/treatment via AMR. Husband voiced great appreciation of pt's care today. 3/4/2021 11:40 PM Addendum: ED charge nurse, RN was notified of patient coming.</p>
1088146	3/10/2021	MD	28	F	3/10/2021	3/10/2021	throat itching No rash or anaphylaxis. No uvular edema.
1087906	3/10/2021	MD	40	F	3/10/2021	3/10/2021	flushed, rapid heart rate. No throat swelling, shortness of breath, vomiting. NO signs of anaphylaxis

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1089731	3/10/2021	CO	43	F	3/10/2021	3/10/2021	44 y.o. female AAO x4. PT had vaccination admin at 1250 hours, summonsed medic in observation area for a scratchy throat. PO Benadryl administered PTA 25 mg. Medical lead went to parking lot and pt. was having a hoarse cough with worsening, starting to get flush in face. ED summonsed via 911. . Pt. then started to have episode of emesis. 0.3 mg epi 1:1000 ordered to be administered, medication was drawn up, verified, and administered to left deltoid. Arrival of ED on scene, hand off given pt. transported to hospital. Allergies PCN. no hx anaphylaxis no reaction to first dose of pfizer covid-19 vaccination. Vitals BP 132/94, pulse rate 94, R 20. Pt. was contacted 1943 hours on 3.10.21 Pt. had stay in ER approximately 5 hours, was discharged home with epi-pen, and an unknown antihistamine. Pt. will follow up with PCP about anaphylactic reaction she had today.
1087293	3/10/2021	NY	57	F	3/8/2021	3/8/2021	Site: Pain at Injection Site-Mild, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Mild, Systemic: Lymph Node Swelling-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Additional Details: Patient did not have any anaphylaxis, main complaint was mild tightness under chin between jaw and lymph nodes 20 minutes post immunization lasting for a max of 30 minutes. Also mild tingling in forearm a few minutes after injection.
1087533	3/10/2021	ME	67	F	3/3/2021	3/3/2021	I became warm and flushed all over a few minutes after shot , then foggy feeling with congestion in sinus. I waited about 20 minutes and left I spoke to my allergist and he said that I had experienced mild anaphylaxis and should not take dose 2 of the vaccine
1085741	3/9/2021	IN	57	F	3/1/2021	3/6/2021	Anaphylaxis - rash and hives from head to toes, severe itching, difficulty breathing, and chest pain. Oxygen Saturation was at 87 when I arrived. Treated with dexamethasone sod phosphate PF last given at 5:45 PM, diphenhydrAMINE (Benadryl) last given at 5:45 PM, EPINEPHrine last given at 5:45 PM, famotone last given at 6:08 PM, GI cocktail oral suspension last given at 6:44 PM, hydrocortisone last given at 8:18 PM, LORazepam last given at 5:48 and 6:45 PM, ondansetron last given at 5:48.

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1086535	3/9/2021	CA	46	F	3/8/2021	3/8/2021	46 year old female with no past medical history or allergies to medications. She received her first Moderna COVID-19 vaccine and reported dizziness and nausea afterwards. She denied any trouble breathing, facial swelling, rashes, vomiting or difficulty swallowing. She denied taking any medications after the first dose of the vaccine. She received her second dose of Moderna COVID-19 vaccine on 3/8/21 and approximately 30 minutes after the dose complained of dizziness, nausea and throat tingling. Her vital signs were stable (HR 76, RR 18, SpO2 97%RA, BP 132/81). Her oropharynx was clear, no lip/tongue or posterior oropharynx swelling. She spoke in clear sentences, no respiratory distress, respirations are unlabored. She was given Benadryl 50mg orally and advised not to drive home. She was given strict allergic reaction/angioedema/anaphylaxis education and go to ED if any symptoms persist/worsen.
1086309	3/9/2021	NV	31	F	3/9/2021	3/9/2021	Patient fainted about 5 minutes after receiving the vaccine. She was in the monitoring area and fell over and hit her head on the ground. I went to her aid and monitored her until the paramedics showed up. She was unconscious for a 10-15 seconds with her eyes open before regaining consciousness. I She was not having breathing problems or other symptoms of anaphylaxis so i did not administer an epi-pen or benadryl to her. I rolled her on her side in case she became nauseas. Then the paramedics arrived and attended to her.
1085840	3/9/2021	CT	58	F	3/9/2021	3/9/2021	Pt received her first COVID19 Moderna vaccine, while sitting in observation she reported a tingling sensation in her bottom lip. Pt reports many allergies to medication but none that caused anaphylaxis. Pt was evaluated by EMS. BP 158/96, 162/99 HR 80, O2sat 98%. Pt signed refusal with EMS for transport. Symptoms did not progress while sitting in observation any further.

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1085747	3/9/2021		46	F	3/9/2021	3/9/2021	ABOUT 10 MIN AFTER VACCINATION, PT FELT WARM WITH SOME SOB AND TINGLING IN HER BODY + RINGING IN HER EARS. HUSBAND WENT TO GET HELP AND PT FELL OUT OF HER CHAIR WITH LOSS OF CONSCIOUSNESS. PT RECOVERED IMMEDIATELY WITHOUT CONFUSION,. VITALS BP: 102/71 HR: 81. PMH STROKE 2008 WITH RESIDUAL L WEAKNESS. MEDS: ASPIRIN, ZYRTEC, FLONATE. NO PREVIOUS VACCINE REACTIONS OR ANAPHYLAXIS. EMS CALLED TO TRANSPORT TO ER. VASOVAGAL LIKELY.
1085705	3/9/2021	WA	57	F	3/7/2021	3/7/2021	HPI: Reaction to Covid vaccine Had second dose today and noted sensation of throat swelling and wheezing approximately 30 minutes after arrival Took 25 mg of Benadryl and 1 albuterol treatment with improvement of symptoms Came to the ER for further evaluation Patient was otherwise well before today had some nausea but no vomiting No rashes, no diarrhea, no pruritus DDX: Likely allergic reaction to second dose of Covid vaccine No symptoms of anaphylaxis Patient took one Benadryl prior to arrival and DuoNeb, so wheezing has improved will treat with Pepcid, steroids, Benadryl, Solu-Medrol, fluids No indication for epinephrine at this time Pt well appearing and HDS. No indication for emergent intervention at this time. Will continue to monitor

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1085186	3/9/2021		32	F	1/28/2021	1/28/2021	Other side effects; Anaphylaxis; Anaphylaxis; A spontaneous report was received from a nurse, concerning a 32-year-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced 2 episodes of anaphylaxis (onset: 28 Jan 2021 and 29 Jan 2021) and other unspecified side effects. The patient's medical history was not provided. No relevant concomitant medications were reported. On an unspecified date patient took her first of two planned doses. On 28 Jan 2021, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (lot/batch: 028L20A) intramuscularly for prophylaxis of COVID-19 infection. On 28 Jan 2021, the patient experienced the event of anaphylaxis (life threatening), within 30minutes after the second dose of vaccine. Hence, she received epinephrine and her condition did not improve so received a second dose of the same, also was treated with diphenhydramine and oxygen and sent home. Next day, on 29 Jan 2021, the patient again went into anaphylaxis, hence, received another epinephrine and was also given with prednisone due to which patient got better and was stable today. But, however, she still having other side effects but not anaphylaxis. The patient's clinical history says that on Sunday night she continued to be symptomatic with vaccine side effects. The patient was confirmed to be not pregnant. Treatment for event other side effects were unknown. Action taken with mRNA-1273 in response to the events were not reported. The outcome of events anaphylaxis (onset: 28 Jan 2021) and anaphylaxis (onset date: 29 Jan 2021) was resolved on 29 Jan 2021. The outcome of event other side effects was considered unknown at the time of this report.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

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1085175	3/9/2021	MO	70	F	3/9/2021	3/9/2021	Approximately 20 minutes after receiving the 2nd covid vaccine pt reported feeling lightheaded and dizzy which progressed to flushed blotchy redness on chest and neck. BP 190/104. Approx 3 minutes later pt reported feeling like throat was swelling and was having difficulty swallowing. Pt had premedicated with Benadryl 25mg po prior to arrival due to history on anaphylaxis to multiple other medications and foods. Benadryl 25mg po was administered and pt assisted to exam room. Pt began to be anxious and said swelling was getting worse. Epinephrine (1mg/ml) 0.5mg IM administered per standing order. Refused ambulance or transfer to ER at this time. Husband at side and said this has happened previously and she knows how to manage without the ER. 10 minutes after 1st dose of epinephrine a second dose of 0.5mg epinephrine administered due to continued swelling. PT was monitored in clinic. Left ambulatory with no resp distress or resp symptoms noted. Pt and husband refused EMS and ER. Instructed to follow-up with PCP and s/s to seek further treatment from ER.
1084101	3/9/2021	NJ	56	F	2/26/2021	2/26/2021	was speaking to patient as she has had hx of anaphylaxis to sulfa medication. she was fine speaking to me and 9mins after vaccine developed blank stare eyes became watery and told me she needed Benadryl she didn't feel well. asked her what she felt and her response was delayed and stated "throat felt like it was closing: trouble breathing. Called a code and told RN to get me epi 0.3mg which was administer to opposite arm (right upper arm) . brought patient to the floor and kept legs elevated. Benadryl 50mg IM given to Left deltoid. unable to get BP as the machine was not giving me BP :manual cuff to small. code team responded within 5mins. EKG leads placed on patient showing sinus tach 140 O2 sat 99% .. patient continued to be responsive and once epi was given spoke more requesting husband.. patient was put on stretcher and taken to ED by code team.
1085370	3/9/2021	CA	50	F	3/5/2021	3/5/2021	anaphylaxis, treated with epinephrine,

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1082334	3/8/2021	IL	60	F	3/5/2021	3/5/2021	<p>No rxn to dose 1. Dose 2: @10 min had tingling of lips; at 12 min had tingling of tongue [and anxiety from the tingling]; @ 15 min had some SOB and knew this was not just anxiety. Had zero intention of being taken to ER as I could easily tx myself. Took inhalers, extra cetirizine. Did not take epi, though have several pens. @4 hour started feeling weak, severe arm pain. At 6 hours, unbearable arm pain, extreme weakness [did not take BP or pulse ox--though I can and wish I had]. Exceeding thirst, could not get water down fast enough. Reactivation of arachnoiditis symptoms. Started unusual muscle fasciculations in arms, leg, and face [face not normal for me]-took valium and baclofen. Next 36 hours unable to get out of bed other than to get water. Severe HA upon waking [@16 H post injection]. Severe myalgias, but in areas of known arachnoiditis that have been quiescent for quite some time. Forgot to mention, as I find this strange: prior to going to sleep I had left eye conjunctivitis. Left eye only that still is slightly persistent and doesn't require any care [for me at least] I am currently 72 hours post. Still with HA and some fatigue, though worked today [I WAH for a population health company]. L arm is not as painful as the excruciating pain @ hour 4-16, and no need for additional acetaminophen. I have an exceedingly high pain tolerance due to the arachnoiditis, but this was the first time I took a narcotic in 5 years. 2 .5 mg oxycodone x1, then 600 mg ibuprofen x1, then 1 gm acetaminophen 2 over next 24 hours and nothing since, but it is still quite painful today. Different today than yesterday is the development of what feels like left shoulder bursitis. We'll have to see how this goes over time. There is extensive edema at the site, but not clear erythema [I'm dark skinned]. Still just can't seem to get enough water. Had my first meal last night [made chicken soup]. It's still pretty early on. I'm not even at the 72 hour mark yet, so hopefully things will settle down over the next weeks. I checked the box as life threatening because that was likely early anaphylaxis -- though at first I seriously thought at first I was just anxious because of the lip tingling. This is in defense of the fact I did not self administer epi when I became SOB. I likely should have, but know myself well and did fine without it and with asthma and allergy care. I didn't need extra albuterol</p>

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1080292	3/8/2021		33	F	3/5/2021	3/5/2021	<p>after the first 24 hours [though writing this makes me feel SOB just from reliving it]. This second dose is a doozy. Hope this was helpful. I provided you guys with my cell but if you want to follow up, I use my phone for work so if you text first I cant tell you availability.</p> <p>Pt initially reported her allergies when questioned and that she has difficulty breathing and vaccinator advised her not to take the vaccine. She requested to speak to supervisor. Clinic manager came to speak to Pt and when asked to confirm that she has difficulty breathing w/ allergies, she denied it. Clinic manager spoke to medical advisor was told that since she answered yes to question 2, she could receive vaccination but would need to be monitored for 30 minutes. Clinic manager explained this to Pt. and also informed her that if she had any s/s of anaphylaxis, an epipen would be administered and 911 would be called; Pt. agreed. At 11:40 Pt complained of feeling dizzy, unsteady gait. PHN had her lie down at 1140am and offered water. She also reported a headache and feeling cold. Pt was conscious, but appeared weak. 1210pm, pt still c/o dizziness. At 12:45pm c/o nausea, no vomiting. AT 12:46pm she appeared to faint, 911 called. Handed off patient to paramedics at 1:05pm. Transported to local hospital 13:10.</p>

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1080335	3/8/2021			U			Anaphylaxis; A spontaneous report was received from a physician assistant concerning a patient of unspecified age and gender, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced anaphylaxis. The patient's medical history was not provided. No relevant Concomitant medications were reported. On an unknown date, prior to the onset of the event, the patient received their first of two planned doses of mRNA-1273 (Lot number: unknown) for prophylaxis of COVID-19 infection. On an unknown date, after receiving vaccine, the patient died due to anaphylaxis. No further details were available at the time of this report. Treatment for the event was not provided. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the event anaphylaxis was fatal. The patient died on an unspecified due to anaphylaxis. Autopsy details were not provided.; Reporter's Comments: Very limited information regarding the event of anaphylaxis has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Anaphylaxis
1080470	3/8/2021	NY	65	F	2/11/2021	2/12/2021	Patient got a pimple the day after vaccine. Redness in both cheeks a few days after first dose of the vaccine. No swelling of tongue or face. No shortness of breath. On occasion without known precipitant, she has had swelling of the uvula. One time with ammonia exposure had swelling of her uvula. She has epi pen and Benadryl and is very competent. This is her second vaccine and no anaphylaxis after the first. No swelling of uvula. Will continue with vaccination and observe for 30 minutes.
1080504	3/8/2021	IN	51	F	3/5/2021	3/5/2021	Patient has a history of anxiety and anaphylaxis to latex. She started feeling weird in head, nauseated, and dizzy a few minutes after her vaccine. BP 153/96 with pulse of 101 5 minutes post vaccine. We continued to monitor her. 20 minutes post vaccination bp 136/89 with pulse 97. 30 minutes post vaccine we tried to sit her up. She was very nauseated. bp 144/99 pulse 85. 35 minutes post vaccination bp 140/108 and pulse 83. She felt sick with her IBS, and we got her into the bathroom via wheelchair. 50 minutes post vaccination, bp was 129/93 with pulse of 83. We called her husband to pick her up because she was exhausted after all of this.

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1080731	3/8/2021	CO	56	M	3/6/2021	3/6/2021	56 yo male here for Covid-19 vaccine clinic, presented to Urgent Care shortly after receiving vaccine to RUE with local swelling to the injection site. No evidence of anaphylaxis or allergic reaction.
1081255	3/8/2021	CO	24	M	3/6/2021	3/6/2021	Minutes after receiving my vaccine my left arm began to go numb with a full head headache following soon after. I was then moved to the observation area where my chest got tight, I had difficulty breathing and my temperature fluctuated which made me shake. When hives began to show on my face, neck and ears the on-site medical staff gave me a shot of epinephrine and Benadryl and put me on oxygen, during this time an ambulance was called by the staff. When I got to the hospital my heart rate and blood pressure was high, I was given oral steroids to help my anaphylaxis. For days after being released from the hospital I continued to have deep muscle pain and weakness in my left arm as well as a very strong headache
1082469	3/8/2021	VA	53	F	3/7/2021	3/7/2021	20 min after dose of moderna vaccine she felt her face get hot and swollen and she felt tingling - 10 more minutes and she felt throat was swelling. Waited another 20 min. Went to ER. Got full body shakes and a full body rash. Given pred, benadryl, treated for anaphylaxis. Symptoms began to recur next day and came to PCP office

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1082544	3/8/2021		41	F	2/17/2021	2/18/2021	<p>o Complaint The patient is a 41 year(s) old Female complaining of allergic reaction, nausea. o Chief Complaint Quote Patient complained of allergic reaction that started about 45 mins ago. She got her 1st dose of Pfizer Covid vaccine yesterday morning. She complained of rash all over the body, swelling on the hands and face including eyes and lips. She denied chest pain, abdominal pain, fever, cough, vomiting and difficulty breathing. She complained of nausea that started 5 mins ago. She has not taken any meds yet for her symptoms. o Time Seen 02-18-2021 01:20 o Historian patient</p> <p>ADDITIONAL HPI: o Additional HPI Pt here with concerns of allergic reaction. Pt fell asleep on the couch approx 2200. She awoke 2 hours later with itching of her hands. Over the next hour she developed a full body rash, itching, and swelling of face. No wheezing, no difficulty swallowing. Upon arrival to ED pt started to feel nauseated. Pt had first dose of COVID vaccine approx 16 hours prior to onset of sx's. No h/o allergic reactions, no h/o asthma. Emergency Department Course and Clinical Decision Making: Patient presents with urticaria and swelling to her face eyes and lips. Shortly upon being roomed she started to feel very nauseated and started vomiting. No stridor or wheezing, no immediate airway compromise but given both cutaneous and GI symptoms, significant concern for anaphylaxis. Patient was immediately given epinephrine intramuscularly, 0.3 mg. An IV was placed and she was given Solu-Medrol, Benadryl, Pepcid, and Zofran. Patient's urticaria and swelling started to nearly immediately improved after the epinephrine. She is feeling much better though slightly anxious. To be reaction from the Pfizer vaccine, no other obvious triggers, patient has no history of allergic reactions or other sensitivities. We will observe in the emergency department in a monitored setting for several hours to assure no rebound symptoms, patient updated on plan. 0500 Pt has been resting. Urticaria resolved, swelling to face resolved. Discussed with pt reporting reaction to CDC, info provided. Also discussed the second dose of vaccine, recommended reaching out to Epi response team or PCP to get recommendations. Will give short course of prednisone, 4 days, Benadryl as needed, ED return precautions discussed, will dc home.</p>

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1082806	3/8/2021	CO	46	M	3/8/2021	3/8/2021	Anaphylaxis shock within 5 minutes after administration of vaccine.

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1082870	3/8/2021	NC	68	F	1/25/2021	1/25/2021	<p>Allergic reaction; Tongue felt full; Did not feel well; Puffiness; Trouble swallowing; rash; Swollen glands; Blood pressure high/ changes in blood pressure; Felt faintness; Feeling hot; Fluid accumulation; Turned a dark, pinkish color/ flushed; Changes in heart rate/ heart was racing; A spontaneous report was received from a health care professional concerning a 68-years-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced allergic reaction/ hypersensitivity, feeling hot, fluid retention, flushing, presyncope, heart rate abnormal, swelling face, tongue felt full/ swollen tongue, hypertension, dysphagia, not feeling well/ malaise, rash, and lymphadenopathy. The patient's medical history, as provided by the reporter, included anaphylaxis to Keflex, lisinopril and sulfa drugs. Concomitant medications reported included HCTZ, diltiazem, rosuvastatin, isosorbide mono, metoprolol and pepcid. On 25 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly for prophylaxis of COVID-19 infection. On the same day patient experienced allergic reactions, feeling hot, fluid retention, flushing, presyncope, high blood pressure, swollen glands. On 26 Jan 2021, the patient was taken into the hospital and kept there for 6 hours. On 29 Jan 2021, the patient still had faintness. Her heart was racing and she did not feel well. On 04 Feb 2021, her tongue felt full and something did not feel right. The patient's vital signs included blood pressure 190/98 and later 140/80. Treatment details included Benadryl, EpiPen, Ativan, Solumedrol, steroids, and Tylenol. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, feeling hot, fluid retention, lymphadenopathy, and rash were considered recovered/resolved on an unknown date. The outcome of the events, flushing, and presyncope, was considered not recovered/not resolved. The outcome of the events, allergic reaction, hypertension, heart rate abnormal, swelling face, swollen tongue, malaise, and dysphagia, was not provided.; Reporter's Comments: This case concerns a 68 Y/O F who had serious unexpected hypersensitivity along with unexpected BP high, heart rate abnormal, presyncope, dysphagia, face swelling, swollen tongue, flushing, feeling hot, malaise, fluid retention, and expected rash,</p>

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1082965	3/8/2021	OR	39	F			lymphadenopathy. Event onset the same day as first dose mRNA-1273. Treated with Benadryl, EpiPen, steroids. Based on current available information and temporal association between use of the product and the start date of the event, a causal relationship cannot be excluded.
1083368	3/8/2021	TX	45	F	3/8/2021	3/8/2021	did not have full anaphylaxis; a sense of her throat swelling; hives; This is a spontaneous report from a contactable physician. A 39-year-old female patient received first dose of bnt162b2 (Pfizer-BioNTech COVID-19 vaccine), via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. On an unspecified date, it was reported that the patient experienced "a sense of her throat swelling" and hives 1 hour after the vaccination occurred. The patient received 1 dose of Benadryl and Tylenol and "felt ok." The physician commented that the patient did not have full anaphylaxis and was asking if it would be safe for the patient to receive the second dose of the vaccine at the time of report. The outcome of the events was recovering. Information on the lot/batch number has been requested.
1081161	3/8/2021	VA	47	F	3/5/2021	3/5/2021	Received vaccination and was observed for 30 minutes prior to leaving site. Patient returned to vaccination clinic with complaints of facial swelling, tightness in throat, splotchy skin, swelling of L wrist and fingers; hands "wrinkly" in appearance. Symptoms lasting 30-40 minutes and had begun to calm down prior to return. Assessment: BP: 178/88, P: 73; O2 Sat: 99 %. Lungs CTA. Epi available-not given. EMS deployed to the scene. States improvement in facial swelling and itching. 3:15 EMS arrived; BP: 188/102.. Patient counseled and transport to hospital offered and declined by patient. Patient acknowledged risks of stroke, MI, and delayed anaphylaxis.

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1080431	3/7/2021		67	M	2/25/2021	2/26/2021	Narrative: 67 year-old male received his 1st COVID vaccine dose at a clinic on 2/25/21 at ~ 11:45am. No known prior COVID infection. No history of vaccine allergies or allergies to any component of the COVID vaccine. Does have history of allergic reactions including hives, angioedema or anaphylaxis to some medications (neomycin, Neosporin, bacitracin) and environmental allergens (yellow jackets, fir trees). Patient reported previously daily use of diphenhydramine (2 caps every morning) and kept an epi-pen on hand. The afternoon of 2/26/21, patient presented to his neighbor's house requesting assistance with an epi-pen. Neighbor reported significant swelling around tongue and lips, and ability to faintly speak. Neighbor administered epi-pen, but unsure if it worked, so administered a 2nd epi-pen. Within a minute or two after the 2nd dose, patient slumped over and became non-responsive. EMS was called and neighbor began CPR. EMS reported that patient was non-responsive upon arrival. A King airway was placed and a Lucas device used for chest compressions. Three rounds of epinephrine were administered during transport to the local emergency room. Patient remained unresponsive with evidence of PEA during transport. Arrival at the ER occurred ~ 4:25pm. On arrival patient noted to be unresponsive with CPR in progress. Dose of epinephrine administered ~ 3 minutes after arrival in ER. No femoral pulse palpable, cardiac monitor did show some electrical activity. Evaluation of oral cavity showed significant swelling of tongue. Additional dose of epinephrine given. Patient remained with no palpable central pulse and showed continued evidence of PEA. Patient was estimated to have been down > 45 minutes. Patient pronounced deceased at 4:59pm.
1078775	3/7/2021	MA	37	F	3/6/2021	3/6/2021	Systemic: Dizziness / Lightheadness-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Additional Details: Patient fainted a few minutes after injection. Felt hot then tried to get up and fell to the ground. She was not injured. EMS was called and evaluated her. No signs of anaphylaxis.

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1078794	3/7/2021	FL	77	M	3/3/2021	3/3/2021	Feeling of impending doom. Felt like I was going to die. Symptoms of Anaphylaxis but did know that was what it was. Failed to call paramedics which I should have . Kept getting worse all night and the onset of vomiting, diarrhea, fever, which lasted three days.

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1078928	3/7/2021	VA	44	F	2/26/2021	2/26/2021	<p>First I got a headache, then I felt extra mucus in my throat. Then I started feeling compression, pressure, and pain in my diaphragm; and then the middle of my chest. Finally, I started coughing, and I wasn't able to breathe. I had told all of the nursing staff that I had anaphylaxis to the first shot, but they acted like they didn't believe me. Also, there was no EMS staff on hand this time, unlike the first time, where they were on site. I think that made the difference in my medical care, because my husband heard the nurses at the facility say they were treating me for anxiety, not anaphylaxis, despite the fact that I was getting worse. The nurses on staff didn't seem to understand or believe that a person could have anaphylaxis from the Covid injection, even though it's on record at the hospital that that's what happened the first time. It wasn't the same staff as last time, which also contributed to the problem. Once the ambulance staff got there, he took me seriously, and finally administered an EpiPen, and also put me on oxygen, which helped a little bit. that was the most comprehensive care I got that day, from someone who was actually listening to me he also took an EKG, which was normal. When I got to Facility, the treatment wasn't as good as last time, either. Apparently they've been really busy the day before, and all of the staff seemed fatigued because of it. Nobody really checked on me, offered me even ice chips to moisten my mouth, and didn't offer me any assistance in getting to the bathroom, either. a respiratory therapist came in to give me a couple puffs on an albuterol inhaler, and I got a Benadryl shot, but nothing else. I think if I had not taken my coterie of prescriptions to stave off anaphylaxis, it would have been worse. 20 minutes before the shot I took: two aspirin, a CBD capsule, and one each of the following pills -cetirizine, benadryl, famotidine, 20 mg of prednisone, hydroxyzine. I think that's what enabled me to recover with only one EpiPen, instead of two, like last time. if there's a third Moderna shot for the variants, or a booster, I'll try to take all those pills an hour beforehand, and see if having them in my system for a longer period of time we'll make the difference. It will be nice to have *no* anaphylaxis, and skip the hospital trip. Since then, it's taken me about a week to recover fully, the same as after the first shot. I've had problems breathing, fatigue, muscle aches and pains, flushing, fever/chills, and in general just felt like I</p>

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							had the flu.
1079105	3/7/2021	TN	64	F	3/2/2021	3/2/2021	Within 10-15 minutes of receiving the shot, my face and ears became very flushed and hot; I felt as if I had a large dose of a Medrol Dose-pak/steroid. I did not have any difficulty breathing, nor did I feel my throat constricting or other symptoms of anaphylaxis. Since my symptoms were relatively minor, I did not alert the volunteers at the vaccine site that I needed to see the paramedic on duty. The only concession I made to my symptoms was that I allowed my adult daughter, who came with me for a vaccine, to drive us home. My symptoms subsided within 30 minutes and have been gone ever since.
1079546	3/7/2021	ID	66	F	3/7/2021	3/7/2021	Pt began feeling lip tingling and dizziness approximately 20 minutes following the injection. About 5 mins later she reported throat tightness, stating that her symptoms felt similar to early symptoms during previous episodes of anaphylaxis. Vital were obtained and pt was stable c an HR of 65, O2 of 98 on room air,. BP was elevated at 180/102, which pt reported was usually around 130/85. EMS was notified and pt was administered a single .15mg auto injector dose of epinephrine. She remained stable and conscious over the next 5 minutes until EMS arrived, Pt intake was given to EMS and pt was transported to the ER within 15 minutes of first notifying staff of symptoms.
1079818	3/7/2021	SC	53	F	3/5/2021	3/5/2021	Anaphylaxis. Onset 10 minutes. Initially responsive to epinephrine, subsequently not. Ultimately requiring endotracheal intubation

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1077305	3/6/2021	TX	59	F	3/5/2021	3/5/2021	03/05/2021 @ 1100: Medic at site called & stated patient w/c/o difficulty swallowing; VS: BP-160/80; HR: 110; O2 sat on RA:96%; This nurse went to check on patient, patient crying and trying to be calm. Patient stated she had anaphylaxis before with abx but did not have an Epi pen. EMS called and we were instructed to go ahead and give patient Epi eventhough she was sating @ 96%. Instructions followed, Epi 0.3 mg auto injected to patients right lateral thigh by EMT. VS before EMS arrival: BP: 156/104; HR: 106; O2 on RA: 97%. Care turned over to EMS. This nurse contacted patient on 03/05/2021 @ 2115 - p/patient, she was given an Epi neb and another dose of Epi in ED. Patient left ED on oral steroids - dcd @ 1600.
1078405	3/6/2021	MI	67	F	3/6/2021	3/6/2021	After 30 minute observation after vaccination per protocol for anaphylaxis history, patient left unit at 5:55pm and as she was leaving facility she reported symptoms to staff of "high blood pressure", "faintness", dizziness, lightheaded, weakness per patient--patient was assessed by EMS on site and BG was 86, BP elevated at 161/76. After further observation but no significant progression or improvement of symptoms she agreed to be transported to ED at 6:30pm.. No medications given on site, juice and crackers provided for low BG and report of missing meal,
1077947	3/6/2021	CA	29	F	3/6/2021	3/6/2021	Patient with prior hx of anaphylaxis - required 30 min wait, ~ 25 mins into wait time - reporting slight swelling of lips, sensation of itchy throat/tightening, appearance of hives on arms. Patient alert and oriented, breathing comfortably. Advised will take to ED dept for further evaluation - patient refusing wheelchair - ambulatory. Walked to ED dept with NP, report given to ED, registration completed.
1077861	3/6/2021	TX	52	M	2/26/2021	3/5/2021	signs of anaphylaxis after eating granola.. full body itching, lightheaded, wheezing, shortness of breath, sensation of throat swelling up

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1077838	3/6/2021	CA	40	F	3/6/2021	3/6/2021	Pt. c/o itching of eyes, abdomen, behind ears and sore throat. Denied SOB or chest pain. Hx of anaphylaxis to TDap and NSAIDs. Pt stated felt similar to other reactions in past. 0917 BP 175/112 and 0927 170/105. Pt. states forgot to take BP meds. 0921 Benedryl 50 mg IM given per Dr. orders. Pt. observed for 20 min and reported all symptoms subsided. Pt. released to home driven by spouse.
1077749	3/6/2021		65	F	3/5/2021	3/5/2021	Pt has hx of anaphylaxis, her daughter has the same allergies as pt. Daughter had vaccine first and was taken to ER due to adverse reaction. This pt spoke with her primary who consulted an allergist and recommended pt pre- medicate with Benadryl. Pt did take Benadryl prior to vaccination
1077726	3/6/2021	FL	51	M	3/6/2021	3/6/2021	Patient rec'd dose #1 of Pfizer without incident 3 weeks ago. Has hx of anaphylaxis to ant bites and PCN. Noted L ear "pressure", sounds are "muffled", sudden onset approx 30seconds after injection of dose #2. Nurse practitioner at chairside assessing patient. VS stable. Denies chest pressure, difficulty breathing, any other s/s reaction. Peripheral IV started and 60mg solumedrol given IVP through free flowing saline line. Patient notes relief within 5 min after solumedrol. Monitored for additional 45min. Patient reports relief of symptoms. Discharged with instructions to take PO benadryl and go to ER immediately if any sx reoccur. MD team notified.
1077672	3/6/2021	VA	44	F	3/6/2021	3/6/2021	Pt @ 14 weeks pregnant, hx of seasme allergy (food ingestion) mild, no anaphylaxis now got first covid vaccination and had mild hand tingling, no CP, no SOB or throat swelling

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1075966	3/5/2021	MO	87	F	3/5/2021	3/5/2021	Summary - ANAPHYLAXIS. Screened via medical questionnaire with no known hx of anaphylaxis after receiving injection. Less than 10 minutes after receiving injection, pt's son reported to staff that pt was overheated and not feeling well. After receiving ice water, pt became non-responsive to questions and developed tongue swelling, blocked airway and audible wheezing. 0.3mg IM epinephrine injected into L thigh. Pt was laid down in empty exam room. Blood pressure 130/80, pulse 96, temp 96.9. Pt able to sit up, answer questions and breathe comfortably without distress within few minutes of receiving epinephrine. Examined by EMS and declined transportation to ER. Called by physician 4 hours later; pt reported doing well.
1075787	3/5/2021	OR	30	F	2/16/2021	2/16/2021	Mild anaphylaxis about 20 minutes after dose. Abrupt painful tightening of the throat, no real difficulty breathing. My face felt "buzzy" but didn't swell and I did not have significant itching. I have had similar reactions in the past to cleaning products and pesticides and usually take a benadryl, though I do carry an epipen and had one with me at the time. Instead of going back in the convention center for medical attention I took a benadryl and waited in the parking garage for about an hour and felt the throat restriction ease a bit. About 10 hours later around 8pm the tightness came back suddenly over about 10 minutes and I took another benadryl. The next morning around 7am I had one more round of tightening and took one more benadryl, and it stopped after that. I told my doctor about it a few days later.

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1075736	3/5/2021	TX	68	F	3/1/2021	3/1/2021	Clinic course: 13:50 patient given covid vaccine #2- Pfizer. 14:10 patient c/o sob and throat closing. O2 sat 94%. EpiPen 0.15 mg given IM to lt thigh. O2 at 4l/nc started. 14:15 EMS called to transport patient to UTMB ER. Bp-150/88, p-75. O2 sAT 98% ON O2@4L/NC. Patient Has audible wheezing and unable to talk above slight whisper. 14:20 Patient feeling a little better. Talking in a louder whisper now. Denies sob. States throat still feels like throat is opening a little. O2Sat 98% on O2 at 4l/nc. Patient was evaluated by NP- Employee Health. 14: 25- patient feeling better. I asked her if she has ever had a reaction needing epi pen before and she stated yes. For allergy shot. I asked her if she told MA when asked and she stated no as I didn't think I would be able to get covid vaccine if I said anything about it. She states no reaction to 1st covid vaccine. ED Course: is a 68 year old female with CAD s/p PCI, HLD, OSA, seizures, HTN, asthma who presents after anaphylaxis following 2nd dose of COVID-19 vaccine. Chest tightness and original EKG concerning for STEMI, but on review EKG was artifact and did not evolve. Normal sinus the following day with resolution of symptoms. EpiPen also improved symptoms which would be inconsistent with ischemia. Patient respiratory status improved on prednisone and breathing treatments. Patient is now stable for discharge.
1075569	3/5/2021	MN	66	M	3/5/2021	3/5/2021	Patient was being monitored for 30 minutes by EMS due to anaphylaxis to Shrimp. About 15 minutes into monitoring, the patient reported to EMS that he was feeling sweaty and had some shortness of breath. EMS reported BP to be 171/89 and pulse of 88. Patient stated that he does take blood pressure medication and reported that BP was elevated for him. EMS contacted ambulance for transport to Emergency room, patient in agreement to transport.

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1075373	3/5/2021	NJ	62	F	3/3/2021	3/3/2021	Within 5 minutes of injection my tongue felt odd and I started to salivate. Shortly after, I found it difficult to swallow (as if throat) was closing up, numbness in lips, flush face, tingling in fingers. Liquid Benadryl (1 capful) was administered by mouth and within 10 minutes swallowing difficulty was less but still difficult. Within 30 minutes all symptoms subsided. At no time did I have difficulty breathing, chest tightness, wheezing or any other anaphylaxis symptoms other than the ones described.

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1074842	3/5/2021	KS	50	F	2/24/2021	2/24/2021	<p>Progress Notes APRN (Nurse Practitioner) Cosigned by: MD at 2/28/2021 7:27 AM Expand All Collapse All</p> <p>COVID VACCINE CLINIC</p> <p>2/24/2021 Date:</p> <p>2/24/2021</p> <p>Subjective: is a 50 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She was given the Pfizer vaccination in the left deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience throat tightness. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to blood pressure abnormality, chest pain, collapse, hypotension, increased swelling, rapid progression of symptoms, respiratory distress, skin changes and tongue swelling. PMH: DM, hypothyroidism, asthma ALLERGY REVIEW OF SYSTEMS: Patient denies chills, fever, malaise/fatigue, facial swelling, sore throat, frequent throat clearing, eyes itching, cough, chest tightness, shortness of breath, wheezing, rash, hives, eczema, itching of skin, abdominal pain, muscle aches, dizziness and headaches Previous Reactions: none Objective Vitals Vitals: 02/24/21 1350 02/24/21 1352 BP: (!) 152/93 (!) 142/80 Pulse: 85 SpO2: 100% Physical Exam Constitutional: General: She is not in acute distress. Appearance: Normal appearance. She is well-developed. She is obese. She is not diaphoretic. HENT: Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Comments: Clear/patent oral airway Eyes: Conjunctiva/sclera: Conjunctivae normal. Neck: Thyroid: No thyromegaly. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Heart sounds: Normal heart sounds. Pulmonary: Effort: Pulmonary effort is normal. No respiratory distress. Breath sounds: Normal breath sounds. No wheezing. Musculoskeletal: Cervical back: Neck supple. Skin: General: Skin is warm and dry. Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: General: No focal deficit</p>

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							<p>present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. Thought Content: Thought content normal. Judgment: Judgment normal. Assessment/Plan Treatment included: antihistamines Follow up response to treatment: excellent. Patient discharge: Stable to go home and follow up with PCP. Differential Diagnosis: Vaccine-Related Anxiety (include misc mental health) and Red flag symptoms (CP, SOB, NVD, Visual/Neuro concerns) VS stable. Improving symptoms/resolved. Monitored for 1 hour. Low suspicion for anaphylaxis. More likely generalized allergies and/or anxiety. Doing well. Pt going home with husband. APRN Electronically Signed 2/24/2021 1:56 PM</p>
1076060	3/5/2021	GA	52	F	3/1/2021	3/1/2021	<p>PATIENT REPORTED FEELING DIZZY AND LIGHT-HEADED WITHIN TEN MINUTES OF RECEIVING VACCINE. SHE FELT NAUSEATED AND STATED SHE FELT LIKE SHE DID WHEN SHE HAD AN ALLERGIC REACTION TO A BEE STING THAT REQUIRED AND EPI-PEN. WE BEGAN ASSESSING THE PATIENT FOR ANAPHYLAXIS. WE GAVE DIPHENHYDRAMINE 50 MG ORALLY AND MONITORED HER HEART RATE AND BLOOD PRESSURE. HER BLOOD PRESSURE AND HEART RATE STAYED WITHIN NORMAL RANGE FOR THE NEXT 45 MINUTES. SHE REPORTED NO ANGIOEDEMA OR ANY OTHER SYMPTOMS OF ANAPHYLAXIS. WE ALSO ADMINISTERED FAMOTIDINE 20 MG TABLET. SHE CONTINUED TO DO WELL AND DID NOT EXHIBIT ANY OTHER SIGNS OF ANAPHYLAXIS. AFTER 45 MINUTES OF MONITORING THE PATIENT WITH SYMPTOMATIC QUESTIONS FOR ANAPHYLAXIS, MONITORING HER BLOOD PRESSURE AND HEART RATE, AND WITH NO OTHER SIGNS OF ANAPHYLAXIS, THE PATIENT WAS RELEASED FROM OBSERVATION. SHE REPORTED TO OUR PHARMACY ON 3/5/21 THAT SHE HAS CONTINUED TO HAVE SEVERE MUSCLE CRAMPING, SOME NAUSEA AND OVERALL FATIGUE. I COUNSELED THE PATIENT TO CONTINUE TO MAKE SURE SHE CONTINUES TO STAY WELL HYDRATED. SHE CONSULTED WITH MD AND HE ADVISED HER TO STAY HYDRATED. SHE ALSO TOOK PREDNISONE PRESCRIBED FOR A PREVIOUS KNEE INJURY, THAT THE PATIENT REPORTED.</p>

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1074230	3/5/2021	AK	33	F	3/4/2021	3/4/2021	Anaphylaxis happened within 12 minutes. I was administered epinephrine at the vaccine site, as well as in the ambulance. FURTHERMORE I was administered DiphenhydrAMINE, Famotidine, solu-MEDROL at the Emergency Department. Those are just a few of what I received. When I was finally discharged I was sent home with 2 epi-pens and a 4 day dosing of Prednisone.
1076103	3/5/2021	VA	66	F	3/4/2021	3/4/2021	Patient felt a tightening in the throat 10 minutes after receiving vaccine. Vitals were stable on the way to the hospital, patient received steroids and benadryl at the hospital (no epinephrine was needed or given). Not a true anaphylaxis, MD described as "slight allergic reaction" and is okay to get 2nd dose in 3 weeks.
1074461	3/5/2021	NJ	30	M	3/3/2021	3/3/2021	Immediate onset of flushing sensation in face and upper extremities, along with slight swelling of the left upper extremity (especially in the hand). Benadryl 37.5 mg oral was administered, and symptoms gradually improved and resolved over the next 10-15 minutes. Patient did not meet the clinical diagnosis of anaphylaxis, and epinephrine was not administered while patient was in the office. Patient never developed respiratory compromise, GI symptoms, or reduced BP/end-organ dysfunction. Vital signs remained normal and stable following reaction and at the time of resolution of symptoms. It was recommended that patient go to the ED (by EMS) for monitoring purposes/delayed reaction. EMS transport was declined by patient.
1077265	3/5/2021	FL	32	F	3/4/2021	3/4/2021	Systemic: Allergic: Anaphylaxis-Mild, Systemic: Allergic: Difficulty Breathing-Mild
1076039	3/5/2021	TX	80	F	3/5/2021	3/5/2021	Non severe anaphylaxis with low BP

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1077293	3/5/2021	RI	41	F	3/5/2021	3/5/2021	Systemic: Allergic: Itch (specify: facial area, extremities)-Severe, Systemic: Allergic: Itch Generalized-Severe, Systemic: Allergic: Rash (specify: facial area, extremities)-Medium, Systemic: Allergic: Rash Generalized-Medium, Systemic: Allergic: Swelling of Face / Eyes / Mouth / Tongue-Medium, Systemic: Flushed / Sweating-Severe, Additional Details: h/o anaphylaxis to flu shot, allergist recommended receiving COVID vax, preferably Moderna. Came prepared w/ benadryl, EpiPen, water. Pt stated she was aware and consenting to receiving vaccine. We advised for her to sit in the observation for at least 30 minutes. After receiving vaccine, she began getting red and itchy at the neck, traveled to arms and up to face. Trunk and upwards red and itching. Gave 2 benadryl at beginning of rxn, +1 as it worsened & called EMS - pt refused care
1077247	3/5/2021	VA	39	M	3/5/2021	3/5/2021	Site: Redness at Injection Site-Severe, Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Fainting / Unresponsive-Severe
1077243	3/5/2021	TX	34	F	2/26/2021	2/26/2021	Site: Bruising at Injection Site-Mild, Site: Itching at Injection Site-Mild, Site: Pain at Injection Site-Mild, Site: Redness at Injection Site-Mild, Site: Swelling at Injection Site-Mild, Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Systemic: Allergic: Itch (specify: facial area, extremities)-Mild, Systemic: Allergic: Swelling of Face / Eyes / Mouth / Tongue-Severe, Systemic: Headache-Mild, Systemic: Tingling (specify: facial area, extremities)-Severe

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1077170	3/5/2021	OR	25	F	1/23/2021	1/23/2021	This is a 25 year old female who presented to the ED with a possible allergic reaction from her 1st dose Pfizer vaccine. The patient received her vaccine on 1/23/21. Within 12 hours of vaccination, the patient developed a rash (no reported symptoms of breathing difficulty). The rash did not resolve, so the patient went to an urgent care on 1/25 and she was prescribed 6 days of prednisone, benadryl and famotidine. She reports that the rash continued, but waxed/waned. She presented to the ED on 1/27/21 with ongoing rash as well as an episode of throat tightness (which developed after she took her prednisone, benadryl, and a zyrtec). On presentation to ED, the patient's BP=123/72, HR=65, RR=16, SpO2=99%. The provider described the rash as "warm, dry, erythematous wheal-like rash over central chest around perimeter of her face and scattered across extremities." No other symptoms observed on physical exam. Throat tightness had resolved. Rash was considered mild and the patient was felt to be stable for discharge to home with a new prescription for Epi-pen. Patient did not respond to post-discharge phone call follow-up. Does not appear to be anaphylaxis,
1077136	3/5/2021	OR	35	F	1/22/2021	1/22/2021	This is a 35 yo female who received her 1st dose Pfizer on 1/22/21. Within 5-10 minutes of administration, the patient developed shortness of breath, chest tightness, lightheadedness, altered mental status, and EMS reported a brief syncopal episode. Patient was transported to ED. On presentation to ED, BP=116/71, HR=96, RR=14, SpO2=95%. No rash or swelling noted. The patient did report nausea without vomiting. All labs and EKG normal. The patient was treated (by EMS and ED) with Epi-pen x 2 doses, dexamethasone, duoneb, benadryl, famotidine, ondansetron, and IV fluids. The patient's symptoms improved and she was discharged to home. Final diagnosis = anaphylaxis.

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1076830	3/5/2021	NY	81	F	2/21/2021	2/21/2021	<p>She is experiencing an Allergic reaction, rash; little coughing spell; Itching eyes/My eyes started itching; Multiple hives all around her right eye; Wheezing; didn't feel comfortable; her upper lip became puffy/bottom lip began to swell; This is a spontaneous report from a contactable nurse (patient) via Medical Information Team. An 81-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EN6201), intramuscular at upper left arm on 21Feb2021 at 08:30 at SINGLE DOSE for COVID-19 immunisation. The patient had no prior vaccination within 4 weeks. The patient had no additional vaccines administered on same date of bnt162b2. Medical history included seasonal asthma, allergy to class A antihistamines that started in her 20s, facial & peripheral edema, blood pressure abnormal, and celiac disease. The patient had known allergy to Benadryl and when she takes it she gets peripheral and facial edema, lip swelling, top and bottom, hives around her whole right eye. The patient also has an allergy to Class A antihistamines that started in her 20s. She said the allergy started with Seldane & Claritin. She said she had giant hives with Claritin. She said she was told there were 2 classes of antihistamines & she couldn't use the Class A antihistamines. She said she previously reported her Seldane, Claritin & Benadryl allergies, saying she has facial & peripheral edema. She said she only uses the Class B antihistamine Cimetidine now. Concomitant medications included metoprolol, omeprazole, and pravastatin. On an unspecified date, the patient was experiencing an allergic reaction, rash. On 21Feb2021, the patient experienced "her upper lip became puffy/bottom lip began to swell," multiple hives all around her right eye, wheezing, and didn't feel comfortable. On 21Feb2021 at 14:00 (reported as about 2PM), the patient experienced "Itching eyes/My eyes started itching." On 21Feb2021 at 21:00 (reported as 9PM), the patient experienced little coughing spell. The reporter considered the events swelling lips, itching eyes, multiple hives all around her right eye, and wheezing as serious medically significant. The patient further reported that she felt fine after the shot, her arm was not sore, nothing. She said her arm was fine, and she had no problems, whatsoever, after receiving the COVID-19 Vaccine. She said she has had some weird allergic reactions in the past, but no</p>

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anaphylaxis. About 12:00 to 12:30 PM (also reported as around midday), the patient's lip felt puffy. She said she had ate an apple and thought maybe something was on the skin of the apple. She said then her bottom lip began to swell, so she took 3 Cimetidine (NDC Number: 49035-820-72, lot number: 9AE2576A, expiry date: Dec2020). The patient stated that she was allergic to what she believe are class A antihistamines as they gave her facial and peripheral edema including Benadryl and everything on the list. About 2PM, the patient's eyes felt itchy, she took allergy eye drops (eye drops seasonal relief with tetrahydrozoline HCL 0.05% and zinc sulfate 0.25%. She said the product packaging reads it soothes eyes, and she said the eye drops worked. Lot number: AC8K275, expiration date: Sep2021). She said when she looked in the mirror, she saw a large hive on her eye (clarified as multiple hives all around her right eye). And about 4PM, she realized that her lips felt puffy, so she repeated the Cimetidine, it kept them from getting worse. At 7PM, her eye felt worse. She had this real hive that surrounded her right eye, she took a picture so she could report it to the doctor. The patient have an appointment on Wednesday. At 7:30PM, the patient's lips were puffy, she repeated the Cimetidine again and took of the 200 mg, she takes 3 at a time, she mentioned she could take 4, but she takes 3. She said she took more Cimetidine at 8:30PM, and talked to a pharmacist, who told her to call Pfizer to report her reaction. She said she attempted to call Pfizer last night, but it was too late, clarifying Pfizer Medical Information was already closed for the day. The patient also reported that she had a little coughing spell at about 9PM, so she stayed up with her husband till 10PM because she didn't feel comfortable. The patient told her husband to wake her up every once in a while. The patient felt a little wheezy, she used both of her inhalers, she could hear the wheezing, she used the serevent diskus (Serevent Diskus 50 mcg Inhaler. She said she has been using the Serevent Diskus Inhaler for seasonal allergies for years and the inhaler works. She said she occasionally uses the Serevent Diskus for colds during the winter. She said she realized she was wheezing last night and thought she should use the Serevent Diskus. NDC Number: 0173-0521-00, Lot Number: VV3E, Expiration Date: Sep2021) and Flovent (Flovent HFA 110mcg Inhaler, NDC Number: 0170719-20, Lot Number:

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C47A, Expiration Date: Jul2021). That seemed to be okay, she went to bed, and had a good night no problems. She said she woke up this morning and felt better. She said she sounds a little gunky this morning, clarifying that was somewhat typical for her. The patient further reported that she got up at 6:30AM, she took a shower, she was having a rebound reaction, and wheezing, so she took 3 more Cimetidine and repeated the inhalers. She clarified while her symptoms worsened after the hot shower this morning, her symptoms are much less than yesterday (21Feb2021), saying she was aware of her symptoms today, and paying attention to them. She said her lips became puffy, and she was wheezy after the hot shower. She said she took Cimetidine and her inhalers again this morning to treat the rebound reaction. She decided to repeat again at about quarter to 10AM, she repeated again trying to keep it under control. In the meantime, she spoke to her doctors office, and they just said keep doing what she's doing, and if she get real bad, call 911 or go to emergency room (ER). The patient have an appointment, the patient's big concern was that she probably shouldn't get the second COVID shot. She read on (website), that there was a very rare, mild anaphylactic reactions. What caught her eye was that this takes place about 4 hours after the dose. This was when her symptoms began, lucky her. Her whole life has been allergy related. The patient don't know if celiac disease has anything with this. The patient wanted to know whether or not there was some way to take the shot without killing herself. She said she was not having breathing difficulty, she was just wheezy. She said she repeated the Cimetidine about a half hour before she called Pfizer today. She said she called her doctor's office this morning, and her doctor said for her to keep treating her symptoms as she had been doing. She said her doctor told her to call an ambulance or go to the emergency room if her symptoms happen to get worse. She said she read online that skin anaphylaxis (hives, itching, and swelling of the eyes, face, lips and throat) can occur with the COVID-19 Vaccine. She clarified she read the information about the COVID-19 Vaccine at (Website name). She said she read skin anaphylaxis was extremely rare and less than 1% of the population has the allergy, and those individuals should not get the COVID-19 Vaccine. She

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							<p>said she was upset because what she read probably means she can't get the second COVID-19 Vaccine shot. She said she read the skin anaphylaxis appears within 4 hours after getting vaccinated with the COVID-19 Vaccine. She said her symptoms occurred in almost the same amount of time as to what she read about a skin anaphylaxis reaction to the COVID-19 Vaccine. She said she has a regular check-up on Wednesday (24Feb2021) with her doctor, and will speak further to her doctor about getting the second COVID-19 Vaccine. The reporter considered the events lip felt puffy, eyes started itching, hives, and wheezing as serious medically significant. The patient had no emergency visit. The patient had no relevant tests done. Therapeutic measures were taken as a result of the events swelling lips, itching eyes, multiple hives all around her right eye, and wheezing. The patient had not yet recovered from the events swelling lips, itching eyes, multiple hives all around her right eye, and wheezing while outcome of the events rash, little coughing spell, and didn't feel comfortable was unknown. The reporter considered the events swelling lips, itching eyes, hives, and wheezing as related to bnt162b2.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.</p>
1076773	3/5/2021	WI	46	F	3/5/2021	3/5/2021	<p>Pt c/o blurry vision. Pt waited 60 minutes following vaccine and double vision is now occurring. BP elevated at 160/90 and 150/96. Co-worker to transport pt to ER. Patient was seen and discharged from the ED. Concern for anaphylaxis.</p>

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1071352	3/4/2021	NC	55	M	3/1/2021	3/2/2021	Rash on legs, arms and torso on second day after vaccine. I noticed the rash in the evening around 6:00pm. I took a benedryl at 5:00pm on Wednesday 3/03/2021. Called my family doctor on Thursday morning and he told me to take 1 Zyrtec in the morning and 1 at night to help clear the rash. My Doctor said it was not anaphylaxis as it did not happen immediately after the vaccine but 24 hours later. I have no trouble breathing as I check myself with oximeter and my oxygen level is 97%. I did have Covid on January 3, 2021 and after the vaccine on 03/02/2021 I experienced nausea, chills and a dull headache and then the rash. I have experienced this type of rash before after a stomach virus and it lasts for 3 or 4 days and clears up.

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1071167	3/4/2021	CA	27	M	1/8/2021	1/8/2021	Occipital neuralgia; anaphylaxis; feeling like passing out on and off for the next 2-3 hours; he felt lightheaded; little short of breath; fatigue; he had a lot of posterior lymph pain in the back of his head, for 2 weeks on and off; heaviness at the back of his head left side; chest tightness; he developed a sensation like he was going to lose control of his mind; This is a spontaneous report from a contactable Other Health Professional, the patient. A 27-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot number EL1283), via an unspecified route of administration on 08Jan2021 at 13:30 (at the age of 27-years-old) as a single dose in the left arm for COVID-19 vaccination. Medical history included asthma exacerbation, GERD, childhood anemia, a retinal tear in the right eye all from unspecified dates and unknown if ongoing. The patient also reported medical history three episodes (June 2019, August 2019 and October2019) of anaphylaxis due to "Exercise Induced Anaphylaxis." Historical vaccinations included the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number EH9899) on 21Dec2020 at 13:30 after which he experienced pain at the vaccination site which lasted twenty-four hours. The patient's past product use included adrenaline (EPIPEN), an unspecified corticosteroid and an unspecified antihistamine for past allergic reactions. The vaccine was administered in a hospital. Prior to the vaccination, the patient had not been diagnosed with COVID-19. Concomitant medications included ciclosporin (RESTASIS), azelastine (AZELASTINE), mometasone furoate (FLONASE), cetirizine hydrochloride (ZYRTEC) and omeprazole (PROTONIX) all for unknown indications from unknown dates and unknown if ongoing. Within four weeks prior to the vaccination the patient had received unspecified "allergy shots" He received "two shots" (one in each deltoid) on 15Dec2021 and "two shots" (one in each deltoid) on 05Jan2021. The patient reported that fifteen to thirty seconds after the second dose of the COVID-19 vaccination he felt lightheaded and a little short of breath. This lasted about eight minutes and then subsided. Approximately thirty to forty minutes (about 30 minutes after he left the facility) later the symptoms returned. He felt short of breath and he thought he was going to pass out. The symptoms included fatigue,

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shortness of breath lightheaded and feeling like passing out on and off for the next two to three hours. He stated he has completely recovered. He continued to say that he was feeling fine for three days then he began having bilateral cervical lymph pain greater on the left than right, a lot of posterior lymph pain in the back of his head (for two weeks on and off). These symptoms also resolved on their own. He also experienced ("a couple of days later") a sensation where he thought he was going to lose control of his muscles and lose consciousness. He also developed a sense that he was going to lose control of his mind with heaviness at the back of his head, left side. He went to the Emergency Room (date not provided) and they provided Valium. He also reports an Emergency Room visit on 13Jan2021 during which he underwent a CT scan of the head which was normal and a neuro consult suggesting occipital neuralgia and he was put on muscle relaxers. He also stated that experienced shortness of breath and chest tightness after his allergy shots on 26Jan2021 and he specified that he had never before had these reactions to his allergy shots. After that he had yet another possible allergic reaction after eating pizza on 30Jan which included throat swelling as well. He further stated that on 04Feb he had anaphylaxis vs asthma exacerbation. On the following day he developed a heaviness to his left occipital head with that same feeling of wanting to lose control of his muscles. He never had that before. He started Prilosec about one and one half weeks prior to the reporting date. In follow up the Other HCP reporter/patient answered "Yes" to the following questions (DCA) about symptoms experienced: Bilateral wheeze/bronchospasm, upper airway swelling, increased use of accessory respiratory muscles, dry cough, difficulty breathing (without wheeze or stridor, sensation of throat closure, tachycardia, nausea. These were reported without dates and without context with regard to the events reported initially. These were also reported as not requiring treatment and having recovered on unspecified dates. Lab data included three SARS COV 2 nasal swab tests (14Jan2021, 03Feb2021 and 11Feb2021) all of which were negative. Unspecified treatment was reported for the events anaphylactic reaction and mental impairment. The clinical outcomes of the events Anaphylaxis, loss of consciousness, dizziness, dyspnea, fatigue and lymph node pain were

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							reported as recovered on an unspecified date in 2021. The clinical outcome of mental impairment, heaviness of head, chest tightness and occipital neuralgia were reported as unknown.
1073817	3/4/2021	WA	63	F	2/13/2021	2/13/2021	Pt received 1st dose of Pfizer Biontech vaccine. Patient reported history of anaphylactic reactions. Pt told to stay 30 minutes for observation. During observation patient reported feeling itchy. VS taken at clinic and were stable: HR 88, BP 135/66 Spo2 94%. Patient's face was slightly red without edema. She reported breathing okay but felt a little tight in her throat. Sent to ER for management. Per ER note "63 year old female with a complex medical history including lupus, scoliosis, Sjorgen's syndrome, and anaphylaxis requiring intubation presents complaining of itching and dizziness following COVID 19 vaccination with the Pfizer mRNA vaccine...patient's exam demonstrates itchy red welts consistent with urticaria and she endorses a foreign body sensation in her throat. Examination of the oropharynx demonstrates uvular edema without stridor. The patient endorses chest tightness but does not have wheeze on exam...endorses nausea. Diagnosed with anaphylactic reaction. Patient received epinephrine 0.3 mg IM, diphenhydramine 50 mg IV, famotidine 20 mg IV, and methylprednisolone 125 mg IV along with albuterol MDI. Had improvement in symptoms within an hour, observed for 6 hours without recurrence of symptoms and was discharged home. Advised not to receive second dose of vaccine until discussion with allergist occurred.

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1073645	3/4/2021	WA	25	M	2/4/2021	2/1/2021	<p>Within 1-2 minutes I experienced full body tingling; facial numbness; vision became distorted/blurry; vision became distorted/blurry; whole body was sweating; abdominal pain; lower extremity aching; nausea; experienced moderate to severe lower back spasms; sciatica; This is a spontaneous report from a contactable other health professional (patient). This 25-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot# ELO739), via intramuscular on 04Feb2021 03:15 at single dose in the left arm for COVID-19 immunization. The patient's medical history included medullary kidney disease, and allergies to iodized contrast and bees (both resulting in anaphylaxis). The patient did not received any other medications within 2 weeks of vaccination. Facility where the most recent COVID-19 vaccine administered was Public Health Clinic/Veterans Administration facility. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Within 1-2 minutes (03:15) patient experienced full body tingling and facial numbness. A minute later his vision became distorted/blurry and he began getting warm. A minute later his whole body was sweating, he was experiencing abdominal pain, lower extremity aching, and nausea. These symptoms other than the sweating persisted for another 5 days. After the 5th day, patient experienced moderate to severe lower back spasms and sciatica that resulted in an urgent care visit and a prescription for muscle relaxers and a mild pain reliever. The muscle spasms have been present for a week now and is slowly getting better. Patient was seen by an orthopedic urgent care where they recommended physical therapy and limited walking/sitting for extended periods of time. The adverse event result in doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. Treatment received for the adverse event included diphenhydramine hydrochloride (BENADRYL) (day of vaccination) and muscle relaxers. Prior to vaccination, patient was not diagnosed with COVID-19. Since the vaccination, patient has not been tested for COVID-19. Outcome of whole body was sweating and sciatica was not recovered, outcome of moderate to severe lower back spasms was recovering, outcome of other events was recovered on an unspecified date in Feb2021. Information on the lot/batch number has been</p>

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							requested.; Sender's Comments: Based on event-vaccine chronological association, a causal relationship between reported events and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
1073004	3/4/2021	MO	29	M	2/26/2021	2/26/2021	Pt had tongue and throat numbness , lightheaded, dizzy, throat swelling and possible early anaphylaxis and went to ER
1072186	3/4/2021	SC	35	F	3/4/2021	3/4/2021	Patient had no reaction to first vaccine, then after the second dose, she quickly had shortness of breath and trouble breathing. Patient's tongue and throat were closing up. I stuck the patient with an EpiPen and she started to do better. Waiting on the EMS to arrive the patient started having rebound anaphylaxis so I stuck her with another EpiPen. Patient was then put into EMS and left for the hospital
1071936	3/4/2021	ME	48	F	3/3/2021	3/3/2021	Reported Labored breathing and slight throat swelling and itchy hives 5 minutes after injection. She was still able to walk and talk at the time. Pre-medicated 50mg Benadryl one hour before injection. Advised per ER to not give EPI shot and have patient come in to ER to be seen, she was taken to the hospital by ambulance. She was administered another dose of Benadryl and 2 EpiPen Shots. She was kept overnight for observation at Medical Center. She needed 1M Benadryl after her 1st dose and had throat swelling, felt dizzy and shaky legs after 1st dose. Per advisement of her Dr. we gave 2nd Dose, her Doctor new possibility of reaction but wanted patient to have due to respiratory illnesses, felt that the benefit outweighed the risk since she could potentially get COVID-19 and have worse issues. Patient was aware of risk of anaphylaxis/allergic reaction.

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1071693	3/4/2021		31	F	3/3/2021	3/3/2021	Chills, urticaria, dizziness, tachycardia Pt complained of palpitations immediately after vaccination. Dizziness, hives, chills and tremor associated. Hx of Mast-Cell d/o and anaphylaxis to NSAIDs. No reaction to first dose. Initial BP 136/93, HR 147, O2 100% RA. Pt appeared pale, tremor Patient sent to ED.
1073922	3/4/2021		49	F	3/4/2021	3/4/2021	After about 2 minutes of receiving the vaccine, patient started to feel itchy, developed hives, and had an "itchy throat"... about a minute later she went into anaphylaxis
1071908	3/4/2021	NY	37	F	3/4/2021	3/4/2021	A few minutes after inoculation, the patient felt chest tightness. She rested for a few minutes. Her chest tightness did not ease. She used her asthma inhaler to try to relieve the symptoms. Immediately (but not necessarily because of the inhaler) her symptoms worsened. I called over the attending EMTs, who put the patient on O2. Soon after, a pulse oximeter showed the patient's O2 sat at 100, pulse at 110. The feeling of tightness continue but the oxygen immediately relieved the patient's distress. After a few more minutes, the patient took another hit of albuterol. That brought immediate relief. Her pulse gradually slowed to the mid-70s. She said she felt tired, as often she does after an asthma attack, but soon felt well enough to leave. She planned to take a cab or equivalent to home, and said she had taken the day off. She said her doctor warned her that because she has a history of reactions (details unknown) to vaccines, she might react badly to Moderna, but the doctor and patient agreed that it was worth the risk. She said her reaction to NSAIDs has been anaphylaxis.

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1068254	3/3/2021	KS		F	2/10/2021	2/10/2021	anaphylaxis; head was feeling funny; sweating profusely; This is a spontaneous report from a contactable consumer (patient). This 79 (unit unknown) female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date: unknown) via an unspecified route of administration, on 10Feb2021 at 12:00, at a single dose, for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient received first dose on 10Feb2021 at 12:00. On the same day (10Feb2021), at 20:00, the patient's head was feeling funny, sweating profusely, and felt like "anaphylaxis". Patient also asked about potential receipt of second dose. Patient stated she will reach out to healthcare professional (HCP). Outcome of the events was unknown. Information on the batch/lot number has been requested.
1069973	3/3/2021	TN	24	F	3/3/2021	3/3/2021	Patient c/o itching all over around 4:48PM. Dr. notified and assessed patient. Diphenhydramine offered, patient declined. At 4:58pm patient notified nurse itching may be getting a little worse and would like Benadryl now. Dr. gave order for administration per Diphenhydramine Anaphylaxis Protocol. Blood pressure assessed at 5pm - 110/70. Administered Diphenhydramine 50mg/ml, 1ML right deltoid. Patient tolerated well. Blood pressure reassessed at 5:05 pm - 120/70 and decreased itching. Pt stable at 5:15pm again with decreased itching and was able to exit clinic at this time. Spouse present to drive.

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1067988	3/3/2021	CA	41	F	1/30/2021	1/30/2021	heart rate suddenly increased; throat felt tight; felt very warm in the head and neck like was flushed; felt very warm in the head and neck like was flushed; This is a spontaneous report from a contactable other healthcare professional (HCP) (patient). A 41-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EL9265) via an unspecified route of administration in the left arm on 30Jan2021 10:30 am at a single dose as Covid vaccine. Medical history included known allergies to penicillin-anaphylaxis. There were no concomitant medications (no other vaccine in four weeks and no other medications in two weeks). Approximately 5 minutes after injection, heart rate suddenly increased and throat felt tight, and felt very warm in the head and neck like was flushed on 30Jan2021 10:45 am. It passed after a minute or two, then happened again around five times within the hour after injection. No treatment was provided for the events. The patient had no Covid prior to vaccination and has not had Covid tested positive post vaccination. The outcome of the events was recovered on Jan2021.

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1068260	3/3/2021	MD	44	F	2/16/2021	2/1/2021	Severe anaphylaxis attack; feeling tired; tachycardia; tingling sensation; sweating; feeling hot; BP = 180/120/her BP was high; feeling lightheaded; This is a spontaneous report from a contactable healthcare professional (HCP) (patient). A 44-year-old female patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE solution for injection; lot: EN6201, expiry: Jun2021), intramuscular (IM) on left (L) arm (at the age of 44years) on 16Feb2021 at 12:00 at single dose for COVID-19 immunization. The patient received first dose of bnt162b2 (lot: EN5318, expiry: Jun2021) IM on L arm on 28Jan2021 at 14:45 that 45 minutes after administration (on 28Jan2021) the patient experienced tingling sensation on lip which was with diphenhydramine hydrochloride (BENADRYL) as treatment and recovered on unspecified date. Medical history included hypertension, allergic to fish (treatment were adrenaline (EPIPEN), corticosteroid and antihistamine) and ongoing BP. Concomitant medications included ongoing hydrochlorothiazide, lisinopril (LISINOPRIL + HIDROCLOROTIAZIDA) and ongoing unspecified Vitamins daily. The patient previously took prochlorperazine maleate (COMPAZINE) and metoclopramide (REGLAN) which were medications she took while pregnancy, gabapentin and hydromorphone hydrochloride (DILAUDID) where the patient experienced allergies from these drugs and treatment were adrenaline (EPIPEN), corticosteroid and antihistamine. There was no covid prior vaccination and was covid tested post vaccination with Nasal Swab (Sofia SARS Antigen) on 04Feb2021 with result of negative. The patient experienced severe anaphylaxis attack on 16Feb2021 at 12:30 (30 minutes after the administration of 2nd dose) which resulted in doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Life threatening illness (immediate risk of death from the event) with treatment included Intravenous IV diphenhydramine hydrochloride (BENADRYL) + prednisone + famotidine (PEPCID), GI cocktail, Heart monitoring. The HCP (patient) was on observation for 30 minutes when she started with tingling sensation, sweating and feeling hot (in Feb2021). They took BP=180/120 (in Feb2021). They administered IV diphenhydramine hydrochloride + prednisone + famotidine. She was feeling lightheaded (in Feb2021).

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							<p>She stayed in observation for 4 hours until recovered. She was sent home and prescribed prednisone and loratadine (CLARITIN) daily. HCP stated that she has an episode yesterday (16Feb2021), she was feeling tired, the sweating came back and her BP was high. Today (19Feb2021) her BP was stable. The patient reported tachycardia under information on organ involvement (in Feb2021). The patient required medical intervention but not hospitalized nor admitted to an intensive care unit. No other vaccine in four weeks and no other medications in two weeks. The patient did not receive any recent vaccines for any other conditions prior to the events and did not receive any recent vaccines for SARS-CoV2 other than Pfizer-BioNTech COVID-19 Vaccine prior to the events. The outcome was recovered for the events anaphylaxis and dizziness both in Feb2021, and hypertension on 19Feb2021 while for the remaining events was unknown.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Anaphylaxis cannot be excluded. The case will be reassessed if additional information becomes available.</p>
1068662	3/3/2021		79	F	2/1/2021	2/1/2021	Anaphylaxis Patient "went into cardiac arrest", was taken to ER. Physician stated this was a reaction from the vaccine.
1068867	3/3/2021	DC	47	M	3/2/2021	3/2/2021	Approximately 45 minutes after injection mild onset of anaphylaxis response. Numb tongue, tingly lips, mild throat constriction but no issues swallowing or breathing. About 60 minutes post-injection, the patient self-administered two 25 mg tablets of Benadryl. Symptoms subsided 120 minutes later.
1068921	3/3/2021	GA	77	M	2/25/2021	2/28/2021	Patient described the event as "severe anaphylaxis" that included redness all over the body and a rash on the face, with a strange feeling in the esophagus but no trouble breathing. The patient self-medicated with prednisone and did not seek medical care. Symptoms resolved later the same day they appeared. The patient indicated he had an appointment unrelated to this event scheduled with his primary care physician on March 3, 2021, and was advised to discuss the reaction with the physician at this appointment.

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1069254	3/3/2021	MI	65	F	3/3/2021	3/3/2021	Patient reported that her heart is racing. I checked her BP three times: 12:37pm 168/98 pulse 97 12:46pm 157/96 pulse 89 12:58pm 147/93 pulse 86 Patient said she felt anxious due to her allergy history. I had her sit in the observation area for 30 minutes and gave her water. She displayed no additional symptoms and nothing that would have been indicative of anaphylaxis. She was vaccinated at 12:30pm and left the store with her husband at 1pm.
1069520	3/3/2021	LA	52	F	2/26/2021	2/26/2021	Anaphylaxis. 2 EpiPens, 50 mg Benadryl PO. Was with patient for 2 hours before ambulance arrived. Tingling and numbness to lips, tongue and mouth. Swelling of lips. Pruritis of throat. Dry unproductive cough. "Feel like I'm being strangled". Grogginess (may have been due to Benadryl). Disorientation. Increase in blood pressure. Increased respiratory rate and labored breathing. Left chest discomfort (non-radiating). Hoarseness. Appeared syncopal and weak.
1069992	3/3/2021	ND	68	M	3/1/2021	3/1/2021	Itching and a morbilliform rash of bilateral hands starting the evening of the injection. No anaphylaxis, pustular rash, difficulty breathing, etc. Started on clopidogrel 2 weeks prior. No rash or itching until the vaccine administered but clopidogrel has a 6% listed incidence of rash.

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1069676	3/3/2021	MA	38	F	3/3/2021	3/3/2021	Patient seen in clinic for first dose of Moderna covid-19 vaccine. Moderna 0.5ml IM administered into left deltoid by vaccinator RN at 0910. Patient with history of pruritic reactions and anaphylaxis. Patient instructed to wait 30 min post injection for observation. At 0930 she reported to this RN torso and upper extremity pruritis and redness, without hives; and feeling of warmth over ears and torso. Benadryl 50 mg PO and cetirizine 10mg PO administered with 8oz water at 0932. Patient able to ambulate to wheel chair and reclined. Three sets of VS obtained all WNL. At 0947 she reported that pruritis was spreading to lower extremities and new onset of headache and two emerging hives to right wrist. Patient drank another 8oz water and continued to rest in reclining chair. At 1020 she noted an overall improvement in symptoms and there were no hives present. She was feeling well on discharge, up and walking about clinic. She was instructed to pick up Benadryl from site pharmacy and repeat dose in 4 hours. Discharged to home at 1045.
1070870	3/3/2021	NY	22	M	2/26/2021	2/26/2021	Swelling in both hands, more in the left hand as it was vaccination arm. Tingling through body. Multiple Hives (about 5) formed on my arms and upper body. Took 50mg benadryl to manage. Was already on Zyrtec at the time in case of reaction. Slight congestion and sinus irritation but no feeling of anaphylaxis or much in the throat. Symtoms stopped worsening and were gone by the next day.
1070813	3/3/2021	CO	42	F	3/2/2021	3/2/2021	anaphylaxis - throat tightness, hoarseness, coughing, trouble swallowing, nausea, dizziness, pallor, watery eyes, urinary incontinence, sense of impending doom

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1070844	3/3/2021	OR	28	F	2/26/2021	2/26/2021	Pt received second Moderna COVID-19 immunization in L deltoid at 1020. Pt had reported hx of anaphylaxis to sesame, wait time was increased to 30 minutes. At 1026 pt alerted nurse in observation area of tightness in her throat, an itchy throat, and shakiness. Denied any change in breathing or tongue swelling/tingling. Pt was moved to a more private area with FNP and 2 RNs. At 1035 administered 50 mg IM diphenhydramine in L deltoid. Symptoms started to improve within 5 minutes. Between 1030-1100, BP 138-140/80-84, P 72-88, RR 18-22, O2 sats 98-99% throughout. Symptoms had improved by 1115 and pt was sent home with colleagues. Advised if symptoms worsened or if she had any difficulty breathing to call 911 or get to the closest ER immediately. Pt verbalized understanding and agreed with the plan of care.
1066605	3/2/2021	NY	51	F	3/2/2021	3/2/2021	Swollen lips, mild anaphylaxis, hives all started 60 minutes after vaccination. We traveled from our home (approx 2 hr drive) & were on road. My husband is a physician & when we noticed symptoms administered Benadryl, Claritin, & famatodine.
1067213	3/2/2021	CA	31	F	3/2/2021	3/2/2021	Adverse reaction after receiving the COVID-19 vaccine in Vaccine Clinic. Medications: No current outpatient medications on file. Allergies: Not on File Medical history: No past medical history on file. This was vaccine dose 2 of the Pfizer COVID-19 vaccine. Describe adverse reaction: Dizziness. Employee was monitored for 40 minutes. Anaphylaxis symptoms: Dizziness Anaphylaxis plan: Provided water, juice and crackers, monitoring on gurney Vasovagal symptoms: dizziness Vasovagal plan: offer water Administration error: n/a MERT called No Transferred to Home VAERS report number: Report online Email sent to Clinic and patient documented in adverse reaction log.

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1066565	3/2/2021	NY	66	F	3/2/2021	3/2/2021	Twenty minutes post 1st vaccine dose on her left arm, patient began feeling light headed, tingling, and warmth in her bilateral forearms. She then developed tingling at the tip of her tongue and had facial flushing. She developed rashes (hives in bilateral UE). She was brought for evaluation. Benadryl 50mg was given, Vitals taken and water was provided as well. She denies any SOB, CP, swelling or numbness. Physical exam: S1,S2, CTA, hives positive in bilateral UE, facial flushing, and neuro exam WNL. She reports her daughter had the Moderna vaccine a few weeks ago and developed full blown anaphylaxis. Her second daughter also had an allergic reaction to the MMR vaccine. She denies any history of allergic reaction to vaccines herself but does report allergies to several medications. About 10 mins post Benadryl administration, facial flushing resolved and the rashes in her forearms began to improve as well. Patient was recommended transport to the hospital/ER but she declined. She was instructed to contact her PCP for further evaluation. She was informed her second vaccine will have to be administered at an ER or facility that provides higher level of care. She was escorted to her vehicle to meet her husband.
1067062	3/2/2021	WY	33	F	2/20/2021	2/20/2021	2/20/21- ?Vaso/vagal vs anaphylaxis, approx 1:20 PM, 10-15 min post vaccine, HA, approx 1:30PM nausea, dizzy, unable to stand on own BP 120/78, low for ct, O2 8L/simple mask, 911 called, throat felt dry, anxious, denied airway prob, no wheezing or stridor, epi not indicated, FIRE/EMS arrived, after a few minutes client able to stand on own, declined going to hospital, felt well enough to drive 20" home. 2 hrs post vaccine, throat scratchy, back became itchy, took Benadryl x 2 with resolution after 2nd dose, At 3:45, spoke County Manager, ct kept feeling the need to clearher throat, ct referred to PCP. 02/25-Client feeling fine now,spoke w/PCP, cleared to get 2nd dose at hospital. Ct has hx asthma/smg

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1066364	3/2/2021	MD	38	F	3/2/2021	3/2/2021	pt reported feeling heavy, unsure and staff noticed poss swelling of her eyes. escorted pt to first aid area. took pt vital signs, medical history, assessed pt , encouraged pt to stay 30 minutes for further monitoring; encouraged pt to call her dr when she goes home if she does not feel well. pt denied symptoms of anaphylaxis-no sob, itching, nausea, hives

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1062022	3/1/2021	MD	37	F	1/27/2021	1/27/2021	tongue and lip tingling; subjective swelling; This is a spontaneous report from a contactable physician reported that a 37-years-old female patient first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiration date were not reported) intramuscularly on 27Jan2021 at single dose for covid-19 immunisation. Medical history included anaphylaxis; nightshade vegetable allergy; Food allergy, migraine, Attention deficit hyperactivity disorder, anxiety, former smoker. Concomitant medication included amphetamine aspartate, amphetamine sulfate, dexamphetamine saccharate, dexamphetamine sulfate (ADDERALL), alprazolam (XANAX), escitalopram oxalate (LEXAPRO), ethinylestradiol, norethisterone acetate (JUNEL), amitriptyline (AMITRIPTYLINE). The patient previously took atropine had anaphylaxis and known allergies. On 27Jan2021, patient developed tongue and lip tingling and subjective swelling within 10 minutes after vaccine administration. No angioedema. The patient was received treatment with benadryl, pepcid, IVF and solumedrol. Did the patient receive any other vaccines within 4 weeks prior to the COVID vaccine was unknown. Prior to vaccination, was the patient was not diagnosed with COVID-19; Since the vaccination, the patient not tested for COVID-19. The outcome of the events was recovered in 2021. Information on the lot/batch number has been requested.; Sender's Comments: Based on vaccine-event chronological association a causal relationship between events "tongue and lip tingling and subjective swelling" and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1063007	3/1/2021	VA	56	F	3/1/2021	3/1/2021	Pt described a difficulty swallowing, slight swelling, and a brief time of altered mental status about 30 minutes after vaccine administration. Pt was able to calm down and described a slight alleviation in symptoms. Pt denied hx of anaphylaxis. Medics were dispatched to the location to transport. No medications given by health department or EMS on scene.

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1062061	3/1/2021	NY	76	F	1/25/2021	1/1/2021	<p>Tinnitus spiked up quite a bit /tinnitus was reported as worsened /her tinnitus increased a great deal. It increased in loudness; arm was sore; stomach ache; upsetting and distressing; This is a spontaneous report from a contactable consumer (patient). A 76-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Lot number: EL3247), via an unspecified route of administration at 13:30, on right arm, on 25Jan2021, at single dose for COVID-19 immunisation. The patient relevant medical history included heart condition, she is mostly allergic to antibiotics (She has allergies to several medications; Specific antibiotic names not provided), blood pressure, anxiety, thyroid (thyroid disorder), urinary tract health, I have had tinnitus for 7 years and Bones (bone disorder) and of them were ongoing. The patient concomitant medication included levothyroxine sodium (SYNTHROID) for thyroid disorder and ongoing at 50ug, daily, hydrochlorothiazide tablet for blood pressure and ongoing at 0.25mg (half tablet) once a day, valsartan(DIOVAN) for blood pressure ongoing at 80mg once a day, verapamil for heart issue ongoing at 100mg, metoprolol tartrate for heart, ongoing at 25mg twice a day, alprazolam (XANAX) for anxiety ongoing at 0.25mg, once a day, d-mannose for urinary tract health ongoing at 300mg once a day, vitamin d nos for bones ongoing at 50ug daily, calcium carbonate (CALTRATE) for bones at unknown dose once day, ubidecarenone (COQ10) for heart ongoing at 200mg, magnesium for the heart. It was reported that patient got tinnitus after taking an antibiotic and had for 7 years. After taking the first dose on Monday (25Jan2021), the tinnitus spiked up quite a bit on 27Jan2021 (noticed when she woke up at about 08:00 in the morning). Tinnitus got very much louder, and patient thought that it was from vaccine. Tinnitus increased a great deal. It increased in loudness and was reported as worsened. On an unknown date in Jan2021, the patient arm was sore and got better. The patient also had little bit of a stomach-ache at first and that got better as well on an unknown date in Jan2021. The patient thought that the tinnitus would return to my normal level of loud. The patient reported that it's very upsetting and distressing on an unknown date in Jan2021. The patient was worried about getting the second shot. The patient also stated that had allergic</p>

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reactions to many drugs and did fine with the vaccine in terms of anaphylaxis. It was reported that prior vaccinations within 4 weeks was none. It was reported that patient had not administered additional vaccines on same date of pfizer suspect administration. The outcome of the events tinnitus spiked up quite a bit /tinnitus was reported as not recovered /her tinnitus increased a great deal. It increased in loudness was not recovered, upsetting and distressing was unknown, stomach-ache and arm was sore was recovering.

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1062223	3/1/2021	VA	67	F	2/7/2021	2/1/2021	not thinking straight; very very intense headache; felt an ungodly pressure in my head; My vision was off; foggy; confused; coughing; felt severe tightness in left side of my chest and that moved to the center of my chest and started to like move up higher, more towards my throat and then it stopped; severe tightness in left side of my chest and that moved to the center of my chest and started to like move up higher you know more towards my throat; rapid heart rate, 100bpm and 102bpm and lasted for couple of days.; my head was more clear but still had some pressure and woozy; Trouble concentrating; ALT High; Test: Cholesterol; Result: Little High/Cholesterol 207 was high; This is a spontaneous report from a contactable consumer, the patient. A 67-years-old female received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EL9269), via an unspecified route of administration on 07Feb2021 (at the age of 67-years-old) as a SINGLE DOSE for Covid-19 Vaccination. Medical history included ongoing asthma, type 2 diabetes mellitus, seasonal allergy (told to take Zyrtec for seasonal allergies prophylactically). Facility in which the vaccine was received was a clinic at a high school through the local hospital. Concomitant medication included fluticasone propionate, salmeterol (WIXELA INHUB), glipizide (GLIPIZIDE). On 07Feb2021, the patient received the first dose and while walking to the observation area (about two minute after receiving the vaccine) the patient experienced very very intense headache, felt an ungodly pressure in my head, vision was off, and trouble concentrating. When she sat down got real foggy, confused and was not thinking straight, was coughing and experienced severe tightness in left side of my chest and that moved to the center of my chest and started to like move up higher, more towards my throat and then it stopped. Patient began taking deep breath. It went back over to left side of my chest and the tightness (stayed in my left chest for probably 3 days but not to the same degree). The foggiess and the intense pressure in my head, it was bad to the point she thought she would not be able to drive home, waiting for 30 minutes, and because she was not thinking clearly she didn't even ask anybody for help. When she got to the car she waited 15 minutes more before driving home. Patient stayed like this for 2 days. When she reached

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							<p>home, she experienced a rapid heart rate, 100bpm and 102bpm and lasted for couple of days. Each day got gradually better, her head was clearer but still had some pressure and woozy. The patient did visit the physician, he did an EKG and other test. The doctor did not think what I had was an anaphylaxis reaction. Physician recommended she make sure to take her inhalers, for asthma and told me to take Zyrtec (for seasonal allergies) ahead of time. Consumer inquired if she should receive the second dose. The patient underwent lab tests and procedures which included blood cholesterol: little high 207 on Feb2021, blood thyroid stimulating hormone: normal on Feb2021, electrocardiogram: normal on Feb2021, full blood count: normal on Feb2021, hemoglobin: 6.9 on Feb2021, heart rate: 100 bpm on Feb2021, heart rate: 102 bpm on Feb2021, metabolic function test: Alt high on Feb2021. No treatment was given for the events. The clinical outcome of the events not thinking straight, pressure in my head, foggy, confused, coughing, tightness in the left side of my chest , it then moved to the center of my chest then moved up towards throat, rapid heart rate, Woozy, intense headache, vision was off and trouble concentrating was recovering while ALT High, and Cholesterol; Result: Little High was unknown.</p>
1062375	3/1/2021	MA	50	F	2/28/2021	2/28/2021	<p>Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Mild, Systemic: Chills-Mild, Systemic: Flushed / Sweating-Medium, Systemic: Nausea-Medium, Systemic: Shakiness-Medium, Systemic: Tachycardia-Medium</p>

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1063973	3/1/2021		31	F	2/17/2021	2/20/2021	Bee sting on sole of foot morning of getting her second Pfizer dose. She then had a "spider bite" on her abdomen the next day. About 3 days later she developed an itching, lacy, red rash on dorsum of foot and sought care at an urgent care. She was given cephalexin for the spider bite and prednisone 40 for the bee sting. She had never had a reaction to bee stings before and no history of any anaphylaxis. She then came to see me, and I noted the rash with a red rash also over her left second toe with no signs of arterial occlusion or neurologic symptoms. She had no symptoms or known Covid exposure and the community positivity rate was 1%. We decided to try a high potency topical corticosteroid for the itching on her foot and use the prednisone if symptoms worsened or go to the ER if severe. The next morning, (7 days post vaccination) she reported lightheadedness, increased pruritus of her foot and went to an urgent care where she started systemic prednisone and had a negative Covid nasopharyngeal swab. She then recovered without complications.
1062381	3/1/2021	CA	30	M	2/28/2021	2/28/2021	Systemic: Allergic: Anaphylaxis-Mild, Systemic: Fainting / Unresponsive-Medium, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Mild

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1061990	3/1/2021	MI	65	F	1/27/2021	1/27/2021	Started with itching on left neck; swelling below left eye; hands were swelling; This is a spontaneous report from a contactable consumer (patient) reported that a 65-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on the left arm on 27Jan2021 14:30 at a single dose for covid-19 immunization. The vaccine was administered at the pharmacy. Patient was not pregnant at the time of vaccination. Medical history included sarcoidosis and hypertension both from an unknown date, and one unknown anaphylaxis a year ago (2020). Prior to vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included amlodipine besylate. On 27Jan2021 16:30, it was started with itching on left neck, then swelling below left eye and hands were swelling. The patient was concerned enough she took a Benadryl. The events result in doctor or other healthcare professional office/clinic visit. Treatment received for the events was Benadryl. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was unknown. Information on the lot/batch number has been requested.
1062382	3/1/2021	CA	30	M	2/28/2021	2/28/2021	Systemic: Allergic: Anaphylaxis-Mild, Systemic: Fainting / Unresponsive-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Hypotension-Mild
1062394	3/1/2021	MD	47	F	2/28/2021	2/28/2021	Perfectly fine until about 25 minutes after the injection. Then, nausea and dizziness started, followed by burning and itching on both sides of tongue. Then the back of the throat started hurting, and it became hard to swallow, followed by becoming very cold, chills, and dry mouth. Finally the skin area around mouth and lips and up through the cheek/jawline became very itchy. It was not anaphylaxis because my breathing was okay. We drove home, and I took two Benedryl (50 mg) upon arriving home. Within 2 hours all symptoms subsided with the exception of a nasty headache. Today, I am fine, but just have a sore arm at the site.

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1063642	3/1/2021	NM	67	F	2/25/2021	2/25/2021	I received the vaccine at approximately 1 p.m. in my left arm. I informed the technician that I had allergies and had previously had anaphylactic reactions to foods and some medications. I had noticed that the Pharmacy was not requiring people to stay after receiving the vaccine, so I told the technician that I would stay until I was sure I did not have a reaction. No one came to check on me, and in about 15 minutes, I noticed that my scalp was starting to itch and my face felt hot. I decided to go home, which was only a 5 minute drive from the store. I took off my mask in the car and discovered that my face was very red and starting to feel tight. I got home and took 1 Benadryl pill. By the time I got home, around 1:25 my ears were itchy and my lips were starting to swell. I waited an hour and started to feel better, the color in my face was returning to normal, and I had no swelling of my throat, which I have experienced with food allergies. At hour 2 I took a second Benadryl and went to sleep for 2-3 hours. When I woke up, I felt better, my lips were still slightly swollen, but my face, scalp and ears were back to normal.
1063860	3/1/2021	MI	51	F	2/24/2021	2/24/2021	Pt presented to the ED in acute anaphylaxis 20 minutes after receiving vaccine dose, in respiratory distress with stridor, wheezing, and difficulty breathing, as well as hives across her chest and arms. Pt had EpiPen with her and ED staff assisted her in administering it. Pt received solu-medrol, pepcid, benadryl, and albuterol in the ED. Pt significantly improved within 1 hour and was admitted to the hospital to be monitored overnight.
1063954	3/1/2021	ID	64	F	2/25/2021	2/25/2021	Patient reported anaphylaxis episode with Shingles vaccine. Patient monitored secondary to history of reactions. Vital signs 132/70-71-13-98% O2Sat. Skin warm and dry. Breath sounds clear. 1300 Vital signs 126/74-71-13-97%O2 Sat. Skin warm and dry. Breath sounds clear bilaterally. Patient continued to be monitored for 30 min. Discharged with no reported side effect at 1318.
1064187	3/1/2021	CA	52	F	2/27/2021	2/27/2021	Anaphylaxis developed over the hours, preceded by confusion, rapid heart rate, tingling of face/arms/chest, and feeling like moving through water.

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1064335	3/1/2021	CO	67	M	3/1/2021	3/1/2021	Received moderna 3/1/21 5:30pm, while waiting in post obs @ ~13 min - daughter rushed to our door said they thought patient was having reaction (543pm). Per wife - patient became clammy, very warm, unresponsive, gurgling at the mouth. I ran out to check on patient Pharm.D. They asked if they could remove his mask , i told them YES! he had a cloth mask over an n95 mask! Upon inspection, patient was not talking to me like he was prior to vaccine. They said patient gets tired and can become out of it, so they were not sure if this was a rxn to vaccine or just one of his episodes. Patient has prior hx of 3 times stroke and is on dialysis. He did not appear to be in anaphylaxis and was breathing (when looking at chest). We called code white to pharmacy, and Manager called EMS 5:44pm. Pharm.D came out to assist me 5:45pm. It was difficult to get a pulse using fingers, so we used BP cuff and got 83/57, with 87 BPM 547pm. I had epi pen ready to go in case we needed to use it but wanted to wait since patient was still breathing. While waiting for EMS, patient became responsive and began to talk. EMS showed up and took over. At this time Patient was talking and joking. 550 pm We decided we wanted patient to be checked out prior to sending him on his way. EMS asked us what we had done, and we discussed the above. EMS took over from there 555pm. Everything turned out ok, EMS left without further intervention. Before they left, I went to speak to family, and they were very happy due to the care they received. Event ending @ 6:15pm
1064412	3/1/2021	WA	78	F	3/1/2021	3/1/2021	I gave the patient her first COVID vaccination today at approximately 10:30am. After about 30 minutes, she reported tingling lips and a puffy tongue but no trouble breathing. After consulting with our clinical pharmacists, I gave her 50mg IM Benadryl and observed her for another hour. Her vitals were stable. She felt like the Benadryl helped (tingling gone, tongue felt achy), and no other symptoms appeared. She went home with instructions to call the ED with concerns if she developed signs of anaphylaxis, and to take more Benadryl if any tingling/itching occurred. I spoke with her at 7pm this evening and she reports her symptoms have mostly resolved (still a bit of an achy tongue).

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1063619	3/1/2021		53	F	2/27/2021	2/27/2021	Angioedema, team; recommended 60 minute evaluation . No further intervention Diagnosed with acute allergic reaction without anaphylaxis. 1120 135/85 24 RR 69 HR 100% O2 Sat. 1130 98% O2 Sat, 20 RR, 71 HR. 1140 98% 68 HR 20 RR. Discharged at 1140. Patient stable.
1063913	3/1/2021	MO	37	F	2/24/2021	2/24/2021	Client vaccinated during drive-through event, in a remote, rural setting approx 40 minutes from nearest hospital, and instructed to wait 30 min due to past h/o anaphylaxis. At 20 min post-vaccine, she reported feeling "funny," with swelling, tightness, and numbness in her face and inside of her mouth, although "not as bad as last time." Noted to be tachy in the 130's, and making constant mouth movements due to the increasing numbness. After brief explanation, adult EpiPen admin to rt thigh. O2 sat remained in upper 90's throughout, and no resp distress was ever noted. BP fluctuated between 96/60 and 142/92 during the course of management. 50mg IM diphenhydramine followed the EpiPen, as ambulance was enroute, unknown ETA. With constant monitoring, client reported chest tightness and variable feeling of swelling, tightness, and numbness inside her mouth and face/chin. After 20 min, with some improvement of symptoms, transported by ambulance to ED, where she received continued monitoring and steroid admin. According to ER note, she was released to home after some hours of observation.
1060542	2/28/2021	OK	65	M	2/25/2021	2/26/2021	Anaphylaxis. Severe Rash, throat closing up, low blood pressure
1059599	2/27/2021	MN	66	F	2/24/2021	2/25/2021	1 day post shot patient had rash over face and cheeks, with some minor cheek swelling. She presented 3 days later with rash over chest and L arm, with some discomfort in throat feeling tight. No difficulty breathing, no lip or tongue swelling, no obvious signs of anaphylaxis. Given delayed allergic reaction and presentation > 72 hours after vaccine, treated with prednisone and an OTC antihistamine with clear return precautions, with close follow up with PCP in 2 days.

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1059251	2/27/2021	WI	53	F	2/26/2021	2/26/2021	Systemic: Allergic: Anaphylaxis-Severe. Systemic: Allergic: Difficulty Breathing-Severe. Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe. Systemic: Allergic: Itch Generalized-Severe. Systemic: Chest Tightness/Heaviness/Pain-Severe. Additional Details: Patient experienced tightness in the throat, followed by coughing, complained of itchy back, was given 2 Benadryl, 2 EpiPens; then transported by ambulance to the ER.
1060275	2/27/2021	TX	73	F	2/25/2021	2/26/2021	Fatigue, 101° fever, chills, anaphylaxis, hives
1059683	2/27/2021	NH	69	F	2/23/2021	2/23/2021	If you had a severe allergic reaction after getting the first dose of an mRNA COVID-19 vaccine, experienced severe allergic reactions?also known as anaphylaxis?after getting a COVID-19 vaccine. I experienced difficulty breathing and had blue on my cheeks and around my mouth. Reported it to my primary care and was told this.... an allergic reaction is considered severe when a person needs to be treated with epinephrine or EpiPen® or if they must go to the hospital. I should have gone to hospital.
1058440	2/26/2021		31	F	2/26/2021	2/26/2021	Anaphylaxis - chest pain, shortness of breath, tingling in throat, lightheadedness Responsive to EpiPen x 2. Given IM solumerol EMS took her stable to ER
1059145	2/26/2021	TX	76	F	1/21/2021	1/21/2021	Anaphylaxis shock, was given a shot of benadryl, put on an ambulance and taken to the nearest hospital. I was on oxygen therapy at the hospital for several hours then sent home.
1059103	2/26/2021	CO	73	F	2/26/2021	2/26/2021	After about 10 minutes after receiving vaccine patient complained of shortness of breath, tingling down to her fingers and feeling strange. I gave her 1 dose of EpiPen at site of injection. She did start feeling a little better. Paramedics came and she was transported to the hospital. I did speak with her later and she was feeling better. She did tell me that they didn't think it was an anaphylaxis reaction but a reaction to the vaccine

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1059035	2/26/2021	AZ	51	F	2/25/2021	2/25/2021	At the vaccine administration location, patient experienced the following symptoms: tightness in chest, tightness in throat, nausea, itchy tingley lips, burning lips, bumps/gives on inside of lips. Patient given diphenhydramine 25 mg oral solution PO x1. Vitals taken: WNL. Patient denied EMS transport to ER and transported self to ER. Per ED Provider Notes: Patient reports vaccine was given about 1.5 hours prior to arrival. Pt reported sensation of swelling of her arms, left eye itchiness, and itchiness on the inside of her lips. She denied any difficult, no abnormal sensation in her throat, throat swelling or swelling elsewhere in her mouth. Pruritus documented, no rash. Nausea. At the time of the ER provider examining patient. it is reported that patient was not having anaphylaxis but does have a flat appearing raised lesions on side aspect of upper lower lip. Pt treated with IV diphenhydramine, PO Prednisone and IV famotidine along with NS. Patient observed for 2.5 hours and then discharged. No swelling, itching or swelling and time of discharge and reports resolution of symptoms.

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1058904	2/26/2021	NC	65	F	2/26/2021	2/26/2021	Pt has a history of multiple drug allergies including anaphylaxis. Prior to COVID 19 vaccination we discussed her reaction to previous Pneumovax 12 years prior. Several minutes following administration of the Pneumovax, she developed scratchy throat and hoarseness. Benadryl was administered with improvement in symptoms. She did not require epinephrine or ER visit. We discussed that she had a higher risk of reaction to the COVID 19 vaccine and advised her to wait 30 minutes post injection. During her wait time she began to develop scratchy throat and hoarseness that progressed over 10 minutes. She was taken to the treatment area where vital signs were obtained and 50 mg of oral Benadryl was given. Initial VS were SpO2 of 98, P 82, BP 140/100. She was alert and oriented. No edema lips or tongue. Heart RRR Lungs CTAB with no wheezes. She remained under observation for 30 minutes, vital signs remained stable and BP ranges from 138-140/80-90. She had noticeable improvement in her throat and voice and she was discharged in good condition to home under the care of her husband. They were advised that Benadryl could be repeated in 4-6 hours if needed. Should she develop any facial swelling, shortness of breath, wheezing or lightheadedness they should proceed to the emergency department. Reviewed the newly updated CDC guidance on reactions. Although her reaction was immediate it was not considered severe. CDC advised against getting the second vaccine. She is advised to discuss further with her allergist, Dr if she would like to discuss the possibility of getting the second dose with premedication or other precaution. She and her husband understood well and all questions answered.
1058779	2/26/2021	CO	33	F	2/11/2021	2/11/2021	Pt received first dose of Moderna COVID19 Vaccine Lot 029L0A. History of allergies and anaphylaxis to pollens and shellfish. Cleared to receive vaccine by her provider. Pt pre-medicated with Zyrtec earlier today. Patient observed for 30 minutes. Cough started without difficulty breathing. Pt went to her office, used her inhaler. Symptoms continued, pt self administered Epi pen. Observation RNs notified. Pt taken to ED, ambulatory for additional treatment. Monitored for 4 hours then d/c'd home

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1058578	2/26/2021	KS	21	F	2/24/2021	2/24/2021	<p>Progress Notes (Nurse Practitioner) ? ? Family Medicine Cosign Needed Expand AllCollapse All COVID VACCINE CLINIC 2/24/2021 Date: 02/24/2021</p> <p>Subjective Patient is a 21 y.o. adult who was seen at COVID Vaccine Clinic today for patients first dose of the COVID 19 vaccination. Patient was given the Pfizer vaccination in the left deltoid muscle. During patient's 30 minute waiting period after the injection, the patient began to experience throat tightness and itching. Patient denied rash, difficulty breathing, difficulty swallowing, wheezing, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling, lip swelling and tongue swelling. This provider was notified of patient reaction and patient was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to blood pressure abnormality , drooling, increased swelling, rapid progression of symptoms, respiratory distress, skin changes and tongue swelling. PMH: includes peanut allergy, carries epi-pen. She takes 75 mg of benadryl nightly to help with insomnia and seasonal allergies. ALLERGY REVIEW OF SYSTEMS: Patient complains of itching of skin Patient denies chills, malaise/fatigue, facial swelling, itching in ears, sore throat, frequent throat clearing, eyes itching, cough, chest tightness, shortness of breath, wheezing, rash, abdominal pain, muscle aches, dizziness and headaches Previous Reactions: she was brought back to bay initially for observation as she reported to pass out when she gets shots. Shortly after injection, she developed symptoms above. No vagal issues arose. Objective Vitals Vitals: 02/24/21 1048 02/24/21 1100 02/24/21 1136 BP: (!) 153/85 106/76 124/72 Pulse: (!) 101 86 81 Resp: (!) 22 16 SpO2: 99% 100% 100% Physical Exam Vitals and nursing note reviewed. Constitutional: General: Patient is not in acute distress. Appearance: Normal appearance. Patient is well-developed. Patient is obese. Patient is not diaphoretic. HENT: Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Comments: Clear oral airway Eyes: General: Right eye: No discharge. Left eye: No discharge. Conjunctiva/sclera: Conjunctivae normal. Neck: Thyroid: No thyromegaly. Cardiovascular:</p>

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Rate and Rhythm: Normal rate and regular rhythm.
Heart sounds: Normal heart sounds. Pulmonary:
Effort: Pulmonary effort is normal. No respiratory
distress. Breath sounds: Normal breath sounds. No
wheezing. Skin: General: Skin is warm and dry.
Capillary Refill: Capillary refill takes less than 2
seconds. Comments: Injection site without rash,
erythema or swelling Neurological: General: No focal
deficit present. Mental Status: Patient is alert and
oriented to person, place, and time. Psychiatric:
Mood and Affect: Mood normal. Behavior: Behavior
normal. Thought Content: Thought content
normal. Judgment: Judgment normal.
Assessment/Plan Treatment included: antihistamines
Follow up response to treatment: excellent. Patient
discharge: Stable to go home and follow up with PCP.
Differential Diagnosis: Vaccine-Related Anxiety (include
misc mental health) and Anaphylaxis (dyspnea, stridor,
drooling, tongue swelling) Close monitoring. Pt
improving. Doing well with medication intervention. Pt
has ride. Pt wheeled out to the front. Pt ambulates
without difficulty. No dizziness. Instructions given on
when she can take her next benadryl dose. APRN
Electronically Signed 2/24/2021 11:25 AM

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1058468	2/26/2021	WA	20	F	2/26/2021	2/26/2021	<p>Patient reported symptoms of: tachycardia, shakiness, vision changes, tongue numbness and shortness of breath following the first dose of the COVID19 Pfizer-BioNTech Vaccine on 2/5/2021. Patient said that historically has experienced tachycardia and shakiness after getting a flu shot or booster a few years ago. Symptoms reported by patient were enough to suspect potential anaphylaxis, and patient consented pharmacist to administer epinephrine. Patient was then advised by the pharmacist to follow-up with her primary care doctor as soon as possible to report the incident and to discuss the risk versus benefit of the vaccine, whether receiving the second dose would be appropriate for her. Patient returned to assisted living facility for her second dose of the COVID19 Pfizer-BioNTech vaccine on 2/26/2021. Patient said that she discussed the incident with her doctor, was told it would be appropriate to get the second dose despite her reaction and was advised to take "cautious measures". Pharmacist reviewed the patient information and screening questions, discussed the potential side effects and reiterated her risk of experiencing the same reaction with the second dose. Patient stated that she decided on getting the second dose because "her boyfriend is high risk and I'm doing this for him". Patient stated that she decided on getting the second dose because "her boyfriend is high risk and I'm doing this for him". Pharmacist asked patient if she had any questions/concerns or additional information to add prior to getting her vaccine, and patient denied having any at that time. After administering her second dose, pharmacist instructed patient to stay in the observation area for at least 30 minutes and to ask the staff for water given her experience with the first dose. Patient asked pharmacist how common it was for someone to get a reaction from the vaccine, and then mentioned that her family member had to drive her to the emergency room after her first dose because her throat was "burning", and was told that her throat was "a little swollen" and received a second dose of epinephrine at the emergency room. Patient included this information after the fact her second dose was already administered. Approximately 5 minutes after receiving her vaccine, the patient reported similar symptoms that she experienced on 2/5/2021: tachycardia, vision changes, shortness of breath and chest tightness. After monitoring patient with</p>

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no resolution of her symptoms, patient was then given a dose of epinephrine by the pharmacist, and the paramedics were called in to assess patient and take her to the emergency room.

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1056642	2/26/2021	TN	20	F	2/5/2021	2/1/2021	anaphylaxis; high blood pressure; elevated heart rate; her throat felt funny, like it was getting tight; very nauseous/sick of her stomach; rash on her chest; She could not swallow; This is a spontaneous report from a contactable consumer (parent of the patient). Information were received also from a Pfizer-sponsored program COVAX US Support. A 20-years-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EL9261), via an unspecified route of administration in the left arm on 05Feb2021 09:30 at single dose for COVID-19 immunisation. Medical history included acne, allergy environmental cats dogs and latex. Adrenaline (EPIPEN) and Corticosteroid were used to treat these allergies. Due to these severe allergies, the patient had to take weekly allergy shots. Got allergy shot the day before the 2nd vaccine shot. Concomitant medication included isotretinoin (AMNESTEEM), buspirone (unknown manufacturer), calcium (unknown manufacturer), azelastine hydrochloride, fluticasone propionate (DYMISTA), gabapentin (unknown manufacturer), melatonin (unknown manufacturer), omeprazole (unknown manufacturer), estrogens conjugated, medroxyprogesterone acetate (PREMELLA), probiotics (PROBIOTICS), fluoxetine hydrochloride (PROZAC) , trazodone (unknown manufacturer), colecalciferol (VITAMIN D), cetirizine hydrochloride (ZYRTEC). The patient previously took clindamycin, bactrim and corticosteroids and experienced hypersensitivity. The patient previously received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EL3249) intramuscular in left arm on 15Jan2021 at 11:00AM. It was reported that 15 minutes after receiving her second COVID-19 vaccine dose the patient developed anaphylaxis, her throat started closing up, her throat felt funny, like it was getting tight. A nurse administered her anaphylactic shot (EPI-PEN shot) and was taken to the hospital by ambulance. The patient was monitored in the Emergency Room because her blood pressure and heart rate were up, but the Emergency Room didn't give her any further treatment. The patient was discharged home on 05Feb2021. On Saturday, 06Feb2021, at 4-5AM she developed anaphylaxis again, the patient had the same throat tightening happen again. The mother gave her an Epi-Pen shot (AUVI-Q) and

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brought her back to the Emergency Room. While in the Emergency Room, the patient was given steroids and Pepcid, and then sent back home. On Sunday, 07Feb2021, at approximately 1:00AM she had the same throat tightening so the mother gave her an Epi-Pen shot (AUVI-Q) again, and brought her back to the Emergency Room. The patient was admitted to hospital and discharged on 09Feb2021 evening (at 16:00). At hospital the patient received some steroid shots in the hospital. The patient was given 3-125mg steroid shots, and 3-40mg steroid shots, every night she spent in the hospital, she woke up with her throat closing and she was administered 125 steroids 50 mg Diphenhydramine (BENADRYL) and 4-5 hours later 40 mg of steroids 20 mg Famotidine (PEPCID) IV. They kept IV fluids. On 10Feb2021 at 7:50AM the patient experienced throat tightness again. The mother gave her some Diphenhydramine (BENADRYL) and steroids which were prescribed at hospital. The patient started a taper dose of Prednisone 10mg tablets. She was to take 2 Prednisone 10mg tablets twice a day for 3 days, then to take 2 Prednisone 10mg tablets in the morning and 1 Prednisone 10mg tablet in the evening for 3 days; then to take 1 Prednisone 10mg tablet twice a day for 2 days, and then 1 Prednisone 10mg tablet daily for 2 days. The patient was prescribed generic Famotidine (PEPCID), 40mg, one tablet, twice a day, and generic Diphenhydramine (BENADRYL) 25mg capsules. On unknown date in feb2021 the patient gets very nauseous when her throat starts to close. She could not swallow and was sick of her stomach. She experienced a rash on her chest. The outcome of the event heart rate increased and blood pressure high was recovered, for anaphylactic reaction and throat tightness was not recovered. For the other events was unknown. The events anaphylaxis, throat tightness, heart rate increased and blood pressure were serious due to hospitalization.

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1058531	2/26/2021	WA	20	F	2/26/2021	2/26/2021	<p>Patient reported symptoms of: tachycardia, shakiness, vision changes, tongue numbness and shortness of breath following the first dose of the COVID19 Pfizer-BioNTech Vaccine on 2/5/2021. Patient said that historically has experienced tachycardia and shakiness after getting a flu shot or booster a few years ago. Symptoms reported by patient were enough to suspect potential anaphylaxis, and patient consented pharmacist to administer epinephrine. Patient was then advised by the pharmacist to follow-up with her primary care doctor as soon as possible to report the incident and to discuss the risk versus benefit of the vaccine, whether receiving the second dose would be appropriate for her. Patient returned to assisted living facility for her second dose of the COVID19 Pfizer-BioNTech vaccine on 2/26/2021. Patient said that she discussed the incident with her doctor, was told it would be appropriate to get the second dose despite her reaction and was advised to take "cautious measures". Pharmacist reviewed the patient information and screening questions, discussed the potential side effects and reiterated her risk of experiencing the same reaction with the second dose. Patient stated that she decided on getting the second dose because "her boyfriend is high risk and I'm doing this for him". Patient stated that she decided on getting the second dose because "her boyfriend is high risk and I'm doing this for him". Pharmacist asked patient if she had any questions/concerns or additional information to add prior to getting her vaccine, and patient denied having any at that time. After administering her second dose, pharmacist instructed patient to stay in the observation area for at least 30 minutes and to ask the staff for water given her experience with the first dose. Patient asked pharmacist how common it was for someone to get a reaction from the vaccine, and then mentioned that her family member had to drive her to the emergency room after her first dose because her throat was "burning", and was told that her throat was "a little swollen" and received a second dose of epinephrine at the emergency room. Patient included this information after the fact her second dose was already administered. Approximately 5 minutes after receiving her vaccine, the patient reported similar symptoms that she experienced on 2/5/2021: tachycardia, vision changes, shortness of breath and chest tightness. After monitoring patient with</p>

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							no resolution of her symptoms, patient was then given a dose of epinephrine by the pharmacist, and the paramedics were called in to assess patient and take her to the emergency room.
1058426	2/26/2021	IL	54	F	12/18/1967	2/26/2021	patient hands became very red and swollen suddenly after administration of the vaccine. no reports of numbness, pain, or tingly. No reports of itchiness or SOB. signs of anaphylaxis was observed. Patient only reported red hands and swelling. Communication was through son-in-law since patient does not speak language. blood pressure was monitored. patient continued to be monitored for 30 minutes. Patient said she felt fine so was sent home. Discussion of signs of anaphylaxis were communicated to her.
1058024	2/26/2021	NC	22	F	2/26/2021	2/26/2021	Urticaria on right arm, chest, and neck starting about 3.5 hours after injection. No concern at time of evaluation for anaphylaxis.

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1056646	2/26/2021	FL	71	F	1/21/2021	1/1/2021	My arm hurt; I started to get little tired; I couldn't watch TV; My stomach suddenly did not feel well; Nauseous; I got cold; Sick; was very hot and so hot; was round up/she was feeling she would faint; waves of feeling like i would pass out; it was just being very hot, then being cold; Blood drained from my head, I just knew I was going to pass out; I took 0.2 rather than the 0.3ml of the first dose; very fast heart rate intermediately for many day; squeezing of chest; muscle hurting/Pain in my body in every muscles, my fingers, my hands, my calves, my feet, my back, neck, everything; digestive disorders; feeling gassy, uneasy; stomach abdomen was just tight; abdominal issue; feeling gassy, uneasy; stomach abdomen was just tight; This is a spontaneous report from a contactable consumer (patient). A 71-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; lot number: E18982), on 21Jan2021 (at the age of 71-year-old) at single dose for COVID-19 immunisation. The patient reported that based on her history of reactions to medications, the nurses giving injections "decided 0.2ml instead of 0.3ml", which is what they gave, so she got 0.2 that is two-third of the shot. The 2nd shot was for 8'oclock on 11Feb2021. She is very sensitive to shots, vaccines, and to all medications and injections and things like that. She has sensitives thanks to two concussions she had in her life. She never was before that she had two concussions. Second one had a crazy man hit her after that just noticed that just have reactions not adverse or dying but definitely take rest of everything. So she take less of a shot, like a dental shot or cortisone shot, which she had taken in the past. If she has dental shot she cannot take Novocain, had to take Carbocaine or Marcaine and they give her half. Also she had been taking cortisone shot for shoulder for rotator cuff injury. They also have to give her less. Or flu shot: she takes half one week and come back for the other half the next week. Just have reactions. She told to when arrive for medication and did have one anaphylactic reaction but that was to cat skin dye, was told to this two nurses who was administering the vaccine and said to them she was really afraid to take. It is just too much for her. She knows her body. She is sure have reaction but is really afraid and don't know what is the first one will do to her. They just did two nurses and she decided that she will be

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taking 0.2 instead of 0.3ml which is what they gave. She got 0.2 so that two third of the shot and waited the half an hour, a nurse watched her card and 7 other cards. She did not have the anaphylactic reaction. She went home. Her arm hurt and started to get little tired. The events started the day that she got the shot. Like about 3 or 4 hours later. It is just few hours later she couldn't watch TV so went to laid down and an hour later she woke-up. She walked to her kitchen and blood drained from her head, she just knew she was going to pass out. Her stomach suddenly did not feel well. She tried to get back her bed but she was round up and as far as the bathroom. She got very nauseous, she laid down on bathroom floor. She thought she was sick but didn't round up having to use toilet of few times. Although while she was feeling she would faint. She was very hot and so hot. While lie down, she couldn't even pulling off her pajamas. So when she got cold so she was pulling a towel down and stop and she laid to for two hours, she finally got to her bed. It was a terrible experience. Next day she drank water and had potatoes prepared and went up eating back to later baked potatoes. Next day luckily she did not have repeat of the nausea. She didn't have that anymore of. She did have abdominal issue just not diarrhea or anything but just not feeling well, feeling gassy, so uneasy. This all lasted, that part lasted for 7 days. What concerned her was especially beside first day it was few days she got off again. She was just feel blood drain but not this first time she laid on floor. She couldn't sit on chair to watch TV for about 3 days. She mostly laid on bed but she would get very hot and then very cold during the day. She would get very fast heart beat not continue but really fast like heart was pounding her chest. She felt like someone has their hand inside her body squeezing her chest. She got afraid but didn't want to go hospital. She didn't think she was sick enough. She was concerned. So that was happened and this last was for about 7 days. Then the squeezing of chest part went away. She doesn't want to wind-up on the floor feeling that sick again, she felt so sick it felt like food poisoning. After that, it was just being very hot, then being cold, the fast heart rate, every muscle hurting. Those were the main things that continued for a week. And digestive disorders. It all lasted for about 13 days. She was concerned she had a very fast heart rate intermediately

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for many days, for about a week. And that's considered an adverse reaction and also she was getting waves of feeling like she would pass out, everything would drain from her head. She experienced stomach ache, feeling hot then cold. She wants to do precautions before taking the second dose on 11Feb2021. She did take may be 3 days later two Tylenol but didn't take anything (clarification requested). She didn't even take vitamins during that time. She was afraid to take anything so she did not. At the same time also there was pain in her body in every muscles, fingers, hands, calves, feet, back, neck, everything. Her stomach abdomen was just tight. She was concerned that last for few days. In last few days she started feel herself and now she is going again tomorrow. So that how she reacted. She doesn't know how much of this shot she told them she could tolerate because everybody is saying second shot will give you more reactions. All she can take this more than that because that was lot. She wants to be herself, don't want laying on floor, don't want to have 105 temperature or anything. The patient was asking if she should take another 0.2ml another two-third of the shot. She just asked them for half that is 0.15 would that be a big difference. She needed to know by 8 o'clock tomorrow. I might be in a queue to get it. She stated: 'So, that's my concern. I'm all alone, I'm a senior, I have no family. I lost my mother to covid. I know I need this vaccine, but I just, I cant get that sick and I'm so afraid I'll wind up with a 105 something, fainting away and no one knowing'. She was asking if reactions after the 2nd dose are worse than the 1st dose, if she didn't have anaphylaxis after 1st one, she shouldn't have it a 2nd time, right. She said, "1st half of flu shot, I get sick, then the 2nd half nothing". She also asked if she can take medications after the vaccine, like Tylenol, or irritable bowel syndrome (IBS) medication she takes as needed. The events resolved, but the patient reported it took her like 13 days before she felt better.

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1056497	2/26/2021		22	F			Severe anaphylaxis allergic reaction; Passed out on the ground; A spontaneous report was received from a consumer concerning a 22-year-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and passed out on the ground and had a severe anaphylaxis allergic reaction. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On an unknown date, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. About 10 minutes after receiving the second dose of the Moderna vaccine, the patient passed out on the ground having a severe anaphylaxis allergic reaction. Treatment for the event included two doses of epinephrine IM in addition to diphenhydramine, ondansetron, and steroids to prevent a rebound reaction. 911 was called and after epinephrine and diphenhydramine were administered, the patient was immediately transported to the hospital where she stayed for 6 more hours for observation, fluids, and further medications. Action taken with mRNA-1273 in response to the events was not applicable. The events, passed out on the ground and severe anaphylaxis allergic reaction, were considered resolved; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Anaphylactic reaction is a listed event in CCDS.

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1056666	2/26/2021	GA	31	F	2/11/2021	2/11/2021	Light cough; Shortness of breath; Anaphylaxis; lost voice entirely; This is a spontaneous report from a contactable consumer (patient). A 31-year-old female patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 11Feb2021 at 13:15, at single dose, for COVID-19 immunisation. Medical history was none. Patient did not have known allergies and did not have COVID-19 prior to vaccination. Concomitant medications included piroxicam (PAXIL) and lisdexamphetamine mesilate (VYVANSE). Patient did not receive other vaccines in four weeks. The patient experienced light cough on 11Feb2021 at 14:45 with outcome of recovering, shortness of breath on 11Feb2021 with outcome of recovering, anaphylaxis on 11Feb2021 with outcome of recovering, lost voice entirely on 11Feb2021 with outcome of recovering. The events required emergency room visit and physician office visit. The patient was hospitalized due to the events in Feb2021 for 1 day. Events were considered life threatening. Clinical course: light cough after half an hour from vaccination. Within 2 to 3 hours had lost voice entirely and was suffering from shortness of breath. Her primary physician told her to go to the emergency room or he was calling an ambulance because he said it sounded like anaphylaxis and that her life was in danger. Therapeutic measures were taken as a result of the events and included treatment with intravenous (IV) Decadron Pepcid and epinephrine. She received the 2nd dose on 21Feb2021 at 01:15 PM. Patient was not tested for COVID-19 post vaccination. The information on the lot/batch number has been requested.
1054954	2/25/2021		55	F	2/25/2021	2/25/2021	Metallic taste in mouth, no other sx. Hx of anaphylaxis. Evaluated by EMS. So resolved and client was discharged at 1:55pm.

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1055721	2/25/2021	PA	59	F	2/25/2021	2/25/2021	Patient started experiencing tingling in mouth area within 5 to 10 minutes of receiving vaccine. Patient is aware of beginning symptoms of anaphylaxis since she has experienced in the past. Patient also started feeling her eyes swell. Patient has an EpiPen and was unsure if she should use or wait longer. I contacted 911 to dispatch a paramedic since we would need to contact them anyway if she decides to use her EpiPen. Paramedics came within 5 to 10 minutes and took her to evaluate/treat.
1053766	2/25/2021	PA	84	M	2/24/2021	2/24/2021	Systemic: Allergic: Anaphylaxis-Severe, Additional Details: Patient taken to emergency medical facility.
1055031	2/25/2021	IL	41	F	2/3/2021	2/3/2021	About 5 minutes after receiving the shot, I experienced a tickle in my mouth, and then shooting burning waves down both sides of my spine (just to the left and right) starting in my neck and settling in my groin. It felt like intense burning and buzzing waves going down from my neck. The paramedics came, said there were no signs of anaphylaxis, and took me to ER. They gave me benedryl and Pepcid in an IV, I felt drowsy. The waves eventually subsided and were gone around the time of the benedryl (not sure if before or after).
1054886	2/25/2021	FL	69	F	2/24/2021	2/24/2021	Within 20-minutes of vaccination, the patient reported pain in their throat, SOB, tingling in their arms, and chest pressure. EMS evaluated patient on-site. Patient was hypertensive (184/96). 12-lead EKG was NSR, rate of 79 bpm, no ST elevation. FSBG was 137 mg/dL. ETCO2 was 40mmHg with normal square waveform. EMS initiated transport to Hospital Emergency Department. En route, patient became more hypertensive (200/106). In ED, she remained hypertensive and was admitted to inpatient telemetry unit. Patient had 1-night stay to rule out cardiac-related events. Anaphylaxis was ruled out. Discharged with diagnosis of vaccine reaction and chest tightness.

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1054573	2/25/2021	AZ	74	F	2/25/2021	2/25/2021	Acute onset difficulty breathing with stridor/difficulty breathing. Tx as allergic rxn/anaphylaxis. Interventions from patient included albuterol breathing treatment. EMS provided Solu-Medrol, DuoNeb breathing treatment. Continued significant stridor on presentation to emergency department. Emergency department provided IM epinephrine, IV Benadryl, IV famotidine, racemic epinephrine breathing treatment. Symptoms improved. Stridor resolved.
1054263	2/25/2021	NY	40	F	2/25/2021	2/25/2021	40 y/o female who developed anaphylaxis to Pfizer vaccine. Pt first developed itchiness of throat , followed by generalized pruritus and the sensation of "throat tightening." Received epi from medical team but initially refused ER visit. Symptoms resolved but returned 15 mins later with numbness of the lips and throat, sensation of throat closing being additional symptoms. She was agreeable to transport after the second episode.
1053953	2/25/2021	MA	86	F	2/24/2021	2/24/2021	Patient reported tongue sensation after 15 minutes of observation. No evidence of facial swelling or tongue edema on exam. She denied throat tightness/itching, shortness of breath, or worsening symptoms. She declined to stay beyond 15 minute interval as she stated she was feeling anxious. Reviewed s/sx anaphylaxis, advised her to call 911 if these occur. She remained well appearing and was speaking clearly in full sentences throughout observation.
1053841	2/25/2021		48	F	2/21/2021	2/21/2021	Following vaccine administration, patient complained of feeling increased heart rate to observation nurse. Vital signs checked and initially her heart rate was 115 but decreased to 75 with next set of vitals. Patients BP was 140/78, pulse ox 98. No SOB, no signs of anaphylaxis. Patient has h/o of anxiety and felt this was related. Patient was monitored for 30 min and felt some intermittent tingling in her hands. Patient was transported to the ED for further evaluation as she was still not feeling well after she was offered a snack and a drink. Patient monitored in ED, workup included EKG and labwork. Symptoms resolved and patient discharged to home.

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1053781	2/25/2021	IL	81	F	2/23/2021	2/23/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Systemic: Seizure-Severe, Additional Details: The incident happened at COVID clinic. Patient was receiving the 2nd dose of the vaccine. The first time we administered the vaccine to the patient, she informed the immunizer that she had a bad cough for 3 days. The patient did mention that she suffers from seizures often. The 2nd dose was administered by the RPH immunizer and was directed to the waiting area for 15 minutes. During that time in the waiting area, she was talking to the.
1055043	2/25/2021	FL	68	F	2/24/2021	2/24/2021	Within 15-minutes of vaccination, the patient reported pruritus around injection site, as well as pruritus and edema in her face, around her mouth and eyes. Patient denied SOB, CP, Abdominal pain, N/V, or HA. EMS evaluated patient on-site. The patient was hypertensive (174/86). Due to patient's complaint and physical exam, EMS administered Benadryl 50mg IV. EMS transported patient to Largo Medical Center Emergency Department. In the ED, the patient had bilateral palpebral edema, pruritus surrounding injection site spreading down the extremity, and lips were erythematous. No SOB or tongue/throat swelling noted. Patient was hypertensive (164/72). ED Physician administered PO Pepcid and Prednisone by provider in triage. The patient stated they felt improvement after the Benadryl treatment and requested to be discharged from ED. Patient was given information and strict return precautions about anaphylaxis.
1052425	2/24/2021	IL	72	F	1/11/2021	1/18/2021	MODERNA COVID - 19 VACCINE EUA Day 7 or 8 post- vaccination noted right arm was red / swollen / firm to the touch over a 3 x 3.5 inch area. Strong headache , shoulder / neck pain , and strong fatigue . All symptoms noted here continued for approximately 6 to 7 days. The 3 rd day of symptoms I went to my Family Doctor who advised me to NOT take Dose # 2 of the Moderna Covid-19 vaccine due to possibility of having a worse reaction , possible anaphylaxis reaction . I notified Health Dept. that same day and cancelled my scheduled 2 nd dose vaccine appointment.

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1051446	2/24/2021	MA	79	F	2/8/2021	2/8/2021	grade 2 allergic reaction; short of breathe; flushed; she was an oncology patient with large granular lymphocytic leukemia and received BNT162B2; she was an oncology patient with large granular lymphocytic leukemia and received BNT162B2; This is a spontaneous report from a contactable other healthcare professional. A 79-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL9262, NDC number of COVID Vaccine: 59267-1000-1; Expiry Date of COVID Vaccine: 31May2021), intramuscularly at Left Deltoid on 08Feb2021 10:30 (either 10:30AM or within that hour or prior) at single dose for COVID-19 immunization. Medical history included anxiety, panic disorder, asthma, obstructive sleep apnea, additional Information for Other Conditions: She was oxygen Dependent, coeliac disease, allergy, Additional Information for Other Conditions: She had Medication, Environmental, and Food Allergies, central neuro hearing loss, vertigo, Allergic rhinitis, gastrooesophageal reflux disease (GERD), Additional Information for Other Conditions: Esophageal Reflux, osteopenia, impaired glucose tolerance, hypothyroidism, claustrophobia, rheumatoid arthritis (she had arthritis for which she took Orencia for), history of coronary heart disease, diabetes, she would be a targeting patient, as she was an oncology patient with large granular lymphocytic leukemia she met criteria for the pandemic, as well as they put down that she was due for immunization. She had anaphylaxis to bees. With adhesive tapes she got dermatitis. With shellfish she got hives. She had a gluten sensitivity and with mango her mouth gets fuzzy. Family Medical History Relevant to AE(s): her sisters had a few cancer. There were no concomitant medications. The patient previously received levofloxacin she had hives, with quinolones drug class she had hives, with thiopental she had hives and needed IV Decadron for it, with sertraline she has syncope, with Revatio she had an adverse event of joint and muscle pain, with ciprofloxacin she had tachycardia, with Enbrel it caused a drug induced pulmonary fibrosis granulomatosis, with Montelukast she had a headache and muscle pain, nitrofurantoin she had headache, with Symbicort it gave her hoarseness, she took Orencia for arthritis, she got the flu Vaccine in Sep2020. That was most recent. The patient had a grade 2 allergic reaction

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on 08Feb2021. The patient was watched after administering the vaccine on 08Feb2021 as she had background of multiple allergies and asthma. She was watched for 30 minutes in the oncology unit infusion suite. The reaction happened within 5 minutes of administration. Seriousness Criteria: Caller explained that this reaction was mild to moderate, there was a grade to intervene but at no point was she unstable, she did have a significant anxiety disorder, and so she was nervous about getting the vaccine. She was short of breathe, odd and flushed. She was physically stable, her vitals were stable and there was no angioedema. Reporter seriousness for grade 2 allergic reaction: Medically significant. The patient recovered, as a treatment they gave her IV Benadryl 50mg and IV fluids, she also had her own albuterol inhaler. In the pandemic, they are not doing nebulizers. The outcome of events allergic reaction, shortness of breath and flushed was recovered on 08Feb2021. Relatedness of drug to reaction(s)/event(s). Reaction assessed: Grade 2 allergic reaction; Source of assessment: Primary Source Reporter. Method of assessment: Global Introspection. Drug result: Related. Causality: reporter stated that she did think the patient's base line anxiety played into the reaction she experienced, the reaction was aggravated by it.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of grade 2 allergic reaction, short of breathe and flushed due to temporal relationship and current known drug safety profile. The patient's underlying allergic physique also predisposed the patient to developing the event. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

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1051526	2/24/2021	AZ	45	M	2/22/2021	2/22/2021	Roughly 30 minutes after administration of vaccine patient endorsed weakness, dizziness and shortness of breath. His blood pressure and heart rate increased during the event. He was treated with epinephrine 0.3mg IM due to concern for anaphylaxis and transferred to the ER via EMS. In the ER his vitals were stable and he was observed in the ER for 3 hours, with improvement in his symptoms. During the course of his stay he was treated with Benadryl, dexamethasone and albuterol. He presented with no hives, pharyngeal edema, wheezing, hypoxia or nausea/vomiting/diarrhea.
1051783	2/24/2021	OK	63	F	2/22/2021	2/22/2021	Pt complained of throat tightness and being lightheaded beginning at 1127 hours (5 minutes after vaccine). She arrived at emergency/symptoms reporting station at 1129 hours. She denied tongue swelling, denied rash, denied difficulty speaking. No rash was seen by medics either. Pt did not have wheezing or stridor. Medics on scene and student medics under the direction of Medics, placed the patient on the monitor. Her HR was stable in the 70s and her sats were 99-100% on room air, with a strong pulse and RR of 16. The pt became more anxious and demanded that someone assist her with her Epi pen administration. RN explained sx's of anxiety and sx's of anaphylaxis. Pt became agitated and again remained adamant that medics give her Epi. At 1132 hours a student medic under the direction of Medics administered the pt's own epi pen to her. Vitals signs after epi were HR of 88, BP of 170/97, RR 22, sats 100% . A transport unit was called as precaution and to potentially transport. Pt appeared to have an increase in agitation as indicated by her speech with medics being short and her stating that she was "irritated" with "everyone talking", that she "can't hear everyone all at the same time", that this is just "too much" and waving her hands in the air. Pt was transported to the ER via Medics for continued care and follow up.
1052316	2/24/2021	GA	30	M	2/15/2021	2/23/2021	Anaphylaxis, severe body rash with hives that's spread all over upper and lower body, along with neck and face.

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1053153	2/24/2021	MT	26	F	2/19/2021	2/19/2021	After receiving Pfizer Covid vaccine, patient developed symptoms of dizziness, nausea, a little shortness of breath. Reported she had a history of asthma and said she felt like "her limbs weren't working". She agreed to be taken to ED for evaluation. Was treated with fluids, ondansetron, and lorazepam IV push one time. Never treated for allergy/anaphylaxis.
1051574	2/24/2021	NY	43	F	2/23/2021	2/23/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Chest Tightness / Heaviness / Pain-Severe
1051587	2/24/2021	NY	43	F	2/23/2021	2/23/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Systemic: Allergic: Swelling of Face / Eyes / Mouth / Tongue-Severe, Systemic: Chest Tightness / Heaviness / Pain-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: epipen was administered at 1:02 PM by, benadryl 50 mg po, and O2 inhalation, and patient was transported to ED at 1:08 PM. patient was given a second dose of epipen in the ambulance and at 2:48 PM, patient is stable and improving-Severe, Systemic: Shakiness-Severe, Systemic: Tachycardia-Severe, Systemic: Weakness-Severe, Additional Details: at 12:20 PM, recieved the pfizer biontech covid vaccine- 1st dose. lot:el9269 exp:05/21 which was mixed by employee and injected by employee. prior to getting the vaccine, patient told employee that she recieves cortisone injections in her elbow, unknown frequency, and due for her next injection on the following day 02-24-2021 and employee told her that she can double check with her doctor and consented to recieving the vaccine. at 12:30 PM
1053314	2/24/2021	HI	76	F	2/11/2021	2/20/2021	Pt experienced redness and warmth around the injection site the night she received the vaccine 2/11/21. It lasted for about 3-4 days, then went away. The redness and warmth returned ~2/20/21, along with some achiness. On 2/23/21, she experienced some itching, but that has gone away. Pt has not experienced any signs of anaphylaxis.

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1049960	2/23/2021	WY	66	F	2/17/2021	2/17/2021	2/17/21-Anaphylaxis-15:17pm (within 30 min waiting period post vaccine), throat scratchy, moved to assessment area, HR 100, labored resp, O2 6L NRmask initiated. (ct reports similar reaction as previous anaphylaxis). 15:22pm-911 called, HR 120, Epi 0.5ml admin. 15:37pm transfer via ambulance to hospital. 02/18/2021 evening, f/u call to client by PHN, throat still feels 'weird', ct reports had 2nd Epi in ambulance, 3rd Epi in ER, plus Benedryl gel, Ct then recalled had anaphylaxis reaction in past to bee sting had ER visit, tx w/ steroids at that time. PHN recommended ct talk with PCP re epi pen order.

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1048199	2/23/2021	AZ	49	F	12/17/2020	12/17/2020	hives; facial swelling; throat swelling; throat itching; nausea; anaphylactic reaction/ Anaphylaxis; This is a spontaneous report from a contactable physician via FDA. A 49-years-old non-pregnant female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscular in the arm on 17Dec2020 at 13:30 at 0.3 ml, single dose for covid-19 immunization. Medical history included ongoing essential hypertension, ongoing protein c deficiency, ongoing lumbosacral radiculopathy, ongoing type 2 diabetes mellitus, ongoing pulmonary embolism, Strep pharyngitis from 29Nov2020 and resolved at the time of vaccination, serious allergic reaction, allergy to iodinated contrast media and Cardiac Arrest after IV contrast. Concomitant medication included apixaban (unknown manufacturer) for Protein C Deficiency, metformin hydrochloride (unknown manufacturer) for Type 2 Diabetes, chlorthalidone (unknown manufacturer) for hypertension, metoprolol (unknown manufacturer), clonidine hydrochloride (unknown manufacturer) for hypertension, atorvastatin (unknown manufacturer), magnesium oxide heavy;tocopheryl acetate (unknown manufacturer), tramadol hydrochloride (unknown manufacturer), diphenhydramine hcl (unknown manufacturer), epinephrine bitartrate (unknown manufacturer) for serious allergic reaction and anaphylaxis. On 17Dec2020 at 13:48, approximately 13min after vaccination while in observation the patient experienced hives, facial swelling, throat swelling/itching, and nausea. Patient was immediately taken to Emergency Department where epinephrine was given 1M in the left thigh followed by 125mg IV solumedrol, 50mg IV benadryl, 1000mL NS, and 20mg IV famotidine. Hemodynamically stable throughout ED course. The events were considered serious as per hospitalization. Medical Tests and Laboratory results related to the adverse event included: CRP: 11.0, Glucose-182, BRN-29, INR-1.1, Remained of CMP and CBC were WNL. The physician stated that anaphylactic reaction onset 6min after vaccination symptoms improved - 20min after epipen administration, Resolved 60 min later. The signs and symptoms of anaphylactic reaction included Diffuse rash, Itching, throat/lip swelling, shortness of breath, cough, BP 128/72, Spon-97% HR-71. The patient rushed to ED from

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vaccination PoD. Received EpiPen approximately 8 min post vaccination. Then received steroid, antihistamines, IVF. Sx improved in 20 min resolved 60 min. The patient was not hospitalized and not admitted to an intensive care unit for anaphylactic reaction. The physician stated that multiorgan involvement included respiratory, dermatological/mucosal. Also reported as Respiratory: Yes; Upper airway swelling: Yes; Respiratory distress: Yes; Tachypnoea: Yes; Dry cough: Yes; Difficulty breathing (without wheeze or stridor): Yes; Dermatological/Mucosal: Yes; Generalized urticarial: Yes; Angioedema (not hereditary): Yes; Generalized pruritus with skin rash: Yes. The following laboratory tests or diagnostic studies performed included Hematology on 17Dec2020 showed: results with units, if applicable: 8/13/299/41; Clinical chemistry on 17Dec2020 showed: results with units, if applicable: 137,103,29/36,22,07 (Less than sign) 182; CRP on 17Dec2020 showed: results with units, if applicable: 11.0. The patient did not receive any recent vaccines for any other conditions prior to the event being reported. The patient did not receive any recent vaccines for SARS-CoV2 other than Pfizer-BioNTech COVID-19 Vaccine prior to the event being reported. The patient had not received any other vaccines around the time of Pfizer-BioNTech COVID-19 Vaccine vaccination. The patient had anaphylaxis on 17Dec2020 at 13:36. The patient was not deceased and received treatment. Treated in emergency room/ epinephrine IM IV steroids, antihistamines, IV fluids. The physician considered the Pfizer product had a causal effect to the adverse event. The outcome of the event anaphylactic reaction/ anaphylaxis was recovered on 17Dec2020, while other events were recovered on 17Dec2020 at 13:48. Information on the lot/batch number has been requested. Follow-up (08Feb2021): New information received from the contactable Physician included: additional medical history and lab data, concomitant medications details, suspect drug information (lot number, dosage regimen details), event information (new event "anaphylactic reaction/ Anaphylaxis") and other clinical courses.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the events anaphylactic reaction/Anaphylaxis urticaria, swelling face, pharyngeal

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							swelling, throat irritation and nausea cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.
1049475	2/23/2021	CT	68	F	2/23/2021	2/23/2021	BP 180/100 , repeat 170/90 Pulse Ox 96 While sitting in observation pt reported having an itchy area on her left wrist. Pt reported a history of CT Scan Contrast Dye and seasonal allergies. Pt was evaluated by EMS paramedic. Pt declined transport to the ED despite recommendation and education on precursor to anaphylaxis. Pt signed refusal with EMS. Pt reported she often gets itchy for no apparent reason. Pt stayed at clinic in observation for over 45 minutes with no progression of itchiness or other symptoms. . Pt was given ED precautions.

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1049972	2/23/2021	HI	43	F	2/19/2021	2/19/2021	<p>Patient presents for evaluation of encounter for immunization. Here for moderna COVID-19 vaccine #1. See scanned vaccination screening form and post vaccine questionnaire.@1713 Patient reports that her lungs "felt tight". She denies mouth swelling, facial swelling, tongue swelling, throat tightness, difficulty breathing or speaking. Denies GI distress, nausea. Denies rashes, itching or other symptoms. She denies allergies. Denies chronic conditions. Denies daily medications. She reports her only medical history is "childhood asthma" and does not take any medication currently. (1715) Patient escorted to exam room for privacy and monitoring. Patient able to ambulate without difficulty or distress. She reports her "chest tightness" is a 6 (0-10 scale). And denies other symptoms including chest pain, itching, mouth swelling, SOB. Patient reports she prefers to sit in chair, vs lying on exam table, VS monitored by RN. ROS: CONSTITUTIONAL: Negative for chills, fatigue, fever, and weight change. EYES: Negative for blurred vision, eye pain, and photophobia. E/N/T: Positive for Denies mouth, tongue swelling. Denies throat tightness.. CARDIOVASCULAR: Negative for chest pain, palpitations, tachycardia, orthopnea, and edema. RESPIRATORY: Positive for Denies cough, distress, endorses "tight chest". GASTROINTESTINAL: Positive for Denies nausea, vomiting, GI distress, diarrhea. INTEGUMENTARY/BREAST: Positive for Denies rashes, lesions, changes to skin.. Vitals: Current: 2/19/2021 4:48:38 PM T: 97.9 F (temporal); BP: 174/104 mm Hg (right arm, sitting); P: 81 bpm (finger clip, sitting)O2 Sat: 100 % (room air) Repeat: 5:38:26 PM BP: 182/108mm Hg (left arm, sitting, 5:17pm) 5:38:59 PM BP: 158/97mm Hg (right arm, sitting, 5:26PM) 5:40:22 PM O2 Sat: 100% (room air, 5:26PM) 5:39:56 PM P: 73bpm (finger clip, sitting, 5:26PM) Exams: Initial Exam completed by NP at 1713, 1720, 1730, 1740 and 1746. No changes from baseline GENERAL: well developed, well nourished, in no apparent distress;; well developed; well nourished; well groomed; no apparent distress EYES: lids and conjunctiva are normal; pupils and irises are normal; E/N/T: normal external ears and nose;; Hearing: grossly normal Lips, Teeth and Gums: normal; Oropharynx: normal mucosa; NECK: Neck is supple with full range of motion; RESPIRATORY: normal</p>

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respiratory rate and pattern with no distress; even and unlabored, no wheezing; CARDIOVASCULAR: normal PMI placement; no thrills, heaves, or lifts; normal rate and rhythm without murmurs; normal S1 and S2 heart sounds with no S3, S4, rubs, or clicks;; normal rate; regular rhythm; irregular rhythm; Radial pulses +2 CR< 3 seconds BUE; GASTROINTESTINAL: no masses or tenderness; SKIN: no ulcerations, lesions or rashes no skin thickening, induration, or subcutaneous nodules; NEUROLOGIC: AOx3, awake, alert, calm PSYCHIATRIC: mental status: alert and oriented x 3; appropriate affect and demeanor; recent and remote memory are intact; good insight and judgement; Procedures: Encounter for immunizationBenadryl 50 mg tab given PO per, NP at 5:14pm 1. Epinephrine given IM, in the right thigh; administered by: employee; (lot #0GM147; exp. 11/2021) 5:37pmVS were monitored closely by RN and NP during reaction, see chart for RN's VS **Requested RN to chart her VS: see "Post COVID-19 Vaccination Questionnaire for VS completed by employees 1714 Benadryl given PO 1726: VS: Ox 100% on RA RR 16 HR 73 BP 158/97 1731 VS: Ox 98% RA RR 16 HR 84 - patient reports chest tightness is worsening: Ordered IM epi, given by RN 1738 VS:Ox 99% RA RR 16 HR 83 BP 167/114 1742 VS: Ox 100% RA RR 16 HR 89 1746 VS: Ox 100% RA RR 16 HR 80 167/98 Plan: Encounter for immunizationvaccine given per protocol.30 minutes after vaccine, patient c/o chest tightness. PO benadryl and IM epi given per protocol, VS monitored per protocol and documented by RN and NP 1) Protocol followed for anaphylaxis 2) Patient remained stable under care. Patient AOx3, awake, no respiratory distress, talking and smiling. 3) (1537) Informed patient we are calling 911 due to administration of Epi and patient's reported symptoms. Patient refused. Re-educated to the importance of calling 911. Patient refused x 3. 4) Husband presented to drive patient to the emergency room. Re-educated to the importance of calling 911 for anaphylaxis. Patient and husband refused. Husband committed to taking patient straight to Emergency Room, and to call 911 on the way if she gets worse in any way. Patient and husband both agreed to this. 5) Educated patient that she must seek emergent medical attention for anaphylaxis. Educated patient to NOT get second vaccine. 6) (1746) Patient reports her

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1050206	2/23/2021	MD	30	F	1/8/2021	1/11/2021	<p>chest tightness has gone from a 6 to a 2 (0-10 scale) 7) Patient and husband v/o and agrees to POC. 8) (1746) Patient left in stable condition, under the care and supervision of husband with plan to go straight to the Emergency Room and to call 911 immediately if anything changes or worsens. 9) Case and chart reported to Medical Director.</p> <p>I had hives despite having taken my daily dose of Claritin that seemed to get worse as the day continued. I reached out to my Healthcare clinic and they were unsure if there was a simple treatment and almost required me to go the emergency room for this. I conducted a telehealth consultation with a doc who was not my primary care physician and was unfamiliar with my preexisting exercise urticaria condition that occasionally results in light hives but never anaphylaxis for me without Claritin. I declined going to the emergency room since this did not seem that serious and instead took another Claritin to try to get the somewhat worsening hives with no apparent cause to stop without an unnecessarily escalated situation. My throat was slightly itchy but I never became anaphylactic likely due to taking an additional Claritin and not doing anything requiring physical effort for the day beyond telecons from home because I left the office to telework mid morning after I started getting continually slightly worse hives. By evening I was ok and the next day just had a slightly sore throat but was able to work and just started the day with 2 Claritin without any further instance of hives appearing. The day after that I returned to my standard 1 Claritin dose with no ill effects. From this event, it seems clear that a 72 hour downing period from dose 1 is insufficient and should be upped to 96 hours. Prior to this more severe event, I had, on days 2 and 3, a sore left arm at injection site that prevented me from even reasonably lifting my arm to a height sufficient to grab my cell phone off it's charger while lying in bed without serious discomfort. That level of arm discomfort prevented me from working out or would have prevented me from anything other than light office work involving my vaccine arm. My level of tiredness for the couple days following this dose also required that I take an hour long nap days 1 and 2, and no nap at all is usually the norm for me.</p>

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1048846	2/23/2021		26	F	1/26/2021	1/26/2021	Anaphylaxis - tachycardia, palpitations, shortness of breath, skin itching. Received epi pen and ER transport. Now undergoing allergy testing.
1046203	2/22/2021		56	F	1/12/2021	1/12/2021	Pt had a reaction to PFIZER vaccine felt flush and dizzy and fast heart rate, Emergency room was called to transport pt to ED and pt was given a epi pen in observation area where pt received epi pen, pt vitals were BP Right arm: 135/81 HR:117 O2 SAT: 100% on RA 9:18AM 56 y.o. female with a past medical history of hypothyroidism, GERD, anxiety, and Hashimoto's thyroiditis (on levothyroxine) presenting with reported allergic reaction. Patient reports that she had received the COVID vaccine today and 10 minutes later, started to have room-spinning dizziness to the point that she thought she was going to fall out of her chair. She also reports that she started to shake, had shortness to breath, and felt her heart rate increase. Patient had notified staff at the vaccination center and was immediately administered an Epi pen to her left thigh and brought down to the ED. She states that she then started "twitching everywhere" and notes chills as well as a scratchy throat, which are still present. She denies any previous similar symptoms as well as any feelings of anxiety prior to the vaccine or difficulty breathing. She reports an allergy to bees and seasonal allergies, but denies any other known drug allergies. No evidence of anaphylaxis or airway compromise. Discussed rebound potential; feel home observation reasonable. Instructed on antigen avoidance. Patient reports she received the vaccine and epinephrine around 9am. She was observed in the ED for 4 hours post injection without complication. Reports shakiness and tingling after epi has resolved. Patient feels better by 1pm and goes home.

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1047436	2/22/2021	NY	70	F	2/22/2021	2/22/2021	Onset of vaccine: 17:19 Onset of symptoms at 17:25 with tongue tingling to entire tongue Onset of other sx at 17:27: red hands Patient opted to stay in waiting room until hand concern She ambulated without assistance to medical center She was given Benadryl 25 mg po with water, tolerated well at 17:47 VS taken and stable 128/74 RR: 14 Pulse 82 At 18:00, sx of tongue tingling improved, but tinnitus BL worsened - this is common for patient She was discharged to home at 18:07 with her partner Instructed to call PCP in AM, and watch for other developing sx of allergy/anaphylaxis overnight
1047425	2/22/2021	WA	71	F	2/21/2021	2/21/2021	anaphylaxis, Rx w/epi X2
1047147	2/22/2021	PA	84	F	2/8/2021	2/8/2021	Patient developed erythema that started on 2/20/21 just below the vaccine site about 2 weeks after vaccination. There is no respiratory difficulty and it got wider today and a little itchy and red. There are no rashes and no signs of anaphylaxis, no GI symptoms. She also had EMG done on both upper extremities prior to this starting. I advised her to use cold compress and local / topical 1% hydrocortisone on it. To contact us if symptoms worsen and to the ER if any worsening symptoms or respiratory compromise.
1045165	2/22/2021	LA	42	M	1/28/2021	1/29/2021	Severe Anaphylaxis onset at 3:00am. Epinephrine administered at home. Transported to ER. BP 80/40 at admission. 2nd Epinephrine administered at ER. IV fluids. BP recovered and discharged at 7:30am. Prescribed Prednisone 20mg, Famotidine 20mg, and Cetirizine 10mg.

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1045619	2/22/2021	TN	62	F	1/22/2021	1/22/2021	The left side of my face, ear, throat and teeth hurt; The left side of my face, ear, throat and teeth hurt; pain in neck; pain in left shoulder; The shortness of breath lasted over; My lips were tingly; I could feel the end of my nose. My throat was closing/throat closing a little bit; I had pain in my arm; my muscles ached.; The left side of my face, ear, throat and teeth hurt; The left side of my face, ear, throat and teeth hurt; anaphylaxis; allergic reaction to the first dose of the Pfizer COVID 19 vaccine; This is a spontaneous report from a contactable consumer (patient). A 62-year-old female patient received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number: EN5318), via an unspecified route of administration on 22Jan2021 at 10:30 at single dose in left arm for covid-19 immunization. Medical history included drug allergies from an unknown date. There were no concomitant medications. The patient experienced anaphylaxis on an unspecified date in 2021. The patient had a little bit of an allergic reaction to the first dose of the Pfizer COVID 19 vaccine in 2021, it was not severe enough to use an EpiPen. The shortness of breath from 22Jan2021 18:00 lasted over a week. Her lips were tingly from 22Jan2021 14:30, she could feel the end of her nose. Her throat was closing from 22Jan2021 14:30. She had pain in her arm from 22Jan2021 11:00, and her muscles ached from an unspecified date in 2021, the left side of her face, ear, throat and teeth hurt (facial pain from an unspecified date in 2021, ear pain from 22Jan2021 23:00, throat pain from an unspecified date in 2021, tooth pain from 22Jan2021 23:00), pain in left shoulder from 22Jan2021 20:30, pain in neck from 22Jan2021 23:00. She did have to take Benadryl for treatment of shortness of breath. She felt better after 1.5 weeks. The outcome of events anaphylaxis, allergic reaction, muscles ached, Facial pain, Throat pain was unknown, outcome of event pain in arm was resolving, outcome of event tooth pain was resolved on 23Jan2021, outcome of shortness of breath was resolved on 01Feb2021, outcome of other events was resolved on 24Jan2021.

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1044064	2/21/2021	MO	57	F	2/13/2021	2/13/2021	Anaphylaxis - could not swallow, flushed. high blood pressure Little less a hour and symptoms eased and I went home. Refuse ambulance because I just wanted to go home. Still feeling the after effects 8days later. Very nauseous everyday, diarrhea for a few days, sore shoulder and arm off and on, confusion
1044217	2/21/2021	WI	43	F	2/17/2021	2/17/2021	?Moderna COVID-19 Vaccine EUA? Symptoms started at roughly 9:30 AM, 5 minutes after receiving the Moderna Covid vaccine. She first experienced mild throat tightness that has persisted since onset. After about 20 minutes she additionally began to experience perioral numbness. Symptoms were consistent with prior anaphylactic reactions during which she did not develop hives and shortness of breath until 4-5 hours later. Currently she reports vague heaviness with breathing though denies feeling short of breath. Associated symptoms include lightheadedness and fatigue. She denies fevers, chills, recent illness, chest pain, abdominal pain, or hives. She was initially treated with diphenhydramine 25 mg and was observed for a couple hours. Symptoms did not significantly improve and she began to develop nausea so she was given a second dose of diphenhydramine and 1 L LR bolus. Roughly 45 minutes later she continued to be anxious and began to report mild chest pain and abdominal pain. She was given Epinephrine 0.3 mg and prednisone 60 mg at that time given concern for developing anaphylaxis. Symptoms did not progress further over the next 2 hours of observation in the ED. Discussed with the patient that symptoms were likely not a result of anaphylaxis and she was comfortable with discharge at this time.
1044630	2/21/2021	IL	27	F	1/28/2021	2/8/2021	Angioedema, anaphylaxis, rash, hives, joint pain & swelling
1044493	2/21/2021	CT	32	M	2/21/2021	2/21/2021	1-2 minutes post vaccine (given in left deltoid) patient developed bilateral tinnitus. No associated headache, dizziness, nausea, chest pain, abdominal or shortness of breath. No other focal neurological motor/sensory deficit. No signs or symptoms of anaphylaxis (no airway compromise). Tinnitus remained consistent over next 1 1/2 hours of observation (until discharge home). Patient reports 1-2 prior mild episodes of tinnitus, none as severe or prolonged as today.

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1044354	2/21/2021	IL	48	F	2/19/2021	2/19/2021	I was observed for 15 minutes and then shuttled back to vehicle. Approximately 30+ minutes after shot, I started to feel something weird in my throat area. I decided to go through a drive through to get a bite to eat and something to drink. While waiting in line, I could tell it was becoming more difficult to swallow. Was hoping the drink would help. I tried to take a bite of the chicken nugget, but about choked and had to spit it out. I live approximately an hour from where the vaccination was administered and my goal was to just head home. While driving on Road, I was talking with a friend. I told my friend what I was experiencing in my throat area and that I needed to hang up to concentrate on what was going on. I unbuckled my seat belt and pulled by coat and sweater out from throat area, wondering if they were compressing on it. That did not help and I could tell something was just not right. I was having a hard time swallowing. I then googled possible side effects from the COVID vaccination and that is when I read about anaphylaxis reactions. I was torn on what to do since by this time I was approximately 30 minutes from the testing site and just wanted to get closer to home. There really were no medical facilities along my route home. My friend called back to check on me. Explained the situation and my friend suggested I stop at a gas station to get Benadryl. I then drove to Town and took a 2 Benadryl tablets. I also knew this town had a fire department and ambulance service in case things started to turn South. I sat in my car for about 20 minutes to assess the situation. I finally felt like I could make it the rest of the way home. I had already put my family on notice in case things got worse. By the time I made it to Town, my swallowing was less difficult. My nurse friend recommended I continue to take Benadryl every 6 hours for 24 hours and then to take a Claritin. That is what I did. I did not report this to my PCP, but in hindsight... I probably should have. It was quite alarming and truly a very scary feeling to experience this, especially while driving. It kind of still feels like there is a lump in the back of my throat when I swallow, but that is something I can deal with.

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1044161	2/21/2021	WI	42	F	2/16/2021	2/16/2021	Moderna COVID-19 Vaccine EUA Pt presented to the emergency department with pruritis and redness appearing throughout arms, chest, and face 10 minutes after receiving the first dose of Moderna covid vaccine. ED assessment: Denies dizziness, shortness of breath, nausea, vomiting, diarrhea. Calm and hemodynamically stable. Erythematous rash throughout BUE, chest, and face. No hives seen, Not in anaphylaxis. Received diphenhydramine 50 mg prior to arrival and dexamethasone 10 mg in the ED. Patient improved clinically throughout ED course was discharged home in stable condition.
1044303	2/21/2021	NM	59	F	2/19/2021	2/19/2021	Anaphylaxis reaction. Shot given around 9am. Around 11am symptoms appeared: extremely hot/flushed, nauseated, felt ill, difficulty swallowing. Went to pharmacist who had me sit down, within 30 seconds could not swallow. Pharmacist injected me with Epi Pen and called 911. Paramedics arrived gave more epinephrine, oxygen, started breathing treatment. Lost my voice as throat started to tighten more. Taken to Hospital where I was given Benadryl, steroids, stomach meds, more fluids and another breathing treatment since my lungs were so tight, I could only take shallow breaths. The crated my lungs, did blood work and kept me overnight for observation because I have a history of secondary reactions when I experience anaphylaxis. I was released from the hospital on 2/20/2021 at 2pm.

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1043056	2/20/2021	NY	77	F	2/20/2021	2/20/2021	3-5 mins post 1st dose vaccination on the left arm, patient began having a "funny taste" sensation on her mouth, tongue, and throat. She had dry mouth and numbness in her upper and lower left lip. She was brought over for observation. Vitals were within normal limit. Neurologic exam was normal. She was given Benardryl 25mg one tab and post administration, the "funny taste" sensation in her mouth resolved but the numbness in her her lips remained for another 20 mins. She reported feeling anxious since she had several deaths in the family within one month. She also admitted to feeling a funny taste in her mouth after getting shots. She denies any chest pain, SOB, wheezing, dizziness or nausea. She declined medical transportation to the ER. She was monitored for over an hour. She was advised to follow up with the ER if worsening symptoms of anaphylaxis. She was informed to follow up with her PCP or allergist for further evaluation prior to having her second dose.
1043427	2/20/2021		62	F	2/20/2021	2/20/2021	Pt assessed after receiving COVID-19 vaccination drive thru site. She reported onset of mild lightheadedness and a non-specific "funny feeling" in her head. No vertigo or presyncope. No other new neurologic changes such as vision changes or extremity weakness. No chest pain, palpitations, dyspnea. No other signs of allergic/anaphylaxis (ie rash, throat swelling, GI side-effects). She reports hx of high blood pressure and is on one BP medication but cannot recall the name. States she took it today. Reports eating breakfast this morning. Exam notable for BP 140/85, HR 60. Pt well-appearing, no acute distress, no obvious CNS or peripheral deficits. RRR, normal s1/s2, no m/r/g. Lungs CTAB. No obvious rash or facial swelling. During course of evaluation pt reported symptoms improved but did not quite resolve. Advised pt to continue monitoring at vaccination site for additional 15 minutes. Offered juice, crackers, fluids which she declined though did drink some of her own water. Upon reassessment pt reported continued improvement though symptoms had not completely resolved. Offered to have EMS come assess pt though she declined. Warning signs/symptoms discussed with pt for when to seek out care at ED. She is in agreement.

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1043814	2/20/2021	KY	81	M	2/20/2021	2/20/2021	Anaphylaxis symptoms began approximately 6-7minutes post vaccination with patient having difficulty breathing, palor, lethargy, sweating, and stating throat was closing/tightening-patient immediately given epi and ems called...patients symptoms improved significantly in about 2 minutes post epi and ems arrived within 11 minutes and took over patients care..patient transported to local ER per EMS for further evaluation and treatment
1043867	2/20/2021		52	F	2/18/2021	2/18/2021	It was her 2nd dose, and she said her throat was itchy and she was having a difficult time swallowing. No nausea or vomitting, no cough or hives or redness at the site. Just subjective stated she had a hard time breathing and swallowing. When asked for history of anxiety she did say yes. This happened maybe after 20-25 minutes of receiving the vaccine. While on the phone with EMT, we informed them we would use an epipen and they were aware. Once they arrived, they found no signs of anaphylaxis but still took her to the emergency room.
1043888	2/20/2021	NY	45	F	2/19/2021	2/19/2021	While sitting in the waiting area I began to feel itchy. it was around 7:50am. I quickly took 2 chewable (12.5mg each) benadryl tablets. after about 5 min. i felt stable enough to leave. on the way home I started to feel the itching intensify and I felt very warm. I had welts forming and hives appeared all over. As I pulled into my driveway(7 min drive from vaccination site) I felt my lips and eyelids swell, and my throat felt tingly. I took another 2 chewable benadryls. (12.5mg each). I immediately called my Doctor and explained what was going on. I also started to wheeze. I used my inhaler. He told me to use my epipen. Which I already had prepared since I knew this was anaphylaxis. I started to feel stable enough to go inside. I called my husband to come downstairs to be with me. I still wasnt feeling well and the tightness and wheezing persisted. At around 8:40, My dr. told me to use the 2nd Epipen and use my nebulaizer. If I wasn't better in 10 minutes he would call an ambulance. Thank GD the itching and hives subsided and the wheezing and tightness diminished by around 8:50am. My dr. continued to monitor me and check up on me. By 3pm I was back to myself.

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1042970	2/20/2021	NC	65	M	2/4/2021	2/16/2021	Anaphylaxis, hives, whips around waist and butt, itching ,swollen lips . Was given epic Pen and Benadryl , Pepsi?s and steroids 24 hours and it returned when to doctors office and received another steroid shot
1040856	2/19/2021		48	F			Anaphylaxis
1041463	2/19/2021	IA	50	F	2/17/2021	2/17/2021	Patient with past medical history significant for anaphylaxis 2 months ago to iron infusion, received PCP clearance to receive COVID-19 vaccine. Patient given Pfizer vaccine # 1 (lot # EN6201). Approximately 12 minutes into 30 minute wait she began to report that she had a "sore/scratchy" throat and took Benadryl 50 mg PO (patients own supply). Patient took medication on her own and was given permission to take by NP. Patient was assessed by NP with breath sounds CTAB, no wheezing or stridor. No visible swelling of the lips, tongue or face. No rash. VS: B/P 124/73, HR 110, SaO2 100% on RA. During assessment she began to clear her throat and therefore was taken to Facility for further evaluation and monitoring. At Facility, pt was monitored for about 30 minutes. Pt admitted to be anxious about the vaccine. Pt received no medications from Facility. Pt instructed to use diphenhydramine Q6-8 hrs PRN. Pt was discharged to home.

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1041317	2/19/2021	KS	38	F	2/19/2021	2/19/2021	<p>COVID VACCINE CLINIC Subjective Patient is a 38 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She was given the Pfizer vaccination in the left deltoid muscle. During her 30 min waiting period after the injection, the patient began to experience throat tightness and wheezy. She denied sob, cp, facial swelling, tongue swelling. She reports of above symptoms about 20 minutes after receiving vaccine. This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including but not limited to abdominal pain, blood pressure abnormality , chest pain, drooling, hypotension, increased swelling, rapid progression of symptoms, respiratory distress, skin changes, tongue swelling and vomiting . PMH: Previous Reactions: allergies including anaphylaxis to shellfish, peanut oil and sulfa drugs. Reaction of arm swelling to location of shot and wheezy when she got the flu shot 7 years ago. Asthma hx. She had taken Singulair, cetirizine and albuterol prior to coming. She did not take any benadryl prior to her injection as pt reports that her sister whom is a nurse told her not to take benadryl in case it masks a reaction. ALLERGY REVIEW OF SYSTEMS: Patient complains of frequent throat clearing (slightly upon arrival. with throat itching) and wheezing Patient denies chills, fever, malaise/fatigue, facial swelling, itching in ears, sore throat, eyes watering, eyes itching, puffy eyes, eye redness, cough, chest tightness, shortness of breath, rash, hives, eczema, cysts, itching of skin, vomiting, abdominal pain, diarrhea, muscle aches, joint pain, dizziness and headaches Objective Vitals</p> <p>Vitals: 02/19/21 0933 02/19/21 0944 02/19/21 0952 02/19/21 1002 BP: (!) 143/83 134/81 126/80 123/70 Pulse: SpO2: 100% 100% 100% Physical</p> <p>Exam Constitutional: General: She is not in acute distress. Appearance: Normal appearance. She is not ill-appearing, toxic-appearing or diaphoretic. Comments: No facial or lip swelling HENT: Mouth/Throat: Lips: Pink. Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Uvula midline. No pharyngeal swelling, oropharyngeal exudate, posterior oropharyngeal erythema or uvula swelling. Eyes: General: Lids are normal. Extraocular Movements: Extraocular movements</p>

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							<p>intact. Conjunctiva/sclera: Conjunctivae normal. Neck: Trachea: Trachea and phonation normal. Cardiovascular: Rate and Rhythm: Regular rhythm. Tachycardia present. Pulses: Normal pulses. Heart sounds: Normal heart sounds. Comments: Slightly tachycardia (103) Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds and air entry. No stridor, decreased air movement or transmitted upper airway sounds. No decreased breath sounds, wheezing, rhonchi or rales. Comments: Speaking full sentences. Musculoskeletal: Cervical back: Full passive range of motion without pain. Skin: General: Skin is warm. Findings: No rash. Comments: Injection site w/o erythema or swelling. No adhesive reactions Neurological: General: No focal deficit present. Mental Status: She is alert. Psychiatric: Mood and Affect: Mood is anxious (slightly). Thought Content: Thought content normal. Judgment: Judgment normal. Re- evaluation of lung sounds and throat was done periodically about every 5-10 minutes. No acute findings seen/heard. Assessment/Plan Treatment included: albuterol, antihistamines, water and solu-medrol IM and pepcid, albuterol (pt used her own). Follow up response to treatment: excellent. Scale of 0-10 based on symptoms of tightness was 7 at first. Upon discharge was 3-4/10. Patient discharge: Stable to go home and follow up with PCP and her allergist. Differential Diagnosis: Anaphylaxis/anxiety (dyspnea, stridor, drooling, tongue swelling) We discussed close monitoring at home and when/if she were to take her epi-pen and call 911 if symptoms were to worsen. She's to let her allergist know about her visit today. She may need to have other medications taken prior to her #2 dose of Pfizer according to her allergist recommendations. Pt appreciative and is ready to go home. Pt wheeled out to front door by security. Accompanied by husband.</p>
1040978	2/19/2021	AL	57	M	2/9/2021	2/18/2021	Anaphylaxis reaction manifesting as hives; most pronounced on both hands and both elbows. I have taken 50 mg of OTC diphenhydramine HCl, and 180 mg of fexofenadine hydrochloride which has lessened the severe itching
1040946	2/19/2021	CT	69	F	2/16/2021	2/16/2021	Mild anaphylaxis

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1040720	2/19/2021	MA	58	F	2/18/2021	2/18/2021	Very swollen eyes, nasal congestion, itchy back, anus, inner ears. Treated with 1 over the counter benedryl. Went to the ER, treated with another benedryl and pepsid. Discharged with an epipen. I have a history of exercise induced anaphylaxis
1040849	2/19/2021		41	F			Anaphylaxis
1040833	2/19/2021		30	F	2/1/2021	2/1/2021	Anaphylaxis
1040826	2/19/2021		54	F	2/1/2021	2/1/2021	Anaphylaxis
1040613	2/19/2021	CA	30	F	1/26/2021	1/26/2021	She is a nurse and received her vaccine outside at the Vaccine Site. She had an immediate reaction to her first dose of the Pfizer Covid vaccine with acute hives within 15 minutes on 12/26. She had hives on her neck, arms chest, headache arm pain and mild dizziness. Symptoms resolved with Benadryl She received her second dose of the Covid vaccine 12/26 with immediate symptoms within 30 minutes of respiratory symptoms, shortness of breath, hives, dizziness, fainting with treatment of epinephrine on site at the Vaccine Site by ambulance to the ER. She reports she was hypoxic with O2 sat 70 to 75%. Went to hospital and received 3 doses of epinephrine, IV Benadryl, IV fluids, Pepcid, and 7 days of prednisone. 1/26: c/o chest tightness had video visit with primarily MD, continued diphenhydramine and refer to allergy. She does have a history of vaccine reaction in the past to Gardasiln (contains polysorbate 80) given at age 16 with delayed hives 24 hours later. Allergist assessment: Covid vaccine 19 mRNA anaphylaxis with 2nd dose and acute hives with 1st dose of Pfizer vaccine S/p repeated doses of epipen With ongoing asthma, dizziness, light headed , nausea and fast heart rate 1.5 weeks after anaphylaxis but normotensive With prior history of delayed hives with gardasil --may be sensitive to polysorbate 80 in both vaccines. Added COVID vaccine to allergy list
1040967	2/19/2021	MI	31	F	2/18/2021	2/18/2021	31 YEAR OLD MALE COMPLAINED THAT HE WAS EXTREMELY HOT. HE WAS SWEATY AND HE SAID HE WAS FATIGUED. ON SITE EMS RESPONDED. NO SIGN OF ANAPHYLAXIS HIS VITAL LISTED BELOW. HE REFUSED ADDITIONAL EVALUATION OR CARE.

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1040536	2/19/2021			F			<p>slight anaphylaxis reaction; difficulty swallowing; swelling at the injection; A spontaneous report was received from a consumer concerning a female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced slight anaphylaxis, difficulty swallowing and swelling at the injection. The patient's medical history was not provided. No relevant concomitant medications were reported. On an unknown date patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. Patient called to inquire about the second dose. She stated she had a slight anaphylaxis reaction. When quired for more details regarding her event she mentioned that it was sort of difficulty swallowing, which didn't last long and some swelling at the injection. No treatment information was provided. Action taken with RNA-1273 in response to the event was unknown. The event difficulty in swallowing was considered as resolved. The outcome of the event slight anaphylaxis and swelling at the injection was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the events, a causal relationship cannot be excluded.</p>

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1042698	2/19/2021	CT	31	F	2/3/2021	2/13/2021	<p>-Initially I had moderate side effects to my 2nd shot, shortness of breath/increase of asthma symptoms, severe joint pain, flu-like symptoms (slight fever, chills, loss of appetite, inability to sleep) lasting for a total of 4 days. I have anaphylaxis to Walnuts (2x needed epipen and hospitalization) and asthma, many seasonal allergies, and am highly biologically sensitive (have broken out in hives several times), -8 days later I traveled to a high altitude location (Aspen, CO), and had 4 glasses of wine over a 8 hour period. For the next two days I skied for 5 hours, going up to 12,500 ft in altitude. On the first morning after arrival I started feeling badly, with symptoms including dizziness, asthma symptoms (unusual for me as it is only exercise-induced), a headache in the front of my head, and a slight redness in my left eye. As the days increase my symptoms increased to the point of inability to leave the house. After 3 days I received an IV, oxygen, that did not help. On day 4 I went to the hospital after a virtual appointment with a clinician and had chest xrays taken as Hospital (never received the results) and was put on Diamox 250MG 2x/day, this helped slightly. Day 6 I left and traveled back to CT at low altitude, my symptoms did not improve immediately and got worse (eyes became significantly more red by this point), asthma and dizziness increased). Two days after arriving home I went to two doctors who misdiagnosed me with a sinus infection, water in my middle left ear and left lung, and conjunctivitis. I was given antibiotic eyedrops that had no improvement for 36 hours. Upon receiving a 1mg cortisone shot these symptoms improved, I was also given 500MG of a Z-pack type antibiotic 1x day/4 days. I went to my PCP, doctor who was able to accurately diagnose my symptoms as an immune response to being unable to acclimatize due to my moderate immune response to the 2nd shot. My body went through significant inflammation. He treated me with Prednisone and continued my antibiotic.</p>

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1038324	2/18/2021	NV	18	F	2/17/2021	2/17/2021	Patient received vaccine around 430pm. As she was sitting for post-vaccine observation she told an associate to call over Rph due to side effects. After speaking with patient she stated that her arm was numb (vaccinated arm) and that it hurt more than when she got her flu shot. I assessed both arms an her vaccinated arm was slightly swollen. I described the signs of anaphylaxis to her and told her that i would like for her to stay longer for extra monitoring and to alarm me or one of my associates if any anaphylaxis symptoms occur. Patients blood pressure was taken reading - 132/96. Patient was unsure of her baseline so i explained i will check again shortly. Patient was given water and one dose of Benadryl (25mg) at 5:25pm as well as an ice pack to place on her arm. At 6:00pm patients blood pressure was retaken (124/82) and patient stated she was well enough to go home. Her grandma was with her and stated she didn't have Benadryl at home, I recommend her to get some and gave the patient another dose (25mg) before her grandma took her home. Patient has no primary care physician.
1038385	2/18/2021	MT	46	M	1/20/2021	1/22/2021	Pt. reports that 2-3 days after receiving COVID shot #1, he developed a rash on his arms. legs, and torso. Rash was "red and itchy". Denies any swelling of throat or anaphylaxis. Self-treated the rash with OTC topical hydrocortisone cream/ointment. Rash resolved within a couple of weeks. Some evidence of rash remains on chest.

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1038576	2/18/2021	WI	84	F	1/27/2021	2/4/2021	On 02/04/2021 client calls to report "red, slightly raised, warm to touch. round, size of a grapefruit" area to injection site (left deltoid). Client denies and symptoms of anaphylaxis and or pain or drainage to area. Writer advised client to apply cold compresses to area, monitor her temperature for fever, and to monitor the area for increased redness or swelling and seek medical treatment if symptoms worsen. Follow-up call made to client on 02/05/2021. Client states that the condition of the injection site remains unchanged despite the use of intermittent cold compresses. Client continues to deny pain or drainage in area. Writer advised client to mark edges of redness and monitor for spreading of redness beyond markings, continue to monitor temperature for fever, continue to apply intermittent cold compresses to the area and wash the area two times daily with a liquid antibacterial soap. Client advised to seek medical treatment if redness spreads or fever develops. Client verbalized understanding of recommendations. Follow up call made to client on 02/08/2021. Client states that area of redness has "faded" and is "half the size" that it was previously. Client states that the area began to resolve after approximately two days of intermittent application of cold compresses. Client also stated that there was some mild itching to the area on 02/06/2021, but that this symptom has completely resolved.
1038771	2/18/2021	CT	43	F	2/13/2021	2/13/2021	Dose #2 pfizer; Pt reported onset of chest pain and SOB within 5 min of vaccine. Followed by nausea, vomiting, and feeling of swelling of lips, . Pt used her own albuterol, 2 puffs. RRT called. BP 166/99, HR 90, pulse ox 100, airway intact, lungs clear, cardio tachy but regular, skin warm and dry with no diaphoresis. Concern for anaphylaxis as pt symptoms continued and some increase in disorientation Epi Pen administered, O2 via NC. IV access attempted but unable to obtain. EMS called. Pt monitored with resolution of CP, SOB, nausea, lips swelling and disorientation. Pt continued to have feelings of swelling of tongue and transported to ED
1039051	2/18/2021	PA	84	F	2/11/2021	2/11/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe

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1040066	2/18/2021	CA	54	F	2/17/2021	2/17/2021	Called to COVID -19 post vaccination observation area to see this patient. Received 1st vaccination of COVID 19 Moderna vaccine (lot 024M20A, exp 8/3/2021) at approximately 10a Was in observation area for 30 minutes (due to prior hx of anaphylaxis with immunotherapy shots as teenager). Pt initially felt well, until approximately 30 minutes after the vaccination, when she started to have sensation of constriction in chest, feeling of heart beating quickly, and mild lightheadedness. Pt awake and alert and appropriately responsive. Denied any itching, rash, sob, throat discomfort or swelling or facial swelling. No rash or redness noted at vaccination site. Pt transferred to clinical reclining chair via wheelchair, with assistance, in private area. VS normal with HR 71 and BP 136/79 Sat 97%, normal respiratory effort, speaking in full sentences. Given po apple juice. Pt with persistent feeling of chest constriction, feeling face slightly flushed/warm (no rash, no visible erythema or flushing). Hx of coronary vasospasm with hx of elevated troponin 4 yrs ago post surgery, cardiac cath 2 yrs ago due to intermittent chest pain. Coronary vasospasm noted on cath per pt, current meds are diltiazem, ASA 81, a statin, and nitroglycerin prn. Last episode of chest pain was approx one year ago. Repeat VS HR 73 BP 130/89 Sat 99% on RA, awake and alert and appropriate 911 called due to chest discomfort with hx of coronary vasospasm in past. Paramedics given report including pt's medical history as above. Paramedics arrived at approximately 10:45a and evaluated patient: ECG done, normal per paramedics. Under their observation CP improved, slight flushing sensation improved, pt feeling better without intervention, no evidence of anaphylaxis. Per paramedics pt offered ambulance transfer by EMS, declined. Per paramedics/EMS, no indications for transfer to ED as ECG normal and pt feeling much better without intervention. Per their evaluation pt can be allowed to go home. They state that they have seen this often in patients post vaccination. When asked, they state that this is not an indication of severe reaction, and there is no contraindication to second vaccine. They discussed this with patient. Pt observed for an additional 20 minutes. 11:15a pt feeling very well, no chest pain or flushing or itching. Ambulating without difficulty. Pt left at 11:19a feeling well.

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1037022	2/17/2021	CA	65	F	2/17/2021	2/17/2021	S/p vaccination at 1110 at 1120 c/o dizziness , hx of acute anaphylaxis, able to walk to stretcher with use of cane. Responses verbally . Vitals signs abnormal to patient: @1135 137/68 HR 83 spO2 99%, @1140 BP 137/68 HR 80 spO2 98%, @1145 pt remains c/o dizziness. pt verbalized she was 'anxious' because her doctor wanted her to get the vaccine. BP increased slightly 160/79 HR 85 spO2 99%. @1149 RRT was called. Vitals taken @ 1150 BP 157/79 HR 81 spO2 99% . RRT arrived at 1155. Pt able to stand but was slightly unbalanced and was safely transferred to wheelchair and was transported to ED by RRT.
1037040	2/17/2021	CT	39	F	12/22/2020	1/12/2021	Anaphylaxis: After my second dose of the vaccine within 3-5 minutes I started feeling swelling of the thong, itchy throat, head, neck, sob. I immediately reported my symptoms to the MD that was in the room monitoring the recent vaccinated employees. Immediately he administered 50mg of Benadryl, 20mg of Pepcid, and salbutamol. I was rushed to the ED and stayed there for couple of hours headed back to my unit and then sent home by my manager.

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1035514	2/17/2021			U			<p>feelings of fainting; high blood pressure in the 160s, normally <120s systolic); severe headaches; dizziness; This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received first dose of BNT162B2 (Lot number and expiry date not provided), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history concomitant medications were not reported. On an unspecified date, the patient developed severe headaches, dizziness, high blood pressure (in the 160s, normally <120s systolic), and feelings of fainting 5-10 minutes after receiving the first dose of the vaccine. This adverse event was reported already, but the pharmacist was wondering if it is still recommended to get the second dose after a reaction like this. Stated "This reaction doesn't meet your definition of anaphylaxis or allergic reaction which is why I am reaching out to see if you have any recommendations on this". The patient underwent lab tests and procedures which included blood pressure: high blood pressure (in the 160s, normally <120s systolic). The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.</p>

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1036980	2/17/2021	AZ	61	F	2/16/2021	2/16/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Additional Details: 5 minutes after taking the vaccine pt stated that she felt dizzy and lightheaded. After about 10minutes later she started grabbing her throat indicating she cannot breath. we gave her 2 epipens 5 minutes after the 1st dose and called the ambulance
1036978	2/17/2021	CT	33	F	2/17/2021	2/17/2021	Pt developed an anaphylaxis reaction to vaccine with resultant "throat tightening" and voice changes. Epi administered. EMS was alerted and patient was transported to the hospital. Of note, prior to leaving she received benadryl.

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1036561	2/17/2021	CT	39	F	1/6/2021	1/6/2021	Pt has h/o HTN (not on medication) and occasional asthma(no hospitalizations), and allergies to Penicillin (tongue swelling), tree nuts (throat swelling), and Bees (local swelling); Pt notes she only takes benadryl for these reactions; she has never been prescribed or used epinephrine. Pt denies heart disease, strokes, diabetes, increased bleeding tendency. No early heart disease in family. LMP in the last week. Pt notes she was supposed to see allergist in past, but has not. Pt was feeling well this morning before she came to COVID vaccine clinic. Pt had received first Moderna Vaccine shortly before 0918am here. At 0938 Pt noted feeling "heaviness" in head and "lump in throat." Pt denied itching/swelling to mouth, itching/hives to body, dyspnea, chest pain, nausea. No lightheadedness/dizziness. Pt walked to stretcher. BP at right forearm was 223/151 and then 221/132 on repeat. Heartrate in 90s. Sao2 on RA 100%. RR 18. Pt notes having high BPs at times, but not often as high here. Pt speaking is slightly hoarse voice. No strider. Pt speaking in full sentences. No oropharyngeal edema. No urticaria. No tachypnea or wheeze. HRT RRR. 2+ left rad pulse. A/P: given Pt's h/o severe allergies and now new Globus sensation and change to voice I discussed with Pt that she was likely having allergic reaction. Given involvement of airway I recommended epi administration to neutralize reaction and transfer to ED for observation. I advised Pt that epi would increase heartrate and blood pressure. I determined benefit of treating anaphylaxis outweighed risk of elevating BP, even though she has hypertensive urgency BP values. Pt has some headache; she could be bordering on hypertensive emergency. I asked pharmacist to call 911 indicating early anaphylaxis and request of paramedic. ~5 minutes after Epi (given at 0942) Pt notes lump sensation and voice improved. I had RN place IV to left AC and gave verbal order for benadryl 25mg IV. Pt notes some nausea and dizziness. Lump sensation continues to improve. EMS arrived ~0950. I gave report to paramedic. I discussed with Pt that I would place referral to Allergy and Immunology; they will determine if and when Pt could receive second moderna vaccine.
1036106	2/17/2021	MO	50	M	2/9/2021	2/10/2021	anaphylaxis, epi pen, resolution

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1036031	2/17/2021	ME		F	1/27/2021	1/27/2021	Anaphylaxis; A spontaneous report was received from a consumer concerning a 61-year-old female patient who experienced anaphylaxis and Anaphylactic reaction. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 27 Jan 2021, 3 minutes prior to onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number 030L20A) intramuscularly (arm location not provided) for prophylaxis of COVID-19 infection. On 27 Jan 2021, within 3 minutes, the patient was hospitalized for anaphylaxis. The patient reported she had never before experienced this type of reaction. Treatment information was not provided. Action taken with mRNA-1273 in response to the event was not provided. The outcome of the event was unknown.; Reporter's Comments: This spontaneous report concerns a 61-year-old female patient who experienced anaphylactic reaction. The event occurred on the same day, 3 minutes after the administration of mRNA-1273 vaccine (Lot number: 030L20A, expiration date: unknown). Treatment administered was not provided and outcome is unknown. Based on the information provided which shows a temporal association a causal association, between the reported events and the administration of mRNA-1273 vaccine cannot be excluded.
1035595	2/17/2021	FL	72	F	2/16/2021	2/16/2021	SEVERE muscle pain, burning sensation in chest cavity and esophagus, slight fever (1 degree), fatigue, headache. These were the most severe manifestations I have ever experienced. Since I have previously had anaphylaxis, I am more worried about the reactions. I was not able to sleep at all due to the strong pain. I do feel better this morning, but nowhere near ok.
1037008	2/17/2021	PA	58	F	2/16/2021	2/16/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Severe, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Severe
1035829	2/17/2021	OH	53	F	2/17/2021	2/17/2021	patient reports shaking and feeling like she can't breathe (more like panic attack not anaphylaxis)

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1035700	2/17/2021	MA	48	F	2/16/2021	2/16/2021	Patient received Moderna COVID vaccine @ 8:23 AM. Around 08:26 pt complained of a "tingling" tongue. She then c/o anxiety & dizziness. She then c/o a "swollen tongue", dyspnea, SOB, pruritus in her LE, & began breathing in the tripod position. At 08:35 the pt's BP was 127/83, HR was 114, & oxygen saturation was 99 %. A ED proceed out was called who came and administered diphenhydramine 50 mg IM and admitted her to the ED. Upon exam, patient was positive for shortness of breath, itching and rash (initial exam in the vaccine clinic no rashes seen. In the emergency department and she had a patch of erythema on her right dorsal forearm approximately 5 cm x 7 cm not raised no signs of urticaria), tachycardia and abdominal tenderness. ED MD assessment: Overall assessment was reaction to COVID vaccine, without anaphylaxis.
1034612	2/17/2021	HI	38	M	2/16/2021	2/16/2021	Patient with history of oral allergy syndrome presenting to COVID vaccine medical after throat tinging 15 min after 2nd Pfizer vaccine. No objective signs of anaphylaxis. Patient was given 25mg of PO Benadryl at 1040 and monitored for 1 hour, with normal vital signs throughout and improved symptoms. Patient released and counseled on red flags symptoms that would warrant evaluation in the Emergency Room
1033917	2/16/2021	GA	72	F	2/16/2021	2/16/2021	Covid vaccine, Moderna, given in right deltoid. Immediate swelling and redness at site of injection. Benadryl 25 mg. given by mouth with no further swelling, no signs of anaphylaxis. Monitored patient x 30 minutes whereupon patient states feeling

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1033541	2/16/2021	NY	58	F	2/16/2021	2/16/2021	Pt reported feeling symptoms approx 10 minutes after receiving injection. She complained of mild shortness of breath and "itchy throat." She was questioned about having any other symptoms and immediately escorted to the medical attention tent. She was seated, and EMS began evaluation; her vital signs were taken: RR 22, HR 82, BP 156/102, PULSE OX 98%. She then reported an increase in symptoms, as face itching, increased tightness in her throat. Objective symptoms observed by myself and EMS: cough/clearing of the throat, increased SOB/labored breathing, facial erythema, hoarseness. EMS asked for her consent to give her Benadryl and Epinephrine. She repeatedly refused this, and refused any attempt at IV placement. She eventually agreed to IM Benadryl, of which 50mg were administered by EMS. Both EMS and I suggested more than once that she allow us to transfer her to the hospital for further management and preparation in the event that she needs further care. I explained that she was having symptoms of anaphylaxis. She repeatedly refused transfer. She reported a decrease in symptoms, saying she felt well enough to go home. Her objective symptoms observed by myself: continued hoarseness and clearing of the throat. VS were repeated: RR 18, HR 68, BP 160/98, PULSE OX 99%. Airway remained patent and clear. Patient again requested to leave, and agreed to EMS escorting her to her car.
1033484	2/16/2021	OR	62	F	2/15/2021	2/15/2021	Anaphylaxis. Used epiPen, taken to ER. Given solumedrol 125 mg, bendadryl, 25 mg IV monitored 4hours. Sent home with solumedrol dose packet and new epipen
1033454	2/16/2021	MI	71	F	2/12/2021	2/12/2021	~~Pt began complaining of dizziness approximately 15 minutes following her COVID-19 vaccination while she was waiting in the waiting room for the recommended 30 minutes post-immunization due to having anaphylaxis to other allergens. Pt was brought back to an exam room and 50 mg IM Benadryl was administered by RN. Following this, patient claimed to begin feeling better within 5 minutes and denied any further symptoms. Patient refused EMS or additional care because she had a scheduled Dr appointment with at 1:40PM that day.~~

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1033234	2/16/2021	VA	30	M	2/16/2021	2/16/2021	Patient was administered the 2nd dose of the vaccine series, previously no reaction to the first dose. Upon standing up, the patient experienced syncope and was caught by the administering pharmacist. Administering pharmacist called for help from the other pharmacists and 911 was called. The patient was set to the ground and administered epinephrine in case of anaphylaxis. The patient was monitored for 3 minutes at which point he seemed to start aspirating. He was then rolled to his side for prevention. Approximately 5 minutes later, the patient came to as EMS arrived on scene.
1033146	2/16/2021	MN	75	F	2/15/2021	2/15/2021	Pt was instructed to wait 30 minutes for observation following vaccination due to history of allergic reaction and anaphylaxis. About 33 minutes following injection, pt began feeling tightness and scratching of the throat and feeling the need to cough/clear throat frequently. Pt refused Epi-pen administration, but accepted Benadryl 50mg orally. EMS was called. Pt refused transport via ambulance but drove self to the ED for eval/monitoring.
1034322	2/16/2021	CA	73	F	2/4/2021	2/10/2021	Patient received first dose of Moderna Vaccine, experienced localized redness and swelling at injection site. One week post first vaccine, patient developed lower extremity petechia and rash consistent with cutaneous small vessel vasculitis. Describes itching associated with rash. Did not develop throat swell, shortness of breath, or other signs of anaphylaxis.

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1030029	2/15/2021			U			<p>One case of anaphylaxis, after an individual received Moderna's vaccine; A spontaneous report was received from other manufacturer Pfizer concerning a patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced one case of anaphylaxis, after an individual received Moderna's vaccine. The patient's medical history was not provided. No relevant concomitant medications were reported. On an undisclosed date, the patient received their dose of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. Other manufacturer forwarded article posted via social media regarding COVID-19 vaccines. The article contained a brief statement from the Center for Disease Control (CDC) that stated, 'they also noted one case of anaphylaxis, which can cause throat swelling and breathing difficulty, after individual received Moderna's vaccine'. No further information was provided regarding Moderna's COVID-19 Vaccine (mRNA-1273). No treatment information was provided. Action taken with RNA-1273 in response to the event was unknown. The outcome of the event was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset of the event, a causal relationship cannot be excluded.</p>

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1030969	2/15/2021		37	F	1/13/2021	1/13/2021	Pt has 2nd dose of Pfizer vaccine today at approx 1037 and at within 5 min experienced nausea, palpitations and a metallic taste similiar to copper pennies. She had breakfast at 0900 and had taken oral SL Zofran at 0930 due to previous reaction to the first vaccine where she had nausea, vomited x 3 metallic taste and had to go home from work. 1055 had vomiting x 2 at present sitting in chair with legs elevated all VSS will list below. 1105 Spoke with Doctor and pt states she wants to go home. He said to offer her a Tryptase test to confirm a diagnosis of anaphylaxis. The Lab was called and the tests results take 5 to 7 days it is sent out to Lab. Informed pt of the offer for testing and the time frame. 1117 Vomited for the third time and VSS are stable in recliner chair. 1125 Doctor informed pt wishes to go and sleep she is now starting to get a headache. She also does not wish to pursue the Tryptase test which she would have to go the urgent care to be seen and ordered. Pt has a co-worker to drive her home and declines to go to Urgent care. She was instructed to return if her symptoms worsen.
1032326	2/15/2021	MN	22	F	2/14/2021	2/14/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Medium, Systemic: Allergic: Swelling of Face / Eyes / Mouth / Tongue-Medium, Systemic: Dizziness / Lightheadness-Mild, Systemic: Fever-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Tachycardia-Mild, Additional Details: Had to use 1 epi pen in left upper thigh

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1031994	2/15/2021	MT	50	F	2/15/2021	2/15/2021	Moderna vaccine given at 1156 DOB 03/01/1970 IM to R deltoid. Lot number 015M20A, exp 7/29/2021. Pt had allergies to shellfish and amoxicillin (stating hives and anaphylaxis). Pt started itching at 1215 so sat by pt and monitored pt closely as she wasn't sure if she was just being nervous. Pt was itching by her mouth under her mask and behind right ear. I couldn't see anything that looked like rash or hives. At 1218 I noticed her R ear was now swollen and red. Pt continued to c/o of itching and states it has now progressed to her feet. She called the ambulance while this nurse gave 0.5mg SQ epinephrine L upper arm. VS: BP 140/82, HR 101, RR 20, 99% RA. Pt breathing easy and regular with no issues with airway. Pt states itching much better and was gone from her feet within a few seconds of giving the epinephrine. Pt questioning if she really needs to go by ambulance. This nurse did encourage going by ambulance as if anything happened that patient went unconscious on the way to the hospital that the ambulance staff could keep her safe by giving her more medications. 1223: Assisted patient by w/c to cot to lie down as she was feeling shaky from epinephrine. This nurse staying with pt at all times while waiting for ambulance. Pt called husband and is talking to this nurse throughout this situation. Pt breathing easy and regular. 1230: Pt states itching better, and redness on R ear is getting better. Husband has arrived to be with pt and wait for ambulance. Pt states still itches but still gone from her feet. Redness on ear remains good. Pt talked with husband about concern of taking ambulance. This nurse did state she thought it was safest way for pt to be transported in case anything happened further on the way to the hospital but the patient does have the right to refuse the ambulance. 1240: Pt states itching feels like increasing some. States itching to her hair, face, and feeling like all itching all over again. This nurse gave 50mg Benadryl IM to RUQ buttock. Pt tolerated well. No bleeding to site after injection. Ambulance arrived right after injection given. Report was given to ambulance staff after they had time to assess patient. Pt and husband agreed for pt to leave with the ambulance. Ambulance staff had pt walk to ambulance at 1245. Pt stable when leaving with ambulance staff.

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1030736	2/15/2021	VA	41	F	2/13/2021	2/13/2021	Site: Itching at Injection Site-Severe, Site: Redness at Injection Site-Severe, Systemic: Allergic: Anaphylaxis-Mild, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Allergic: Itch Generalized-Severe, Systemic: Allergic: Rash Generalized-Severe
1031664	2/15/2021		34	F	2/9/2021	2/9/2021	0830- Patient reports that her face / upper back and chest are itching. Red spots are appearing on her chest. No redness on face or back. Also reports itching of palate - no SOB / wheezing. VS - BP 147/81 HR 105 (pt reports that these are elevated from her normal) O2 sat 100% RR20 History of multiple allergies and anaphylaxis (to Humerma). Currently taking prednisone. Has taken Benadryl in the past for allergic reactions. 0832 - Benadryl 25mg PO given 0835 - no increase in sx 0840 - decreasing redness of chest, continued itching of face near hair line 0849 - feeling well, minimal itching. Offered Urgent Care or ER visit... Patient declines both. She is on her way to work and will continue to monitor for any increase in reactive sx. 0850 - left covid observation area by her own decision

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1030126	2/15/2021	OH	59	F	2/6/2021	2/6/2021	Adverse event: Anaphylaxis reaction. High blood pressure. Body shivering. Rash on neck and chest.; Adverse event: Anaphylaxis reaction. High blood pressure. Body shivering. Rash on neck and chest.; Adverse event: Anaphylaxis reaction. High blood pressure. Body shivering. Rash on neck and chest.; Adverse event: Anaphylaxis reaction. High blood pressure. Body shivering. Rash on neck and chest.; Adverse event: Anaphylaxis reaction. High blood pressure. Body shivering. Rash on neck and chest.; Adverse event: Anaphylaxis reaction. High blood pressure. Body shivering. Rash on neck and chest.; This is a spontaneous report from a contactable consumer (patient). A 59-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number EL9269), via an unspecified route of administration into left arm on 06Feb2021, at 15:15 as first single dose for covid-19 immunization. Medical history included high blood pressure from an unknown date, known allergies to peanuts, tree nuts from an unknown date (elaborated as allergies to peanuts, non-steroidal-anti-inflammatory drugs (NSAIDs), tree nuts, penicillin), from unknown dates. Concomitant medication included lisinopril (MANUFACTURER UNKNOWN) and unspecified multivitamins. No other-vaccines were given with four weeks. On 06Feb2021, at 15:45, the patient experienced adverse event: anaphylaxis reaction. high blood pressure. body shivering. rash on neck and chest. The events were serious as they were life-threatening. The events were noted as resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, and was life threatening illness (immediate risk of death from the event). The patient underwent lab tests and procedures which included blood pressure measurement: high on 06Feb2021. Therapeutic measures were taken as a result of the adverse events; dexamethasone sodium phos- diphenhydramine (BENADRYL), famotidine. No covid infection was noted prior to vaccination. No covid test has been administered post vaccination. The outcome of events was recovered in Feb2021.

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1030316	2/15/2021	IA	35	F	12/17/2020	12/17/2020	Pfizer-BioNTech COVID-19 Vaccine Shortly after receiving the dose 1 of the Covid vaccine, the patient became slightly nauseated. After 15 minutes, the nausea became worse. Patient vomited a small amount of mucus. Patient was observed for an additional 15 minutes then taken to walk-in clinic for observation or about 1.5 hours. Nausea went away and patient went back to work at COVID vaccination clinic. It is difficult to tell if this was perhaps nausea with vomiting associated with anxiety surrounding the COVID vaccination or this may have been potentially a COVID vaccination side effect. It occurred relatively quickly but there are no signs of anaphylaxis. She was observed in the clinic for approximately 1.5 hours with no ill effects. Pt was strongly encouraged her to discuss the 2nd vaccination with her primary care physician as side effects may be more intense with the 2nd shot. 1/10/21: Pt received 2nd dose with no adverse effects.

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1031463	2/15/2021	CA		F	1/12/2021	1/12/2021	Anaphylactic reaction; A spontaneous report was received from a healthcare professional concerning a 24-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced Anaphylactic reaction. The patient's medical history included allergy to milk. No concomitant medications were reported. On 12 Jan 2021, 5 – 10 minutes prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly in an unknown arm for prophylaxis of COVID-19 infection. The patient experienced chest tightness and tachycardia symptoms following which she was transported via gurney to the observation area. The patient looked sleepy and had trouble arousing her. The blood pressure was at 140/80 mmHg, heart rate was in the 90s to 100s heartbeats per minute. The patient's breath sound decreased bilaterally. It was also noted that her throat felt uncomfortable. The reporter stated that anaphylaxis reaction was suspected due to the rapid decline in status. Following an increasing heart rate and complaints of chest discomfort the patient was treated with a dose one of epinephrine pen. It was noted after a minute or two the patient's chest felt better. Her blood pressure was stable at 140/80's mmHg, the heart rate initially increased to 110 and then back down to 100 about 5 minutes after the first dose. At about 8 minutes from dose one of epinephrine pen, the patient's heart rate increased to 160 and developed additional symptoms of chest tightness again so a second dose of Epinephrine pen was administered. The patient was somnolent but protecting airway. Oxygen was added 2 liters after second dose of epinephrine pen. The patient's oxygen saturation dropped right around second dose of epinephrine pen to 94% but about 2-3 minutes later it was back at 98%. The paramedics arrived 5 minutes after second dose of epinephrine pen and care was transferred to them. The patient was transported in a stable condition. Action taken with mRNA-1273 in response to the events was not provided. The outcome for the Anaphylactic reaction was unknown.; Reporter's Comments: This case concerns a 24 year old, female patient, who experienced serious unexpected event of Anaphylactic reaction. The event occurred 1 day (5-10 min) after mRNA-1273 (Lot# Unknown). Treatment included EpiPen (2 doses). Very limited information regarding this event has been provided at this time.

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1030317	2/15/2021	NY	54	M	1/21/2021	1/24/2021	Based on temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Additional information has been requested. 3 days after 1st dose of moderna began to have mild generalized pruritis and "prickly heat" rash after showers. Has persisted since 1/24. No anaphylaxis.

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1030378	2/15/2021	SC	36	F	2/5/2021	2/5/2021	Initial On Call Documentation 2/5/21 at 20:36: Patient called after-hours line with complaint of swollen tongue 5 hours after her second Covid vaccine. She reported initial lip swelling with the first vaccine. She took Benadryl when she had lip tingling initially this afternoon. However, now she is noting indentations on her tongue. Heart rate around 125. Patient with no previous history of allergy and anaphylaxis. No epi-pen in home. Patient is tearful over the phone requesting advice. Discussed with patient that the safest option would be for her to report to urgent care versus ED for further evaluation and potential management for impending anaphylaxis, especially given lack of EpiPen in the home. Patient voiced understanding and is getting a ride to an urgent care. Follow Up Message from Patient 2/8/21 at 11:23: Update: I developed sudden swelling of my tongue on Friday night approx. 4 hours after receiving my second dose of the Moderna vaccine. I spoke to on call Dr. She advised me to go to urgent care if still open or ER. Throat started to tingle on the way their urgent care. I was given a dose of EpiPen, Pepcid, Benadryl, and Solu-Medrol. They wrote prescriptions and recommended following up with you this week. I've been taking prednisone, Benadryl, and Pepcid. Tongue is still a bit swollen, but it has not worsened. I now have two EpiPen's to use if needed. Follow Up PCP Appt 2/11/21 at 15:46: S/O: Patient had the second COVID 19 vaccine on Friday 2/5 and she premedicated with 10mg of Pepcid 10mg and post medicated with Benadryl 25mg. Later that evening she was resting when she felt some swelling of her tongue. She called the Dr who was on call and she was advised to go to the urgent care. She felt some tingling of her throat on the way there. She had no rash, difficulty breathing, or difficulty swallowing. She was given Solu-Medrol, Benadryl and Pepcid IV and was given a dose of an Epi-pen. She took Benadryl for 3 days. She finished a round of 60mg daily prednisone (for 5 days) yesterday. She felt jittery on the prednisone and this has persisted but is improving. She continues to have a feeling of chest pressure. First dose Moderna 025J20A 1/8/21; second dose Moderna 031L20A 2/5/21. She continues to note some mild swelling of her tongue but is otherwise improved. She does continue to have some pressure type pain in her chest which is also somewhat improved and more diffuse in nature. A/P: She is okay to taper off

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							of her Benadryl. She has an EpiPen should she need it, though I do not anticipate this being necessary. She should note continued improvement in her symptoms to include the mild swelling that is persistent in her tongue.
1030442	2/15/2021	ME	72	F	2/15/2021	2/15/2021	Patient became lightheaded and pale. No syncope. No symptoms/signs of anaphylaxis. Vital signs remained stable. Symptoms resolved within 45 minutes with laying supine, water, and carbohydrate. Completely asymptomatic before leaving building.
1030552	2/15/2021	IN	61	F	2/12/2021	2/12/2021	Systemic: Allergic: Anaphylaxis-Severe, Systemic: Allergic: Difficulty Breathing-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Shakiness-Medium, Systemic: Tingling (specify: facial area, extremities)-Medium
1030574	2/15/2021	FL	51	F	2/12/2021	2/12/2021	Systemic: Allergic: Anaphylaxis-Medium, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Medium, Systemic: Allergic: Swelling of Face / Eyes / Mouth / Tongue-Medium, Systemic: Confusion-Medium, Systemic: Dizziness / Lightheadness-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Other-Anxiety/Panic-Medium

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1031464	2/15/2021		31	F	1/11/2021	1/11/2021	Anaphylaxis; Hives; A spontaneous report was received from a healthcare professional concerning a 31-years-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced anaphylaxis and hives. The patient's medical history was not provided. No relevant concomitant medications were reported. On 11 Jan 2021 at 4:50 pm, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly in the arm for prophylaxis of COVID-19 infection. On 11 Jan 2021 at 4:50 pm, after receiving the vaccine, the patient experienced anaphylaxis and hives. She was given epinephrine and 50 mg of diphenhydramine. Emergency Medical Services (EMS) and the fire department were called. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, anaphylaxis and hives, were unknown.; Reporter's Comments: This case concerns a 31 year old, female patient, who experienced serious unexpected event of Anaphylactic reaction, a non-serious unexpected event of urticaria. The event occurred 1 day (few min) after mRNA-1273 (Lot# Unknown). Treatment included EpiPen. Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Additional information has been requested.
1031682	2/15/2021	MI	64	F	2/12/2021	2/12/2021	Patient received Moderna vaccine on 2/12/21 at 3pm. She sat in our waiting area under observation for 15 minutes (she reported no allergies, prior issues with vaccination such as fainting/anaphylaxis). Once she was home, she started feeling nauseous (and vomiting), severe joint and body pain, headache (reports feeling like, "her head is going to explode). These issues were worst over Friday/Saturday but improved over Sunday and today, Monday. Patient stayed home over the weekend and did not contact emergency services. Patient contacted her doctor on Monday to report the events of the weekend. At this time, her doctor has not recommended any treatments or issued prescriptions, and their plan is to have the patient follow up with the office should things worsen or change.

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1028923	2/14/2021	KY	46	U	2/13/2021	2/13/2021	<p>Patient is a 46-year-old female who has known history of previous reactions to immunizations with anaphylaxis as well as seizures who presented to the emergency department with some symptoms after receiving Covid vaccination. She reported onset of some mild headache and dizziness as well as ringing in her ears. She states that these are symptoms sometimes that precede a seizure episode. She has managed on Keppra 750 mg twice daily and has been on this regimen for some time. Here in the emergency department she had no significant concerning findings on exam. Vital signs were fairly unremarkable, there was no rash, there is no stridor or throat swelling, lungs were clear. There is no seizure activity or any other neurological findings. I spoke at length with the patient and her significant other regarding this symptomatology but I do not see any reason at this time that she would need to be admitted to this hospital. She could still potentially develop a seizure-like episode although I do not anticipate this to be the case. There is definitely nothing at this time that would point towards anaphylaxis. There was a Keppra level that was drawn and is pending at this time. I have sent a letter to neurology to let them know that it is still pending at this time.</p>

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1028963	2/14/2021	PA	42	F	2/8/2021	2/12/2021	Adverse event: I had anaphylaxis on 2/12/21 that required transport via ambulance to the nearest emergency room for life saving treatment. Background information. I took a 7 day course of celebrex (200mg orally once daily) on 1/25/21, prescribed by my primary physician for a flare up of low back pain. A 14 day course was prescribed; I stopped taking it after 7 days because my stomach was getting upset and I didn't want to take it close to my 2nd covid moderna booster. I got my 2nd moderna covid vaccine booster on 2/8/21. For 1-2 days, my left arm (injection site) was sore and I was mildly fatigued. I took over the counter advil (200mg twice daily) and tylenol (500mg twice daily); the day I took advil, I was sneezing and developed signs of allergic rhinitis (congestion/runny eyes and nose). I did not have any other immediate adverse reaction and by Thursday, 2/11, the arm soreness and fatigue resolved. My low back pain began to bother me again, so I took a 200mg oral dose of celebrex at 7:30a on 2/12/21. I went to work (I am a veterinary neurologist. While at work, at 9:30a on 2/12/21, I had a severe anaphylactic reaction and had to be taken via ambulance to Medical Center. I developed hives/welts/burning/itching all over my body, within 5 minutes my throat closed up, I couldn't breathe, I became hypotensive/collapsed; in the ambulance, I was given IM epinephrine; then at the ER, I was given IV steroids (solumedrol), benedryl, famotidine, zofran (due to abdominal pain/nausea) and IV fluids. This stabilized my signs within 1 hour and I improved and was going to be discharged at 2pm. However, the hives returned at that time, so I was given additional IV benedryl, famotidine, fluids and oral prednisone and kept in the hospital overnight for monitoring; I was discharged to go home on 2/13/21 on a 4 day course of oral famotidine, benedryl and prednisone; I remained itchy and continued sneezing at home on 2/13/21. Today, 2/14/21, all signs of this reaction have resolved. The ER doctors and myself believe the 2nd moderna covid booster on 2/8/21 stimulated my innate immune system, leading to this anaphylactic reaction to celebrex (a medication I had taken 2 weeks prior with no problem). The doctors feel the celebrex is what set off the anaphylactic shock, but that my immune system was primed to do so after the vaccine. In hindsight, I realized that I was having allergic rhinitis symptoms after taking oral advil on 2/9 the day

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after my booster (which has never happened to me before either). I am a person with no pre-existing allergies of any kind. There was nothing different at all in my routine including food or potential environmental exposures) on 2/12, the day of my anaphylactic reaction, other than my taking a 200mg dose of oral celebrex. I am not allowed to take NSAIDs until I see an allergist for testing now. I am reporting this adverse event as I believe the moderna booster caused an anaphylaxis to the celebrex medication.

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1029407	2/14/2021	PA	35	F	2/12/2021	2/12/2021	I received my vaccine, sat in a chair facing the clock and noted it said 5:00pm. Within a minute I notice tingling and slight numbness of my soft palate. I found this odd, but didn't notice any swelling or difficulty breathing. At 5:02 I texted my husband to make sure my EpiPen was in the glove compartment in case I needed it later after leaving the vaccination clinic. Over the next few minutes the numbness increased and started to spread to my oropharynx area. I noticed my heart beating faster and wondered if my body was subconsciously anxious about the numb feeling even though I didn't feel worried because I was breathing fine. Very suddenly my heart started to pound very hard, my entire laryngopharynx went numb and I felt like a deck of cards was sitting in the back of my throat. I looked at the clock, it was 5:07. I started to feel dizzy and weak, my heart felt like it was about to explode, my hands were suddenly cold, clammy and shaking, I started to get sharp stomach pains similar to other anaphylactic events, but still no effects on my breathing. I looked at the clock, 5:09, I knew I had to tell someone before I couldn't get up to walk. As I started to talk to a staff member I felt very disoriented and suddenly went from feeling like I was going to faint to very hypertensive with pain shooting into my left arm. The staff quickly took my BP and HR, I noted my BP was 166/100 (I am normally 114/72) and the doctor stated I was too tachycardic and needed to go to the ER. At the ER I received Benadryl, Pepcid and an IV, but never needed any epinephrine. The medications resolved numbness and stomach pain. I left with the feeling of a tight turtleneck around my throat and it continues to come and go. Every 6-8 hours I have had to take Benadryl and a steroid to keep the intense itching numb feeling in my soft palate away. I still have tightness around my neck that returns every 6-8 hours, but still no airway or edema issue. I felt like I had anaphylaxis without the edema.
1029735	2/14/2021	KY	26	F	2/13/2021	2/13/2021	Anaphylaxis
1029683	2/14/2021	CT	27	F	2/14/2021	2/14/2021	Anaphylaxis. Hives, anterior/posterior throat swelling, shortness of breath. Resolved with epinephrine drip, receiving three epinephrine injections and Benadryl from EMS. Likely will be kept for observation given epi drip.

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1029545	2/14/2021	OH	68	M	2/14/2021	2/14/2021	Vaccine given ~2:05 PM. Patient reported no problems 15 minutes post vaccine. Patient called around 3:30 PM to state he may be experiencing "itchy tongue" and "scratchy throat", which started about 15 minutes after he left the store (~30 min post vaccine). He reported no other signs/sx at the time. He was advised to seek immediate medical attention since wife was with him, he's ~5 min from local hospital, and no other severe sx were currently present. However, he was advised to contact 911 if any severe reaction (e.g., difficulty breathing, passing out, etc.) appears. Pt said he would discuss this with his wife, and we discussed that an allergic reaction can progress quickly. He said he has benadryl on hand, but we discussed that benadryl will not be enough if patient does develop a severe allergic reaction/anaphylaxis. Patient was advised to contact his on-call Dr. for a second opinion at the very least if he does not go to the ED and to continue monitoring for additional signs/sx of allergic reaction. Patient was advised to follow up with us in a few days for update.

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1029034	2/14/2021	WA	62	M	2/13/2021	2/13/2021	<p>a 62 y/o M who presents with concerns for an allergic reaction to the second dose of the Covid vaccine. According to him he got the vaccine around 8:45 AM. He has a history of anaphylactic type reactions with a swelling and urticaria in the past but has not had any symptoms in the last 5 years. He felt sudden onset pit in his stomach, tingling and warm sensations over his face and some chest tightness. He denies all the symptoms currently. He did get medications prior to arrival but states his symptoms were already getting better before he been given anything. He was given epinephrine as well as Benadryl beforehand. He denies any symptoms currently. Denies headache, change in vision, difficulty swallowing, lightheadedness or vertigo, chest pain, sore throat, wheezing, cough, nausea or vomiting, rash, falls or injuries. Denies any recent foreign travel or sick contacts. He did work a full shift yesterday and was coming off a 24-hour shift prior to getting his vaccination. He denies any significant reactions to the first vaccine.</p> <p>Medical Decision Making On initial presentation is an overall well-appearing 62-year-old male who has normal vital signs without fever or tachycardia. He is presenting with concern for allergic reaction of the field to a recent vaccination. The vaccine was given roughly 1 hour prior to arrival. He was given epinephrine intramuscularly as well as IV Benadryl. He states he is currently feeling mildly tired from the Benadryl. He denies any other recurrent symptomatology and feels better. Examination is not concerning for anaphylaxis at this time, no evidence of airway involvement or multisystem involvement. No evidence of local allergic reaction. Low clinical concern for occult infection, metabolic abnormality, ACS or arrhythmia for a cause of his symptoms. He is overall very well-appearing. Labs have been obtained as part of screening for reactions to the vaccination per CDC recommendations including a tryptase and C4 complement. They were drawn over an hour after the vaccine was administered. ECG was within normal limits. After observation patient remained asymptomatic. Did offer steroids, however he wanted to hold off on them as he just got his vaccination which seems appropriate at this time. He was sent home with a new EpiPen. We also gave him follow-up in the allergy clinic. He has any worsening symptoms we do recommend he use the EpiPen as well as call 911. He is</p>

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							understanding. At this point he stable for outpatient management. I did tell him he should expect to feel aches and potentially have inflammatory response to the vaccine, he is understanding of this. Pt was discharged home/self-care. Pt provided strict return precautions, including but not limited to, any worsening symptoms or any new concerning symptoms. Otherwise, Pt instructed to see PCP on an as needed basis.
1028116	2/13/2021	CA	34	F	12/18/2020	12/18/2020	Patient received the Pfizer-BioNTech COVID-19 Vaccine EUA at 1006. Developed flushing tongue itching, local redness on shoulders at 1010. Patient was given Benadryl 25mg po in the clinic and remained for observation. After observation, patient cleared to leave clinic - was instructed to call 911 and go to ED if exhibiting any signs or symptoms of anaphylaxis. Patient was given an extra dose of Benadryl, 25mg to take if needed.
1028027	2/13/2021	AZ	73	F	2/13/2021	2/13/2021	Pt reported having palpitations after receiving the first dose of COVID vaccine. Pt states she began feeling a little light headed. Pt was taken to the triage area and assessed by EMS and this ED Nurse. There were no s/s of anaphylaxis. 4 lead cardiac monitor was placed by EMS. Sinus tachycardia was noted with at rate of 117. Blood pressure was 191/125. Spo2 was 100% without oxygen supplementation. Repeat blood pressure was 202/92 with a heart rate of 104. Pt remained in the observation area for 30 minutes. Pt declined staff and EMS request for hospital transport. Pt left observation area ambulatory with friend who agreed to stay with the patient and assist her home. Pt was instructed to call 911 for any worsening of symptoms or cause for concern. Patient agreed.
1027716	2/13/2021	WA	45	F	2/11/2021	2/11/2021	patient reported localized pain at injection site day of shot 02/11/21. called into general advice line to report results worsening symptoms of whole body aches, fever, HA, whole body itchy rash with no shortness of breath or airway compromise. given delayed reaction, sounds most like side effect and is not consistent with anaphylaxis but recommended ED/911 if develops airway compromise, and discussed possibility could be allergic

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1031115	2/13/2021		66	M	2/11/2021	2/11/2021	syncope, c/o itchy throat Narrative: Patient was seen prior to administration of the Moderna COVID-19 vaccination. He has allergies to bees/egg and a h/o anaphylaxis 2/2 receiving an injection of penicillin in the past. Discussed that prior h/o anaphylaxis to PCN injection was not a contraindication to this vaccination, but is a precaution. Discussed risks of receiving the vaccination vs benefits of the vaccine, which patient states "I already had this discussion with Dr.!" He has multiple comorbidities which place him at a higher risk for more severe illness from COVID-19. Again received the risk vs benefit discussion. Patient stated understanding and desire to proceed with the vaccination. He will be monitored for at least 30 minutes in area where staff can directly observe him. Patient received the COVID vaccination at 13:00. At 45 minutes later, staff alerted that he was c/o palpitations. Due to confusion and weakness, we were unable to transport him to an examination room. Oxygen, water, and vitals machine were brought to him. He presented with SOB, confusion, lightheadedness. Exam demonstrated acute distress, speaking in staccato sentences. HR in 80s, with lungs CTAB and no stridor - despite increased RR to 20s. Vitals with HR in 70s, SpO2 remained 97% or greater on RA. BP was initially 140/72. A code blue was called and Drs. presented to the area. Patient c/o itchy throat and still p/w confusion/combativeness, loss of orientation, and SOB. No visible swelling noticed. At around 13:58, patient syncopized. HR and SpO2 remained 70-80s and >98% on room air respectively. Pulse remained palpable. At that time, an epipen was administered. Patient woke up. During the entire episode, he was able to recognize a staff member with whom he was previously familiar. EMS arrived, vitals remained stable. EMS transported patient to the ER for further monitoring and f/u. Concern for immediate allergic reaction 2/2 vaccination. After event, patient in need of referral to allergy provider for evaluation prior to consideration of 2nd dosage.
1027119	2/12/2021	UT	25	F	2/11/2021	2/12/2021	lip swelling approx 26 hours following vaccination. No other s/s of anaphylaxis. 50 mg of benadryl taken with no improvement

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1025126	2/12/2021	SC	34	F	1/18/2021	1/29/2021	A week after the shot, starting at the injection site wrapping around inside of my bicep and down towards the elbow a: red; occasionally warm; hyper sensitive; pain with touch mark appeared. It was rectangular in shape approximately 3" x 5 ". It was present for no less than 1 & 1/2 weeks. I do not believe it was anaphylaxis in nature. I did not take anything.
1025403	2/12/2021	PA	35	M	2/5/2021	2/5/2021	Patient received second dose of Pfizer COVID-19 vaccine 2/5/2021. 4 days later developed mild hives at 8 am, 11 hours later developed hives again, more severe and lasting 3 hours. Spoke with his wife. She did give him 25 mg of Benadryl and 40 mg of famotidine. This seemed to help. Advised if hives do not continue to improve with measures provided to go to urgent care for evaluation, if he should develop any symptoms of anaphylaxis - heavy tongue, difficulty breathing, throat swelling to go directly to the ER. Understanding verbalized. Chart updated to reflect potential allergy due to hives after getting the vaccine. ? Widespread hives
1025587	2/12/2021	OH	31	F	2/12/2021	2/12/2021	Patient received second dose of covid vaccine within 5 minutes of injection developed anaphylaxis reaction, 2 doses of epinephrine was administered on site. EMS was called and patient was transported to local emergency department for treatment.

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1026008	2/12/2021	CT	47	F	1/8/2021	1/8/2021	New sensitives to face cleansers; Anaphylactic shock; A spontaneous report was received from a consumer, concerning herself, a 47-year-old female patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced anaphylactic shock and "newsensitives to face cleansers". The patient's medical history was not provided. Concomitant product use included face cleansers. On 08-Jan-2021, the patient received the first of two planned doses of mRNA-1273 (lot number unknown) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 08-Jan-2021, approximately five minutes after receiving the vaccine, the patient experienced anaphylactic shock as evidenced by throat warm and tingling, arms was bright red and warm to touch, trouble breathing, felt like choking, and nausea. Hence, she was treated with "epinephrine quite a few times along with steroids and ranitidine". On 09-Jan-2021, the patient went to the hospital two more times for "breathing issues", however she was not admitted. On 10-Jan-2021, in the morning, the patient had "passed out" and was given another epinephrine injection as she went into anaphylaxis shock again. On-29 Jan-2021, the patient also reported her arm, legs and chest are "bright red" and "burns". The patient also experienced new sensitivities to the face cleansers she has used for over 12 years. Action taken with mRNA-1273 in response to the events were unknown. The events, anaphylactic shock, was considered newsensitives to face cleanser" were considered not resolved.; Reporter's Comments: This case concerns a 47-year-old female patient, who experienced serious event of anaphylactic shock and non-serious event of sensitive skin. The event of anaphylactic shock occurred on the same day and re-occurred again approximately 2 days after first dose of mRNA-1273, lot # unknown. Based on the current available information and temporal association between the use of the product and the onset date of the events, a causal relationship cannot be excluded.

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1026612	2/12/2021	HI	77	F	2/3/2021	2/4/2021	There was no adverse event, and wanting to report that she put that she indicated no to the disclaimer that she had not had any anaphylaxis to any vaccine. She researched the ingredients and felt that she was safer in getting the vaccine than not getting it. She does carry an Epi-Pen and felt that for your statistics that somebody at the age of 77 with highly adverse reactions to medications was able to get the vaccine.
1027078	2/12/2021	TX	56	F	2/11/2021	2/11/2021	Anaphylaxis, itching, tightness of the throat, shortness of breath, low oxygen levels Treatment: 1 Benadryl 1130am, 1 EpiPen 1155am, 1 EpiPen 1225, steroids intravenously 1pm Outcome: Released home
1027456	2/12/2021	CA	30	F	1/15/2021	1/15/2021	Before vaccine I did take Benadryl and took my advice 500 inhaler concerned about previous anaphylaxis. I was fine in observation and about 1hour after my heart started racing and I became flushed with hives on my chest and mild difficulty breathing. My mother is a nurse and I had her stay with me and took 50mg more Benadryl and my albuterol inhalers and breathing issues subsided and I went to sleep for about 4 hours. When I woke up my heart rate was fine, flush was gone but I still had mild hives. For the next 4 weeks I have had hives on and off and itching. I have had this happen before during almond harvest but never this time of year. I am currently breast feeding and hives have resolved everywhere except for my chest.
1027005	2/12/2021	PA	66	F	2/12/2021	2/12/2021	Pt was administered COVID-19 Pfizer vaccine on 2/12/2021 at approximately 1415. At 1440 pt was observed to be coughing. Pt stated, "It feels like there is something in my throat". POX remained 98% on RA with HR 105-112. Pt observed by nursing staff until 1445 when she was taken to the ED from the vaccination tent. At this time pt exhibited increasing SOB with notable tongue swelling. Pt reports previous anaphylaxis reaction to bee venom.

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1024553	2/11/2021	NM	37	F	2/11/2021	2/11/2021	The patient developed an itchy, red rash on her neck almost immediately after receiving the vaccine. She said she's had that type of reaction before. She's been to the allergist, and they said she's allergic to dustmites. The patient said she felt fine other than the rash. After the 15 minute period, there was no signs/symptoms of anaphylaxis. She drank water and took 2 diphenhydramine 25mg tablets.

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1023356	2/11/2021	KY	64	F	1/16/2021	1/1/2021	Anaphylaxis; SOB (shortness of breath)/ difficulty breathing; Chest tightness; dizziness; Wheezing; Anxiety attack; Medication-induced allergic reaction; Blood pressure (BP) increased for 130/89; This is a spontaneous report received from a contactable pharmacist. A 64-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; Lot number: EL3249), intramuscular on left arm on 16Jan2021 at single dose for COVID-19 immunization. Medical history included HTN (hypertension), myopericarditis, anxiety and allergy to antihistamine tabs. The patient's concomitant medications were not reported. It was reported that, the patient was experiencing chest tightness, SOB (shortness of breath), and dizziness on 16Jan2021. 50 mg of Benadryl and 20 mg of famotidine was administered around 14:10. Patient was still experiencing chest tightness and was having difficulty breathing. 0.3 mg of epinephrine was administered at 14:20. EMS was called. Breathing improved. Pulse Ox 100%, HR (heart rate): 68, blood pressure (BP) increased for 130/89. EMS arrived and assumed patient care. ED COURSE: Patient was seen and examined with doctor. Patient developed of SOB, dizziness, wheezing after receiving first shot of Pfizer COVID vaccine. She received Benadryl upon development of symptoms, which actually made them worse given her allergy to antihistamine tabs, but her symptoms improved upon administration of 0.3 IM epinephrine shot. Differential diagnoses include but were not limited to anaphylaxis, anxiety attack, medication-induced allergic reaction on 16Jan2021. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. It was unknown whether the patient received any other medications within 2 weeks of vaccination. The patient visited emergency room/ department or urgent care due to the events. The patient was not diagnosed with COVID-19 prior to vaccination. It was unknown whether the patient has been tested for COVID-19, since the vaccination. The events were assessed as non-serious by the reporter. Therapeutic measures were taken as a result of events. The outcome of the events was reported as recovered on an unspecified date in Jan2021.; Sender's Comments: Based on the information provided and temporal relationship, a causal association between BNT162B2

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							and the reported events cannot be completely excluded. The treatment with Benadryl most likely contributed to the events as the patient is known allergic to antihistamine tabs. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.
1024568	2/11/2021	OH	31	F	2/10/2021	2/11/2021	Approximately 5 minutes following administration of my second dose of the Pfizer COVID 19 vaccine I began to have signs of lip numbness and lip swelling at the same time. No issues were noted with tongue or throat swelling associated with anaphylaxis. Additionally I noted an odd taste in my mouth, potentially metallic. I also experienced some abdominal pain at that time that passed in approximately 10 minutes. Discomfort and swelling feeling of the lips has persisted for the past 2 hours. Still no difficulty breathing, racing heart or other signs of anaphylaxis. Lips are only slightly swollen on outside appearance if at all but the feeling of swelling is noticeable
1024320	2/11/2021		50	F	2/10/2021	2/10/2021	Patient with hives and no anaphylaxis Benadryl 50 mg IM given with resolution of symptoms

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1023494	2/11/2021		43	M	1/28/2021	1/1/2021	anaphylaxis; This is a spontaneous report from a non-contactable healthcare professional (patient himself). A 43-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on 28Jan2021 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Jan2021. The outcome of the event was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation and known safety profile of suspect drug. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

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1023486	2/11/2021			F	1/27/2021	1/27/2021	low grade head ache; GI c/o; anaphylaxis; Difficulty breathing; Lightheaded; throat felt like swollen/Throat getting narrower; did not feel well; hr 112; nausea; Didn't feel right; This is a spontaneous report from a contactable Physician who reported for a patient (staff member). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 27Jan2021 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient received the first dose of vaccine and during 15 min observation window did not feel well. It was later reported by the same reporter that within 3-5 minutes after injection the patient didn't feel right. Felt lightheaded, wasn't there. Having difficulty breathing and felt throat was getting narrower. Stated throat felt like swollen and heart rate was 112. Went up to people at vaccine center, was given Benadryl and sent to the Emergency Room (ER). Told she was having anaphylaxis. ER was not convinced of anaphylaxis, but was given epinephrine. Ultimately was given epinephrine although they stated that unclear if anaphylaxis or not. Was given 50mg of Benadryl. Was given Zofran for nausea. 'Today' (28Jan2021) had low grade head ache and GI c/o (gastrointestinal complaints of). Had no previous issues with vaccine or drug reaction. Has comorbidities. The reporter was seeking recommendations for the second COVID-19 Vaccine. The outcome of the events was unknown. Information on the lot/ batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation and safety profile of suspect drug. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

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1023485	2/11/2021			F	1/27/2021	1/27/2021	anaphylaxis; she didn't feel well; she felt weak; felt like throat was closing; Her heartrate was 113; low grade headache; This is a spontaneous report from a contactable physician. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiry date not reported), via an unspecified route of administration on 27Jan2021 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Reporter was not sure if patient made her symptoms worse with her attitude, but in the first 5 minutes (27Jan2021), patient reported she didn't feel well, she felt weak, and felt like throat was closing. She was referred to the ED (emergency department) for anaphylaxis and given 1 dose of epinephrine. The ED said they do not know if it was an anaphylactic reaction. Her heart rate was 113 (27Jan2021). After that, she rested for the rest of the day and now has a low grade headache and some of the typical side effects (unspecified). Reporter asked for the recommendation for the second dose. The events were not serious as per reporter. Therapeutic measures taken as a result of the event anaphylaxis. The outcome of the event anaphylaxis, didn't feel well, felt weak, felt like throat was closing, heart rate was 113, and low grade headache was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation and known safety profile of suspect drug.. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

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1024411	2/11/2021	WA	82	F	2/11/2021	2/11/2021	PATIENT VACCINATED AT 10:10AM, WAITED FOR 15 MINUTES. FELL AT 10:42 AM WHILE ENGAGED IN RECREATIONAL ACTIVITY. NO ANAPHYLAXIS. NO FAINTING. AMBULANCE CALLED AND PATIENT TRANSPORTED TO HOSPITAL.
1022919	2/11/2021	MI	76	F	2/11/2021	2/11/2021	Client received Pfizer covid vaccine, and during her observed wait time, she became hot and felt a flush through her body. She also reported tingling in her tongue and throat. She reported itching of her chest, cheeks, and ears. Client was brought back to emergency area, and was assess by nurses. Client did have a prior history of allergy to Iodine and shellfish- but never anaphylaxis. 10:20am, pulse 68, bp 142/83, 98% O2. 10:25am, bp 140/85, still complaining of throat swelling and itching, pulse ox stil 98%. Once client was in a private area, she reported that the flushing and feeling of being hot, had gotten much better. Per Client , her tongue and throat, were not getting worse. Our Medical Director was contacted, and the decision was made to give Benadryl IM. 10:39 pulse 70, O2 95%, . 10:41 am 1ml (50 mg) Benadryl given IM in the right deltoid (lot # 080014, exp. 8/2022). Within a few minutes patient reported that signs and symptoms were better but had not completely gone away. 10:44, respirations 14/minute, O2 94%, patient sat up at this time to help clear some phlem. 10:46 client states tongue feels better. 10:53 am 96% O2, pulse 93. Nurses continued to monitor client, and asked if she felt any worsening of her symptoms to warrant more medication. Client stated she felt a little better and would like to go home. 11:15 am, spoke to Docter again, per his instruction, client was allowed to go home with her sister. Instructed to take more Benadryl in 4 hours if symptoms return. Client was told if anything gets worse than her original symptoms, regarding her airway, tongue, lips, swallowing, she should call 911.
1022187	2/11/2021	MA	77	F	2/9/2021	2/9/2021	Pt complained of tingling around mouth after injection.Symptoms quickly resolved. VSS 130/61 67, 99% ; observed for 30 minutes. Counseled to call 911 for any symptoms of anaphylaxis

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1022076	2/11/2021		85	M	1/27/2021	1/27/2021	unresponsiveness for 2 minutes in seated position; bilateral arm tremor; pallor; eyes rolled back; drooling; nausea; vomiting; This is a spontaneous report from a non-contactable pharmacist. An 85-years-old male patient started to receive first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EL9262), intramuscular on 27Jan2021 10:30 AM at single dose on Left arm for covid-19. Medical history included anaphylaxis history of unknown cause. The patient's concomitant medications were not reported. 30 minutes into observation, patient experienced bilateral arm tremor, pallor, eyes rolled back, drooling and unresponsiveness for 2 minutes in seated position on 27Jan2021 11:00 AM. 911 called immediately. Patient became alert and oriented after 2 minutes but experienced nausea and vomiting on 27Jan2021 11:00 AM. While seated, vital signs were taken- BP 148/76, HR 73, O2 98% on 27Jan2021. No falls or medication administered. (name withheld) arrived around 11:10 am and assessed cardiac rhythm and vital signs. Patient initially wanted to go home, but based on (name withheld) assessment, recommendation was to go to the ER. No treatment received. Outcome of events was recovered on 27Jan2021. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the compatible time association, the contribution of suspect vaccine BNT162B2 to the events bilateral arm tremor, pallor, eyes rolled back, drooling and unresponsiveness is possible. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1021947	2/11/2021	ID	48	F	12/30/2020	12/31/2020	allergic reaction; severe lip/facial swelling on left side of face and top lip/swelling two days later on right bottom side of face and lip; severe lip/facial swelling on left side of face and top lip/swelling two days later on right bottom side of face and lip; This is a spontaneous report from a contactable consumer (patient). A 48-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, first dose on 30Dec2020 at 09:00 (Lot number: EL0140) in the right arm and second dose on 20Jan2021 (Lot number: EL3246) in the left arm, both at the age of 48-years-old at a single dose for COVID-19 immunization. Medical history included low vitamin D, hypothyroid, Von Willebrand's, and idiopathic anaphylaxis (years ago, outgrew). The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included unspecified medications within two weeks of vaccination. The patient previously received botulinum toxin type A (BOTOX) in the forehead years ago. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced severe lip/facial swelling on left side of face and top lip/swelling two days later on right bottom side of face and lip and allergic reaction on 31Dec2020. The events were reported as non-serious. The clinical course was reported as: The patient woke up with severe lip/facial swelling on left side of face and top lip. The patient went to doctor and they thought it was allergic reaction, but not sure if it was the vaccine. After the patient received the second dose, she had swelling two days later on right bottom side of face and lip. The patient had no lip/facial filler. The patient did not receive any treatment for the events. The clinical outcome of severe lip/facial swelling on left side of face and top lip/swelling two days later on right bottom side of face and lip and allergic reaction was recovered in Jan2021. It was also reported that since the vaccination, the patient had not been tested for COVID-19.

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1021924	2/11/2021	FL		F	1/27/2021	1/27/2021	Anaphylactic shock; A spontaneous report was received from a consumer who is also a 71-year-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced anaphylaxis. The patient's medical history was not included. Products known to have been used by the patient were not provided. On 27 Jan 2021, prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (Lot number: 029L20A) intramuscularly for prophylaxis of COVID-19 infection. On 27 Jan 2021, after the mRNA-1273 vaccine was being given, the patient noted anaphylaxis symptoms, was rushed to the hospital and hospitalized for 24 hours. Treatment information included hospitalization, epinephrine and breathing treatments. Action taken with mRNA-1273 will be discussed with her physician. The outcome of the event anaphylaxis was unknown.; Reporter's Comments: This case concerns a 71-year-old female patient. The medical history is not provided. The patient experienced a serious unexpected event of Anaphylactic reaction on the same day after receiving their first of two planned doses of mRNA-1273 (Lot # 029L20A). Treatment included epinephrine and breathing treatments. Based on the current available information and temporal association between the use of the product and the onset of the event, a causal relationship cannot be excluded and the event is considered possibly related to the vaccine.

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1023483	2/11/2021	CA	76	F	1/27/2021	1/27/2021	BP;A bit high for her; Anaphylactic reaction; back rash; burning sensation; swollen face; itchy back; Back getting hot; This is a spontaneous report from a contactable consumer (patient) via a Pfizer sponsored program. A 76-year-old female patient received their first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EL9262, expiry date not reported) , via an unspecified route of administration on the left arm on 27Jan2021 14:00 at single dose for COVID-19 immunization. Medical history included anaphylaxis with contrast media (Biaxin and eucalyptus), allergies: latex, antihistamines, sulfa, olive trees; allergic reactions to iodine, asthma, cardiac arrest, has a pacemaker; all from unknown dates. Concomitant medication included levothyroxine sodium (LEVOTHYROXIN), vitamin D3, levocabastine hydrochloride (ZYRTEC), iron, diltiazem, salbutamol sulfate (ALBUTEROL). The patient previously took Biaxin, eucalyptus and tiger balm and experienced anaphylaxis, Cipro, sucralfate, adrenaline (EPIPEN), corticosteroid and experienced allergies. The patient previously received Shingles vaccine on Nov2020 for immunization and experienced intermittent itchy back sensation. The patient reported that after vaccine reaction today (27Jan2021) - back rash, burning sensation, swollen face. It was further reported that the patient experienced potential anaphylactic reaction; 15 minutes after the administration she got her back getting hot and Itchy and a rash breakout. It was also reported that the patient's BP was a bit high for her on an unspecified date. The patient underwent lab tests and procedures which included blood pressure measurement: a bit high for her on an unspecified date. Therapeutic measures were taken as a result of anaphylactic reaction, back rash, burning sensation, swollen face, itchy back, back getting hot which included treatment with Benadryl (Took one 25 mg Benadryl. Then she took another 25 mg Benadryl); it was reported that 30 minutes later symptoms started to subside. The patient recovered from anaphylactic reaction, back rash, burning sensation, swollen face, itchy back, back getting hot on 27Jan2021, while the outcome of BP was a bit high for her was unknown.

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1023622	2/11/2021	AZ	44	F	1/13/2021	2/3/2021	On 2/3, 2 hours after vaccine, I experienced extreme heat to my face. (The feeling I get when I'm going into anaphylaxis) but anaphylaxis never came. It dissipated after a couple of minutes, but red face and ears all day. On the 7th, I started noticing partial paralysis on the right hand side of my face. It is still there. I have not been around anyone outside of my home since March 2019 nor have those who live with me. The only exception has been when I got my two vaccine doses.

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1020328	2/10/2021	MT	39	F	2/5/2021	2/6/2021	<p>Morning of vaccination I took a Benadryl 25mg and a zertec 10mg, because I was a little worried since I have previously gone in to anaphylaxis when starting immune boosting allergy shots, at my allergists office. I took another Benadryl at 5pm that day and 20mg of zertec the evening of the 5th along with my normal medications. Other than a headache and a very sore arm, everything seemed fine. I was happy to get vaccinated. The morning of the 6th I had planned on taking a Benadryl and zertec again, but got sidetracked and forgot. I had taken my normal morning thyroid pills, and drank my morning coffee, nothing else out of the normal. Nothing to eat, everything was fine until 11:30am (26 hours after vaccination shot) I noticed my throat & tongue starting to shooting pain and then starting to swell. I immediately took a Benadryl & zertec, took my albuterol inhaler and grabbed my epic pen. 15 mins later my pulse was at 139bpm (according to my iWatch) and I felt like I was going to pass out. I auto injected with epic pen, but didn't know to hold it for 3-10 secs, so I didn't receive a full dose of the medication. My heart rate started going up again and I was having to focus on my breathing and called 911. An ambulance came and I had to give myself another Epi Pen injection as I couldn't breathe. The ambulance crew (two people -were not EMT's and just a volunteer crew), so I had to inject myself, as they watched and I pulled the epi Pen away again, which I learned from them was incorrect to do. Just the little amount of medication I got from the Epi Pen semi calmed things down for around 20 mins, then 10 mins away from ER - my HR went up to 149bpm (I was informed by ambulance attendant and verified with the heart monitor on iWatch later), I was fighting unconsciousness (was told by attendant my BP dropped out and I lost all my color) and could not breathe. I went limp and couldn't hold my head up, the attendant helped to support my arm as I auto injected myself with the last Epi Pen, and held it for a 10sec count. [ER report has misinformation. All of my Epi Pens were expired and I knew this, but its all I had. I also injected myself with all of them unlike the ER report says. For some reason the ER doctor was not fully listening to what had happened (from the ambulance crew and from me) and made mistakes in the ER Report. I have been advised to contact the hospital and address the ER Doc actions and report issues for my visit.] As we</p>

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pulled up to ER, the epi pen had calmed most everything down, my heart rate was just slightly elevated and my breathing was still difficult and I had to focus on that. I was administered Steroids and Pepcid AC, intravenously at the ER and was monitored. Then was released an hour or two later when all my functions where at a normal readings. Everyday since I have continued a course of Benadryl, Zertec, Pepcid AC, albuterol, 200mg Celebrex, and 11mg ER Xeljanz. I have still been experiencing throat tightness and extra phlegm and have also started to take a daily 20mg steroid course to help with remanding allergic symptoms, I have been having as directed by my allergist. I?m hoping the vaccine clears my system soon as it still seems to be affecting my system and my body is very ?hyper vigilant? it seems. My allergist said he does feel it to be safe with the Johnson&Johnson Vaccine (when/if) it gets approved for further vaccinating me, as I have had no issues with any other vaccines in the past.

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1019142	2/10/2021			F	1/1/2021	1/1/2021	Anaphylactic reaction; I felt as if my throat was closing off; I have cramping feelings in my throat; felt as if my throat was closing off; I was very sick for 3 days; This is a spontaneous report from a contactable nurse. A nurse of unknown age reported that she received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number unknown), in Jan2021 at single dose for COVID-19 immunization. Medical history and concomitant drugs were unknown. The nurse reported that she had her COVID 19 shot the past week and she reported her symptoms and wondered should not take the second dose because she was very sick for 3 days but that did not bother her. The thing that bother her was that she felt as if her throat was closing off, she had cramping feelings in throat. She was afraid that it was beginning to be 'anaphylaxis' but it was not. She reported that it did not go any further than that but she was fearful that her throat was going to close completely off. At the time of reporting the outcome was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The suspected anaphylaxis with throat tightness and throat spasm were probably causally related to the use of the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) due to temporal relationship. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

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1019162	2/10/2021	MO	30	F	1/14/2021	1/14/2021	Anaphylaxis; persistent throat swelling; nasopharynx/oropharynx edema; difficulty breathing; difficulty swallowing; choking sensation; This is a spontaneous report from a contactable Physician. A 30-year-old female patient (pregnant: No) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231), via unspecified route of administration on 14Jan2021 at single dose for COVID-19 immunization. The relevant medical history included known allergies: sulfa from an unspecified date. Concomitant medications were not reported. The patient experienced anaphylaxis: followed by persistent throat swelling, nasopharynx, oropharynx edema causing recurrent difficulty breathing, choking sensation and difficulty swallowing on 14Jan2021. The events resulted in doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event). The patient underwent lab test included Covid which showed negative on an unspecified date post vaccination. The outcome of the events was unknown.; Sender's Comments: Based on a close chronological association a causal relationship between reported events and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
1019350	2/10/2021	MN	32	F	2/6/2021	2/6/2021	Body aches, fever, fatigue, swollen lymph nodes, soreness red and inflamed at injection site. Anaphylaxis later that night and next day
1019828	2/10/2021	NC		F	2/4/2021	2/4/2021	Systemic: Anaphylaxis-Severe, Systemic: Other-shortness of breath
1019967	2/10/2021	MD	68	F	2/10/2021	2/10/2021	Felt dizzy but states she was "very emotional" about getting her shot. HX of anaphylaxis from IV contrast. HR 100, O2 98%, BP 175/100. Declined observation and drove home.

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1020343	2/10/2021	NY	44	M	1/28/2021	1/28/2021	Patient arrived to ED via ambulance Patient is a 44-year-old male who presents to the emergency department for evaluation of an allergic reaction. Patient reports that he is in EMS paramedic and that he had received his second dose of the COVID-19 Materna vaccine today at approximately 10 AM. Since noon he noticed that he felt his ears tingling and that his skin became beet red and he broke out in hives. He has a history of recurrent allergic reactions and anaphylaxis. He went back to his EMS facility. He noted that it was starting to get worse and so he was given IV with Benadryl and a dose of epinephrine and transported to the emergency department. He still complains of itchiness and redness to his skin but says he feels better. He denied having any tongue swelling or lip swelling or shortness of breath or wheezing or abdominal pain or diarrhea. In the ED he also received dexamethasone 10mg IV and 1L IV 0.9% sodium chloride
1020379	2/10/2021	VT	79	M	2/9/2021	2/9/2021	PT states active lymphoma, sees Doctor. Did not discuss vaccine with PCP. Received verbal permission from Pt to contact D=providers. TC to Doctor's office, spoke with nurse, who states, spoke with Doctor who gave permission to vaccinate. 14:22 - After vaccination patient stood and stated he felt dizzy. Mentioned has a history of anxiety with vaccination. Rested while seated. After 5 minutes, c/o nausea, denies SOB, urticaria, or other SX anaphylaxis. Escorted via WC to first aid area. 14:33 VS: BP- 162/78 P 56 O2 Sat 98%. Provided rest / H2O. 14:45 - States SX resolved. VS - BP 164/72P - 52, O2 Sat 97%. Escorted to driver @ 15:00.

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1021251	2/10/2021	OH	40	F	2/5/2021	2/5/2021	Within 1 1/2 to 2 mins after receiving vaccine pt states starting having an anaphylaxis reaction. Immediately transported to the emergency department. Pt had audible wheezes and stridor noted. Patient was given EPI pen her rt outer thigh. IV started. Pt started having relief within 30 seconds. Wheezing and stridor was decreasing. Pt was also started on a racemic epi neb. Pt placed on monitor and oxygen monitor. One hour later the symptoms of feeling "throat was swelling off" returned and EPI 3 mg given and another racemic treatment given. Treated with solumedrol, Benadryl and Pepcid. Patient was admitted to the hospital where she remained overnight with no additional symptoms. She was released next day.

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1019834	2/10/2021	NJ	81	F	2/4/2021	2/4/2021	<p>Patient assessed and monitored by EMS on 2/4/2021 post vaccination: Chief Complaint: Difficulty breathing; tremors Secondary Complaint: Dizziness; full body weakness History of Present Illness: Patient was receiving COVID 19 vaccine. After injection, patient began experiencing labored breathing, full body tremors, and became extremely weak. Patient requested to be checked out. Medical History: Obtained From: Not Recorded Current Medications: None - Reported By Patient Allergies: Albuterol Lidocaine Sulfur Neurological Exam Level of Consciousness: Alert Loss of Consciousness: No Chemically Paralyzed: No Stroke Scale: Cincinnati Negative Mental Present: Oriented-Time, Oriented-Event, Oriented-Place, Oriented-Person, Normal Baseline for Patient Pupils Left, Right Size: Normal, Normal React: Reactive, Reactive Motor, Sensory LA: Normal, Normal RA: Normal, Normal LL: Normal, Normal RL: Normal, Normal Airway Status: Patent Performed By: Patient Outcome: Unchanged Respiratory Effort: Normal Sounds: L: Clear R: Clear Sounds: breath sounds clear all fields Cardiovascular JVD: Not Appreciated Cap. Refill: Less than 2 Seconds Edema: Not Appreciated Pulses Left, Right Carotid: Not Checked, Not Checked Radial: Strong, Strong Femoral: Not Checked, Not Checked Injury Details Reason for Encounter: Injury/Trauma Drugs/Alcohol?: None Initial Physical Findings Assessment Skin: Capillary Nail Bed Refill less than 2 seconds, Dry, Normal, Warm Skin Findings: Skin CTC normal, warm, dry, pink Left Shoulder Findings: Injection site of vaccine; no swelling noted Mental Status: Normal Baseline for Patient, Oriented-Event, Oriented-Person, Oriented-Place, Oriented-Time Impression / Diagnosis Symptoms: Breathing Problem, Tremor, unspecified, Weakness, Tachypnea, not elsewhere classified Impression: Dizziness, Weakness Initial Patient Acuity: Emergent (Yellow) Activity 15:40: HR=98, BP= 106/70, Alert, RA SpO2=99, Resp.= 22 Labored Crew was requested over to RN vaccine station to assess female patient presenting with labored breathing, slight tachypnea, full body tremors, and general body weakness. Patient had just received first dose of Moderna COVID-19 vaccine. Patient is AAOx4, (-)LOC, (-) signs of anaphylaxis. Patient is assisted onto stretcher, secured with straps x3 and side rails raised and brought over to ems triage area.</p>

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Patient denies any pain, complains of uncontrolled full body tremors. 15:47: HR=78, BP=134/90, Alert, RA SpO2=98, Resp.=20 Labored, Cincinnati Negative Crew assesses, patient shows no signs of anaphylaxis, lung sounds clear in all fields. Patient feels light headed and is lowered to supine position. Patient states she has had an episode similar to present in doctors office a few years ago when administered albuterol, and event had subsided approx. 30 minutes later. 16:01: HR=78, BP=136/p, Alert, Resp.= 18 Labored, Cincinnati Negative Vitals reassessed. Still above normal baseline for patient. 16:10: HR=80, BP=120/p, Alert, RA SpO2=98, Resp.=18 Labored, Cincinnati Negative Vitals reassessed, patient now showing full body involuntary tremors and complains of extreme weakness when moved to fowlers. Patient Cincinnati negative, no signs of anaphylaxis. Patient moved back to supine position. 16:18: HR=76, BP=122/68, Alert, RA SpO2=97, Resp.=18 Normal Vitals reassessed, breathing no longer labored, patient states she feels better and wishes to go to bathroom. Patient is assisted to bathroom with assistance from RN. 16:35: HR=74, BP=126/68, Alert, RA SpO2=97, Resp.=18 Normal Vitals reassessed, patient wishes to walk around and see how they feel, crew monitors. No tremors are noted for several minutes, patient now sitting fowlers on stretcher. Patient is advised that at any time they can call 911 if they feel they don't feel right or are unsure of condition. Patient is always made aware that ems crew does not diagnose and does not have the ability to see and diagnose underlying conditions that a hospital would have the capabilities to do so. After several more minutes of walking and discussion of patient condition, patient wishes to sign RMA , and go home with husband, daughter was waiting at residence. patient signs RMS, AMA, RN signs as witness. Patient care diminished. 2/5/2021 at 11:08am: Public health nurse called patient at for follow-up. Patient stated she was ?not steady on feet for a while? on prior night. Patient stated she started to feel ?back to normal? today. The only symptom patient is reporting today is feeling tired. Received verbal consent from patient to update her HCP, Dr. , about her reaction post vaccine. , RN

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1021530	2/10/2021		36	F	2/9/2021	2/9/2021	Pfizer-BioNTech COVID-19 Vaccine Anaphylaxis reaction Background -I have had one other anaphylaxis event in my history in reaction to horse dander many years ago. As such per the guidance I remained in the waiting room for 30 minutes. After 30 minutes I had a light rash on both forearms and near the injection site on my left upper arm. I felt fine otherwise. I went up to the nurse in the monitoring room and showed her the rash. She asked if I was having trouble breathing. At the time I was not. She said I could take Benadryl for the rash as long as I had no allergy to Benadryl. I started driving home. During my drive my throat started to feel itchy and irritated. It proceeded to get worse and when I looked at my throat in the mirror it was very red and starting to be visibly swollen. I drove to the nearest hospital and checked myself in to the emergency room.
1020385	2/10/2021	NJ	36	F	1/26/2021	1/26/2021	Anaphylaxis While driving home: difficulty breathing, tightness in chest, swelling of tongue and lips, difficulty swallowing, tingling in left arm
1021050	2/10/2021		43	F	2/1/2021	2/1/2021	Patient reported rash developing on face within 24 hours of vaccination. No lip/tongue edema or other sign of anaphylaxis. Patient given oral antihistamine, symptoms resolved. Patient was monitored for anaphylaxis and released once no signs and symptoms of anaphylaxis were noted.
1020732	2/10/2021	OR	36	F	2/8/2021	2/8/2021	Per COVID Vaccine Clinic nurse, employee/pt was screened for ASE and asked to stay for 30 minutes after immunization at 1430 on 02/08/2021; pt did not report any s/sx of anaphylaxis and left the COVID Vaccine Clinic at 1500 on 02/08/2021. Per Dr. from Care Center, which is located in the same building as the employee's COVID-19 Vaccine Clinic, pt returned at 1545 on 02/08/2021 reporting "generalized itching as well as nausea and feeling of swelling and itching n her throat and bilateral ears." She was treated by employer's ICC for s/sx of anaphylaxis and given epinephrine 1 mg/mL 0.5 mL IM, cetirizine 10 mg PO, and Prednisone 60 mg PO. Per ICC, pt was monitored for 1 hour, symptoms resolved, and she was advised to "go to the ER if she has return of symptoms, but this is unlikely.~~

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1020682	2/10/2021	CO	50	F	1/21/2021	1/21/2021	After receiving the COVID-19 vaccination the patient experienced the following adverse events during the 15 minute observation period post-vaccine administration: rash/urticaria, itching and difficulty breathing. Patient at 15 min post injection complained of throat fullness, itching, flushing, rash to chest area. Vital signs stable with Pulse ox at 100%. Rapid response called. Patient taken to ED for more in depth evaluation. Patient received epinephrine IM, methylprednisolone, famotidine, diphenhydramine. Patient had slight recurrence of some throat itching approximately 3 hours post arrival to ER. Given oral diphenhydramine & symptoms resolved. After 4 hours of observation there was no recurrent anaphylaxis. Patient was discharged with prescriptions for EpiPen & oral prednisone.
1020460	2/10/2021	NC	31	F	2/9/2021	2/10/2021	Had tongue numbness, paralysis for a short period of time today. Concern for anaphylaxis due to proximity to throat. Pain around top of head in the shape of a semicircle. Very tired, weak. Drained.
1022902	2/10/2021		72	M	1/19/2021	1/29/2021	death Narrative: 71 yo male who passed away on 1/29/2021, medical cause of death "cholangiocarcinoma, interval between onset and death 14 months. Since patient passed away within 42 days of the covid19 vaccine administration, we are required to complete a report to VAERS. Vaccine (Pfizer) was administered without complications. The patient denied any prior severe reaction to this vaccine or its components or a severe allergic reaction such as anaphylaxis to any vaccine or to any injectable therapy. Synopsis- 1/23 71 yo male presented to ED with upper GI bleed. PMH: DM, HTN, cholangiocarcinoma of biliary tract requiring recurrent paracentesis, COPD, perigastric and lower esophageal varices (not on beta blockers due to bradycardia). Pt has had 2 episodes of coffee ground emesis. Lactic 2.6, ammonia 52. Rec'd protonix, octreotide, and ceftriaxone in ED. Family has been previously encouraged to speak to palliative care but has never been willing to. GI consulted. 1/24 EGD completed. No signs of active bleed. MDs recommending hospice. CT + for small bowel ileus. 1/26 Requires placement of NG tube to suction. Palliative care consulted. 1/27 Paracentesis completed. 4100mls removed. 1/28 Pt changed to palliative status. 1/29 Pt passed away.

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1017200	2/9/2021	IN	47	F	1/5/2021	1/19/2021	She began having hives (urticaria) one week after first dose of vaccine. It was assumed that terbinafine caused hives, so these were stopped. She got second vaccine on 2/2/21 and had a spreading of the hives. No angioedema or SOB, wheezing, and no anaphylaxis symptoms occurred.

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1017743	2/9/2021	WA	69	M	2/6/2021	2/6/2021	69 YO M CARDIAC ARREST. PT HAD JUST RECEIVED HIS COVID VACCINATION AND WAS PULLING INTO THE OBSERVATION AREA WHEN HE LOST CONTROL OF HIS TRUCK, BECAME UNCONSCIOUS AND CRASHED INTO A LIGHT POLE. THIS OCCURRED IN FRONT OF THE STANDBY MEDIC UNIT AND OTHER FIRE DEPT STAFF. PT WAS IMMEDIATELY REMOVED FROM THE VEHICLE AND THE PATIENT WAS DETERMINED TO BE IN CARDIAC ARREST. CPR WAS INITIATED WITHIN SECONDS OF BEING REMOVED FROM THE VEHICLE. EMS WAS IMMEDIATELY AVAILABLE AND THE PATIENT WAS DEFIBRILLATED FOR WHAT APPEARED TO BE A SINE WAVE VT/COURSE VF WITHIN ONE MINUTE OF HIS ARREST. PT WAS PLACED ONTO A BACK BOARD AND MOVED TO AMBULANCE IN A PULSED VT AND WAS AWAKE AND RESPONSIVE. ONCE IN THE BACK THE PT WAS WIRED INTO THE FOUR LEAD AND WAS SYNCHRONIZED CARDIOVERTED AT 100 J WITH A CONVERSION TO A PULSED JUNCTIONAL RHYTHM WITH A RATE OF ABOUT 58. THIS RHYTHM CHANGED INTO A SINUS TACH AT ABOUT 100 BPM. IV ACCESS WAS OBTAINED AND 100 MG LIDO BOLUS WAS ADMINISTERED WITH A 2:1 LIDO DRIP HUNG. AMBULANCE BEGAN TRANSPORT TO ER. OVER NEXT SEVERAL MINUTES PT BEGAN HAVING VENTRICULAR ECTOPY IN THE FORM OF PVCs COUPLETS AND EVENTUALLY 4-5 BEAT RUNS OF VTACH WHILE ON PHONE WITH ER MD. DISCUSSED GIVING ANOTHER BOLUS OF LIDO AND INCREASING DRIP TO 3:1 DUE TO INCREASING VENTRICULAR ECTOPY. THE ER PHYSICIAN CONCURRED AND ANOTHER 75 MG LIDO BOLUS WAS GIVEN FOLLOWED BY INCREASING THE DRIP RATE TO 3MG/MINUTE FOLLOWING THE SECOND LIDO DOSE AND DRIP ADJUSTMENT THE PATIENT'S VENTRICULAR ECTOPY RESOLVED AND THE PATIENT REMAINED IN A SINUS RHYTHM / SLOW SINUS TACH THROUGHOUT TRANSPORT AND TRANSFER OF CARE TO THE ER. A 12 LEAD WAS OBTAINED JUST PRIOR TO ARRIVAL IN ED THAT SHOWED SINUS TACH WITHOUT VENTRICULAR ECTOPY BUT WHAT APPEARS TO BE PACs, FLIPPED T WAVES IN aVL, AND ST DEPRESSION IN V4, V5, V6. PT WAS MOVED

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FROM AMBULANCE TO ER AND CARE TRANSFERRED TO ER MD AND STAFF. HEENT - WHEN PT WAS FIRST PULLED FROM VEHICLE HE WAS UNCONSCIOUS, NOT BREATHING, AND PULSELESS, PT WAS BRIGHT RED BUT DID NOT APPEAR TO HAVE HIVES ON FACE/NECK OR ANGIOEDEMA. CX - PT WAS BRIGHT RED FROM THE NIPPLE LINE UP, NO OBVIOUS HIVES, EKG QUICK COMBO PADS ATTACHED AND PT'S INITIAL RHYTHM WAS WHAT APPEARED TO BE A TORSADES LOOKING VT OR VF WITH THE CHARACTERISTIC SINE WAVE PATTERN. EXTREM - PT WAS PWD, WITH PULSED VT HAD RADIAL PULSES, NO PURPOSEFUL MOVEMENT AT THAT TIME. DUE TO THE PATIENT RECEIVING THE COVID VACCINE MINUTES BEFORE THE PT'S ARREST AND THE BRIGHT RED/FLUSHED APPEARANCE FROM THE NIPPLE LINE UP AN ALLERGIC REACTION/ANAPHYLAXIS (ALTHOUGH UNLIKELY) WAS CONSIDERED BUT AS THE PATIENT DID NOT HAVE ADDITIONAL SIGNS OR SYMPTOMS IT WAS DECIDED OBSERVE PT FOR ADDITIONAL OR WORSENING SIGNS AND WITHOLD ANY TREATMENT FOR SAME UNTIL/UNLESS ADDITIONAL S/S PRESENTED. THIS WAS LATER DISCUSSED WITH ER MD AND HE CONCURRED. R/O SUDDEN CARDIAC ARREST WITH ROSC EXAM, CPR, DEFIB, MOVED TO MEDIC UNIT, OXYGEN 15 LPM NRB, SYNCH CARDIOVERSION, VS, IV X3, LIDO BOLUS AND 2:1 DRIP, TX SPH ER, BASE CONTACT WITH ER PHYSICIAN, 2ND LIDO BOLUS AND DRIP INCREASED TO 3:1, 12 LEAD, TRANS CARE TO ER MD AND STAFF

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1015641	2/9/2021	NC	51	F	1/19/2021	1/19/2021	yesterday started a flare up but she is not sure if this is related to the vaccine use; fever/was 105.00 with Tylenol; increased dizziness/light-headed; body aches; severe headache; nausea; chills; sweating/sweats; Fatigue; feeling crappy; blood pressure tends to be low but was 95/81 at the time she got the shot; The initial case was missing the following minimum criteria: no adverse effect. Upon receipt of follow-up information on 25Jan2021 this case now contains all required information to be considered valid. This is a spontaneous report from a contactable consumer. A 51-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EL3247, expiration date was not reported), via an unspecified route of administration on 19Jan2021 17:45 at single dose on the left arm for COVID-19 immunization. Medical history included ongoing severe Crohn's disease, pneumonia, allergy to eggs/anaphylactic reactions to eggs, anaphylactic with bee stings on 2020 (this has happen twice in 2020), collapsed her lung (reaction to anesthesia that collapsed her lung), high fever, anaphylactic reactions. Concomitant medication included sertraline (SERTRALINE), cetirizine hydrochloride (ZYRTEC [CETIRIZINE HYDROCHLORIDE]). The patient previously took Hep B and experienced fever, flu like symptoms, achy, and lethargic (no issue with the first 2 doses but with the 3rd dose she had a high fever); MMR and had an adverse reaction. It was reported that the shot was given on 19Jan2021. She experienced the following severe dizziness which started that day (17:45) and lasted 3 days. It has resolved. Nausea which started that day (17:45) and stayed constant for 3 days. Now it has only been happening in the late afternoons or evenings. Light headed which started that day and last 3 days. Headache (17:45), the initial headache felt like her whole head was going to explode into a 1000 piece. Now it just starts about 4-5pm in the evening. It was better and not as severe but like a migraine with nausea (17:45), feeling crappy (17:45), and body aches. Body aches which started on the day of the shot (17:45) and lasted 3 days. Fatigue which started on the day she got the shot (17:45) and was ongoing in the evening now chills and sweats which started on the day she got the shot and was ongoing. Her husband asked about if this was being related to the change of life but she doesn't think so.

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Fever which happened on the day she got the shot (17:45) but not at the site, later that night and was 105.00 with Tylenol. It has resolved. She noted that her blood pressure tends to be low but was 95/81 at the time she got the shot (17:45). The patient has not taken her blood pressure and does know if this has resolved. It was relayed that she took Tylenol and Benadryl before the shot due to her history and was still taking it as treatment for the symptoms. She has a lot of drug and other allergies, the only that was anaphylaxis was bees and egg. This was why she brought 2 EpiPens when she had the shot. She didn't have to use her EpiPen and was really proud of that but did have some reactions. The patient reported she did not go to the doctor. At this point she was somewhat expected that she had a not great reaction so the fact that she could still breath after getting it was a good thing. She also noted she could not have driven home due to dizziness. The patient was not brought to the emergency room and did not went to a physician's office. The patient has an ongoing medical history of Crohn's disease and reported that yesterday (as reported) started a flare up but she was not sure if this was related to the vaccine use. The patient recovered from fever on 23Jan2021; was recovering from dizziness, body aches, severe headache, nausea, chills, sweating, and fatigue; while outcome of blood pressure tends to be low, feeling crappy and Crohn's flare up was unknown.

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1015650	2/9/2021	AL	37	F	1/25/2021	1/25/2021	1st dose: 01Jan2021/ 2nd dose: 25Jan2021; Angioedema and systemic anaphylaxis; Angioedema and systemic anaphylaxis; itchy face; Lips swollen; itchy mouth; tongue tingling; This is a spontaneous report from contactable Pharmacists. A 37-years-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number: EN5318, Exp Date: 31May2021) intramuscular in right arm on 25Jan2021 15:45 at single dose for COVID-19 immunisation. She received the first dose on 01Jan2021 for COVID-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient is not pregnant. The patient did not receive any recent vaccines for any other conditions prior to the event being reported. The patient experienced angioedema and systemic anaphylaxis on 25Jan2021, events resulted in emergency room/department or urgent care. The signs and symptoms of the anaphylactic reaction were described as itchy face and mouth 20-30 minutes after the vaccination, lips swollen, tongue tingling. Patient was scared and crying. Her lips started to swell. The patient require medical intervention, the patient was seen in the emergency department. It was unknown if the patient hospitalized, the patient was not admitted to an Intensive Care Unit. It was unknown if the patient received treatment. The patient did not receive any recent vaccines for SARs-CoV2 other than Pfizer-BioNtech Covid-19 Vaccine prior to the event being reported. Events outcome was unknown.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of serious events cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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1015988	2/9/2021	MA	33	F	2/8/2021	2/8/2021	Patient reported mild headache after ~10 minutes after vaccine administration, and lip numbness ~15 minutes after vaccine administration. Vitals 167/52, O298%, HR 67. Patient was evaluated by Dr. ~20 minutes after administration and monitored for 45 minutes. Headache and lip numbness resolved during observation period. Patient remained well appearing throughout. Reviewed s/sx anaphylaxis, advised her to call 911 if these occur at all today.

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1016608	2/9/2021	PA	30	F	1/13/2021	1/16/2021	sudden onset lower lip angioedema- only on the right side of my lip; This is a spontaneous report from a contactable Other HCP. This other HCP reported different events for the same patient during different vaccination dose. This case is referred to the second vaccine dose A 30-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number EL3247 intramuscular on 13Jan2021 12:30 second dose at SINGLE DOSE for covid-19 immunisation. Facility type vaccine: Hospital . Vaccine location: right arm Medical history included asthma, eczema, hypersensitivity, anxiety and depression. Concomitant medication included ethinylestradiol, norethisterone acetate (JUNEL FE 1/20), bupropion hydrochloride (WELLBUTRIN XL), fluoxetine hydrochloride (PROZAC), rizatriptan (RIZATRIPTAN), salbutamol sulfate (ALBUTEROL [SALBUTAMOL SULFATE]), fluticasone propionate (FLONASE [FLUTICASONE PROPIONATE]), levocetirizine dihydrochloride (XYZAL), betamethasone (BETAMETHASONE). The patient previously took aspirin and experienced rash. The patient experienced flushing, palpitations and hyperhidrosis after the first dose of bnt162b2 vaccine. The patient experienced sudden onset lower lip angioedema- only on the right side of my lip on 16Jan2021 20:30 with outcome of recovered. The action taken was not applicable. Therapeutic measures were taken: benadryl inhaler self treated, consultation w/allergist and allergy testing. The reporter stated "developed sudden onset lower lip angioedema only on the right side of my lip. I took 50mg benadryl and my inhaler and monitored- I never developed itching, additional swelling, difficulty breathing or other symptoms of anaphylaxis. Swelling had resolved by morning. I had no other new exposures that have yet been identified, although I am going through a work up with an allergist."; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021073355 Same patient/ drug, different dose/AE.

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1016746	2/9/2021	CA	37	F	2/5/2021	2/6/2021	2/9/21 0800 Pt called regarding delayed rxn to vaccine moderna. Pt rcv'd moderna 2nd dose on 2/5/21 and developed sx's 2/6/21 around 1700-1800. Pt contacted PCP. PCP stated it was a delayed rxn to vaccine. PCP informed pt to tx with tylenol, ibuprofen, benadryl and cold compress. PCP also informed pt to go to ED for anaphylaxis sx's. Pt reports hx of rxn to previous vaccination. Pt stated 1st vaccination of moderna was not severe. Pt sx's verbally reported following 2nd moderna dose: -swollen lymph nodes in neck and axillary region -streaking on arm of injection -rash on arm of injection -fevers 101-102 -chills -diarrhea -H/A -Muscle pain -ear pain and swelling
1017075	2/9/2021	CA	33	F	2/8/2021	2/8/2021	Systemic: Other- patient had blueness in one hand, states she had problems breathing, and vomiting, epipen was given and paramedics were called, she was taken to the hospital, not believed to be anaphylaxis
1017430	2/9/2021	MA	63	F	2/5/2021	2/5/2021	Systemic: Anaphylaxis- Medium
1017478	2/9/2021	AZ	44	F	2/6/2021	2/6/2021	Provider stated patient had anaphylaxis (facial swelling) at around 2:16, 1 dose epi pen was administered and rapid response called. Patient was transported to the ed . Per providers note, developed sensation of Facial swelling, lip swelling, tongue swelling and difficulty breathing

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1017754	2/9/2021	OH	27	F	12/28/2020	12/28/2020	Employee became SOB and warm soon after vaccination. Helped to floor; O2 at 2L per N/C started. HR elevated; having difficulty breathing so EpiPen 1:1000 given IM in left thigh. Adult code blue called. Code team arrived within 30 seconds to one minute and employee transported to ER via gurney. Per ER Notes: DEXAmethasone (DECADRON) 10 mg/mL injection for oral use 10 mg (10 mg Oral Given 12/28/20 1301) Patient is in no acute distress, states that she feels well. History and physical exam as above. Patient states that her symptoms have resolved as of arriving in the emergency department. We will assume that this was an anaphylactic reaction, she was not given time to develop all signs and symptoms of anaphylaxis, however she was given an EpiPen and her dyspnea rapidly improved and therefore we will treat her as if she experience anaphylaxis. She will be kept in the emergency department for 6 hours for observation, she was given 10 mg of p.o. Decadron. At the time of my shift change she continued to be hemodynamically stable, awake, and talkative. She still required ~3 hours of observation at that time. I saw this patient with attending physician, please see her note for ultimate disposition or further developments.
1018152	2/9/2021	VA	47	F	1/16/2021	1/17/2021	Anaphylactic Reaction

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1022302	2/9/2021	WA	45	F	1/2/2021	1/11/2021	<p>Briefly, patient had severe side effects until 16 days post vaccination #1, when she developed hives.</p> <p>Unfortunately, by that time, an new medication had been introduced which clouded the picture as to which product was the offending agent. Please see continuation page for further details. Chronologically, the events occurred as follows: Day 1, 01/02/2021, first shot, Right Deltoid. Headache (HA), muscle cramps, especially right side of neck and right trapezius area (expected side effects).</p> <p>Day 9, 01/11/2021, Right upper arm(posterior) deltoid area, red, hot, swollen, but no itching or significant pain. Erythema covers greater than half the circumference of the upper arm. Center of erythema is the injection site.</p> <p>Day 11, 01/13/2021, Patient see her Ophthalmologist for xerophthalmia, possibly secondary to ocular rosacea, given Rx for Doxycycline 100mg, 1 BID x 14 days. Has not taken Doxycycline previously. No know sensitivity.</p> <p>Day 13, 01/15/2021, Hives. Started on chest. Patient adds liquid Benadryl and OTC Cortaid HC topical cream (hydrocortisone) 0.5% to daily medications. Breathing has not been affected. Day 19, 01/21/2021, First patient visit with history as above, Is it the vaccine or the Doxycycline that has caused the hives? Consider the vaccine but the Doxycycline is more likely because of timing. Discontinue the Doxycycline. Day 19, 01/21/2021 continued, Start prednisone taper per usual instructions for asthma (10mg tabs, # tabs: 5/d, 4/d, 3/d, 2/d, 1/d, 1/2/d x 4d and stop). Rx for mometasone topical ointment 0.1% use until hives/discomfort resolved. Continue other allergy medications. Discontinue the Benadryl (too sedating). Until this time, reactions were considered at the upper end of expected side effects for the vaccine, i.e. redness around injection side, HA, muscle cramps. (? Will taking the prednisone cause the vaccine to be ineffective? Unknown.) Since the allergen is considered to be Doxycycline, and the patient works at a large medical facility, she is advised to get the second dose of vaccine as planned. Day 21-22, 01/23-24/2021, Hives gone within 48 to 72 hours of starting prednisone taper; Day 24, 01/26/2021, Second shot. Covid19, Moderna, Lot # 042L20A, Intramuscular, Right Arm. Hives begin within 12 hours of vaccination. More extensive than first hives. Continue all meds. HA and cramps worse than with first shot, patient told that this is common. No respiratory distress. The VAERS report asks about</p>

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							vaccines given with the previous month, but does not ask about subsequent months or vaccines requiring more than one injection. Day 25, 01/27/2021 day 2 after 2nd shot, Second patient visit. Increase prednisone back to 20mg/day, Rx written to cover extra tabs needed. Hives over trunk, anterior and posterior, and beginning to appear on extremities. No respiratory distress. Rx for updated EpiPen which she carries for asthma and allergic reactions. Has had two episodes of anaphylaxis, unknown etiology, in the distant past, i.e. years ago. Day 33, 02/04/2021 or day 3 after 2nd shot, 3rd patient visit. Hives gone by Day 28, 01/30/2021, Saturday, 72 hours after prednisone increase to 20mg QD. Feeling better. Gather info for VAERS. Patient brings shot record from work, where shot was given for lot numbers. Day 34, 02/05/2021, Day 10 after second shot, Hives are back at 0200. They awaken patient from sleep because she feels her skin is "on fire." They are more extensive than the second episode, including buttocks and face this time. No respiratory distress. She increases the prednisone to 50 mg per day for the next 2 days. Since the hives are not improving she goes to an ER/Clinic. The ER doctor has her begin taking 40mg prednisone per day for the next 5 days and then discontinue. Day 38, 02/09/2021, day 14 after second shot, Spoke with the patient on the phone. Hives had resolved by 72 hours. Has been back to work and is doing "OK," at the moment. She needs to restart the doxycycline but I advise she wait a full 2 weeks after this current resolution of the hives before re-trying the antibiotic in the event that she is sensitive to both the vaccine and the doxycycline. And to be prepared, that she may have hives again within 48 hours of starting the doxycycline.
1017402	2/9/2021	OH	52	F	2/9/2021	2/9/2021	Patient received 1st dose 3 weeks prior without reaction. She received second dose today at approximately 11:30am. She felt fine after the second vaccination, until about 1:30-1:45pm. Patient c/o a "heat rush", headache, and hives on BUE. Patient vitals were WNL except HR was slightly tachycardia at 107bpm. Respirations were baseline at 18. Patient denies SOB/anaphylaxis. Benadryl administered orally, and monitored. No reaction was had with the first vaccine.

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1010718	2/8/2021	FL		F	1/9/2021	1/1/2021	<p>Arm at the site a little bit above the elbow where biceps are, were sore.; slight headache; exhausted; bad cold/cold type symptoms; upper respiratory infection with a sinus infection; upper respiratory infection with a sinus infection; mild respiratory infection; not feeling well; like a viral cold; nausea; This is a spontaneous report from a Pfizer sponsored program via a contactable consumer (patient). A female patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiration date not provided), via an unspecified route of administration (anatomical location: arm) on 09Jan2021 at SINGLE DOSE for COVID-19 immunisation. Patient's medical history included psoriatic arthritis from an unknown date and unknown if ongoing. Concomitant medication included paracetamol (TYLENOL). It was reported that patient wanted to know if she should get the second vaccine in the series. Patient mentioned that she had the first Pfizer Covid vaccine 09Jan2021. Approximately three weeks later, she developed a mild respiratory infection. It was mentioned that patient has psoriatic arthritis (one Dr told her she would experience more symptoms getting the second dose- another Dr told her she could die) and her physician wants her to start methotrexate, however, she is not currently taking this product. Patient is currently only taking paracetamol. Patient also mentioned that she had three friends who had the Pfizer Covid vaccine and they felt awful like they had the flu for 48 hours post vaccination. Patient asked if there was no allergic reaction to the first vaccine, will there be no allergic reaction to the second vaccine. Patient also asked if it is okay to start on methotrexate after having the vaccine and if this will decrease effectiveness. On an unknown date in Jan2021, patient stated she is not feeling well last night, something like a viral cold. Patient also stated "It was not bad at all. Arm at the site a little bit above the elbow where biceps are, were sore, slight headache the day after the 1st dose, after 3-4 hours I was exhausted, 2 days exhausted, maybe slightly nausea". Patient also mentioned Thursday night that she had a very bad cold from the beginning and has upper respiratory infection with a sinus infection. It was also reported that patient was not on immunosuppressants and has never had anaphylaxis. It was also reported that patient had swelling in her hand from the arthritis. On 21Jan2021, it</p>

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							was reported that patient went to urgent care with upper respiratory symptoms and a COVID test was performed which was negative. Patient stated that she is to have #2 covax this coming Saturday and is still dealing with some cold type symptoms and asks if she should get the second covax. Patient is not running a fever. Outcome of the event 'bad cold/cold type symptoms' was not recovered, outcome of the remaining events was unknown. Information on lot number/batch number has been requested; Sender's Comments: Based on the temporal relationship, the association between the event upper respiratory tract infection with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
1014642	2/8/2021		47	F	2/4/2021	2/4/2021	Experienced pruritis immediately after injection. Pt had pruritis with first vaccine 1/15/21 however, did not report symptoms and took Benadryl 50mg po and symptoms resolved on their own. Pt thoroughly examined, no swelling noted to tongue, lips, uvula midline, vss, no urticaria present, no nausea. Pt. Given 25mg po of Benadryl and observed for 30 mins: after and remains without s/s of anaphylaxis. Pt. Reports improvement of itching.
1012722	2/8/2021	CO	40	M	2/5/2021	2/6/2021	Elevated heart rate (130 at rest for 10+ hours, my normal is 70-80) Elevated blood pressure (150/89 at rest for 10 + hours, my normal is 110/70) Extreme headache, light sensitive Nausea Mild anaphylaxis itching/burning/tingling in lips, tongue and throat Feeling of intoxication, disoriented, slurred speech, dizziness Rash/redness that spread beyond injection site on to back of shoulder Agitation Itchiness Peeling of skin in mouth/cheeks Blisters on roof of mouth Chest tightness with normal breathing Jaw pain Treatment as listed below; continue with Benadryl every 6 hours and ibuprofen; return if symptoms continue or worsen

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1009995	2/7/2021	OH	59	F	2/6/2021	2/6/2021	Adverse event: Anaphylaxis reaction. High blood pressure. Body shivering. Rash on neck and chest. Treatment: dexAMETHasone sodium phos (PF) given at 4:49 pm. diphenhydrAMINE (Benadryl) given at 4:46 pm. famotidine (PEPCID) given at 4:47 pm.
1008908	2/7/2021	MO	65	F	2/4/2021	2/4/2021	Patient received Moderna COVID Vaccine. Minutes after receiving the vaccine, patient reported swelling in throat and a cough. Patient took an Epi-Pen, 50mg injectable diphenhydramine, and 20mg famotidine. EMS was activated. Upon arrival, EMS administered 125mg Solu-Medrol and 25mg additional diphenhydramine. Patient was taken to ED and observed for 2 hours. Labs were drawn, charted diagnosis was anaphylaxis.
1008728	2/6/2021	OR	60	F	2/6/2021	2/6/2021	Patient stated that she had a tight and tingly throat. Patient was evaluated. Was in no respiratory distress and vital signs were stable. Patient had no skin rash and no evidence of anaphylaxis except for subjective tightness of throat and hoarseness of throat. Patient evaluated by EMS. She was given IM diphenhydramine and was told to go to ER for further evaluation. Patient refused ambulance transport and said she would be taken by her husband.
1008686	2/6/2021	NM	59	F	1/24/2021	2/1/2021	A patient called and informed me that she received the Moderna Covid-19 vaccine 2 weeks ago (1/24/20) and one week later, around 2/1/20 her arm started to get red around the injection site. The patients stated around 2/3/20 the redness started to subside but was itchy so she thought she may have been bitten by an insect and started applying rubbing alcohol to right deltoid daily. The patient stated, since 2/3/20, the redness has grown down her arm to her bicep. I instructed the patient to take Benadryl and informed the her of the signs and symptoms of anaphylaxis and when to seek medical attention. I also instructed the patient to report the reaction to her Doctor. A couple hours later the patient presented to the pharmacy and showed me the rash on her arm. I showed the patient where the Benadryl is located and how to take it. I called the patient 5 hours later and the patient stated that she has taken one dose of Benadryl and the rash has somewhat reduced in size.

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1008241	2/6/2021	CT	60	F	1/2/2021	1/27/2021	On 1/27/2021 was to have stress echo done with imaging -- when injected with Lumason -- I had an immediate, severe anaphylaxis shock requiring transport to hospital, intubation, and short MICU stay -- was referred to allergist who felt the PEG in Covid vaccine sensitized me to the PEG in Lumason thus resulting in severe allergy
1006541	2/5/2021	FL	54	F	2/5/2021	2/5/2021	Itching on head, arms and back. BP 160/100, feels warm. P 88. Due to anaphylaxis in past called 911
1005304	2/5/2021	PA	35	F	2/3/2021	2/3/2021	Began shaking and face tingling 6 minutes after shot, started to feel slightly better. 10 minutes after shot, neck became red, red welts appeared on bilateral upper arms. took 25mg of po benadryl at my desk. 25 minutes after shot felt hot, dizzy, arms and legs tingling, breathless, limbs went numb, rushed to ER via wheelchair. Treated in er for anaphylaxis. Arms and legs felt covered in "icy hot," tachycardia for several hours, numerous times felt impending doom. hospitalized overnight on cardiac monitor. ER gave steroids, benadryl, pepcid, 2L ivf. ativan given later in evening for nervousness.
1006697	2/5/2021	VA	78	F	2/4/2021	2/5/2021	chest pain with throat irritation 1 day after receiving vaccine. no anaphylaxis. symptoms resolved.
1006063	2/5/2021	CA	49	F	1/27/2021	1/27/2021	Pfizer-BioNTech COVID-19 Vaccine EUA She has h/o anaphylaxis to flu vaccine and 5 minutes after COVID vaccine she experienced SOB, throat and tongue itching, flushing, very anxious, her BP 144/102, HR 120s, RR 20. She had Epi-pen and we injected it for her per her request. She transferred herself to a wheel chair and went to ER with Crisis Nurse. Symptoms resolved. Patient discharged from ED.
1005627	2/5/2021	MI	64	F	2/5/2021	2/5/2021	Anaphylaxis - treated with epipen.

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1005346	2/5/2021	NY		F	1/9/2021	1/9/2021	Anaphylactic reaction; A spontaneous report (United States) was received from a consumer who is a female patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced an anaphylactic reaction. The patient's medical history included allergy to azithromycin (hives). Concomitant medications were not reported. On 09 JAN 2021, the patient received her first of two planned doses of mRNA-1273 (Batch number: unknown) for the prophylaxis of COVID-19 infection. On 09 JAN 2021, while sitting in the waiting area, 8 to 10 minutes after the injection, the patient experienced warm feeling, tongue getting bigger and collapsed. She was given intravenous medications and health care professionals were monitoring her vitals. The patient was transported to emergency via ambulance and was given two doses of EpiPen in the ambulance and by the time she arrived hospital she was doing better and was discharged after 4 hours. Treatment provided included EpiPen and intravenous medications. Action taken with mRNA-1273 in response to the event was not reported. The outcome of event anaphylactic reaction was unknown.; Reporter's Comments: This case concerns a female patient of unknown age with relevant medical history of allergy to azithromycin who received her first of two planned doses of mRNA-1273 (Batch number: unknown) for the prophylaxis of COVID-19 infection and experienced a serious medically significant unlisted event of an anaphylactic reaction within 8-10 minutes after the injection. The reaction was described as warm feeling, tongue getting bigger and collapsed. Patient was transported to ER and given two doses of EpiPen while in the ambulance. By the time she arrived at the hospital, she was doing better and was discharged after 4 hours. Treatment also included IV medications. Based on temporal association between the use of the product and the start date of the event within 8-10 minutes after the vaccine administration, a causal relationship cannot be excluded and the event of anaphylaxis reaction is possibly related.

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1007072	2/5/2021	AZ	32	M	1/27/2021	1/27/2021	<p>Patient received his vaccine and was waiting in the post-vaccination waiting space. Within 5-10 minutes he slumped in his chair and became unresponsive. Became responsive to voice but was slurring his words. Patient was diaphoretic. HR in 90s, O2 98%. His eyes rolled back in his head suspecting vasovagal episode, we moved patient to the floor and raised his legs. He became more responsive. Was fully oriented although did not seem incredibly alert. Cycled multiple BPs with 100s-110s/60s-70s. HR 70s-80s supine, O2 sat 96-98%. EMS was called for transport to ED given patient's lack of prompt recovery. We attempted to sit patient up and he again became lightheaded and had to lie back down. While in supine position, remained with normal and stable VS. At no time did he manifest any rash, respiratory symptoms, throat or chest tightness, abdominal discomfort, or other overt signs of anaphylaxis. Patient was transported to the ED where ROS was reported as: - CONST: +fatigue, denies fevers or chills - EYES: Denies vision changes - ENT: Denies rhinorrhea, sore throat - CV: Denies new chest pain - RESP: Denies SOB or cough - GI: Denies abd pain, n/v, diarrhea - GU: Denies dysuria - MSK: Denies new joint swelling or pain - SKIN: Denies new lesions or rash - NEURO: Denies new HA, numbness, or weakness - PSYCH: Denies suicidal ideation Vitals: BP 116/67, O2 99% on RA, Temp: 97.7F, Pulse 79. ED provider felt this was most likely vasovagal episode given occurrence following vaccine administration and associated sx's. EKG without evidence of dysrhythmia. No PE risk factors, SOB or CP. Pt with HA that was not thunderclap nor severe in nature and was consistent with prior migranes, thus do not suspect SAH. No hx to suggest anemia and no anemia on blood work today. No report of seizure. Pt is alert without report of post-ictal period.</p>

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1005074	2/5/2021	MA	61	F	2/2/2021	2/2/2021	employee presented to Covid Vaccine Clinic for 2nd Moderna vaccine. Following administration sx onset began at 0845: dizziness, a feeling of a "headrush", feeling faint. 0846, BP 100/70, HR 85, shaky. "I just don't feel right, I can't describe it. I feel like my heart is racing, My head feels really weird. My throat feels like it has a little tickle but I can't be sure." NO h/o anxiety, panic, anaphylaxis. 900 am "my throat feels like it is swelling on the inside~~
1004252	2/5/2021	NY	69	F	1/20/2021	1/20/2021	I had the sensations of facial tingling; eye swelling; lip swelling; This is a spontaneous report from a contactable Nurse. A 69-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EL3247), via an unspecified route of administration on the right arm on 20Jan2021 08:15 at a SINGLE DOSE for covid-19 immunisation. Medical history included drug hypersensitivity from an unknown date and unknown if ongoing known allergies: Sulfa and allergy to animal (cats) from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. On 20Jan2021 08:45 AM, the patient stated, "I had no symptoms during the 15 minute observation after the vaccine. After leaving the site, about 30 minutes after the shot I had the sensations of facial tingling, eye swelling and lip swelling (nothing visible on a photograph). My pulse remained stable and I had no throat symptoms or trouble breathing. This all resolved spontaneously within an hour after the shot. I am allergic to cats and sulfa but have never had anaphylaxis. I plan to stay in observation for a little longer after the 2nd shot. Any other recommendations?" No treatment was received for the events. The outcome of the events was recovered on 20Jan2021.

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1004406	2/5/2021			F	12/30/2020	12/30/2020	<p>little nervous; little more scary for her as she is kind of scared of anaphylaxis, normal anxiety range; sensation of throat fullness and tingling with a strange itchy feeling; sensation of throat fullness and tingling with a strange itchy feeling; sensation of throat fullness and tingling with a strange itchy feeling; allergic reaction; This is a spontaneous report from a contactable psychiatrist reported for herself and another physician and consumer. This female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number unknown) via an unspecified route of administration on 30Dec2020 as a single dose for COVID-19 immunisation. Medical history included occupational exposure to COVID-19. The patient had been taking care of patients as a psychiatrist throughout this COVID-19 pandemic. Concomitant medications were not reported. The patient experienced a sensation of throat fullness and tingling with a strange itchy feeling about 10 minutes after the vaccine was given on 30Dec2020. The patient was monitored in the emergency room (ER) for six hours and did not need to give epinephrine (EPIPEN) or antihistamines and she was sent home. By the next morning, her throat was back to normal. The patient reported that she knew at least three other people who had the same reaction and had heard others too (AER 2021058666). The patient stated that she had read a bunch and there were differing theories on whether this is complement mediated, IgE or something else. The patient and her immunologist/allergist are trying to figure out how to go about next dose. Her immunologist/allergist wanted to do a skin test but it is impossible to get a sample of the second shot to do that. The patient and her immunologist/allergist were very reluctant for her to get it because of the uncertainty about the possibility of increased allergic reactions from the second shot. The patient is supposed to get next dose tomorrow 22Jan2021, but she is getting a little nervous about how much is unknown. At the same time, she is face-to-face with patients daily and does worry about her exposures. The patient wanted to get Pfizer opinion on all this if company think it would be worthwhile to "risk it" and just get the dose under observation with epinephrine around or if waiting for more information would be better. The patient stated that she was not an anxious person, but this one is a little more scary for her as she is kind of</p>

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							scared of anaphylaxis (which as a psychiatrist, she would put in normal anxiety range). Another reporter also mentioned the allergic reaction and asked if there is any possibility of getting a small sample of the second shot for skin testing and ask for advice on what the patient should do. The outcome of the events sensation of throat fullness and tingling with a strange itchy feeling and allergic reaction was resolved. The outcome of the other events was unknown. Information on the lot/batch number has been requested.
1004765	2/5/2021	NY	23	F	2/3/2021	2/3/2021	Systemic: Anaphylaxis-Severe
1004775	2/5/2021	NY	43	F	2/4/2021	2/4/2021	15 minutes after first Pfizer Covid injection, pt developed itchy throat, given benadryl 50 po and monitored. Continued to have itchy throat and some rash, felt like prior episodes of anaphylaxis, reported some sob though stable vital signs, sent to ED
1004714	2/5/2021	MA	51	F	1/27/2021	1/27/2021	10:16 Pt came up to me and said she worked downstairs. She had her vaccine earlier and was feeling very itchy, like hives all over. She stated she was shaky and felt anxious. I walked her over to the AMR team. 10:17 epinephrine given by AMR in Right Arm 10:20 VS:140/81, 137, 100% 1025 EKG leads applied 1025 IV L arm with flush 1028 Benadryl 50 mg IV given by AMR 1029 BS 156 Patient had a blank expression and when asked to respond she stated it felt like she couldn't take a breath. We asked if she wanted some water and she said yes. We gave her water but she didn't drink any. AMR transferred her to stretcher and transported to ED at 1035. 1034 VS HR128, 100% She stated that she had a hx of anaphylaxis of unknown cause Pfizer vaccine dose #1 given 1/6/21 in right arm- only side effects were fever and chills
1002882	2/4/2021	AZ	41	F	1/21/2021	2/4/2021	Anaphylactic reaction to COVID-19 booster (2nd shot) Refractive Asthma brought on due to anaphylaxis

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1002846	2/4/2021	WV	75	F	2/4/2021	2/4/2021	Doctors reporting the patient developed rapid, shallow breathing with chest heaviness. Patient had facial flushing with a blood pressure reportedly at 212/90. However, a second opinion from another doctor stated they were unsure if true anaphylaxis. Epi pen was administered LOT 0FM498 and patient left in ambulance to go to ER.
1002839	2/4/2021	OR	45	F	1/28/2021	1/28/2021	client completed 15 minutes but then switched to 30 minutes, client complaint of itching around neck and increased salivation and jaw tension; denies any difficulty with breathing or tightness in throat, denies hx of anaphylaxis. BP 126/90 pulse 71. At 1620 50 mg diphenhydramine given IM Right deltoid per protocol . EMS called, arrived. AT 1632 client reports symptoms improving. BP 159/104, pulse 76. EMS took over medical care. Client declined transport from EMS
1002817	2/4/2021	MD	52	F	1/28/2021	2/3/2021	Day 6 I felt extremely lethargic, fatigued and with extreme joint pain upon waking. I took lunch at 3:30 pm consisting of almonds, cranberries and cheese bites and 2 mandarin oranges. Approx 10 minutes after eating I began to cough uncontrollably and had difficulty clearing my throat. Drank water thinking orange juice had gone down wrong. 10 more minutes my bottom lip began tingling, tongue felt thick, chest tightness, light headed. I called clinic who suggested I call for medical emergency because of my previous anaphylaxis. Taken to ED, given epi pen, prednisone, pepcid, monitored and discharged after 2 hours
1002807	2/4/2021	CA	56	F	2/4/2021	2/4/2021	2nd dose of pfizer covid vaccination today with a prior h/o scalp itchiness but no rash , angioedema or anaphylaxis with the first dose of covid vaccination 3 weeks ago. pt today with itchy palmar rash but no generalized itchiness no angioedema no anaphylaxis . exam remarkable for palmar urticarial rash with sparing of the dorsum no urticaria elsewhere no angioedema no anaphylactic signs. pt noted improvement of pruritis and rash after 25mg of oral benadryl.. pt called for family member to provide home due to mild sedation from the benadryl. pt observed for a full hour without any other sequelae
1002482	2/4/2021	OK	50	M	12/31/2020	12/31/2020	Anaphylaxis

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1001196	2/4/2021	NY	30	F	1/13/2021	1/13/2021	anaphylactic reaction; had a fever of 100.8; This is a spontaneous report from a nurse reporting for herself. A 30-years-old female patient received the first dose of bnt162b2 (BNT162B2; Lot # EL0140) vaccine , via an unspecified route of administration on 13Jan2021 at single dose for Covid-19 prophylaxis . Medical history included ongoing asthma Diagnosed when she was a child , seasonal allergy , food allergy , contrast media allergy (gadolinium). There were no concomitant medications. The patient experienced anaphylactic reaction on 13Jan2021 with outcome of recovered , had a fever of 100.8 on 13Jan2021 with outcome of recovered. The patient underwent lab tests and procedures which included allergy test: unknown results on Jan2021 , body temperature: 100.8 on 13Jan2021. The reaction began 28 minutes later. She says she started to get jumpy, her hands swelled and got itchy. She couldn't bend her hands, they were so swollen that she couldn't bend them. Her legs were shaking. Then saline and eventually her mouth started to get numb and they used an Epi pen twice. Her throat never closed, she thinks it did not close because the Epi pen was done twice, She had 2 masks on she cannot say for sure if she had trouble breathing but her mouth began to get dry and tingly and she started to no be able to feel her mouth. She says she would says it was resolved completely the next day. The patient also received Decadron and Benadryl. The reporter would say the event were life threatening because they treat it that way due to anaphylaxis precautions. Follow up information has been requested.

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1002262	2/4/2021	OR	30	F	2/2/2021	2/2/2021	[Tuesday 11:35 AM] 09:45 Second dose Moderna vaccine lot number 007M20A exp 7/2021 given at vaccine clinic. 10:00 Pt reports feeling light headed, dizzy, pt walked a few steps with supervision to stretcher. Vitals remain stable though hypertensive at 148/90. 10:20 BP 128/97 HR 92 Reports tingling to roof of mouth. Observed baseline oral exam due to pt past report of anaphylaxis in the setting of allergy shot, oral exam appears normal, pink mucosa, no swelling. Will continue to monitor on stretcher. Pt drinking water without any problems and does not appear in distress. 10:35 Noted hoarse voice, re-examined oral mucosa and patient's tongue, palate and, uvula now appears flushed, red and slightly but noticeably swollen, face is also now flushed. Lips appear same size and not swollen. Called RRT immediately. Advised transfer to ED. Pt remains in no distress. 10:40 RRT arrives to vaccine clinic in auditorium, gave report to RRT, reexamined oral mucosa which appears the same as 10:35 assessment (lightly but noticeably red, swollen tongue, palate and uvula). Face remains flushed as documented at 10:35. BP 128/90 HR 89. 10:45 Pt en route to ED with RT at bedside in no apparent distress.

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1002056	2/4/2021	CO	44	F	1/20/2021	1/20/2021	Anaphylaxis reaction; Angioedema; Shortness of breath; Wheezing; Fast heart rate; A spontaneous report was received from a physician concerning a 44-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced an anaphylaxis reaction, angioedema, shortness of breath, wheezing, and increased heart rate. The patient's medical history was not provided. No relevant concomitant medications were reported. On 20 Jan 2021 at 18:00, approximately 10 minutes prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 041L20A) intramuscularly for prophylaxis of COVID-19 infection. On 20 Jan 2021, approximately 10 minutes after receiving her injection, the patient began to have tongue swelling. She was given diphenhydramine and epinephrine by epi pen. She went to the emergency room where she displayed symptoms including a fast heart rate, wheezing, and shortness of breath with an angioedema or anaphylaxis like appearance. She was given more epinephrine, famotidine, scheduled diphenhydramine at 50 QAs intravenously (IV), IV steroids, was intubated and placed on a ventilator. She was on the ventilator for approximately 18-20 hours following admission. She eventually responded to a high dose of dexamethasone. She was also given duonebs for her shortness of breath, regular sedation for the ventilator, and a dose of ketorolac. Consent was given for Safety to follow up. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events were unknown at the time of this report.; Reporter's Comments: This case concerns a 44 year old female patient who experienced a serious unexpected event of Anaphylactic reaction. The event occurred approximately 10 minutes after first dose of the study medication administration. She was treated with epinephrine, famotidine, diphenhydramine, IV steroids, intubated and placed on a ventilator. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
1000873	2/4/2021	FL	49	F	2/1/2021	2/1/2021	Systemic: Anaphylaxis-Severe, Systemic: Fainting-Severe, Systemic: Seizure-Severe

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1000116	2/4/2021	IL	33	M	1/19/2021	1/19/2021	flu like side effects; increased temperature (99.9); lower back pain; chills; muscle aches; This is a spontaneous report from a contactable consumer (patient himself) reported that a 33-year-old male patient received his second dose of bnt162b2 (BNT162B2 also reported as Covid vaccine, lot EL3247), via an unspecified route of administration in the left arm on 19Jan2021 09:00 at SINGLE DOSE for Covid-19 immunisation. Medical history included eosinophilic esophagitis and carry an epi-pen for gastrointestinal anaphylaxis, had food allergy to quinoa, shrimp and mango. He had his first dose of bnt162b2 on 29Dec2020 (lot EK9231,) in the left arm. Concomitant medications included pantoprazole, cetirizine hydrochloride, fluticasone propionate (FLONASE) and melatonin. On 19Jan2021 22:00, she had flu like side effects, increased temperature (99.9), lower back pain, chills, and muscle aches. She self-administered acetaminophen and ibuprofen. The outcome of event was recovered with sequelae (Recovered with lasting effects).
999945	2/4/2021			M	1/16/2021	1/16/2021	nose tickling; spasming in sinuses; unusual side effects with throat; swollen gums; breathing was inflamed; This is a spontaneous report from a non-contactable consumer. A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 16Jan2021 at single dose for covid-19 immunisation. Medical history included Lyme's disease, inflammation/high sed rate (inflammation/high sed rate). The patient's concomitant medications were not reported. The patient received vaccine last Saturday and within an hour developed nose tickling, spasming in sinuses, unusual side effects with throat, not sore throat and not swollen lymph nodes, swollen gums, breathing was inflamed for a few days. He states its "not anything like anaphylaxis." The outcome of the event was breathing was inflamed was not resolved, while the outcome of the other events was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.

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1002465	2/4/2021	NC	39	F	1/29/2021	1/29/2021	<p>Patient received Pfizer vaccine #2 today. After the vaccine, the employee reported the following symptoms: flush feeling. She was already in her car. She looked in the mirror and noted redness on her neck. She then came back to the clinic. redness on her neck and chest Lot: EL3247 Time of Administration: 01/29/2021 1106am Time Symptoms Began: 15-20+ minutes</p> <p>When arriving back in the clinic, she was taken to the medical observation area. Initial Assessment @ 1141am: Patient is AAO. The employee sat on the sofa. The employee is pink and does not appear to be in distress. They are talking and making conversation. She has some redness on her neck. Vitals @:1142 HR: 107 BP: O2: 98 Given a water to drink. NO itching, tingling, scratchy feeling. Vitals @: 1145 HR: 94 BP: O2:99 Allergies: Percocet. Started as a rash on her chest. Then she had facial swelling. Was treated with prednisone. No anaphylaxis ever. Employee was discharged without treatment. Advised to take a benadryl when she gets home. She lives about 15 minutes from the clinic.</p>
1003615	2/4/2021	OK	63	F	2/4/2021	2/4/2021	<p>6 minutes post vaccination patient reports feeling "wonky" and similar to reaction she has had after Xolair injection(s). Pt has own epi pen and was assisted to couch, feet elevated. Pt denies respiratory distress, no urticaria or angioedema. Pts vitals taken while recumbent on couch: O2 98%, HR 76, BP 160/100. Offered water, juice, crackers. Pt remained resting on couch; at 14:40 reports nausea and patient agrees to 12.5 mg IM diphenhydramine in opposite arm of vaccination. Pt remained resting on couch denies respiratory distress and no other s/s of anaphylaxis noted. Pt vitals taken several times while on couch ranging from 130/90 - 158/100, O2 98% and HR 72-76. Pt remained resting on couch without further symptom progression until family member arrives to transport home 85 min post vaccination.</p>

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1000969	2/4/2021	MA	49	F	2/3/2021	2/3/2021	<p>Patient post vaccine administration approx 20 minutes. Reported feeling tightness in chest, spreading to throat. Patient was taken to observation portion of clinic. Patient was hypoxic in 70's. Supplemental oxygen applied. Oxygen saturation increased to 88. Epipen administered and albuterol nebulizer treatment started while waiting for ED/Rapid response team to arrive. Patient transferred to ED for further observation. From the physician that treated the patient: "It was a bit of a bizarre presentation. She reported throat tightness after the vaccine. She had a completely normal exam and no other complaints. no signs of airway/oral/pharyngeal abnormality. no respiratory abnormality. Unfortunately she was significantly hypoxic when I took her vitals. as low as 76%. Good waveform. I even checked the pulse ox on myself because I didn't believe it. In addition, with supplemental oxygen, her sats went up. I had to pull the trigger and treat her even though she looked well and I had no objective exam findings to explain her profound hypoxia. She received IM Epinephrine and Albuterol neb. By the time she was in ED she was satting 100% and her throat tightness resolved. So, not sure how to answer your question. Clinically I pulled the trigger and treated her for anaphylaxis following a vaccine administration. I wish it was a problem with my sat monitor but I don't believe it was. I was using a life-pack with wave form and verified with two other people that the O2 saturation function was working properly. Intuitively, it doesn't make sense but I think we should probably consider it a reaction to the vaccine. ~~</p>
1002962	2/4/2021	CA	56	F	2/4/2021	2/4/2021	<p>@ 0925 Patient had subcutaneous inflammation immediately after administration of Moderna vaccine. Vaccine was administered on left deltoid 0.5ml. She did not complain of pain, denied of any itching, no redness or tenderness noted. RN provided her with an ice pack and was monitored for 15 minutes. @0940 Patient continued to deny any s/s of anaphylaxis, inflammation decreased, was sent home shortly after RN advised patient if to contact her healthcare provider if any sudden changes occur.</p>

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1013011	2/4/2021		30	F			Received initial COVID vaccine at about 1200 today. About ten minutes later started to feeling burning CP, SOB, feeling of tongue swelling, and had a loose stool. Now feeling lightheaded. Was feeling fine prior to the immunization. Anxiety. Anaphylaxis. 30 yo female known hx of allergic reaction/atopy to vaccines presented with anaphylaxis approx 10 minutes after the covid-19 Pfizer vaccine.
1003599	2/4/2021	MN	57	F	2/3/2021	2/3/2021	Patient was screened using the COVID vaccine screening and eligible to receive first dose, which was administered at 6:37 PM in the L Deltoid. Patient was instructed on anticipated side-effects from this vaccine, and to wait in clinic "Rest & Recovery" for a minimum of 15 minutes post-vaccination. RN in Rest & Recover area was observing and checking in with patients during waiting period, patients were instructed to honk or get staff's attention if not feeling well. Patient indicated at around 6:50 that her ears were "ringing", so was instructed to wait an additional 10 minutes past initial wait time. At approximately 6:59 patient reported feeling a lump in her throat and having more difficulty breathing and hearing. At 7: 03 RN called over clinic staff radio system "Medical-Rest & Recovery", and staff person in R&R called 911, while grabbing anaphylaxis emergency kit. Two Lead RN's from Vaccination station came running to R&R and found patient holding her throat and shaking uncontrollably, with increased respirations. Patients mask was removed and epinephrine was administered in patients right thigh via auto injector at 7:05 PM, BP taken simultaneously was 215/85, P-130, O2 sat. 99% on room air. Patient breathing rate started to decrease and vitals at 7:10 BP-211/90, P-114, R~28, O2 98% on RA. First Responders arrived on-site at 7:15 PM, report given. 7:18 PM BP-207/92. Patient stated to develop increased respirations again, and began shaking; First Responders administered half dose of epinephrine via auto injector in right thigh at 7:25 and applied non-rebreather mask w/15L O2 BP 203/93. Ambulance arrived at 7:28 and transported patient to nearest hospital.

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1003484	2/4/2021	CA	35	F	2/4/2021	2/4/2021	Patient felt faint & "tingly" with some mild anxiety post-administration. No true syncope. BP 114/68 sitting, 112/64; no orthostatic hypotension. Remained in an upright position. c/o suborbital ocular twitch x 20 seconds which was observed by this writer. Visual onset of mild swelling L upper cheekbone. Treated with cold pack to area, Benadryl 25mg IM PRN to RD, decrease in environmental stimuli, reassurance, and direct observation x 15 mins. Interventions effective; no further swelling, no s/sx anaphylaxis, anxiety & other symptoms relieved. Client observed with steady gait "I'm better~~
1003479	2/4/2021	UT	60	F	2/4/2021	2/4/2021	About 3 PM she received her second vaccination for Covid. She states that she has a history of adverse reactions to flu vaccines that are anaphylactic like in the past. She usually premedicates with Benadryl and steroids. Today she did take 100 mg of Benadryl prior to her vaccination. Shortly after receiving the vaccine, she did feel like her throat was getting a little bit tight but she did not feel like it was true anaphylaxis. However she then felt very off. After this vaccine her throat started to feel tight, and she stated she did not feel well overall. She did have some tunnel vision and was shaky. At about 1730 her heart rate drops to the 30s, she started feeling itchy, and then she went into a coughing fit and started to feel her throat close. She received 0.3 mg IM epinephrine, 20 mg IV famotidine, 125 mg IV methylprednisone, 0.5 mL of nebulized racpinephrine, and 500 mL NS bolus. She has since recovered and is stable on room air.
1003432	2/4/2021		51	F	2/4/2021	2/4/2021	Anaphylaxis

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1003384	2/4/2021	CA	76	M	2/4/2021	2/4/2021	<p>Patient received first dose of Moderna vaccine at 11:11am. Patient then moved to observation area to be monitored and at 11:26 am he reported feeling dizzy and a slight flush. No redness or hives visible on patient. Continued to monitor patient, breathing was even and unlabored, O2 sat assessed at 98%, HR 61, patient sitting upright in chair. Patient had 3 sweaters on and 2 facemasks. Patient removed the second facemask. Patient refused to remove sweaters to assess BP. Patient reported he played tennis prior to his vaccine appointment and had diet coke and a bag of chips following. Patient given bottled water and monitored for additional 15 minutes. Patient reported feeling better and had a ride home. Patient in no signs/symptoms of distress or anaphylaxis, respirations even and unlabored, denied itching, swelling, shortness of breath. Patient left facility at 11:47, gait steady. Informed to f/u with his PCP and seek emergency medical attention if any signs of anaphylaxis develop.</p>

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1003206	2/4/2021		55	F	2/3/2021	2/3/2021	<p>Patient felt she had warmth at site of injection, 89 HR 81. Patient says normal BP 120's/80's. Patient states she is not anxious. She then started feeling like her throat and chest were getting itchy. Continued monitoring and she felt she needed to be evaluated in ER. Taken to ER. ED notes as follows: 55 y.o. female who arrived by to the emergency department for Throat and chest discomfort associated with voice change and pruritic rash. Past medical history of food and environmental allergies, Addison's disease, thyroid disease, primary immune deficiency disorder. Half an hour ago, the patient received her first injection the Covid vaccine. Seconds later, the patient started having a pruriti rash where the site of the injection was. She then noticed her chest getting red and warm. About 15 minutes later, the patient noticed her voice becoming hoarse her and associated with throat and chest discomfort. Reports that she is unable to take a deep breath. Denies any noisy breathing, nausea, vomiting, abdominal pain, shortness of breath, difficulty swallowing, drooling. She has never been hospitalized for anaphylaxis. She denies any past medical history of asthma or COPD. Vital signs demonstrate hypertension with systolic blood pressures into the 180-190s. No oropharyngeal swelling. Hoarse voice. Scleral injection present bilaterally. Chest wall nontender. Mild, blanching, erythematous, pruritic rash on anterior chest. Shallow breathing when asked to take a deep breath. Injection site covered with bandaid with no other obvious rashes or swelling. Patient arrived to the ED in no acute distress and in stable condition. She was complaining of throat discomfort with voice changes. She has never had an anaphylaxis reaction before. She was given benadryl, famotidine, and methylprednisolone initially for her reaction. With her hypertension and reported chest discomfort, epinephrine was not given initially. Her symptoms mildly improved with the initial treatment. Patient complained of chest discomfort and EKG showing T wave inverted in leads V4-5. She was given aspirin. Initial troponin negative and repeat was ordered. After four hours of observation, the patient reports her voice change has resolved but continued to have pruritis in different, migrating areas of the body such as ears, neck, and arms. 1330: patient complaining of increasing chest and abdominal pain. Described as a cramping chest pain that radiated to her abdominal.</p>

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							Denies nausea, vomiting or diaphoresis. Continues to deny shortness of breath. Given morphine for her pain and aspirin for her nonspecific EKG changes. Internal Medicine consulted for admission due to allergic reaction. Patient is agreeable to this plan. Patient was transferred under stable condition to the IM service. Initial Vital Signs [02/03/21 1159] Blood Pressure 168/101 Heart Rate 73 Respiratory Rate 15 Temp 36.8 °C (98.3 °F) Temp src Oral SpO2 96 % Following one day admission she was discharged to home with Zio patch monitoring while on new beta-blocker therapy for symptomatic PVCs with plan for PCP follow-up. Regarding adverse drug reaction, she was advised to follow-up with PCP and immunologist for further discussion on benefits:risk of subsequent vaccine in series.
1003192	2/4/2021	MS	69	F	2/4/2021	2/4/2021	The patient was referred by her primary care provider's office to receive COVID-19 vaccination. She received her first dose of Pfizer-BioNTech COVID-19 vaccine at approximately 15:07 hrs. Due to her history of allergic reactions to multiple medications (including sulfa antibiotics and ceftriaxone), she was advised to extend her monitoring period to at least 30 minutes post-injection. At around 15:50 hrs I was notified that the patient was feeling a tingling sensation in her throat, itching, and a change in her voice. She was transferred to a stretcher for acute management of suspected anaphylaxis. Airway, breathing, circulation, and mentation were assessed immediately. EMS was called immediately via 911. Her vital signs were obtained, with a BP 168/90 mm/Hg, HR 105/min, RR 24/min. She reported shortness of breath at the time. There was no stridor or wheezing on exam. She appeared in mild respiratory distress. At 15:54 hrs she was given an intramuscular EpiPen injection (0.3 mg autoinjector) in her left thigh. At 15:58 she was given an intramuscular methylprednisolone injection (125 mg) in her right thigh. Immediately after that EMS team arrived and took over her care with plans to administer diphenhydramine intramuscularly, and will transfer to ED for further management. Throughout the event the patient remained awake, alert, and fully oriented.

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1003183	2/4/2021	FL	92	F	2/4/2021	2/4/2021	PATIENT WAS MONITORED FOR 15 MINUTES AFTER RECEIVING INJECTION. AFTER LEAVING, RETURNED TO VACCINE POD COMPLAINING OF SWELLING OF TONGUE AND THROAT AND SHORTNESS OF BREATH. EMS EVALUATED PATIENT AND SHE WAS TAKEN TO HOSPITAL WHERE SHE WAS TREATED FOR ANAPHYLAXIS AND RELEASED.
1003083	2/4/2021	FL	39	F	1/27/2021	1/27/2021	I had previous anaphylaxis events that were treated and did not require hospitalization. I brought epinephrine pen and premedicated with Xyzal 5mg 9 hours before and Benadryl 25mg 1.5 hours before vaccine. 20 minutes after vaccine I felt flushing, nausea, low blood pressure. They had released me from the drive through vaccination site and I was driving and felt panicky, so I pulled over. I waited 10 minutes because I wasn't sure if it was anaphylaxis or not. I felt OK after 10 minutes, so I drove to nearest ER and waited in parking lot several hours then drove home. I probably should have administered epinephrine and called 911 when I had that reaction. Continued with 25mg Benadryl every 4 hours and nightly Xyzal 5mg. The next morning (24 hours later) I woke up scratching my face. I had a diffuse sandpaper rash all over my head and neck and was very itchy. Doubled my dose of Benadryl to 50mg every 4 hours. Also took 400mg of quercetin. The itching resolved and the rash was gone the next day, which was 48 hours after vaccine. I was fatigued for several days but fatigue is my baseline as a narcoleptic plus I was taking benadryl. I continued the Benadryl for a total of 4 days. I normally do not develop rashes unless I rub against hay and I did not have any contact with hay.
998712	2/3/2021	CA	31	M	2/1/2021	2/1/2021	31 year old male with of c/o generalized itching 20 minutes post 2nd dose of Moderna Covid vaccine. He was given 50 mg of benadryl injection and his symptoms progress to scratchy throat . Patient premedicated with zyrtec prior to his vaccine. He was given prednisone 60 mg and monitored in clinic for an hour. Patient symptoms resolved and was discharge home. Patient was initially hypertensive and mildly tachycardia and his VS was stable. Patient has a hx of anaphylaxis.

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998224	2/3/2021	IL	28	F	1/25/2021	1/25/2021	Anaphylaxis. Epi Pen given and ambulance called. Given anaphylaxis cocktail in ER. 2:30pm: Vaccine administered 3:30pm: Headache & teeth ache which continued 7:00pm asthmatic cough which continued throughout 11:00pm fever and chills 9:00am felt generally very ill--stomach pain (more anaphylactic type pain) 10:00am nausea, severe stomach pain, diarrhea, vomiting, lungs very tight, continued coughing 11:00am excruciating stomach pain (stomach on fire) Throat felt "thick", feeling faint, brain fog, dizzy (These are my typical anaphylactic reactions) Epi pen administered & ambulance called Anaphylaxis symptoms returned in ER. The pain was the worst since my bowel obstructions several years ago.

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996739	2/3/2021	CA	75	F	1/18/2021	1/19/2021	Approximately 22 hours after vaccination had a seizure. Felt fine up until the seizure occurred. Never had a seizure in past. No other illness or symptoms. No fever or change in blood sugar.; This is a spontaneous report from a contactable Physician. A 75-year-female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Intramuscular on 18Jan2021 19:30 at single dose on left arm for COVID-19 immunization. Medical history included Stroke, diabetes, hypertension, anaphylaxis to bee stings. The patient had no covid prior vaccination. The patient had no covid tested post vaccination. The patient was not diagnosed with COVID-19 prior to vaccination. Concomitant medications included sitagliptin phosphate (JANUVIA), hydrochlorothiazide, telmisartan, rivaroxaban (XARELTO), gabapentin and baclofen. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously had allergy to Morphine and experienced Hives. Approximately 22 hours after vaccination the patient had a seizure on 19Jan2021 17:15. She felt fine up until the seizure occurred. She never had a seizure in past. No other illness or symptoms. No fever or change in blood sugar. No treatment was received for the event. The patient had not been tested for COVID-19 since the vaccination. The outcome of the event was resolved. Information on the lot/Batch number has been requested.; Sender's Comments: Based on the time association and previously allergic reactions to bee stings and other drugs, the possible contribution of suspect BNT162B2 to the event seizure cannot be excluded in this elderly patient with multiple medical histories including stroke, diabetes and hypertension. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
997279	2/3/2021	NE	47	F	2/2/2021	2/2/2021	Systemic: Anaphylaxis-Severe

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997304	2/3/2021	NJ	26	F	2/2/2021	2/2/2021	I am a pharmacist for pharmacy and received my first dose of Pfizer Covid-19 vaccine while at work by another pharmacist. Vaccine given around 2:15 PM on 2/2/21 Less than 5 minutes after vaccine - arm tingling at site of injection, arm tingling spread from injection site to fingers, tingling and pins/needles traveled through underarm area and moved across left side of chest, slight chest pain on left side, whole body started tingling, dizziness, racing heart. While experiencing all of these symptoms, I sat on the ground, took two tablets of 25mg Benadryl, drank water, and tried to breath steady to make dizziness go away. Working in this healthcare setting, I was aware I was having an adverse reaction to the vaccine and was prepared with an epi-pen in case of any severe anaphylaxis shock - I did NOT have to use the epi-pen. Less than 15 minutes after vaccine - the chest pain, arm pins/needles stopped, I felt lightheaded still, another co-worker checked my blood pressure which had risen to 178/120 and pulse of 120. About 1 hour after vaccine - still felt light headed, blood pressure still elevated at 158/107, pulse of 107. Around 5:45 PM - After consulting personal friend physicians, I was instructed to go to ER and have an EKG of my heart since my blood pressure and pulse had spiked so high and suddenly. I was able to find coverage at work so that I could leave my shift and get a ride to the emergency room. After 6 PM (admitted into ER) - upon admission blood pressure of 176/117 and pulse of 113

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998031	2/3/2021	TX	24	F	2/3/2021	2/3/2021	1326 patient in general observation area, states she is beginning to have a rash at the vaccine site in Lt. arm. Ambulated to Private observation area. Rash on left arm about 3 inch circumference. Has small red flat dots on chest. Denies itching or burning. EMT in attendance 1327 - Gave two 25 mg tablet Benadryl by mouth. Swallowing water without difficulty. Denies throat involvement. O2 sat 99% on room air (r/a) HR 113, BP 132/87 1340 - Rash localized left arm, few red spots on chest, continues to deny throat involvement. States, "I know what anaphylaxis feels like and this is not it" HR 104; O2 100% r/a 1354 - Cheeks, chin and neck have blotchy flat red rash. Denies throat involvement, denies itching/burning. Declined ice for comfort 1412 rash less red on left arm, has extended to face and neck area. Denies throat involvement. Denies itching/burning. EMT advised patient to be transported to ER for evaluation by a physician. Patient refused and said she would seek medical car if symptoms worsened. 1414 HR 99; BP 129/81; RR 16 unlabored; O2 100% on r/a 1428 - Patient ambulated without difficulty to personal vehicle.
998047	2/3/2021	UT	42	F	1/21/2021	1/21/2021	Patient received 2nd Dose of COVID-Vaccine. Approximately 7-8 minutes later she became light headed, ten minutes after that she her face and neck became very red , hives began to appear on arms, throat very scratchy, voice altered. Patient transferred to the ER where she was treated for Anaphylaxis. Drugs given included IV fluids, Benedryl (PO and IV), Epinephrine, Solumedrol, and Pepcid. Patient was observed for several hours but was discharged the same day.
998120	2/3/2021	OK	59	F	12/22/2020	12/22/2020	Moderate anaphylaxis 1 hour after the injection which lasted for approximately 10 minutes. Heart pain and shortness of breathe which started within 15 minutes of the injection. The heart pains lasted 8-10 days. Headache, fatigue and shooting muscle pains throughout the body starting 2 hours after injection and lasting 8-10 days.

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996733	2/3/2021	FL	46	F	1/5/2021	1/5/2021	<p>sensory neuro bilateral hearing loss worse on one side; tinnitus; This is a spontaneous report from a contactable physician (patient). A 46-years-old female patient started to receive the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284), intramuscular into right arm on 05Jan2021 at 0.3 mL, single for covid-19 immunization. Time the vaccination was reported as 10:00-10:30. Medical history included food and environmental allergies. The patient had a history of autoimmune antibodies to thyroid but with normal thyroid numbers. No medication was needed, but autoimmune antibodies was found in the past. She had a propensity for autoimmune disease, it was just not active. She was diagnosed the first time she found auto antibodies 12 years before 19Jan2021 (2009) and checks her thyroid yearly and they had been normal. She still had antibodies, but thyroid hormone levels are normal without intervention. The patient's concomitant medications included Vitamin C and Vitamin D. Historical vaccine included Pneumovax 30 days before getting the COVID vaccine (06Dec2020, 46-years-old). Her pneumonia titers were low. Historical vaccine also included flu shot, she felt sick but like everyone else, she did not consider that abnormal. She thought most people felt kind of down and it did not have long term effects. It did not require any doctor visits. She did not have a rash or anaphylaxis. The patient was a physician and well versed in terms of symptoms. By evening of 05Jan2021, she developed tinnitus, which she had never had and has been there ever since. She was on day 13 post vaccine and still having bilaterally, every day and it never went away. She had a physician visit on 12Jan2021 and hearing test performed that day. They did find sensory neuro bilateral hearing loss worse on one side, her test confirmed bilateral hearing loss at 11:00 on 12Jan2021. It was mild so far in the high frequency ranges. So, they gave option to start 14 day course of high dose steroids with steroid injections into the ear, because in some cases of acute hearing loss, it can curb or reduce it. She decided to do that. Now she was going to be on steroids. She would be temporarily immunosuppressed. She did not know if that will affect the vaccine. She had not decided if she will get second shot. It is due next week, but she was a little nervous. She was considering delaying the booster a couple months out to see if more</p>

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information develops. She provided her weight as between 175 to 180lb. Right now, the hearing loss was mild and it won't be that bad, but normally, it was permanent, which would be disabling hearing loss. She was going 20Jan2021, for the steroid injection in the ear canal. That would be the first injection. She was taking oral steroids now. They would see if this limits the progression. The events outcome was not recovered.; Sender's Comments: The possible causality between the reported tinnitus/sensory neuro bilateral hearing loss and the administration of COVID-19 vaccine, BNT162B2, cannot be fully denied based on the reasonable temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.

997801	2/3/2021	VA	55	F	2/2/2021	2/2/2021	Systemic: Anaphylaxis-Severe
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998565	2/3/2021	NC	71	F	2/2/2021	2/2/2021	<p>Pt noted after approx 15 minutes a tingling/burning sensation of tongue At 4:45 pm. No associated SOB, facial swelling. She does have prior anaphylaxis reaction to pineapples for which she carries and epi Pen but has never needed to use. Cardiac exam RRR Lungs CTA bilat HEENT, no visible erythema of face or tongue and no noteable facial swelling. She was agreeable to 25 mg dose of diphenhydramine and another 15 minute observation. During this time, she began to feel anxious and a mild headache. Vitals at that time were notable for bp 178/81, HR 101 and o2 sat 98%. Still no SOB, facial swelling or other new complaint. She felt improvement in anxiety within 5 minutes, and repeat vitals in 10 min with BP 152/83, HR 89 and O2 sats 96%. She still continued with mild sensation change of tongue, but no facial swelling. She does have benedryl at home but I also sent her home with additional 25 mg dose in case she noted recurrent symptoms on the way home. She understands to seek emergency care with any worsening symptoms, or new SOB or facial swelling. She can also use her EPI pen if needed. She felt comfortable returning home- husband picked her up. I will call her to check in this evening and in the morning and will provide updated recommendations regarding second dose of vaccination. I spoke with patient at 8:09 pm - she was at home- feeling much better, however, she did take the second diphenhydramine on the way home, as she began to feel she was having some swelling between her eyes. No SOB Or trouble swallowing. This improved with the second benedryl and has not recurred. She will take an additional 50 mg benedryl before bed, and then she awakes before 6 am- if she has any residual symptoms she will take another dose. Again, she understands to seek emergency care with any worsening symptoms, or new SOB or facial swelling. She can also use her EPI pen if needed. She felt comfortable with this plan. We also reviewed current CDC guidelines and she understands at this time we would not recommend she receive the second Vaccination. She will continue to follow CDC in the event that this recommendation changes. I will submit a VAERS report after following up with her in the morning. ADDENDUM 2/3/21: I spoke with patient again on 2/3/21 at 07:45 am. She is feeling almost completely back to baseline this morning, but planning to take 25 mg diphenhydramine this morning as</p>

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							well. She does note mild headache, which is not abnormal for her. No residual tongue sensitivity or facial swelling. She noted that when she got home last night, she felt very sleepy and sedated from the diphenhydramine and went to bed, and did not take an additional dose of diphenhydramine last night. No SOB, trouble swallowing or any new complaint. No urticaria or itching. We reviewed current CDC recommendations to decline second vaccination given her moderate severe allergic symptoms within first 4 hours of first vaccination. She will follow up with PCP or kidney specialist if she has any continued concern with ongoing symptoms or new issues. She was very appreciative of the followup and care provided.
998627	2/3/2021	VA	76	F	1/13/2021	1/15/2021	Anaphylaxis symptoms started three day after the shot I started having chills, trembles, sore throat, very high BP, Swelling and numbness on tongue and lips, pain and burning of feet, tingling all over, joint pain,
998801	2/3/2021	OR	43	F	1/28/2021	1/28/2021	Anaphylaxis refractory to IM episode x3, steroids, H1 blocker requiring incubation. Specifically respiratory distress with stridor, nausea, and generalized abdominal pain.
999026	2/3/2021	CA	56	F	1/14/2021	2/2/2021	Anaphylaxis: abrupt throat swelling, shortness of breath, facial redness, GI distress
999167	2/3/2021		25	F	2/2/2021	2/2/2021	Mild anaphylaxis less than 5 min after injection. Symptoms onset immediately, including dizziness, rapid heart rate, tightening of the throat, making breathing/swallowing difficult, ears felt strong pressure/itch. Symptoms went away on their own, but several episodes of similar symptoms/intensity persisted throughout the evening roughly every 30min-1hour.

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999265	2/3/2021	CA	28	F	1/21/2021	1/21/2021	28 yo F here at 30mdg for covid vaccine. pt with h/o "anaphylaxis with other shots." Pt notes had facial/nose/lip tingling with prior vaccines, requiring steroids and oral Benadryl. Patient received the covid vaccine at approx 1715 on 21 Jan 2021. At approx 15 minutes, pt developed numbness and tingling to her nose and lips. pt notified Rapid Response Team, who notified Physician. monitored patient for 5-7 min, pt noted that her symptoms were worsening, to include numbness and tingling affecting most of her face, cheeks, lips and nose. No trouble breathing. no lip swelling or tongue swelling. HR 78. Gave oral benadryl - gave her 4 ml of po benadryl (12.5 mg/5ml) at approx 1735, and another 4 ml po benadryl (12.5 mg/5ml) at approx 1740. pt prefers to be treated with steroids because a similar previous episode resolved with benadryl and steroids. pt symptoms persisted with facial numbness and tingling ... and subjectively were worsening. no coughing, no tongue swelling. no lip swelling. no shortness of breath. FM physician arrived - prepped for 60 mg im solumedrol. at approx 1750, FM physician gave IM Solu-Medrol in R shoulder. pt waited for approx 15 min - felt better. numbness and tingling of face and nose were lessening, almost gone - only tip of nose was affected. no facial swelling. no lip or tongue swelling. no trouble breathing. no shortness of breath. physician gave return parameters - benadryl prn overnight. called patient the following monday - stated she slept that night (from benadryl), felt better the next day. no further concerns
998292	2/3/2021	CT	63	F	2/3/2021	2/3/2021	Pt was designated as a 30 minute wait time due to anaphylaxis to Quinolones. Pt reported at the 30 minutes mark feeling a tingling down her left arm. Observation volunteer evaluated pt. VSS BP 117/78 HR 77 O2 98% mild rash on arm where injection was administered. EMS on site to evaluate. Pt signed a refusal for transport to the ED as she stated she was feeling better and symptoms resolved.

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998604	2/3/2021	WA	45	F	1/1/2021	1/9/2021	I received the first dose of the Moderna vaccine on 1/1/21. Initially, I had a sore arm for 24 hours but otherwise no problems. Then, on day 8, my left deltoid area started itching and there was a red, slightly raised area just larger than a golf ball. I called the hotline at that time and took a Benadryl. Then, 24 hrs later, the area had expanded to over 3 times the size and felt warm. I actually went and saw a friend who lived in my neighborhood who is a general surgeon and he thought I should get it checked out to make sure it wasn't an NSTI. Being Saturday at 9pm, I went to the ER where they started me on Keflex/Bactrim for a presumed cellulitis. By the next morning, the redness and itching were gone and my arm felt totally back to normal the next day after that. Unfortunately, on day 3 of the antibiotics (Tuesday the 12th), I had symptoms of anaphylaxis (chest tightness, wheezing, throat clearing, lip swelling, hoarse voice, impending doom sensation). I took Benadryl 50mg and got my epi pen ready but did not use it. (I have a tree nut allergy). The symptoms resolved completely about 1 hour later.
994938	2/2/2021	OH	42	F	1/27/2021	1/27/2021	Developed cough and throat tightness, difficulty breathing, inability to talk. Seen at local emergency department and treated for anaphylaxis
995510	2/2/2021	CO	49	F	1/28/2021	1/28/2021	SOB; not anaphylaxis

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995629	2/2/2021	NY	32	F	1/29/2021	1/29/2021	Pt. with known allergic type reaction after first dose of vaccine, discussed getting the 2nd vaccine by intensivist and pulmonologist and was advised to go ahead and get second vaccine. 1st vaccine Reaction: Itchiness of entire body, fatigue, tongue "felt funny," stomach cramping. She was premedicated with Prednisone 40 mg po, Benadryl 25 mg po, Pepcid 20 mg morning of vaccine. Pt. was administered vaccine at 12:15 am and at 12:40, she started to have tongue and throat itching, swelling, voice change, H/A and abd. pain. Medical first response was called and Dr. (Anesthesia) and FNP was present on-site at 12:41 Epi 0.3 mg sq was given. Additional 50 mg IM of Benadryl was also administered. Pt. was transported to ED via wheelchair and found to have angioedema and dx of anaphylaxis. Pt. was administered Benadryl IV, Pepcid IV, Solu-Medrol IV, Epi IV was administered in the ED due to persistent angioedema. She was discharge home same day at 16:03 and asked to f/u with PCP in 1-3 days. 2/2/21- Still on prednisone, pepcid and Zrytec. Tongue still feels itchy and a little swollen, but overall feeling well.

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995797	2/2/2021	CA	70	F	2/1/2021	2/1/2021	After receiving the injection, I was directed by an RN to sit in a chair for 15min in the same room. Five minutes after the injection I felt my upper back muscles, ribcage area, contract. The contraction continued around to the front of my chest with next 3 minutes. I felt tightness with each breath. The RN who gave me the injection came to see if I felt alright. She informed the charge nurse that my chest felt tight and the charge nurse came to ask me questions. The charge nurse called the hospital pharmacist to come to see me. The pharmacist arrived with various medications and talked to me. He instructed me to do breathing exercises and meditate. I told him that I was familiar with these techniques and using them. I also informed the pharmacist that I had a heart attack in 2018 and had atrial tachycardia but I wasn't feeling any problems with my heart, that it was beating normally. I also informed the pharmacist of my severe allergies to certain items but I wasn't experiencing any anaphylaxis that I've experienced in past allergic episodes. The pharmacist left and told the charge nurse to keep me a half hour longer under observation and to call him if I felt worse. During that half hour, the muscle contractions stopped and I was able to breathe normally. The charge nurse asked me if I was ready to leave after the half hour was up, I told her I was feeling odd so she said to stay another 20min. I began to experience intestinal cramping and asked to leave to go to the bathroom. In the bathroom I had a bout of diarrhea that lasted 10minutes. After that I drove home but was experiencing a headache that started. The headache lasted for 20hrs. It felt like I was wearing tight hat, squeezing. I've not had that type of headache before. My right arm site of injection feels a little warm and is pink but isn't painful.

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996225	2/2/2021	TX	47	F	12/28/2020	12/28/2020	12/28 Vaccine 6:30 AM. 2 hours later rash appeared @ injection site and 3" around in diameter. Around 8 hours after, I felt SOB and rash spread to all extremities. I took hydrosteroids; prednisone and benadryl. The rash started to get better about 4 hours later. 12/29 Body aches, fatigue. Swollen lymphnodes for at least 5-6 days. History of Severe allergies; eggs, shellfish, sulfa, etc. (listed on first page). Carry epi pen 24/7. Have not had Anaphylaxis reaction for 4 years. *premedicated with benadryl before 2nd vaccine. No rash. but still had body aches.

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996313	2/2/2021	NC	77	F	1/20/2021	1/20/2021	<p>Patient waited 30 min given prior history of reactions to medications (rash, no anaphylaxis) with other medications. Left after 30 min with no complaint.</p> <p>Allergies Allergen Reactions ? Niacin Other (See Comments) Other Reaction: Other reaction ? Penicillins Rash ? Amlodipine Swelling ? Flagyl [Metronidazole Hcl] Other (See Comments) Other Reaction: Other reaction ? Lipitor [Atorvastatin] Rash ? Zocor [Simvastatin] Other (See Comments) and Unknown Other Reaction: Other reaction ? Colesevelam Other (See Comments) severe ? Metronidazole Rash ? Colesevelam Hcl Other (See Comments) severe She returned after approximately another 20 minutes to report rash and mild pruritis on upper chest and face. No complaints of shortness of breath, chest tightness, lightheadedness or dizziness. No facial swelling, pallor or cyanosis. No increased effort of breathing or wheezing appreciated. Skin only reaction, no respiratory, cardiovascular or GI reaction. On exam- 140/70 HR regular rate and rhythm. Lungs clear No cyanosis or pallor noted Patient able to converse normally, A+O , in no acute distress Mild erythema around mouth, no tongue swelling appreciated. Mild erythema between brows. Mild blotchy erythema on upper chest. Given oral diphenhydramine 25 mg at 4:30. No progression of symptoms and patient observed another 30 minutes without change. Given a oral diphenhydramine 25 mg to take with her in the event symptoms progress or to take as a second dose in 4 hrs. If any worsening symptoms she is to seek emergency medical attention. I will follow up with her this evening and tomorrow. I will provider her formal recommendations regarding her second vaccination. I spoke with her at 6:50- she is stable, still mild rash on upper chest, but no new symptoms. She will repeat with diphenhydramine 25 mg at 8 pm and I will check on her tomorrow. She is motivated to receive her second dose but asks if receiving a different medication is an option We will discuss this further tomorrow. I spoke with patient again on 1/21/21 at 8:30 am. She continues with mild rash on upper chest, will continue benedryl for mild itching, but no further progression of rash, no residual facial erythema and no shortness of breath or other new symptoms. I have asked her to consider premedicating with 50 mg diphenhydramine 1 hr prior to dose 2 of</p>

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							vaccine. I have also asked her to register with v-safe and have sent her the information in case she did not keep the paperwork. Pt then saw PCP several days later who suggested she not receive second vaccination
994731	2/2/2021		78	F	1/18/2021	1/29/2021	[Pfizer covid -19 vaccine] treatment under Emergency Use Authorization(EUA): Patient in clinic for 2nd dose of covid vaccine. Within 8 minutes of receiving her injection, pt developed a rash on both arms; pt states both arms are itch and her throat felt as if it were closing. Rapid response called and patient was given Epinephrine per anaphylaxis protocol by LPN at 4:26pm. BP-146/98 p88 R17 Rapid response team arrived at 427pm. 429pm: Assessment: patient stable but felt no improvement in her throat. Pt was transported to ED for assessment.
996316	2/2/2021	WA	39	M	1/10/2021	1/11/2021	Anaphylaxis of face, neck and lymph nodes. Noted with pictures Fever Nausea Body aches Oxygen levels into the low 90s Dizziness Fatigue Eyes not staying aligned with each other. Noted in pictures

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994807	2/2/2021	SC	47	F	2/1/2021	2/1/2021	Received shot at approximately 2pm and was in observation chairs. Around 205pm I took a dose of tylenol to attempt to prevent fever. I immediately noticed that the medication felt stuck in my esophagus and it was hard to swallow them down. Being a nurse I began to monitor more closely my breathing. I was able to take air into my lungs easily. Next I noticed that my nose became very stuffy and was difficulty to breath through but my airway continued to seem ok and I was breathing without difficulty through my nose. By about 210pm I had noticed that my face felt strange. As another few minutes progress my entire face felt numb like when your dental lidocaine is wearing off. It was a very disturbing feeling. I never had difficulty breathing but the throat and nasal swelling lasted about 1 1/2 hours. The facial numbness lasted at least 4 hours and my nose and tongue still feel a little strange even at this moment. I stayed in the observation area for about 35 minutes just to make sure I was not going to lose my airway before leaving. I am a nurse and I didn't want to get sent to the ER for hours just to be given benadryl since my airway was ok so I didn't report it at the time of incident. I had preloaded with zyrtec, pepcid and ibuprofen the morning prior to injection to try and avoid reaction or side effects that others were reporting. I think if I had not had antihistamine in my system I would have had anaphylaxis for sure. I went straight home and took more antihistamine. Contacted my doctor so she knew of the symptoms. She told me to continue the antihistamines for a few days and to go to the ER if severe issue happened. This was a VERY VERY scary incident. For a little history: after my first vaccine I noticed itching on my chest but couldn't see any rash. About day 3-4 a rash appeared. I was unsure if this was vaccine related since it took 3 days to appear. It was cleared after a few days of steroid cream.
994342	2/2/2021	OR	60	F	1/30/2021	1/30/2021	Systemic: Anaphylaxis-Severe; symptoms lasted 1 day

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994105	2/2/2021		35	F	1/29/2021	1/29/2021	Patient given first dose of Pfizer Covid vaccine. Upon administration felt burning at the injection site. patient then stated she felt tingling in her hands, feet, and mouth. Patient also stated that she felt her heart racing. BP 172/103, HR 149, SPO2 100% on room air. Denies SOB and difficulty breathing. Pt was transferred to ED. In ED was given oral prednisone and diphenhydramine. Assessment for possible drug reaction, not thought to be anaphylaxis, with mild anxiety contributing. Patient monitored and discharged in stable condition.

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993626	2/2/2021	NV	49	F	12/18/2020	12/19/2020	Lips swelling and face; Lips swelling and face; Anaphalaxis; Anaphalaxis; This is a spontaneous report from a contactable other HCP (patient). A 49-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: Eh9899) via an unspecified route of administration on 18Dec2020 18:30 at single dose in left arm for COVID-19 immunisation. She received the second dose (lot number: E11283) in right arm on 08Jan2021. Medical history included Idiopathic anaphylaxis and was allergic to penicillin, had COVID-19 from May2020 to an unknown date. Concomitant medication included unspecified birth control pills. The patient experienced anaphalaxis on 19Dec2020 06:00 AM. She talked with her doctor lips swelling and face. Treatment received for events lips swelling and face. But her question is she had an IGG antibody test and it was negative. She had COVID in May2020 and have been tracking her antibodies. She wanted to know 'does this antibody test show the same antibodies?' She had negative after the two vaccines. The patient is not pregnant. Events outcome was recovered.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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993543	2/2/2021			F			lip tingling; This is a spontaneous report from a non-contactable nurse (patient). This female patient of unspecified age received dose 1 of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number and Expiration date unspecified) on unspecified date as single dose for COVID-19 immunisation. Medical history included anxiety, heart was pounding, and palms were sweaty long before the shot. Concomitant medications were not reported. The patient experienced lip tingling on an unspecified date. Tingling lasted moments not even full minute and went away. Patient is asking if lip tingling with no itchiness and no swelling, is considered anything of concern or in someone without any adverse reactions like anaphylaxis. She already talked to her physician/allergist and was told that event was due to anxiety and panic. She wants to get her second dose of the vaccine but the pharmacist at her employer are reluctant to give it. Outcome of event lip tingling was recovered. No follow-up attempts are possible. Information about Lot/Batch cannot be obtained.

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993521	2/2/2021	FL	49	F	1/13/2021	1/13/2021	<p>a knot in her arm; sore to the touch; Exhibiting flu-like symptoms; Fever; Severe body aches; Runny nose; Cough; Anaphylaxis; This is a spontaneous report from a contactable consumer(patient). A 49-year-old female patient received second dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot: EL3246), intramuscular in right bicep(arm) on 13Jan2021 around 16:15 at single dose for preventative. Medical history included high blood pressure from 2016 and ongoing. Concomitant medication included ongoing chlortalidone for high blood pressure. She received first dose of covid vaccine BNT162B2 (Lot: EL0140) on 23Dec2020 around 13:00., in right bicep(arm), a little above where she received this second dose for covid-19 immunization, she previously received flu shot for immunization and had a knot in her arm where it is tender to the touch and sore. She had an anaphylaxis event directly after her shot on 13Jan2021, she was kind of knocked out for the anaphylaxis event and her body was hurting. She was not sure if it was from the shot or from the trauma anaphylaxis event. She received an epi shot in the clinic, diphenhydramine (BENADRYL) into her arm. She was taken to the ER(Emergency Room) where she stayed till about 9:30pm. She was not admitted. Anaphylaxis recovered on 13Jan2021. She also stated that she got sick after the shot, she was exhibiting flu-like symptoms, she never lost her taste or smell, she had a fever, severe body aches, runny nose, and a cough. These symptoms started the next day on the 14Jan2021 and got worse on the 15Jan2021, on 17Jan2021, She feeling better morning and recovered completely by the time she went to bed in regards to her flu-like symptoms, she felt like herself and normal. She felt rested. This morning she felt good. Treatment included paracetamol (TYLENOL) and she was taking diphenhydramine every night since the anaphylaxis occurred. She still had a knot in her arm that it was very sore to the touch which she stated was pretty common even with flu shot(not know the name of the flu shot or have lot, NDC, or expiration date) where it was tender to the touch and sore. There was no relevant test. Outcome of anaphylaxis was recovered on 13Jan2021, of a knot in her arm, sore to the touch was unknown, of other events was recovered on 17Jan2021.</p>

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994816	2/2/2021		26	M	1/21/2021	1/21/2021	10 minutes after the second dose, patient developed headache, lightheadedness, dizziness, shortness of breath/anaphylaxis. Transferred to ED, and experienced chest pain, SOB, tightness in throat. Patient was sent to the emergency department. Received 25 mg Benadryl prior to arrival as prophylaxis. Received Combivent in the ED, and symptoms improved. Patient was observed for 4 hours in the ED. Eventually patient was discharged home.
990421	2/1/2021	MI	65	F	1/15/2021	1/15/2021	I had anaphylaxis yesterday; Throat is still swollen; This is a spontaneous report from a contactable consumer (patient). A 65-years-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL3249), via an unspecified route of administration on 15Jan2021 at single dose for COVID-19 immunisation. Medical history included diabetes mellitus. Concomitant medication included metformin (unknown manufacturer), levothyroxine sodium (LEVOXYL), fluoxetine (unknown manufacturer), empagliflozin (JARDIANCE), rosuvastatin (unknown manufacturer). The patient experienced anaphylaxis and throat was still swollen on 15Jan2021 about 30 minutes after when she received the shot, with outcome of recovering. The patient was transferred to emergency and was treated for the event.
990127	2/1/2021	MD	32	F	1/29/2021	1/29/2021	Approximately 1 hour after injection I developed chest tightness, burning eyes, scratchy throat and hives. No anaphylaxis. If Benadryl was not taken regularly the hives would return for the first 48 hours.

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990670	2/1/2021		30	F	1/7/2021	1/15/2021	Pt received first dose of COVID-19 vaccination on 7 Jan 2021. She reports 8 days after receiving the vaccine she woke up with her left arm (vaccine arm) feeling like "deadweight". The vaccine sight was warm to the touch, swollen, and an erythematous, raised, pruritic rash was present. The rash stayed localized, did not spread. Interventions include ice, Tylenol, and Motrin with no relief. Pt reported resolution of above symptoms 72 hours after they presented. She reports some lingering fatigue and a swollen lymph node in axillary chain n the arm pit of the arm she recieved the vaccine. She denies drainage/discharge from site, pain in area, or overlying pore/punctum. She denies angioedema or anaphylaxis reaction to the vaccine.
990946	2/1/2021	KS	81	F	1/26/2021	1/26/2021	Systemic: Anaphylaxis-Medium
990988	2/1/2021		32	U	1/29/2021	1/29/2021	32-year-old female with a history of allergic reactions in the past, anaphylaxis, asthma, carries an EpiPen presents with shortness of breath after receiving a vaccination. Unclear exactly what patient is allergic to prior to this, however at this time patient was brought to the emergency department a few minutes after receiving a coronavirus vaccine. Within 1-2 minutes after receiving vaccine patient began to feel short of breath, began to have chest tightness, "difficulty breathing, itching of the skin, erythema to the chest skin, and distress. CODE BLUE/RRT was called and patient was brought into the emergency department immediately, thus far has not received any medications. Upon arrival patient having difficulty speaking secondary to shortness of breath, able to answer simple questions, reports feeling very short of breath, reports feeling itchy, denies that she feels swelling of the lips or tongue.

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991148	2/1/2021	FL	68	M	1/30/2021	1/30/2021	HCP was called to a patient with "tongue swelling". HCP asked MD for an Epi Pen and the paramedics are O2. O2 was applied at 2L per NC. . HCP approached vehicle where a 68yo white male was sitting in his vehicle on the driver side. Quick assessment revealed erythema of the face and angioedema. Pt was able to speak clearly, was CTA and had RRR. 911 was called. BP 160/90. EpiPen dose 1 was injected into right vastus lateralis and pt reported improvement at 1057. HCP asked for injectable diphenhydramine. HCP continued to monitor pt with RRR and CTA but erythema and angioedema began again along with swollen tongue so EpiPen dose 2 was injected into right vastus lateralis. 50mg IM diphenhydramine was injected into the right deltoid while fire rescue began to arrive on scene. Pt did not report difficulty breathing. Pt did report previous anaphylaxis to fire ant bites/stings and did report being allergic to bee stings. Fire rescue transported patient without difficulty. HCP called pt later that night at 2030 who reported doing better but still having tongue swelling.
991187	2/1/2021	IL	63	F	1/28/2021	1/28/2021	Developed hives within 2 hrs/took Benadryl that night; swelling that traveled up the arm and neck in the morning with shortness of breath/used rescue inhaler at 0400 and then again at 0800; and then anaphylaxis by 0900. Treated in ED with EpiPen then IV Solumedrol, Benadryl and Famotidine. Recovered and started on prednisone taper pack starting at 6 tabs for 3 days etc. Suggested to make follow up Dr appt for one week following incident/set for Feb 8
991579	2/1/2021	KS	39	F	1/29/2021	1/29/2021	Systemic: Anaphylaxis-Severe, Systemic: Seizure-Severe
991968	2/1/2021	DE	62	F	1/30/2021	1/30/2021	Systemic: Anaphylaxis-Severe, Systemic: Exhaustion, Systemic: Nausea
992035	2/1/2021	CA	44	F	1/28/2021	1/28/2021	Anaphylaxis: hives all over her body, lightheadedness, throat closing. Hypotension about 2 hours after the moderna was administered.. She received 2 doses of epipen before paramedics took her to the ER.

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992122	2/1/2021	FL	73	F	1/24/2021	1/26/2021	Approximately 48 hours after first dose given, pt developed generalized urticaria (hives) There was no angioedema, no anaphylaxis. Symptoms resolved with antihistamine, but recurred on 2/1/21 when she stopped- although very mild recurrence. Pt has h/o hives, intermittent, she describes as related to spicy foods, but more likely idiopathic hives by her history.
992554	2/1/2021	FL	91	M	1/13/2021	1/14/2021	Approximately 36 hours after first dose, he developed generalized hives, no angioedema, no anaphylaxis. He did go to urgent care and was given oral steroids prior to my visit with him, hives had mostly resolved at my visit on 1/27/21-- although he remained dermatographic. He has no prior h/o hives or allergies
992900	2/1/2021	SD	52	F	1/20/2021	1/22/2021	Anaphylaxis, tongue swelling, difficulty breathing, & hives, Ambulance transported pt to the nearest ER, required Epinephrine injections 1mg IM X3, IV Methylprednisolone 50mg and IV Benadryl 50mg, pt had to be transferred to higher level of care due to ongoing symptoms and was kept until 1/24/21. Pt said staff at the ER told her they knew they should report the reaction to someone but didn't know how to report it.
993086	2/1/2021		34	F	1/28/2021		34 y.o. female who arrived on-campus presented to the emergency department for increasing facial swelling, associated with tongue swelling and hives over lips and tongue that appered approximately 3-4 minutes after receiving the Moderna vaccine around 1406 hours today. Patient endorses being allergic to antibiotics, menthol, and several nuts, however, patient has not had any allergic reactions to other vaccines. She further denies any hx of anaphylaxis or need of intubation secondary to an allergic reaction. She also reports currently having a sinus infection that may be developing bronchitis which are unrelated to her current symptoms. Patient is currently on Augmentin for sinus infection diagnosed 1/23/21. Reports she has been having sinus drainage and "bronchitis". Patient monitored in ED and given diphenhydramine, famotidine, methylprednisolone, and lorazepam Discharged from ED in stable condition. Initial Vital Signs [01/28/21 1422] Blood Pressure 182/87 Heart Rate 105 Respiratory Rate 18 Temp 36.9 °C (98.4 °F) Temp src Oral SpO2 98 %

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992952	2/1/2021	KY	34	F	2/1/2021	2/1/2021	About 5 minutes after receiving the shot, I started having intense dizziness, and nausea, and my body felt very hot. My eyes teared up as well. This feeling subsided a little after 15 more minutes, so I went home. At home (and within 30 minutes of receiving the vaccine), the lymph nodes in my throat swelled considerably and I had great difficulty speaking. Having experienced anaphylaxis in the past, this was not anaphylaxis but something else entirely - it was like my vocal cords were paralyzed. I took ibuprofen to help with the swelling, but it did not seem to impact my throat or ability to speak. About 4 hours later my throat muscles seemed to loosen and I was able to speak fairly normally again.
991659	2/1/2021	OR	45	F	1/11/2021	1/11/2021	Pre-medicated with 25mgs Benadryl at time of vaccination 10:00am. At 6pm, started with feelings of being flushed all over body with tingling in extremities to include face, tongue, throat felt like it began to swell with voice beginning to get raspy. Beginning of chest tightness. By 7pm marked shortness of breath with increased chest tightness, more difficulty swallowing, raspy voice and oxygen saturations dropped to low 90's. Complete activity intolerance. Injection site had rash extending over entire upper arm and forearm that was hot, raised and painful. Took 50mgs Benadryl, multiple doses of rescue inhaler (albuterol) due to difficulty breathing following by steroid based inhaler (3 doses). Sx continued through night and slowly improved. At 5 am took another 25mgs of Benadryl and took repeated doses of albuterol and steroid inhaler for 48 hours. (normally don't use at all). Oxygen saturation level returned to normal within 8 hours. Rash resolved with persistent Benadryl use x 2 days. Due to lack of insurance coverage did not go to ER for Tx as recommended. I am a front line nurse so monitored at home. Contacted MD via messaging system MD has stated I cannot receive vaccine number 2 due to risk for complete anaphylaxis. Was notified my Lot was same lot OHA put notice out as having higher incident of vaccine reaction.

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989090	1/31/2021	LA	78	F	1/29/2021	1/29/2021	Patient in clinic for 2nd dose of covid vaccine. Within 8 minutes of receiving her injection, pt developed a rash on both arms; pt states both arms are itch and her throat felt as if it were closing. Rapid response called and patient was given Epinephrine per anaphylaxis protocol by LPN at 4:26pm. BP-146/98 p88 R17 Rapid response team arrived at 427pm. 429pm: Assessment: patient stable but felt no improvement in her throat. Pt was transported to ED for assessment.
989224	1/31/2021	KY	52	F	1/17/2021	1/17/2021	Pt received Pfizer COVID-19 vaccine. Approximately 8 minutes after administration, pt alerted me to feeling hot with mild chest tightness. She stated she has anxiety and was anxious about receiving vaccine. She confirmed no swelling of the tongue, no SOB, no itching or other signs of anaphylaxis. Pt given diphenhydramine x2 and famotidine x1 along with a cup of water. Pt requested O2 and BP be monitored. O2 sat never below 97, BP was high initially at 153/112. Pt also had jacket on initially. Pt advised to breath and relax. Pt reassessed after 10 minutes. Removed jacket for BP check which had come down to 132/94 which pt states is baseline for her as she does have a bit of high BP. She also reported at that time feeling better and had calmed down. She stated she really felt it was anxiety. She left with instructions to call 911 or seek emergency attention if Sx reoccur.

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988372	1/30/2021	KY	64	F	1/16/2021	1/16/2021	COVID- 19 Vaccine. She was experiencing chest tightness, SOB, and dizziness. 50mg of Benadryl and 20mg of famotidine was administered around 1410. Patient was still experiencing chest tightness and was having difficulty breathing. 0.3mg of epinephrine was administered at 1420. EMS was called. Breathing improved. Pulse ox 100%, HR 68, BP 130/89. EMS arrived and assumed patient care. Pt seen in Emergency Room 1/16/2021 1513 CHIEF COMPLAINT: reaction to COVID vaccine HISTORY OF PRESENT ILLNESS: Patient is a 64y F with PMHx significant for Myopericarditis, Anxiety and HTN who presents to ER after developing tongue swelling, wheezing, tunneled vision and shortness of breath. Patient states that she was getting first shot of COVID19 Pfizer vaccine at 2:00 pm. After getting vaccine she waited 15 minutes like she was told and recalls room getting very hot at approximately 6 minutes after getting vaccine. She also states that her tongue felt swollen. She then noticed her vision started to turn dark and then she felt dizzy. She told pharmacist about symptoms and then she was given one pill of Benadryl. This did not help and actually made her symptoms worse. She recalls wheezing. She was given another pill of what she believes was Benadryl. She also recalls pharmacist measured her BP and her husband, who was present, reported that her blood pressure was in the 140s This did not improve so she was given 0.3mg IM epinephrine shot. This significantly improved her symptoms. However, she was sent to ER. She denies any hx of recent UTI or GI infection. She denies fevers, chills, nausea, diarrhea, chest pain, generalized itching, vomiting, abdominal pain, generalized swelling, headache or syncopal episode. She denies any past reactions to vaccines. She denies current SOB and feels like her symptoms resolved. Denies hx of COPD or asthma. Physical exam did not show any recurrent signs of wheezing or tongue edema. Her SaO2 was 100% on RA and BP was within baseline 140-160s. Given episode, we decided to obtain tryptase levels. We also observe patient to ensure she did not have any recurrence of symptoms. She remained hemodynamically stable and SaO2 remained in mid 90s to 100. She was given a rx for epinephrine pen should symptoms recur though this is highly unlikely as she remained stable throughout ER stay. She was also given

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							instructions to pick up OTC Benadryl and Pepcid. She does have antihistamines listed as an allergy but patient states that she gets tachycardic upon taking tabs, so this could just be a side effect. We will follow up with tryptase levels but even if tryptase levels return as normal, it does not mean she did not have an anaphylactic reaction to vaccine. Her clinical picture puts this diagnosis high in the differential. Teaching and instructions were given to patient and her husband. She was advised to return to ER if symptoms recur. IMPRESSION: Anaphylaxis Anxiety attack
987586	1/30/2021	ME	21	F	1/27/2021	1/27/2021	Pt was administered the first dose of Moderna Covid-19 vaccine at 1930 hours and then monitored for 15 minutes post admin. During that time, pt developed some face and neck skin flushing, dizziness and "heart racing." Pt notes she has allergies to shellfish and tree nuts. Pt does not appear to have any respiratory compromise, denies any pain or trouble breathing, denies CP, HA, N/V/D, SOB, LOC. Pt airway is patent and pt does not appear to be in anaphylaxis. Pt denies any PMH; pt hx IUD placement and pt states she takes vitamins. Four-lead and 12-lead ECG monitoring showing sinus tachycardia, with a max sustained rate in the 170s at one point. Pt is otherwise asymptomatic. Transported to ED as a precaution. Pt HR gradually decreased en route to the 130s. Vagal maneuvers attempted twice, briefly dropping pt HR into the 70s and sinus rhythm, but effect was unsustained. Transport otherwise unremarkable

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988066	1/30/2021	CA	48	F	1/29/2021	1/29/2021	After ten minutes my throat began to feel swollen, a feeling of a lump in my throat. After around 20 minutes I also began to feel more light headed/dizzy. I was moved to be observed by a nurse for another 20 minutes and when symptoms did not subside I was moved to the Emergency Department where they administered Epinephrine at 9:27am, Pepcid, 9:24am, Solu-medrol 9:24-10:50am. Diagnosis: Anaphylaxis. Dr. wanted to prescribe Benadryl IV but I declined as I needed to drive home and the facility was far from home. I was discharged around 1:00pm. A prescription for an Epi Pen was made by Dr. and filled that day at pharmacy. and spoke to my Dr. at another healthcare organization at 4:30pm. Benadryl OTC was then rx'd by my primary care doctor at 4:30pm-50mg every 6 hrs moving to 25 mg every 6 hours the next day. Symptoms of swollen throat continued into the next day and have not yet abated but also have not worsened. Due to continued throat swelling I have taken 50mg of Benadryl the next day as well. Dr. my primary care Dr. scheduled an allergist appt for Feb. 3, 2021 and advised I should not get the second dose of the COVID19 vaccine until I speak with an allergist and have a treatment plan developed.
988542	1/30/2021	CA	47	F	1/30/2021	1/30/2021	Pt with mild tingling and itching in her throat approximately 10 minutes after receiving 2nd dose of COVID vaccine. Administered 25 mg PO benadryl with improvement in sx. Pt again started to develop itching and tingling in her throat. Administered 25 mg PO benadryl. Sx remain the same and then started to worsen after about 10 minutes. Started to feel slightly SOB. BP 146/92, HR 80. Rapid response called. Rapid response team at bedside; pt transported to ED for further observation. Pt given 40 mg PO prednisone in the ED. No further ED notes available at this time. Pt endorses hx of anaphylaxis with her last flu shot. Also had allergic reaction with her first COVID shot including throat tingling and itching that resolved with PO benadryl.

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988702	1/30/2021	MI	67	F	1/14/2021	1/16/2021	Pfizer-BioNTech COVID-19 Vaccine EUA. 48 hours after I had 2nd vaccine I had major swelling of mouth and lips/gums; this gradually increased over night and diminished by end of next day. I have had delayed reactions before. Of note, I have significant hx of angioedema but no hx of anaphylaxis. I had no food, drink nor medication that would have caused this reaction; I'm sure it was a delayed reaction to the vaccine
988739	1/30/2021	CA	84	F	1/30/2021	1/30/2021	RN called into waiting area in the hallway to assist in evaluation of patient having possible vaccine reaction approx 1505. She had reported her face was itching, attended by doctor who administered 25mg liquid Benadryl orally. Pt complained of facial flushing but felt ok otherwise. 1510: BP184/98, HR 99 1517: BP 168/92, HR 75, Sats 96% on RA 1525: BP 78, Sats 96% on RA Pt remained breathing comfortably. After taking the Benadryl, pt c/o hoarse voice but denies sensation of tightness or trouble breathing. She is breathing and sitting comfortably. No rash. Cheeks slightly flushed, but no change over 30 min. No dizziness upon standing. Feeling fine otherwise. Released by provider who attended patient for the duration to go home and check her BP there, she will take an additional 25mg of Benadryl at home if any s/s continue. If any worsening, she agrees to go to the hospital. She states that her anaphylaxis/angioedema episodes in the past were nothing like she is feeling today - were much worse and more rapid onset.

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988493	1/30/2021	OR	43	F	12/28/2020	12/28/2020	During the 15 minute observation following the 1st Moderna vaccine dose, the patient reported her tongue 'felt thick,' flushed skin, redness on face, neck, hands, BP=98/60, HR=100. Patient felt 'jittery' and 'heart racing.' Was transferred to ED for evaluation given that patient reported her tongue 'getting tighter.' In the ED, the patient was treated with diphenhydramine 25mg x 2 doses, methylprednisolone 125mg x 1 dose, famotidine 20mg x 1 dose, and NS IV fluids. Hypoglycemia was ruled out with CBG=87. The physician avoided treatment with epinephrine due to it being listed on her allergy list with a reaction of 'shortness of breath.' Symptoms resolved over the next 3 hours. The patient was discharged home with a new prescription of oral prednisone taper. Subsequent follow-up with her primary care provider, in consultation with an ID provider, recommended that this patient NOT get a 2nd dose. Covid-19 vaccine was added to her allergy list with a reaction of 'anaphylaxis.'
987893	1/30/2021	VA	44	F	1/29/2021	1/29/2021	At first I was feeling dizzy, then the back of my throat felt itchy. EMS came over, and took my temperature, which was 98 degrees. Then I started to feel compression and pain in my ribs on both sides, and the middle of my chest - like an elephant was sitting on it, or I had a corset wrapped too tightly around my diaphragm. Then I started having uncontrollable coughing fits, followed by wheezing. EMS got me some ice packs for my ribs and the middle of my chest, but I had to get up and use the bathroom. When I get anaphylaxis, I usually take two aspirin, a benadryl, a cetirizine, a CBD capsule, a famotidine, a 20 mg steroid pill, and a hydroxyzine pill - all at once. EMS agreed I should take it, and they gave me a shot of epinephrine in the arm. then they loaded me on to the ambulance, where I got a shot of steroid, and we went to the hospital in. EMS also started an IV for me. At the hospital, they gave me another shot of EpiPen, over 20 minutes after the first one, and a shot of Benadryl. by the end of 2 hours, my breathing was back to normal, and I was able to go home. Today I still feel a little bit dizzy, but mostly my arm is sore where I got the vaccination. I also still have a headache.

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984979	1/29/2021	IL	51	F	1/20/2021	1/20/2021	Presented to ED on 1/21/21 with chest tightness and shortness of breath. Patient reports chest pain with deep inspiration. Shortness of breath started shortly after receiving vaccine on 1/20/21 and persisted into 1/21/21. Patient reports no cough, positive lightheadedness with no syncope, positive nausea with no vomiting. Per exam no fever, no rash, no tongue/mouth swelling. Emergency Department MD states does not meet threshold for anaphylaxis thus no epinephrine administered. Patient received Benadryl 50mg IV, Pepcid 20mg IVPB, Solu-Medrol 125mg IV, and 0.9% NaCl 1L IV bolus.
985939	1/29/2021	CA	60	U	1/13/2021	1/13/2021	Anaphylaxis-like symptoms; A spontaneous report was received from a physician concerning, 60-year-old, patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced anaphylaxis-like symptoms. The patient's medical history included rheumatoid arthritis, hypertension and allergies to diphenhydramine and meperidine. No concomitant medications were reported. On 13 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 041L20A) intramuscularly for prophylaxis of COVID-19 infection. On 13 Jan 2021, the patient experienced anaphylaxis-like symptoms that included, anaphylaxis, angioedema, shortness of breath, itching, swelling of eyes, and sleepiness. The patient was treated with epinephrine injections and taken to the emergency department. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event, anaphylaxis-like symptoms, was unknown.; Reporter's Comments: This case concerns a 60-year-old patient who received their first of two planned doses of mRNA-1273 (Lot 041L20A), and who experienced the serious unlisted event of anaphylaxis-like symptoms. Very limited information regarding this event has been provided at this time. Based on the current available information and temporal association between the use of the product and the onset of event on the day of vaccination, a causal relationship cannot be excluded and the event is considered possibly related to the vaccine.

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985937	1/29/2021	CA	43	U	1/13/2021	1/13/2021	Anaphylaxis-like symptoms; A spontaneous report was received from a physician concerning a, 43-year-old patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced anaphylaxis-like symptoms. The patient's medical history included breast cancer. The patient had no history of allergies or prior vaccine reactions. No concomitant medications were reported. On 13 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 041L20A) intramuscularly for prophylaxis of COVID-19 infection. On 13 Jan 2021, the patient experienced anaphylaxis-like symptoms that included, anaphylaxis, angioedema, shortness of breath, itching, swelling of eyes, and sleepiness. The patient was treated with epinephrine injections and taken to the emergency department. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event, anaphylaxis-like symptoms, was unknown.; Reporter's Comments: This case concerns a 43-year-old patient with medical history of breast cancer, who received their first of two planned doses of mRNA-1273 (Lot 041L20A), and who experienced the serious unlisted event of anaphylaxis-like symptoms. Based on the current available information and temporal association between the use of the product and the onset of event on the day of vaccination, a causal relationship cannot be excluded and the event is considered possibly related to the vaccine.
985695	1/29/2021	FL	50	F	1/21/2021	1/21/2021	Pt reports itchiness and swelling of her tongue. Visually inspected by paramedic onsite which confirmed oral cavity, tongue and back of throat swollen. Pt stated NO difficulty breathing or talking. Lung sounds clear as per paramedic. O2 sats 100%. 911 called to assess, pt refused care or transport. Pt made aware of potential outcomes of angioedema and anaphylaxis.
985428	1/29/2021	TX	54	F	12/31/2020	12/31/2020	Anaphylaxis
985370	1/29/2021	FL	72	F	1/10/2021	1/11/2021	Mild anaphylaxis 14 hours later!! Upper palate and tongue slight swelling and very itchy all over extremities

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984395	1/29/2021	WI		F	1/13/2021	1/13/2021	Anaphylaxis; Burning sensation in the arm; This spontaneous report was received from a consumer who was a 39-years-old female patient who received the Moderna COVID-19 vaccine (mRNA-1273) and experienced an immediate burning sensation in the arm and anaphylaxis. The patient's medical history was not provided. Concomitant Medications were not reported. On 13 Jan 2021, prior to the onset of the symptoms, the patient received the first of two planned doses of mRNA-1273 intramuscularly in the left arm (Lot number: 025L20A). She immediately felt a burning sensation in the arm, dizziness, and developed hives on her arm, face and chest. The hives on her face were itchy. She presented to the Emergency Department and was treated for anaphylaxis. Treatment included intravenous diphenhydramine and intramuscular epinephrine. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events, burning sensation in the arm and anaphylaxis, were considered resolved on an unknown date.; Reporter's Comments: This case concerns a 39-year old female patient with unknown medical history and concomitant medications. The patient experienced an unexpected event of Anaphylaxis that was considered medically significant. Additionally, the patient experienced expected non-serious event of Burning sensation in the arm. The events occurred immediately after receiving their first of two planned doses of mRNA-1273 (Lot number: 025L20A). Based on temporal association between the use of the product and the onset of the events, a causal relationship cannot be excluded and the events are considered possibly related to the vaccine.
985251	1/29/2021	OH	43	F	1/27/2021	1/27/2021	Anaphylaxis. 2 minutes after injection I developed tingling of lips and tongue. 5 minutes after I couldn't speak well and developed a cough. 10 minutes after ER doc gave me pepcid 20mg and zyrtec 10mg. Cough and shortness of breath started and tongue swelling. I was then taken back to an area with team including ER doc and 2 nurses. Given benadryl liquid and ultimately epi injection. Called Ambulance and taken to Hospital where I was given more benadryl IVP, ativan, and monitored for 8 hours. Pruritic, congestion, and difficulty talking since day of shot. this is day 2 after injection

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984793	1/29/2021	PA	67	F	1/27/2021	1/27/2021	7:07 Started coughing then became nauseated proceeded to vomit. Nurse suggest after about 10 mins that she should take me to ED for Zofran. Upon getting to ED I was wheezing badly and trying to find inhaler in purse; wheezing and unable to catch a breath I was placed in a room, by then my body was turning red and wheezing worse. I was given epinephrine and prednisone immediately for anaphylaxis. They reacted immediately upon my arrival. Time I unsure. I just say thank God for them. Meds Given- Tylenol Duoneb, Decadron, Benadryl, Epinephrine, Pepcid, Nss
984397	1/29/2021	CA	59	U	1/13/2021	1/13/2021	Anaphylaxis-like symptoms; A spontaneous report was received from a physician concerning a 59-year-old, White, patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced anaphylaxis-like symptoms. The patient's medical history was not reported. No concomitant product use was reported. On 13 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 041L20A) intramuscularly for prophylaxis of COVID-19 infection. On 13 Jan 2021, after vaccine administration, the patient experienced anaphylaxis-like symptoms that included, anaphylaxis, angioedema, shortness of breath, itching, swelling of eyes, and sleepiness. The patient was treated with epinephrine injections and taken to the emergency department. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event, anaphylaxis-like symptoms, was unknown.; Reporter's Comments: This case concerns a 59 year old subject with unknown medical history, who experienced a serious unexpected event of Anaphylactoid reaction. The event occurred after first dose of the study medication administration. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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985940	1/29/2021	CA	23	U	1/13/2021	1/13/2021	Anaphylaxis-like symptoms; A spontaneous report was received from a physician concerning a, 23-year-old patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced anaphylaxis-like symptoms. The patient's medical history included allergy to soy. No concomitant medications were reported. On 13 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 041L20A) intramuscularly for prophylaxis of COVID-19 infection. On 13 Jan 2021, the patient experienced anaphylaxis-like symptoms that included, anaphylaxis, angioedema, shortness of breath, itching, swelling of eyes, and sleepiness. The patient was treated with epinephrine injections and taken to the emergency department. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event, anaphylaxis-like symptoms, was unknown.; Reporter's Comments: This case concerns a 23-year-old patient who experienced a serious, unexpected event of Anaphylactoid reaction. The event occurred same day (exact time not provided) after the first dose of mRNA-1273 (Lot number: 041L20A) administration. The treatment included EpiPen injection. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
985192	1/29/2021	UT	24	F	1/7/2021	1/7/2021	Initial adverse event occurred 25 minutes after injection. Sudden confusion, burning heat and hives and burning red rash spreading from injection site, up neck and throat and down arm to hand. 5 days after the injection, a severe allergic reaction occurred where my entire body broke into hives and a red burning rash, again starting at the injection site. Throat tightness, itchiness in scalp and groin, and difficulty concentrating (all my usual symptoms of anaphylaxis) occurred. Advised by health care provider to take Benadryl immediately and to have epi-pens on hand. Loratadine was prescribed.

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987259	1/29/2021	MN	32	F	1/29/2021	1/29/2021	Client received vaccine at 12:00pm after passing risk screening and completing consents at a vaccination clinic event at a local fire station. At 12:09pm, while client was sitting in the waiting area after vaccination as part of the recommended protocol to monitor for adverse events post-vaccination, she began feeling unwell. She started to walk toward the vaccination stations and was stumbling. Staff escorted her to a preassembled cot and had her lie down. The patient reported feeling "tingling" in her face, throat and lips and felt like her lips and tongue were swollen. There was no swelling visually apparent. Staff called 911, and assessed patient, collected some vital signs (BP 140/90, pulse 83, O2 sats 100,%) and prepared epinephrine auto injector pen. First responders who were in the fire station building arrived promptly. The patient continued to feel swelling in her throat, but no difficulty breathing. She appeared pale and weak but did not exhibit other signs of anaphylaxis. The healthcare team administered epinephrine in left deltoid. EMS arrived, and team gave report. Care was transferred to EMS. EMS transported patient to local hospital. Patient walked to ambulance without difficulty.

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985941	1/29/2021	CA	56	U	1/13/2021	1/13/2021	Anaphylaxis-like symptoms; A spontaneous report was received from a physician concerning a 56-year-old patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced anaphylaxis-like symptoms. The patient's medical history was not reported. No concomitant medications were reported. On 13 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 041L20A) intramuscularly for prophylaxis of COVID-19 infection. On 13 Jan 2021, the patient experienced anaphylaxis-like symptoms that included, anaphylaxis, angioedema, shortness of breath, itching, swelling of eyes, and sleepiness. The patient was treated with epinephrine injections and taken to the emergency department. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event, anaphylaxis-like symptoms, was unknown.; Reporter's Comments: This case concerns a 56-year-old patient . The patient's medical history was not reported. The patient experienced a serious, unexpected event of Anaphylactoid reaction. The event occurred the day the patient received the first dose of mRNA-1273 (Lot number: 041L20A) at an unspecified time. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
985164	1/29/2021	IL	49	F	1/27/2021	1/27/2021	Presented to ED @ 0815 (approx 45 mins after 2nd Moderna vaccine) c.o. dizziness, N/V, chest pain. Patient reports throat swelling although no obvious facial/throat swelling on exam, no wheezing. Treated as anaphylaxis. Temp 36.2, BP 186/103, HR 70, RR 24, O2 sat 99. Benadryl 50mg IV, Epinephrine 0.5mg IM, Pepcid 20mg IV, Zofran 4mg IV, Solu-Medrol 125mg IV, Tylenol 1000mg po, 1L NS IV bolus. H/o covid infection ~ 3 months ago, now recovered from COVID PNA as well.
987516	1/29/2021	AZ	49	F	1/29/2021	1/29/2021	Patient experienced anaphylaxis to first dose of Covid 19 vaccine. Throat tightness and swelling. She received IM diphenhydramine at 4:28pm, followed by dose of epinephrine IM at 4:30pm and second dose of epinephrine IM at 4:37pm. Patient was transferred via ambulance to hospital.

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987229	1/29/2021	PA	43	M	1/29/2021	1/29/2021	Patient (DOB 09/20/77) had a reaction to the Moderna Covid-19 vaccine given on 1/29/2021. On the screening form, patient indicated she had allergies. She verbally said she had multiple allergies and had an anaphylactic reaction previously to allergy shots received in a doctor's office. She said she does carry an EpiPen. RPh counseled on the cases of anaphylaxis with the Pfizer vaccine and recommended a 30 minute monitoring period following the vaccine in accordance with CDC guidelines. Patient agreed and received the vaccine at approximately 11:30am with instructions to check back in with RPh at 12:00pm. A few minutes later (at least 5 minutes), a friend of Patient alerted RPh that patient had fainted. The friend was able to catch patient before she fell off the chair and lower her to the ground. Patient was awake and answering questions but appeared to be having trouble maintaining consciousness. She denied shortness of breath, itching, swelling, and no rash or wheezing was evident. An EpiPen was available and present but not administered due to lack of respiratory symptoms. 911 was called at 11:39am with the patient's permission. Her symptoms remained the same until EMS arrived and she left in the ambulance at 11:57am.
986681	1/29/2021	MN	33	F	1/5/2021	1/5/2021	facial and eye swelling. No anaphylaxis noted.
986584	1/29/2021	MD	33	F	1/19/2021	1/20/2021	Excess sneezing that started approximately 18 hours after the vaccination and lasted for 12 hours. The patient sneezed a total of 30 - 40 times. There were no other symptoms, such as rhinorrhea, rhinitis, or anaphylaxis, therefore this may have been a mild allergic reaction to the vaccine. The sneezing resolved without intervention.
986545	1/29/2021	CA	55	M	1/25/2021	1/26/2021	Serious anaphylaxis started at 630 PM the day after the Moderna dose was administered. I ended up at the Medical Center ICU for two days before conditions abated and I could be discharged.
986426	1/29/2021	AL	43	F	1/21/2021	1/23/2021	Took vaccine on 1/21/21. Symptoms on 1/23/21 included widespread rash, lips swelling, hives, dizziness, trouble breathing. Received epinephrine, steroids, benadryl. Diagnosed with acute anaphylaxis due to possible allergy to Polyethylene Glycol

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986226	1/29/2021	VA	39	M	1/29/2021	1/29/2021	1/29/2021 1000 10 minutes after Moderna COVID-19 vaccination, resident reports "heart racing" and pruritis. No SOB, no throat complaints, no n/v/d, abd cramping, rhinorrhea, or dizziness. On exam, NAD, lungs CTAB, HR 103, rhythm regular, no murmur; lungs CTAB, no increased WOB. No oropharyngeal edema. No difficulty speaking or swallowing, no hives.O2 sat 97% RA. 1006: Physical exam unchanged, continues to report pruritis. 25 mg benadryl PO given. 1017: physical exam unchanged, reports L side chest burning, 4/10. No other complaints. Escorted to medical for EKG, which is unremarkable and unchanged from prior: SR, rate 90 BPM, nonspec t wave abnormality. QRS 93ms, QTc 414 ms. Symptoms resolved by end of visit in medical clinic. 1325 call to cookchill LPN: resident completely asymptomatic. A/P: abnormal s/s after vaccination, No evidence of anaphylaxis. No rash ever evolved. Pruritis resolved very soon after benadryl administration. report in VAERS.
986180	1/29/2021	MO	35	F	1/28/2021	1/28/2021	Patient reported feeling abrupt onset at about 5 minutes after injection of a sensation of 1/2 of her head feeling hot like she was in a hot shower and a flushed feeling. No other sx that would suggest anaphylaxis. 40 minutes in while still experiencing above affected side ear was flushed. Given 50mg of benadryl at that time and all symptoms resolved by 65minutes

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986006	1/29/2021	WA		M			His reaction was swollen lymph nodes nearly blocking his airway; His reaction was swollen lymph nodes nearly blocking his airway; This is a spontaneous report from a contactable consumer (pharmacy intern) reported a male patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date not reported), via an unspecified route of administration from an unspecified date at a single dose for Covid-19 immunization. The patient medical history and concomitant medications were not reported. On an unspecified date, the patient reaction was swollen lymph nodes nearly blocking his airway. He did not seek treatment and it did subside. It was reported that a patient received the first dose of the Pfizer Covid vaccine and it seems like there was swelling of the lymph nodes in the neck to the point where it started to block the airway. Patient had no swelling of the tongue or shortness of breath, but there was swelling that was starting to block the airway due to that. Patient had no anaphylaxis reaction. They are wondering if he should get the second vaccine. Knows there is extensive guidance on the CDC and on Pfizer website about not to get the second dose if anaphylaxis occurs, but they don't consider this anaphylaxis reaction in this case. Should patient get it or not or if he can get it to go to a facility where he can be monitored and have Epi pen on stand by if needed. They know normally it would be treated with steroids, but they tend to counter interact with the vaccine which can affect the immune system. Outcome of the events was recovering. Information about lot/batch number has been requested.
987534	1/29/2021	OR	33	F	1/24/2021	1/24/2021	Patient received COVID Vaccine #1 and reported that about 20 minutes later had onset of left sided facial tingling. No oral or facial swelling noted. No SOB or wheezing. Hx of anaphylaxis + has Epi pen at home. Felt like she had some difficult swallowing but this is her baseline + her mouth was very dry. She was monitored for 60 minutes with improvement of her symptoms. Benadryl + Zyrtec provided but patient did not take them at the time of observation.

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982893	1/28/2021	CA	25	F	1/28/2021	1/28/2021	Sudden rise in temp from 98 to 99.8 in five minutes Flushing, mild SOB, tachycardia. BP is 128/88. Transported via ambulance to hospital. Did state that she had previous anaphylaxis to food allergies. Allergic to eggs. Always has EpiPen on hand. Positive for Covid in June 2020.
981919	1/28/2021	NC	67	F	1/26/2021	1/26/2021	On 01/26/21, 67 yo F with anemia, asthma, Afib (on rivaroxaban), fibromyalgia, DM2, HLD, and osteoarthritis was administered COVID-19 Moderna vaccine 0.5 mL in left deltoid (Lot #011J20A, Exp: 05/11/21). Pt has numerous documented allergies including iodine (hives, facial swelling), Shellfish Containing Products (Hives, facial swelling) and penicillin (edema). Pt initially tolerated injection without incident and was sent for post-injection observation. Within 10 minutes, pt developed acute SOB, increased WOB, wheezing, and cough. Pt also reported itching skin and scratchy throat. Provider notified and exam found pt in respiratory distress with increased work of breathing, bronchospasm and wheezing. Pt had no rash, lip swelling or vomiting. Vitals assessed as O2 sats >96%, BP 140-150s/60s, HR 70-80s. Pt was administered albuterol 2.5 mg via nebulization x 2, diphenhydramine 50 mg IM and epinephrine 0.3 mg IM. Pt was subsequently transported to ED. By time of arrival, pt's symptoms had significantly improved. Pt administered famotidine 20 mg IV and prednisone 60 mg PO and placed on continuous cardiac and pulse oximetry monitoring. After complete symptom resolution, pt was discharged in stable condition. Pt's allergy profile was updated to include Moderna Covid-19 Vaccine (eua) (rxn: Anaphylaxis; severity: High).

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980365	1/28/2021	CA	45	U	1/13/2021	1/13/2021	Anaphylaxis-like symptoms; A spontaneous report was received from a physician concerning a 45-year-old, patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced anaphylaxis-like symptoms. The patient's medical history included hypertension. The patient had no history of allergies or prior vaccine reactions. No concomitant medications were reported. On 13 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 041L20A) intramuscularly for prophylaxis of COVID-19 infection. On 13 Jan 2021, the patient experienced anaphylaxis-like symptoms that included, anaphylaxis, angioedema, shortness of breath, itching, swelling of eyes, and sleepiness. The patient was treated with epinephrine injections and taken to the emergency department. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event, anaphylaxis-like symptoms, was unknown.; Reporter's Comments: This case concerns a 45-year-old patient with medical history of hypertension, who experienced a serious, unexpected event of Anaphylactoid reaction. The event occurred the day the patient received the first dose of mRNA-1273 (Lot number: 041L20A), at an unspecified time. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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981402	1/28/2021	AK	38	F	1/26/2021	1/26/2021	C-O was working in the vaccine clinic today assisting in scheduling customers. She obtained her second COVID-19 vaccine at approximately noon today. At 1330 she approached my desk with c/o left sided abdominal pain, scratchy throat, voice changes, and feeling tachycardic. Denied hx. Anaphylaxis or hx. Adverse reactions to any vaccines. She was given 50mg of diphenhydramine at 1332. At this time her pulse was 125, oxygen saturation 97%, unable to obtain BP due to small cuff size available. Med rec completed. Medical history taken, no contraindications to COVID-19 vaccine noted. She was advised to lay down during this time and reported feeling a little better within 30 minutes of taking diphenhydramine, though noted onset of headache starting and mentions hx migraines. By 1409 her pulse was reduced to 98 bmp. 1434 C-O reported feeling a little lightheaded upon standing from laying, pulse 92 and oxygen saturation 98. C-O was advised to sit and dangle for a time and then she decided to lay back down. At 1443 C-O reported improvement in symptoms except now had headache and drowsiness, BP 118/78, Pulse 90, oxygen saturation 98. C-O requested to leave to coordinate pickup from relative and I felt she was stable and did not require further treatment or monitoring at this time so agreed she could leave
981498	1/28/2021	PA	67	F	1/27/2021	1/27/2021	SOB - wheezing nausea, vomiting - Anaphylaxis treatment Epinephrine, Tylenol, Duoneb, Decadron, Benadryl, Pepsid Nss
981634	1/28/2021		22	F	12/29/2020	12/30/2020	Anaphylaxis - throat closing/ difficulty breathing
981762	1/28/2021	MA	17	F	1/27/2021	1/27/2021	Systemic: Anaphylaxis-Medium, Systemic: Rash (other than injection site)-Mild, Systemic: Other- wheezing, shortness of breath, coughing-Medium

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983907	1/28/2021	MD	43	F	1/21/2021	1/21/2021	Had anaphylaxis reaction 5 minutes after receiving COVID vaccine at 0916. She was having wheezing, tightness of throat, and difficulty breathing, nausea. She was treated with Albuterol inhaler followed by self injecting epipen at 0925 with improvement subsequent respiratory distress. She was given supplemental oxygen and code team was called and arrived within 3 minutes. IVs started and given IV benadryl 50 mg and IV solumedrol 125mg @0941. She continue to be in respiratory distress and 2nd dose of epipen at 0946 was administered. She continue to revert back to anaphylaxis, She was administered 3rd epi injection at 0958 am administered by the paramedics and transported to Hospital.
982408	1/28/2021	NH	29	F	1/28/2021	1/28/2021	At 07:30 patient approached this writer and stated he was feeling lightheaded and sweaty and felt as though she may faint. This writer instructed her to sit down. This writer then requested assistance from RN. As RN approached where patient was sitting, patient stated "yeah I'm going to faint" she then fell forward from her chair onto the floor, with the top of her head hitting the floor first. RN instructed staff to call the Rapid Response Team who was unavailable. This writer gathered the anaphylaxis/reaction supplies that were on hand. Patient's body postured and at that time RN rolled her onto her side. Patient quickly regained consciousness. Vitals were taken and stable. Patient was given the opportunity to be seen in the ED multiple times but she declined. She stated that her lips felt "tingly" and was given 50mg/20mL Diphenhydramine oral solution. She remained in the COVID vaccination clinic at Medical Center for observation for 40 minutes, at which time her husband retrieved her and escorted her home.

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982943	1/28/2021	MO	36	F	1/28/2021	1/28/2021	Client felt her heart was "Racing" and felt dizzy and light headed. Vital signs were elevated but no anaphylaxis or stridor. Client lowered to the floor and cooling measures initiated as face and neck reddened. Controlled breathing initiated with client responding positively with Blood pressure lowering along with pulse. Client did re enter the facility after leaving briefly following resting for a while. On re-entering stated she felt the same as before. Recovered quickly and was able to leave feeling better, but not quite back to baseline. Client had a light sugary breakfast before a work out then came to get her second shot. Advised to follow up with her physician if she became symptomatic again, Also advised to eat on leaving. Instructions understood by client.
983113	1/28/2021		45	F	1/25/2021	1/25/2021	Patient is a nurse and received her 2nd COVID vaccine dose 1/25/2021. She knew she was at risk for anaphylaxis so she was kept under observation at the vaccine administration site. Ten minutes after receiving her shot she felt her lips starting to tingle along with lightheadedness. She did not have any other symptoms. She was given 50mg IM benadryl, and the patient was transported to the emergency department. Her symptoms resolved after receiving benadryl. After being evaluated in ER, where no further treatment was warranted, she was discharged with Pepcid, prescription for 4 days of prednisone, and EpiPen. She was given a referral to allergy clinic.

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983625	1/28/2021	CO	79	F	1/28/2021	1/28/2021	79 y/o female patient presents with "shakes" after having received the Moderna COVID Vaccine. Pt state she "feels like a mac truck hit her". Her hands are shaking but it feels like her insides are shaking. "Too much trouble to stand up, really, really tired." General Examination: GENERAL APPEARANCE: alert pleasant, in no acute distress female. HEAD: normocephalic atraumatic. ORAL CAVITY: mucosa moist. THROAT: clear, no erythema or swelling. LYMPH NODES: no cervical adenopathy. SKIN: warm and dry. HEART: regular rate and rhythm. LUNGS: clear anteriorly and posteriorly good air movement no wheezes, rales, rhonchi. CHEST: normal shape and expansion. ABDOMEN: soft and nondistended. NEUROLOGIC: alert and oriented. Adverse effect of other viral vaccines, initial encounter - T50.B95A Patient observed for a full hour after vaccine administered. No signs of anaphylaxis appreciated. Patient warned of warning signs of worsening adverse reaction and allowed to go home. Patient was somewhat improved prior to allowing to leave. Adverse reaction will be reported to CDC.
981948	1/28/2021	NC	49	M	1/23/2021	1/23/2021	EE presented at COVID vaccine clinic for Pfizer #2. Lot: EL3247 Administered at: 1001 He noted that he was itching and went to the observation room. I repounded. Pt reports that after 15 minutes or so, pt began to itch Notes that he did not itch with the first vaccine he is itching all over. His not scratching and does not appear to be in distress 10:20 124/69 HR 73 O2 99 AAO, pink, talkative 10:26 HR: 78 O2: 98 not scratching or itching by appearance no anaphylaxis in the to vaccines or food in the past previous reaction to Belpuca-- cannot swallow and tongue feels fat Discharged home. He will go home and take benadryl. Will notify us if anything more happens

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977568	1/27/2021	MA	37	F	1/22/2021	1/22/2021	Pt presented to COVID vaccine clinic today and developed a mild reaction after receiving her first Pfizer vaccination. Denies hx of known allergies or hx of anaphylaxis reactions. Pt reported palpitations and metallic taste in mouth 15 minutes after receiving the vaccination as well as a slight tightness sensation in her throat like there was something stuck in her throat. Metallic taste resolved after a few minutes. Pt denied SOB, swelling of face/tongue/throat, difficulty swallowing, nausea, rash, itchiness, dizziness. No visible swelling. BP: 127/66 HR: 80 O2: 100% Paged Allergy. Pt advised to stay for 30 more minutes and reassess. After 30 minutes pt reported palpitations had resolved. Throat symptoms improved but not completely resolved. Paged Allergy again to check in. Advised to give Zyrtec 10 mg and observe to see if there is any improvement
977427	1/27/2021	FL	69	F	1/12/2021	1/24/2021	The injection site on my right upper arm is swollen, red, itchy, and warm to the touch. Measures 4? long and 3? wide and is oval shaped. I noticed an itch on 1/24/21 @ night and again the next morning and upon close inspection found the reddened oval shape that was warm and swollen. It continues today on 1/27/21. I am not exhibiting any signs of anaphylaxis. My concern is whether is is safe form me to receive the second Moderna vaccine on February 9th.
977251	1/27/2021	AL	29	F	1/25/2021	1/25/2021	Systemic: Anaphylaxis-Severe, Systemic: Rash (other than injection site)-Medium, Systemic: Headache-Severe, Systemic: Other- Itching-Severe

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976758	1/27/2021	CA	60	F	1/4/2021	1/4/2021	like an anaphylactic reaction but not in her throat; itching and inflammation, in eyes as well/eyes were swollen and itchy; itching and inflammation, in eyes as well; swelling on her eyes and itching on her eye lids; swelling on her eyes and itching on her eye lids; welts; whelps on her hip, inflamed and itchy/general arthritis symptoms; Headache dull; shingle like rash on tailbone, genital area / raised itchy rash on the tailbone like shingles; itching on her face that she couldn't see / raised itchy area on her left cheek and eyes; rash / rash down her thighs/rash that was across her body; rash vulva; swelling / vulva was swollen; itching / itching around the genital area, vulva; itching / itching around the genital area, vulva; This is a spontaneous report from a Pfizer-sponsored program. A contactable Nurse (patient) worked in outpatient mental health reported that a 60-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284, Expiry Date: Apr2021) via an unspecified route of administration on 04Jan2021 at 16:20 in the left arm at single dose for COVID-19 vaccination. Vaccine administered at hospital and not military facility. No additional vaccines administered on same date of the Pfizer suspect. Medical history included ongoing Graves' disease (the patient had her thyroid irradiated away for Grave's disease 25 years ago). Family Medical History was none. Concomitant medication included ongoing levothyroxine 1.25 mcg once daily by mouth Graves' disease taking for 25 years. Prior vaccination within 4 weeks was none. The patient received her Pfizer COVID 19 vaccine on 04Jan2021. Since then she started to experience a genital itch immediately; a rash that was across her body; eyes were swollen and itchy; new itchy rash 13Jan2021. She felt okay going home then she started to have itching around the genital area. She thought she might have a yeast infection but she didn't have any other symptoms for a yeast infection. Her vulva became swollen from 05Jan2021 and itchy from 04Jan2021 and she noticed rash around her body. It all started in the genital area. The next day the rash spread down her thighs and she noticed an itchy place on her face, but you couldn't see it. Her thighs were inflamed and she noticed patches of angry whelps on her hips as well as a itchy rash area on her tailbone that seemed more like shingles; size of a quarter; raised, itchy, rash, that felt like it was radiating

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out. Then she noticed the rash on her face on her cheek, general swelling on her eyes and itching on her eye lids. Now the genital itching was less and most of her symptoms were improved but her eye was driving her crazy and it was more swollen on the outside. She tried to treat her eyes with eye drops Dry Eye Relief (manufacturer Similasan; no UPC seen, lot number: 15942; expiration date: Sep2022, ingredients include Belladonna) but it didn't help. They were still itchy and weepy. The eye drops were not working. She also treated the rash and itching with Benadryl at night and it improved the symptoms overall. She took Tylenol (UPC 300043760; lot number: PMA003; expiration date: Aug2022) and Bayer Aspirin (81mg; lot number: NAA93E1; expiration date: Feb2023. No UPC code on bottle) every day for general arthritis symptoms, but they didn't touch her dull headache she has had on and off since the vaccine. Before she got the vaccine, she had a little tag on her vulva, it was tiny. Now after experiencing the itching, swelling, rash on her vulva, the tag was gone. It just took a layer of skin right off. It was not uncomfortable but the whole layer of the skin was gone. It was very uncomfortable while it was happening but now it was okay. When she noticed these symptoms, she tried to call occupational health and a institute but didn't get anyone. She also contacted her HCP but had not heard back. It seemed to her like a lot of side effects and a lot of itching. She didn't have it in her throat, but all that itching seems a lot like an anaphylactic reaction. She was curious whether we would recommend her to take the second dose since they say the reaction to the second dose was worse. She had multiple COVID tests that have all come back negative. A friend tested positive so she had a test; and she had a test when she traveled. The events did not require a visit to physician or emergency room. The patient had reactions: itching, rash, swelling, welts, shingle like rash on tailbone, genital area, hips moving to her face, itching and inflammation, in eyes as well. She wanted to know if the 2nd dose was recommended. It was "like an anaphylactic reaction but not in her throat." itching around the genital area, vulva started from 04Jan2021, vulva was swollen started from 05Jan2021; Rash vulva started from 06Jan2021 to 10Jan2021; rash down her thighs started from 07Jan2021; Raised itchy rash on the tailbone like

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977240	1/27/2021	AL	37	F	1/25/2021	1/25/2021	<p>shingles started from 06Jan2021, wheals on her hip, inflamed and itchy from 07Jan2021; itching on her face that she couldn't see started from 06Jan2021; raised itchy area on her left cheek and eyes started from 07Jan2021; Headache dull started from 06Jan2021. The events Headache dull, itching on her face that she couldn't see; wheals on her hip, inflamed and itchy and raised itchy rash on the tailbone like shingles were reported as non-serious by the reporter and other events were considered as medical significant by the reporter. Investigation assessment for the events was reported as No. The outcome of the event anaphylactic reaction, inflammation in eye, welts was unknown, outcome of the event Rash vulva was recovered on 10Jan2021; of Headache dull, swelling eye was not recovered, of other events was recovering.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. Severe allergic reaction is the known risk for the product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p> <p>Systemic: Anaphylaxis-Severe, Systemic: Other-Angioedema, complained of systemic burning sensation most severe on face-Severe</p>

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976830	1/27/2021	NJ	43	F	12/21/2020	12/22/2020	a little tiredness and achiness the next day; a little tiredness and achiness the next day; This is a spontaneous report from a contactable physician (patient). A 43-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EL0140, expiry date: 31Mar2021) intramuscular on left arm (left deltoid) single dose for COVID-19 immunization on 21Dec2020, 10:20 am, at 43-year-old. No medical history, drug allergies and family history. Concomitant medication included: multivitamins (unspecified) daily whenever she remembered to take them. The patient had no issues with that vaccination, maybe a little tiredness and achiness the next day (22Dec2020), but no reactions, no asthma, anaphylaxis or anything. Had a CBC, CMP, and 2 chest x-rays and they were all normal. The patient was not deceased. Relevant tests included: CBC, CMP and twice Chest X-ray; all with normal results. Action taken for BNT162B2 was not applicable. Outcome of the events was unknown.
977797	1/27/2021	VA	43	F	1/26/2021	1/26/2021	Several minutes after receiving Moderna COVID-19 vaccine, patient's face started to become flushed, swollen, and she had trouble breathing. This anaphylaxis reaction started at 3:40 PM . First dose of epi was given at 3:43 PM. After first dose of epi was given, patient's breathing normalized and swelling was reduced. EMS was called during this time period. At 3:49 PM, patients lips and mouth started to swell and patient couldn't breathe. At 3:50 PM, a second epi pen was given and patient could breathe easier. EMS arrived shortly after and was taken to emergency room.

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976797	1/27/2021	MI	43	F	1/12/2021	1/12/2021	hot sensation/weird very hot rush down her right arm that was vaccinated and went up the back of her neck only on the right side; dizzy; Heart racing; Her arm was very sore- it was difficult to lift it; Her arm was very sore- it was difficult to lift it; She did feel a little out of it, as it produced a little bit of anxiety; A mild allergic reaction; This is a spontaneous report from a contactable Other Health Professional (patient). A 43 years old female patient received 1st dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot: EL3248, Expiration Date: Apr2021), via an unspecified route of administration on 12Jan2021 at 13:22 at single dose on right arm for covid-19 immunisation. Medical history included vasovagal (she did have a history of vasovagal. She talked to her doctor about this prior to the vaccine. At first when she had it her previous doctor felt a little confused. She was unsure if it was vasovagal or a blood clot in her lungs. She did get it checked out with a cat scan and there was no clot. They had to have tested her for anaphylaxis at that time. It was not a clear diagnose. Then she saw a cardiologist. She was diagnosed with vasovagal at that time. It lasted only a few months and she was fully recovered). Concomitant medications included ongoing ergocalciferol (VIT D) and ongoing vitamins NOS (MULTIVITAMIN). Patient received the vaccine on Tuesday, 12Jan2021. Her appointment was at 12:54, but she got the vaccine at 13:22. She was looking at her phone to re-schedule her second dose. She felt totally fine. At 13:27 she had this weird very hot rush down her right arm that was vaccinated and went up the back of her neck only on the right side. She looked up from her phone and was very dizzy. She stood up and as she did her heart started to race. It was a really weird feeling that she has never felt. She was a little out of it. She had no trouble breathing. Within 30 seconds she was completely fine. She did feel a little out of it, as it produced a little bit of anxiety. She had no other symptoms. She stayed at the facility for 30 minutes. As she was leaving one person asked how she felt and she was told to let the EMTs know. She let them know what happened. One woman working there said it could have been an anxiety attack. She did not have a lot of anxiety but she did have some. It did not feel like that. She had never had the warm sensations or heart racing. She was totally fine when talking to the EMTs. They did not seem concerned and

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they let her schedule her second shot. She read on Pfizer about allergic reactions. She was assuming this was what happened. A mild allergic reaction. She had no breathing issues or hives. Her arm was very sore- it was difficult to lift it. She had also never had this type of soreness with vaccines. Dizziness: She has had the dizziness a couple of times. Twice now. One when she had gotten home. It was very mild and nothing compared to what she had when she got the vaccine. Then another last night at bedtime. It was a woosh of dizziness. Arm soreness: very improved now. felt like she would normally have after getting a vaccine. The first day was intense but after a few hours was less. The next day she woke up and it was pretty much gone. She still had a little but it has mostly improved. Caller stated she would still like to get the second dose but she was a little nervous. She had it maybe once or twice since then and it has been mild with no extreme pressure drops. They thought maybe it was a virus that affected her. Her reaction to the vaccine was different. The difference was pretty significant. Vasovagal felt like her heart will stop and she will pass out. After the vaccine she felt dizzy but didn't feel faint, and had a racing heart. Nobody seemed concerned about her reaction and getting the second dose. But she read that Pfizer does not recommend getting the second dose even if you had a mild reaction. She was wondering what she should do. Her second dose is scheduled for 02Feb2021. Outcome of hot sensation/weird very hot rush down her right arm that was vaccinated and went up the back of her neck only on the right side and heart racing was resolved on 12Jan2021, dizzy was resolved on 13Jan2021, outcome of anxiety was unknown, outcome of her arm was very sore- it was difficult to lift it and a mild allergic reaction was resolving.

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979680	1/27/2021	LA	34	F	1/27/2021	1/27/2021	Within a few minutes of receiving vaccine, she reported feeling warm, lightheaded. Exhibited tremulousness. Vitals were checked, bp was 170/101 and HR was 130, O2 sat was 98. She was noted to be taking shallow rapid breaths, however lungs were clear. No rash. Reported chest pain. Due to acharectistic symptoms for anaphylaxis, hypertension and tachycardia, and history of arrhythmia, we elected not to administer epinephrine. 911 was called and she was transported via EMS to nearby hospital.
977208	1/27/2021	AL	42	F	1/25/2021	1/25/2021	Systemic: Anaphylaxis-Severe
980032	1/27/2021	WA	83	F	1/24/2021	1/25/2021	Diffuse urticarial rash beginning approx. 18 hours post first injection. Presented to urgent care 72 hours post injection. No airway or anaphylaxis symptoms.
979464	1/27/2021	MA	70	F	1/27/2021	1/27/2021	Patient reported feeling flushed 6 minutes after vaccine administration. Vitals at 1513 were: BP 117/60, HR 74, O2 97%. Patient reported that symptoms resolved about five minutes later. Patient was observed for 25 minutes (she declined to stay longer) and did not develop any new or worsening symptoms. Vitals at 3:24 PM BP 107/56, HR 72, O2 98%. Reviewed s/sx anaphylaxis, advised patient to call 911 if these occur.
978131	1/27/2021	CA	35	F	1/20/2021	1/20/2021	Patient received her first dose of the Moderna COVID-19 Vaccine on 1/20/21 at 1531 and subsequently had complaints of closing airway (patient felt her posterior oropharynx closing up), noted stridor and hives over her torso. Of note: patient has a known history allergic reactions to foods/drugs (including anaphylaxis). Patient brought her personal epi pens with her to the vaccine clinic and self-administered an epinephrine 0.3mg dose. Nursing staff in the clinic then gave her a Benadryl 25mg and an additional epi 0.3mg dose given no improvement in symptoms after first dose. CODE BLUE activated via security officer nearby. Volunteer staff member obtained wheel chair from main lobby to transport patient to the ED at 1548. In the ED, patient was given x1 dose Solu-Medrol IV 125 mg and later cetirizine IV 10mg. Per the ED note, no airway edema, wheezing, or strider noted and patient was reported to be doing well after medications. Patient remained in the ED for observation and was discharged at 2211.

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1293989	1/27/2021	CA	45	F	1/14/2021	1/14/2021	Swollen throat, tongue, dizziness, difficult breathing, increased blood pressure, nausea, difficulty swallowing, headache. This were the immediate adverse effect with in 5 to 10 minutes of receiving the shot. Followed by aches, chills, loss of appetite and days of swollen tongue and sore throat and difficulty swallowing. My breathing was not affected as I did not experience a full anaphylaxis reaction but I continue with the discomfort a week and a half later. I have been taking benedryl, claritin, and fatmotidine which is what my doctor sugested I take to calm down the allergic reaction and it has helped a bit with the nausea and the feeling of having a lump in my throat.
979863	1/27/2021	CO	28	F	1/27/2021	1/27/2021	Anaphylaxis shock- patient became hypoxic with shortness of breath, chills and tachycardia. EpiPen was administered and 911 was called. Patient was transported to ER.
979600	1/27/2021	CA	55	F	1/15/2021	1/15/2021	Approximately 10 minutes after vaccine administration patient had red flushing of face and chest, itching sensation of entire body. Vitals were normal, no angioedema, wheezing, shortness of breath, GI symptoms, or other signs of anaphylaxis. Given 50 mg of diphenhydramine and observed for 30 minutes, symptoms resolved, sent home with ED precautions. Referred to allergist/ immunologist after event for counseling on second dose
979449	1/27/2021	ID	60	F	1/17/2021	1/17/2021	Anaphylaxis within 15 minutes. Throat tightened wheezing began given Benadryl at clinic then taken to ER downstair at Hospital. Given more benadryl, then epinephrine, Decadron, then breathing treatment. once undercontrol sent home and then recommended seen by own doctor. I saw doctor on the 21st.

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979441	1/27/2021	CO	52	F	1/23/2021	1/23/2021	Pfizer-BioNTech COVID-19 Vaccine EUA: Shortly after receiving the vaccine patient stated they had chest pain, shortness of breath, nausea, back pain, and sweating. On evaluation a mild systolic murmur and irregular heartbeat were noted. Patient was transferred to the emergency department where initial vitals were within normal ranges except for blood pressure 145/104 mmHg. No wheezing, vomiting, respiratory distress, or anaphylaxis noted. Patient administered aspirin, morphine, acetaminophen, diphenhydramine, ibuprofen, and ondansetron and symptoms resolved. Repeat vitals were within normal ranges and patient discharged to home stable.
979350	1/27/2021	AK	47	F	1/23/2021	1/23/2021	Systemic: Anaphylaxis-Severe
979082	1/27/2021	SC	76	F	1/22/2021	1/22/2021	Severe anaphylaxis shock, received 5 drug injections at vaccination site, transported to ER for observation. released later that evening.
976084	1/26/2021	OK	32	F	1/26/2021	1/26/2021	22 min post vaccination c/o of nausea and light headedness and shortly thereafter started with emesis. Pt alert and oriented and without signs/symptoms of anaphylaxis including no respiratory distress, urticaria, or angioedema. Pt given 8 mg Zofran 40 min post vaccination without effect followed by 12.5 mg diphenhydramine 55 min post vaccination without effect. Emesis continued throughout but without worsening or other symptoms. Pt transferred to ER by facility administrator for further evaluation 80 min post vaccination. Pt monitored with O2 sat and at 99% throughout and BP taken aprox every10 minutes with SBP ranging from 128 to 152. Pt w/ tachycardia during most of monitoring ranging from 113 to 131.
974136	1/26/2021		21	F	1/15/2021	1/15/2021	Patient received their first injection of Pfizer COVID-19 vaccine. About 20 minutes post-injection, patient began swelling in throat similar to anaphylaxis reaction patient has with peanuts. Took Zyrtec, better after 1-2 hours. Pt. transferred to ER for follow-up from vaccine clinic.

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973216	1/26/2021	CA	49	F	1/19/2021	1/19/2021	? Covid-19 Vaccine, Mrna, Bnt162b2, Lnp-S (Pfizer) Anaphylaxis sleepiness, Swelling face and throat, breathing difficulty, cough, aphasia-pt was not able to express her thoughts or needs, pt felt that her heart was beating slow, vomiting started next day and lasted for 4 days, self treatment immediately by pt- Benadryl 50 mg and albuterol inhaler, later Prednisone course by medical professional symptoms completely resolved after 5 days
973831	1/26/2021	NY	47	F	1/19/2021	1/19/2021	Felt a little "weird" right after vaccine, after an hour she felt like she was suffocating. Went to ED for SOB, felt like throat was closing. Given prednisone, benadryl. Questionable if she was given epinephrine in ED. Will follow up with allergist before second dose. HX of allergy to cats and grass. No hx of anaphylaxis.
973849	1/26/2021	MD	32	F	1/14/2021	1/21/2021	Site: Bruising at Injection Site-Mild, Site: Itching at Injection Site-Mild, Site: Pain at Injection Site-Mild, Site: Redness at Injection Site-Mild, Site: Swelling at Injection Site-Mild, Systemic: Anaphylaxis-Mild; symptoms lasted 8 days
973928	1/26/2021		39	F	1/13/2021	1/13/2021	Anaphylaxis

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973112	1/26/2021		34	F	1/9/2021	1/9/2021	Anaphylaxis; A spontaneous report was received from a consumer concerning a 34-years-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced anaphylaxis. The patient's medical history was not provided. No relevant concomitant medications were reported. On 09 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 026L20A) intramuscularly in the right arm for COVID-19 infection prophylaxis. On 09 Jan 2021, 15 minutes after receiving the mRNA-1273 vaccination, the patient was taken to the hospital for anaphylaxis. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome of event, anaphylaxis, was unknown.; Reporter's Comments: This case concerns a patient who experienced a serious unexpected event of Anaphylaxis. The event occurred 1 day after first dose of mRNA-1273. Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
974153	1/26/2021		21	F	1/15/2021	1/15/2021	Patient received vaccine and about 20 minutes post-injection began experiencing throat swelling similar to anaphylaxis with peanuts. Pt. took Zyrtec and felt better 1-2 hours later. Pt. was transferred to ER for follow-up.
974424	1/26/2021	WI	46	F	1/25/2021	1/25/2021	Patient reported her tongue felt tingly 5 minutes following the first dose. She reported this finding at today's visit. She said she just took a Benadryl when she got home following her first dose. I did question if she has had anaphylaxis in the past to any meds, etc, and she said no, but reported having allergic symptoms with an antibiotic. No other allergic history to vaccines, meds, etc. Patient wanted to continue with second dose of vaccine today. Vaccinated at 1615. Patient reported tongue tingling at 1640. 25mg PO Benadryl given at 1640. Patient left the clinic at 1700 stating that she felt ok to leave. She had Benadryl at home and knew who to call if symptoms worsened. Writer called the patient back on 1/26/2021 at 1100. Patient stated that at 1900 last night (1/25/2021) she had to go to the Emergency room and received 2 doses of Epinephrine. She then had to stay the night to be observed. Patient stated that she was being discharged today.

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974547	1/26/2021	MI	32	F	1/20/2021	1/21/2021	HISTORY OF PRESENT ILLNESS: SHORTNESS OF BREATH (CHEST PAIN, SOB , BACK PAIN STARTING TODAY AT 0900, STATES ADVIL AT 1000, SSENCOND COVID VACCINE YESTERDAY AT 1500) 32-year-old female with past medical history of anxiety, asthma, Hashimoto's thyroiditis, psoriasis who presents the emergency department with chief complaint of body aches and shortness of breath. Patient is a nurse. She received her 2nd dose of the Moderna vaccine for COVID-19 the day prior to arriving in the emergency department. This morning she did feel some mild body aches but otherwise was feeling fine. Starting later today after her shift at work she developed severe body aches bilateral upper shoulders and down her spine, she also reports some shortness of breath, dizziness. She felt unsafe to drive home feeling like this. She had taken some Advil earlier in the day around 10:00. She denies any fever, nausea or vomiting. No history of severe vaccine reaction or anaphylaxis. She has had anaphylactic reaction to Enbrel prior. She denies any throat swelling, muffled voice, difficulty swallowing, abdominal pain. patient is mildly tachycardic and hypertensive. Likely due to pain. Patient is experiencing adverse reaction to the 2nd dose of the Moderna COVID-19 vaccine. I discussed with her she is having an immune response to the vaccine. She does have a history of rheumatoid arthritis which could contribute to the elevated immune response as well. The patient is given 30 mg of IM Toradol for body aches here in the emergency department. She is instructed to call PCP for close follow-up, rest, drink plenty of fluids. She has no signs or symptoms consistent with anaphylaxis at this point.
975959	1/26/2021	NH	63	F	1/26/2021	1/26/2021	anaphylaxis (throat tightness, swelling, pruritis, GI upset, cramping, diarrhea

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976123	1/26/2021	NJ	58	F	1/21/2021	1/21/2021	Having Ehlers Danlos and Mast Cell Degranulation as well as Dysautonomia... Anaphylaxis is often referred to as slow roll and without the typical face swelling and rash. It is more subtle and can be harder to detect. And that was my experience: as follows: I became faint and briefly passed out within 2 minutes of injection. I stabilized quickly within a 30 minute hold although developed increasing nausea, I and med tech was satisfied that it might just be my dysautonomia. I spent the evening with severe headache vomiting as passed out again. I experienced throat tightening but not full closure. The next day I had flue like symptoms that I assume were normal and vaccine related. When this passed in the evening I again suffered nausea and dizziness, vomiting and throat tightening when I tried to eat. These symptoms were not similar to the flush feelings earlier in the day. The symptoms ebbed and waned for 2 days with increased frequency as I took chromalyn , Benadryl with some effect at first and ate with great care as not to introduce more allergens. I had increased chest pain, sweating, fainting, throat tightening became severe Benadryl was not effective. I was having trouble swallowing. I was forced to use an epi pen and call 911. This is a typical anaphylactic response for EDS< Mast Cell patients. It became clear that I could not get past this on my own and the symptoms were increasing. I started to shake with chills and feared shock as my chest pains increased. The epi pen injection and hospital visit via ambulance occurred Monday 1/25-1/26. I became very faint during the Ems intake with the techs having to hold me up to check vitals etc.. My HR dropped despite the Epi. At the ER I was given IV steroids, IV Benedryl and Potassium, tablets and fluids throughout the night, admitted for evaluation.

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975625	1/26/2021	MN	19	M	1/22/2021	1/22/2021	I called my insurance provider's RN hotline at the onset of dizziness, which was then followed by a bout of ear ringing and nausea. I was advised to seek immediate medical attention, so I had an RA at my university dorm walk with me across the street to M Health Fairview hospital. I was seen by an RN in their emergency room, but was ultimately never seen by a Doctor as I did not present a clear risk of anaphylaxis at the time. After waiting in the ER for four hours for medical care, I ultimately left because most of my symptoms subsided. My most lasting symptoms cleared up late yesterday (1/25) and they were extreme soreness/tenderness at injection site and fatigue.
975578	1/26/2021	GA	56	M	1/23/2021	1/24/2021	I did not experience any adverse symptoms with the first dose of Pfizer-BioNTech vaccine with the exception of injection site pain after the first dose that began on day 2 through day 5 or for 3 days. The first Pfizer-BioNTech dose was received on December 30, 2020, LOT EK5730. I would rate the pain as a 5 out of 10 on VAS on 12/31/20. Please note that I completed the same pretreatment protocol 1.5 hours prior to dosing with Pfizer-BioNTech of Diphenhydramine 25 mg plus Pepcid 20 mg for both COVID-19 doses. I elected to complete a self-administered pretreatment protocol due to a shellfish allergy and literature reports of anaphylaxis with COVID-19 mRNA vaccines in food allergy recipients. I did not experience any adverse symptoms on Saturday afternoon after receiving the second dose of the Pfizer-BioNTech vaccine at 4:45pm on 1/23/21. On Sunday morning 1/24/21, I awoke feeling "cold." I dressed warmly, but the feeling progressed to chills by 3pm. Malaise ensued around 1pm. I also experienced injection site pain on the morning of 1/24/21 beginning at 7am. The pain lasted until 1/25/21. I would rate the pain as a 5 out of 10 on VAS ON 1/24/21. I began to feel uncomfortable with malaise and chills at 6:15pm on 1/24/21 and self-administered one dose of OTC Aleve, Naproxen sodium 220mg plus one dose of Benadryl 25 mg. I began to feel better by 9pm on 1/24/21. I awoke on 1/25/21 without any symptoms or discomfort with the exception of some injection site pain (2 out of 10 on VAS). I have been asymptomatic since 1/26/21.

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975146	1/26/2021	WA	67	F	1/25/2021	1/25/2021	Patient felt flushed and dizzy. Per smart watch HR increased to 95 and complained of chest tightness. Symptoms occurred 10-15 mins after vaccine. Benadrl 25 mg orally given. Symptoms resolved. HR decreased to 75. No signs/symptoms of anaphylaxis.
972095	1/25/2021	MI	49	F	1/12/2021	1/12/2021	anaphylaxis
971900	1/25/2021	IL	65	F	1/22/2021	1/22/2021	PT RECEIVED COVID VACCINE AT 15:38 PT C/O AFTER 1 MIN OF CHEST PAIN AND SHORTNESS OF BREATH. PT REPORTS H/O ANAPHYLAXIS REACTION TO FISH AND NO OTHER ALLERGIES WERE REPORTED,PT STATES FEELINMG SAME SYMPTOMS AT THIS TIME. VITALS WERE TAKEN 169/89 p. 104 PULSE OX% 95. PT WAS SPEAKING IN FULL SENTANCES AND DID NOT APPEAR IN RESPIRATORY DISTRESS ,PT REPORTED CONTINUED TO FEEL CHEST PRESSURE AND TIGHTNESS IN THROAT, AT THIS POINT EPINEPHRINE 0.3 ML WAS ADMINISTERED BY RN ON LEFT THIGH AND 911 WAS CALLED. ON ARRIVAL OD PARAMEDICS AND EVALUATION OF PT REPORTED FEELING BETTER AFTER EPINEPHRINE AND DECLINED TO GO TO ER. PT LEFT THE CLINICON HER OWN IN STABLE CONDITION.
970834	1/25/2021	UT	54	F	1/22/2021	1/22/2021	Patient had her second dose of Covid Vaccine.. She has hx of anaphylaxis, so she took bendryl 50 mg before bed last night and then took 10 mg Zyrtec before getting the shot. She states about 15 mins after administration she began to have numbness and tingling of her hands, forearms, lower legs, neck, face and lips. She came to ER was monitored for a few hours, about 3 hours post administration while in ER her voice became more hoarse and she noticed edema under her eyes bilaterally. Pt was given 25 mg IV bindery and remained under observation for another 1.5 before being DC. She maintained airway the entire time, VSS and AOX4;

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970033	1/25/2021	PA	29	F	1/9/2021	1/9/2021	Body aches; chills; nausea; headache; arm pain; fatigue; received second dose of BNT162B2 on 09Jan2021; This is a spontaneous report from a contactable nurse (patient). A 29-year-old female patient received second single dose of BNT162B2 (Pfizer, solution for injection, batch/lot number and exp date not reported), intramuscular (left arm) on 09Jan2021 11:00 for COVID-19 immunization. Facility type vaccine: Hospital. Medical history included migraines. The patient was not pregnant. There were no concomitant medications. No other vaccine was received in four weeks. No other medication within two weeks. The patient previously took acetylsalicylic acid (ASPIRIN) wherein patient had known allergies and anaphylaxis. The patient received the first single dose of BNT162B2 on 22Dec2020 15:00, Intramuscular (left arm). The patient received second dose of BNT162B2 on 09Jan2021 11:00. The patient experienced body aches, chills, nausea, headache, arm pain, and fatigue on 09Jan2021 21:00 (09:00 pm). The patient did not have COVID prior vaccination. Patient was not Covid tested post vaccination. Treatment for AE included paracetamol (TYLENOL) OTC every 4 hours x 24 hours. The patient recovered from the events body aches, chills, nausea, headache, arm pain, and fatigue on an unspecified date in Jan2021. Information about lot/batch number has been requested.

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969655	1/25/2021			M			Anaphylactic reaction; A spontaneous report was received from a healthcare professional concerning a male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced an anaphylactic reaction. The patient's medical history was not provided. Concomitant product use was not reported. On an unknown date, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, after vaccine administration, the patient had an anaphylactic reaction. The patient reported he was "all smooth" now, and would not be receiving the second dose. Treatment for the event included epinephrine. The second dose of mRNA-1273 was discontinued in response to the event. The event, anaphylactic reaction, was considered resolved.; Reporter's Comments: This case concerns a male patient who experienced a serious unexpected event of anaphylaxis. The event occurred on an unspecified date after first dose mRNA-1273 (Lot# unknown) administration. The subject's concomitant medication was not provided. The event was treated with epinephrine. Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

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969615	1/25/2021	OR		F	1/4/2021	1/4/2020	High Troponin Levels; Felt dizzy; Chest felt tight; Mitral valve filling defect; Difficulty breathing; Concern of anaphylaxis; Passed out unconscious; A spontaneous report was received from a physician concerning an approximately 28-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced the events, felt dizzy, chest felt tight, difficulty breathing, passed out unconscious, concern of anaphylaxis, non-ST segment elevation myocardial infraction, high troponin levels, and mitral valve filling defect. The patient's medical history as provided by the reporter included a history of anxiety. Concomitant medication use included sertraline, buspirone, acyclovir, propranolol, hydroxyzine and lorazepam for unknown indications. On 04 Jan 2020, prior to the onset of the events, the patient received her first of two planned doses of mRNA-1273 (Lot number: 011L20A, Exp. date: 03 Jul 2021) intramuscularly, in her left deltoid, for prophylaxis of COVID-19 infection. On 04 Jan 2020, a couple of minutes after receiving the vaccine, the patient experienced dizziness, chest felt tight, difficulty breathing, and she passed out unconscious. Due to concern of anaphylaxis, while the patient was still unconscious, she was treated with epinephrine followed by intramuscular injection of cetirizine hydrochloride. In addition, ammonia salt was used. The patient woke up briefly and passed back out. Emergency medical services (EMS) arrived and almost had to intubate the patient. The patient stayed overnight in the hospital due to lab values indicating non-ST segment elevation myocardial infraction, high troponin levels, and a mitral valve filling defect. It was noted that the patient has never had an allergy to anything, including the excipients in the Moderna vaccine. In addition, the patient had no history of loss of consciousness or anaphylaxis. Relevant laboratory tests conducted included an echocardiogram which found no issues with cardiac function and noted a mitral valve filling defect. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, felt dizzy, chest felt tight, difficulty breathing, passed out unconscious, concern of anaphylaxis, non-ST segment elevation myocardial infraction, high troponin levels, and mitral valve filling defect was unknown.; Reporter's Comments: This case concerns a 28 year old female patient with medical

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							history anxiety who experienced Concern of anaphylaxis , high troponin levels, dizziness, chest discomfort, difficulty breathing, loss of consciousness and Mitral valve filling defect same day after administration of the first and only dose of the mRNA-1273 (Lot number: 011L20A, Exp. date: 03 Jul 2021). Based on temporal association between the use of the product and the start date of the reported events and the absence of any other etiology factors, a causal association cannot be excluded.
972180	1/25/2021	MI	49	F	1/22/2021	1/22/2021	Systemic: Anaphylaxis-Medium, Systemic: Fainting-Medium
969185	1/24/2021	MA	29	M	1/21/2021	1/21/2021	After the mandatory 15 minute waiting period in the vaccine waiting area at Hospital, I felt okay and did not feel the need to remain in the waiting area. After I returned home between an hour and an hour and a half after receiving the first dose of the Moderna Vaccine, I felt the onset of an anaphylaxis reaction in which my mouth felt dry and my throat began to feel swollen. I used my EpiPen and took Benadryl to help the allergic symptoms subside. After this treatment, the symptoms subsided and I did not seek further medical attention as it was unnecessary. I was in the care of my father who is a physician.
968633	1/24/2021	MN	48	F	1/7/2021	1/7/2021	chest tightness, cough, runny nose, nausea, dizzy, red chest, high pitch voice, difficulty speaking. anaphylaxis EKG monitoring, IVF, IM Epinephrine, IV Benadryl, IV Pepcid, Albuterol dual neb, CXR, Labs sent home after 6 1/2 hours of treatment and monitoring. Sent home with Epi pen
969628	1/24/2021	CA	30	F	1/1/2021	1/1/2021	I experienced an allergic reaction at the injection site (red circle with swelling and pain) when I got the shot. It went away and came back even larger a week after the shot. No anaphylaxis. Please let me know if I should consult my doctor.
968569	1/24/2021	MO	82	F	1/21/2021	1/21/2021	C/O feeling weak and felt like her throat was closing almost immediately after receiving vaccine. Patient was evaluated by ED. No evidence of anaphylaxis. Treated and released without.

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968278	1/23/2021	AK	47	F	1/23/2021	1/23/2021	Anaphylaxis with shortness of breath, throat tightness, dizziness and wheezing with near syncope.
966354	1/22/2021	MD	54	F	1/22/2021	1/22/2021	Within 5 minutes patient with dizziness and fast heart rate (reported by patient as in the 80s). Patient also with worsening of her baseline essential tremor (R>L). No other signs of anaphylaxis or other symptoms. Vitals taken with BP 128/68, HR 68, RR 16. Patient observed for 30 minutes with no other side effects. Discharge in stable condition with no medications administered.
966610	1/22/2021	VA	37	F	1/22/2021	1/22/2021	Patient was vaccinated with the Moderna COVID-19 vaccine at facility at approximately 3:50 PM. She was then moved to the observation room per clinic. At approximately 3:59 PM, patient stated her throat was closing and that she had a rash/hives on the side of her face (on her left cheek bone) - all indicating an anaphylaxis reaction. A staff member in the observation room immediately administered 0.3 ml of Epinephrine and told the site director to call 911. After administration, patient was able to breathe and the throat swelling subsided. EMS services arrived around 4:10 PM and took patient to emergency room. Patient was able to talk and sit-up before being carried off by EMS.
964108	1/22/2021	CA	35	F	1/12/2021	1/12/2021	Extreme shoulder pain in and around injection site, nausea, vomiting, body aches, fever, chills, headache. Felt as though nurse either struck the bone or I could go into anaphylaxis at time of injection. Began flu like symptoms approximately 2 hours after injection. Heavy (almost drove myself to the hospital) began 18 hours after injection. Ended approximately 35 hours later.
964910	1/22/2021	OH	59	F	1/20/2021	1/20/2021	Systemic: Anaphylaxis-Medium, Systemic: Chills-Severe, Systemic: Generalized Body Aches -Medium, Systemic: Headache-Severe, Systemic: Vomiting-Mild
964931	1/22/2021	PA	50	F	1/21/2021	1/21/2021	Systemic: Anaphylaxis-Severe, Systemic: Seizure-Medium, Systemic: Tingling, tremors, convulsions, numbness and difficulty breathing -Medium

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965554	1/22/2021	CO	46	F	12/28/2020	1/11/2021	Full body numbness, able to feel pressure, no pain. Dizziness, burning rush sensations scattered settled in right side of head neck chest arm and back, feel of passing out with standing up or sitting; Full body numbness, able to feel pressure, no pain. Dizziness, burning rush sensations scattered settled in right side of head neck chest arm and back, feel of passing out with standing up or sitting; Full body numbness, able to feel pressure, no pain. Dizziness, burning rush sensations scattered settled in right side of head neck chest arm and back, feel of passing out with standing up or sitting; Full body numbness, able to feel pressure, no pain. Dizziness, burning rush sensations scattered settled in right side of head neck chest arm and back, feel of passing out with standing up or sitting; Full body numbness, able to feel pressure, no pain. Dizziness, burning rush sensations scattered settled in right side of head neck chest arm and back, feel of passing out with standing up or sitting; This is a spontaneous report from a contactable Other HCP. A 46-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via intramuscularly on 28Dec2020 10:30 at single dose for covid-19 immunisation. Vaccine location: Left arm, dose number: 1, facility type vaccine: hospital. Medical history included viral asthma, hypertension, mild depression, anaphylaxis to Bee Stings, vertebral artery dissection with brainstem injury and covid-19 (If covid prior vaccination: Yes). Concomitant medication included acetylsalicylic acid (ASPRIN), metoprolol (METOPROLOL), omeprazole (PROTONIX [OMEPRAZOLE]), hydrochlorothiazide (HYDROCHLOROTHIAZIDE), bupropion hydrochloride (WELLBUTRIN). The patient previously took erythromycin and experienced drug hypersensitivity and fentanyl and experienced drug hypersensitivity. On 11Jan2021 02:00 the patient developed "full body numbness, able to feel pressure, no pain. Dizziness, burning rush sensations scattered settled in right side of head neck chest arm and back, feel of passing out with standing up or sitting up". The patient was taken to emergency room (ER) /department or urgent care. In the ER all labs and CT with and without contrast clear, but was unable to find any other reason for the event. No treatment received. The events outcome is recovering. The action taken was not applicable.

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965822	1/22/2021	TX	48	F	1/8/2021	1/19/2021	. On Friday 1/8/21, Pt was vaccinated with Moderna first dose in the left deltoid muscle. No immediate issues/complications. Beginning Tuesday 1/19/21 (eleven days post-vaccine), she reports noticing itching in the injection site; no rash or other symptoms (e.g. temperature elevation, shortness of breath, wheezing, swelling, hives). Today 1/20/21 her arm has a noticeable ?rash? type reaction. She reports continued itching but no particular pain or tenderness. No visible pustules but the area is reddened and very slightly warm but not ?hot-to-touch?. At about 4:15 pm, the affected area measured approximately 2 ¼ inches (5.5 cm) wide by 2 ½ inches (6.5 cm) long. 1/21/20, Pt reported taking oral diphenhydramine overnight (1/20/21) with reduced itching/swelling but again today notes return of redness, swelling and warm to touch. Pt reports about 3 years ago having a "tetanus" booster ? had a reaction of the entire upper arm with swelling, redness and hot-to touch. No reported anaphylaxis. Based on consultation with the regional medical director, and the Infectious Disease Specialist, they will defer providing the second dose of Moderna. Pt has been referred to her private health care provider with a recommendation to consider referral to an infectious disease practitioner for any future COVID-19 vaccine administration.

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966491	1/22/2021	WI	55	F	1/21/2021	1/21/2021	Patient is a 55-year-old female who had presented to the vaccination clinic this afternoon to receive her COVID-19 vaccine. She does have a history of migraine headaches and other comorbidities as described below. Has had reactions to a number of medications, mostly narcotics as noted in her allergy list some of which could in theory be compatible with urticaria. Does not have true anaphylaxis in her history. Today at about 15 minutes after administration of her COVID-19 vaccine she began to rather precipitously developed an itchy crawling feeling in her skin, nausea with retching and some shortness of breath. She did not have the sensation of her throat closing off. Did not have coryza. Within about 10 minutes she did develop difficulty with speech that she says is typical for her migraine headache. She received, in the vaccination Clinic, epinephrine 0.3 mg subQ, 125 mg of Solu-Medrol and 50 mg of Benadryl all IV. An IV was started and a 500 mL bolus of saline was initiated. With this she was then transferred to the emergency room for further evaluation. In the emergency room she did develop chest heaviness but no palpitations. She was not dyspneic. Her nausea and vomiting by then had seem to resolve.
967253	1/22/2021		57	F	12/29/2020	12/29/2020	Patient had vaccine at 1430. At 1600, patient returned to vaccine clinic complaining of swollen glands and feeling of potential throat swelling, asking for benadryl. Patient states she has had an anaphylactic reaction in the past, but never to a vaccine or medication. Vital signs taken - BP 166/90, pulse 103, SpO2 100%. Patient monitored for few minutes and continued to feel additional tightness in her throat. Crisis nurse called and patient transported to ED for further evaluation. diphenhydramine 25mg PO given in ED at 1838. Pt reports self taking ibuprofen 600mg at 1535. She has had anaphylaxis in the past 5 years ago to food (treated with solumedrol and benadryl) and once walking thorough the park>25 years ago an
965724	1/22/2021	MA	29	F	1/19/2021	1/21/2021	Anaphylaxis treated at Tufts Medical Center -Full body hives on 1/21- treated w Benadryl, Claritin, Famotidine - 1/22 woke up with lip swelling, throat itching, lip tingling- came to ER on this date for evaluation, given epinephrine IM, Benadryl IV, fluids IV, prednisone PO

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966769	1/22/2021	GA	68	F	1/22/2021	1/22/2021	Dry throat with onset of anaphylaxis
967669	1/22/2021	VA	38	F	1/22/2021	1/22/2021	ANAPHYLAXIS, EPI, BenADRL TRANSPORT To ER Pt initially complained about feeling hot and then complained about weakness. Pt later developed a slight rash on the neck and complained about difficulty swallowing.
967219	1/22/2021	CA	66	F	1/20/2021	1/20/2021	Yesterday, she had COVID19 vaccine (believe Moderna) at 9 am, no immediate or local injection problems until 2 pm when she started itching from left wrist/ hand, up her arm to chest, back, neck, right arm and lower extremities. She took an allegra in the evening which did not help. That night she has persistent itching and shortness of breath with wheezing in her throat. This morning similar symptoms but woke with posterior headache, but over the day the rash improved receding from her legs, back, chest and remained on her chin and bilateral forearms. She was recommended to come to UCC for evaluation. - prior to the vaccine, for the past week, she reported having sore throat, wheezing in throat, shortness of breath, no coughing or diarrhea - currently being treated for h pylori, taking levofloxacin qday (has one or two more tabs) and metronidazole (has another week). She has taken metronidazole before without adverse effects and no known allergy to levofloxacin. - denies known food allergy or recent change in diet - other than dust but she does not equate this reaction to past reactions to dust, denies known environmental or contact allergy and denies recent contact with plants, nickel, new cosmetic/ personal care product use, or occupational/ home exposure to chemicals - She denies using lotion, change in soap, detergent, clothes, sheets. She lives with family who do not have similar rash. Denies history of similar skin problems or rashes. Apart from augmentin (stomach pain, vomiting), but otherwise no known food or medical allergy. - denies throat/ tongue swelling, history of severe allergic reaction or anaphylaxis

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967176	1/22/2021	CA	31	F	1/22/2021	1/22/2021	At approximately 1:50 pm received her vaccination. A few minutes later she exhibited signs of allergic reaction. Pharmacist attended to her, and after some questioning she exhibited signs of Anaphylaxis. At 1:56 an EpiPen 0.3 mg/0.3 ml dose was administered and 911 called. At 2:00 we checked her BP and it was 132/78 and pulse 95. A few minutes later, before a second check of BP was done, the EMT took over.
967160	1/22/2021	CA	42	F	1/22/2021	1/22/2021	Anaphylaxis. Face, lips, throat swelling. Epi in each leg. Benadryl in right arm.
967157	1/22/2021	HI	29	F	1/22/2021	1/22/2021	Anaphylaxis. Upper Extremity Rash, and Shortness of breath with throat swelling.
967075	1/22/2021	OK	61	F	1/22/2021	1/22/2021	16 min post Moderna COVID vaccination pt complained of nausea, dizziness, and headache. No s/s of anaphylaxis including no respiratory distress, urticaria, or angioedema. 21 min post vaccination patient given 12.5 mg diphenhydramine IM in opposite arm of injection. 35 min post vaccination and after no improvement of symptoms pt given another 12.5 mg of diphenhydramine IM. Pt under continuous observation by RN with normal O2 and HR but with BP ranging from 156/102 - 192/92. During the entire observation no s/s of acute anaphylaxis. Pt denies history of hypertension and denies medication for hypertension. 42 min post vaccination patient symptoms continued and reports chest tightness but no respiratory distress and normal O2. EMS called for transport to hospital. 45 min post vaccination EMS arrived and patient transported to hospital.
966954	1/22/2021	PA	38	F	1/22/2021	1/22/2021	Itching, chest tightness, SOB, tingling lips, loss of voice. Administered 100mg of benadryl within 5 min of symptom onset followed by Epi Pen with call to 911. Paramedics transported to ED. Patient was admitted with anaphylaxis. Used Adverse Event Emergency Policy.

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963521	1/21/2021	AZ	41	M	1/20/2021	1/20/2021	Patient developed shortness of breath approximately 10 minutes after vaccine administration. Patient received a dose of 0.3mL epinephrine IM 2 minutes later and was transported to the ED. VS in the ED were normal. Patient did not develop any other signs or symptoms of anaphylaxis. He was monitored for 1hr and discharged from the ED.
961498	1/21/2021	AZ	26	F	1/12/2021	1/12/2021	Pfizer Covid Vaccine; 26 y.o. female who presents after feeling weak and dizzy after COVID vaccination. Patient received the vaccination at 1230 and is still symptomatic. There is no sign of anaphylaxis. Obtained orthostatics at bedside and she is not orthostatic. Patient appears very anxious. Will give patient juice and crackers as well as obtain a glucose. Gave the option to obtain labs however she declines at this time. Patient was given 216 oz bottles of water and a 12 oz bottle of grape juice and a muffin and also saltines. Patient is now stable for discharge
962387	1/21/2021	PA	46	F	1/20/2021	1/20/2021	Systemic: Anaphylaxis-Severe
961607	1/21/2021	PA	51	F	1/20/2021	1/20/2021	Systemic: Anaphylaxis

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961659	1/21/2021	PA	27	F	1/8/2021	1/15/2021	-Pt is an employee in dental. -Reporting reaction at site of vaccine (left deltoid). -Received vaccine 1/8/2021 (Moderna). -No rxn at time of vaccine, was observed. -Presented TODAY (7 days later) 1/15/2021 while at work for rash at injection site and on her face and neck. -Pt denies itchy throat, difficulty swallowing, shortness of breath, chest pain, n/v, abdominal pain, fevers, chills, numbness/tingling. -Denies allergies to food, meds, seasonal allergies. -Denise hx of allergic rxns. -Denies hx of anaphylaxis reactions. -Of note pt also has asthma. Reports she has not seen PCP about it in awhile. -She is using her albuterol inhaler 4x/day. Some dyspnea on exertion. -Not on controller inhaler. -No cough, wheezing, shortness of breath at rest. -Not taking any other medications besides albuterol inhaler. -Pt with itchy rash at site of injection and on face. -Pt without signs of anaphylaxis. -Denies respiratory symptoms. -Gave pt 25mg Benadryl PO. -Observed pt for 1 hour. -Vitals normal besides elevated HR - likely due to reaction/anxiety about situation. -Pt's rash diminished and she was less itchy ~10 minutes after Benadryl. -No worsening of symptoms during observation. -Pt discharged after 1 hour. -Will f/up with patient (she is employee) later today. -ED precautions given.
961731	1/21/2021	IL	55	M	1/20/2021	1/20/2021	Systemic: Anaphylaxis-Medium; symptoms lasted 1 day

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962204	1/21/2021	WI		F	1/8/2021	1/8/2021	shortness of breath (SOB) with hyperventilation; shortness of breath (SOB) with hyperventilation; Lightheaded; red blotching on face and neck; appeared shaky; This is a spontaneous report from a contactable pharmacist. An adult female patient (pregnant unknown) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 08Jan2021 for first dose at single dose (lot number: EL1283) for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced lightheaded, shortness of breath (SOB) with hyperventilation on 08Jan2021. She was laying on the floor and appeared shaky with red blotching on face and neck on 08Jan2021. Medical response called. Anaphylaxis medication given epinephrine (adult) IM outer thigh. Patient was placed on stretcher and taken to emergency room (ER). Patient also received Diphenhydramine and Famotidine. The events resulted in emergency room/department or urgent care. It was unknown if covid prior vaccination and if covid tested post vaccination. The outcome of the events was recovered in Jan2021.; Sender's Comments: Based on the compatible time association, the possible contribution of suspect BNT162b2 to the events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
962322	1/21/2021	WI	27	F	1/20/2021	1/20/2021	Systemic: Anaphylaxis

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961559	1/21/2021	VA	68	F	1/20/2021	1/20/2021	97.1kg 68 yo with PMH: hypertension, sleep apnea, asthma, "severe GERD", depression, meningioma status post resection, status post Nissam fundoplication x2 and long list of allergies with some reactions described as anaphylaxis. 1/20/21 presented to clinic for first Covid Vaccination. Ate a light lunch at 11:30 AM. Patient was given Moderna vaccine in left deltoid at 1335 1/20. Lot # 013L20A. ~15 minutes after vaccination, patient felt heartburn/indigestion, hot, and was burping and feeling nauseous. Patient described burning sensation in the substernal region which is rated 9/10 at maximum. Presented to urgent care for observation. Burning sensation 5/10 at time of assessment.
962675	1/21/2021	CA	39	F	1/20/2021	1/20/2021	Roughly between 1400 and 1410 the patient received the Moderna vaccine in the right deltoid. Patient stated 5 minutes after injection she felt "a warm feeling from my head to my chest area. Like a burning feeling". Since this symptom was not cardiac or respiratory in nature and the patient did not appear in distress, Benadryl 25 mg PO was administered roughly at 1415. Patient was closely observed afterward. Patient alerted staff 3 minutes after the Benadryl administration that she felt tightening in the throat and itchiness. Epinephrine was administered to left thigh. Patient stated immediate relief. Emergency medical services were offered, but the patient declined. The first set of vitals retrieved were 136/78 BP, 81 pulse, patient lung sounds clear, no wheezing present. Patient is awake and alert. Onsite physician assessed the patient. Patient monitored for additional 30 minutes after epinephrine injection. Last set of vitals 120/81 BP, pulse 88, lung sounds clear no wheezing. Patient is calm, awake, and alert. ODR clinical representative and patient educated on anaphylaxis signs and symptoms and advised to seek medical attention if symptoms occur. Patient released from observation at 1455.

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963069	1/21/2021	ME	52	F	1/20/2021	1/20/2021	15 minutes after administration patient described her lips as feeling "sunburned" and that the tip of her tongue felt "tingly". She denied any rash, feeling of swelling in her throat or tongue and had no trouble breathing. Patient declined to have EMTs called because she did not feel it was anaphylaxis. A dose of 50mg of Benadryl was via orally and she was closely monitored. Her blood pressure was 128/84 and heart rate was 80. She had offers to drive her to either the ER or urgent care but declined saying it was isolated to her lips and the tip of her tongue. Patient is a nurse and was aware of what to watch for. Pharmacy staff continued to observe her for an additional 45 minutes. At that time she said the issues were resolving and she would like to go home. She was counseled on what to look for with worsening reaction but said she felt more frustrated than anything. Pharmacist encouraged her to reach out to her PCP and also explained we would be unable to give her the next shot at a clinic. She was advised to speak more with her doctor regarding if she should get a second dose. Patient was followed up with 2 hours after vaccination by phone and reported symptoms resolved and she was just tired from the Benadryl. Patient was also called the day after and said she had a bad headache but otherwise no other signs of adverse reaction.
963079	1/21/2021	MA	40	F	1/21/2021	1/21/2021	anaphylaxis throat closing ,hives, feeling faint Benadryl 50mg I.M. no effect then epi 1mg I.M. little effect Emergency services called patient was sent to E.R. via ambulance
963267	1/21/2021	CO	44	F	1/20/2021	1/20/2021	Anaphylaxis, angioedema. Unresponsive to epinephrine, steroids. Patient required intubation, mechanical ventilation, and ICU admission. Patient started on high dose steroids, BID IV famotidine, nebulizer therapy, with improvement in symptoms. Pt still in ICU at time of this submission.

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963514	1/21/2021	OK	77	F	1/21/2021	1/21/2021	Pt seen at COVID vaccination event at her adult health care facility. 17 min post vaccination pt complained of itchy throat, "funny feeling" and "just feel off." Pt evaluated by RN and no s/s of anaphylaxis including no respiratory distress, low O2, no evidence of urticaria or angioedema. 21 min post vaccination pt given 12.5 mg diphenhydramine IM in different limb from vaccination. RN continued to monitor and no changes in symptoms and no deterioration in symptoms or vitals. 34 min post vaccination another 12.mg diphenhydramine IM administered in different limb from vaccination and continued monitoring by RN with no changes in vitals and no s/s of anaphylaxis. At 11 am pt reported "feeling fine" with no distress. Pt discharged from RN supervision with complaints resolved.
963550	1/21/2021	PA	27	F	1/21/2021	1/21/2021	At 11:55am pt reported left arm swelling and 25mg of oral diphenhydramine was given to patient (30 minutes after injection). Patient was monitored by staff from thereafter. At 11:52am a second dose of 25mg diphenhydramine was given to patient due to possibly lip swelling reported by nurse. Patient denied shortness of breath or chest pain. By 12:12pm marked lip and face swelling reported by nurse monitoring patient. Again patient denied shortness of breath/whoeeze/chest pain. However, we advised patient that lip/face swelling is considered anaphylaxis and because symptoms were progressing and not mitigated by diphenhydramine epinephrine would be advised. Epinephrine 0.3mg via auto injector pen was administered to patient on left outer thigh and 911 was called. EMS arrived at 12:22pm and took patient to local emergency department.

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963591	1/21/2021	IN	70	M	1/21/2021	1/21/2021	Patient received first dose of COVID vaccine at 1800 and waited 15 minutes and left on his own accord. He sat in his car a few more minutes with his wife not feeling as if he was completely well. He returned to the clinic reporting tightness in his neck and throat area. His blood pressure was taken 189/99. He did not have difficulty breathing or any other signs of anaphylaxis but was given 50mg of benadryl as a precaution. We continued to monitor blood pressure for 30 minutes and did not resolve. He has a history of high blood pressure but reports that it is controlled by taking Metoprolol and Amlodipine daily. Physician was consulted and felt it was best to be seen in the ER. The patient was transported to ER by his wife and seen.
963627	1/21/2021	ME	34	F	1/21/2021	1/21/2021	Described "Dry tongue" No other symptoms consistent with anaphylaxis
961076	1/21/2021	MA	26	F	12/29/2020	12/29/2020	Pt presented to COVID vaccine clinic today and developed a reaction after receiving the vaccination. Denies hx of anaphylaxis. Pt has allergy to Cefzil (rash). Pt reported immediate flushing sensation after receiving vaccination. Pt also reported slight tightness of her throat and a sensation of a scratchy throat 15 minutes after administration. Pt denied SOB, difficulty swallowing, chest tightness, nausea, rash, itchiness, dizziness. No visible swelling. HR: 70 O2: 100% BP: 120/78 Flushing resolved after 15 minutes. Throat symptoms continued to be the same. Paged Allergy (Itchy). Pt given 10 mg Cetirizine PO. Pt observed for another 15 minutes and symptoms continued to improve. Pt sent home, advised by Allergy to follow up/seek emergency care as needed with any changes or new symptoms and to continue to take an antihistamine for a few days at home. Pt will f/u with Allergy for second vaccination.
963371	1/21/2021	ME	53	M	1/21/2021	1/21/2021	Patient described bilateral "tingling" in the hands and wrists. Lasted for 15 minutes and resolved. DID NOT manifest any symptoms consistent with anaphylaxis, including NO angioedema, no difficulty breathing, no wheezing/stridor, no urticaria, no GI symptoms of pain/N/V/D
961200	1/21/2021	FL	58	F	1/14/2021	1/14/2021	anaphylaxis - treatment ED / ICU epinephrine, famotidine, methylprednisolone

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961027	1/21/2021	TX	28	F	1/16/2021	1/16/2021	Received vaccine at 10:11AM, COVID-19 Moderna Lot #042L20A 10:48AM: Provider called to evaluate 28 year old white female who complained of bilateral numbness and tingling to both lips. No other adverse reaction. Patient is awake, alert and oriented x3 10:51AM: Vital Signs: BP-122/76 HR-61 RR-23 O2 Sat-98%. Patient denies difficulty breathing and difficulty swallowing or chest pain. 10:52AM: Patient states, "I feel extremely thirsty.", "My lips feel like they're swelling but I checked and they're not actually swollen." No symptoms of anaphylaxis. No visible swelling of lips. 10:54AM: Patient given water 8oz x2 bottles and states; "I feel better." 11:15AM-11:25AM: O2 Sat - 99% HR-55 BP-118/70. No difficulty breathing, no visible swelling of lips. Bilateral lip numbness almost resolved per patient. 12:05PM: Patient is sitting in wheelchair, no signs and symptoms of acute distress. Patient denies numbness and tingling of lips. No signs and symptoms of anaphylaxis. O2 Sat 99% HR-61 BP-116/70. Patient wheeled to driveway and discharged home via private vehicle. Patient's father is the driver of the vehicle.
960984	1/21/2021	VA	52	F	12/30/2020	12/30/2020	10 min. after vaccine injection: headache, scratchy throat and throat tightening lasting for about 10min and subsided. 50 min. after vaccine injection: flushed, redness in face, ears, and neck progressing to rash on chest, neck. Lasted for about 10min and subsided. Never progressing into full anaphylaxis reaction. No treatment taken.

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960861	1/21/2021	TX	28	F	1/16/2021	1/16/2021	Received vaccine at 10:11AM, COVID-19 Moderna Lot #042L20A @10:48AM: Provider was called to evaluate 28 y/o white female patient complaining of numbness and tingling to both lips. No other adverse event. Patient is awake, alert and oriented x3 @10:51AM: Vital signs: BP - 122/76 HR-61 RR-23 O2 Sat 98%. Patient denies difficulty breathing and difficulty swallowing or chest pain. @10:52AM: Patient states: "I feel extremely thirsty.", "My lips feel like they're swelling but I checked and they are not actually swollen." No signs of anaphylaxis. No visible swelling of lips. @10:54AM: Patient given water, 8 ounces x2 bottles and states; "I feel better." @11:15AM-11:25AM: O2 Sat 99% HR-55 BP-118/70. No difficulty breathing, no visible swelling of lips, bilateral lip numbness almost resolved per patient. @12:05PM: Patient sitting in wheel chair, no signs and symptoms of acute distress. Patient denies numbness and tingling of lips. No signs and symptoms of anaphylaxis. O2 Sat 99% HR-61 BP-116/70. Patient wheeled to driveway and discharged home via private vehicle. Patient's father is the driver of the vehicle.

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960409	1/21/2021			F	1/9/2021		flushing/ facial flushing; Hives; felt warm; short of breath/ audibly gasping for air; wheeze; throat tightening; throat got so swollen and itchy; throat got so swollen and itchy; could not swallow; This is a spontaneous report from a Pfizer-sponsored program Corporate (Pfizer) Social Media Platforms. A non-contactable consumer reported that a 40-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunisation. Medical history included food severe allergic reaction to influenza vaccine with eggs preservative. Concomitant medications were not reported. The patient previously took influenza vaccine and experienced severe allergic reaction to the eggs preservative. The patient received BNT162B2 vaccine and informed of prior history of severe allergic reaction to influenza vaccine with eggs preservative. She has previously received flu vaccine without egg without problem. Due to her prior history of severe allergic reaction/ anaphylaxis to another vaccine, in this case flu vaccine with eggs, it was noted to proceed with caution. She was told that the vaccination could be differed until more information became available but opted to proceed with receiving the vaccine and be observed for 30 minutes. The patient developed throat tightening approximately 20 minutes after vaccination. She received EpiPen within one minute of symptoms and was sent to the emergency room immediately in a wheel chair by Nursing staff. She was evaluated in the emergency department and was hemodynamically stable. She was given IV Benadryl and was stable throughout observation. The patient then reported that 40 minutes after injection, her throat and tongue started to feel weird and tight. The pharmacy at her work hospital gave her 25 mg Benadryl and 650mg Tylenol. At about 1 hour 45 minute after injection, her throat got so swollen and itchy to the point that she could not swallow. She went to the nearest emergency room hospital and they administered decadron and Pepcid orally, and Toradol intramuscularly. On an unspecified date, the patient also reported that 5 minutes after the vaccine administration, she developed flushing, hives, felt warm and eventually short of breath. She started to wheeze and was wheeled into the emergency room with complaint of "cannot breathe, while

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							holding throat and thrashing with facial flushness noted." She took two Benadryl and had several epinephrine shots. She was discharged from the emergency room but later that day, she started to feel short of breath again. In the emergency department, she was audibly gasping for air, however had no wheezing, had a normal saturation and normal blood pressure. She had taken another dose of her EpiPen intramuscularly and diphenhydramine 50mg by mouth prior to coming. She was then admitted to the hospital for further observation. While on the floor, she started to feel short of breath again (about 9am on 18Dec2020), which required an "RRT." The patient received another dose of diphenhydramine IV, methylprednisolone 125mg IV and several doses of IM epinephrine and also required oxygen. She was then transferred to an ICU for further care. Outcome of the events was unknown. No follow-up attempts are possible, information about batch number cannot be obtained.
961186	1/21/2021	PA	35	F	1/18/2021	1/18/2021	Erythema Multiforme Major on all limbs- This was present after first dose; however, became worse after the second dose. Was sent to Urgent Care immediately due to increased coughing and fear of anaphylaxis reaction. Was given IM Solumedrol, Epi Pen, and PO steroid taper
959359	1/20/2021	CA	40	F	1/8/2021	1/8/2021	Delayed anaphylaxis after receiving the vaccine. Symptoms including hives, shortness of breath, and felt like her throat was closing. Her initial symptoms included hives which began 6 hours after receiving the vaccine. This eventually progressed to anaphylaxis and she went to the ED 2 days later.
958221	1/20/2021	AK	36	F	1/18/2021	1/18/2021	Systemic: Anaphylaxis-Severe
958278	1/20/2021	KY	93	F	1/19/2021	1/19/2021	Systemic: Anaphylaxis
958331	1/20/2021	GA	48	F	1/18/2021	1/18/2021	Site: Itching at Injection Site-Severe, Systemic: Anaphylaxis-Medium, Systemic: Rash (other than injection site)-Medium

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958335	1/20/2021	MA	34	U	1/5/2021	1/5/2021	Pt presented to COVID vaccine clinic today and developed a reaction after receiving the vaccination. Pt received the Moderna vaccine. Denies allergies or hx of anaphylaxis. Pt reported immediate flushing sensation, tingling of the tongue, and dizziness after receiving vaccination. Pt was slightly diaphoretic. VS immediately following vaccination: HR: 90 O2: 100% BP: 125/74 Pt denied SOB, difficulty swallowing, chest tightness, nausea, rash, itchiness at this time. No visible swelling. Flushing, tongue tingling, and dizziness started to resolve after laying down for 15 minutes but then quickly returned and worsened. Pt also then developed nausea, ?tongue thickness?, difficulty breathing, and tingling shooting down her arms and legs. HR: 87 O2: 99% 129/77 Code Blue called. Epi Pen injector (one dose) administered at 0951. ED code team arrived and transported patient to ED for further workup and observation. Paged Allergy
958396	1/20/2021	MA	34	F	1/5/2021	1/5/2021	Pt presented to COVID vaccine clinic today and developed a reaction after receiving the vaccination. Pt received the Moderna vaccine. Denies allergies or hx of anaphylaxis. Pt reported immediate flushing sensation, tingling of the tongue, and dizziness after receiving vaccination. Pt was slightly diaphoretic. VS immediately following vaccination: HR: 90 O2: 100% BP: 125/74 Pt denied SOB, difficulty swallowing, chest tightness, nausea, rash, itchiness at this time. No visible swelling. Flushing, tongue tingling, and dizziness started to resolve after laying down for 15 minutes but then quickly returned and worsened. Pt also then developed nausea, ?tongue thickness?, difficulty breathing, and tingling shooting down her arms and legs. HR: 87 O2: 99% 129/77 Code Blue called. Epi Pen injector (one dose) administered at 0951. ED code team arrived and transported patient to ED for further workup and observation. Paged Allergy
958576	1/20/2021	VA	44	F	1/19/2021	1/19/2021	Systemic: Anaphylaxis, Systemic: Seizure-Severe

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958623	1/20/2021	MA	54	F	12/29/2020	12/29/2020	atient presented to COVID vaccine clinic today and developed an allergic reaction after receiving the Moderna COVID-19 vaccine. Pt reports hx of allergies to sulfa and cat dander. Denies any allergies to PEG or vaccines. Denies any hx of anaphylaxis. Ten minutes after vaccine administration pt reported chest tightness, mild SOB, mild dizziness and a sensation of a ?cotton ball? in her throat. Pt reported throat sensation similar to her cat dander allergy. Pt developed slight swelling and tingline of the lower lip. Denied difficulty swallowing or nausea. HR 78. Pt placed on 2 L of O2 for SOB. Epi pen and albuterol inhaler present. Code Blue called & ED code team arrived and transported patient to ED for further workup.
958964	1/20/2021	NC	66	F	1/19/2021	1/19/2021	Patient received first dose of COVID-19 vaccine and within 15 minutes felt tongue swelling and lip swelling and felt heart was racing like she has been exercising. Feels lightheaded and dizzy. No trouble breathing. Patient was immediately assessed. Benadryl 50 mg given in clinic. Minimal improvement in lip and tongue swelling. Patient feeling more lightheaded. Vitals: BP 120/70, Pulse 69-72 O2 saturation 98-99%. PE: CV: normal rate: Respiratory: CTAB. HEENT: swollen upper and lower lip and tongue swelling (angioedema) Skin: mild redness in left hand, no hives noted Patient has had hx of anaphylaxis in the past to compazine and phenergan. Recommend ER Evaluation and monitoring.
959901	1/20/2021		45	F	12/22/2020	12/22/2020	Patient is a 45 year old female with no significant PMHX who presents today high blood pressure, nausea and chills within 30 min of receiving the 1st dose of the COVID-19 vaccine 4 hours ago Denies rash, shortness of breath, vomiting, diarrhea, trouble swallowing or breathing, swelling of throat, tongue, lips or eyes. No fever. Patient states her BP was taken when she was having the symptoms and it was 170s systolic. Patient is presenting today with report of nausea, chills and elevated BP s/p COVID-19 vaccine. Patient has no evidence of anaphylaxis or severe allergic reaction. . Patient has normal vitals and in no respiratory distress. Will discharge home with close outpatient follow-up.
958626	1/20/2021	AK	37	F	1/19/2021	1/19/2021	Systemic: Anaphylaxis-Severe

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959928	1/20/2021		50	F	1/20/2021		Agitation, BlurredVision, Confusion, Anaphylaxis, UrticariaPruritus, Syncope, Pt experienced reaction three days PRIOR to first vaccine - event documentation only. Narrative: Pt has history of likely environmental allergies resulting in 4-5 mild reactions annually. Has seen allergist-immunologist in the community and has epi-pens, ranitidine and diphenhydramine. Had reaction three days PRIOR to first covid vaccine dose. She did NOT experience any untoward reaction to either dose of vaccine.
957544	1/20/2021		23	M	1/15/2021	1/16/2021	Pt reported to clinic for 1x left axillary lymph node enlargement secondary to COVID-19 vaccination, pain 7/10 and swelling the size of a ping pong ball. No anaphylaxis. Pt reported to clinic on 20 Jan 2021, 5 days after swelling presented.
959843	1/20/2021	CA	44	F	1/18/2021	1/18/2021	Nervous before vaccine and history of anxiety/asthma. Patient vomited x 1 after injection, experienced dizziness/shaking. BP readings: 163/85, 137/89, and 128/77. Patient received Benadryl 25 mg, Albuterol x 1, and Epi-Pen. Patient refused to go to ED - got better and left vaccine clinic with friend. Advised to monitor for signs of anaphylaxis for next 12-24 hours.
959800	1/20/2021	NM	66	F	1/20/2021	1/20/2021	Pt had anaphylaxis reaction 10 minutes after administration. Sensation of light headed, could not talk, sensation of tongue swelling and throat closing. Pt was immediately given one dose of epi using standard adult epi pen, IVF, and 25mg benadryl IV. Pts vitals were always wnl, including oxygen. Pt stabilized and in 60 minutes was ready to go home wo any adverse outcome.
959505	1/20/2021	CA	48	F	1/15/2021	1/15/2021	Anaphylaxis - received Epi-Pen x 2 and Benadryl 50 mg - resolved.

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959465	1/20/2021	MI	48	F	1/20/2021	1/20/2021	Client received vaccine at end of our clinic day around 4:05 pm. No history of severe allergies, only prior sensitivity to Avocado. During clients 15 minute wait she stepped outside complaining of being hot. A nurse provided water for client, as well as juice. She stated she felt better. Nurse accompanied her back in side, and went over other signs and symptoms of anaphylaxis. Client stated she was not experiencing any of those symptoms and that she felt better. When her wait was complete, she walked to the coat room with other employees, and her throat and ears began to itch, and she was coughing to help itch her throat. At this time the vaccine director was alerted and anaphylactic protocol was initiated. EMS was called- the time was 4:37 pm, pulse was 80, blood pressure was 178/108. 4:39- client refused epi, so 1mL/50Mg, IM Benadryl was given in the right deltoid. Simultaneously, a tourniquet was placed above the vaccine site on the left deltoid. Distal pulses monitored in left arm every 5 minutes. 4:41 itching and coughing increased, client agreed to Epi. 0.3 mg Epi pen given in right thigh. EMS arrive and transported client to hospital for observation.
959417	1/20/2021			U			Anaphylaxis Allergic reaction COVID-19 vaccine: dizziness, vomiting and shortness of breath. Received vaccine and about 5/10 minutes later developed symptoms of chest tightness shortness of breath wheezing. Arrived to ED at 1156 and discharged at 1507. Given epi IM Solu-Medrol, Pepcid, Benadryl, albuterol.
959960	1/20/2021	IL	41	F	12/28/2020	12/28/2020	Admitted in Hospital for Anaphylaxis.

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955498	1/19/2021	IL	69	F	1/12/2021	1/12/2021	Patient received covid Moderna vaccine 1st does at Health Department on 1/12/21 (lot number unknown). Due to hx of anaphylaxis observed for 30min. After 15-20 minutes, patient experienced mouth and tongue swelling. Also c/o dry mouth. 911 was called and patient was given epinephrine 0.3mg IM and 25mg diphenhydramine per EMS without improvement in symptoms. The sensation included the upper portion of her throat. Pt has known allergies to Shellfish and iodine. Patient was referred for allergy follow up. Per review with allergy - second dose is not recommended. In ED - patient received additional diphenhydramine 50mg IV, famotidine 20mg IV, methylprednisolone 125mg IV. Was already given epinephrine by EMS Discharged home in good condition after approximately 3+ hour observation in ED. Seen by allergy on 1/15/21 who recommended not to administer 2nd vaccine.
955316	1/19/2021	GA	57	F	1/19/2021	1/19/2021	At about 12 minutes after she said her head was hurting a she felt a little dizzy. She had no complaints of SOB, Chest pain or any other signs of anaphylaxis. Initial vitals were 147/79, HR 51, O2 sat 98%. She felt as if her heart was racing so we listened to her heart it was regular and slightly bradycardic at 52 (Pt says the bradycardia is not new for her). We have been monitoring her close to an hour and she feels slightly better after she took Tylenol she had brought. We gave her a donut and some water. She is feeling better and headache is going away, but still slight dizziness. We recommended patient's son come pick her up and keep an eye on her the rest of the day. She was advised if she has any SOB, Chest Pain, throat swelling, rash..etc to take Benadryl and seek medical attention immediately. Vitals at time of departure were BP: 145/84, HR 54, O2 sat 98%. Pt felt much better at departure just stated she feels like "she needs to sleep it off~~

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954800	1/19/2021	ME	59	F	1/14/2021	1/14/2021	Patient received first COVID vaccine given at 3:10 pm approximately. Patient monitored closely at approximately 3:40pm began experiencing itching on left arm by injection site and up in hairline. Noted red patches, no hives, Provider on site made aware of patient itching. No issues with breathing, swallowing able to talk in complete sentences. She was eating a snack and drinking juice without issue 3:45 pm itching both arms and upper back plus up in hairline, complained of chest being heavy. Provider assessed lung sounds lungs clear per provider 4pm this writer notes red patches under chin and on side of face, noted patient scratching their back. Checked shoulder areas hives noted. Provider over to assess. Adult Anaphylaxis Kit accessed and guidelines followed Per Provider, Dr, IM Benadryl given 25mg from Anaphylactic kit. Injection given in Right deltoid no issues noted. Per provider Epinephrine pen 0.3mg given in right upper thigh. Oxygen saturation is 99% and heart rate 121. 4:05pm Patient noted to be shaking she states "this is normally what happens after the Epi Pen" Blood pressure checked and was 121/71 4:15 shaking has subsided she states breathing better 4:17pm reported to RN that breathing normal and patient reports minimal itching. 4:20pm Provider spoke with patient advised to go home and rest Patient understands not recommended to have second shot. Patient was driven back to her work location by employer to get her vehicle. Provider cleared patient to drive home. Patient symptoms had resolved speaking clearly with no issues
955388	1/19/2021	GA	57	U	1/19/2021	1/19/2021	12 minutes after shot patient said her head was hurting a she felt a little dizzy. She had no complaints of SOB, Chest pain or any other signs of anaphylaxis. Initial vitals were 147/79, HR 51, O2 sat 98%. She felt as if her heart was racing so we listened to her heart it was regular and slightly bradycardic at 52 (Pt says the bradycardia is not new for her). We have been monitoring her close to an hour and she feels slightly better after she took Tylenol she had brought. Patient was given a donut and drink and shortly after felt a lot better. Her headache has cleared up but she is still complaining of being slightly dizzy. Her son picked her up and is keeping an eye on her. VS 140/78, 52, 98% upon departure.

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955478	1/19/2021	NC	81	F	1/15/2021	1/15/2021	Systemic: Anaphylaxis-Severe; symptoms lasted 1 day
955491	1/19/2021	NC	48	F	1/15/2021	1/15/2021	Systemic: Anaphylaxis-Severe, Systemic: Seizure-Severe
955966	1/19/2021	OH	31	F	1/5/2021	1/5/2021	Anaphylaxis less than two hours after vaccination. I had no symptoms immediately after vaccine however did develop symptoms within one minute of completing a run. Developed b/l hand swelling and tingling, diffuse hives and itching, tachycardia, elevated blood pressure, lips tingling and swelling which required emergency room visit and EpiPen, IV fluids, Benadryl and IV steroids. This is similar to previous reactions I have had to running previously. Symptoms resolved within one hour after treatment in ED.
956348	1/19/2021	VT	81	M	1/17/2021	1/17/2021	Systemic: Anaphylaxis-Severe
956954	1/19/2021	WA	61	F	1/12/2021	1/12/2021	tri-phasic anaphylaxis
957248	1/19/2021	MA	56	F	1/19/2021	1/19/2021	I was fine for the 15 minute observation period - but at about 20 minutes, while driving home, I experienced a distinctive tingling in my lips and around my mouth. I also felt a bit of a tightening or light tingling in the left side of my face. No hives, no itching, no difficulty breathing. I returned to the vaccination site for further observation, where paramedics took my vitals twice over a 20-minute period (all normal). At that point the tingling began to subside, I declined transport to the hospital, and drove home. It's now 8 hours past the time of my injection, and I feel fine for the moment - but I'm concerned that I may have experienced a mild anaphylaxis, and am wondering if I should consider not getting the follow up vaccine. I am reporting even though this is a very slight reaction, because I have read that officials are wanting to monitor side effects very closely.
955563	1/19/2021	ME	21	F	1/18/2021	1/18/2021	Systemic: Anaphylaxis-Severe, Systemic: Rash (other than injection site)-Severe

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956986	1/19/2021	MD	28	F	1/18/2021	1/19/2021	Individual was vaccinated on 1/18 at 3pm, at time of vaccination she had no adverse events. Upon waking in the morning she noticed lower lip swelling, denies itching, denies trouble breathing or other symptoms. No history of allergy, anaphylaxis. Pt spoke with her PMD who recommended benadryl and she noticed slight improvement.
954378	1/18/2021	WA	51	F	1/14/2021	1/15/2021	No side effects immediately after the vaccine. 30 hours later I developed uticaria on my left arm. 1/15/21. Reported to my physician, allergist. Woke up with uticaria under gluteus 1/16/21. Overnight developed increasing uticaria over my left arm, right side, back and gluteus, feeling quite tired. 1/17/21. Called service I used over Christmas when I had the anaphylaxis to the shingles vaccine. Doctor recommended I take Famotidine 20 mg 1/day which has antihistamine and can be taken with the Allegra. Started 1/17/21. Today, 1/18/21 very small uticaria on gluteus. Feeling much better than I have all weekend.
951824	1/18/2021	CA	28	F	1/5/2021	1/5/2021	Pt. felt hot and flushed, she c/o itching of arms and back, also itching of throat but felt it calming down after 10 minutes and drinking water. Her face did appear flushed but she also said it was flushed before she got the injection. No difficulty breathing, no obvious urticaria. She was emotional about losing her mom to anaphylaxis at age 10, stated that her sister also has similar allergy profile. She questioned if she should et the second vaccine dose.

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951992	1/18/2021	VA		F	1/9/2021	1/9/2021	<p>anaphylactic reaction/anaphylaxis; This is a spontaneous report from a Pfizer Sponsored Program from a contactable pharmacist. A female patient of an unspecified age received first dose of bnt162b2 (Pfizer BioNTech COVID vaccine, lot number: EK4176), via an unspecified route of administration on 09Jan2021 at 0.3 mL, single (standard like 0.3ml by injection once to deltoid, side unknown) to prevent from getting COVID. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylactic reaction/anaphylaxis on 09Jan2021. Clinical course: The patient got the vaccine while waiting to go into the watch room, to be watched for a few minutes, and she experienced anaphylactic reaction/anaphylaxis, she went down, they gave her an Epinephrine, she didn't respond to the first dose, a second dose was given in the arm where the vaccine was given, then she was picked up by an ambulance. Agent stated the caller has been on hold for almost an hour. Caller clarifies dose was given in the arm, it occurred on Saturday with the same lot. Saturday and it went away on Saturday, the patient was worried about it coming back, thus why she asked about Epinephrine pen, the patient was taken to the hospital, and given Epinephrine a couple more times, and it resolved eventually, the patient was not admitted, she went to the Emergency Department. It could have required hospitalization but would most likely say life threatening had she not been treated. Reporter seriousness for anaphylaxis is life threatening. The outcome of event was recovered on 09Jan2021. Relatedness of bnt162b2 to reaction anaphylaxis is related for primary source.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset anaphylactic reaction/anaphylaxis cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>

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952009	1/18/2021		33	F	1/11/2021	1/11/2021	Breast feeding/first dose 24Dec2020 14:30/second dose 11Jan2021 07:30; She was also breast feeding; first dose 24Dec2020 14:30/second dose 11Jan2021 07:30; Fever of 101.7/ temp is still a little elevated at 99.5; full body aches; Chills; Headache; Breast feeding and experienced painful let down; This is a spontaneous report from a non-contactable nurse (patient) reported for herself. This Nurse reported information for both herself and her baby. This is a mother report. A 33-years-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot: EL1283) via an unspecified route of administration on 11Jan2021 07:30 at single dose for COVID-19 immunization. The patient received the first dose on 24Dec2020 14:30 at age of 33 years old at single dose for COVID-19 immunization, and only had a sore arm and maybe fatigue. Medical history included ongoing breast feeding, asthma, Anaphylaxis to tree nuts. Concomitant medication included bifidobacterium lactis (PROBIOTIC) and prenatal multivitamin. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced fever of 101.7, full body aches, chills, headache. She was also breast feeding and experienced painful let down at the time (she did not have mastitis). She had all these symptoms on 11Jan2021 16 hrs after receiving second dose. Now at 24 hours all symptoms have resolved except her temp is still a little elevated at 99.5. No treatment was received for the adverse event. Events outcome of full body aches, chills, headache, painful let down at the time (breast feeding) was recovered, for fever was recovering, while for others was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021027460 Mother/Baby case

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952049	1/18/2021		33	F	12/24/2020	12/24/2020	Sore arm; Fatigue; Patient also breast feeding; Patient also breast feeding; This is a spontaneous report from a non-contactable nurse. This patient reported information for both herself and her baby. This is a mother report. A 33-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 24Dec2020 14:30 at single dose for COVID-19 immunization. Medical history included ongoing breast feeding, asthma, Anaphylaxis to tree nuts. Concomitant medication included bifidobacterium lactis (PROBIOTIC) and prenatal multivitamin. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. For the first dose the patient only had a sore arm and maybe fatigue. No treatment received for the adverse event. She was also breast feeding. Events outcome was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021027460 Mother/Baby case
952382	1/18/2021	ID	60	F	1/17/2021	1/17/2021	Patient being observed for 30 minutes due to hx of anaphylaxis to bee's. 15 minutes post vaccine patient stated SOB and throat tight. HR 77, O2 94%, wheezy, alert. administered 0.3ml epi in left thigh. transferred to ER
952707	1/18/2021	NH	38	M	1/14/2021	1/15/2021	Anaphylaxis (urticaria, tongue swelling, subjective difficulty breathing) starting approx. 24hrs first moderna dose. No prior episodes of anaphylaxis/allergic rxn. Treated with Benadryl 100mg PO (prior to arrival, pt administered), famotidine 20mg IV, Epinephrine 0.3mg IM. Monitored in ED, complete resolution of symptoms, discharged home.
952896	1/18/2021		26	F	1/9/2021	1/15/2021	A 26-year-old female presents for evaluation treatment of a rash around vaccine site on her left upper arm. Received the 1st dose of her covid-19 vaccine on 1/9. Initially with some soreness and aching. That resolved and 2 days ago developed an erythematous, mildly pruritic rash around the injection site. She denies any nausea/vomiting, anxiety, globus sensation or respiratory symptoms. Nothing to suggest anaphylaxis. Recommend cetirizine or loratadine 10 mg twice daily. May also treat with hydrocortisone 3 times daily

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953790	1/18/2021	NY	36	F	1/18/2021	1/18/2021	1 hour post injection patient returned with redness and borderline hives in her left arm, chest, neck and face. She complained of feeling very hot and with mental confusion. We administered 50 mg of diphenhydramine, and 15 minutes later sent her to the ED. At the ED they diagnosed her with a minor anaphylaxis reaction, gave her methylprednisolone and epinephrine.
955333	1/18/2021		46	F			Pt presented to ED with allergic reaction after receiving Pfizer Covid vaccine itching, swelling in right upper lips, slight tingle Patient received the Pfizer vaccine and developed right upper lips swelling plus pruritus within a span of approximately 45 minutes. After presenting to the ED, she was found to be hemodynamically stable with no further complaint in regards to pain, fever, nausea/vomiting, rash or other systemic responses. Airway appeared to be intact. Patient had a tryptase lab drawn (4ug/l which was within normal limits). Patient had a distant history of hives although the med/agency was unknown. No other signs of allergic reaction. Speaking in a clear voice. Maintaining good oxygen saturation. less likely anaphylaxis. Given 50 mg of Benadryl in triage. Pt Observed for 3 hours after the vaccine for progression of the swelling. Patient continued to do well and was sent home with follow up occupation health regarding recommendations regarding the second dose in 3 weeks. Given the limited nature of exam findings, mild form of vaccine reaction could not be ruled out. However, the cause of her symptoms could also be due to other factors including food (no detailed history on this).

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955348	1/18/2021		44	F			Patient had Pfizer vaccine and came in with Mild urticaria and hives after receiving COVID vaccine Mild urticaria and hives after receiving COVID vaccine, with no signs of anaphylaxis or shock and no indication for medication administration (e.g. epinephrine, diphenhydramine). Symptoms spontaneously resolved. Tryptase level was 6.7 ug/l (within normal limit). Patient discharged in stable condition. Further follow up showed that patient is feeling fine after allergic reaction. Plan is underway to schedule for the second vaccine, although they have tentatively told her that she will get her second dose in the allergy clinic. Possible this was due to the vaccine given the proximity of timing and adverse event but since the second dose will be given in allergy clinic, the pt will be monitored closely.
952432	1/18/2021		49	F	1/13/2021	1/14/2021	49 y.o. female who presented to the emergency department on 1/14/21 for possible allergic reaction. Patient states that she got her first Covid vaccine yesterday afternoon and states that she has noted some swelling in her hands and also feels as though she has burning pain and pins-and-needles in her hands. She denies any weakness in her distal extremity. She states the sensation extends from her fingertips to her mid forearm. She also states that she has noted some lymph node pain in her groin and neck. She denies any fevers or chills. She denies any throat tightness, shortness of breath, wheezing, abdominal pain, nausea, vomiting or rash associated with her symptoms. Patient is alert and oriented x3, cranial nerves II through XII intact bilaterally, no pronator drift, paresthesias in glove like distribution from hand to mid forearm bilaterally. Sensation intact in bilateral lower extremities, 5/5 strength in upper and lower extremities, cerebellar function intact with finger to nose bilaterally. No visual field deficits by confrontation. Discussed laboratory findings with patient. She did also does have a mildly elevated creatinine outside of kidney injury however suspect may be source for mildly elevated phosphorus. Given 1 L of fluids. Recommended close follow-up with PCP for laboratory recheck and further evaluation. No signs of acute anaphylaxis or angioedema. Discussed return precautions with patient if she were to have worsening symptoms

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953393	1/18/2021	TX	33	M	1/5/2021	1/8/2021	Widespread rash from injection site across back of neck, shoulders, down the opposite arm, and across entire chest. First noticed symptoms on 1/8/21 and was treated at the ER where I am employed. Symptoms persist until the present moment, but do not appear to be progressing beyond the current locations. Rash is red, raised, hive-like and itches/burns mildly. Overall reaction moderate in severity and appearance. No anaphylaxis experienced.
952365	1/18/2021	ID	60	F	1/17/2021	1/17/2021	Patient was a 30 minute observation due to hx of anaphylaxis with bee's. 15 min post vaccination, patient stated "Short of breath and my throat is tight". HR 77, O2 94%, wheezy. gave 0.3 ml epi in left thigh, immediately transferred to ER
954168	1/17/2021	AR		F	12/31/2020	12/31/2020	Anaphylaxis after Covid 19 vaccine #1. Pfizer Lot # EH9899
951174	1/17/2021	AZ	29	F	1/16/2021	1/16/2021	Approximately 6 hours following the second dose in the two-dose Pfizer COVID-19 vaccination series, I began experiencing nausea, vomiting, moderate body aches, and headaches. I have been unable to keep down liquids (including water, gatorade, and soup broth) and solids. At this time, I have continuous vomiting, with each following the intake of food and/or beverages. Physical exam is negative for redness, swelling or rash at the injection site. Additionally, I have not appreciated any fever or signs of anaphylaxis. Following my first dose in the two-dose series, I did not experience any side effects other than the expected sore arm for 24-48 hours.
955173	1/17/2021	AR		F	12/31/2020	12/31/2020	Anaphylaxis after Covid 19 vaccine #1. Pfizer Lot # EH9899

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949903	1/16/2021	WI	35	F	1/15/2021	1/15/2021	That morning I had taken amlodipine for the 2nd time in my life to help Raynaud's. Both times I have taken amlodipine now I have felt lightheaded and less cognitively sharp than normal basically the entire day. I received the above Pfizer COVID-19 vaccine around 12:45 PM, within about 3-5 minutes of receiving the vaccine and standing in line to check out I suddenly felt I was going to loss consciousness/collapse so started lowering myself to the ground and then became unconscious and fell. Healthcare staff informed me I was unconscious for about 20-30 seconds. I woke up and initially felt confused, but quickly realized what had happened. Then I felt nauseated, had some stomach cramps and thought I was going to have diarrhea. They considered giving me Epi for possible anaphylaxis, but I requested they observe further for any skin reaction/hives, airway symptoms, etc given I was skeptical the syncope may have been fully or partially related to the amlodipine I took that morning. Symptoms slowly improved over 20-30 minutes, but the lightheaded feeling and nauseated lasted hours. No Epi, medications, or interventions were needed.
949845	1/16/2021	HI	34	M	1/15/2021	1/15/2021	34-year-old male presenting with lightheadedness and transient episode of hypertension following vaccine administration. Appears most consistent with vasovagal episode and patient does report similar episodes in the past. ECG performed without any acute ischemic change. Symptoms have resolved by the time of my evaluation. Blood pressure within normal limits. No clinical features concerning for anaphylaxis

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949931	1/16/2021	IN	47	M	12/19/2020	12/19/2020	Patient complained of feeling light-headed and a little dizzy at 10 minutes post-administration. Pulse-oximetry applied revealed normal spO2, but tachycardia to 140bpm (this patient's resting HR is approximately 55-65). Apple Watch data confirmed rapid increase in HR at that moment. BP increased from normal baseline to about 150-160 SBP. No chest pain reported. No signs/symptoms of anaphylaxis (rash, wheezing, etc.). HR gradually recovered to normal levels within 30 minutes and patient was released after 60 min observation. Patient reported generalized fatigue in weeks following injection. Nineteen (19) days after injection, patient developed unprovoked resting tachycardia to approximately 180bpm (following some moderate weigh-lifting exercise). Symptoms did not resolve sufficiently and patient was transported by EMS to ER for evaluation
950054	1/16/2021	AZ	36	F	1/13/2021	1/13/2021	anaphylaxis
950070	1/16/2021	OH	47	F	1/16/2021	1/16/2021	Pt with known anaphylaxis with prior Flu Shots x 2. Pt received COVID vaccine, dose #1 at 10:30am, checked with patient @ 10:37am who stated that she was nervous and her throat felt tight. Patient was taken to a separate room by this RN and clinic MD. O2, pulse ox and EpiPen available. Placed pulse ox on patient, O2 sats 98%. Patient continued to complain of throat feeling tight and she was visably getting more nervous and stated her throat felt worse. Decision was made by this RN and Clinic Doc to administer 0.3mg of EpiPen and 911 was called @ approx 10:42am. Called patients daughter and explained what happened, sat with patient until squad arrived. Squad transported to ED.
950619	1/16/2021	IL	48	F	1/11/2021	1/11/2021	About 40 minutes after the vaccine i noted my throat was dry and my voice started to change and it was deep and scratchy, The change in voice got worse as i was speaking to my friend so i went to the ED (building next to where I work). I had no problems breathing but was eventually treated for anaphylaxis with epi, prednisone, benadryl, and pepcid

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950640	1/16/2021	AL	34	F	12/29/2020	12/30/2020	Day 1-3 after the dose flu like symptoms Day 3-7 swelling in lymph nodes on left side of body (baseball sized) took ibuprofen and Tylenol Day 8 angioedema, anaphylaxis. Received epi subq, IVP 50mg Benadryl, Pepcid 20mg IVP, liter of NS Day 9 raised red rash all over body and face still going on Day 16- present: severe joint pain and fever, unable to obtain any relief
950759	1/16/2021	IL	63	F	1/6/2021	1/6/2021	Pounding headache, heart racing to over 145 bps, chest burning and tightness and hard to breath. I was taken to the Emergency Room at Hospital immediately. Reaction occurred within 30 minutes of the injection. An EKG was administered. I was prescribed prednisone and Benadryl. I was diagnosed with Anaphylaxis.
950797	1/16/2021	MN	53	F	1/15/2021	1/15/2021	Patient reported chest tightness (1-2 on 0-10 pain scale) and left arm tingling approximately 10 minutes after receiving the 2nd COVID vaccine dose. Patient reported symptoms felt similar to times when she had exposure to cats or after exercising. She denies any previous treatments for anaphylaxis or any previous severe reactions. Vital signs at time of initial assessment were BP 147/100, pulse 80, O2 Sat 99% on room air. Patient was observed for 50 minutes and chest tightness/arm tingling symptoms resolved. Patient did also develop a dry "tickly" cough about 60 minutes post vaccination. Patient was administered albuterol 2 puffs via MDI and reported improvement of cough. She again reported the cough to be similar to the type of cough she had gotten when exposed to cats. No further treatment needed. Patient stable and released to go home.
950102	1/16/2021	GA	69	F	1/16/2021	1/16/2021	Upon injection, immediately swelled up to size of golf ball, no erythema or other signs/symptoms of anaphylaxis, reports no other symptoms. 30 minutes later swelling has gone down some and seems to be healing.

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949460	1/15/2021	AK	39	F	1/15/2021	1/15/2021	11:20 - pt observed post vaccine, states she's feeling "shaky". Asked by nurse if she ate breakfast which she had not. Provided snack and water. 11:30 - no improvement, vitals WNL, 11:32 - pt states "trouble breathing", SpO2 98%, RR WNL, c/o nausea, no vomiting. 11:34 - d/t anaphylaxis hx, SOB and nausea, first dose of epi given. Called 911. 11:39 - continues to have symptoms (SOB, diaphoretic, shaking), second dose of epi given d/t no improvement. continued to monitor vital which were stable with the exception of tachypnea. 11:50 - EMS arrives, pt remained A&Ox4, report to EMS given by RN. Two used epi pens given to EMS.
947164	1/15/2021	PA	64	F	1/15/2021	1/15/2021	Pt got her COVID vaccine waited her 15 mins for observation went out to her car felt flushed face a little red and felt a slight tingling in her lip. Pt came back into the office , we put her in room 15 for observation pt was given 1000mg tylenol evaluated by Dr. advised to stay for further monitoring and observation. Pt was observed no other adverse reactions she has had anaphylaxis with compazine in the past , she does not have any other allergies at this time. Pt takes metoprolol no other medications at this time. she has COPD or asthma she does not know definitively .
947314	1/15/2021	NJ	26	F	1/13/2021	1/14/2021	Chest pressure/tightness starting approximately 24h after the vaccine. No allergic reaction or sign of anaphylaxis. No shortness of breath or trouble breathing, just general chest tightness. Got a little better the next day, but still a bit of chest tightness. Almost feels like the type of chest pressure you get when you have a bad cold with postnasal drip.
947674	1/15/2021	FL	67	F	1/15/2021	1/15/2021	Instant itching Localized reaction at injection site Left deltoid red dened area size of golf ball with a raised center. EMS Medic responded with Diphenhydramine 50mg Intramuscular Right Deltoid 1315 . Local EMS at site Patient declined transport to local hospital for evaluation. At 1333 patient left building. accompanied by spouse. Advised of anaphylaxis reactions to observe for and to seek medical attention immediately. Advised patient to seek counsel from her Primary MD for second vaccine.

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947796	1/15/2021	CA	30	M	12/30/2020	12/30/2020	At 0803 employee complained of his throat tightening and he was placed on an AED and EMS was called and a non-rebreather and Anaphylaxis kit were brought 0805 HR 118 RR 22 employee breathing was not labored AED "no shock advised" employee now reporting centralized tight feeling chest pain 0807 HR 122 RR 20 employee breathing was not labored. AED "no shock advised" 0809 HR 118 RR 22 AED "no shock advised" 0811 HR 102 RR 18 employee breathing was not labored. AED "no shock advised" Employee reported Chest pain "less tight" still with dry mouth ,difficulty swallowing and now burning sensation in throat 0811 HR 104 RR 18 AED "no shock advised" employee breathing was not labored 0813 EMS arrived and care of employee handed over. O2 and pharmacy monitoring applied. They assessed and took patient to ED Received Solu-Medrol, Pepcid, and Benadryl in ED
947992	1/15/2021	CA	41	F	1/13/2021	1/13/2021	About 10 minutes after getting my vaccine I noticed the roof of my mouth itching as well as my tongue and back of my throat. I waited to see if it would go away and then a couple minutes later noticed my lips started itching and swelling and from there it just got worse. I told the nurse practitioner that I think I was having a reaction, she had me take a seat told her my entire mouth throat & lips felt swollen and itching and she looked and said it was full blown anaphylaxis reaction. Administered EpiPen, benadryl and called ambulance where they took me to medial emergency department.
948073	1/15/2021	NJ	65	F	1/14/2021	1/14/2021	Immediate sensation of slight mental status change which resolved but within 2 minutes started to feel slightly woozy and pre-syncopal, as if anaphylaxis starting. Informed staff. Put on stretcher. Vital signs obtained. O2Sat upper 90s. BP elevated with diastolic in low 100s with sensation of pre-syncope and very slight confusion. Resolved slowly over 30 minutes to about 90% of prior mental status. Continued to feel somewhat dizzy for several hours. Went to bed early. Had very intense disturbing dreams. Very sore vaccine site. Resolved by morning. Arm soreness about 50% of day prior.
949691	1/15/2021	NJ	57	M	1/14/2021	1/14/2021	Anaphylaxis

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948410	1/15/2021	NC	40	F	1/14/2021	1/14/2021	<p>This facility staff member received her first dose of the MODERNA COVID-19 vaccine (Lot037K20A/EXP 6/22/21) at clinic at approximately 9:15AM on 1/14/21. She initially answered "no" to any allergies on the VAR but revealed to the pharmacist reviewing the VAR that she had experienced an allergy to food and contrast dye that required an epi-pen and hospital attention. She did not offer additional details and explained that she had tolerated other shots (including the 2020 flu shot) without incident. I advised patient to remain for a 30 minute monitoring period post-vaccination due to history of allergic reaction. Patient presented with some anxiety before the shot and immediately started to complain of feeling "sick" and said she was having trouble breathing due to chest pressure. We advised patient to remove her mask and provided her with water and a trash can though no vomiting occurred. After 15-20 minutes, patient still complained of chest pressure and difficulty breathing. When asked if she was experiencing any itchiness or throat swelling, patient said she did feel some throat swelling so she was given 25MG of Benadryl. After an additional 15 minutes, patient's condition seemed unchanged (not worsening, not improving) so the facility's nursing team was called to evaluate patient. Patient said she was still experiencing difficulty breathing and throat swelling so nursing advised use of EPI-PEN and patient consented. I administered a dose of 0.3MG (LOT0FM4066/EXP 02/2022) to the right lateral thigh and nurse called for EMS. Immediately after injection, patient's eyes fluttered and she seemed to be on the verge of fainting. Nursing checked her oxygen saturation which was 100%. Patient reported no improvement after 5 minutes so another EPI-PEN 0.3MG was administered to the left lateral thigh. Nursing also gave the patient 81MG chewable aspirin due to the patient experiencing a stroke last month. EMS arrived a few minutes after the second EPI-PEN dose and patient was transported to the hospital for evaluation. Facility reported that patient went home that afternoon but did not provide details. Based on my assessment of patient's symptoms and behavior, I feel it is likely that she experienced either an acute panic attack or anaphylaxis due to vaccine administration. I called the patient today (the day after the incident) and she confirms that she received treatment for an anaphylactic reaction to the Moderna COVID shot and is</p>

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							doing well without any lasting adverse effects.
949568	1/15/2021	WI	59	F	1/15/2021	1/15/2021	Received Vaccine at 1545 - Reported symptoms of throat thickening consistent with her previous anaphylaxis reactions at 1553. STAT team initiated at 1553, VSS, Benadryl 25mg PO given. Transferred to ED by Wheelchair - ED course treated with Pepcid 40mg, solumedrol 125mg and epinephrine 0.3mg IV at 1604 and given 1L bolus of 0.9 NaCl. Patient observed in the ED until all s/sx resolved. Discharged Home with 40mg Prednisone PO daily x4 days. Pt only complaint throughout was throat "thickening". No other s/sx per chart review.
949597	1/15/2021		27	F	1/15/2021	1/15/2021	Anaphylaxis- throat closing, feels SOB 15 minutes after vaccine.
946951	1/15/2021	NJ	66	F	1/14/2021	1/14/2021	Systemic: Anaphylaxis-Severe
948297	1/15/2021	AK	43	F	1/15/2021	1/15/2021	Immediate itching and hives. Progressed quickly into anaphylaxis - stridor, difficulty breathing. Taken immediately to ER, O2 sats observed of 84%. Given IM Epi in ER triage area. Brought back to room, racemic epi started and given additional IM dose. Please refer to ED for further treatment.

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947110	1/15/2021	CA	48	F	1/9/2021	1/12/2021	Patient states she noticed a welt on her arm 3 days after receiving the 2nd dose of the vaccine. She tried applying ice on the most red part on the arm but the swelling continued to grow. Then she started applying heat in addition to applying HPR+ cream that she uses for urticaria. The only thing that the patient stated that helped a little was the ice pack. The patient ended up going to the emergency department on 1/14/2020 for the rash / welt that developed beyond her arm and to the neck and eyelid area which she described as itchy. The patient was prescribed a 4 day prednisone 50mg daily course along with Benadryl as needed and Pepcid 40mg daily which she states have helped alleviate the itchiness but has not completely resolved yet as of today 1/15/2020. Per ED note, patient presented with mild erythema around the injection site and non-specific rash to the neck. Patient has clear speech and no oral swelling and no signs of anaphylaxis. Patient discharged home in stable condition and advised to follow up with primary care doctor in 2-3 days.

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946901	1/15/2021	ME	47	M	1/13/2021	1/13/2021	1/13/21 0740 Received second dose of COVID-19 vaccine, which was scheduled for that morning. Did not experience anaphylaxis or other symptoms of vaccine injury. I took 1gram of Tylenol PO when I got back to my motel by 0830. By 0924 I noted that my left deltoid (injection site) and arm were very sore/achy. I fell asleep until 1740. I noted that I was experiencing more body aches at this time (joint and muscle, especially in my bilateral shoulders, lower back, knees and pelvis). Calf muscles were quite sore. I made pasta with red sauce and made a pot of blueberry tea, ate and went back to bed. 2327 I woke again with weird fever dreams and my right bicep was intermittently twitching. I think I was starting to run a low grade fever at this time (my ears felt hot, and my stomach was queasy but was not nauseous), no diaphoresis, shortness of breath or airway constriction. I remained awake until 0200, 1/14/21. By 0400 I was experiencing mild chills, face was flushed, headache on the right, with pressure behind my right eye, parietal and occipital areas of my skull. The pain extended into the right muscles of my neck (trapezius, levator scapulae and sternocleidomastoid muscles). Bilateral upper arm muscles and joints were 5:10 pain. I was also experiencing mild photophobia, but not migraine related, and a mild non-productive cough and pressure behind my facial and ethmoid sinuses with scant viscous secretions at the back of my throat. 0433 I forced myself to get out of bed and head to the bathroom. My temp was 101. I took a very hot shower and am back in bed. Experiencing a lot of malaise and lethargy. 1/15/21 0830 temp is currently 99.1, headache is present, 3:10. Joint aches have mostly subsided. Injection site is warm and tender, but no erythema is present.
946553	1/15/2021	NM	26	F	1/14/2021	1/14/2021	anaphylaxis by lethargy, nausea, vomiting, palpitations, funny feeling in chest, swollen lips

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946542	1/15/2021	NY	26	F	1/10/2021	1/13/2021	<p>Patient developed angioedema of her eyelids after COVID-19 vaccination. She received her Covid vaccine on 1/10/2021 at 11:30 AM. She received the Pfizer vaccine. She works at a nursing home. She had some fatigue and tiredness during the day but woke up on the second day without any symptoms. On 1/30/2021, she developed bilateral eyelid swelling. The swelling is mild to moderate intensity involving the upper and lower eyelids bilaterally with a prickly burning sensation associated with pruritus. The reaction lasted less than a day and resolved without any skin desquamation, scarring or bruising. She denies any hives anywhere else. She does not have a large local reaction at the injection site. She denies respiratory complaints, GI symptoms, lightheadedness, loss of consciousness, wheezing, swelling of her throat or other symptoms consistent with anaphylaxis. She used Benadryl with significant improvement. She had a significant reaction after influenza vaccination consisting of swelling of her face and her eyelids with development of dry patches bilaterally within 2 days, resolving with skin desquamation. The reaction lasted for 1 week. She received her influenza vaccination in October 20, 2020. She was seen in our office in 2012 for bilateral eyelid angioedema with associated urticaria shortly after swimming in the pool. She was given oral antihistamines ?Zyrtec once daily? with significant improvement as well as prevention of this reaction. She has not had this reaction for more than 6 years.</p>

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945956	1/15/2021	WI	57	F	1/8/2021	1/8/2021	difficulty breathing and stridor; difficulty breathing and stridor; noises on inspiration; dizziness; headache; sore throat; Anaphylaxis developed within 2 hours of injection; This is a spontaneous report from a contactable other health professional (patient). A 57-year-old female patient (not pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number EL0142), via an unspecified route of administration in arm left on 08Jan2021 09:00 at single dose for covid-19 immunisation. Medical history included Idiopathic Angioedema, Hypothyroidism. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not have COVID tested post vaccination and did not have COVID prior vaccination. The patient's concomitant medications were not reported. Reported Event: Anaphylaxis developed within 2 hours of injection. 9:00 am injection; 9:05 am Developed sore throat, 9:20 am Developed dizziness and headache, 10:00 am developed noises on inspiration, 10:20 am Presented to Emergency Services, 10:40 am IV (intravenous) diphenhydramine (BENADRYL) and dexamethasone (DECADRON), 10:45 am difficulty breathing and stridor, 11:00 am intramuscular Epinephrine, 11:10 am Racemic Epi Nebulizer, 11:20 am Breathing improved, 14:00 Discharged home. The adverse events result in Emergency room/department or urgent care. The outcome of all the events was recovering.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis reactions considering the plausible temporal relationship and the known adverse event profile of the suspect product. The underlying predisposing condition included Idiopathic Angioedema. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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946997	1/15/2021	NH	26	F	1/15/2021	1/15/2021	Pt developed itching, mild rash around injection site several minutes after injection. She also reported some itching to face bilaterally. No evidence of anaphylaxis. Symptoms improved after 1/2 hour. She refused EMS services. Band-Aid was removed and new band aid was placed on other arm where the pt then developed mild rash there as well. Suspect new allergy to bandaid adhesive. Doubt this was a reaction to the vaccine. Pt was counseled to follow up with PCP for further guidance regarding 2nd dose.
943073	1/14/2021	CT	39	F	1/7/2021	1/7/2021	Systemic: Anaphylaxis-Severe, Systemic: Vomiting; symptoms lasted 2 days
943504	1/14/2021	WI	74	F	1/9/2021	1/9/2021	Systemic: Anaphylaxis-Severe; symptoms lasted 1 day

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943386	1/14/2021	VA	38	F	1/14/2021	1/14/2021	Treated by NP attending vaccine event. HPI: Abnormal sensation in throat approx. 15 min after receiving Moderna novel coronavirus vaccine. Denies SOB, wheezes, tongue swelling. No n/v/d, no abdominal cramping, no weakness, no faintness. History of similar reaction to multiple medications. In the past when she has had this throat sensation in reaction to a medication or food, she takes 12.5 mg of oral Benadryl and finds the reaction stops or progresses to hives to posterior knees and thighs, she typically takes more Benadryl and Zantac and the reaction ceases. One episode of anaphylaxis to oral sulfa. Hx hives reaction to one injectable for RA, cannot recall the name. No hx of anaphylaxis to injectable medications. Also reports remote history of severe episodes of hives of unknown origin over a 3 week period about 10-12 years ago; her provider speculated they were stress induced. ROS: otherwise negative. PE: Constitutional - No acute distress. Speaks in full and lengthy sentences without difficulty. ENT: No oropharyngeal edema. Voice clear. No drooling. Airway patent. Neck: Supple, no LAD, no masses, no torticollis. Respiratory: CTAB, no increased WOB. Cardiac: HRRR, no murmur. A/P: Adverse rxn to vaccination, hx multiple food and drug allergies. Administer diphenhydramine 12.5 mg as she usually takes. Continue monitoring for extended period. Further intervention as needed, EM care if condition deteriorates. Report to VAERS. 0918 - diphenhydramine 12.5 mg oral administered. 0930 ? reports less fullness sensation in throat. 0935 ? reports abnormal sensation is completely resolved. Lungs CTAB, no increased WOB. No hives, no n/v/d, no faintness. No oropharyngeal edema. 0940 ? patient now questioning if she has reacted to the orange Juicy Juice she drank; she has never had one before. 1020 ? continues to be asymptomatic. Lungs CTAB, no increased WOB. No hives, no n/v/d, no faintness. No oropharyngeal edema. Discussed the importance of PCP follow up to be advised on whether or not a 2nd vaccine is prudent, she plans to seek this guidance. She may opt to rec the 2nd injection at the health department if her PCP advises it is safe, has been information on how to make an appointment there. Encouraged to seek re-evaluation for new symptoms.

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943364	1/14/2021	AL	61	F	1/4/2021	1/4/2021	Systemic: Anaphylaxis-Severe, Systemic: Fainting, Systemic: Pharmacist submitting: unable to determine if anaphalaxis or panic attack, patient experienced facial weakness, chest tightening, tremmors, inability to breathe, and fainting within 10 min of administ
943722	1/14/2021	CA	28	M	1/9/2021	1/9/2021	Systemic: Anaphylaxis-Severe, Systemic: Rash (other than injection site)-Medium, Systemic: Minor Rash/Itching/Shakiness on left side, followed by trouble breathing; symptoms lasted 1 day
943258	1/14/2021	TX	41	F	1/8/2021	1/8/2021	Systemic: Anaphylaxis-Mild, Systemic: felt tingling and warm sensation inside the body, felt tightness in throat; symptoms lasted 0 days
944261	1/14/2021	WI	33	F	1/9/2021	1/9/2021	Systemic: Anaphylaxis-Severe, Systemic: Headache-Medium, Systemic: Nausea-Medium, Systemic: Vomiting-Medium; symptoms lasted 1 day
943070	1/14/2021	VT	22	F	1/3/2021	1/3/2021	Systemic: Anaphylaxis-Severe, Systemic: Rash (other than injection site)-Medium, Systemic: chest/throat tightness-Medium

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942710	1/14/2021	NY	33	F	1/6/2021	1/7/2021	Swollen lymph nodes upon palpation to left armpit; visible swelling to left armpit; pain to left armpit; This is a spontaneous report from a contactable nurse (patient). A 33-year-old female patient received the second dose of BNT162B2 (also reported as Pfizer brand, lot no: EK5730), intramuscular on 06Jan2021 at 06:30 at a single dose on the left arm (as reported, also reported as left deltoid) for COVID-19 immunization. Medical history included anaphylaxis to "unknown chemical substance" while jogging in Oct2014 that resulted in a 4 hr hospitalization in an emergency department. The patient's concomitant medications were not reported. The patient previously received the first dose of BNT162B2 on 16Dec2020 at 8:00 PM intramuscular on the left arm for COVID-19 immunization. The patient reported swollen lymph nodes upon palpation to left armpit with noted visible swelling to left armpit as well as pain to left armpit on 07Jan2021 at 6:30 AM. The symptoms were present 24 hours post vaccination intramuscular to the left deltoid (as reported). The patient did not receive any treatment for the reported adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination the patient has not been tested for COVID-19. The outcome of the events was unknown.
943272	1/14/2021	MO	42	F	1/8/2021	1/8/2021	Systemic: Anaphylaxis-Medium; symptoms lasted 1 day
943775	1/14/2021	VA	52	F	1/5/2021	1/5/2021	Systemic: Anaphylaxis-Severe, Systemic: Nausea-Medium, Systemic: Fainting-Medium
943938	1/14/2021	NY	84	M	1/2/2021	1/2/2021	Systemic: Anaphylaxis-Severe; symptoms lasted 0 days
944709	1/14/2021	CA	31	F	1/11/2021	1/11/2021	Anaphylaxis, hives, given epinephrine and 50mg Benadryl, EMS and fire department called
944923	1/14/2021	CO	33	F	1/12/2021	1/12/2021	Systemic: Anaphylaxis-Medium; symptoms lasted 1 day
945182	1/14/2021	OR	30	F	1/9/2021	1/9/2021	Itching, facial tightness, flushing, throat changes. Was given Epi x 1, Bendaryl x 1 and Hospital Rapid Response called and she was brought to ED. At ED, evaluation done, pt stable, felt to be likely anxiety/panic attack as cause of symptoms, and low likelihood of anaphylaxis. Pt was given rx for Epi pen to keep on hand just in case.

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945213	1/14/2021	CO	41	F	1/13/2021	1/13/2021	I was approached by a person in the center at approx 1000 stating she had an employee that received their first COVID vaccine and was not feeling well. I went over to find the employee sitting in the person's office in a chair. She was able to tell me she received her first COVID vaccine approx 30 mins ago. She stated she stayed there for the 15 mins after the vaccine with no reaction. She is now having ringing in her ears, feeling lightheaded, hot, nauseaus, and "I feel like I am in a cloud." She denies allergies or past hx of vaccine reactions. Denies hx of anaphylaxis. She denied any SOB or chest pain. Employee was holding her head. She stated she had only had some coffee and juice today and was feeling hot. BP was taken and was 112/90 and she is not tachy and no resp distress observed. Patient was able to speak to me in full complete sentences initially. Another person came over and the employee was asked if she could stand and walk. Employee stated she felt she could stand and walk and when she did this she had to hold onto something to avoid falling and she was sat back down. Emergency services was called and employees speech was slow and almost slurred at times. Emergency services arrived and transported employee.
945596	1/14/2021	CT	41	F	1/13/2021	1/13/2021	Anaphylaxis- throat tightness , nausea , rash , pruritis , chest tightness, wheezing . 9-11 called epinephrine x 2 , decade on , IV Benadryl , duo-nebs, famotidine, admission to icu high dose prednisone , nebulizers , zofran , duo-neb nebulizers
1349867	1/14/2021	MS	48	F	1/11/2021	1/11/2021	Dizziness & Anaphylaxis
943685	1/14/2021	OH	71	F	1/14/2021	1/14/2021	PT. REPORTED A BRIEF EPISODE OF "LIGHTEADINESS, AND TACHYCARDIA" EMS ON SCENE EVALUATED PT. PT. REPORTS ALL SYMPTOMS RESOLVED WITHIN MINUTES, PT. ABC'S INTACT, WITH NORMAL WOB, LUNGS CLEAR, PT. SYMPTOM FREE,AND DENIES CHEST PAIN OR SOB. PT. NOT TRANSPORTED, PT. REMAINED IN OBSERVATION FOR FULL 30 MINUTES D/T HX. OF ALLERGIES, PT. DENIES HX. OF ANAPHYLAXIS.
943825	1/14/2021	NJ	80	F	1/10/2021	1/10/2021	Systemic: Anaphylaxis-Mild, Systemic: trouble breathing, wheezing; symptoms lasted 1 day

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943443	1/14/2021	NV	24	M	1/4/2021	1/4/2021	Systemic: Anaphylaxis-Severe
941021	1/13/2021	WI	26	F	1/8/2021	1/8/2021	Pfizer-BioNTech COVID-19 Vaccine Symptoms experienced: Lightheaded, shortness of breath with hyperventilation. She was laying on the floor and appeared shaky with red blotching on face and neck. Actions taken: Medical Response called. Anaphylaxis Medication given epinephrine (adult) IM outer thigh. Patient was placed on stretcher and taken to ER. Diphenhydramine and famotidine given in ER
943624	1/13/2021		58	M	1/11/2021	1/6/2021	Anaphylaxis tongue swelling and throat soreness Narrative: developed throat pains and tongue swelling 1/6/21 whereas mRNA vaccine Covid 19 Pfizer was given at Hospital. Advised not to taken 2nd dose until etiology of tongue swelling and throat pains identified. His 1/6/2021 covid 19 test (biofire- which include Covid 19 infection and all possible viral etiology was negative.
942459	1/13/2021	AZ	62	F	1/10/2021	1/12/2021	1st 24 hrs just arm soreness, 2nd 24 hrs itching and fatigue, 48 hrs, anaphylaxis, hives, rash, itching, lymph swelling, chills

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942333	1/13/2021	DE	30	F	1/13/2021	1/13/2021	Recipient reports having an idiopathic autoimmune disorder where she can have random events where exposures can cause an increase in her histamine production resulting in rash and itching. She denied history of any previous anaphylaxis. She was advised prior to the start of the clinic to follow up with her allergist to discuss risk v. benefit of the vaccine with her condition. On the date of the clinic she reports that she consulted her allergist who encouraged her to accept the vaccine but be monitored for 30 minutes. Approximately 10 minutes after receiving the vaccine the injection site reddened, felt hot to the recipient, and was itchy. She reported the itching spread to her scalp. She verbalized this is a typical reaction that she has and that it can self resolve or improves with benadryl. It was at his time that she reported she had taken benadryl 25 mg approximately 1 hour prior to vaccination. The reaction did no spread beyond her injection site and scalp itching resolved quickly. She verbalized symptom relief with a cold pack and was under observation for 45 minutes at which time the redness decreased. She verbalized that she felt safe to leave the clinic, vital signs were stable and no signs of reaction progression or anaphylaxis. She was instructed to notify her allergist and to call 911 if symptoms worsened, as well as to notify the Primary vaccine coordinator when able to for any further issues and updates. By 1330 she called and reported she was fully back to baseline and that she was instructed by her allergist to take prednisone and that she had also taken another benadryl once she got home. She reports the allergist called it a mild reaction and "was not concerned".

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942114	1/13/2021	OR	33	F	1/6/2021	1/6/2021	Received the 1st dose of COVID vaccine, felt well when she left, but developed a lot of fatigue and was in bed by 7 pm, very unusual for her. She woke up next day and had some swelling on her forehead and generalized itching. She took an Allegra and facial swelling resolved. No perioral swelling or lesions. No erythema. Then had 3 episodes of vomiting. Still feels nauseated. She contacted her PCP, who advised being seen. Pt uses Singulair at night, Allegra or Zyrtec in morning if she is itchy. Pt denies cough, shortness of breath, abdominal pain, diarrhea, skin irritation. For Nausea and vomiting, intractability of vomiting not specified, unspecified vomiting type- ondansetron ODT (ZOFTRAN ODT) 4 mg oral tablet,disintegrating; Dissolve 1 tablet on tongue and swallow every eight hours as needed for nausea/vomiting. Dispense: 15 tablet; Refill: 0. Pt appears well. No facial swelling. History consistent with allergic reaction to COVID vaccine. No evidence of anaphylaxis.Pt to self-report to Occ Health and agency. I also left message at Occ Health. Zofran ordered prn nausea. Pt has an EpiPen. She lives with her husband, who can also monitor her. To ED if she develops swelling, shortness of breath, cough, wheezing, persistent vomiting, or otherwise worsens.
941958	1/13/2021		27	F	1/7/2021	1/7/2021	Patient reported itching at injection site immediately after vaccine given. States it decreased while she was in the observation period. She states it has not resolved; she did have a bruise. Patient reported itching at injection site immediately after vaccine given. States it decreased while she was in the observation period. She states it has not resolved; she did have a bruise. She was not given any BENADRYL at the clinic and did not take anything for symptoms at home. Resolved by 2 days after injection. She denies: Feeling of impending doom, Skin symptoms present in 90% of people with anaphylaxis, including pruritus, flushing, angioedema, Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness, Shortness of breath, wheezing, bronchospasm, stridor, hypoxia, Hypotension, tachycardia, Nausea, vomiting, abdominal cramps, diarrhea.
941948	1/13/2021	NJ	50	F	1/13/2021	1/13/2021	Hives diffusely involving arm back eye and chin. No anaphylaxis.

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941861	1/13/2021	CA	59	F	1/12/2021	1/12/2021	@0950 about 10minutes post vaccination, patient complaint of anxiety and rapid heart rate. Patient has a history of allergies - anaphylaxis. Vitals taken: b/p 197/116, hr 70, temp 97.5, O2 sat 99% on r/a. States she has HTN and takes meds. She did take her medication this morning. With meds she is around 140s/80s. Stayed with us for about 30 minutes. Repeat vs 186/104 hr 68, 98% RA. Still reporting anxiety but states she feels her b/p is high because she is anxious. She never experienced SOB, difficulty breathing. Stated at first a little bit of a scratchy throat but that went away shortly after. She stayed until she felt less anxious.
941848	1/13/2021	CA	37	M	12/23/2020	12/23/2020	~~PMH htn who c/o n/v/d and flu like symptoms. Patient received first dose of pfizer vaccine 12/23/20 at 3pm. A few hours later started having epigastric pain to his back with numerous episodes of n/v nbnb. +chills and myalgias. Denies having any prior adverse reactions to vaccines. Denies any nsaid or etoh use. Denies any abd surgeries. Took 12mg zofran, about 4mg which were IV w/o relief. Denies any itching or rash or hx pancreatitis or anaphylaxis. +mild sob. ~~
941469	1/13/2021	MO	31	F	1/7/2021	1/7/2021	Systemic: Anaphylaxis-Severe, Systemic: Hives across neck and face-Mild; symptoms lasted 0 days
941389	1/13/2021	TX	58	F	12/30/2020	12/30/2020	Systemic: Anaphylaxis-Severe
1349849	1/13/2021		28	F	1/8/2021	1/8/2021	Anaphylaxis c/o chest tightness and "unable to breathe"- epi pen administered with immediate response. Narrative: c/o chest tightness. epi pen administered with immediate response. "I can breath now," pt. stated. Monitored, d/c'd to home/released from work.
941121	1/13/2021	WI	26	F	1/8/2021	1/8/2021	?Pfizer-BioNTech COVID-19 Vaccine EUA? Symptoms experienced: Lightheaded, Shortness of breath with hyperventilation. She was laying on the floor and appeared shaky with red blotching on face and neck. Actions taken: Medical Response called. Anaphylaxis Medication given epinephrine (adult) IM outer thigh. Patient was placed on stretcher and taken to ER. Pt also received diphenhydramine and famotidine in ER

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940784	1/13/2021	ND	28	F	12/23/2020	12/23/2020	Anaphylaxis reaction; A spontaneous report was received from a nurse concerning her co-worker, a 28 year-old female patient, who received Moderna's COVID-19 Vaccine and experienced anaphylaxis reaction. The patient's medical history was not provided. No relevant concomitant medications were reported. On 23 Dec 2020, prior to the onset of the event, the patient received the first of two planned doses of mRNA-1273 for prophylaxis of COVID-19 infection. On 23 Dec 2020, within five minutes of vaccine administration, the patient experienced anaphylaxis reaction. The patient had symptoms of throat tightness, dizziness, nausea, weakness, and increased heart rate. Treatment for the event included an epinephrine pen. On 29 Dec 2020, the nurse reported that the patient was still having some of the symptoms, including dizziness, nausea, and weakness. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event, anaphylaxis reaction, was considered not resolved. The reporter assessed the event, anaphylaxis reaction, as related to Moderna's COVID-19 Vaccine.; Reporter's Comments: This case concerns a 28 year old female patient, who experienced a serious unexpected event of anaphylactic reaction. The event occurred apparently 5 min after first dose of mRNA-1273 (Lot# unknown) vaccine administration. She was treated with epinephrine pen. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
940999	1/13/2021	WI	26	F	1/8/2021	1/8/2021	Pfizer-BioNTech COVID-19 Vaccine EUA Symptoms experienced: Lightheaded, shortness of breath with hyperventilation. She was laying on the floor and appeared shaky with red blotching on face and neck. Actions taken: Medical Response called. Anaphylaxis Medication given epinephrine (adult) IM outer thigh. Patient was placed on stretcher and taken to ER. Patient also received diphenhydramine and famotidine in ER.

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940955	1/13/2021	NY	66	F	1/11/2021	1/11/2021	Cardiac Arrest; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; This is a spontaneous report from a contactable other healthcare professional (HCP). A 66-year-old female patient (pregnant at the time of vaccination: no) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284) via intramuscular at left arm on 11Jan2021 12:15 PM at single dose for COVID-19 immunization. Medical history included diastolic CHF, spinal stenosis, morbid obesity, epilepsy, pulmonary hypertension and COVID-19 (Prior to vaccination, the patient was diagnosed with COVID-19). The patient received medication within 2 weeks of vaccination included amiodarone, melatonin, venlafaxine hydrochloride (EFFEXOR), ibuprofen, aripiprazole (ABILIFY), lisinopril, cranberry capsules, diltiazem, paracetamol (TYLENOL), famotidine, furosemide (LASIX [FUROSEMIDE]), ipratropium bromide, salbutamol sulfate (IPRATROPIUM/ALBUTEROL), buspirone, senna alexandrina leaf (SENNA [SENNA ALEXANDRINA LEAF]), polyethylene glycol 3350 and morphine. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient used took Penicillin, propranolol, quetiapine, topiramate, Lamictal and had allergy to them. Patient used took the first dose of BNT162B2 (lot number: EJ1685) via intramuscular at right arm on 21Dec2020 12:00 PM at single dose for COVID-19 immunization. Since the vaccination, the patient been tested for COVID-19 (Sars-cov-2 PCR) via nasal swab on 06Jan2021, covid test result was negative. Patient was found pulseless and breathless 20 minutes following the vaccine administration (11Jan2021 12:30 AM). MD found no signs of anaphylaxis. Patient died on 11Jan2021 12:30 AM because of cardiac arrest. No treatment received for the events. Outcome of pulseless and breathless was unknown. the autopsy was performed, and autopsy remarks was unknown. Autopsy-determined cause of death was unknown. It was reported as non-serious, not results in death, Life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect.; Sender's Comments: Based on the available

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							information this patient had multiple underlying medical conditions including morbid obesity, diastolic CHF, epilepsy, pulmonary hypertension and COVID-19 diagnosed prior to vaccination. All these conditions more likely contributed to patients cardiac arrest resulting in death. However, based on a close temporal association ("Patient was found pulseless and breathless 20 minutes following the second dose of BNT162B2 vaccine administration, contributory role of BNT162B2 vaccine to the onset of reported events cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Cardiac arrest; Autopsy-determined Cause(s) of Death: autopsy remarks was unknown. Autopsy-determined cause of death was unknown
940775	1/13/2021	AZ	48	M	1/7/2021	1/7/2021	This patient is a 48 y.o. male presenting to the emergency department with a chief complaint of allergic reaction s/p 1st COVID vaccine at 1330 this afternoon. Patient states he became very flushed to his face/chest 2-3 minutes after receiving the vaccine. EMS was on scene and evaluated the patient. He was found to be a little confused/disoriented upon questioning which quickly resolved. Patient was also having mild difficulty swallowing, however states he was not gasping for air. He had an IV placed for precautions, however no medications were given. Patient was transferred here for evaluation. He currently feels asymptomatic aside from a dry throat. Patient denies having any hives, shortness of breath, or syncopal episodes. He also denies having prior episodes of anaphylaxis requiring epinephrine.
940575	1/13/2021	AK	42	M	12/28/2020	12/28/2020	Systemic: Anaphylaxis-Severe
940548	1/13/2021	AK	38	M	12/28/2020	12/28/2020	Systemic: Anaphylaxis-Severe.

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940490	1/13/2021	IA	47	F	12/29/2020	12/29/2020	Received injection at 0930 on 12/29/2020 and was observed for 15 minutes after injection. Around 1630 I developed a headache so I took a Fioricet as I have a history of migraines. I had a few body aches and only ate toast for supper that night. By 2330 my headache seemed to be worsening and I started experiencing a fever of 102, tremendous body aches, nausea, sore throat. At that time I took 500 mg Tylenol at 2330. By 2 am on 12/30/2020 my fever had reached 103 and I had difficulty walking as my body joints ached so bad. My headache was unbearable and I asked my husband to drive me to the ER as I could no longer take the pain. I also was hyperventilating. In the ER I was given normal saline 500 cc, Tylenol 1000 mg IV, and Zofran 4 mg IV for the nausea. I did feel prominently better thereafter, except I continued to have a headache. I was given Toradol 30 mg IV and advised not to take my Celebrex that day. The ER Doctor did call and speak with ER physician, and discussed the validity of lab testing for Covid after vaccination as well as his recommendations as to whether I should receive the second dose of the vaccine. Since I did not really have anaphylaxis, the doctor recommended that I proceed with the second vaccination with extended observation. I was discharged and instructed to take Tylenol 650 mg orally every 4 hours as needed advised for fever/analgesia.
939803	1/13/2021	CO	46	F	12/22/2020	12/22/2020	patient stated her tongue was tingling similar to "anaphylaxis" she had previously. Please note description of her anaphylaxis events prior were to a topical application of peppermint oil before a nursing school test and she didnt react until hours later with a racing heart and tingling mouth. Told ER doctor she had similar reaction to avacados. Patient stated tongue felt zingy like touching tip to battery so we proceeded from unit to ER where she was give prednisone and bendadryl and symptoms resolved within 20 minutes. She was monitored for an hour total and released without any more symptoms.
939738	1/13/2021	PA	44	F	1/6/2021	1/8/2021	Moderate anaphylaxis reaction per urgent care provider. Developed severe hives and swelling, fever, severe headache 2 days after vaccination. Was treated with Benadryl, Solumedrol IM, and Prednisone taper at local urgent care center.

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939490	1/13/2021			F	12/29/2020	12/29/2020	1st dose of the vaccine last 29Dec2020/she is already scheduled to take it next Friday; she felt kind of itchy; saw pink all over her body; broke out in a rash; This is a spontaneous report received from a contactable nurse (who is also the patient). A female patient of an unspecified age received her 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot number and expiry date not reported), via an unspecified route of administration, on 29Dec2020, at single dose, for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported to have received the 1st dose of the vaccine last 29Dec2020. After a few hours, she felt kind of itchy and saw pink all over her body and broke out in a rash for a few days. She mentioned that it was not anaphylaxis and is looking for recommendations if she can receive the 2nd dose of the vaccine as she is already scheduled to take it next Friday (15Jan2021, pending clarification). The outcome of the events was unknown. Information about batch/lot number has been requested.
941315	1/13/2021	WI	53	F	1/7/2021	1/13/2021	Anaphylaxis requiring administration of Epi
940653	1/13/2021	PA	29	F	1/8/2021	1/8/2021	-Pt received COVID19 vaccine on 1/8/2021 in the morning. -Pt was initially observed for 30 minutes, given hx of anaphylaxis to iodine. -Pt initially had no symptoms - no itchiness, itchy or watery eyes, rash, difficulty swallowing, itchy throat, swelling, chest pain, shortness of breath, N/V. -She came back a few hours later with one right chest wall hive and few hives on her left arm. -No respiratory symptoms. No other symptoms besides those few hives. -Pt was evaluated by myself and Nurse. -Pt was observed for another 30 minutes & given Benadryal IM 25mg. -Pt also took 2 500mg Tylenol. -Pt felt better and was then discharged

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936837	1/12/2021	MA	30	M	1/7/2021	1/10/2021	The evening of 1/10 I spontaneously developed diffuse urticaria of my trunk and face, associated with itching, mild abdominal discomfort, and facial flushing. Symptoms somewhat improved with cetirizine. The evening of 1/11 developed recurrent spontaneous diffuse urticaria, mostly in the face. Having persistent intermittent sweats and significant fatigue. Per Patient, He have had urticaria rarely in the past, associated with shellfish. I have never had anaphylaxis before.
939081	1/12/2021	OK	45	F	1/12/2021	1/12/2021	20 min post vaccination (conducted in workplace setting), patient report feeling of swelling of tongue; in her words "thick feeling tongue." Also reported L upper chest tenderness and "very tired and no energy." RN found no SOB, not appearance of swollen tongue or other angioedema, no evidence of urticaria, no respiratory distress including no wheezing. Not evidence of vasovagal response. After consultation, RN provided 12.5 mg Benadryl IM in opposite arm of vaccination. Pt remained under observation of RN and after 30 min states she feels better, previous symptoms abated, and again without evidence of anaphylaxis. Pt was released back to office 45 min after first presenting with symptoms. Pt stated "I think I was anxious." on departure.

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938868	1/12/2021	VA	34	F	1/12/2021	1/12/2021	-0715 vaccine administered. -0735 started to feel dizzy/off and right side of tongue felt like it was mildly swelling and itchy. -0735 asked to have blood pressure taken as know when I am having anaphylaxis my blood pressure escalates. -0740 took blood pressure and it was 141/86 in right arm. Normal is 110s/60s-70s. No anxiety feelings. -0740 throat started to have increased mucous production. Had the tickle and tightness in throat. Asked and received 25mg Benadryl with cup of water. -0742 started clearing throat frequently and slight cough. Knew it was anaphylaxis and told the team I need to go to the ER. Asked for additional 25mg Benadryl. Also took 20mg Famotidine and 2 puffs Albuterol inhaler--this is my prescribed anaphylaxis routine. Had Epipens on standby. -0743 put on O2 saturation monitor and watched O2 drop into 90-92 range. Asked for epipen on standby as I know when I need to start it. Didn't want to take that when I knew I was about to get it in the ER and knowing self hadn't progressed that far. Felt chest tightness and shortness of breath. Voice started becoming hoarse. -0800 EMS arrived (delay as team didn't know if they were supposed to call 911 or a Code-- they chose EMS even though in hospital). Then staff at COVID vaccine clinic kept emphasizing need to go in ambulance while EMS and self fought to go through hospital (much quicker route). Finally cleared to go through hospital to ER. To get some air via breathing in had to sit up leaning forward. Voice completely hoarse by this time. -About 0817 arrived to ER bay. At this time, frequently coughing and cough started to sound stridorous. Difficulty getting breaths in. Had chest pain near heart. Greeted by MD, 2 RNS, and technician. - 0819 received IM epinephrine. Attached to 5 lead EKG monitoring and O2 monitoring. Blood pressure done again. Higher than previous. -About 0821 had working IV (previous two attempts failed as veins were constricting). Given IV Solumderol. Started bolus of 1L Normal Saline. - Not sure how long after by cough subsided, increased mucous production subsided, as well as hoarseness decreased. -Held for observation for 2hours (would be longer if not resolved). - Discharged around 1015. At this time, hoarseness almost all gone. Minimal throat clearing. Cough resolved. -Prescribed epipen inhalers (mine expired) and Prednisone. Prednisone is PRN for mild breathing difficulties if it starts again tomorrow

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							1/13/21. -At 1400 took 50mg Benadryl and 20mg Famotidine as previously prescribed for anaphylaxis maintenance. Will continue this as previously prescribed every 6hours until symptoms stay resolved. -Made follow up appointment with Primary Care Physician per protocol
938815	1/12/2021	TX	41	F	12/21/2020	12/27/2020	5-6 days after my shot I had a allergic reaction. Anaphylaxis.
938534	1/12/2021	NC	28	F	1/7/2021	1/7/2021	Anaphylaxis Chest tightness started @ 6:00pm following vaccine. Developed wheezing in all lung fields (confirmed by MD.) Developed hives- Albuterol, Benadryl and epinephrine administered @ 700pm. EMS called and transported to Hospital.
938244	1/12/2021	KY	47	F	1/7/2021	1/8/2021	Moderna COVID- 19 Vaccine Moderna Lot #012L20A January 2021 left deltoid CC: Itching reaction, remote to the site of Moderna vaccination, 26 hrs post-injection 47 year old presents with rash rt. thigh on 1-7-21 at the Health Services, Employee Health Received Moderna Covid 19 mRNA vaccination #1 yesterday 1-7-21 at 8:50 am, left deltoid. Noted itchy area on rt. thigh ~ 26 hrs post-vaccine. No trouble breathing, no throat or facial swelling, no h/o problems with vaccination, no h/o anaphylaxis. No new topical exposures. No new supplements, no recent antibiotics. Denies fever. She apparently rubbed/scratched through pant leg, when felt itching, and then saw a bruised/red area after this. Exam: Skin: 5 xc 10 cm nonblanching petechial and ecchymotic area rt. ant. thigh, no papules or pustules, no warmth to touch. Pt. encouraged to register with V-safe. Rec. oral antihistamines as directed/needed. I spoke with patient on 1-11-21, no new itchy areas, still using Benadryl for the localized itchy area that she reports is resolving. Was harm caused: employee is fine. Difficult to say if this is vaccine reaction vs. coincidental occurrence.
939190	1/12/2021	IL	32	F	1/7/2021	1/7/2021	Started to feel lightheaded, weak, faint like I was going to pass out, heart rate increased, confusion, trouble speaking, brought to the ED, throat started to swell and started having thick spit and clearing my throat excessively. Diagnosed as anaphylaxis.

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936941	1/12/2021	OH	41	F	1/5/2021	1/7/2021	- Pain and swelling of left armpit x 5 days (received the Moderna COVID-19 vaccination on 1/5/2021). No airway or ocular involvement; No acute anaphylaxis; No acute infection or lymphangitic streaking appreciated. Supportive measures were advised. May take counter Tylenol or Motrin, as needed, for pain relief. Continue to monitor symptoms. Monitor for signs and symptoms of secondary infection. - Patient also reported, on the evening of 1/5/2021, after receiving the vaccination, experienced acute chills and fatigue ? resolved by 16/2021.
938693	1/12/2021	CA	51	F	12/29/2020	12/29/2020	~~EOHD Note 12/29 EE states she recieved the COVID19 vaccine (first dose) 12/28 at 7 pm at the Metro EOHD location. She stayed 15 minutes for observation and was feeling fine, however 30 minutes after vaccine administration started feeling her left upper lip was swollen and tip of her tongue felt thick. When she looked in the mirror her lip and tongue appeared normal, but she had the sensation they were swollen. She then took 50 mg of PO Benadryl and about 4 hours later felt swelling had resolved. Today, feels normal. Pt denies hx of allergies but her mother has a hx of anaphylaxis with IV contrast. EE denies throat tightness, SOB, wheezing. Numbness on left leg. Advised EE to go to ER if she experiences throat tightness and itchyness, SOB, or wheezing. Advised pt that she should consult her PCP to decide whether or not the benefits of recieving the second dose of the vaccine outweigh the risks and if she should pre-medicate with benadryl for the second dose if she choses to recieve it. ~~

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936666	1/12/2021	IL	47	F	1/8/2021	1/8/2021	Anaphylactic reaction; Flushed; Diaphoretic; redness and rash; hives on chest; Tachycardia; shortness of breath; Chest tightness; Dizziness; Headache; This is a spontaneous report from a contactable nurse, the patient. A 47-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EL1283), via an unspecified route of administration on 08Jan2021 at 08:49 (at the age of 47-years-old) as a single dose for COVID-19 immunization. There were no known medical history or concomitant medications. The patient previously received the first dose of BNT162B2 on 18Dec2020 (Lot Number: EK5730) for COVID-19 immunization and experienced nausea, headache, and fatigue. On 08Jan2021, about 5-10 minutes after the second dose, the patient experienced anaphylactic reaction, flushed, diaphoretic, redness and rash, hives on chest, tachycardia, shortness of breath, and chest tightness, reported as life-threatening. She reported that these events occurred within less than 10 minutes of receiving the vaccine. She went to the emergency room and was treated with methylprednisolone (SOLUMEDROL), diphenhydramine hydrochloride (BENADRYL), famotidine (PEPCID), and epinephrine (MANUFACTURER UNKNOWN). She was sent home and prescribed methylprednisolone and epinephrine (EPI-PEN). Later on 08Jan2021, she experienced dizziness and headache, which were consistent. She stated she would most likely take ibuprofen (MOTRIN) as treatment (not specified if taken). The clinical outcomes of the flushed, diaphoretic, redness and rash, hives on chest, tachycardia, shortness of breath, and chest tightness were recovered on 08Jan2021; while the outcomes of the dizziness and headache were not recovered and that of the anaphylaxis was reported as recovering.; Sender's Comments: The reported information is limited. Based on the close temporal relationship and the description of the events, there is a reasonable possibility that the events are related to BNT162 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified

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to regulatory authorities, Ethics Committees, and
Investigators, as appropriate.

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936612	1/12/2021	CA	51	F	1/6/2021	1/6/2021	<p>anaphylaxis; throat tightening; throat tightening/tingling; throat tightening/tingling/soreness; dry wheezy cough a little dizziness; dizziness; tachycardia; Itching; chills; numb R foot; Low grade temp; h/a today; This is a spontaneous report from a contactable Nurse (patient). A 51-years-old female patient (no pregnant) started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number el3248), via an unspecified route of administration on 06Jan2021 11:00 at the first single dose at left arm for covid-19 immunisation. Medical history included supraventricular tachycardia, adrenal insufficiency, hypothyroidism, attention deficit hyperactivity disorder, hypermobility syndrome, developmental hip. Concomitant medication included hydrocortisone, trazodone, levothyroxine sodium (LEVOTHROID), bupropion hydrochloride (WELLBUTRIN). The patient previously took erythromycin, morphine and experienced drug hypersensitivity. The patient experienced anaphylaxis, throat tightening/tingling/soreness, dry wheezy cough a little dizziness and tachycardia. Itching, numb R foot, Low grade temp and chills and headache on 06Jan2021 11:15. Seriousness criteria reported as life threatening. Taken to ER had IV benadryl, solumedrol, pepcid for anaphylaxis. Placed on O2 and given albuterol nebulizer. Had IV fluid bolus. Now on benadryl and 5 days of prednisone. The patient felt completely fine prior to vaccine. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 06Jan2021. The outcome of events was recovering. No other vaccine in four weeks; No covid prior vaccination.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis presented as throat tightening/tingling/soreness, dry wheezy cough a little dizziness and tachycardia. Itching, numb R foot, Low grade temp and chills and headache cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The underlying predisposing condition of drug allergies may put the patient at high risk of anaphylactic reactions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern</p>

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identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

She thinks there has been more anaphylactic reactions than usual and said that a physician female friend had experienced one; This is a spontaneous report from a non-contactable Other Health Professional via Pfizer sales representative. A female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. During a conference call, (Name) mentioned that she thinks there has been more anaphylactic reactions than usual and said that a physician female friend had experienced one. It was unclear whether it was after a Pfizer or Moderna vaccine. She did mention that her friend recovered without any issues. Outcome of event was recovered on an unspecified date. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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936388	1/12/2021	NM	47	M	12/18/2020	12/21/2020	<p>if a patient experienced an allergic reaction to the first dose is there anything prophylactically needing to be done when administering the second dose of the Covid vaccine; delayed hyper sensitive reaction; Angioedema; Urticarial rash; This is a spontaneous report from a contactable other hcp. A 47-years-old male patient received first dose of bnt162b2 (BNT162B2), unknown on 18Dec2020 (lot number: EK5730) at SINGLE DOSE for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. Caller is a Physician Assistant. Caller states that she is calling about the Covid Vaccine. She had a patient received his first dose of the vaccine on Friday 18Dec2020, 3 days later on 21Dec2020 he had an urticarial rash that persisted, The urticarial rash was treated with prednisone and resolved by 27Dec2020, it has not reoccurred. The allergist said it was a delayed hyper sensitive reaction that was Prompted by the immune stimulation from the vaccine. The Patient was treated for the urticaria. Caller would like to know if a patient experienced an allergic reaction to the first dose is there anything prophylactically needing to be done when administering the second dose of the Covid vaccine? Caller is very upset and frustrated and stating she wants to speak to someone that is a clinician with the clinical trial team who can give her recommendations for a specific patient. Caller asks if they should do Prophylaxis with antihistamines for the second dose. He did not have anaphylaxis but he had angioedema. Caller states that she did a Vaers report on 22Dec2020, but no one contacted her. He started taking Zyrtec and Vistaril. The Allergist said it was fine and he will still need the 2nd Booster Dose. The Angioedema started on 22Dec2020, it was also treated with prednisone, in addition to being administered Benadryl IM, and Vistaril. The outcome of the event urticarial rash was recovered on 27Dec2020 and Angioedema was recovered on 22Dec2020. No follow-up attempts are needed; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the angioedema and the other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including serum tryptase level and</p>

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complement panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

anaphylaxis; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), on an unspecified date as single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis on an unspecified date. The outcome of anaphylaxis was unknown.

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936194	1/12/2021	OR	63	F	12/23/2020	12/23/2020	Soreness injection site; The initial case was missing the following minimum criteria: unspecified product and adverse event. Upon receipt of follow-up information on 04Jan2021, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable healthcare professional, the patient, from a Pfizer sponsored program. A 63-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration in the arm on 23Dec2020 (at the age of 63-years-old) as a single dose for COVID-19 immunization. Medical history included penicillin allergy and anaphylaxis to a penicillin type drug. The patient's concomitant medications were not reported. The patient previously took ampicillin (MANUFACTURER UNKNOWN) from an unknown date to an unknown date for an unknown indication and experienced drug allergy. On 23Dec2020, the patient experienced soreness at injection site. The patient did not receive any treatment for the event. The clinical outcome of the soreness at injection site was recovered in Dec2020 after about 48 hours. The reporter considered that there was a reasonable possibility that the soreness at the injection site was related to the vaccine. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

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938085	1/12/2021	MD	61	M	1/5/2021	1/6/2021	High fever; Vomiting; Severe fatigue; Weakness; This is a spontaneous report from a contactable physician (patient himself). This 61-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EL1442), via intramuscular, on 05Jan2021 at single dose for COVID-19 immunisation. Age at vaccination was 61-year-old. Vaccine location was deltoid left. The subject did not have a relevant medical history and concomitant medications. On 06Jan2021, the patient developed high fever, vomiting, severe fatigue and weakness. He did not experience anaphylaxis. The events were considered serious as medically significant. The patient stated that side effects mentioned lasted 3 hours and he felt much better now. However, the final clinical outcome was unknown. The patient is not sure if he should get the shot again in 3 weeks since he was really sick. The reporting physician considered the events 'high fever', 'vomiting', 'severe fatigue' and 'weakness' related to BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE).; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events pyrexia, vomiting, fatigue and asthenia cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.
938524	1/12/2021	NY	43	F	1/8/2021	1/11/2021	first day after shot, nausea, body aches, 2nd day Sunday headache, Monday 5 am woke up itching, then 9 am hives everywhere, trouble breathing, anaphylaxis, went to ER, got epi X 2, solumedrol, benadryl, pepcid, then still with hives, tachycardia, dyspnea, iv fluids were infusing and epi drip started, went to ICU

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933766	1/11/2021	MT	41	F	1/5/2021	1/5/2021	Patient given Moderna vaccine 1455. Patient reported feeling numb tongue, dizzy and nauseous. Patient took 25 mg diphenhydramine oral. Observed at vaccine clinic. began feeling more nausea. Tongue numbness not improving, took another 25 mg diphenhydramine. Patient sent to ED - taken by PALS/RN. Arrived in ED at 1600 complaining complaining of chest tightness with tingling in her throat. Out of concern that she may have progression to anaphylaxis so 0.3 mg of epinephrine was ordered intramuscularly. Patient also given 25 mg of Benadryl IV as well as Pepcid and Solu-Medrol. Patient was observed here in the emergency department for several hours. She did have some complain of some itchiness of her skin so additional 25 mg of Benadryl was given. She also was having some persistent chest tightness and appeared quite anxious and due to concern for anxiety is possibly a contributing factor, IV Valium was given for anxiolysis. On reevaluation, symptoms have improved significantly. She was counseled in regards to use of an EpiPen and a prescription was given for this. Prescription was also given per few days of prednisone and Pepcid. Provider recommended avoiding further covid19 vaccination.
933608	1/11/2021	MT	31	F	1/8/2021	1/8/2021	Moderna covid vaccine administered 1720 Hx of anaphylaxis to flu shot ?about 8 years ago? (of note, was not intubated/admitted/etc) Patient requested extended monitoring due to hx. Placed in wheelchair at pharmacy station. 1730 patient states a scratch throat and itchy nose. Able to swallow water provided. 1800 patient continues to experience throat ?lump? and is clearing throat, nose itches Requests diphenhydramine-given 25mg PO x 1 ingested without issue 1830 patient complains of itchy scalp and has a red flush to chest and upper arms 1832 patient wheeled to ER by From ED note: Electrocardiogram was without acute change. The patient was observed in the emergency department, is feeling much improved. Still has a very slight sensation of a lump in her throat, but no angioedema of lips or tongue. No stridor. No shortness of breath. O2 sat is excellent at 100%. She is comfortable being discharged to home. No meds given in ED.

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933957	1/11/2021	WI	64	F	1/11/2021	1/11/2021	As per RN documentation, Pt with hx of anaphylaxis with the 4th infusion dose of Rotuxin a couple years ago. PCP discussed benefit to prevent complications of COVID vaccine outweighs risk to get COVID vaccine. Discussed this as well with patient. She agrees to get the vaccine. I stayed with the RN and patient for 30 minutes post vaccination and she had no symptoms other than BP and Pulse elevated further to 150s/90s. P upper 80s. She was transitioned to another office with plan to continue observation for another 15 mins and recheck her BP. About 45-50 mins post vaccine, she reported her lower arms and right side of her neck felt swollen but had no SOB or mouth swelling or itching. She was talking in normal sentences. Her face became more flushed as well as the posterior aspect of her forearms and she said the neck felt more swollen. Epi Pen was administered at 8:40 am and EMS was contacted. Her BP was 160/100, pulse ox 96%, RR 26, Pulse 88. Transferred to ED.
934714	1/11/2021	NY	23	F	1/9/2021	1/9/2021	headache soon after vaccine (gone), hard to take a deep breath(denies anaphylaxis), wheezing with activity, coughing, fatigue later the same day as vaccine
935576	1/11/2021	SC	36	F	1/11/2021	1/11/2021	Patient reported prior to vaccination hx of anaphylaxis to shellfish and macrobid. She was a 30 minute post-vaccine nurse monitoring. ~15 minutes after receiving vaccination, patient reported to the nurse dizziness, nausea. Nurse placed patient on stretching and called for provider assistance. SBP in 160s, DBP >100, HR 130s or higher, oxygen saturation on room air ~98%. Epinephrine 0.3mg IM administered. Nurse placed Nasal cannula oxygen with oxygen saturation 100%. Patient BP improved, HR improved to low 100s occasionally in 110s if patient talking to someone new such as Fire response. Patient reported continued dizziness. BP prior to EMS arrival 146/91 left arm automatic cuff, Temp 98.3F, P 106, oxygen on nasal cannula 100%. Upon EMS arrival, patient transferred to ER.

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935904	1/11/2021	WA	33	F	1/8/2021	1/9/2021	I have a history of prior anaphylaxis in 2009 when I received (separate arms, same date and time) the 2009 seasonal flu vaccine and the 2009 H1N1 vaccine. Both were from multi-dose vials and providers I established care with following the reaction believed I likely had a reaction to a preservative. I've received single-dose flu vaccines with no issues since then. When I received the Moderna covid vaccine on 1/8/21 I had some right-sided throat swelling about 15 minutes after injection. It did not worsen and I was monitored for 1 hour after shot time. I went home and the feeling in my throat resolved after about 4-5 hours with no medication or intervention needed. I did not have any other symptoms until 3pm on 1/9/21. Started with mild abdominal pain, an hour and a half later I had chills, headache, fatigue and fever around 100.8F. No medication taken. The fever resolved within about 6-7 hours. On Sunday 1/10/21 the abdominal pain worsened and was a constant pain around umbilical region that felt as if it radiated outward, LLQ slightly worse. It was severe, directly affected normal daily functions. I could not walk, move, eat or drink room-temp water without pain increasing. Walking 20ft at one point even caused me to crumble to the floor and cry, had to stay there for 5 minutes before even attempting to get back to the couch. No diarrhea, no vomiting, no fever, no nausea. I did have loss of appetite. The pain continued through the night and was constant. I could not find a comfortable position to lay in and tossed and turned most of the night. At 0430 on 1/11/21 I got up out of bed to pee, abdominal pain was so bad it kept me awake for about an hour after. Pain finally started to improve and I was able to sleep from 0530-0930. When I woke up on 1/11/21 around 0930 my abdominal pain was very mild and continued to improve as the day went on. Currently (1600 on 1/11/21) my abdomen feels about 90% better, I have no other symptoms. The symptoms, specifically the fever and abdominal pain, caused me to miss 2 days of work (Sunday 1/10/21 and Monday 1/11/21).
936011	1/11/2021	CA	33	F	1/9/2021	1/9/2021	Anaphylaxis within 5 minutes of dose given. Tachycardia 130-140s, hot body temperature, trouble swallowing, lightheaded/dizzy, ekg changes, feeling like I was going to pass out even when in bed. IV fluids, benedryl, soul-medrol, famotadine and IM epi given.

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936072	1/11/2021		31	F	1/11/2021	1/11/2021	hives, anaphylaxis, given epinephrine and Benadryl, EMS called
936075	1/11/2021	OK	24	F	1/11/2021	1/11/2021	1 hour after vaccination client complained of dizziness, swelling of right hand. No general s/s of anaphylaxis noted. Pt was given juice, crackers and asked to rest in recumbent position. Symptoms did not improve and 12.5 mg of benadryl IM given in opposite arm of injection. After 15 minutes same general symptoms present; another 12.5mg of benadryl IM given again in opposite arm of injection. Pt remained lying down and 20 min after 2nd dose of benadryl patient reported feeling improved and able to ambulate independently. And monitored in her workplace without further intervention.
935903	1/11/2021	PA	30	F	1/11/2021	1/11/2021	rash on left arm, rash on right arm, rash on left leg. Given diphenhydramine 25mg PO and observed for 1 hour, no increase in reported symptoms. No difficulty breathing / SOB/ wheeze / anaphylaxis noted.
932597	1/10/2021	NY	49	F	1/10/2021	1/10/2021	Patient reported symptoms of numbness of lower jaw and difficulty swallowing 16 minutes post vaccination. Patient was familiar with symptoms of anaphylaxis due to her history of anaphylactic reactions to both shellfish and iodine. Patient was given an Epi-Pen (self-administered) and waited for an additional 45 minutes after initial vaccination. Patient also self-administered 25mg Diphenhydramine. Patient then left clinic and was later contacted by phone by Chief Medical Officer for follow up. Pt had admitted herself to the ED and received antihistamines and steroids. She then reported that she'd felt better but will remain in ED for observation.
933175	1/10/2021	KS	40	F	1/8/2021	1/8/2021	Immediate redness/burning of the injection site. Progressed to itchy throat/tongue and hoarse voice with persistent wheezy cough after 5 min Progressed to itchy/burning/red face/chest/ears after 10 min. Wheeled to the emergency department 20-25 minutes after injection. Had to have benadryl, solumedrol, pepcid, zofran, and an epinephrine injection to stop the anaphylactic reaction.

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932322	1/10/2021	KS	32	M	1/7/2021	1/9/2021	Anaphylaxis Please note previous VAERS report of Bell's Palsy 8 days following the first dose and subsequently treated with prednisone and valacyclovir. This neurologic diagnosis was not reported by the patient during the consent process with the COVID19 vaccination center staff. Confirmed following review of the consent form. Documentation from Emergency Department Provider: Patient is serially reassessed following treatment for anaphylaxis. Patient has significant improvement in diffuse erythema and hives within 20 minutes. He has gradual improvement in his sensation of throat swelling. He is observed while in the emergency department serially over 4 hours with no recurrence of symptoms. He does not require any repeat dose of epinephrine and feels at baseline. Discussed my suspicions that patient may have had a reaction to COVID-19 vaccine as he has had no other new medications or exposures that he is aware of. As he will not be receiving another vaccine there is nothing to necessarily stay away from. Make sure he notifies individuals about this for any new vaccine should he receive them. Patient is observed for sufficient time but discussed possibility for biphasic reaction. Recommend he return should he have recurrence of symptoms. Recommend he take EpiPen as prescribed for any throat swelling or progressive shortness of breath. Recommend follow-up with a primary care provider for this visit..
932143	1/10/2021	NY	29	F	12/30/2020	12/30/2020	I got palpitations and tongue numbness 5-7 mins after receiving the IM injection. No rash/wheezing/hypotension/angioedema. Got treated like anaphylaxis with epinephrine, decadron, benadryl, pepcid
932286	1/10/2021	NY	26	F	1/8/2021	1/8/2021	About 30 minutes after vaccination, patient noticed itchiness which progressed to hives on her bilateral arms and face. Around two hours after the vaccination while on the phone with our covid vaccine team, she developed tachycardia and shortness of breath. She called EMS and was evaluated at home at which time her symptoms were improving. They advised that she was not having anaphylaxis and could stay at home. She went to urgent care and received PO Benadryl.

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930984	1/9/2021	ME	57	M	1/5/2021	1/5/2021	55 y/o male with hx of anaphylaxis due to peanut allergy. Guardian pharmacist noted the change in facial color and alerted RN who was monitoring s/p vaccination of her observations. He was red with facial edema upon my arrival. Benadryl 25mg PO while he was still able to swallow by RN. EMS called while he took the Benadryl. After Benadryl, checked vitals ? VERY hypertensive and increasing diaphoresis; Started to wax and wane with consciousness. Administered epi pen by RN in attendance once change in level of consciousness was noted. After epi, became pale, increasing diaphoresis with change in level of consciousness. BP was lower, still hypertensive. Placed on floor by staff. While on the floor, consciousness improved. EMS arrived and assumed care.

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954160	1/9/2021		37	F	1/6/2021	1/6/2021	Anaphylaxis severe anaphylaxis; SOB, stridor Narrative: Patient has multiple allergies including severe anaphylaxis to peanuts and a reaction to a previous flu vaccine. Patient desired COVID vaccination and was cleared by private PC to receive vaccine from Employee Health. Patient had with her her own Epi-pen and albuterol inhaler. Patient was administered vaccine and observed in the observation area. Approximately 14 minutes after vaccination physician in observation area responded to patient with stridor and code white was called. Code team responded to vaccination testing site. Upon arrival, patient seated and alert sitting using albuterol inhaler. BP 160/93, HR 97, 99% room air. She was tachypneic and in respiratory distress following the first dose of her COVID 19 vaccine. Patient gave herself OT of EPI, and then our on call team arrived. Upon arrival as noted above, she was using her albuterol inhaler, 12.5mg benadryl attempted to be given however patient with difficulty swallowing. She was taken to ED and on way 2nd dose of epinephrine given. Patient was stabilized. Follow-up: Take Prednisone for 3-5 days. Take an antihistamine like Benadryl or Zyrtec for the next 3-5 days. Also take Pepcid 20 mg 2 times daily for the next 3-5 days. Return for worsening reaction. Timeline of event: Situation: 1001 Pt was given her first Covid vaccine, staff was watching her time and at 1014 it was noticed that she was not breathing well. 1015 Code white called. 1015 Pt gave herself and dose of Epi, 1018 pt took own inhaler, 1019 Benadryl 12.5 given. 1021 pt to ED for evaluation, on the way 2nd dose of Epi given- 1025 1030=pt was a code white from the area from where getting covid vaccine shots, pt states received shot at 1001 this am and with in 30 min she began to feel SOB, when pt arrived to ER respirations of stridor. pt spo2 at 99% on room air. 1045-pt has had a 20g placed by Rn in It ac with blood draw, pt has been placed on monitor. VS WN. 1055- pt has received pepcid 20mg IV in 50ml to run over 30 min. sol-medrol 125ng ivp benadryl 50mg ivp 1100- pt now resting with warm blanket pt no longer having stridor. upper resp clear. pt spo2 at 99% ON ROOM AIR. will continue to monitor. 1120- pt states she feels much better. 1200-pt still sleeping in room. 1225- pt has been D/c to home with instructions from provider.

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931772	1/9/2021	OH	30	F	1/7/2021	1/7/2021	Anaphylaxis
931742	1/9/2021	CA	41	F	1/1/2021	1/1/2021	Recipient came in c/o feeling "flushed". Denies asthma, allergies. lightheadedness. Color pink, no hives ,uticaria, SOB. @0916 VS=88-116/60-22 lungs ausc. clear. @ 0920 stated she felt increase in HR. HR = 102 RR=24 116/70 . HR 104. No c/o nausea. color continues to remain pink, lungs clear. continued observation. at 0940 HR decreased to 71, which she states is normal for her. RR-16 115/80. States she feels "better". Given instructions to call 9-1-1 if s/s of anaphylaxis or if symptoms return to notify PCP.
931348	1/9/2021	CT	55	F	1/7/2021	1/7/2021	Patient felt tongue swell, and then her throat started to close. -Anaphylaxis
931300	1/9/2021	IL	59	F	1/5/2021		Pt reported onset of "quivering" lips & Headache 15 min after vaccine. Vitals recorded. MD contacted & interviewed (Dr.) patient. Ambulance called. Vitals re checked Benadryl 25 mg PO given. Paramedic & Ambulance arrive 4:35 59 y/o who states she had anaphylaxis before her symptoms started the same as today. C/o quivering lips & H/A No rash or respiratory comp (EMT's exam - normal except ? movement. Assessment - Possible allergic RXN Plan - Ambulance transport to ED

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931271	1/9/2021	CA	35	F	12/20/2020	12/20/2020	? After her shot in the afternoon, she sat outside for 15 minutes. She came back in and said her throat is warm and scratchy, and her left hand felt cold. ? I escorted her over to the ER and she was checked in. I then went right back to HD since we were so busy. ? Around 4pm in the afternoon after we closed HD, I went back to the ER. She was recovering and doing fine. Her ER nurse and patient did have a question about receiving the 2nd dose, and I provided the same answer that Dr provided to Dr about taking an Allegra 30 minutes before the second dose. ED Note: Patient presents with symptoms concerning for angioedema or anaphylaxis after immunization with Covid vaccine. Patient described a sensation of warmth and also later tingling in her throat which was treated aggressively with medication for this problem so as to prevent airway closure or further worsening symptoms. Patient was treated with IV fluid hydration along with H1 and H2 blockers, IV steroids and also subcutaneous epinephrine. On my reevaluation, her symptoms completely resolved with treatment. She was without other concerning findings on examination or by history and was without further angioedema or anaphylaxis after period of observation. She was discharged with prescription medication in good condition and asked to return should she have any further problems. Impression: Angioedema, allergic reaction to vaccine, throat tingling, throat warmth MEDS in ED: Sodium Chloride 0.9% (Sodium Chloride 0.9% Bolus) 1,000 mL once IV Bolus, Reason for Infusion = Abnormal fluid losses diphenhydramine (Benadryl) 25 mg = 0.5 mL once IV push methylprednisolone (SOLUMedrol) 125 mg = 2 mL once IV push famotidine (Pepcid) 20 mg = 2 mL once IV push EPINEPHrine 0.3 mg = 0.3 mL once intraMUSCULAR

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981477	1/9/2021		50	F		1/4/2021	Agitation, Tachypnea & Cough Wheeze Narrative: Patient has HX of anaphylaxis with animal allergies and has not received the flu shot in many years because reactions (Arm Swelling) were getting worse. Today after vaccine administration she stated that she was having problems breathing and became tachypneic and that she felt like her throat was closing. She wanted her home dose EPI pen. Doctor administered clinic EPI pen and symptoms resolved quickly. Vital were stable. 911 was called per protocol but patient refused going to ER for 6 hours of monitoring per protocol. form signed.
927734	1/8/2021			U			severe anaphylaxis; This is a spontaneous report from a non-contactable Consumer. This Consumer reported similar event for six patient. This is 6th of sixth reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced severe anaphylaxis on an unspecified date with outcome of unknown. No follow-up attempts are possible. Information about batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003207 same drug/event and different patients
927733	1/8/2021			U			severe anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 6 patients. This is 5th of 6th reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on an unspecified date at a single dose for vaccination. The patient's medical history and concomitant medications were not reported. The patient experienced severe anaphylaxis on an unspecified date. Outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003207 same drug/event and different patients

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930328	1/8/2021	TX	41	F	1/8/2021	1/8/2021	anaphylaxis with immediate whole body swelling. Epinephrine 0.3mg IM administered
927896	1/8/2021	PA	44	F	1/6/2021	1/6/2021	Initially the recipient felt tightness in her throat, which she relates is similar to past episodes of anaphylaxis .
928455	1/8/2021		42	F	1/8/2021	1/8/2021	Started with hives approximately 15 minutes after and then went into full Anaphylaxis. Required epi and Benadryl.
928759	1/8/2021		34	F	1/6/2021	1/6/2021	Transferred to ED. ED documentation below. Initial Vital Signs [01/06/21 1754] Blood Pressure 146/97 Heart Rate 78 Respiratory Rate 16 Temp 36.9 °C (98.4 °F) Temp src Oral SpO2 97 % 34 y.o. female who arrived by From on-campus presented to the emergency department for an allergic reaction to the Pfizer COVID-19 vaccine. Pt received the first round of injections at 1707 tonight and experienced adverse reactions. Pt endorses dizziness which is accompanied by central abdominal pain and itching of her left thigh. Pt states that her throat is dry, but adds that it could be from not drinking much fluids today. Pt has a hx of anaphylaxis from shellfish and angioedema. She says these current symptoms are not similar to the ones she experienced from anaphylaxis or angioedema. Pt has not started or changed any medications, but had an IUD inserted about a week and a half ago. Pt denies any fevers, chills, coughs, cold symptoms, chest pain, palpitations, shortness of breath, headaches, nausea, vomiting, bowel or bladder problems, or urinary complaints. Clinical exam shows central abdominal pain just above the umbilicus with itching of the posterior aspect of the left lateral thigh. Will administer PO Prednisone and PO Diphenhydramine in the ED and observe the pt. No epinephrine injection was deemed necessary at this time. DDx: allergic reaction 1910 hours: Discussed further treatment and vaccine advice with the pt. Will discharge pt to home. Provided follow up instructions to her PCP, for reevaluation. Discussed return precautions. Vital signs are stable at time of discharge.

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929115	1/8/2021	CA		F			Experienced swelling at the injection site; experienced redness at the injection site; experienced tenderness, and pain at the injection site; Her arm was very tense; Felt itchy; itchy at the site; A large red hive appeared; discomfort; This is a spontaneous report from a contactable consumer (patient's husband). A 48-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: unknown), via an unspecified route of administration on an unspecified date at single dose (dose 1, arm) for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient is a physician who received the shot at work. Reporter stated patient had a localized reaction to the COVID-19 Vaccine. On the first day after receiving the vaccine, she experienced swelling, redness, tenderness, and pain at the injection site for 24 to 48 hours, and her arm was very tense. After 3 days, the discomfort disappeared but her arm was still tight. 8 days after the injection patient felt itchy and itchy at the site and a large red hive appeared, the injection site was again tender and swollen, the next day the hive was gone but patient's arm was still tight and swollen at the site of the injection. 13 days after the vaccination she returned to normal. Reporter wanted to know if the only contraindication to not receiving the second dose of the vaccine is if someone experienced anaphylaxis after the first dose. Information on the Batch/Lot number has been requested.
929117	1/8/2021	OR	62	F	1/8/2021	1/8/2021	patient has a hx of anaphylaxis to pears. Within 5 minutes of vaccine developed tingling and numbness to lips and tongue. patient escorted to the emergency department for further evaluation and treatment.
929310	1/8/2021	WA	50	F	1/7/2021	1/7/2021	Anaphylaxis with a hives, itching, and airway involvement
929338	1/8/2021	WI	33	F	1/7/2021	1/7/2021	Anaphylaxis - started with metallic taste in mouth followed by tongue swelling and chest heaviness

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929439	1/8/2021			U			severe anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 6 patients. This is the first of 6 reports. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration from an unspecified date at a single dose for vaccination. The patient's medical history and concomitant medications were not reported. The patient experienced severe anaphylaxis, on an unspecified date. Outcome of the event was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003208 different patient/same drug/event;US-PFIZER INC-2021003209 different patient/same drug/event;US-PFIZER INC-2021003210 different patient/same drug/event;US-PFIZER INC-2021003211 different patient/same drug/event;US-PFIZER INC-2021003212 different patient/same drug/event
930079	1/8/2021	TX	20	F	1/8/2021	1/8/2021	Swelling of throat and tongue, anaphylaxis, hives, redness, swelling
927732	1/8/2021			U			Severe anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the second of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced severe anaphylaxis on an unspecified date. The outcome of the event was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003207 same drug/event; different patient

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930548	1/8/2021	WA	45	M	1/7/2021	1/7/2021	While on duty and in uniform as an emergency paramedic I received my second scheduled covid19 vaccination. Approximately five minutes after receiving C19 dose 2 vaccination (1335hrs). I experienced a syncopal episode while walking back to my work area and was lowered to the ground by another EMS provider. I was then placed in a wheelchair by the EMS provider and an RN and taken to the emergency department at Medical Center. (1337hrs) I regained alertness and felt severe nausea and general weakness and was assisted into in ER bed. Staff doctor attended along with RN . An assessment was completed, 12 lead EKG completed, IV established, 8mg Zofran administered, 1000ml of Normal Saline was bolused. Labs were drawn. ED staff continued to monitor me for the next 2 plus hours I was monitored for anaphylaxis and other symptoms. My symptoms of nausea mostly resolved and my strength returned. A Resident MD completed a final evaluation and determined it was safe for me to be discharged. (1607hrs)

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930881	1/8/2021	AZ	19	M	1/3/2021	1/3/2021	At time of vaccination ~5 minutes after the injection of the pfizer vaccine I developed a tightness in my throat, I was still waiting in line and I did not think much of it, therefore I did not alert the medical personnel about the reaction. Approximately @15mins after the injection I left the site and developed a sense of something wrong and did not feel "right", my chest became tight, hoarseness in my throat and speech, lightheaded, and I remember taking a sip of my coffee thinking it was more difficult to swallow than usual. May I note I was in the passenger seat and not driving the vehicle. I alerted my mother of the reaction, both sceptical because of my hx of no known allergies. We both figured as long as I can breath and I was still conscious, with no signs of cyanosis I would be fine. At around 10:45 I took my BP: which was 106/62 I typically run low. I then took two 25mg Benadryl capsules which did help the throat tightness to an extent, however the tightness in the chest, lightheaded and dizziness still persisted. I was aware of the potential for Bi-phasic anaphylaxis so we had an Epi-pen on stand by just in case. I was stable for the rest of the day. At approximately 10pm I did notice a small erythematous non-pruritic rash across my chest. The symptoms of the reaction did subside within 24hrs. I remained in stable condition and recovered with time.
944398	1/8/2021		39	F	12/29/2020	12/29/2020	Tachycardia (see above, tachycardia) Narrative: Recipient immediately felt "bad" s/p vaccination - vitals demonstrated HR 133. No other signs or symptoms of anaphylaxis. Tachycardia resolved within 1-2 minutes of rest without intervention to HR of high 70s-low 80s. BP 131/91, SpO2 98% on room air, temperature 98.4F. Recipient able to ambulate on own to exam room. Exam benign, including recipient's HR observed prior to/during/after exam to be high 70s. Tolerated oral intake without issue, no further intervention indicated. Recipient observed for 30 minutes after vaccine administration without further issue.

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929440	1/8/2021			U			This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is third of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported) via an unspecified route of administration on an unspecified date at a single dose as vaccination. Medical history and concomitant medications were not reported. The patient experienced severe anaphylaxis with vaccination on an unspecified date. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003207 same drug/event and different patients
930315	1/8/2021	CA	33	F	1/7/2021	1/7/2021	With in 10 mins of receiving 1st dose, I started to feel hot and light headed, my body became very hot, I started to sweat and then my throat started to dry up and close. I notified the provider on watch that was monitoring me during my 15 mins after injection and as the walked me to the room I became more and more dizzy, my throat continued to swell and close, my mask was removed where my face was covered with a rash and hives . The dr. Gave me 50 mg benedryl, and a shot of epinephrine. After wards 911 was called, my heart rate was eventually brought down with the epinephrine as my symptoms began to be controlled. An inhaler was administered because I was short of breath. 3 hours later I was stabilized. I then was recommended to go to urgent care rather the emergency room since the wait was 13 hours to be monitored at the local hospital MLK. I went to urgent care near my home at Hoag hospital and they monitored me and gave me a steroid injection IM. I was discharged with an epi pen just in case abs to take benedryl every 6 hours . The following morning 1/8/21, at 8 am the swelling of my throat retuned I became light headed abs my tongue became numb. I was taken to fountain valley hospital where an IV was started, 500 mg of iv benedryl, another epinephrine injection was given abs I remained under surveillance for another 6 hours. They stated that a lot of people are coming with reoccurring episodes of anaphylaxis after the phizer injection.

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930003	1/8/2021		37	F	1/6/2021	1/6/2021	Hx of anaphylaxis to bee stings. Rash and hives over upper chest began immediately following vaccine. Taken to ED and given IV Benadryl, Famotidine and Solu-medrol. Discharged home from ED. Recommended to not receive second dose of covid vaccine.
929875	1/8/2021	CA	24	M	1/8/2021	1/8/2021	Patient walked out fine after receiving the vaccine. Was able to walk up to the registration desk and carried a conversation with the staffs. He sits down in the waiting area to be monitored. We heard his phone dropped, looked up and saw him tilting over on the right side was about to fall off the chair. Staff grabbed him and held him back onto the seat, proceeded to pick up his right arm and held him in place. He looked unconscious while staff held him. He came back to his senses approximately 10 seconds later. After he regained consciousness, staff took his blood pressure which was 111/44, SpO2 was 100%, and heart rate 58. Patient looked pale but not critical. Conversed with our staff and stated that this has happened before when he receives other vaccinations. Patient's father is a physician and reported that the patient is scared of needles and did not need any medications from anaphylaxis kit or crash cart. We gave him water and he left after sitting for a while.
929670	1/8/2021	NY	22	F	12/29/2020	12/29/2020	After vaccination, she reported to the ER. She stayed in observation for about 4 hours. States about 20 minutes afterward developed some sensation of tightness in her throat, upper chest pain, and some dizziness. Patient has a history of allergic reactions and in the past has had anaphylaxis she does carry a EpiPen. Patient took Benadryl prior to vaccine this morning and then again afterwards a total of 50 mg, did not notice any swelling of her face tongue or lip, there is no wheezing or difficulty breathing not noticed any rash or hives. Received Famotidine, methylprednisolone and IV fluids when in the ER. The next morning she was found be Covid Positive and they did not know it previous.

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929441	1/8/2021			U			severe anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for 6 patients. This is 4th of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date at a single dose for vaccination. The patient's medical history and concomitant medications were not reported. The patient experienced severe anaphylaxis with vaccination on an unspecified date. Outcome of the event was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021003207 same drug/event and different patients
951312	1/8/2021		43	F	12/23/2020	12/23/2020	Angioedema, HYPERTension & Tachycardia Acute mild allergic reaction //Patient placed in a cardiac monitor //Given Solu-Medrol as well as Pepcid //No evidence of anaphylaxis, epinephrine is not indicated at this time //No worsening of sx. vs improved. //will DC home with steroids.
926344	1/7/2021	SC	48	F	12/17/2020	12/17/2020	I received my covid -19 vaccine at work at hospital. I sat for my fifteen minutes after vaccination and felt fine. When I got home two hours later from work and got in the shower, I noticed that I had a red, slightly raised, pinpoint and very defined red rash. The rash was all over my abdomen, my back and my neck. The areas felt warm but I did not have itching, pain or any other anaphylaxis symptoms. The rash faded entirely in the next 48 hours.
925262	1/7/2021	NE	28	F	12/30/2020	1/6/2021	Rash started on 1/6 around the injection site. Developed into L axillary lymphadenopathy, fatigue, myalgias, and headache. Erythema does recede with benadryl but does not resolve. was a little wheezy on 1/6. She has h/o anaphylaxis due to latex and has an epi pen

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925494	1/7/2021	PA	41	F	1/4/2021	1/6/2021	Hives, sneezing, anaphylaxis, wheezing, itchy throat, stuffy, started in evening, hives first then itchy throat, probably about an hour, as that got worse throat started swelling. Took 50mg prednisone 2 benadryl and albuterol inhaler. Breathing got better and hives went away but still had swollen throat and took pepcid. Headache afterwards but that's typical of an allergic reaction. I can't be sure it was from the vaccine or not but nothing I did yesterday would normally trigger that reaction
925758	1/7/2021	AK		M	12/1/2020	12/1/2020	experienced eye puffiness; light headed ness; scratchy throat; This is a spontaneous report from a non-contactable consumer via Pfizer Sales Representative. A male patient (Health care worker) of an unspecified age and gender received BNT162B2(Pfizer BioNTech COVID-19 vaccine) via an unspecified route of administration in Dec2020 at single dose for COVID-19 immunization. The medical history and concomitant medications were not reported. The patient experienced eye puffiness, light headed ness and scratchy throat 10 minutes after vaccination in Dec2020. Reaction was not considered anaphylaxis. Patient received epinephrine, Pepcid and Benadryl in the ED, felt completely back to normal within an hour and was released. Event took place after use of product. The outcome of events was recovered in Dec2020. No follow-up attempts are possible; information about batch number cannot be obtained.
926608	1/7/2021	OH	72	F	1/6/2021	1/6/2021	itching, chest tightness, dizziness, shortness of breath no angioedema or anaphylaxis
926738	1/7/2021	OH	45	F	1/7/2021	1/7/2021	Anaphylaxis - throat itching and Shortness of breath
937256	1/7/2021		51	F	12/29/2020	12/30/2020	Headache, Fever, fatigue, muscle spasms 12/29 received the vaccine. Woke up tired on 12/30. That night woke up with muscle spasms all over her body and took her temp which was 101. The muscle spasms stopped at 0300 on 12/31. After that she developed a migraine. Headache last 22 hours and then just went away. She was tired the following day 1/1. All symptoms resolved on 1/2. She received the first vaccine in the ED and is scheduled to receive the second one in the ED as well. She has h/o anaphylaxis to food and bugs.

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939982	1/7/2021		50	F	12/31/2020	12/31/2020	Myalgia, Skin Rash, Rash, HYPERTENSION, Pain at the insertion site, myalgia, rash to neck & back, itchiness to the throat Narrative: Developed pain at the insertion site and myalgia on 12/31/2020 1 hour after vaccination. On 01/01/21 developed rash to the neck & back and itchiness to the throat. She was seen at ER on 01/01 with a temp of 36.8 C, B/P 175/90, and HR 102. She was given Solu-u-Medrol 125mg IVP, Pepcid 20mg IVP, and Benadryl 25mg IVP. Symptoms resolved and B/P post treatment 125/80. Discharged home with Prednisone 40mg x 5day PO, Vistaril 25mg Q 6 hours PRN, and Pepcid 20mg x 5 days PO. Reports today 01/2/21 rash completely resolved. Has a history of allergic reaction to antibiotics. Reports had an anaphylaxis reaction to cephalosporin 4 years ago requiring a Epi injection in the ER. Reports history of allergic reaction to antibiotics; PCN, Macrolide, and Fluoroquinolones treated with High Dose Steroids.
925780	1/7/2021	UT	38	F	12/30/2020	12/30/2020	Within 5 minutes of vaccination patient began to experience tachycardia and throat tightening. She was given 25 mg cap Benadryl PO and assistance was called when her heart rate reached 150 BPM about a minute later and further climbed to 188 BPM. She was transported to the Emergency Department where she was administered epinephrine, lorazepam, methylprednisolone, racepinephrine, and lactated ringers. She spent several hours in the Emergency Department and was discharged home but returned later that night at 06:00 PM for return of symptoms (tachycardia: 185 BPM, anxiety) and was administered Benadryl, solumedrol, Pepcid, Ativan, and Lactated Ringers. She was diagnosed with acute allergic reaction, nascent anaphylaxis, and panic attack. She went home again after this second ED visit. On Monday, 1/4/21, the patient reported to Employee Health with resumption of symptoms. Calming techniques were discussed and she went to a quiet area for 15 minutes to compose herself. Employee Health Nurse referred patient to Employee Assistance Program for anxiety care.
926690	1/7/2021	NY	30	F	1/4/2021	1/5/2021	Chills, myalgias, rash to chest and ear that is pruritic (started day after the vaccine and continued to day 3 post vaccine). No signs of anaphylaxis.

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924234	1/6/2021	WA	31	F	1/6/2021	1/6/2021	anaphylaxis
922700	1/6/2021	MA	61	F	1/6/2021	1/6/2021	Ee stated upon observation entrance, that she would be observed until 10:15am r/t "anaphylaxis" to Morphine. Informed us that she became "itchy" for "3" days prior to the 1st dose on 12-16-20. Ee c/o "itching" to this nurse @ 1005. Benadryl 25mg given @ 1005. Remains to c/o "itching" @ 1015. Ice pack applied to chest to relieve itching @ 1015. Around 1025 Ee stated she felt "relief of itching". This nurse also gave Ee (1) Benadryl 25mg to take w. Her. Ee stated she was feeling better @ 1034. Left observation @ 1035.
922858	1/6/2021	ME	50	F	12/21/2020	1/3/2021	Presented in ED with a reddened and swollen area of her left deltoid region.. The patient states that she received the Moderna vaccine on 21 December in the left deltoid. She states that she had no problem with the vaccine initially. She states that she even hiked this last weekend and felt fine. She states that she developed a reddened area of the skin 3 days ago that has been increasing in size. It is now tender and somewhat warm to the touch. She states that she also felt some itchiness of her upper chest. She is not sure if she has any true hives in this area. She denies facial, tongue, or lip swelling. She denies difficulty breathing. She denies chest pain. She denies abdominal pain, nausea, vomiting. ASSESSMENT and PLAN Erythematous, hive-like region of the left deltoid that began 12 days after the Moderna vaccine. This is likely a localized delayed type IV hypersensitivity reaction. Bedside ultrasound performed by myself. I do not note any pocket of fluid to indicate an abscess. However, there is a small possibility that this could be cellulitis. A cellulitis would be much more concerning. From an allergic perspective, she has no evidence of anaphylaxis based on the timeframe and her current symptoms. As a result, she will continue on Benadryl for now at 50 mg every 6 hours and will be placed on doxycycline 100 mg twice a day for 10 days. May use prednisone taper but she should wait for 48 hours. If she has improvement with doxycycline and Benadryl, she should continue with this. The Benadryl is truly as needed and if it is improving, she does not need to continue on it. She will.

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923230	1/6/2021	PA	50	F	1/5/2021	1/5/2021	She presents to the emergency department after receiving a COVID-19 vaccination today and having signs and symptoms of anaphylaxis. She described having sensation of swelling in her throat as well as cutaneous rash. On presentation she is also coughing very frequently. She is treated with IM epi, IV Benadryl and IV Solu-Medrol. This rapidly improved her overall symptoms. Reported per: Moderna COVID - 19 Vaccine EUA requirements
922464	1/6/2021	SC	38	F	12/28/2020	12/28/2020	A couple minutes after injection I felt flush over my chest area. It lasted about 30 seconds then my heart started racing. My iwatch heartrate notified me that my heart rate was 162. This lasted for about 7 minutes. My throat felt a little scratchy but not to where I had anaphylaxis reaction to seafood.
923549	1/6/2021		62	M	12/24/2020	12/25/2020	Headache, Myalgia, Anaphylaxis, Fever, HYPERTension, oral thrush Narrative:

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923572	1/6/2021	CA	40	F	12/23/2020	12/23/2020	anaphylaxis; ALOC/decreased level of consciousness; This is a spontaneous report from a contactable Pharmacist (patient). a 40-year-old female patient (no pregnant) received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EL0140) via intramuscular at Left arm on 23Dec2020 at single dose for COVID-19 immunization. The patient's medical history included known allergies to egg, seafood, azithromycin, orange and seasonal allergies. The concomitant was reported as cetirizine hydrochloride (ALLERTEC) and PRN 1371. The patient with no known past medical history brought in by CODE Team to RUH ED with concern for ALOC after getting the COVID vaccination 30-40 minutes PTA. Patient was a nurse and experienced decreased level of consciousness following her COVID vaccination. Patient reports h/o anaphylaxis. She was given epinephrine PTA. Denies SOB, oral swelling, CP. Blood glucose (BGL) within normal limits. Patient denies any other complaints or symptoms at this time. Adverse event start date: 23Dec2020. Treatment was unknown for decreased level of consciousness. The outcome of the events was recovered in Dec2020.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis /decreased level of consciousness cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The underlying predisposing condition of allergies to multiple materials may put the patient at high risk of anaphylactic reactions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
924050	1/6/2021	HI	55	F	1/6/2021	1/6/2021	anaphylaxis, dyspnea
924380	1/6/2021	WI	33	F	1/6/2021	1/6/2021	Anaphylaxis requiring epinephrine and ER visit, no hospitalization required

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924525	1/6/2021	FL	39	F	1/6/2021	1/6/2021	Patient complained of tingling and numbness in left arm at completion of the 15 minute observation time. Neuro-Vascular assessment was performed by and was found to be within normal limits. Capillary refill was brisk, skin was dry and warm to touch, no localized reaction was observed at the injection site, bilateral grip was of equal strength and quality. Observation period was extended for an addition 15 minutes, with no worsening of symptoms. Patient was offered follow up examination and medical care at the in-house Urgent Care, which the patient denied any further medical treatment at that time. Patient advised to continue to monitor for neurological changes, loss of mobility or sensation, signs and symptoms of anaphylaxis and if experiencing worsening symptoms, to seek immediate emergency medical care.
924733	1/6/2021	PA		F	1/6/2021	1/6/2021	Anaphylaxis. Lip swelling, hives, SOB, nausea. For 1 hour post Epi given.
923043	1/6/2021		45	F	12/30/2020	12/30/2020	Patient stated she started having symptoms < 5 minutes after receiving the vaccine (while waiting), she initially had significant headache (which has now resolved), full-body itching, some throat irritation, and lacrimation. Patient also noticed swelling in her bottom lip. Patient states she's only allergic to pineapple, has never reacted to vaccines before, and states she's never had anaphylaxis before this. She does not carry an Epi pen with her regularly." Patient also had chest tightness, sore-throat/neck muscles. Patient was given Epi, benadryl IV, decadron IV, and bolus fluid. She was monitored for 4 hours and discharged once stable.

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923805	1/6/2021	CT	72	F	1/6/2021	1/6/2021	Received the Moderna COVID-19 vaccine 1/6/2021 at approximately 11 AM. Pt stated she does not have any history of allergy or anaphylaxis. Pt reported about 5 minutes after vaccine administration a runny nose. Pt reported she did not have a runny nose prior to administration of the vaccine. Pt notes a history of nasal problems. Pt denies difficulty swallowing, swelling of airway, difficulty breathing, itching, rash, flushing, swelling of lips, face, throat, or eyes, sensation of throat closing, change in voice, wheeze, cough, n/v/d, abd pain, dizziness, weakness. Pt confirmed she felt well other than her runny nose. Pt was observed in our observation area for 45 minutes with no progression of symptoms. Epinephrine not administered. RN consulted with medical advisor Dr. over the phone as he was off site. EMS on site. VS done by paramedic patient signed refusal with paramedic as she did not want to go to the ED. Pt was advised by RN about delayed anaphylaxis, to continue to monitor her symptoms, call 911 if additional symptoms arise. Pt declined recommendation to go the ED. Advised pt to call her PCP asap for further guidance. Advised pt there is a local urgent care she should be checked out in if she cannot get in with her PCP today. Pt verbalized understanding and agrees to the POC. 2:26 PM RN called patient to check on her and obtain additional information for VAERS form. Pt reports she is feeling well, no other symptoms developed. Pt called her doctor and is waiting for a call back.

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923406	1/6/2021	GA	50	F	12/29/2020		anaphylaxis; throat swelling; This is a spontaneous report from a contactable physician. A 50-year-old female patient (non-pregnant) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 at single dose for COVID-19 immunization. Medical history included hypertension, lipids (as reported) and asthma. The patient was known allergies: codeine, iodine, shellfish, latex, and cefatrizine propyleneglycolate (CEFTIN). Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The most recent COVID-19 vaccine was administered in hospital. The patient experienced anaphylaxis and throat swelling on 22Dec2020 with outcome of recovered in Dec2020. The events were reported as non-serious. The events resulted in Emergency room/department or urgent care. Treatment of epinephrine, steroids, antihistamines, observation was received for the events. Information on lot/batch number has been requested.; Sender's Comments: A possible causal association between administration of BNT162B2 and the onset of anaphylaxis and throat swelling cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The underlying predisposing condition of allergies to multiple materials may put the patient at high risk of anaphylactic reactions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
923556	1/5/2021		51	F	12/23/2020	12/23/2020	Headache, Anaphylaxis, UrticariaPruritus & NauseaVomiting

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920496	1/5/2021	OR	53	M	1/4/2021	1/4/2021	hx of anaphylaxis to MMR. during prolonged observation period developed sensation of heat across chest and into throat, and lip felt numb. had taken Benadryl prior to arriving to clinic. Started to improve but with concern of symptoms worsening once Benadryl wears off, he was directed to the ER by private auto. not permitted to drive himself, wife came and picked him up.

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920624	1/5/2021	TX	41	F	12/21/2020	12/27/2020	41-year-old female HCW who received Pfizer BioNTech vaccine (Lot # EK5730) on 21 Dec 2020 in her left upper arm. No other vaccines were received that day. She reports a sensation of warmth and tenderness locally right after vaccination. On the evening of vaccination, she noted a small area of redness and swelling at the vaccination site. She denied anything out of the ordinary with regard to vaccine administration, except the vaccine might have been given "a little lower" than usual. She did not experience any respiratory, CV, dermatologic, or gastrointestinal signs/symptoms during observation post-vaccination or during the next several days. Post-vaccination day (PVD) one, patient noted some tenderness, warmth, redness, and some bruising surrounding the vaccination site. (SEE PVD 1 Photo); local reaction gradually resolved (SEE PVD 7 Photo) and currently, all that remains is a big bruise. On the evening of 26 Dec, patient reported having some "congestion" and took some Nyquil. She reports a good night's sleep, but upon awakening, she noted mild shortness of breath and she "couldn't open" her eyes due to swelling. She also noted her bottom lip and tongue were swollen and she experienced a tight feeling in her throat and chest. She also reports mild swelling of her hands. She denies hives/urticaria, wheezing, stridor, dysphagia, loss of consciousness, or gastrointestinal-related symptoms. Patient self-treated with oral Benadryl, Pepcid, and Zyrtec, as well as using her Albuterol inhaler. After 2 hours, her symptoms had not improved, so her spouse took her to the Emergency Room. In the ER, she was placed on a cardiac monitor, and shortly after arrival, she received IM Epinephrine (x2), followed by IV Solumedrol. She was observed for 8-10 hours and discharged home with a 5-day course of oral steroids. She was diagnosed with "anaphylaxis" and instructed to follow-up with her Primary Care Provider. Since discharge, she has continued to note some facial swelling, and on 29 Dec, she was having problems breathing for which she used her inhalers, and symptoms resolved. On the day of vaccine receipt, patient reports feeling well prior to vaccination. She denies previous vaccine reactions. She denies any exposures that might have been potential triggers to her reaction on 27 Dec – "the only thing different was the vaccine~~

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920962	1/5/2021	MA	42	F	12/17/2020	12/26/2020	I had soreness; started with itching, redness and swelling at site of immunization.; started with itching, redness and swelling at site of immunization./5.0 cm area of redness and induration; 5.0 cm area of redness and induration at site; started with itching, redness and swelling at site of immunization.; This is a spontaneous report from a contactable physician (patient herself). A 42-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ek5730, expiry date not reported), via an unspecified route of administration on the left arm on 17Dec2020 10:15 at single dose for COVID-19 immunisation. Medical history included food allergy, oral allergy, no anaphylaxis. Concomitant medications were not reported. On 26Dec2020 18:00, the patient started with itching, redness and swelling at site of immunization. Patient also had a 5.0 cm area of redness and induration at site. Patient also had soreness on an unspecified date but no other reaction. No therapeutic measure was taken as a result of the events. Clinical outcome of pain was unknown while for the other events was not recovered. Follow-up attempts are not possible. No further information is expected.

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921320	1/5/2021	IL	63	F	12/17/2020	12/18/2020	significant fatigue; temperature was taken when waking up - 101F orally; she slept more; localized injection site pain and redness; localized injection site pain and redness; This is a spontaneous report from a contactable nurse (patient). This 63-year-old female Nurse reported for herself that she received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), via intramuscular at right arm on 17Dec2020 08:30 PM at single dose for COVID-19 immunization. Facility type of vaccine was hospital. Medical history included shingles in Jun2020 after illness that mimicked COVID-19 but all tests came back negative - was sick for 3 weeks; no other chronic health conditions; severe beef/pork allergy - anaphylaxis. No COVID prior vaccination. No COVID tested post vaccination. Concomitant medications were not reported. No other vaccine in four weeks. On 18Dec2020 02:00 PM, patient experienced significant fatigue; she slept for 1 hour and temperature was taken when waking up - 101F orally; she slept more; she had localized injection site pain and redness for 3-5 days. No treatment was received for events. It was reported as non-serious. Outcome of events was recovered in Dec2020.
921539	1/5/2021	ME	31	F	1/5/2021	1/5/2021	Throat tightness, tongue swelling ~30 minutes following vaccine. No hx of anaphylaxis. Symptoms resolved with benadryl
921553	1/5/2021	TX	19	F	1/5/2021	1/5/2021	19 yo female received COVID Vaccines at 0930, reported to Primary care around 1200 pm with pruritus, erythema and warmth on upper extremities, chest and back. Airway intact, Lungs CTA bilar, NEURO WNL, VS wnl. Will tx for mild allergic reaction, Educated on Anaphylaxis protocol. SM v/u
921702	1/5/2021		36	F	1/5/2021	1/5/2021	Patient was on a 30 min observation due to previous anaphylaxis to emgality. As she was leaving, she c/o swelling and tingling of lips and appeared anxious. We asked to stay so we can monitor her a little longer. She appeared to stabilize, then she began coughing and trying to clear her throat. She stated it seems have worsened. Epi given and she was transferred to ED.

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921749	1/5/2021		36	F	1/5/2021	1/5/2021	Patient completed 30 min observation (due to hx of anaphylaxis to emgality) and as she was leaving she c/o lips swelling and tingling in throat. Pt was asked to stay for further observation. A few minutes later pt began to cough and stated worsening swelling in throat. Epi given and pt transferred to ED
921817	1/5/2021	CO	28	F	12/23/2020	12/23/2020	45-60 minutes after receiving the vaccine she had numbness on the left side of her face/cheek associated with some mild swelling to the area. Maybe some mild left tongue swelling. Normal swallowing, normal breathing. No cough. No vomiting or diarrhea. No rash. She called an urgent care who recommended Benadryl, which helped minimize the tingling sensation and swelling over the next 2 days. Over the following week she had soreness at her left jaw joint near her ear and some left eye dryness. No facial droop. Normal blinking and smiling. No facial muscle weakness noticed. She was not sick when she received the vaccine. No new medications. Tolerates NSAIDs normally without reaction. No facial fillers. Never had anaphylaxis before to anything -- foods, medications, injectables, other vaccines. No known PEG allergy. Has not used Miralax before.

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921974	1/5/2021	WA	45	F	1/2/2021	1/2/2021	24 minutes post shot developed itchy scratchy throat, clearing throat, dry cough, sweating, sense of impending anaphylaxis (same feeling I get with shellfish reaction) Bp stable, o2 says dropped 88%RA, tachycardia. Epi x 1 given 50 mg IM Benadryl and O2 placed seats normalized. Symptoms did not resolve, 6 minutes later second Epi shot given. Within 3 minutes symptoms starting to resolve. 125 Iv solumedrol, and given oral pred 40 mg daily x 3 days Felt fine next day(1/3) then 1/4/2020 recurrence of symptoms (2nd dose pred a little late 30 hours after last dose) Gave Epi shot, Benadryl 50 mg po (pred on board) Symptoms did not resolve but no desaturation , bp stable, tachy, persistent throat clearing and dry cough 2nd Epi shot given Iv famotidine Iv solumedrol 125 mg, symptoms resolved, albuterol helpful lungs clear Pred 40 mg daily x 3 days add famotidine bid, add cetirizine bid 1/5/2021 felt fine in am, sensation of throat swelling itching and dry cough recurred , albuterol used helped temporarily (had already taken morning cetirizine, famotidine and pred 40 mg) Saw allergist. Says fine, breathing fine slightly tachy, lungs clear, O2 says wnl, sweaty Albuterol given, helped Laryngoscopes with ENT negative for swelling, just mild vocal cord swelling from cough Started on pred taper 40 mg daily x 3, 20 mg qd x3, 10 mg dailyx3 Add Benadryl prn Add advair bid Continue cetirizine and famotidine
923543	1/5/2021		48	F	12/23/2020	12/28/2020	Tachypnea throat tightness, short of breath, concern for anaphylaxis Narrative: Present to ED five days after vaccine w/c/o tightness in throat and shortness of breath; treated in the ED w/epinephrine, benadryl, famotidine and methylprednisolone and observed for two hours; prescribed Epi-pen for take-home. Discharged home.
923554	1/5/2021		55	F		12/23/2020	Agitation, Sedation, Anaphylaxis, Rash & HYPOtension
923557	1/5/2021		69	M	12/23/2020	12/23/2020	Anaphylaxis throat itchiness, throat tightness, sinus swelling, ear fullness Narrative: Patient reported throat itchiness, throat tightness, sinus swelling, ear fullness. Transported via EMS to nearest ER

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925190	1/5/2021		43	M	12/23/2020	12/23/2020	Anaphylaxis Narrative: Pt reported trouble swallowing around 20 minutes into the observation period and was transferred to the treatment area in the vaccine clinic. Vital signs were assessed by a Registered Nurse and a Physician. Oxygen saturation was noted to be 88% on 2 liters of O2 by nasal cannula. Verbal order received at 10:03am from Physician and EpiPen administered to right thigh with improvement of symptoms. She was transferred to the Emergency Department (ED) via stretcher. In the ED, she was re-dosed with an EpiPen secondary to her airway type symptoms. She was reevaluated after 15 minutes and received Solu-Medrol, Pepcid, Benadryl IV, as well as IV fluids. She also received Ativan for her generalized jitteriness and anxiety. She improved and felt significantly better at approximately 11:43am. She was monitored for 3 hours in the ED and was discharged home at 3:34pm in good clinical condition and advised to continue to take Benadryl as needed. She carries an EpiPen on her person and was advised to return immediately if symptoms return.
925062	1/5/2021		48	F	12/30/2020	12/30/2020	Anaphylaxis, Tachycardia, Lips numbness, tingling, Throat feels full, increased saliva Narrative: employee with an adverse reaction to the Covid vaccination. Reported to RN 10 minutes post vaccination Lips numbness/ tingling, throat fullness and slightly anxious. NP assessed employee and 50mg of IM Benadryl given in the opposite arm (right). No SOB or wheezing noted. VS pre treatment 158/99, 98%-RA, 98-HR, 18-RR. Ten minutes post treatment Lip tingling and throat fullness improving. At 20 minutes post treatment all S&S of adverse reaction resolved VS taken throughout even with 60 minutes of observation time total VS 139/84, 99%-RA, 81-HR, 14-RR. She is feeling tired and will consider calling for a ride to go home as advised by staff.
925061	1/5/2021		42	F	12/28/2020	12/28/2020	Anaphylaxis, CoughWheeze & UrticariaPruritus History of asthma, EpiPen given with good improvement.

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925060	1/5/2021		59	F	12/23/2020	12/23/2020	Dizziness, Anaphylaxis, UrticariaPruritus & NauseaVomiting Narrative: Patient complained of nausea and numbness and tingling in fingertips 5 minutes after administration of vaccine and proceeded to bathroom. Patient with unwitnessed vomiting prior to RN assessment. RN assessed patient and taken safely to private evaluation room. AED pads applied per protocol. Epi-Pen administered. EMS called. Vital signs stable. Patient complained of itching and erythema in left arm around injection site. MD evaluated patient and advised to be further assessed in ER. Patient continuously evaluated by RN and EMS. Patient transported to ER in stable condition.
919916	1/5/2021	PA	53	F	12/18/2020	12/18/2020	The next day a rash appeared on my forearms and now is on my ankles, calves and scalp.; Severe headache; chills; flu like symptoms; This is a spontaneous report from a contactable other healthcare professional (patient). A 53-year-old non-pregnant female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK5730), intramuscularly at left arm on 18Dec2020 at 14:00 at single dose for covid-19 immunization at workplace clinic. Medical history included hypolipidaemia, allergic to sulfa drugs (hives), allergy to adhesive (severe skin blistering). There was non other vaccine in four weeks and no other medications in two weeks. The patient previously took naproxen (NAPROSYN) and amoxicillin clavulanic acid (AUGMENTIN) and was allergic to both drugs, and experienced anaphylaxis for naproxen. The patient experienced severe headache, chills and flu like symptoms the night after the shot on 18Dec2020. The next day on 19Dec2020 at 10: 00 AM a rash appeared on her forearms and was on her ankles, calves and scalp at time of the report. No treatment for the events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was not resolved.

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919966	1/5/2021	PA	44	F	12/18/2020	12/18/2020	lips, tongue and throat became numb and tingly; lips, tongue and throat became numb and tingly; lips, tongue and throat became numb and tingly; developed a cough once the numbness and tingling reached my throat; This is a spontaneous report from a contactable nurse (patient). A 44-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EK5730), via an unspecified route of administration at the left arm on 18Dec2020 15:30 at a single dose for COVID-19 immunization. Medical history included thyroidectomy for thyroid cancer, anaphylaxis to mangoes and allergic to multiple medications. The patient was not pregnant at the time of vaccination. Concomitant medication included levothyroxine and liothyronine. The patient received the vaccine at 3:30pm, ten minutes later her lips, tongue and throat became numb and tingly. She developed a cough once the numbness and tingling reached my throat. She was given Benadryl at the time, 15 minutes after injection. She was still having numbness and tingling to the back of her tongue currently (8 days after injection). The patient was not hospitalized for the events. The events were reported as non-serious. The vaccine was administered in a hospital. The patient has not received any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was recovered on an unspecified date in Dec2020 with sequel.
918568	1/4/2021	AZ	28	F	12/31/2020	1/1/2021	36 hours after vaccine my face started swelling rapidly. I had extreme swelling and hardening in the areas where I have HA fillers - lips and tear troughs. Both Restylane products. Ended up going to the ER at 2 AM and receiving angioedema/anaphylaxis protocol. IV benedryl, famotidine, and solumedrol. Was put on prednisone and hydroxyzine for at home care for the next 3 days after event. Swelling went down by the next afternoon.

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918990	1/4/2021	NY	37	F	1/4/2021	1/4/2021	Received Moderna vaccine at 9:00 am today and while waiting in the monitoring room, complained of feeling her heart was racing, was put on stretcher, vitals were monitored, BP noted to be 160/ 100 initially and for next 25 mins monitoring came down to to 140 -150/ 95, did not complain of shortness of breath, no rash or pruritus noted, ambulance transport was requested and husband was with patient, was transported to ED, and discussed with ED attending Dr. Followed up with pt in ED subsequently , did not have any additional symptoms and initial symptoms nearly resolved and discharged from ED subsequently at 12:30. This does not seem to be an anaphylaxis reaction, nonetheless VAERS reporting is being filed, has set her up to discuss with allergy and immunology group here.
919347	1/4/2021	AZ	32	M	12/23/2020	12/23/2020	During his 15min waiting period after receiving the Moderna COVID19 vaccine, patient got somewhat anxious... tachycardic, htn, wobbly knees, felt unwell. Didn't want any intervention, but agreed to lay down. While resting, BP down to 135/65, HR to 89, looked better and calm but then after 10-15min complained that his throat felt itchy. Then said he was allergic to peanuts, but only when eaten in lg quantities. No signs of anaphylaxis, but was sent to ER for evaluation and obs. Left ER w/o getting seen.
919459	1/4/2021	CO	34	M	1/4/2021	1/4/2021	MODERNA COVID-19 VACCINE EUA Approximately 12 minutes in to the patient's 15 minute post vaccination observation period he reported new onset headache. No reported symptoms of anaphylaxis at this time; the patient was alert and oriented x4. The patient was asked to wait for an additional 15 minutes of observation. After 15 more minutes of observation, the patient continued to endorse a headache and fatigue; no additional symptoms present and the patient was alert and oriented x4. We reviewed common side effects which include headache and fatigue as well as signs of anaphylaxis. We made a plan for patient to contact PCP for any changes or concerns or to contact emergency medical services for evidence of anaphylaxis. Client was discharged from the clinic following a second 15 minute observation period with no acute change in status.

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918892	1/4/2021	NY	50	F	1/4/2021	1/4/2021	About 1.5 hours after dose administration, patient began to feel lightheaded and weak, unable to stand up. He then noticed a rash on his forehead, chest, arms and back of neck. He had no swelling of the lips, tongue or throat. No shortness of breath or wheezing noted. VS 157/110, 101, 20, 97.7. Pulse ox 99% on room air. No acute distress, but a little anxious. No oropharyngeal erythema or swelling seen. Lungs clear to auscultation. Skin revealed red macular rash on the face. Other areas had faded. Benadryl 50mg po given with good effect. Weak feeling subsided quickly and hives began to fade. Repeat vitals over 30 minutes were largely unchanged. He was allowed to go home with instructions to contact his PMD and to use Benadryl 50mg po Q4H PRN. If he develops any signs/symptoms of anaphylaxis he should call 911.
919503	1/4/2021	WA	29	F	12/22/2020	12/22/2020	rash, hives, anaphylaxis, throat tightening, felt out of body
919680	1/4/2021	WA	37	F	1/4/2021	1/4/2021	Anaphylaxis reaction
918914	1/4/2021	OR	41	M	1/4/2021	1/4/2021	Employee received the vaccine at 0805, reported at 0812 that he was dizzy, lightheaded, nauseated and diaphoretic. Employee assisted to cot to lie down. Skin pale, continued to be diaphoretic, respirations in the 20's, BP 115/82, HR 110, O2 98% on RA, denied any difficulty breathing, no coughing or evidence of throat tightening, no sign of any swelling at vaccination site, no rash. Code called overhead, Code team arrived. No medications given at time in clinic. Near syncopal episode. No anaphylaxis. Employee taken to ED for further evaluation and observation.

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918493	1/4/2021	OH	41	F	12/30/2020	12/30/2020	?Moderna COVID- 19 Vaccine EUA? Flu vaccine allergy discussed at length with patient prior to Moderna vaccine. Patient's arm became red and very swollen on two separate occasions after receiving flu vaccine but patient did NOT experience difficulty breathing, respiratory distress, throat swelling, shortness of breath, or anaphylaxis. Approximately 11 minutes after receiving Moderna vaccine, patient complained of warmth and redness at injection site. Immediately after this complaint, patient began to faint and complain of difficulty breathing and pain when breathing. Rapid response was called. Patient continued to complain of painful inspirations and difficulty breathing. EpiPen, albuterol inhaler, and diphenhydramine IM were administered. Patient improved and was transported to emergency room for further monitoring. Patient improved in emergency room and was discharged sooner after.
918182	1/4/2021	RI	53	F	1/3/2021	1/4/2021	shortness of breath, hypotension, presumed anaphylaxis
918086	1/4/2021		31	M	1/4/2021	1/4/2021	Patient developed SVT 15 minutes after receiving vaccine. Admitted to ICU. ER presentation: BP: 160/109 heart rate 132. No e/o anaphylaxis or allergic reaction.
918516	1/4/2021	NE	30	F	12/30/2020	12/30/2020	I administered the vaccine and as the patient has a history of childhood anaphylaxis to shellfish, I instructed her to wait for 30 minutes in the observation area, instead of the standard 15 minutes, It was in the observation area, where she was being observed that she began to feel "hot and flushed". The health staff observing will also be submitting a VAERS report, as they provided interventions to the patient.
917941	1/3/2021	TX	66	M	1/3/2021	1/3/2021	TINGLING IN EXTREMITIES AND TONGUE, TONGUE SWELLING, MILD HTN, TREATED FOR ALLERGIC RXN WITH DIPHENHYDRAMINE 25MG IM INJECTION AND MONITORED FOR SIGNS OF ADDITIONAL ALLERGIC RXN/ANAPHYLAXIS. S/S RESOLVED S/ DIPHENHYDRAMINE AND TIME. PT WAS ALSO MILDLY HYPOCAPNIC ON ET/CO2 MONITORING AND STATED THAT S/S COULD BE DUE TO MILD ANXIETY.

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917854	1/3/2021	PA	57	F	12/18/2020	12/18/2020	Patient received vaccine and was fine through her 15 minute observation period. She left the clinic and came back about 40 minutes later complaining of tingling in her tongue and weakness in her legs and felt like she needed to sit down. Her blood pressure was taken and it was elevated and a decision to take her to the ED was made. In the ED, she denied shortness of breath and did not have any other signs of anaphylaxis. She was given diphenhydramine 50 mg (at 11:36AM), famotidine 20 mg (@11:36AM) and prednisone 50 mg (at 11:43AM). At 12:23PM, documentation from the ED notes that tongue symptoms resolved, but patient still felt weak.
917955	1/3/2021	AZ	55	F	12/20/2020	12/20/2020	25 minutes after receiving the injection, there was a sudden onset of facial swelling, hives, itching and airway constriction. I had already left the drive-thru vaccination clinic and was driving to the hospital emergency room where I work. I informed my colleagues of my symptoms and was treated for anaphylaxis with IV diphenhydramine and famotidine over several hours. I was given a prescription for a prednisone taper for the next 6 days.
917712	1/3/2021	NY	24	F	12/23/2020	12/23/2020	Anaphylaxis. The COVID shot was given, no reaction then. After 7 minutes, congestion, severe cough, vomiting phlegm, feeling like throat closing started happening. Code was called, Benadryl was immediately given intramuscular in the left arm, blood pressure, pulse ox was taken, and then was taken to the Emergency Department. In the ED, I was given prednisone, one EPI, anti-nausea medication all through I.V. and many more medications given to me via I.V. that I don't sincerely remember. I was under observation for 4 hours. I was discharged after all symptoms dissipated and was given Prednisone 20 MG (3 tabs a day) to take to help my lungs. Management followed up almost immediately, everyone from the moment I had the anaphylactic reaction was quick and prepared.
917557	1/2/2021	MI	40	F	1/2/2021	1/2/2021	itching sensation. No rash. No shortness of breath. No anaphylaxis.
917221	1/2/2021	FL	33	F	12/30/2020	12/30/2020	45 minutes post vaccination, at my place of work, I got hives all over my body and my blood pressure became extremely high. It took two days of benadryl every 4 hours to get the hives to stop. No anaphylaxis.

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917490	1/2/2021	CA	63	F	12/23/2020	12/23/2020	Approximately 1 hours after injection, I felt an unusual feeling at base of throat. It progressively got worse and I felt throat swelling and my voice was effected. No itchy throat like my anaphylaxis reaction to shellfish only swelling. I mildly panicked and wanted to take Benadryl. About 1/2 hour later by the time I got home reaction was over. No repeat of symptoms ever again.
916653	1/1/2021	AZ	49	F	12/30/2020	12/30/2020	Anaphylaxis- needed 3 doses of epinephrine before admission to ER. In ER received IV steroid and famotidine. Was given prescriptions for epipen and oral steroids (60mg x 5 days).
916756	1/1/2021	IL	45	F	12/30/2020	12/30/2020	Anaphylaxis, allergic reaction: Throat swelling, facial and ear numbness on left side. Ear redness and swelling. Went to ER, treated with IV Benadryl, Epinephrine, Famotidine, Solumedrol, Klorcon M.

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915897	12/31/2020	ID	35	F	12/31/2020	12/31/2020	35 y.o. year-old female RN that presented to the clinic today for a Pfizer-BioNTech COVID-19 vaccine. Pfizer-BioNTech COVID-19 vaccine was administered at: Time: 0852 Date: 12/31/2020 Patient presented with symptoms at time 0905 while being observed following vaccine. Patient's symptoms include the following: Skin and Mucosal symptoms: No Respiratory Symptoms: Yes: Sensation of throat closing. If described on scale of 1-10 with throat closure being a 10, stated "throat closure could feel like a 2-3 on 1-10 scale. Symptoms also described as "scratchy throat". She hadn't had any breakfast today. She reported history of reaction after pneumococcal ppsv 23 vaccine which consisted of very red, sore, swollen arm with fever following vaccine. Reported to healthcare provider who let her know she "suffered an allergic reaction to one or more components of the pneumococcal vaccine and not just side effects". She was treated with ibuprofen, ice, and advised to take zyrtec, allegra, or benadryl. She reports she took benadryl and never required any epinephrine. She denied any shortness of breath, difficulty breathing, or swelling of the face, mouth, or throat with that reaction. She does report a possible reaction to bees/wasps for which she felt previous tingling in the lips, but when reviewed with her PCP, they opted to not order epi pen for her use at the time. She denies ever needing epinephrine or epi pen use in the past that she is aware of. Gastrointestinal Symptoms: No Cardiovascular: Yes: Dizziness The following actions were performed: Patient was brought to exam room to lie down Feet were elevated Given some water Given some juice Vital signs: @0915 BP 130/85, Pulse 84, Oxygen on room air 100%, Temp 98.8 F, @0923 BP 126/85, Pulse 75, Oxygen on room air 100% Airway, Breathing, Circulation, and level of consciousness assessed and normal Bendaryl 50mg administered as a single dose Patient reported dizziness was resolved quickly after lying down. She stated her "throat closure" symptoms were also improved. She drank water, apple juice, and had 2 saltine crackers without incident. Airway, Breathing, Circulation normal throughout assessment period. Vital signs again checked at 0945: BP 135/85, Pulse 80, Oxygen 100%, Temp. 98.9 F. Discussed normal adverse events following this vaccine with patient. Also discussed more severe adverse events

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915235	12/31/2020	WA	34	F	12/30/2020	12/30/2020	<p>which can include difficulty breathing, swelling of face/throat, fast heartbeat, bad rash all over body, and dizziness or weakness. Discussed she could take another dose of benadryl if she was concerned about any continued, mild swelling of throat in 4-6 hours. If she has severe swelling of face/throat that is worsening or not resolved with benadryl, she should call 9-1-1 immediately. She voiced understanding. We discussed that she would need to weigh the benefits/risks of a 2nd dose, and if she does choose to get a 2nd dose based on a minor reaction not causing severe anaphylaxis, she would need to make sure staff are prepared with benadryl and epinephrine to be used if needed. She voiced understanding. Her husband was notified and he came and picked her up after she was observed for an additional 30 minutes in the observation area outside the clinic. She left the observation area at 1016.</p> <p>anaphylaxis (generalized urticaria approx. 9 hours post-injection)</p>

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916412	12/31/2020	CO	36	F	12/30/2020	12/30/2020	Moderna COVID- 19 Vaccine: Approximately five minutes after receiving vaccine reported dizziness, lightheadedness, "weird taste" in mouth, sensation of throat closing , and throat itching. Diphenhydramine 25 mg orally was administered and vital signs were: blood pressure- 158/96 mmHg, pulse - 88 beats per minute, oxygen saturation - 96% on room air. Patient reported throat swelling was worsening. and sensation of throat closing comes and goes. Another diphenhydramine 25 mg dose orally was administered and repeat vital signs were blood pressure - 183/91 mmHg, pulse 98 beats per minute, oxygen saturation 94% on room air. Patient was transported to the emergency department where they arrived in no acute distress. On physical exam no rash, diaphoresis, respiratory distress, or swelling of the uvula or pharynx were noted. After being observed repeat vital signs were blood pressure 125/90 mmHg, pulse 82 beats per minute, respiratory rate 16 breaths per minute, and oxygen saturation 94% on room air. No hypotension, loss of consciousness, or gastrointestinal symptoms developed. Patient diagnosed with allergic reaction, provider stated did not suspect anaphylaxis, prescribed prednisone and diphenhydramine, and patient was discharged to home stable. On follow-up visit with primary care provider the following day, patient noted to have residual throat itchiness and lightheadedness but no other symptoms and is taking prednisone and diphenhydramine as prescribed. Vital signs: blood pressure 110/68 mmHg, pulse 83 beats per minute, temperature 36.8 degrees Celcius, oxygen saturation 97% on room air.
915371	12/31/2020	TN	34	F	12/30/2020	12/30/2020	vaccine at 5:56pm, at 6:08 pt reported itchy throat and took 25 mg Benadryl; at 6:13 pt was red and itchy all over and took another benedryl; pt reported having an epi pen but did not want to use any epi (even ours) because she would have to go to ED; at 6:29 she used her inhaler because she had some tightness; at 6:56 pt was less sloptchy and red; O2 sats remained above 93 the entire event and boyfriend drove her home; contacted her at 7:30 and she was much better. This lady is a nurse practitioner and was acutely aware of her symptoms as she has experienced anaphylaxis multiple times.

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915676	12/31/2020	MA	58	F	12/31/2020	12/31/2020	~~Tickle" in back of throat, cough. Due to pt hx of anaphylaxis to flu vaccine, prednisone 10 mg PO given with good effect. Symptoms resolved.
915770	12/31/2020	CO	51	F	12/30/2020	12/30/2020	Anaphylaxis Throat swelling Difficulty swallowing
915974	12/31/2020	MA	30	F	12/30/2020	12/30/2020	Patient came back to vaccine clinic area experiencing paresthesia in her upper and lower extremities. Every 15 minutes patient would experience decrease in pulse and increased breathing rate. Patient was monitored by vaccine clinic staff and was provided ginger ale, apple juice and candy. After approximately 20 minutes of monitoring patient went back to work station, however came back due to experiencing symptoms again. Patient was given a dose of diphenhydramine 25 mg and a nurse monitored her blood pressure which was normal. Patient was seen by provider who determined she was not experiencing anaphylaxis, therefore it would be safe to stop monitoring. Patient was counseled on visiting ER if symptoms worsened and was picked up by family member. Patient confirmed understanding.
916211	12/31/2020		44	F	12/31/2020	12/31/2020	30 minute monitoring required d/t reported anaphylaxis to Bee's. Tingling all over with itching sensation to the throat at 15 minute mark. No respiratory distress and PCP and pharmacy onsite gave Benadryl 25mg PO at 1145am. Tingling was slowly improving at 1200. Left with no further reaction/complaint at 1210pm.
916260	12/31/2020	NY	41	F	12/31/2020	12/31/2020	mild anaphylaxis

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916267	12/31/2020	WY	58	F	12/31/2020	12/31/2020	A few minutes after the 15 minute observation period, patient was on her way to her car to leave, developed copper penny taste in mouth, perioral itching/tingling, and some itching/tingling on arms. She said it felt the same way it feels after she eats walnuts. Was brought to medical clinic treatment room, vital wnl, no difficulty breathing, vomiting, hives, or signs of anaphylaxis. Patient was given 10mg zyrtec (declined benadryl), and monitored for an additional 30 minutes (45 minutes after vaccination). Her symptoms were almost fully resolved (mild perioral tingling remaining only) and vital signs every 15min stayed WNL before she was discharged home. She is a healthcare worker and as an epi pen in her car and was given instructions if symptoms return, she wanted to leave and felt comfortable with plan of care.
916268	12/31/2020	OH	51	F	12/31/2020	12/31/2020	Shortly after receiving the vaccine (within 10 minutes) the patient's tongue swelled, facial redness, gasping for air. This resident was marked for a 30 minute observation due to previous anaphylaxis type reaction. Immediately administered 0.3mg epinephrine x 1 dose. Then administered 50mg IM Diphenhydramine. This treatment course resolved the adverse reaction. Patient was monitored onsite at facility. Her husband came to pick her up and take her home. Tried to reach patient several hours after but was unable to at this time.
915762	12/31/2020	ME	49	F	12/31/2020	12/31/2020	Vaccine administered at 0945. At 0955 patient developed symptoms including: tightness in chest, lump in throat, voice changes, BP 130/88, Pulse 66, Cap refill <3. No past anaphylaxis, but severe past reaction to codeine.

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913162	12/30/2020	AZ		F			near syncope episode, orthostatic; feels a little foggy; This is a spontaneous report from a contactable Physician. A 38-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on unspecified date in 2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The emergency medicine physician was monitoring a patient that came in from a vaccination event, stated that it was Pfizer BioNTech Covid 19 vaccine. The patient had a near syncopal episode. They did orthostatics (unspecified) and found that she was orthostatic (near syncope episode, orthostatic). There was no anaphylaxis reaction or allergic reaction. She still felt a little foggy. The physician did a blood glucose, labwork and EKG that look good. The physician wanted to know if there was any data for things that they should looking for with the vaccination and will direct the patient to contact Pfizer to report it. The outcome of the events was unknown. Information on the lot/batch number has been requested.
914013	12/30/2020	MO	21	F	12/23/2020	12/29/2020	ARM WAS SORE FROM TIME OF SHOT UNTIL 12/25/20 AM. ON 12/29/20 AT 11 PM EMPLOYEE NOTED ITCHING TO INJECTION SITE. ARM WAS ALSO SWOLLEN AND RED. THIS HAS PROGRESSED TO MUSCCLE PAIN TO ENTIRE RIGHT ARM. EMPLOYEE CALLED PCP WHO OFFEREN NO ADVICE. EMPLOYEE THEN CALL INFECTION PREVENTION NURSE AT HER EIMPLOYMENT (MEDICAL CENTER). IP CONSULTED WITH PHARMACIST WHO ADVISED EMPLOYEE TAKE BENADRYL. IP REVIEW SIGNS TO WATCH FOR- ANAPHYLAXIS AND INFECTION. WAS ADVISED TO COME TO THE ED IF SYMPTOMS WORSEN.

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914318	12/30/2020	KS	55	F	12/22/2020	12/22/2020	<p>Progress Notes (Physician Assistant) ? ? General Surgery/Trauma Cosigned by: MD at 12/29/2020 12:36 PM Expand All Collapse All COVID VACCINE CLINIC 12/22/2020 Date: 12/22/2020</p> <p>Subjective Patient is a 55 y.o. female who was seen at COVID Vaccine Clinic today for her first dose of the COVID 19 vaccination. She denied any history of previous adverse reactions to vaccines. She was given the Pfizer vaccination in the left deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience dizziness, anxiety. She denied rash, hives, difficulty breathing, difficulty swallowing, throat tightness, hoarseness, itching, facial swelling and tongue swelling. This provider was notified of patient reaction and she was then assessed in the emergency bay area. Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with stridor, wheezing, dyspnea and increased work of breathing, vomiting and abdominal pain. Problem list, past medical/surgical hx, medication list reviewed and discussed with pt. She has no hx of previous hypersensitivity reactions to immunizations. Review of Systems Negative, except for above. Objective Vitals Vitals: 12/22/20 1123 12/22/20 1130 BP: 131/65 114/56 BP Location: Right arm Pulse: 78 70 SpO2: 99% 99% Physical Exam Constitutional: Appearance: Normal appearance. HENT: Head: Normocephalic. Nose: Nose normal. Mouth/Throat: Mouth: Mucous membranes are moist. Pharynx: Oropharynx is clear. Neck: Musculoskeletal: Normal range of motion. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Heart sounds: Murmur present. Pulmonary: Effort: Pulmonary effort is normal. Breath sounds: Normal breath sounds. Abdominal: Palpations: Abdomen is soft. Skin: General: Skin is warm and dry. Capillary Refill: Capillary refill takes less than 2 seconds. Neurological: General: No focal deficit present. Mental Status: She is alert and oriented to person, place, and time. Psychiatric: Mood and Affect: Mood normal. Assessment/Plan Assessment: Transient anxiety associated with covid vaccine administration Plan: Treatment included observation, serial examination, monitoring of vital signs.</p>

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							Follow up response to treatment: no side effects. Patient discharge: Stable to go home and follow up with PCP. Patient was monitored for approximately 45 minutes post injection with multiple physical exams and serial vitals signs with no observance of local or systemic hypersensitivity response. At the time of discharge she had no complaints and was able to ambulate easily without assistance. Signs and symptoms of anaphylaxis were reviewed and discussed, and she was instructed to call 911 or report to the ED immediately if those signs/symptoms develop. She verbalized understanding. PA-C Electronically Signed 12/22/2020 11:53 AM
913595	12/30/2020	MO	34	F	12/26/2020	12/26/2020	anaphylaxis history - hands felt tingly and tight. "Swelling" Benadryl given initially bp and pulse up. last vitals are 130/89; 71; 99% and 16 Symptoms improved
913746	12/30/2020	PA	60	F	12/30/2020	12/30/2020	hx of "anaphylaxis at 3yo due to pcn so patient was observed post covid vaccine for 30 min. At about 40 min post vaccine she reported some itching in scalp only. No chest pain, SOB, lightheadedness, No oral/facial swelling; ; hx of asthma on meds but no wheezing now. evaluated in emp health - BP 122/70; P80; NAD; Lungs clear; Skin clear Given 50 mg Benadryl po (has taken this "many times before") Mild scalp itching at 10 am ; back to work and rechecked at 11:50 am - "only very mild scalp itch" Advised ED if worse.
913714	12/30/2020	MN	34	F	12/30/2020	12/30/2020	Anaphylaxis- generalized hives
913774	12/30/2020	CA	38	F	12/29/2020	12/30/2020	Patient is a 38 y.o. female presenting with nausea with middle taste sensation after immunization. Presentation most consistent with vasovagal reaction versus allergic reaction. No signs of severe allergic reaction or anaphylaxis, no signs of cardiopulmonary compromise.
914042	12/30/2020	AZ	37	F	12/23/2020	12/30/2020	Woke up with at 3:30am with extremely sore throat, swollen uvula, could not swallow, multiple scattered petechiae on soft and hard palate. Afraid of angioedema or delayed acute anaphylaxis. Paramedics called. Treated at Facility with IV dexamethasone, diphenhydramine, Pepcid. Swelling resolved in 2 hours. Petechiae still present.

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914192	12/30/2020	TX	40	F	12/23/2020	12/25/2020	Moderate to severe pain at injection site; 2 days after vaccination I had swelling, redness, hives and itching on both eye lids.; 2 days after vaccination I had swelling, redness, hives and itching on both eye lids; 2 days after vaccination I had swelling, redness, hives and itching on both eye lids; 2 days after vaccination I had swelling, redness, hives and itching on both eye lids; This is a spontaneous report from a non-contactable physician reporting for herself. A 40-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 23Dec2020 12:00 at single dose for covid-19 immunization. Vaccine location was Right arm and it was the first dose. The COVID-19 vaccine was administered at Hospital. Medical history included Asthma and Ehlers Danlos, and Known allergies: Hives with amoxicillin and anaphylaxis with shellfish. Concomitant medications included budesonide/formoterol fumarate (SYMBICORT), ethinylestradiol/levonorgestrel (QUARTETTE). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced Moderate to severe pain at injection site, and 2 days after vaccination I had swelling, redness, hives and itching on both eye lids on 25Dec2020. Treatment received for the adverse events included Benadryl 50mg once. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The outcome of the events was recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.
913233	12/30/2020	UT	56	F	12/29/2020	12/29/2020	10:30 AM After receiving the COVID-19 vaccine, the patient experienced an anaphylaxis reaction that included, throat closing and tongue swelling sensation, itchiness, and hives on her bilateral arms and legs. Patient received 65 mg of Benadryl IV, 125 mg SoluMedrol IV, two doses of 0.3 epinephrine IM, 1 mg of Ativan, and 4 mg of Zofran, then taken to the ED for further monitoring. Patient was on 2L NC for comfort, sats in mid 90s off oxygen, and monitored the patient for a few hours. Patient discharged to home with stable vital signs off oxygen and a steady gait.

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914293	12/30/2020	TX	34	F	12/29/2020	12/29/2020	Patient arrived for her COVID vaccine and informed us prior to vaccine she was immunocompromised; however, her physician recommended she get the COVID vaccine. Patient received the COVID vaccine at 0920. Patient was informed to remain in the room where we were vaccinating for 30 minutes (due to immunocompromised status). , approximately 10 minutes after the vaccine was given patient started complaining of nausea. Patient escorted to exam room, and placed on exam table. Patient complains of chills, nausea, and joint pain. She stated she did not eat today; juice and a snack bar provided. Vital signs stable (BP = 108/73 - HR = 69), no apparent signs/symptoms of anaphylaxis. The doctor notified and agrees with a continued monitoring. Monitored for an additional 15 minutes, patient states she is feeling better. The nurse escorted patient to her car. She was feeling better. Unfortunately we wrote her phone number down wrong; however, we sent an email 12/30/20 am to check in. Update 12/30/20 - The patient contacted the nurse via email, she is doing well - reports bicep area is hard with mild swelling and generalized body aches.
913445	12/30/2020		24	F	12/27/2020	12/27/2020	Pt developed anaphylaxis, was given IM Benadryl, and was sent to the ED. Pt spent 1 night in the hospital, went home, and has come back and is in the ICU. Pt had hives, itching, chest tightness, swollen lips.
914574	12/30/2020	WV	43	F	12/30/2020	12/30/2020	started as tachycardia, then started have anaphylaxis reaction

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914580	12/30/2020	FL	53	F	12/29/2020	12/29/2020	Employee was given the Moderna Vaccine and within 2 min employee started to feel chest discomfort, generalized tremors and light headed. The patient was given 2 doses of IM epinephrine and sent to the ER- 2:24 1st dose and 2:29 second dose. Arrived in the ER given diphenhydramine/famotidine/prednisone. RX given 0.3 IM for Epinephrine(Epi-pen)/Zyrtec and Famotidine and Predisone. Seen in ER at 2:36 - patient states to ER MD that after epinephrine she feels much better. Evaluation done and monitoring of vital sings in the ER . Doctor spent 38 minutes with patient and felt she was stable and discharged the patient home to self monitor and return to the ER at 4:28 PM. ER Doctor states no current signs of anaphylaxis, severe dehydration, live threatening emergency. Advised to follow-up with PCP in 1-2 days. Employee was called and states she feels good and has no current symptoms other than a sore arm- 12/30/2020.
914695	12/30/2020	PA	56	F	12/30/2020	12/30/2020	Patient reports that she received the 1st dose if the COVID-19 vaccine approximately 2 hours ago. She reports that she started to feel flushed about 10 minutes after the administration. After about 30 minutes started feeling better and was able to tolerate some juice. Started to drive home and became very flushed again and lightheaded. Reported back to Occupational Health and was evaluated and found to be significantly hypertensive. After further observation, patient continuing to have elevated blood pressure. Sent to the emergency department for further evaluation. Patient notes that she has had some intermittent issues with hypertension, but does not currently take medications, most recent blood pressures have been within normal limits to borderline. No prior significant allergic reactions to immunizations. Patient does note that she had an episode earlier this year of near anaphylaxis to unknown substance. Has not had recurrent issues since. No prior known history of COVID-19. No chest pain or shortness of breath. No sore throat. No difficulty swallowing. Patient medicated with IV Benadryl and normal saline. Feeling better following medication. Blood pressure improved. Return instructions provided. Patient follow up with primary care.

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914884	12/30/2020	KS	70	M	12/30/2020	12/30/2020	Patient developed swollen hands and swollen ankles/feet that was visually noticeable approximately 2 to 3 hours after receiving vaccine. Onsite staff noticed the symptoms and sent the patient immediately to the local Emergency Department for further examination and treatment. The patient did not show signs of severe anaphylaxis (oral-facial swelling/difficulty breathing).
914927	12/30/2020	CA	38	F	12/18/2020	12/18/2020	mild lip swelling and itchy 30 minutes post vaccine. Took benedryl and pepcid at home. Develop throat tightness next day. Took dose of prednisone and epi pen for fear of developing anaphylaxis. Reported to ED for evaluation. Got IV and another epi pen in ED
914998	12/30/2020	WA	50	F	12/22/2020	12/22/2020	The patient is a nurse who was well until COVID vaccination. She was observed for 15 after vaccination and did well. She then returned to her medical unit. About 30 minutes after vaccination, she became extremely cold, dizzy, had a transient headache, and was found to be hypertensive. Her nurse colleagues placed her in a Bair hugger and she was still cold. On arrival to the ED, she was hypertensive (max 170/107), subdued and initially reporting dizziness, headache now resolved, otherwise well-appearing on exam, with no signs or symptoms to suggest classic allergic reaction or anaphylaxis. A tryptase level sent to further assess for the possibility of atypical allergic reaction, and she was initially just observed. When she didn't improve and continued to report dizziness especially with standing, and reported that she hadn't had much to eat or drink all day, she was given a fluid bolus and a snack. After 2.5 hours of observation, during which time the blood pressure fluctuated, the patient felt much improved. She was less hypertensive (150/89 at discharge) with no intervening symptoms. She was discharged and did not return to the ED. I am not aware of follow-up.

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915024	12/30/2020	AK	36	F	12/29/2020	12/29/2020	Vaccine administered at about 13:00 on 12/29/20. Within 5 minutes, patient developed became flushed and developed tachycardia as high as 160, and a feeling of being "overstimulated". The patient self-administered 10 mg Claritin. Within 20 minutes of injection, the patient developed profuse diarrhea and erythematous modeling around the injection side. In the evening, she had fatigue body aches, and nausea. The following morning, it was clear that the patient had an injection site reaction with firmness, redness, and warmth. The erythematous modeling had spread to the wrist of the left arm as well as to the chest and down to the elbow on the right arm. No rash on rash or any other sign of allergy or anaphylaxis.
914274	12/30/2020	NC	48	F	12/30/2020	12/30/2020	mild anaphylaxis. Began with flushing about 5-10 minutes after vaccine. Proceeded to stomach cramping with diarrhea and itching in throat and of tongue. I took 2 diphenhydramine 25mg capsules and famotidine 20mg. Proceeded to the ED with the administering RN, Received 1 dose epinephrine IM, SoluMedrol and famotidine IV. Coughing, itching and cramping subsided in about 10 minutes. Discharged on 60mg prednisone QD for 5 days after ED monitoring until vitals were stable.
913602	12/30/2020	CO	44	F	12/29/2020	12/29/2020	Was being monitored x 30 minutes after vaccination. Approximately 15 minutes after administration, eyes began to get heavy and swell. "My heart was racing." Wheelchair to ED. They could not get IV access. Throat was dry. They got an IV and gave Benadryl. "My throat starting swelling and I could not swallow." "I was panting and my heart was beating out of my chest." The ED staff administered epinephrine pen via IM injection. Anaphylaxis resolved and she was monitored x 4 hours in ED. Sent home on prednisone and fomatidine.

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911282	12/29/2020			U	12/1/2020	12/1/2020	anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the third of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: AK 5730, EG 1685), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Dec2020. The clinical outcome of anaphylaxis was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020505820 different patient/same drug/event
913214	12/29/2020	CA	39	F	12/29/2020	12/29/2020	39 yo female scheduled for COVID vaccine. Reports only incident of anaphylaxis d/t pineapple allergy 4 years ago; medication allergies limited to migraine s/s, not anaphylaxis. Denies possibility of pregnancy. Tolerated injection well. Upon standing ~5 min after injection, pt began experiencing lightheadedness and warmth/diaphoresis. Pt's monitoring and care transferred to clinic. Pt given Benadryl 25mg, famotidine 20mg, 1000ml NaCl IV, Solumedrol 125mg IV. Pt symptoms resolved and sent home with Epipen 2-Pak, Loratadine 10mg, prednisone 20mg, Benadryl 25mg/
912996	12/29/2020	WI	49	F	12/20/2020	12/20/2020	Wheezing, throat tingling and anaphylaxis, dizzy, mostly the breathing. I was coughing nonstop

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912903	12/29/2020	CA	44	F	12/23/2020	12/26/2020	12/29/20- Spoke to CG. Received Pfizer COVID-19 vaccine, dose #1 on 12/23/20 @ 4pm. Stayed in Observation area for 15 minutes without any problem. Suddenly, on 12/26/20 (3 days after receiving the COVID vaccine), CG felt "itching to throat, gum, mouth and body; itching head to toe", also noticed "lip, mouth swelling" as well as "wheezing". Stated she has history of "asthma". CG then self-medicated with "Claritin and Albuterol inhaler" without much improvement on 12/26/20. Then the next day, on 12/27/20, itching to throat and mouth is resolving but still had shortness of breath and itching body. On 12/28/20, CG came to work but still experienced itching body and "hard to breath" when wearing surgical mask (required at work). CG was sent home and saw primary care physician (PCP) via virtual visit. Per PCP's evaluation, CG has had "delayed allergic reaction" to COVID-19 vaccine. PCP recommended CG to continue with Benadryl and Albuterol inhaler until recheck on January 4 for re-evaluation and discussion on preparation of 2nd dose with steroid and EpiPen. CG would like to complete the vaccination series to receive 2nd dose. As of today, 12/29/20- CG stated she still has shortness of breath and itching and will be off work until re-evaluation by PMD on Jan 4, 2021. Reviewed CG's consent form of COVID-19 Vaccine- Date received 12/23/20 @3:37pm. Answer of NO to question ?Do you have a history of severe allergic reaction (e.g. anaphylaxis) to another vaccine or injectable medication??
912879	12/29/2020	NY	63	F	12/29/2020	12/29/2020	Patient (aRN) felt dizzy was tachycardiac stayed in area for 1 hr symptoms persisted then was taken to ED there was no evidence of Anaphylaxis is. Patient states she was given to large of dose RN administering denies states gave 0.5 IM she was monitored for several hours because patient has cardiac history
912867	12/29/2020	CA	40	F	12/23/2020	12/23/2020	Patient is a 40 y.o. female with no known past medical history brought to ED with concern for ALOC after getting the COVID vaccination 30-40 minutes PTA. Pt is a nurse and experienced decreased level of consciousness following her COVID vaccinationn. Pt reports h/o anaphylaxis. She was given epinephrine PTA. Denies SOB, oral swelling, CP. BGL within normal limits. Pt denies any other complaints or symptoms at this time.

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911283	12/29/2020			U	12/1/2020	12/1/2020	anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the fourth of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: AK 5730, EG 1685), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Dec2020. The clinical outcome of anaphylaxis was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020505820 different patient/same drug/event
912619	12/29/2020	IL	38	F	12/16/2020	12/16/2020	Right side tongue numbness, tingling and burning in/around lips, elevated heart rate 136+, Blood pressure spike 165/105. Shortness of breath believed to be r/t elevated heartrate. Within 10 mins of shot. Face flushed, redness worsened with some swelling to ears and tongue skin felt like a sun burn rawness. Throat tugging noted. Dispatched an ambulance, had my husband take me around corner to ER where I was treated for anaphylaxis with 1 dose of Epi IM, IV solumedrol, and two rounds of benadryl IV. I was monitored and sent home on steroids, benadryl, and cimetidine for several days. I was issued an Epi Pen at that time. The rash and redness with feeling of burning has come and gone since as well as the tongue numbness on right side.

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912301	12/29/2020	AZ	43	F	12/26/2020	12/26/2020	<p>In Clinic: Pt received Moderna vaccine on right arm. She immediately felt numbness and tingling sensation on both shoulders and right neck. Neck felt tight, pain and + weakness on left wrist and 4th / 5th digit. BP was 149/78, O2 sat 99%, pulse 82. Pt then felt nausea, dizziness, burning sensation of left thigh, "not feeling well". Pt abvle to move all extremities, denies SOB. Hx of allergic reaction to Reglan and compazine. Repeat Vitals: 160/74, pulse,83,O2sat 100%, 2 pm: 135/85, pulse 75, O2 sat 99% Paramedics was called and arrived at 2:11 pm. Pt to be further evaluated in ER. In ED: Gen: Patient is in NAD, non-toxic appearing, cooperative HEENT: NC/AT, MMM, no conjunctival injection, b/l sclera anicteric. Mallampati 1 oropharynx clear, no exudates, tonsils within normal limits. No edema or erythema. Neck: Supple. Cardiovascular: RRR Pulmonary/Chest: CTAB, no increased WOB, no respiratory distress, no wheezes/rhonchi/rales, chest wall tenderness. Abdominal: Soft. NT/ND, no r/g, no masses Extr/MSK: Well perfused, distal pulses intact. No tenderness. No LE edema. Back: No CVAT Neuro: No evidence of facial droop, normal speech, mentation appropriate, steady gait. Sensation intact to light touch to upper lower extremities. Cranial nerves 2-12 within normal limits. Psychiatric: Normal affect. Mood not labile nor depressed. Skin: No rashes, lesions, or wounds appreciated on exposed skin. ED Course & Clinical Decision Making: 43 year old female with PMHx as listed in HPI presents with intermittent numbness after receiving the coronavirus vaccination. - History of present illness also notable for symptoms started 20-30 minutes after receiving the coronavirus vaccination. - Vitals reviewed and all wnl - Physical exam notable for neurologically intact, no rashes, no airway abnormalities, otherwise unremakrable. - Given above findings, presentation is concerning for side effects from the coronavirus vaccination, electrolyte abnormality. Will check basic lab work here in the emergency department. Will give symptomatic control with 1 L of IV fluids and Zofran for the nausea. Will monitor here in the emergency department. Disposition pending clinical improvement. Lab work grossly unremarkable here in the emergency department. Mild hypo phos of 2.6. Electrolytes otherwise within normal limits. No leukocytosis. Hemoglobin of 10.2, no baseline but the</p>

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							<p>patient does have a history of chronic anemia given uterine fibroids. The patient was able to ambulate with steady gait. She continues to have burning sensation to her left leg and her right arm. She will be given lidocaine patches for symptomatic control. She also be given ibuprofen 600 mg. Return precautions returning to the patient. At this time presentation does not appear consistent with anaphylaxis. Min presentation most consistent with side effects from coronavirus vaccination. Patient tolerated p.o. here in the emergency department. She was able to ambulate with steady gait. Symptoms mildly improved after lidocaine patch and ibuprofen. Return precautions given. Patient re-evaluated and is stable for discharge. At this time, suspicion is low for acute injury/illness requiring hospital admission or emergent intervention. No indication for inpatient management; No medical or surgical emergent care needed at this time. However, it was stressed to the patient that symptoms may persist or worsen, in which case she should be reevaluated. Patient should also get appropriate and timely follow up for further evaluation and continuation of care. The patient indicates understanding of these issues. Patient is ready for discharge. Return precautions (advised to return to ER if their symptoms persist, change, or worsen) and follow up plan reviewed with patient and understood.</p>
912285	12/29/2020	CO	26	F	12/23/2020	12/23/2020	<p>Received Moderna vaccine, approximately 11:40AM. Onset of throat fullness, tongue fullness about 12:30 PM Mild difficulty swallowing associated. ANAPHYLAXIS, INIT - diphenhydrAMINE Injection 50 mg (BENADRYL) - EPINEPHrine (ADRENALINE/EPIPEN) 0.3 mg/0.3 mL Injection AutoInjector; Inject 0.3 mL intramuscularly as needed for severe allergic reaction . Inject in upper thigh - predniSONE (ORASONE) 20 mg Oral Tab; Take 2 tablets by mouth daily with a meal Mild reaction. Improved with PO Benadryl. Reviewed home care, handout provided. Home epi prescribed. Prednisone 2 day course.</p>

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911281	12/29/2020			U	12/1/2020	12/1/2020	anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the second of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: AK 5730, EG 1685), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Dec2020. The clinical outcome of anaphylaxis was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020505820 different patient/same drug/event
911285	12/29/2020			U	12/1/2020	12/1/2020	anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the sixth of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: AK 5730, EG 1685), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Dec2020. Therapeutic measures were taken as a result of the event and included administration of epinephrine (MANUFACTURER UNKNOWN). The clinical outcome of anaphylaxis was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020505820 different patient/same drug/event

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912201	12/29/2020	NY	62	F	12/18/2020	12/19/2020	redness above eyebrow, nose and cheek and left hand had few reddened marks on skin, neck had a thin red line; right eyebrow was swollen and neck had a thin red line; The initial case was missing the following minimum criteria: unspecified event. Upon receipt of follow-up information on 23Dec2020, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable nurse. A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EK5730), intramuscularly in the left deltoid on 18Dec2020 10:30 at a single dose for COVID-19 immunization. Medical history included hypertension (diagnosed at 47 years old), hypothyroidism, Hashimoto's disease from 2000 to an unknown date (diagnosed 20 years ago), anxious person and weight loss. Concomitant medication included hydrochlorothiazide (MANUFACTURER UNKNOWN), taken for blood pressure from 2000 to an unspecified date, levothyroxine sodium (SYNTHROID), taken for hypothyroidism and Hashimoto's disease from 2015 to an unspecified date, rosuvastatin calcium (CRESTOR), taken prophylactically from 2010 to an unspecified date and semaglutide (OZEMPIC) taken for weight loss from May2020 to an unspecified date. Family history included; the patients mother had an allergy to Sulfa and allergy to penicillin and the patients father had unspecified allergies and hay fever. There were no prior vaccinations within 4 weeks. On 19Dec2020, the patient experienced redness above eyebrow, nose and cheek and left hand had few reddened marks on skin, neck had a thin red line and right eyebrow was swollen. The reporter considered the events to be non-serious. The patient was worried about anaphylaxis, so they went to the emergency room (ER) for the reported events but was not admitted. The patient was treated in the ER for the events with diphenhydramine hydrochloride (BENADRYL), prednisone (MANUFACTURER UNKNOWN) and famotidine (PEPCID). Relevant tests were none. The outcome of the events was recovering. The reporter stated that there was a reasonable possibility that the events were related to the suspect product.

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912166	12/29/2020	MO	50	F	12/29/2020	12/29/2020	Upon registration, pt informed staff she normally gets hives and itching with flu vaccine. Pt received COVID vaccine at 1205. Pt sat down in monitor area at 1209. At 1221, pt stated she started to feel slight itching. At 1230, pt stated itching had increased. RN also noted redness to neck. Pt denied any SOB, difficulty breathing, tingling in mouth, or any other anaphylactic symptoms. At 1234, RN gave 25mg Benadryl orally. Pt requested to receive smaller dose instead of the entire 50mg. Pt stayed to be monitored until 1255. No other symptoms noted. Pt educated to monitor for further signs of anaphylaxis.
912099	12/29/2020	VA	31	M	12/29/2020	12/29/2020	Approx 25 minutes after vaccination, client developed mild, red, raised rash with itching on lateral left wrist distal to injection site. Client denies any other adverse signs/symptoms of angioedema or anaphylaxis 1 hour after administration of vaccine.
912018	12/29/2020	MI	41	F	12/23/2020	12/23/2020	Anaphylaxis requiring epinephrine
911998	12/29/2020	MI	42	F	12/22/2020	12/22/2020	Anaphylaxis requiring epinephrine
911732	12/29/2020	ME	58	F	12/28/2020	12/28/2020	At 8:50 AM she developed nausea, diffuse headache, malaise, tingling of her hands, elevated blood pressure and metal taste in mouth. She denied any trouble breathing. No swallowing difficulty, swelling of the tongue or lips observed. Subject stated she did not feel safe driving and was brought to ED by EMS. She has a history of fibromuscular dysplasia and is on aspirin and Plavix. Emergency Department ASSESSMENT and PLAN This is a 58 y.o. female who presents with vaccination side effects. She is well-appearing on exam. There is no evidence of airway swelling or anaphylaxis. Will observe. 11:34 AM Has been observed for 2 hours and her symptoms have not worsened. She did take her own dose of Tylenol for headache. She is comfortable returning home. She does have the Moderna fact sheet and we discussed signs and symptoms of when to return. She is comfortable with plan. All questions were answered.~~

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911462	12/29/2020	OK	62	F	12/18/2020	12/18/2020	she is better but still not good; not to be able to breath; sore right arm; This is a spontaneous report from a contactable nurse (patient herself). A 62-year-old female patient received bnt162b2 (BNT162B2, lot EK5730), intramuscular on 18Dec2020 at single dose for immunisation. Medical history included asthma (hospitalized on Jan2020 and has not had any issues since that time, referring to her asthma) diabetes, high blood pressure, swelling, sciatica, blood cholesterol abnormal, rosacea, reflux, allergies, sinus congestion, shingles and post carpal tunnel surgery. Concomitant medications included lisinopril, hydrochlorothiazide, gabapentin, rosuvastatin, metformin, glipizide, doxycycline, sucralfate, cetirizine hydrochloride (ZYRTEC), pseudoephedrine, ascorbic acid, ergocalciferol, nicotinamide, retinol, riboflavin, thiamine hydrochloride (VITAMINS) and tramadol. The patient reported that she not to be able to breath (seriousness criteria-life threatening) on 22Dec2020. She woke up this morning and could not breathe and there was no reason for her to not be able to breath. She thought she may have had a reaction to the COVID vaccine. It was the only thing she could think of that might have caused her not to be able to breathe this morning. As treatment for not to be able to breath, she used Budesonide and Levosalbutamol in her nebulizer. She had sore right arm on 18Dec2020. She informed that she had done everything she can and she was better but still not good. She planned to take the second dose of the COVID Vaccine because she thought it was more important to be protected. She suspected that the vaccine was related to the events sore right arm and could not breathe. The outcome of the event not to be able to breath was recovering; for sore right arm was recovered on unknown date in Dec2020; for she is better but still not good was unknown.; Sender's Comments: Severe allergic reaction including anaphylaxis is the known risk factor; a possible causal association between administration of BNT162B2 and the onset of not being able to breath cannot be excluded, considering the plausible temporal relationship and the known adverse event profile of the suspect product. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any

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911420	12/29/2020	KY	36	F	12/21/2020	12/21/2020	<p>safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p> <p>itching skin; injection site immediately red and hot; injection site immediately red and hot; could not locate hives or welts; This is a spontaneous report from a contactable pharmacist. A 36-year-old female patient (pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730), intramuscularly on 21Dec2020 13:15 at single dose on left arm for COVID-19 immunization. Medical history included anaphylactic reaction to food, Anaphylaxis to sesame and lidocaine, had never had anaphylactic reaction to vaccines in past. The patient's concomitant medications were not reported. The most recent COVID-19 vaccine was administered at Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 21Dec2020 13:15 (01:15 PM), the patient experienced itching skin, could not locate hives or welts, injection site immediately red and hot, no wheezing observed, no tachycardia observed. Treatment included observed for an hour, ice pack on injection site x2, 50mg diphenhydramine hydrochloride (BENADRYL), 1 10mg cetirizine hydrochloride (ZYRTEC), 20mg famotidine (PEPCID). Advised to pre-medication prior to booster dose and alert vaccinator of this reaction to be prepared. The events were non-serious. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. The outcome of the events was recovered in Dec2020.</p>

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911414	12/29/2020	NY	60	F	12/17/2020	12/20/2020	Joint pain and swelling 3 days after the first dose. Affected joints: right elbow, right wrist and right third interdigital joint; Joint pain and swelling 3 days after the first dose. Affected joints: right elbow, right wrist and right third interdigital joint; This is a spontaneous report from a contactable consumer (patient). A 60-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EK5730), via an unspecified route of administration on left arm on 17Dec2020 at single dose for COVID-19 immunization. Medical history included wasp venom with anaphylaxis. There were no concomitant medications (No other-vaccine-in-four weeks, no other-medications-in-two weeks). The patient previously Stage 4 breast cancer in remission on Xeloda. The patient experienced joint pain and swelling 3 days after the first dose. Affected joints: right elbow, right wrist and right third interdigital joint on 20Dec2020. All events were reported as non-serious. The patient did not receive treatment for the adverse events. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The outcome of events was not recovered.
911284	12/29/2020			U	12/1/2020	12/1/2020	anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the fifth of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: AK 5730, EG 1685), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Dec2020. Therapeutic measures were taken as a result of the event and included administration of epinephrine (MANUFACTURER UNKNOWN). The clinical outcome of anaphylaxis was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020505820 different patient/same drug/event

<i>VAERS_ID</i>	<i>RECVD</i>	<i>STATE</i>	<i>AGE_YRS</i>	<i>SEX</i>	<i>VAX_DATE</i>	<i>ONSET_DATE</i>	<i>SYMPTOM_TEXT</i>
911280	12/29/2020			U	12/1/2020	12/1/2020	anaphylaxis; This is a spontaneous report from a non-contactable consumer. This consumer reported similar events for six patients. This is the first of six reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: AK 5730, EG 1685), via an unspecified route of administration in Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis in Dec2020. The clinical outcome of anaphylaxis was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2020505821 different patient/same drug/event;US-PFIZER INC-2020505822 different patient/same drug/event;US-PFIZER INC-2020505823 different patient/same drug/event;US-PFIZER INC-2020505824 different patient/same drug/event;US-PFIZER INC-2020505825 different patient/same drug/event
910907	12/28/2020	MN	37	M	12/22/2020	12/22/2020	Anaphylaxis symptoms starting about 45 minutes after injection. Initial symptoms were severe light headedness and tachycardia. Epi-pen self administered 5 minutes after onset of symptoms. Symptoms resolved within 30 minutes of Epi-pen administration.
910221	12/28/2020	IN	47	F	12/26/2020	12/26/2020	Patient experienced dizziness, sweating, and nausea in the 15 minutes following vaccination. Patient was taken to the emergency department, all vital signs were normal, no symptoms of anaphylaxis. Patient stayed in emergency department for further monitoring
911092	12/28/2020	TX	36	M	12/28/2020	12/28/2020	Pt developed hives on bilateral arms, wrist and hands. Vital signs stable, no other complaints of tongue or throat swelling. No other s/s of anaphylaxis. Pt given Benadryl 50 mg po and observed for 60 minutes. Hives resolved and patient sent home.
909988	12/28/2020	FL	56	F	12/28/2020	12/28/2020	Anaphylaxis - epi pen X 2, transported to the ED for evaluation and further treatment.

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910337	12/28/2020	IL	28	F	12/18/2020	12/18/2020	vaccine at 11:30 am on 12/18/20 and after 15 mins she felt the room started to spin, dizzy and tunnel vision. nausea and dry heaves also 2-3 mins after. persistent dizziness. pruritic rash and was taken to the ER by wheel chair. About an hour after the vaccine, she felt something in the back of her throat, speech ok, able to swallow. No SOB. She was treated with benadryl, pepcid, zofran and fluid. She felt very hot and shaking. In the ER, she noticed that the rash had progressed to her back. Notes chest redness, back with erythematous, raised pruritic bumps on back and arm (smaller size of dime) Within 4 hours of treatment, she had improved. That night at 2am she had a rash -not as pruritic. She took more benadryl. No rash after. No new meds, no NSAIDs. She has never had any medical problems or rashes before. Her symptoms are concerning for anaphylaxis but it is reassuring that her vitals were ok and that she did not progress and improved with benadryl and pepcid - advised to not get 2nd vaccine dose - will plan on skin testing her in the future
910338	12/28/2020	NH	23	F	12/18/2020	12/19/2020	Arm pain and Migraine .. Took Migraine medication and that's when I had a anaphylaxis reaction . I have an appointment to see a specialist to verify if the reaction was caused by the COVID vaccine or the medication I took that day

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910595	12/28/2020	RI	57	F	12/21/2020	12/21/2020	broke out in hives on face and hoarseness, tightness in throat; broke out in hives on face and hoarseness, tightness in throat; broke out in hives on face and hoarseness, tightness in throat; throat pain, coughing; throat pain, coughing; This is a spontaneous report from a contactable Other HCP. This Other HCP reported for self that the 57-year-old female patient received first dose of bnt162b2 (BNT162B2, Brand Pfizer), via unknown route of administration in Left arm on 21Dec2020 12:00 PM at single dose for covid-19 immunisation. Medical history included Known allergies to medications, food, or other products: Azithromycin Flushing, Spinach-anaphylaxis, mild allergic reactions to the Ocrevus, azure and Seasonal allergies, Multiple Sclerosis, Irritable bowel syndrome (IBS-C), post herpetic neuralgia. Concomitant medications included other medications the patient received within 2 weeks of vaccination baclophen, clozapine (KLOPIN), ocrelizumab (OCREVUS), sertraline, cetirizine hydrochloride (ZYRTEC [CETIRIZINE HYDROCHLORIDE]), mo. She is not pregnant at the time of vaccination. Facility type vaccine was Hospital. No other vaccine in four weeks. The patient experienced within 15 to twenty minutes of vaccine, broke out in hives on face and hoarseness, tightness in throat then sent to ED where hives continued to form on back the arms, throat pain, coughing, hoarseness increased from 21Dec2020 12:15 AM. AE resulted in: [Emergency room/department or urgent care]. Outcome of the events was unknown. Treatment received included Epinephrine, solumedrol, Benadryl IV. No covid prior vaccination. Covid tested post vaccination. Covid test post vaccination: covid test type post vaccination was Other, covid test name post vaccination was Nasopharyngeal Sofia2 SARS Antigen on 21Dec2020 with result of Negative. Facility where the most recent COVID-19 vaccine was administered was Hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, has the patient been tested for COVID-19. Test Name was Nasopharyngeal Sofia2 SARS Antigen. Vaccine Facility information available. Information on the lot/batch number has been requested.; Sender's Comments: Based on the close temporal relationship, the association between the reported events with BNT162b2

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910604	12/28/2020	TX					
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can not be completely excluded. Medical history of known allergies may have predisposed patient to react this way. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Developed vomiting, four to five times; Diarrhea; Abdominal pain; Slightly flushed face and minimum facial flowing; Numb ears/Numb body; Bleeding; Anaphylaxis; This is a spontaneous report from a contactable consumer. A 43-year-old female patient received bnt162b2, via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced anaphylaxis on 20Dec2020. Clinical course: the patient received the COVID vaccine on 19Dec2020, and since then she had developed onset of vomiting after 3 o' clock this morning on 20Dec2020, four to five times, numb ears, numb body. She also had diarrhea and bleeding. She had some abdominal pain and she also complained of having slightly flushed face and the minimum facial flowing. The outcome of events was unknown. Information for Lot/Batch number has been requested.; Sender's Comments: There is a reasonable possibility that the event anaphylaxis was related to BNT162b2 based on known drug safety profile. Based on the close temporal relationship, the association between the event bleeding with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

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910811	12/28/2020	WV	62	F	12/28/2020	12/28/2020	Patient with a history of severe anaphylaxis was observed for 30 minutes post vaccine. Right at the 30 minute mark, patient started to look pale, started with frequent throat clearing followed by sense of shortness of breath and chest tightness. 2:37p: No wheezing, good air movement, breathing was not labored, no cyanosis, no noted lip or tongue edema, able to speak. BP 160/54. P 98, O2 sat 98%. Severity of symptoms per patients = 8/10 "tightness" at time of medical evaluation/medical provider response. 2:38p 911 called, 2:39p epipen, benadryl 50mg oral, and solumedrol 125mg IM administered (patient tolerated well, able to swallow) 2:42p patient reports symptoms improved to ~4/10 severity O2 sat 98%, P97 2:46p , O2 96%, P 99, BP 148/52 2:48p patient reports symptoms still at ~4/10 severity/stopped improving, O2 sat 95%, p 85; discussed option of doing 2nd epipen 2:54p EMS arrived prior to administration of second epipen. Patient transported to Emergency Department for further evaluation for possible anaphylaxis
911052	12/28/2020	CA	49	F	12/28/2020	12/28/2020	Tingling and numb feeling at back of tongue immediately after injection Weird sensation of lump in throat without anaphylaxis that got better with time
910718	12/28/2020	WI	26	F	12/28/2020	12/28/2020	Warm, tingling & numbness 10 minutes post injection. Monitoring indicated elevated HR & BP. Team member released after 50 minutes. TM was driving to her clinic and developed left side numbness to her cheek, upper arm and lower left back areas. Supervisor completed incident report and had team member go to urgent care and then went to ER. TM drove herself. ER provider Dr. contacted EH and informed us that TM did not have anaphylaxis and has no known allergies. She also drew CBC, Mag, Urine pregnancy & performed a CT scan w/o contrast to rule out kidney stone. No significant findings were noted.

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909607	12/27/2020	CT	41	F	12/18/2020	12/22/2020	Received Pfizer COVID-19 vaccine without untoward effects on 12/18. Given her usual allergy shot by her allergist on 12/22 (she has been receiving these for several years; I was told this is a protein antigen in a glycerine suspension). Within 15 minutes, patient developed anaphylaxis: generalized erythema, swelling, pruritus and hypotension requiring epinephrine, and diphenhydramine. Patient recovered over several hours.
909447	12/26/2020	TX	42	F	12/26/2020	12/26/2020	Moderna COVID-19 Vaccine Vaccine administration was okay and without issue. Patient reports having sensation of "vice around heart" that spontaneously resolved less than 5 minutes after injection. No anaphylaxis or shortness of breath, but sensation of tightness in chest that subsequently resolved within the 10-15 minutes after injection.
909309	12/26/2020	CT	20	F	12/23/2020	12/24/2020	Full body hives beginning about 36 hours after vaccination. Angioedema in the hands, feet, and lips beginning about 48 hours after vaccination. Hives did not improve with Benadryl so doctor prescribed prednisone. No severe reaction such as anaphylaxis, but reaction was moderate enough to make daily life difficult.
909209	12/26/2020	PA	35	M	12/24/2020	12/24/2020	Mild anaphylaxis with angioedema of the tongue within minutes of injection.
909952	12/24/2020	TN	70	F	12/23/2020	12/23/2020	approx. one hour after receiving vaccine pt started having throat tightness, nausea, lips tingling, SOB and "feeling weird". States has had anaphylaxis in the past from nuts and uses an EPI pen. States she used her pen but did not get relief so went to ER where she received IV benadryl, tagment and steroids. EKG was abnormal. States no problems at injection site. F/U with patient approx. 7 hours after incident and pt states she is doing fine and not having any issues now.
909000	12/24/2020	CA	63	F	12/21/2020	12/23/2020	Subsequent idiopathic anaphylaxis event 1 1/2 days later

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908464	12/24/2020	NY	42	M	12/22/2020	12/22/2020	Patient received the COVID-19 vaccine. Patient described feeling dizzy and light headed. Patient placed on floor. Syncopal event / vaso-vagal. No signs of anaphylaxis or allergy, but epipen 0.3mg was administered. antecubital IV line placed for access if needed. Patient taken to ED for observation. Returned to duties within 1 hour of the event.

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908262	12/24/2020	NY		F	12/17/2020	12/17/2020	Anaphylaxis; This is a spontaneous report from a contactable pharmacist. A 55-year-old female patient received the bnt162b2 (BNT162B2; also reported as: PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. The patient's medical history included eosinophil process allergic reaction, fish, iodine and shellfish allergy; all from an unknown date and unknown if ongoing. Concomitant medications were not reported. The patient previously took rabies vaccine for immunization and experienced anaphylactic reaction on an unspecified date. On 17Dec2020, the patient experienced anaphylaxis; which required hospitalization, and was assessed as medically significant. The patient was hospitalized for anaphylaxis from 18Dec2020 to an unknown date. The clinical course was reported as follows: The pharmacist called about a patient who received the COVID-19 vaccine on 17Dec2020 and started having a reaction approximately 30 minutes later. The patient used epinephrine (EPIPEN) and 50 mg of diphenhydramine hydrochloride (BENADRYL) and returned to the hospital on 18Dec2020. The patient was currently in the intensive care unit (ICU) receiving an epinephrine drip. The patient had a previous history of an anaphylactic reaction to the rabies vaccine, eosinophil process allergic reaction, fish, iodine and shellfish allergy. The patient was stabilized but continued to have reactions (not specified). The pharmacist had not seen the patient and was reaching out to Pfizer on behalf of the physicians. The pharmacist believed this had been reported by the hospital. The pharmacist had no patient information. Therapeutic measures were taken as a result of anaphylaxis. The clinical outcome of the event, anaphylaxis, was unknown. The batch/lot numbers for the vaccine, BNT162B2, were not provided and will be requested during follow up.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event anaphylaxis due to temporal association. However patient previous history of allergic reaction cannot be excluded to have played a contributory role

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907187	12/23/2020	SC	48	F	12/17/2020	12/17/2020	Possible allergic reaction - paresthesias of L tongue and throat; Possible allergic reaction - paresthesias of L tongue and throat; Possible allergic reaction - paresthesias of L tongue and throat; Sensation of tongue and throat swelling; Sensation of tongue and throat swelling; This is a spontaneous report from a contactable Health Care Professional. A 48 years old non-pregnant female patient received BNT162B2 (Pfizer-Biontech covid-19 vaccine) on 17Dec2020 at 15:15, at single dose, for COVID-19 immunisation. The vaccine was administered at hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Relevant medical history included food and drug allergy. The patient received concomitant medications (unspecified, received within 2 weeks of vaccination). Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient has not been tested for COVID-19. On 17Dec2020 at 15:15, the patient experienced possible allergic reaction - paresthesias of L tongue and throat, with sensation of tongue and throat swelling. No anaphylaxis. No abnormal physical exam findings. Emergency Room Visit required and the patient received the following treatment: diphenhydramine hydrochloride (BENADRYL), prednisone, and loratadine (CLARITIN). Clinical outcome of the adverse events was unknown at time of this report. The case was assessed as non-serious. Information on the lot/batch number has been requested.

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907574	12/23/2020		55	M	2/18/2020	12/18/2020	Approximately one hour after receiving the vaccine, as the patient was driving home he began experiencing throat tightness and tongue swelling. Once home, they call 911 and administered 0.3 epi (had previous severe allergy to lidocaine). EMS then administered iv benadryl and an albuterol treatment. The patient was reported to go unresponsive en route and received bag and mask ventilation very briefly as well as additional 125g solumedrol and another IM epi injection. On arrival he was reported to be stable, talking, tolerating secretions, without significant complaints. He was observed in the ER for several hours without any symptoms nor objective findings to support anaphylaxis (tongue and airway normal, no wheeze, no rash). He was anxious in the ER and the treating physician wrote that he felt it may likely have been anxiety and not anaphylaxis based on their evaluation.
907256	12/23/2020	AK	35	F	12/22/2020	12/22/2020	*Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.) S: 35 yo F who received Pfizer vaccine at 16:47 w/acute onset of left sided facial swelling and difficulty swallowing. Within five minutes of being administered vaccination, pt reported pain at the injection site radiating up to her jaw followed by left sided facial swelling. She started reported palpitations and subsequently reported a ball in her throat O: Pulse was in the 60's, BP of 128/72, pulse of 88-97 satting at 99% on RA. General: young female, anxious. HEENT: NC, AT, mild left sided cheek swelling, OP clear, MMM. Neck: Supple, left sided tender cervical LN. Lungs: CTAB. CV: tachycardic rate, regular rhythm. Extremities: Hands are clenched and cold. Neuro: Alert & oriented. A/P: Anaphylaxis -Given left facial swelling, 25 mg Benadryl PO administered. pt tolerated well. -17:22-Throat swelling reported. EPI #1 administered right thigh. -17:32-EPI #2 administered. Throat felt better at 17:35. 17:36-FD EMS arrived. BP 194/126. -17:38-EPI #3 administered right thigh. HR 135, BP 154/105. -17:43-EPI #4 administered left thigh. -17:46 pt transported to ER via EMS.
907173	12/23/2020	NC	52	F	12/22/2020	12/22/2020	Anaphylaxis reaction with hives, stridor/airway edema, wheezing

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907911	12/23/2020	KS	67	F	12/21/2020	12/21/2020	Patient with past medical history significant for thyroid cancer was given Pfizer COVID-19 vaccine at approximately 1430 at our facility. After receiving vaccine patient felt flushed, face hot, felt something squeezing neck (similar to tight collar). 25 mg PO diphenhydramine given X 1. Patient having shivering on and off. Felt swelling progress up into back of throat. Had to clear throat and swallow harder. At 1511 patient was checked into the emergency department at our hospital. At 1527 famotidine 20 mg IV once given. BP was found to be 232/100. Amlodipine 5 mg IV once given at 1909. Labetalol 10 mg IV once given at 1812, labetalol 20 mg IV once given at 2034, clonidine 0.1 mg PO once given at 2127. Patient sent home at approximately midnight. Diagnosed with possible anaphylaxis and hypertensive urgency (no history of HTN).
907616	12/23/2020	NM	53	F	12/18/2020	12/18/2020	12-22 HPI 53-year-old female with a history of Addison's disease, anaphylactic reaction who presents to the ED complaining of hives and shortness of breath. Patient reports that 3 days ago she received the COVID-19 pfizer vaccine. She reports that since that time she has developed progressively worsening hives on her legs and arms. Approximately 1 hour ago she began to develop shortness of breath and so she presented to the ER. Patient reports a previous history of anaphylactic reactions multiple times. Denies any other acute complaints at this time. MDM Patient came in with shortness of breath and hives. Suspect allergic reaction to the COVID-19 vaccine. Patient had already taken 50 mg of Benadryl. She was given Solu-Medrol and EpiPen. She reported feeling better with improvement in the pruritus. She reports that she has had rebound reaction requiring EpiPen at 24 hours. Given the distance that she lives from adequate medical care and the possibility for recurrent severe reactions, the patient will be hospitalized for further observation. 12-23 Female with history of asthma and addison's had anaphylaxis to covid vaccine. Admitted over night to ensure that she did not rebound. Received IV Dex and this am has had no reoccurrence of hives or shortness of breath. Will discharge home on epipen, hydrocortisone prn, prednisone bid for 5 days. Return to ER or go to PCP for worsening symptoms.

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906684	12/22/2020	NJ	38	F	12/19/2020	12/19/2020	sensation in throat/a menthol cough drop stuck in the throat; flushed; diaphoretic; burning into my chest; some random hives; This is a spontaneous report from a contactable consumer (patient herself). A 38-year-old female patient received first dose of bnt162b2 (lot number: EL0140), via an unspecified route of administration at site of left arm at 11:30 on 19Dec2020 at single dose for COVID-19 immunization. Medical history included Oral Allergy Syndrome, ADHD (attention deficit hyperactivity disorder), multiple food allergies, and allergies: PCN, Ceclor and Lovenox multiple. Concomitant medication included cetirizine hydrochloride (ZYRTEC), montelukast sodium (SINGULAIR), diphenhydramine hydrochloride (BENADRYL) and amphetamine aspartate, amphetamine sulfate, dexamphetamine saccharate, dexamphetamine sulfate (ADDERALL). Within minutes after vaccination, the patient became flushed and diaphoretic followed by a sensation in her throat, it felt that she had a menthol cough drop stuck in the throat and the burning into her chest. Once the medics administered IV Benadryl, the sensation in her throat went away. She was in the emergency room for about 3 hours and had some random hives throughout the rest of the evening. She had anaphylaxis previously to avocado and to an allergy shot. This was definitely nothing close to anaphylaxis. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of events was recovered in Dec2020.
907052	12/22/2020	UT	41	M	12/22/2020	12/22/2020	Pt with dizziness and chest pain that started about 10 minutes after getting the Moderna Covid19 vaccine. No shortness of breath, no rash, no fever, no swelling, no weakness. Feels pain in center of chest and on L side. Pt also has been having stress with work. Pain started in the R side of the chest and migrated to the L side. It improved with Nitro and Aspirin but pt states he still feels, "fussy." He has no symptoms of allergic reaction or anaphylaxis. Pt has no known hx of cardiac dz, nonmoker, nondrinker. His Mom has a cardiac murmur but no other known history of heart disease.

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907160	12/22/2020	CA	54	F	12/21/2020	12/21/2020	(I'm a physician who received the vaccine at my medical clinic). 5 minutes after receiving the vaccine, I felt very dizzy and faint. We checked my BP (which is usually 120/70; I do not have hypertension), and it was 190/120, HR 120-130 bpm. We rechecked it several times and it stayed there. After 5 minutes, I suddenly felt better and my BP had dropped to 140/70, HR 70. I felt exhausted. No other problems. They watched me for 30 minutes and I felt fine. I had my husband drive me home. As we were driving home (now one hour after the vaccine), I realized that my throat was closing up. I was breathing fine but I realized I was having an anaphylactic reaction from the vaccine. I have never had any allergic reactions before to vaccines, etc. He drove me back to the emergency room of my hospital, where they diagnosed me with an allergic reaction/anaphylaxis to the vaccine. They gave me emergently IV solumedrol (steroids), pepcid, and benadryl, which fortunately worked immediately. They observed me for several hours and I was fine. They sent me home. The next morning, I felt exhausted and my throat was hoarse and sore, but that went away several hours later. It was a terrifying, terrible experience. I thought I was going to die. I had to pay \$1000 out of pocket for the ER deductible.

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906056	12/22/2020	MI	29	F	12/21/2020	12/21/2020	<p>Patient notes that she received the COVID vaccine around 1800 today. After receiving the vaccine she notes she had developed a headache. She was otherwise doing fine until around 2000-2100 when she noticed her left arm become numb with paresthesias from her left bicep to her hand with whole arm localization. She felt her hands and wrists were puffy at this time and somewhat swollen. She reports feeling "floaty"/Dizzy at this time, and at least once had to sit down due to this. She started feeling her heart race and some associated SOB, this has since resolved. She notes that she had two loose stools around this time as well. This progressed to develop into right numbness/paresthesias from her mid right forearm down to her hands. As the evening progressed she developed itchiness of her bilateral arms and torso. She notes that she has had a waxing/waning reddish rash on her arms that has been pruritic. She has since developed intermittent nausea, and still endorses feeling some "skipped beats." While in the ED from Triage to repeat evaluations her lips began having progressive swelling. She had been given Benadryl 50mg, Zofran 4mg, 1L IVF. Given ongoing tachycardia and lip swelling she was given Prednisone 40mg and Epinephrine for allergic reaction and concern for anaphylaxis.</p>

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906123	12/22/2020			F			waves of flushing through out her body; severe dry mouth; nausea; elevated heart rate into 120s; panic attack; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in 2020 (at 0810 her time) at single dose for immunization. The patient's medical history and concomitant medications were not reported. The reporter is a Certified Nursing Assistant (CNA) who received the Covid 19 vaccine at 0810 her time. Five minutes after receiving the vaccine (2020) she reported having three episodes of the following symptoms: waves of flushing through out her body, severe dry mouth, nausea and elevated heart rate into 120s. She denied any shortness of breath, swelling or anaphylaxis. She was treated in the Emergency Room (ER) with fluids and lorazepam (ATIVAN) and sent home. She contacted her doctor who advised she was probably having a panic attack and was told her to take lorazepam. She reported sleeping when she got home but experienced the elevated heart rate and flushing again after waking. She spoke to her doctor a second time and was told to return to the ER to be treated for the elevated heart rate. She did not go to the ER because she took more lorazepam and the HR declined into the 90's. She stated her doctor was prescribing a beta blocker for her but advised to go to the ER if her heart rate goes over 100 again. She would like to report and Adverse Event. The outcome of the events was unknown. Information regarding lot/batch has been requested.; Sender's Comments: Based on the information available as reported at this point, a possible contributory role of the suspect products cannot be excluded for the reported event flushing, dry mouth, heart rate increased, nausea and panic attack due to temporal association.
906495	12/22/2020	CA	51	M	12/19/2020	12/19/2020	11 minutes into the vaccination, patient noted to have tongue and mouth tingling and heart racing. No noted tongue/lip/throat swelling, dyspnea, n/v, abdominal pain, rash, near-syncope. Started to improve after 30 seconds.. H/o tachycardia secondary to salmon, no prior anaphylaxis or use of epinephrine in the past. Sent to ED for evaluation

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906733	12/22/2020	MD	50	F	12/21/2020	12/21/2020	anaphylaxis
906775	12/22/2020	CA	47	F	12/22/2020	12/22/2020	Chills at 5-10 min after vaccination, with voice change and SOB 15-20 min after vaccination concerning for anaphylaxis. Epi given im x1. given immediately at voice change and immediately taken to ED.and currently receiving care
906887	12/22/2020	NY	51	F	12/21/2020	12/21/2020	Pfizer-BioNTech COVID-19 Vaccine EUA: Systemic: Anaphylaxis, Fainting
906988	12/22/2020	AL	52	F	12/22/2020	12/22/2020	PT WAS OBSERVED IN HOLDING AREA LEANING FORWARD IN HER CHAIR ABOUT 7 MINUTES AFTER RECEIVING THE VACINE. RN ASSESSED AND NOTED: AUDIBLE WHEEZE, RESP 40/MIN, LIP SWELLING AND PT COMPLAINED OF NAUSEA. PT WAS ESCORTED TO ER IN WHEELCHAIR ACCOMPANIED BY 2 RN'S (2 MINUTE WALK) ONE HOUR LATER - AS REPORTED BY DR (ER) WORKING DIAGNOSIS - ANAPHYLAXIS / STATUS ASTHMATICUS MEDS RECEIVED: SOLUMEDROL 125, DIPHENHYDRAMINE 50MG, FAMOTIDINE 20MG -- ALL IV EPINEPHERINE 0.3MG IM X1 FOLLOWED BY 0.3MG IV X 1 FOLLOWED BY 0.1MG IV X1 PT IS RECEIVING O2 - AND PROGRESSING TO BIPAP
907022	12/22/2020	OH	44	F	12/22/2020	12/22/2020	Anaphylaxis/Angioedema Patient was given EpiPen 0.3 mg IM; Methylprednisolone 125 mg once; Diphenhydramine 25 mg IV push once; Famotidine 20 mg IV push once; Dexamethasone 10 mg IV push once Patient was intubated and put on propofol and midazolam drips for sedation

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906373	12/22/2020	KY	36	F	12/21/2020	12/21/2020	Pfizer-BioNTech COVID-19 Vaccine EUA On 12/21/2020 13:17 the patient received the first dose of COVID-19 vaccine. During monitoring, the patient experience itching skin. Hives and welts were not located. The injection site was read and hot. No wheezing occurred, no tachycardia observed. The patient report a history of anaphylactic reactions to food (Sesame), but has never had an anaphylactic reaction to vaccines in the past. Patient also reports anaphylaxis to lidocaine. The patient was treated with ice pack on injection site, 50 mg diphenhydramine, 10 mg cetirizine, and 20 mg famotidine. Patient was observed for a full hour. Advised to pre-medicate at 2nd dose and to alert vaccinator of this reaction.
905993	12/21/2020	RI	48	F	12/21/2020	12/21/2020	The patient was in her normal state of good health prior to the vaccination. Almost immediately after receiving the vaccination, she began having a headache, then got an urticarial rash. She then felt a "lump in [her] throat." She was coughing uncontrollably. She was brought immediately to the Emergency Department where I assessed her with my resident. She had signs of a Type I Hypersensitivity Reaction including a hoarse voice, globus feeling and diffuse urticaria. She was treated at the vaccination site in the hospital with Benadryl 50 mg PO prior to ED evaluation and she self-administered Ibuprofen 400 mg. She did not have stridor or airway swelling. She was able to speak in full sentences. She was NOT treated with epinephrine, as she was in stable respiratory condition and improved with Benadryl (as previously administered at the vaccination clinic, Pepcid IV and Solumedrol IV. My concern over this reaction is that the patient has NO PRIOR HISTORY OF ANY ALLERGIES AT ALL. I have read and seen in the media reports of anaphylaxis with a history of allergies, however, this is the first case I have heard of regarding an anaphylactoid reaction in a patient with no prior history.
905133	12/21/2020	TX	45	F	12/19/2020	12/21/2020	anaphylaxis

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904886	12/21/2020	MA	51	M	12/18/2020	12/18/2020	I was ok for first 15-20 mins post vaccine and was sitting in chair and calling family and friends When I stood up I felt 'funny'- kind of hard to describe I walked around and mostly felt ok but not hundred % but didn't feel dizzy but didn't feel 100% myself either I checked my radial pulse and it felt normal and there was no BP machine there to have a check done I left hoping to feel 100% soon I walked to my car in the parking lot and started driving home Around 200 yards from the hospital I felt weird warm rush like feeling through my whole body Knowing that anaphylaxis can occur at this stage I panicked and turned car around and went directly to ER to be checked out My BP was not low and I was observed for short duration and discharged home then- vitals were taken almost half an hour post vaccine Further records can be sought from ER as they should have reported this as well I also had arm pain/malaise and low grade temp of 100.5 at home for 24 hrs that resolved subsequently The initial symptoms within first half an hour made me file this report
904881	12/21/2020	SC	44	F	12/16/2020	12/16/2020	Staff member stated that she had an allergic reaction "after the vaccine"...unsure of time frame and was still at work. She has a rash, hives and swelling around eyes....no immediate anaphylaxis. She verbally described her incident. Was treating with Benadryl (even though there was a stated allergy from 2013), then followed up with her family doctor, for steroid therapy on 12/18. She has not communicated with me further or have any absences from work at this time.

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905300	12/21/2020	TX	39	F	12/20/2020	12/20/2020	39-year-old female with history of ADHD, anxiety, melanoma presents with palpitations. Patient received a Covid vaccine today and started having palpitations, lightheadedness, shortness of breath and feeling flushed a few minutes afterwards. Rapid response called and patient taken to ED for assessment. Patient denies facial or oral swelling, rash. patient denies any recent fever, nausea, vomiting, cough, diarrhea. Denies chest pain, abdominal pain. Last menstrual period end of November. Has allergies to Bactrim and clarithromycin. Presentation concerning for possible vaccine reaction, no anaphylaxis. EKG and labs within normal limits. Patient was rehydrated in the ED. Patient was discharged home on same day (12/20/2020). Pt alert and oriented x 4. Pt ambulated out of ED with a steady gait in no apparent distress.

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905726	12/21/2020	TN	49	F	12/16/2020	12/16/2020	hives on my neck and above my ear/few sparse hives; This is a spontaneous report from a contactable nurse (patient). A 49-year-old female patient received bnt162b2 (BNT162B2) lot number and expiration date were not reported, via an unspecified route of administration on 16Dec2020 at 07:15, 0.3 ml single dose for immunization. Medical history included seasonal allergy and seasonal asthma. The patient's concomitant medications were not reported. The patient stated that she received the product this morning (16Dec2020) at 0715. She mentioned that she took a shower this evening, 13 hours later, and observed hives on her neck and above her ear. She confirmed that she was not having an anaphylaxis and there are no other symptoms. She also denied any soreness at the injection site or pain. She stated that she has no other symptoms and no pain, no soreness. She added that she received vaccine on 16Dec2020 and wondered if there was a side effect of some hives, she meant that she was not having an allergic reaction and she got the vaccine at 7:15 this morning and she have been fine, but she just have like a few sparse hives at 20:30. When asked about causality, the nurse stated "Yes I do. I have never had hives before." She did not think that she needed treatment but she was wondering if it was common or she wasnot having any anaphylactic reaction and they were sparse. She doesn't have it on her trunk, she just have some on her neck and there was like one above her ear. She put BENADRYL cream on them, they are fine, and they don't itch. She was just like preemptively treating them because of her high risk for work. Therapeutic measures were taken as a result of hives on my neck and above my ear (urticaria). The outcome of the event was unknown. Information on the lot/batch number has been requested.

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905896	12/21/2020	CA	49	F	12/20/2020	12/20/2020	Patient observed for over an hour due to symptom development including complaints of pressure in head, diaphoretic, swelling and increase muscle tone/rigidity in her left arm, tongue feeling thick. Brought to ED for care after an hour of observation. In the ED, left arm rigidity/spasm worsened. Here is the physician note: Patient's headache is improved. She has no neurological deficits or subjective complaints or objective exam consistent with a recurrent CVA. She has no evidence of significant anaphylaxis related to the immunization. May be a recurrence of her underlying medical problems that she has been seen by neurology for something similar. Possible unmasking of this is related to the Covid vaccine is difficult to determine. We will have her work individually with our pharmacy, infectious disease team to determine whether she is a candidate for a second vaccination. She would like to return home right now her CT labs are otherwise unremarkable I think this is reasonable. Return precautions for more significant etiologies were discussed at length. Received lorazepam 0.5 mg IV x1, diphenhydramine 25 mg IV x1, and methylprednisolone 60 mg IV x1.
905302	12/21/2020	TX	39	F	12/20/2020	12/20/2020	39-year-old female with history of ADHD, anxiety, melanoma presents with palpitations. Patient received a Covid vaccine today and started having palpitations, lightheadedness, shortness of breath and feeling flushed a few minutes afterwards. Rapid response called and patient taken to ED for assessment. Patient denies facial or oral swelling, rash. patient denies any recent fever, nausea, vomiting, cough, diarrhea. Denies chest pain, abdominal pain. Last menstrual period end of November. Has allergies to Bactrim and clarithromycin. Presentation concerning for possible vaccine reaction, no anaphylaxis. EKG and labs within normal limits. Patient was rehydrated in the ED. Patient was discharged home on same day (12/20/2020). Pt alert and oriented x 4. Pt ambulated out of ED with a steady gait in no apparent distress.
904418	12/20/2020	CA	38	F	12/18/2020	12/18/2020	Initially started as numbness of the lips, then progressed to angioedema (swelling of the lips) with face itchiness. Then progressed to throat tightening and swelling feeling, consistent with anaphylaxis.

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904504	12/20/2020	MA	60	M	12/19/2020	12/19/2020	Throat closure (angioedema/anaphylaxis) requiring ambulance transport to Hospital emergency room and stay IV infusion of Benedryl, solumedrol, and Pepcid with excellent results. Observed twelve hours, then discharged.
904485	12/20/2020	CA	38	F	12/20/2020	12/20/2020	Sensation of tightening in throat and sensation of difficulty swallowing. No rash. No dyspnea. No stridor/wheezing. Vital signs unremarkable. Suspect globus sensation. Plan observation until resolution or progression to anaphylaxis.
904398	12/20/2020	WA	35	F	12/20/2020	12/20/2020	Anaphylaxis type reaction, stridor, treated with 02, epi pen, moved to hospitals ED
904210	12/19/2020	CO	32	F	12/17/2020	12/17/2020	Anaphylaxis within 15 minutes of administration
903690	12/18/2020	TX	54	F	12/18/2020	12/18/2020	About an hour after vaccine, felt itchy inside, watery eyes and congestion - treated with 25 mg Benadryl. No anaphylaxis
903957	12/18/2020	TX	41	F	12/18/2020	12/18/2020	Immediately after vaccination, pt had arm, neck and facial pain, which improved, but did not go away. Rash developed on her abdomen this evening. Recommended benadryl and close observation for anaphylaxis and medical attention if it continues to spread.
903925	12/18/2020	CA	27	F	12/18/2020	12/18/2020	5 minutes after shot administered, became very hot and flushed. Felt tingle in throat. Turned bright red. Sent to ER. Throat tingle subsided after about 30 min. No anaphylaxis. Given Zyrtec for slight itchiness

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903713	12/18/2020	MI	27	F	12/18/2020	12/18/2020	<p>Patient reported feeling hot shortly after receiving her vaccine with an itchy arm. We provided and ice pack and laid her down on a stretcher. Patient became slightly erratic and we proceeded to wheel her down to ER. ER summary below. ED Course: Patient's pertinent past medical, social, family medical history were reviewed from both the nursing notes and the electronic medical record. This is a 27-year-old female with a past medical history as above presenting with a chief complaint of concern for urticarial rash in anaphylaxis following a COVID-19 vaccination. I did speak with Occupational Health who stated that this patient is well-known to the hospital, stating specifically that she becomes very anxious with vaccinations/needles and breaks out in hives on previous injections. This information was given to his after her initial presentation. Patient had already been removed provided epinephrine given concern of possible anaphylactic reaction given her area, diaphoresis, pruritus and diffuse urticaria. I was called into the room multiple times as patient continued to ask to be discharged. I did have multiple conversations with her in regards to need for continued monitoring given possibility of anaphylactic reaction. She feels that this was due to her anxiety and states that she is completely asymptomatic and at her baseline at this time. She once again is asking to leave. I did discuss my recommendation for continued monitoring as well as the risks of leaving without continued monitoring. The patient is able to choose, communicate and make choices clearly and understandably. The patient is able to understand risks, benefits and alternatives of therapy explained by myself. The patient can make a logical and rational decisions according to my assessment. The choice made by the patient is consistent with the patient's values and is consistent with character and decision capacity in the patient's past, according to friends and family present. There is no impending medical risk to this patient to warrant my holding the patient against their will.</p> <p>Patient will be discharged in stable condition at this time with strict return precautions and instructions for close outpatient follow-up. She was provided EpiPen given possibility of anaphylactic reaction in the future.</p>

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903693	12/18/2020	IL	27	F	12/18/2020	12/18/2020	Patient has history of anaphylaxis to foods and medications, carries Epi-Pens. 20 minutes post delivery, patient "feels throat swelling" and slight shortness of breath. Patient checked by on staff physician. Patient took 25mg (self) of Benadryl (oral).
903327	12/18/2020	OR	61	F	12/17/2020	12/17/2020	Patient reported that she started to feel unwell immediately after the vaccine with some nausea. She presented to the Emergency Department where she was treated by myself approximately 17 hours vaccine administration. She was having vomiting, diarrhea, diffuse rash, and throat discomfort. She was successfully treated for anaphylaxis and was able to discharge to home.
903132	12/17/2020	AK	40	F	12/17/2020	12/17/2020	40 year female received Pfizer-BioNTech COVID-19 Vaccine today Patient reported prior h/o severe allergic reaction to influenza vaccine with eggs preservative. She has received flu vaccine w/o egg w/o problem. Due to her prior history of severe allergic reaction/ anaphylaxis to another vaccine, in this case flu vaccine with eggs, we should proceed with caution. She was told we could defer vaccination until more information becomes available. She opted to proceed with receiving Pfizer-BioNTech COVID-19 Vaccine and be observed for 30 minute observation period. Patient developed throat tightening approximately 20 minutes after vaccination. She received EpiPen within 1 minute of symptoms and was sent to ER immediately in wheelchair by nursing staff. Patient was evaluated in ED and was hemodynamically stable. She was given IV benadryl and was stable throughout observation

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903016	12/17/2020		54	F	12/16/2020	12/16/2020	Approximately 11 minutes after receiving the vaccine, the patient complained of shortness of breath, tingling in arms and hands, numbness and tingling in legs and feet, and was observably shaking, with no complaints of swelling in throat or other signs of anaphylaxis. Patient was brought to ER in same facility via stretcher and was examined by staff there. ER report states the patient presented with shortness of breath and what appeared to be a panic attack, with fast breathing, slight flushing, and shaking. Per ER report, the patient was treated for an acute anaphylactic reaction, with clear lungs and given an EpiPen shot in the right thigh. IV was initiated and given a fluid bolus, solu medrol, famotidine, and lorazepam. Labs and a chest x-ray done and reviewed. After treatment, patient found to be stable and was discharged home at 4:42 pm with orders for famotidine, albuterol inhaler, and epinephrine pen.
902674	12/16/2020	WY	38	F	12/16/2020	12/16/2020	Patient has a prior anaphylaxis reaction to Doxycycline. 10minutes after immunization, she developed sweaty palms and lightheadedness. No throat swelling or difficulty breathing. Placed supine, BP 160/100, HR 60-70, O2 97% RA. After a period of monitoring the symptoms improved. No intervention given.
902837	12/16/2020	AK	29	F	12/16/2020	12/16/2020	Patient feeling very anxious before and after vaccination. Described having difficulty swallowing water shortly (~15 min) post vaccination. Patient was tearful but breathing normally. Walked under her own power from the pharmacy down to the Emergency Room for anxiety over anaphylaxis. Given dose of Vistaril in ER.

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902836	12/16/2020	NE	25	F	12/16/2020	12/16/2020	<p>Patient received covid-19 vaccine. 20+ minutes later patient states she began feeling flushed and nauseous. Patient states she look at her injection site, and it was hot and red. Local reaction approx. 2 inches x 2 inches. Dr. ordered 25 mg oral Benadryl. Vitals stable at 1840 133/88, 66 for pulse and regular, SPO2 99% on room air, respirations 20. Patient continued having complaints of light headedness and nausea. 1850 119/79, 74, 99% RA. Dr. states patient may depart from clinic if able to sit up and walk out, patient given instructions go to ED in symptoms progress. 1857 120/82, 70, 99.4. Patient's face becomes flushed and hot on left side, patient states she is shaky, and does not feel well at all. 1905 patient transferred to ED on 2L O2 for further evaluation and workup. Narrative ER Medical decision making narrative: Accu-Chek was obtained noting a glucose to be at 80. She received IV fluids as well as Solu-Medrol Benadryl and IV Pepcid. She also received IV Tylenol as she developed a headache while in the emergency department. Headache resolved and she was able to ambulate without assistance. Requested to go home states she felt much improved near normal. Clinical Impression: Adverse reaction to drug Patient Education: Anaphylaxis (ED)</p>