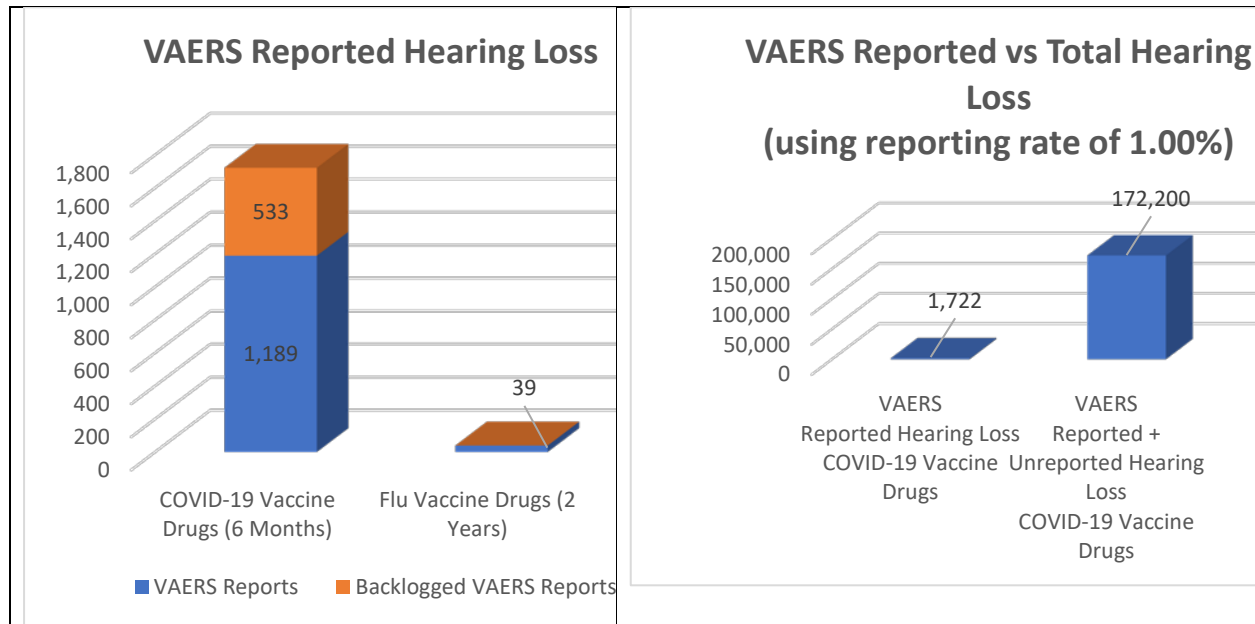


# COVID-19 Vaccine Drug Reactions: Hearing Loss

Preliminary Notes – Reactions Listings Start on Page 2 Below



1. Hearing Loss cases 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#Backlog)

[https://www.covid19vaccinefacts.net/VAERS\\_FAQ.shtml#ReportingRate](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 hearing loss reactions. As you read through the cases below, it is possible that there will be an occasional erroneous case not related to fainting because of the query criteria. The exact query is as follows:  
symptom\_text like "\*hearing loss\*" or symptom\_text like "\*loss of hearing\*" or symptom\_text like "\*deaf\*" or symptom\_text like "\*hearing problem\*"

## Hearing: COVID-19 Vaccine Drugs

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
1373942	6/4/2021	NY	59	M	5/28/2021	5/29/2021	First, I suffer from Chronic Tinnitus / Hearing Loss and occasional Vertigo. The day following my vaccine, my tinnitus became significantly more intense and started "pulsating". Best I can describe is the volume of the ringing pulses louder with my heartbeat. In addition, I had two brief episodes of Vertigo within the past week whereas I normally get them no more than once or twice per year. I'm unsure at this time whether a second shot will make it unbearable.
1373432	6/4/2021	CO	66	M	3/4/2021	3/5/2021	chills with shaking; low-grade fever; headache; lethargy; body aches; This is a spontaneous report from a contactable consumer (patient). A 66-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection; Batch/Lot Number and expiration date were not reported), via an unspecified route, administered in the left arm on 04Mar2021 01:15 PM (at the age of 66-years-old) as first dose, single dose for COVID-19 immunisation at a hospital. Medical history included Mediterranean anemia, bilateral profound hearing loss, gout and mild hypothyroidism; all from an unknown date and unknown if ongoing. Concomitant medications included levothyroxine sodium, rosuvastatin calcium and febuxostat; all taken for an unspecified indication, start and stop dates were not reported. No other vaccine was given to the patient in four weeks. The patient had no COVID prior vaccination and was not tested for COVID post vaccination. The patient has no known allergies. On 05Mar2021 06:00 PM, the patient experienced chills with shaking, low-grade fever, headache, lethargy and body aches. No treatment was taken as a result of the events. The outcome of the events was recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

<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>
1373761	6/4/2021	VA	63	M		5/4/2021	Complete loss of hearing in right ear; This is a spontaneous report from a contactable consumer (patient). A 63-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Solution for injection; Lot number: unknown) via unspecified route of administration on an unspecified date (at the age of 63-year-old) in the hospital as single dose for COVID-19 immunisation. Patient had no relevant medical history, concurrent conditions or any known allergies. Concomitant medications were not reported. 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 patient has not been the patient been tested for COVID-19. Patient previously received first dose of BNT162B2 on an unspecified date for COVID-19 immunisation. On 04May2021, at 10:00, patient experienced complete loss of hearing in right ear and visited doctor or other healthcare professional office/clinic visit. Reporter considered the events as non-serious. Therapeutic measures in response to the event included treatment with steroid injections in ear and oral steroids. Outcome of the event was recovered with lasting effects (resolved with sequelae) on an unspecified date in 2021. Information on the lot/batch number has been requested.

<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>
1373773	6/4/2021	OK		M	3/23/2021	3/1/2021	50% hearing loss; He is on the verge of suicide; insomnia; I cant live with this; can't think; it's driving me crazy; driving me insane; He is desperate; spike headaches; rash under my eyes/rash in his eyes appeared in the right eye and then got to the left eye; incredible ringing in my ears and a spike headache/high pitched ringing in my ears; This is a spontaneous report from a Pfizer-sponsored program via a contactable male consumer (patient himself). A male patient of an 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 23Mar2021 as 1st dose, single for COVID-19 immunization. The patient medical history and concomitant medications were not reported. It was reported that, caller and his 20y/o son received their first dose of the Pfizer BioNTech COVID 19 Vaccine on 23 Mar 2021. His son had a runny nose for 10 days but was fine after. However, 4 days later, on an unspecified date in Mar2021, the patient developed a rash under his eyes and he woke up with an "incredible ringing in my ears and a spike headache". Caller claims that he has never experienced that in his life. He also reported a rash under one of his eye that later on spread to the other eye, as well as insomnia on an unspecified date. He has seen his HCP and was referred to an Audiologist, who he has visited 3 times since then. He was diagnosed with 3 times % loss of hearing and 10500 Hertz tinnitus, which the Audiologist mentioned is "really high". It was also reported that, this high pitched ringing in his ears that just won't go away and its driving him crazy. He was prescribed with high dose Prednisone for 7 days, but caller mentioned "it did not help and had no effect whatsoever". His HCP wanted to be "super cautious" and recommended a brain scan this week just to make sure he didn't develop a blood clot. Caller is upset that no one can give him answers. He has reached out to CDC and asked for medical advice, but he stated that everyone is giving him the same answers - there is not enough data. He is on the verge of suicide and said, "I can't live with this for the rest of my life. I can't sleep and can't think, it's driving me crazy" on an unspecified date. Patient stated "I'm just trying to get to the end of this. I cant live like this its driving me crazy." Patient went on to mention "I'm at

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my wits end with this it is truly driving me insane on an unspecified date. I'm not kidding. I can't sleep, I can't think, I cant function with this ringing. The rash didn't even go away under my, I've been to the dermatologist twice and they just don't know..." Patient wanted to speak to someone because "I cant spend my life with this high pitch ringing in my ears it is driving me crazy". On an unspecified date, he was desperate for answers and even tried reporting to Vaccine Adverse Event Reporting System (VAERS) but there was no way to submit it. The patient also asked about what in the vaccine could affect the auditory complex. He added that he did not get the second dose of the Pfizer covid vaccine, that the rash in his eyes appeared in the right eye and then got to the left eye. Also he mentions that this is "all over the internet and you just have to google it", that the percentage that reported this is above 10% for both Moderna and Pfizer vaccines and he estimates that is about 17% all over the world and that the DNA vaccines started since the 90's. He also mentions that he knows at least 15 more persons affected with the same side effects as him and he lives in a small town and a CEO just committed suicide because of this. Sometimes he refers at it as "tinnitus". He says that he feels miserable and this is driving him crazy. He wants to make this public and that Pfizer acknowledges this. The patient underwent lab tests and procedures which included tinnitus: 10500 Hertz which the Audiologist mentioned is "really high". The outcome of the events, incredible ringing in my ears and a rash under eyes was not recovered and for other events was unknown.

<u>VAERS_ID</u>	<u>RECVD</u>	<u>STATE</u>	<u>AGE_YRS</u>	<u>SEX</u>	<u>VAX_DATE</u>	<u>ONSET_DATE</u>	<u>SYMPTOM_TEXT</u>
1373830	6/4/2021	MI	81	F	5/12/2021	5/1/2021	My teeth were sore/teeth were so sore she felt like she had abscessed teeth on lower jaw: Medically significant; Inflamed gums; Abscessed teeth on her lower jaw; some kind of side reaction; My gums and the roof of my mouth (Incomplete sentence)/my gums were so raw, I couldn't brush my teeth; My mouth became all inflamed; I have a very hard time hearing you; Equilibrium affected; But I am still deaf in my right ear; This is a spontaneous report from a contactable Nurse (patient). An 81-year-old female nurse received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for Injection, Batch/Lot Number: EW0169; Expiration Date: 31Aug2021), via an unspecified route of administration, administered in arm left on 12May2021 20:00 (at the age of 81-year-old) at a 2nd dose, single for COVID-19 immunization. Medical history included macular degeneration (diagnosed about 3-5 years ago), low thyroid hormone (seems like she's had forever), high cholesterol just beyond normal (has had for years), banana, avocado, and kiwi allergy (stated all are interrelated because they are cousins to the rubber tree plant. Also, healthcare personnel allergic to latex can and may develop a cross allergy to psyllium which is metamucil); psyllium allergy (patient had an anaphylactic reaction to a metapower bar in 2015. About 7 minutes after eating the bar, she went into a severe reaction and ended up in the emergency room and stayed overnight), flu (every flu shot she received, she has gotten the flu and only takes periodically. She had to take in 2016 and 2015. It had been 5-10 years before that, and another 5-10 years before that), latex allergy (since the 1980's), shingles (having shingles vaccination in 2014 and had shingles 2-3 weeks later, can't remember details. Stated it was a mild case. Patient gets the shingles vaccine and gets the shingles, gets the flu vaccine and gets the flu), atrial tachycardia from 2015 to an unknown date, anaphylactic reaction to a metapower bar from 2015 to an unknown date (about 7 minutes after eating the bar, she went into a severe reaction). Concomitant medications included levothyroxine tablet at a dose of 50 ug, 1x/day, vitamin B complex and akurit (not clarified hence not captured in tab). The patient previously took first dose of BNT162B2 (Batch/Lot Number: TR2613; Expiration Date: 31Jul2021), administered in arm left on 21Apr2021 09:00 for COVID-19 immunization and

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experienced deaf in my right ear, I woke up with pressure in both of my ears, I could not hear and arm soreness. The patient drug history included synthroid from an unknown date to ongoing (started about 15 years ago) for low thyroid hormone, simvastatin from an unknown date to ongoing (started about a year ago) for cholesterol is slightly elevated, ocuvite preservative from an unknown date to ongoing (taking about 3 years. Macular degeneration has not changed or gotten worse in 3 years) for macular degeneration age related, vitamin D3 (taking for 3 years) for bone health from an unspecified date to ongoing, calcium with magnesium (it has calcium citrate. Been taking a long time. 5-10 years) to prevent osteoporosis, glucosamine chondroitin (taking since late 1990s. About 20 years) for joint health from an unspecified date to ongoing, vitamin C (about 3 years ago. started with the Ocuvite. Eye doctor thought it was a good idea to take together), multivitamin (taking since 1995 or 1996. about 25 years) for general health; metoprolol ER for atrial tachycardia from Jan2016 to an unspecified date, baby aspirin from Jan2016 to ongoing (81 mg daily, cardiologist thought it would be a good idea). The patient reported, she received first Pfizer vaccine on 21Apr2021 and equilibrium affected and on 28Apr2021 she could not hear in her right ear and the day before on 27Apr2021 it was like she woke up with pressure in both of her ears. It sounded like heck like she was in the airplane and by yawning she could not relieve the pressure and went to the doctor and was under treatment with steroids and antivirals and she was still deaf in her right ear. She got second vaccine on 12May2021 and on 16May2021 and 17May2021 her gums and the roof of my mouth became all inflamed and her teeth were so sore she felt like she had an abscessed tooth. My gums were so raw, couldn't brush my teeth. So she gargle with some peroxide and some saline and then her teeth were sore like you have an abscess teeth on lower jaw. And then that went away within two days. Pressure in both ears has subsided, but then confirms it is a lasting effect comes and goes a little bit from 27Apr2021 to ongoing. First the doctor put her on valacyclovir and methylprednisone 4 mg tablet by mouth started dose at every 4 or 5 hours, dose was a decreasing frequency of dose over 7 days. Started 05May2021 for 7 days. And then last week he started me

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on the dexamethasone injections through tympanic membrane into her middle ear last Thursday, 20May2021. Is scheduled to receive a dose today, will skip next week, and then one the following week, and then one the following week after that, states it is a series of four doses and then if that doesn't help, she will have an MRI. States cortisone decreases irritation and inflammation. Adds she is pretty healthy and moves about, gardens takes care of business, goes to exercise class twice a week now partially participates because she gets dizzy from moving her head. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Outcome of the events I am still deaf in my right ear, I have a very hard time hearing you was not recovered; equilibrium affected, some kind of side reaction was unknown; my teeth were sore/teeth were so sore she felt like she had abscessed teeth on lower jaw, inflamed gums, abscessed teeth on her lower jaw, my gums and the roof of my mouth (incomplete sentence)/my gums were so raw, I couldn't brush my teeth, my mouth became all inflamed was recovered on an unspecified date in 2021. Information on lot/batch number was available. Additional information has been requested.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events, unilateral deafness, non infective gingivitis, tooth abscess, toothache, balance disorder cannot be completely ruled out. 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



<u>VAERS_ID</u>	<u>RECVD</u>	<u>STATE</u>	<u>AGE_YRS</u>	<u>SEX</u>	<u>VAX_DATE</u>	<u>ONSET_DATE</u>	<u>SYMPTOM_TEXT</u>
1373827	6/4/2021	MI	81	F	4/21/2021	4/22/2021	Equilibrium affected; I could not hear; I woke up with pressure in both of my ears; Deaf in my right ear; arm soreness; This is a spontaneous report received from a contactable Nurse (patient). An 81-years-old female patient received bnt162b2 (BNT162B2, solution for injection, Batch/Lot Number: TR2613; Expiration Date: 31Jul2021), dose 1 via an unspecified route of administration, administered in left arm on 21Apr2021 at 09:00 as 1st DOSE, SINGLE for covid-19 immunization. Medical history included atrial tachycardia (From: 2015 To: Unspecified), macular degeneration diagnosed about 3-5 years ago, low thyroid hormone seems like she's had forever, high cholesterol just beyond normal has had for years, latex allergy since the 1980's, banana, avocado, and kiwi allergy (states all are interrelated because they are cousins to the rubber tree plant and also healthcare personnel allergic to latex can and may develop a cross allergy to psyllium which is Metamucil), Psyllium allergy (states she had an anaphylactic reaction to a metapower bar in 2015. About 7 minutes after eating the bar, she went into a severe reaction and ended up in the emergency room and stayed overnight. thankfully was at work). Reported having shingles vaccination in 2014 and had shingles 2-3 weeks later, can't remember details. States it was a mild case. NDC, lot, expiry unknown. She stated every flu shot she received, she has gotten the flu and only takes periodically. States she retired in 2017 and had to take in 2016 and 2015, she would have lost her job if she didn't take. It had been 5-10 years before that, and another 5-10 years before that. States she stays away from the flu shot. Concomitant medications included metoprolol ER from Jan 2016 for atrial tachycardia, SYNTHROID started about 15 years ago for low thyroid hormone, Simvastatin ongoing, started about a year ago for cholesterol slightly elevated, OCUVITE PreserVision(Ongoing) taking about 3 years for macular degeneration age related has not changed or gotten worse in 3 years, baby aspirin started Jan 2016 (Ongoing) as cardiologist thought it would be a good idea, Vitamin D3: taking for 3 years (ongoing) for bone health, calcium with magnesium been taking a long time. 5-10 years to prevent osteoporosis (ongoing), glucosamine chondroitin taking since late 1990s. about 20 years for joint health (ongoing), multivitamin taking since 1995 or 1996. about 25 years for general health,

VAERS\_ID RECVD STATE AGE\_YRS SEX VAX\_DATE ONSET\_DATE SYMPTOM\_TEXT

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vitamin C about 3 years ago started with the Ocuville (eye doctor though it was a good idea to take together. On April 28th2021 patient could not hear. She was deaf in right ear and the day before on April 27 it was like she woke up with pressure in both ears. It sounded like hell like she was in the airplane and by yawning she could not relieve the pressure and went to the doctor and was under treatment with steroids and antivirals and still deaf in right ear." She confirmed pressure is gone, but still deaf and under medical treatment with otolaryngology. She was kind of tossing whether to get the vaccine or not. First went to family doctor to see, didn't think she had an ear infection because no pain and was hoping maybe she would have wax in her ear, but ears were clean and no wax. So they sent her to an ear specialist and they did hearing test and she has pretty severe hearing loss in that ear. So she was still being treated. First the doctor put her on valacyclovir and methylprednisone for about 7 days and then that didn't seem to do anything and now she's getting dexamethasone injections into her middle ear. States she is due for one about lunch time. Pressure in both ears: patient reported has subsided, but then confirms it is a lasting effect comes and goes a little bit. Left ear is pretty much clear but right ear still has pressure and cannot hear and has not subsided. On an unknown date her equilibrium affected and stated has gotten slightly better, minuscule. Patient added she's pretty healthy and moves about, gardens takes care of business, goes to exercise class twice a week now partially participates because she gets dizzy from moving her head. Patient was treated with Valacyclovir: 1 gram tablet every 6 or 8 hours, states can't remember. Started 05MAY2021 for 7 days. Caller confirmed it did not help and she threw bottle away. Methylprednisone: 4 mg tablet by mouth started dose at every 4 or 5 hours, dose was a decreasing frequency of dose over 7 days. Confirmed she threw package away. Stated cortisone decreases irritation and inflammation. And Valacyclovir is an antiviral. Started dexamethasone injections last Thursday, 20 May 2021. Is scheduled to receive a dose today, will skip next week, and then one the following week, and then one the following week after that, states it is a series of four doses and then if that doesn't help she will have an MRI. Airborne: started taking about one week ago after first dexamethasone injection through

VAERS_ID	RECVD	STATE	AGE_YRS	SEX	VAX_DATE	ONSET_DATE	SYMPTOM_TEXT
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tympanic membrane into middle ear. Relevant Tests: Hearing Test (Date: 05MAY2021)Result: pretty severe hearing loss in right ear, Test: Ear exam (Date: 03MAY2021; 05MAY2021) Result: Normal. Outcome for pain in extremity was recovered, for ear discomfort and deafness it was resolving, for hypoacusis and equilibrium affected it was unknown. Reporter seriousness for pressure in both ears and equilibrium affected: Medically significant, Deafness right ear: Disabling, Arm soreness: non-serious Reporter causality: deafness in right ear: Causality: strong suspicion it's related to the vaccine, maybe not necessarily the vaccine itself, but her immune system reaction to the vaccine. Causality for pressure in both ear, arm soreness and equilibrium: related; 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 such as deafness, balance disorder and ear discomfort cannot be totally 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.

<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>
1370568	6/3/2021	MO	26	M	4/20/2021	4/20/2021	swelling of lymph nodes; loss of hearing in right ear; right ear began to feel full with pressure/pain; right ear began to feel full with pressure/pain; dizziness; vertigo; ringing in right ear (tinnitus); This is a spontaneous report from a contactable consumer (patient). A 26-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 20Apr2021 (Lot Number: EW0171) (at the age of 26-year-old) as single dose for COVID-19 immunisation. Medical history included non-alcoholic fatty liver disease, allergies, asthma, autism, sensory integration disorder, appendectomy, pilonidal cyst removal, all from an unknown date and unknown if ongoing. 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's concomitant medications were not reported. The patient previously took penicilline, tetracycline, amoxillin [amoxicillin sodium] and hydrocodone. The patient experienced dizziness/vertigo within a couple of hours of first vaccine on 20Apr2021. Developed ringing in right ear (tinnitus) on same day. By 21Apr2021, right ear began to feel full with pressure/pain. All symptoms continued with swelling of lymph nodes and loss of hearing in right ear by 22Apr2021. The events were assessed as serious, disabling. The patient saw otolaryngologist (ENT) for hearing test and evaluation on 27Apr2021, hearing test showed substantial loss of hearing in right ear. Steroids were prescribed and taken. The patient underwent lab test and procedures which included magnetic resonance imaging (MRI): unknown results on an unspecified date. Dizziness/vertigo either resolved on 29Apr2021. The patient outcome of the other events was not recovered. No follow-up attempts are needed. No further information is expected.

<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>
1369975	6/3/2021	CA	33	F	4/10/2021	4/10/2021	On the evening of 04/10/2021 (after first Pfizer COVID-19 vaccine), tinnitus in right ear flared to an excruciatingly high pitch and high volume, of which had not been experienced before. On the morning of 04/15/2021, I first began to experience dizziness as the tinnitus continued at a high level. As the day progressed I experienced hearing loss in the right ear along with "fullness" in the same ear. On this same day I experienced vertigo with a spinning room sensation which caused me to vomit. I also began to have trouble with balance. The intense vertigo subsided within two days, but for about three weeks I felt dizzy and had trouble with balance. On 04/22/2021 a hearing test confirmed sudden loss of hearing in my right ear. I was immediately placed on a 10 day regimen of prednisone steroids. Within days of starting the steroid, my tinnitus returned to its normal low level and I felt my hearing return as well. On 05/04/2021 a balance test confirmed 40% reduction of balance on right side as compared to left side, but it has been compensated for. On 05/06/2021 an MRI Intra-auditory Canal with Contrast demonstrated findings consistent with hydrops from the right ear canal. On 05/13/2021 I received my second Pfizer COVID-19 vaccine and experienced no symptoms of dizziness, balance or hearing loss, nor increased tinnitus. Chills, a slightly tender arm and fatigue were the only side effects I experienced from the second shot. On 05/20/2021 a second hearing test demonstrated returned hearing in my right ear and both ears were symmetrical. In summation, my reaction to the first Pfizer COVID-19 vaccine started within hours of injection, with extreme tinnitus in my right ear. Then, five days later, I experienced hearing loss in my right ear for about a week before the loss was confirmed by a hearing test. My PCP started me on prednisone the day of my hearing test. The steroids preserved and restored my hearing within days and lessened my tinnitus. Also five days after the first vaccine, I experienced intense vertigo for a couple days and lingering dizziness with balance issues for about three weeks. It took me about a month to feel comfortable enough to drive. I experienced little to no adverse side effects from the second Pfizer COVID-19 vaccine.

<u>VAERS_ID</u>	<u>RECVD</u>	<u>STATE</u>	<u>AGE_YRS</u>	<u>SEX</u>	<u>VAX_DATE</u>	<u>ONSET_DATE</u>	<u>SYMPTOM_TEXT</u>
1370340	6/3/2021	NJ	36	F	5/10/2021	5/10/2021	R ear hurt,is not listening, it is as if covered; L ear plugged; cough/ alot of phlegm; nose is stuffed with mucus; L ear hurt for 2 days, then right ear hurt, today left ear plugged and it hurts; arm pain for 3 days; fever; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEAFNESS UNILATERAL (R ear hurt,is not listening, it is as if covered) in a 36-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) 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 2020. On 10-May-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-May-2021, the patient experienced PAIN IN EXTREMITY (arm pain for 3 days) and PYREXIA (fever). On 15-May-2021, the patient experienced PRODUCTIVE COUGH (cough/ alot of phlegm), RHINORRHOEA (nose is stuffed with mucus) and EAR PAIN (L ear hurt for 2 days, then right ear hurt, today left ear plugged and it hurts). On 17-May-2021, the patient experienced DEAFNESS UNILATERAL (R ear hurt,is not listening, it is as if covered) (seriousness criterion medically significant) and EAR CONGESTION (L ear plugged). The patient was treated with IBUPROFEN at an unspecified dose and frequency; BENZATHINE BENZYL PENICILLIN (MEGACILLIN [BENZATHINE BENZYL PENICILLIN]) 15-May-2021 at a dose of 1 UNK; BENZATHINE BENZYL PENICILLIN (MEGACILLIN [BENZATHINE BENZYL PENICILLIN]) 24-May-2021 at a dose of 1 dosage form; AMOXICILLIN TRIHYDRATE, CLAVULANATE POTASSIUM (AUGMENTIN S) at a dose of 875 mg and FLUCONAZOLE at a dose of 1 dosage form. On 13-May-2021, PAIN IN EXTREMITY (arm pain for 3 days) and PYREXIA (fever) had resolved. At the time of the report, DEAFNESS UNILATERAL (R ear hurt,is not listening, it is as if covered), PRODUCTIVE COUGH (cough/ alot of phlegm), RHINORRHOEA (nose is stuffed with mucus), EAR PAIN (L ear hurt for 2 days, then right ear hurt, today left ear plugged and it hurts) and EAR CONGESTION (L ear plugged) had not resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. Based on the

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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.

<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>
1370531	6/3/2021	NC	62	F	4/15/2021		hearing loss in both ears; hypersensitive to sound; painful; trouble sleeping; tinnitus; tinnitus; This is a spontaneous report from a contactable consumer (patient). A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 1 via an unspecified route of administration, administered in Arm Right on Mar2021 16:00 (Batch/Lot Number: er8727), age at vaccination of 62-years-old, as single dose, dose 2 via an unspecified route of administration, administered in Arm Left on 15Apr2021 10:00 (Batch/Lot Number: ew0151), age at vaccination of 62-years-old, as single dose for covid-19 immunisation. Medical history included asthma from an unknown date and unknown if ongoing (mild asthma), drug hypersensitivity from an unknown date and unknown if ongoing (allergies: sulfa drugs), tinnitus from an unknown date and unknown if ongoing (mild tinnitus diagnosed 10 years ago), deafness from an unknown date and unknown if ongoing (diagnosed 10 years ago). The patient received tetanus vaccine in left arm on 12Mar2021 within 4 weeks prior to the COVID vaccine (age at vaccination of 62-years-old). The patient was not pregnant and was not pregnant at the time of vaccination. Concomitant medications included pantoprazole (PANTOPRAZOLE) taken for an unspecified indication, start and stop date were not reported; levothyroxine sodium (SYNTHROID) taken for an unspecified indication, start and stop date were not reported; losartan (LOSARTAN) taken for an unspecified indication, start and stop date were not reported and hormone replace taken for an unspecified indication, start and stop date were not reported After the vaccine (both doses) tinnitus rose exponentially, and patient was diagnosed with hearing loss in both ears. Not sure when the additional hearing loss took place. The patient also become hypersensitive to sound, it was almost painful. The patient had trouble sleeping, listening to tv, music, going out to restaurants, etc because of this reaction. ENTs can only recommend hearing aids. After 9 weeks tinnitus has quieted a little bit but not back to pre vaccine level. The events resulted in doctor or other healthcare professional office/clinic visit. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Facility where the most recent COVID-19 vaccine was administered:



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							Pharmacy or Drug Store. Treatments were given for the events (after first vaccine took a course of prednisone). Outcome for the events was unknown. Follow-up attempts are possible. Further information is expected.
1371635	6/3/2021	NY	43	M	4/18/2021	4/1/2021	Primary symptom is tinnitus in both ears (more left) that has increased slowly since second vaccination. Of possible relevance, two additional temporary symptoms occurred roughly one week following second dose: two separate incidences of scintillating scotoma (bilateral visual artifact on left side of visual periphery; each episode lasting approx. 40 minutes; occurred two days apart); and two or three incidences of very brief (5 sec.) SSHL (sudden sensorineural hearing loss) in right ear (incidences occurred approx. two days apart).
1369962	6/3/2021	NV	16	F	6/2/2021	6/2/2021	Immediately following administration, patient walked out of room and sat down in waiting area. Patient felt very dizzy and almost fainted. Complained of hearing loss then tinnitus. Initial BP was 82/31 then gradually increased back towards normal over 20-30 minute period. Hearing loss recovered after 1-2 minutes then complaint of tinnitus which then stopped after 5-6 minutes. Approx 30 min after admin, pt felt much closer to normal and parent felt comfortable bringing her home.
1371535	6/3/2021	MN	69	F	3/18/2021	4/25/2021	On March 18, 2021, I received my second dose of the Covid vaccine. I had no immediate adverse effects, but beginning on or around April 25, 2021, I lost most of my hearing in my left ear with some tinnitus associated with it. I checked out the internet for possible side effects and saw hearing loss as a possible, unverified side effect. It has been 4-5 weeks since my hearing loss and it hasn't returned. I don't know what to do about it except to tell you and hope that I'm not going to be deaf as a result of taking the Covid vaccine for the rest of my life. Thank you.
1371164	6/3/2021	MA	54	M	6/1/2021	6/2/2021	Patient had severe unilateral sudden sensorineural hearing loss upon waking morning after vaccination. Seen here at ENT and is being treated with oral high dose steroids as well as intratympanic steroid injections

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1370819	6/3/2021	MD	64	F	2/23/2021		<p>Conductive deafness; Ear discomfort; Paranasal sinus discomfort; Ear congestion; Hypoacusis; sensorineural hearing loss; This spontaneous case was reported by a health care professional and describes the occurrence of CONDUCTIVE DEAFNESS (Conductive deafness) and DEAFNESS NEUROSENSORY (sensorineural hearing loss) in a 64-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 026A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was provided by the reporter. Concomitant products included PREDNISONE, FLUTICASONE PROPIONATE (FLONASE [FLUTICASONE PROPIONATE]), LEVOTHYROXINE SODIUM (SYNTHROID), ESTRADIOL (ESTRACE VAGINAL), PROGESTERONE, DEXLANSOPRAZOLE (DEXILANT) and ESTRADIOL (MENOSTAR) for an unknown indication. On 23-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 23-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced CONDUCTIVE DEAFNESS (Conductive deafness) (seriousness criterion medically significant), EAR DISCOMFORT (Ear discomfort), PARANASAL SINUS DISCOMFORT (Paranasal sinus discomfort), EAR CONGESTION (Ear congestion), HYPOACUSIS (Hypoacusis) and DEAFNESS NEUROSENSORY (sensorineural hearing loss) (seriousness criterion medically significant). The patient was treated with NEOMYCIN at an unspecified dose and frequency; POLYMYXIN on 25-May-2021 at an unspecified dose and frequency; FLUTICASONE PROPIONATE (FLONASE [FLUTICASONE PROPIONATE]) (nasal) at an unspecified dose and frequency and PREDNISONE on 20-May-2021 at an unspecified dose and frequency. At the time of the report, CONDUCTIVE DEAFNESS (Conductive deafness), EAR DISCOMFORT (Ear discomfort), PARANASAL SINUS DISCOMFORT (Paranasal sinus discomfort), EAR CONGESTION (Ear congestion), HYPOACUSIS (Hypoacusis) and DEAFNESS NEUROSENSORY (sensorineural hearing loss) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if</p>

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1370600	6/3/2021	IL		F			
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available): On an unknown date, Acoustic stimulation tests: mixed sensory neuro/conductive hearing loss (abnormal) mixed sensory neuro/conductive hearing loss. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Action taken with the drug in response to events was not applicable. 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. Symptoms were still ongoing and present at the time of this report; 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.

could not hear from 1 ear; ear/hearing totally stuffed; vertigo; ringing in the ear; This is a spontaneous report from a contactable consumer (patient). A 67-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. Patient mentioned "Pfizer leaving people in the middle of nowhere, make decisions based on what. You should support and provide more medical information about permanent hearing loss or how long this should last. You can't put the responsibility on doctor, they don't know. Patient reported AE symptoms such as ear/hearing totally stuffed, could not hear from 1 ear, had vertigo and ringing in the ear after receiving the first dose of the Pfizer BioNtech COVID-19 vaccine. Patient had a follow up with her HCP on 10May2021 as hearing has improved, but she was still experiencing vertigo and ringing in the ear. Patient wants to know if she should receive the second dose of the Pfizer BioNtech COVID-19 vaccine, as HCP could not recommend her. She also read or heard that hundreds of people already reported this effect. Serious: No. Outcome of events could not hear from 1 ear and ear/hearing totally stuffed was recovering, for vertigo and ringing in the ear was not recovered. Information about batch/lot number has been requested.

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1370577	6/3/2021	MO	26	M	5/11/2021	5/11/2021	sudden onset of hearing loss in right ear; within minutes tinnitus decibel increased substantially in right ear and developed in left ear.; This is a spontaneous report from a contactable consumer (patient's parent). A 26-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration, administered in the left arm on 11May2021 at the age of 26 years old (Batch/Lot Number: EW0176, Expiration date: unknown) as the 2nd dose, single for COVID-19 immunization. The patient received the 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection) administered in the left arm on 20Apr2021 at the age of 26 years old (Batch/Lot number: EW0171, Expiration date: unknown) for COVID-19 immunization and experienced dizziness/vertigo within a couple of hours on 20Apr2021; tinnitus (ringing in right ear) on same day; and right ear began to feel full with pressure/pain by 21Apr2021 in the morning (am), which all continued with swelling of lymph nodes and loss of hearing in right ear by 22Apr2021. The facility where the most recent COVID-19 vaccine was administered was at the pharmacy or drug store. Relevant medical history included non-alcoholic fatty liver disease, asthma, autism, appendectomy, pilonidal cyst removal, sensory integration disorder, allergies, allergy to Penicillin, and allergy to all Sulfa medications and all Cephalosporins; all from an unknown date and unknown if ongoing. Concomitant medications included cetirizine hydrochloride (ZYRTEC ALLERGY) and montelukast sodium (SINGULAIR), both taken for an unspecified indication, start and stop date were not reported. The patient previously took tetracycline, amoxicillin sodium (AMOXILLIN), and hydrocodone and experienced allergy from these drugs. 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 11May2021, the patient received the second dose of Pfizer vaccine and within minutes tinnitus decibel increased substantially in right ear and developed in left ear. Tinnitus stopped in left ear and lowered to decibel level he has had since first shot in right ear. The patient was diagnosed with sudden onset of hearing loss in right ear on an unspecified date and

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							magnetic resonance imaging (MRI) showed no tumour. All symptoms were ongoing with no prognosis of resolution. Both the events resulted in disability. The adverse events did result in a doctor or other healthcare professional office/clinic visit. The patient underwent further lab tests and procedures, which included a second hearing test with unknown results on an unspecified date. The patient received treatment for the adverse events, which included a prescription for steroid pack. The patient was not recovered from both the events. No follow-up attempts are needed. No further information is expected.
1370576	6/3/2021	TX	61	F	3/12/2021	4/18/2021	36% sudden hearing loss in left ear; 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: EN6199) via an unspecified route of administration, administered in Arm Left on 12Mar2021 12:00 (at the age of 61-year-old) as 1st dose, single for COVID-19 immunisation. Medical history included allergy to sulfa antibiotics. Patient was not pregnant. Concomitant medications included escitalopram oxalate (LEXAPRO) and levothyroxine (LEVOTHYROXINE); both taken for an unspecified indication. The patient experienced 36% sudden hearing loss in left ear on 18Apr2021. The event resulted in physician office visit and she was currently using a hearing aid. Outcome of event was not recovered. Follow up needed, further information has been requested.
1372331	6/3/2021	HI	60	M	5/29/2021	6/1/2021	Saturday shot, on Tuesday my ears started feeling clogged, by late Tuesday they were clogged enough that I felt I had about a 50% loss of hearing and loud ringing in my ears. kept me up late Tuesday, by wednesday morning I my hearing was slowly getting better. by midmorning it was feeling getting better as far as hearing. Ringing in ears is still very intense in both ears as of time of this report.
1368216	6/2/2021	CA	59	M	1/8/2021	1/18/2021	Sudden unilateral hearing loss, moderate severity. No treatment. No recovery of hearing

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1368385	6/2/2021	MT	60	M	2/14/2021	2/22/2021	Tinnitus presented 8 days following first dose (2/22/2021) and has persisted since with concomitant high frequency hearing loss.
1367151	6/2/2021	NY	29	F	5/14/2021		slight hearing loss; I've experienced ear pain; ringing in my ears; This is a spontaneous report from a contactable consumer who reported for herself that a 29-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at the age of 29-years, via an unspecified route of administration, administered in left arm on 14May2021 16:45 at single dose for COVID-19 immunisation, in pharmacy/drug store. Medical history included prior to vaccination, was diagnosed with COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medications were reported as none. No other medications the patient received within 2 weeks of vaccination. On an unspecified date (reported as on 08May2021), the patient experienced ear pain and ringing in her ears and slight hearing loss. Outcome of the events was not recovered/not resolved. Since the vaccination, the patient has not been tested for COVID-19. No follow-up attempts are possible; information about lot/batch number cannot be obtained
1368488	6/2/2021	CA	30	F	4/27/2021	4/29/2021	Two days after shot 1, I experienced very loud, high pitched, bilateral tinnitus. It has significantly decreased my quality of life and I'm now struggling with anxiety and depression due to it. I have never had tinnitus before and am otherwise perfectly healthy - no structural issues to the ear, no hearing loss, etc. The vaccine caused it. I will not be getting a second shot, especially as there is still limited information available.
1368547	6/2/2021	UT	51	M	3/1/2021	3/12/2021	Severe tinnitus. Right side only. 30% hearing loss high range 30 to 45 k
1368622	6/2/2021	NY	56	M	4/30/2021	5/2/2021	Prior to receiving the Moderna vaccine, I had an extremely mild case of tinnitus (minor ringing in my ears that would typically go away after a few minutes). Within a day of getting the vaccine the ringing in my ears is now constant, has increased several decibels and has resulted in some hearing loss.

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1368705	6/2/2021	NC	67	F	2/23/2021	2/24/2021	On February 23, 2021 I received the second Pfizer vaccine at 10 AM. Upon awaking at 7 AM the next day I had severe constant high pitch hissing in both ears. The left ear was worse. The left arm was the vaccine injection site. On March 1st the level intensity decreased about half. It has been over three months, since the symptom started, with no additional improvement. I have not experienced any tinnitus symptoms before the vaccine. I was examined by ENT and my hearing tested. I have no hearing loss. I have no health issues nor do I take any medicines.
1369021	6/2/2021	WA	57	M	6/1/2021	6/2/2021	Sudden extremely loud tinnitus and loss of hearing in left ear beginning at 9AM on 6/2. Body aches and low grade temp beginning approximately 7AM. At 4:00 PM tinnitus has reduced but hearing loss is still at 85-90%
1368318	6/2/2021	CA	59	M	5/21/2021	5/23/2021	He got his shot on 5/21/21 and on 5/23/21 awoke with profound deafness in both ears.

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1366889	6/2/2021	WA	20	M	4/6/2021	5/2/2021	Had vertigo; Patient can't hear out of his left ear; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEAFNESS (Patient can't hear out of his left ear) in a 20-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 010A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included MRI in May 2021. On 06-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-May-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 02-May-2021, the patient experienced DEAFNESS (Patient can't hear out of his left ear) (seriousness criterion medically significant). On 03-May-2021, the patient experienced VERTIGO (Had vertigo). The patient was treated with CHLORAMPHENICOL (ANTIBIOTIC [CHLORAMPHENICOL]) in May 2021 at a dose of 1 dosage form. At the time of the report, DEAFNESS (Patient can't hear out of his left ear) and VERTIGO (Had vertigo) had not resolved. The patient was not taking any concomitant medications. Treatment for events included 2 steroids injections in ear. Action taken with mRNA-1273 in response to the events was not Applicable. Company comment: Very limited information regarding the events has been provided at this time. Further information is requested. This case was linked to MOD-2021-155536 (Patient Link).; Sender's Comments: Very limited information regarding the events has been provided at this time. Further information is requested.



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1367210	6/2/2021	NJ	52	F	5/2/2021	5/4/2021	<p>had a flu.; vertigo; severe pain.; depression; mental health; Severe pain in my right ear and sudden loss of hearing in my right ear; Severe pain in my right ear and sudden loss of hearing in my right ear; her ear started ringing; she started to lose sleep.; This is a spontaneous report from a contactable consumer reported for self. This 52-year-old patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 02May2021 at the age of 52-year-old (Lot number: EW0172) arm left as 2nd dose, single for covid-19 immunisation. Medical history included COPD, asthmatic when was a child. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 11Apr2021 at the age of 52-year-old (LOT#: EW0158) for covid-19 immunisation. After her 1st dose, she said she had a robust reaction. After the 2nd dose, she said she felt like she had a flu. Then on Tuesday night, 2 days after the 2nd dose (04May2021), her ear started ringing, and her right ear was in pain. She said that her ear was ringing so loudly that she started to lose sleep. She said she had a sudden loss of hearing in right ear that has caused her emotional damage. She was sudden loss of hearing in right ear, along with ringing and severe pain for 13 days now. She said that her ear has become so sensitive ever since she received the vaccine. She also mentioned that she was given Prednisone to treat the symptoms. She also said that her ENT told her that tinnitus can be caused by a previous traumatic injury to the ear and head injury. She said she had neither, so she is sure that this is really from the vaccine. She also said she had vertigo and was in severe pain. She said her daughter saw something on social media about vaccinated people being able to stick magnets to their arms, so she tried it as well. She said she can now also stick a magnet to her left arm from where she received the vaccine, and she wants to know why this is happening. She said she has searched about these symptoms, and said that it was all over google. She stated, "On 04May2021 in the evening, ears started ringing very loudly. started getting a severe pain in right ear and lost hearing on right ear." She went to doctor. She was referred to an ENT. Got a hearing test. The doctor told that what he was seeing is going on with right ear is usually seen, when a person has fluid their ears</p>

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which the patient did not or if they have a traumatic ear injury which the patient also didn't have and he has given Prednisone (treatment) today, need to go back to another hearing test. Dose of Prednisone, consumer stated, "He got me 60 mg for 3 days. Step down the doses and then for 4 days I have to take 1 pill, then for 3 days I have to take 2 and then step down to half." She added, "Because she was truly deaf, it is kind of a 'depression' because it did kind of ruined part of it, you know quality of my life. She was probably in need of hearing aids, It is very upsetting. She experienced mental health on 18May2021. Lab data included Weight 88.45 kg. Outcome of the events was unknown.

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1367379	6/2/2021	OK		M	3/23/2021	3/1/2021	runny nose; This is a spontaneous report from a contactable consumer or other non hcp. A 20-years-old male patient received BNT162B2 (: PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 23Mar2021 (Batch/Lot number was not reported) as a Single dose for covid-19 immunization. The patient past medical history and concomitant medications were not reported. The patient experienced runny nose 10 days but was fine after on Mar2021. However, 4 days later he woke up with an incredible ringing in my ears and a spike headache that he has never experienced that in his life. He also reported a rash under one of his eyes that later spread to the other eye, as well as insomnia. He has seen his HCP and was referred to an Audiologist, who he has visited 3 times since then. He was diagnosed with 50% loss of hearing and 10500 Hertz tinnitus, which the Audiologist mentioned is high. He was prescribed with high dose Prednisone for 7 days, but caller mentioned it did not help and had no effect whatsoever. His HCP wanted to be super cautious and recommended a brain scan this week just to make sure he didn't develop a blood clot. He has reached out to CDC and asked for medical advice, but he stated that everyone is giving him the same answers - there is not enough data. He is on the verge of suicide and said, I can't live with this for the rest of my life. I can't sleep and can't think, its driving me crazy. The event outcome was recovered on Apr2021. He is desperate for answers and even tried reporting to VAERS but there was no way to submit it. No follow-up attempts are needed; information about lot/batch number cannot be obtained.

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1367561	6/2/2021	FL	44	F	4/17/2021	4/18/2021	<p>Body pain; Extreme muscle weakness; Night sweats; Headache; Chills; Nausea; Temporary loss of hearing in her right ear; Stiffness in both upper arms and upper legs; This spontaneous case was reported by a health care professional and describes the occurrence of DEAFNESS TRANSITORY (Temporary loss of hearing in her right ear) in a 44-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 048A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 17-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 18-Apr-2021, the patient experienced MUSCULOSKELETAL STIFFNESS (Stiffness in both upper arms and upper legs). On 19-Apr-2021, the patient experienced DEAFNESS TRANSITORY (Temporary loss of hearing in her right ear) (seriousness criterion medically significant), PAIN (Body pain), MUSCULAR WEAKNESS (Extreme muscle weakness), NIGHT SWEATS (Night sweats), HEADACHE (Headache), CHILLS (Chills) and NAUSEA (Nausea). At the time of the report, DEAFNESS TRANSITORY (Temporary loss of hearing in her right ear), MUSCULOSKELETAL STIFFNESS (Stiffness in both upper arms and upper legs), PAIN (Body pain), MUSCULAR WEAKNESS (Extreme muscle weakness), NIGHT SWEATS (Night sweats), HEADACHE (Headache), CHILLS (Chills) and NAUSEA (Nausea) had resolved. 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. Concomitant product use was not provided by the reporter. Treatment information was not provided. 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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1367806	6/2/2021	CA	57	M	4/12/2021	5/3/2021	Patient called call center only to report side effects from 1st dose Pfizer vaccine on 4/12. Pt denied emergency symptoms at time of call. Only wanted to report what happened after first dose, per advisement from PCP. 4/12 pt received 1st dose Pfizer vacc 4/21 evening pt experienced intense tinnitus. 4/22 pt states she experienced complete hearing loss in one ear. Received medical attention from PCP @outside insitutation. Per PCP pt was told not to receive 2nd dose of Pfizer vaccine. Pt is on 2 week steroid treatment, still reports complete hearing loss in one ear.~~
1368175	6/2/2021	OH	65	F	3/30/2021	4/8/2021	Hearing Loss in both ears, Tinnitus in both ears-but has now become most prominent in right ear. Saw ENT Doctor & Audiologist at the Clinic.
1368176	6/2/2021	TX	54	M	4/27/2021	5/1/2021	Constant bilateral tinnitus of varying degrees of severity from strong to debilitating, with episodes of deafening/muffled, pressure-like sensation in the left ear. During these events of functional loss of hearing in the left ear, the tinnitus is often debilitating, affecting my ability to participate in a conversation, concentrate or even perform common tasks. These episodes last from hours to days. Tylenol 1000mg PO has not remedied the symptoms

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1366836	6/2/2021			U			HEARING LOSS; TINNITUS; This spontaneous report received from a patient.. concerned multiple patients. 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) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient experienced hearing loss, and tinnitus. Reporter stated that there were many people in his group affected by tinnitus or hearing loss after being vaccinated (more than 2000). The reporter wanted to know that if the side effect would go away. And he also prayed if the side effects were temporary. The action taken with covid-19 vaccine ad26.cov2. s was not applicable. The outcome of the tinnitus and hearing loss was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210559168.; Sender's Comments: V0: 20210600421-COVID-19 VACCINE AD26.COV2.S-Hearing loss. This event(s) is considered un-assessable. The event(s) 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 event(s).
1364794	6/1/2021	GA	50	F	4/23/2021	5/15/2021	May 15 %100 Sudden hearing loss in my right ear that has not returned.

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1364068	6/1/2021	OH	93	M	1/19/2021		<p>stated when he took the shot that he is breathing harder than he was before; This is a spontaneous report from a contactable consumer. A 93-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Batch/Lot number: not reported), via an unspecified route of administration on 19Jan2021 (age at vaccination 93-year-old) at 1ST DOSE, SINGLE for covid-19 immunisation. Medical history included hearing problem, hearing aid user, amyloidosis. The patient's past drug included Coumadin and Vyndamax. The patient's concomitant medications were not reported. On an unspecified date, the patient stated that he had a Pfizer shot on 19Jan and is due to get another on 09Feb. he is 93 years of age. He stated that he was diagnosed with amyloidosis and was using a Pfizer medication called Vyndamax to help him keep the protein off the major parts of his body. He took the shot that he was breathing harder than he was before. He wanted to know if this is possible and also stated that he had a hearing problem and hearing aids before the shot. Stated that he was diagnosed with amyloidosis and taking Coumadin and Vyndamax before the shot. The outcome of events was unknown. Reporter details: Stated that he was going for medicine many years ago but ended up in business. Follow-up (01Feb2021): New information received from a contactable consumer. 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 attempts have been completed and no further information is expected. Information on the lot/batch number has been requested.</p>
1365150	6/1/2021	CA	59	M	5/20/2021	5/20/2021	<p>Left sided sudden sensorineural hearing loss - seen at ENT specialist 5/21/21, confirmed with audiogram and treated with steroid course. At 2 weeks, the hearing has recovered to his baseline.</p>

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1364893	6/1/2021	FL	40	F	4/15/2021	4/22/2021	April 15- second Covid shot April 22 - first big vertigo spell. Deafness then ringing in right ear April 23 - mild ringing in both ears and thumping, pressure in head May 4th - very noticeable ticking in right ear May 9th - felt sick, off, hard to take a deep breath, pounding head, fullness in ears, ringing, emotional May 11th - ENT visit. Ears clear, hearing fine May 18th - May 23- off and on headaches, difficulty breathing May 24th - Headache that didn't go away with medicine. Fullness in ear. Nausea May 25th - Sleepless night, stiff neck, very full head. Medicine providing no relief(Excedrin, Sudafed, Flexeril) can feel fast heartbeat, ringing, and pulsation in ears, stiff jaw May 26-28 - light head congestion May 29- headache returns May 30- head congested even after Sudafed. Ears feel ?wet? hard to take a deep breath, lots of yawning. Flushed face and blotchiness on neck. May 31 - Difficulty breathing, ringing in both ears
1365712	6/1/2021	CA	69	M	1/23/2021	4/28/2021	Acute sudden total hearing loss in left ear
1365929	6/1/2021	LA	35	F	1/13/2021	1/14/2021	Memory fog, vision loss right eye, dry eyes, partial hearing loss in right ear. Multiple visits to eye center. Dr diagnosed me with Encephalopathy. Seen my Dr. an audiologist at Center. Dr. diagnosed with partial hearing loss in my right ear. I had the actual Covid 19 virus in August of 2020. At that time I lost my sense of taste and smell for approximately 2 weeks. I had no long term side effects related to the virus. I received my first COVID 19 vaccine in December 23 2020. I had no side effects from that vaccine. The day after receiving my second Covid 19 vaccine, I started having light sensitivity, right eye itching, and visual disturbance of the right eye. Weeks later I started noticing changes in my ability to hear out of my right ear. Then people started noticing that I wasn't hearing them appropriately. I've had multiple visits from specialist. I've had to buy new glasses, eye meds, contacts, take off work many times, and now I'm saving for a hearing aid. I was told by both specialist that the outcome is unknown at this time because there is not enough information on the virus and the vaccine to make that judgement.



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1365750	6/1/2021	PA	47	F	1/10/2021	6/1/2021	Approximately 6 to 8 weeks after receiving my second Pfizer Covid-19 vaccine, I developed tinnitus and hearing loss in my left ear.
1365550	6/1/2021	IL	57	M	3/17/2021	4/7/2021	LOSS OF HEARING IN LEFT EAR. AFTER 10 DAYS OF CHILLS. (VACCINE) 3 WEEKS AFTER FIRST SHOT. TREATMENT: I HAD A HEARING TEST,(HEARING LOSS VERIFIED) 10 DAYS STERIOD TREATMENT (HEARING IS STILL GONE), MRI (NO TUMOR), AND VGN FOR SLIGHT VERTIGO. (HAVE NOT GONE FOR THE VGN) HEARING LOSS TO ME, IS NO BETTER. HAVE TROUBLE UNDERSTANDING SPEECH AND WHERE/WHAT NOISES ARE. DR. SAID I COULD HAVE GOTTEN A VIRUS OR IT JUST HAPPENED. (DID NOT BLAME IT ON VACCINE) I HAVE A 50/50% CHANCE OF GETTING HEARING IMPROVEMENT. ?? I AM IMMUNE DEFFICIENT DO TO "HUMIRA" AND THINK THE VACCINE TRIGGERED THE HEARING LOSS? DID NOT HAVE ISSUES WITH HEARING BEFORE VACCINE. NOT SICK, LOUD NOISES, JUST THE SIDE AFFECT OF VACCINE, AND THEN HEARING LOSS.
1365277	6/1/2021	FL	45	M	5/10/2021	5/10/2021	Profound hearing loss in right ear; Tinnitus in left ear. These symptoms began the evening after the dose was administered and were intermittent throughout each day, eventually resolving entirely about a week later.
1365163	6/1/2021	TX	48	M	4/1/2021	4/1/2021	Loss of hearing to right ear lasted approximately 3 wks

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1364023	6/1/2021	TX	45	M	4/30/2021		<p>Gone deaf in his right ear after getting the 2nd dose and cannot hear anything on right side; Tongue was also swollen; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS UNILATERAL (Gone deaf in his right ear after getting the 2nd dose and cannot hear anything on right side) in a 45-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 30-Apr-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) (unknown route) 1 dosage form. On an unknown date, the patient experienced DEAFNESS UNILATERAL (Gone deaf in his right ear after getting the 2nd dose and cannot hear anything on right side) (seriousness criterion medically significant) and SWOLLEN TONGUE (Tongue was also swollen). At the time of the report, DEAFNESS UNILATERAL (Gone deaf in his right ear after getting the 2nd dose and cannot hear anything on right side) and SWOLLEN TONGUE (Tongue was also swollen) outcome was unknown. Concomitant medications and treatment details were not provided. The action taken with mRNA-1273 in response to the event was not applicable. The patient reported that he had gone deaf in his right ear after getting the 2nd dose and could not hear anything on right side. His tongue was also swollen after getting the 2nd dose. Company comment:Very limited information regarding this event/s has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.</p>

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1365325	6/1/2021		54	F	4/13/2021	4/19/2021	- Teeth nerve pain - Extreem thirst - Swelling and warm hands and feet and aching - Ear pain and tinnitus and muffled sound (hearing loss) - Neck pain - Lower Back pain (4/19) - Middle back pain - Hiccups - Dry leathery skin (skin around fingernails and toenails peeled, hang nails (toes and fingers), lips cracked peeled overall skin looked dry wrinkled) no amount of oil or lotion helped. - Mouth painful blisters in the back that never popped just went away - Narcolepsy like tired episodes 35 minutes after vaccine 2x since - Dizzy when standing (evening of vaccine) - Knee patella dislocated and both knees seem unstable like they are going to dislocate entirely when leg is twisted like turning. - Tender to the touch and pain under left rib cage 4/13/21 one episode of narcolepsy weird tire episode that lasted a total of maybe 10 minutes with complete waking up just as I laid down to nap. Right arm hurt but not bad. Chills with a temperature of 97.1F and later was drenched in sweat with a temperature of 97.8F. Woke up super thirsty and was so thirsty for several days drinking 1.5 gallons of water and still being thirsty even when I tried some salt pills. 4/16/21 Really red, swollen and itchy eyes (allergies) with sinus headache 4/17/21 lower back went out slowly all day till I was stuck in bed with ice. Right arm tingling like pins and needles. Lips super dry cracking and peeling. 5/14/21 started prednisone
1362128	5/31/2021		45	M	1/26/2021	3/12/2021	Bowel discomfort and stuffed right ear, partial hearing loss, vertigo, nausea, shingle like rash on right side of the body. Treated with antibiotic and beclomethasone , seems to help with vertigo. vertigo came back one week later after finishing the antibiotics round. now on 30 days round of doxycycline, no vertigo , very little dizziness and nausea. 2 weeks back started a high dose of vitamin C that it seems to help with the dizziness and nausea. Right ear still stuffed and feeling weakness from time to time.

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1362088	5/31/2021	WA	27	M	5/11/2021	5/21/2021	Right ear started ringing suddenly Friday may 14 2021 as I was sitting down at my computer after work. It has been growing in intensity over time since then, and on may 25th 2021 I went to urgent care, advised them I thought I may have a wax or ear infection problem and was prescribed "ofloxacin 0.3% otic solution commonly known as: FLOXIN" and have been taking the daily drops. The ringing is getting worse and the only thing I can think of that changed in my life recently was the vaccine. I no longer suspect ear infection as I have experienced those before and never taken this long to recover, much less getting worse while taking medication. My day to day life otherwise has been the same. The ringing is so deafening now I cannot sleep and I wanted to make record of this before seeking additional medical help in the morning.
1362248	5/31/2021	MI	49	M	3/23/2021	3/24/2021	Odd taste in mouth, heart racing, sweating. Next day developed tinnitus and pain in right ear/eye. Fatigue and brain fog. Severed headache. Felt like stabbing pain in head. Saw ENT 6 days later. Was prescribed steroids and ear drops. Have hearing loss in right ear and tinnitus
1361974	5/30/2021	IL	26	F	2/9/2021	2/20/2021	I do not have vaccine information other than Moderna. Pt is a CPS teacher and I saw her for the sudden hearing loss.
1361899	5/30/2021	CA	71	M	2/26/2021	3/12/2021	~2 weeks after receiving second dose of Moderna vaccine, pt. developed ringing in ears, drastic hearing loss in right ear, dizziness, nausea (w/emesis), achy muscles and headache. PCP diagnosed pt. with Meniere's disease. Since initial onset, symptoms have improved but patient is still not fully back to normal (some hearing loss, achy muscles and dizziness persist).
1361661	5/30/2021	WA	45	M	4/28/2021	5/12/2021	Dizziness, loss of hearing and heavy fatigue two weeks after first dose. Hearing recovered three days after loss. The resting issues lasting for almost three weeks so far. I'm currently on medical leave of absence. Doctor diagnosed me with dizziness and vertigo. Looking at computer screens and walking trigger this the most. Driving is fine.

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1361499	5/30/2021	NC	51	F	4/13/2021	4/25/2021	Sudden hearing loss in left ear, diagnosed by audiogram and doctor exam; diagnosis: Sudden Sensorineural hearing loss
1360483	5/29/2021	MI	57	M	4/7/2021	4/8/2021	deaf in left ear; Could not keep balance; This is a spontaneous report from a contactable healthcare professional (patient). A 57-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) at age 57-year-old, via an unspecified route of administration, administered in arm left on 07Apr2021 16:30 (Batch/Lot number was not reported) as 1st dose, single for covid-19 immunisation. The patient's medical history was reported. There were no concomitant medication and no other vaccine received within 4 weeks. The patient could not keep balance and went deaf in left ear on 08Apr2021 12:00. The events resulted in doctor or other healthcare professional office/clinic visit. Unspecified treatment was given for the events. Patient recovered on an unspecified date. Patient was not diagnosed with COVID prior to vaccination and has been tested post vaccination on 13Apr2021 (nasal swab) with negative results. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 vaccine can not be excluded for the reported events of balance disorder and deaf in left ear due to temporal relationship. Case will be re-assessed upon the additional information provided. 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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1361245	5/29/2021	SC	68	F	3/8/2021	3/11/2021	The night of the shot (3/8/2021) i felt like I got "hit by a truck". I went to be early and slept through the night. The next morning, I felt better, but for a slightly sore shoulder at the injection site. The night of 3/11, I woke up to go to the bathroom and felt dizzy and "off", but went back to sleep and slept through the night. The morning of 3/12/2021 I woke up and could not hear ANYTHING in my left ear! I went to a local Urgent Care facility. They treated me for a bacterial infection in my ear and gave me the following medicines: Antivert 25 mg oral tablet: = 1 tab(s) ( 25 mg ), Oral, tid, x 7 day(s), PRN: for dizziness, # 21 tab(s), 0 Refill(s), Type: Acute pharmacy, 1 tab(s) Oral tid,x7 day(s),PRN:for dizziness, 63, in, 03/12/21 18:08:00 EST, 03/12/21 18:0... cefdinir 300 mg oral capsule: = 1 cap(s) ( 300 mg ), PO, q12hr, x 10 day(s), # 20 cap(s), 0 Refill(s), Type: Acute, 1 cap(s) Oral q12 hr,x10 day(s), 63, in, 03/12/21 18:08:00 EST, 03/12/21 18:08:00 EST I continued the medication as directed, but nothing improved. I did secure a family Dr. by then and scheduled an appointment for him to check my ears because I was supposed to fly and was worried about flying with a bad ear. he said my ears looked good and I was OK to fly. Still nothing improved, so upon returning home at the end of April, I got an appointment for an ENT here to check my left ear. After extensive hearing tests, they determined I have "Profound Hearing Loss" in my left ear! I am scheduled for an MRI to see if anything else could be the culprit,. but at this time, they are thinking I the hearing loss as a result of the Pfizer vaccine, since they've treated other patients with the same problem!!! they did say that mine is definitely the worst they have ever seen!!!
1360974	5/29/2021	NY	44	F	3/22/2021	3/29/2021	Sudden hearing loss and tinnitus in left ear.
1360720	5/29/2021	PA	67	M	2/19/2021	3/11/2021	Occurrence of tinnitus which Had long been in remission in one ear, and sudden unexplained hearing loss in same ear

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1360659	5/29/2021	VA	61	F	3/19/2021	4/10/2021	Several weeks after second shot starting hearing ringing in ear when laying down and all during the day. Put off visit to ent thinking it may be water in ear. Just had ent visit, no inner ear fluid but kept questioning any new medications I had taken which was no. He has scheduled me for hearing test to see if any hearing loss. Said may be titanatis? Came home and looked up sudden ringing in ear, and see where it is showing up after second shots in a lot of patients a side effect of COVID shot being reported. Shocked. Pray it goes away. Unbearable to think this is what I will deal with. Also afraid if tied to shot, what do I do about boosters? Do I loose my hearing?
1360404	5/29/2021	CA	43	F	4/7/2021	4/7/2021	next night I couldn't sleep because I was itchy and feeling ticking all over my body; next night I couldn't sleep because I was itchy and feeling ticking all over my body; next night I couldn't sleep because I was itchy and feeling ticking all over my body; Hearing loss; tunnel vision; After a couple of minutes, started feeling faint/dizziness; weakness; nausea; got hot; started sweating excessively; Sore arm; This is a spontaneous report from a contactable consumer (patient). A 43-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration, administered in arm left on 07Apr2021 20:15 at age of 43-year-old (Batch/Lot Number: Ew0151) at single dose for COVID-19 immunization. Medical history included know allergies to wheat. The patient is not pregnant at the time of report. Prior to vaccination, the patient was not diagnosed with COVID-19. There was no other vaccine in four weeks or other medications in two weeks. After a couple of minutes on 07Apr2021 at 20:30, the patient started feeling faint. Hearing loss, tunnel vision, dizziness, weakness, nausea, got hot and started sweating excessively. The patient was able to walk with assistance after 20-25 minutes. The patient also developed sore arm on 07Apr2021, then the next night of 08Apr2021, she couldn't sleep because she was itchy and feeling ticking all over her body. The events did not result in emergency room visit or physician office visit. There was no treatment for the events. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the events was resolved in Apr2021.

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1360665	5/29/2021	VA	66	M	3/15/2021	3/18/2021	MY tinnitus had been an afterthought after a few years when it first occurred in 2004. Soon after the 2nd moderna vaccine, it has gotten progressively worse. Met with my ENT a few days ago and he informed me he has had numerous patients complain about tinnitus after receiving a COVID vaccine. Some of my friends and relatives have also mentioned the same thing. The ringing in left ear is constant and is getting worse. Since a hearing test on 5/26 showed I have "Asymmetrical sensorineural hearing loss, unilateral, with restricted hearing on contralateral side", he has ordered a "MRI BRAIN+INTERNAL AUDITORY CANAL, W/WO CONTRAST. My MRI appt is 6/3.
1359861	5/28/2021	CA	29	F	4/15/2021	5/26/2021	Within 15 minutes, ringing in left ear, inner ear canal pain, loss of hearing left ear. Ringing ended in 3-4 hours, ear pain and loss of hearing lasted around 2 days.
1358304	5/28/2021	CA	67	M	4/27/2021	4/28/2021	Tinnitus without sensorineural hearing loss
1357888	5/28/2021	CA	44	M	5/27/2021	5/27/2021	Extreme increase in tinnitus in left ear and also new tinnitus in right ear. Uncertain if additional hearing loss has occurred.
1357821	5/28/2021	CO	20	F	5/7/2021	5/7/2021	Immediately after receiving the Pfizer injection, I began to feel lightheaded and dizzy. Moments after that, I felt a general sense of unease and began feeling too hot. I was nauseated, sweating, shaking, experienced tingling in the hands and feet, tunnel vision, and temporary loss of hearing. Within 10 minutes, these had all subsided, and after my 15 minutes of waiting was up, I was allowed to leave with no further adverse reactions.
1357784	5/28/2021	AL	39	F	5/23/2021	5/23/2021	Systemic: claims "loss of hearing, ringing, popping in right ear along with numbness in face-Medium, Systemic: Numbness (specify: facial area, extremities)-Medium, Additional Details: pt did not directly contact pharmacy-she filled out survey from a receipt-tried to follow up twice with pt but pt did not call back



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1357206	5/28/2021	FL		F		4/9/2021	Sudden hearing loss - 100% hearing loss upon waking up in the left ear; Sudden hearing loss - 100% hearing loss upon waking up in the left ear; This is a spontaneous report from a contactable consumer (patient). A 45-year-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration on an unspecified date as UNKNOWN, SINGLE for COVID-19 immunisation. It was reported that patient received first dose of BNT162B2 on 06Apr2021 09:00 (lot number: EP7533) in right arm, and second dose also on 06Apr2021 (lot number: EW0171) in left arm; both information has pending clarification. Medical history included underlying hearing loss from childhood. The patient was not pregnant at the time of vaccination. The patient received unspecified birth control, and vitamins within 2 weeks of vaccination. No any other vaccines received within 4 weeks prior to the COVID vaccine. The patient experienced sudden hearing loss - 100% hearing loss upon waking up in the left ear on 09Apr2021 05:30. Therapeutic measures were taken as a result of sudden hearing loss - 100% hearing loss upon waking up in the left ear which included steroid and antibiotics. The event resulted in emergency room/department or urgent care. The patient was recovering from the event. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient has not been tested for COVID-19 since the vaccination.

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1357191	5/28/2021	FL	61	F	2/3/2021	2/3/2021	<p>Tinnitus; hearing loss; Gout; Dry heaves; extreme abdominal cramping; Chills/Fever; Chills/Fever; Body Aches; Slept most of the day; Extreme sore arm; Quarter size hard lump X3weeks;; This is a spontaneous report from a contactable consumer (patient). A non-pregnant 61-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), dose 1 via an unspecified route of administration, administered in the left arm, at age 61 years, on 03Feb2021 (Batch/Lot Number: EL9269) as 1st DOSE, SINGLE for COVID-19 immunisation. Relevant medical history includes hypertension, asthma, glaucoma and cataracts, and blood clot from unspecified dates. Prior to vaccination, the patient was diagnosed with COVID-19 on unspecified date. Concomitant medications included chlorthalidone; apixaban (ELIQUIS); losartan; and verapamil, all taken for an unspecified indication, start and stop date were not reported, received within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient previously received ciprofloxacin (CIPRO) and vancomycin on unspecified dates and experienced known allergies. On 03Feb2021 14:00, the 1st day, patient experienced extreme sore arm; quarter size hard lump X3weeks. On 04Feb2021 14:00, second day, patient experienced chills, fever, body aches, slept most of the day. On 05Feb2021 14:00, third day, patient experienced dry heaves for 2 hours followed by extreme abdominal cramping that required the patient to lay flat for the whole day. On 06Feb2021 14:00, fourth day, patient woke up to gout in his right big toe that lasted for a week. On 08Feb2021 14:00, sixth day, patient had tinnitus in both ears and hearing loss. ENT doctor prescribed oral steroids w/ taper and when that didn't work. Patient went through 4 torturous treatments where ear drum was initially punctured and shot of steroids was inserted through the hole. That didn't work either and around the time of reporting, patient was told that she have permanent hearing loss and the tinnitus has not gone away. She is now looking at needing hearing aids and will not be subjecting herself to the second dose. Hospitalization prolonged was not involved. The adverse event resulted in doctor or other healthcare professional office/clinic visit. Since the vaccination, the patient has not been tested for COVID-19. Facility where the most recent COVID-19 vaccine was administered</p>

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1357165	5/28/2021	MI	76	M	2/1/2021	2/2/2021	<p>was at a doctor's office/urgent care. The outcome of the events was not recovered.</p> <p>hearing loss; my nose started to run non stop; type of vertigo symptom's; This is a spontaneous report from a contactable other HCP (patient herself). This 76-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot number el3249), via an unknown route, on 01Feb2021 (at the age of 76-year-old) at single dose for COVID-19 immunisation. Historical vaccine includes the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot number not provided) on unknown date for COVID-19 immunisation. No relevant medical history was provided. Relevant concomitant medications included lisinopril and atorvastatin. The patient received the last shot on 01Feb2021. The next day "my nose started to run nonstop". The runny nose lasted for about 6 days. The next thing that happened was a type of vertigo symptom's that lasted for 4 days. On 12Feb2021 "I woke up and could not hear out of my left ear". The hearing loss was trying to come back but did not. The events required a physician office visit. She was treated for the events. On 23Mar2021, the patient performed a hearing test, but results were not provided. On 12Apr2021, a nasal swab was done and resulted negative. The patient had recovered from 'my nose started to run non stop' on 08Feb2021 and from 'type of vertigo symptom's' on 06Feb2021. The outcome of 'hearing loss' was not recovered.; Sender's Comments: As there is limited information in the case provided, the causal association between the event and the suspect drug 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 drug 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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1359000	5/28/2021	WA	13	F	5/17/2021	5/17/2021	PATIENT DID EXPERIENCE A REACTION WITIN 5MINS AFTER VACCINATION WITH PFZIER 1ST SHOT. SHE EXPERIENCED BLURRY VISION, LOSS OF HEARING AND DIZZINESS FOR 15MINS WITH HOT FLASHES. GAVE HER APPLE JUICE AND HAD HER PUT HER FEET UP ON CHAIR. AFTER 20 MINS SHE WAS FEELING FINE AGAIN AND LEFT WITH DAD.
1355115	5/27/2021	TX	55	M	3/25/2021	3/30/2021	Symptoms started as ringing in left ear . The symptoms increased over 10-14 days with addition of dizziness and hearing loss in the left ear.

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1353350	5/27/2021	WI		U	2/1/2021		<p>Cough and it is not like usual coughs; it seems odd; heaviness at top of my chest or bottom of my throat that could be when I cough; was like an attack; Cough and it is not like usual coughs; it seems odd; heaviness at top of my chest or bottom of my throat that could be when I cough; was like an attack; Cough and it is not like usual coughs; it seems odd; heaviness at top of my chest or bottom of my throat that could be when I cough; was like an attack; Cough and it is not like usual coughs; it seems odd; heaviness at top of my chest or bottom of my throat that could be when I cough; was like an attack; Aching in my body; Extreme tiredness; Never went to sleep because started aching all over my body; This morning my temperature was 99; This is a spontaneous report from a contactable consumer (patient). A 97-year-old patient of unspecified gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as unknown, single for covid-19 immunisation. Medical history included macular degeneration, hearing problem, and COVID-19 (when patient got the injection, patient already had the virus). The patient's concomitant medications were not reported. After vaccination, patient never felt a thing, for may be 4 or 5 days and all of a sudden about 3 or 4 days ago, patient had a cough and it was not like the usual coughs that patient got where patient can blame it on anything. Well than patient was having a little aching in body. Now this was in last 3, 4 days and back and from side, it was a different thing. Now patient will get to point, last night, last evening, all around 7 o'clock, patient really noticed a lot of aching and at 9 o'clock patient went to bed because patient just felt have to and tiredness, extreme tiredness and then patient never went to sleep because patient started aching all over body and patient got up about 7 times during the evening. Now when patient got up this morning, patient have definitely improved. Right now, patient could not say really say that patient was aching noticeably anywhere. Patient was almost wondering when patient got the virus do not see the symptoms for a while and patient thought what if patient got the virus and when patient went in and got the injection patient already had the virus. Temperature was 90, last night it was 98. This morning it was 99 and patient felt a little bit nothing to talk about. A little bit of heaviness at the top of chest or the bottom of throat but that could be when patient cough like this to show patient can cough. So patient thought it</p>

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was better to check and see if should ignore all this because definitely what happened last night was almost like an attack, it is gone now, aching all over body. The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

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1353443	5/27/2021	NY	55	M	4/14/2021	3/25/2021	<p>he has slight hearing loss which is normal with tinnitus/there was slight hearing loss going; after first shot on 24Mar I had severe tinnitus of the right ear. After second shot on 14Apr, it got progressively worse; Experienced a very disturbing ringing in the ears (Tinnitus); This is a spontaneous report from a contactable consumer (patient) via Pfizer-sponsored program . A 55-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot Number: EJ1686 and Expiration date was not reported), via an unspecified route of administration on 24Mar2021 (at the age of 55-years-old) at 1st dose, single for COVID-19 immunization. The patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot Number: EN6205 and Expiration date was not reported), via an unspecified route of administration on 14Apr2021 02:45 as 2nd dose, single for COVID-19 immunization. Medical history included gastric reflux. Concomitant medications included pantoprazole (a proton pump inhibitor for the indication of gastric reflux), Dosage: 140mg (as reported), Tablet, Twice a Day. No other vaccines were taken within four weeks. Other medications included Multivitamin-vitamin c, pantoprazole in two weeks. No known allergies were reported. No other medical history was reported. The patient did not have covid prior vaccination and was not tested post vaccination. The patient also reported that the day after first shot on 25Mar2021, he experienced a very disturbing ringing in the ears (Tinnitus), severe tinnitus in the right ear, there was slight hearing loss going. On an unknown date, after the second shot, the patient experienced worsening of the tinnitus. The patient wanted to make sure this was documented since it was life changing and because of this it was very hard for him to sleep, concentrate and was very depressing. The patient wanted to know if this was one of the side effects of Pfizer vaccine. He stated that he got the second shot thinking that tinnitus will go away, but it got worse after the second dose. The patient stated that he believed that it was certainly directly related to the vaccine. The patient stated that he had an audiology appointment Monday on 26Apr2021 with a follow-up ENT appointment Wednesday on 28Apr2021. The patient reported that he went to the ENT where his hearing was tested and told</p>

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							that he had slight hearing loss going but tinnitus was not explained. He was worried if this was some kind of permanent condition. He stated that no one had answers not even the immunologist and there were thoughts that it might be histamines or an irritation. The patient stated that he had not done any blood test. He had regular lab test to check his iron and cholesterol levels low or high. He reported that his blood levels were fine that was probably a couple of weeks before he got the shot. The patient reported that he had to ask his ENT to provide prednisone as treatment. Events caused to visit doctor or other healthcare professional office/clinic visit. The outcome of the event tinnitus was reported as not recovered whereas the outcome of the events slight hearing loss was unknown. No follow-up attempts are needed. Information about lot/batch number cannot be obtained. Follow-up (24Apr2021): This is a follow-up report combining information from duplicate reports 2021457050, 2021494963 and 2021469710. The current and all subsequent information will be reported under manufacturer report number 2021469710. Patient demographics, Lot number, medical history, concomitant medications, event details updated. Follow up needed, further information was requested. Follow up (30Apr2021): This is a follow up spontaneous report from a contactable consumer. Patient details updated, events caused condition and Hcp information added.
1354334	5/27/2021	NH	67	M	2/13/2021	3/1/2021	right ear hearing loss / change (low frequency)
1355043	5/27/2021	MD	69	F	3/4/2021	3/17/2021	Two weeks following the first COVID vaccination I awoke with Sudden Onset Hearing Loss in my right ear. No prior hearing loss, no other symptoms. No other changes in health prior to the hearing loss.. Hearing loss confirmed by audiologist on 3/23/21.
1355278	5/27/2021	MD	52	F	5/12/2021	5/13/2021	swollen lymph nodes in right armpit appeared after about 24 hours from vaccination, the bulge grew the size of chicken egg over the next 2 days+ fullness/swollen ear canals, both ears. arm pit nodes returned to almost normal condition after 5 days from onset of symptoms, some discomfort remains under armpit but transient (sometime tender nodes are present and other times not). swollen ears remains a problem 2.5 weeks later, partial hearing loss due to swelling. no medical treatments



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1356487	5/27/2021	VA	16	F	5/27/2021	5/27/2021	PATIENT EXPERIENCED DIZZINESS, BLURRY VISION, HEARING LOSS AND BECAME SHAKY AND PALE ABOUT 2 MINUTES AFTER GETTING THE VACCINE. SHE WAS STILL SEATED IN THE IMMUNIZATION ROOM AT THE TIME THE ADVERSE EVENT OCCURED. SHE REMAINED SEATED IN THE ROOM FOR ABOUT 20 MINUTES BEFORE FEELING WELL ENOUGH TO LEAVE. SHE WAS GIVEN WATER AND AN ICE PACK.
1354667	5/27/2021	CT	58	M	5/10/2021	5/16/2021	Sudden sensorineural hearing loss on the right ear. Symptoms started 1 week after the 2nd dose of the COVID-19 vaccine on Monday 5/17. The hearing loss was accompanied by continuous buzzing sound, static noise, sensation of ear fullness, local discomfort, headache. It progressed over the first week. On saturday 5/22, I performed an online hearing test that confirmed the hearing loss (see section 19 for results). I went to urgent care to get the ear checked and cleaned, with no noticeable improvement in symptoms. On Sunday 5/23 I was started on 30 mg predinsone po. On Monday 5/24, I went to specialist care, she increased dose to 60 mg of prednisone and order additional tests.

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1349273	5/26/2021	WV	72	M	3/1/2021	3/3/2021	Increase in tinnitus levels; harder to hear people talk than before; Very very distracting; This is a spontaneous report from a contactable consumer. A 72-year-old male patient received BNT162b2 (PFIZER BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Lot number-UNKNOWN) via an unspecified route of administration in left arm on 01Mar2021 14:15 as 1st dose single (at the age of 72-years-old) for COVID-19 immunization. Vaccination facility type was reported as Other. Patient did not receive any other vaccine in four weeks. Patient did not receive any prior COVID vaccination. Patient was not tested for COVID post vaccination. Patient medical history included CLL, stenosis of spine, occasional SVT, previously mild tinnitus, some hearing loss and had known allergies to Aspirin, Ginger, NSAIDs. The concomitant medications were not reported. On 03Mar2021, patient experienced increase in tinnitus levels, which is very distracting now, when in silence, harder to hear people talk than before. First noticed that a few days later. It has not gone away. The outcome of the event was not recovered. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

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1349426	5/26/2021	TX	67	M	3/1/2021	3/8/2021	Left ear sudden hearing loss; increased tinnitus; This is a spontaneous report from a contactable consumer (patient). A 67-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: EN6202), via an unspecified route of administration on 01Mar2021 at 11:00 in arm left as a single dose and second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: ER2613), via an unspecified route of administration on 22Mar2021 in arm left as a single dose for COVID-19 immunisation. The patient's medical history was not reported. The patient's concomitant medications in two weeks included lisinopril (LISINOPRIL), atorvastatin (ATORVASTATIN), citalopram (CITALOPRAM) and pantoprazole (PANTOPRAZOLE). It was reported that, the patient had no known allergies. No other vaccine in 4 weeks. No covid prior vaccination and no covid tested post vaccination. On 08Mar2021, the patient experienced left ear sudden hearing loss and increased tinnitus. Treatment medication included prednisone. The events resulted in doctor or other healthcare professional office/clinic visit. The outcome of the events was recovered with lasting effects.

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1349557	5/26/2021	MN	59	M	4/12/2021	5/2/2021	Sudden idiopathic hearing loss of the left ear; This is a spontaneous report from a contactable consumer. A 59-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Right on 12Apr2021 11:15 (Batch/Lot Number: ER8729) as 2ND DOSE, SINGLE for covid-19 immunisation. Medical history included Alcoholism, diverticulosis, allergies Penicillins. Patient previous received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6204) in Mar2021 in Right arm for covid-19 immunization. Concomitant medication(s) included naltrexone taken for an unspecified indication, start and stop date were not reported; folic acid taken for an unspecified indication, start and stop date were not reported; cyanocobalamin (VITAMIN B-12) taken for an unspecified indication, start and stop date were not reported. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced sudden idiopathic hearing loss of the left ear on 02May2021 12:00 with outcome of not recovered. Therapeutic measures were taken as a result of sudden idiopathic hearing loss of the left ear. Case was reported as serious as Disabling/Incapacitating. Information on Lot/Batch number was available. Additional information has been requested.
1350696	5/26/2021	WV	57	F	1/1/2021	3/29/2021	Sensorineural hearing loss moderate left ear and mild right ear: sudden onset
1350782	5/26/2021		18	M	4/27/2021	4/30/2021	sudden onset sensorineural hearing loss on the left
1350789	5/26/2021		21	M	4/27/2021	5/4/2021	sudden onset partial sensorineural hearing loss sibling had complete
1351960	5/26/2021	CA	40	F	4/1/2021	4/1/2021	Slight tinnitus that comes and goes in both ears. More concerning is intermittent hearing loss in right ear. Feels like hearing volume turns up and down, as though there is a blockage. There is also pressure that won't go away (pop). I have not sought treatment and am waiting to see if issue resolves on its own. I don't want to take steroids.

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1348862	5/26/2021	CO	47	F	5/6/2021	5/8/2021	Within 48 hours of receiving the second Covid shot, I woke up with vertigo and sudden hearing loss and ringing/buzzing in my left ear. I was taken to urgent care and prescribed nausea medication and Dramamine. I made an appointment with an ENT doctor who prescribed steroids. I finished taking the steroids 3 days ago and I still have vertigo and hearing loss and ringing/buzzing in my ear. This has been going on for coming up on 3 weeks now.
1351902	5/26/2021	OH	46	M	3/18/2021	3/28/2021	Loss of hearing in my right ear - Sudden Sensorineural Hearing Loss and now constant Tinnitus 10 days after 1st Phizer Covid vaccine I woke up with a plugged ear. A week later I went to an Urgent Care to have my ear checked out. I was put on antibiotics. After that not clearing up my ear, I visited an ENT doctor who diagnosed me with Sudden Sensorineural Hearing Loss. I also now have constant Tinnitus in my right ear. Dr did 2 injections into my eardrum with steroids and I was also put on Prednisone pills for 2 weeks. After these course of treatments I had no improvement in the hearing loss.

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1351618	5/26/2021	WA	49	F	1/26/2021	3/18/2021	(First dose of Moderna Covid 19 vaccine was 1/2/2021 and lot #025L20A) Approx. 3 weeks following the second dose of the Covid 19 vaccine I noticed a sudden hearing loss in my left ear. I first tried to use wax softeners/bulb syringe flushes for a few days to see if hearing loss was due to wax. When there was no resolution, I contacted my primary care provider and obtained an appt for 3/16/2021. At that time, provider saw "negative pressure" w/L eardrum and fluid bubbles behind L eardrum and placed me on Zyrtec, Flonase and Mucinex for 6 weeks to see if hearing resolved. When it did not, I was referred to ENT. A hearing screen was performed on 4/27/2021 prior to scheduled ENT appointment which showed "Mild-Severe Sensorineural Sloping" and an urgent appointment was made with ENT the following morning. On 4/28/2021 the ENT felt the hearing loss was most likely permanent as too much time had passed since initial loss was noted. She put me on an oral course of Prednisone as a "salvage attempt". The doses were 60mg for 3 days, 40mgs for 3 days, 20mgs for 3 days and 10mgs for 3 days. A follow up hearing screen on 5/17/2021 showed "no significant change in hearing status." Further treatment has been deemed unlikely to improve hearing and I have been advised to consider a hearing aid. (Of note, following first Covid vaccine I only had significant soreness at injection site (L arm for that injection). Following the 2nd Covid vaccine, I had a Tmax of 100.5 with significant injection site pain/soreness in R arm, generalized muscle aches and significant fatigue. Tmax and height of symptoms were 31hrs following injection. At 43.5 hrs past injection, temp was 98.2 and fatigue/muscle aches were improved with just mild headache developing at that time. By 56hrs following vaccine, felt 100% back to normal.) I kept a journal following the second dose of symptoms because I am a nurse and I wanted to keep an accurate record of my experience since I had heard such a wide range of responses reported which is how I have such accurate times following that dose.
1351590	5/26/2021	CA	20	F	5/21/2021	5/21/2021	Loss of hearing and vision, everything dizzy for about 15 minutes Fainted Lips turned grey

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1351513	5/26/2021	MI	22	F	5/26/2021	5/26/2021	After her shot, Patient felt dizzy sitting down on floor, I helped her lift up and had her seat in the chair. She might have passed out for a few seconds because her head was leaning on one side, upon asking her if she was ok, she did respond and complained of feeling dizzy and loss of hearing. After giving water to her, she started feeling better, her hearing came back but she still felt a little light headed and dizzy. We still monitored her and mom was called to pick her up. She was doing lot better after few minutes. Mom came to pick her up and we explained what happened to her to mom.
1351376	5/26/2021	WI	42	M	4/14/2021	4/18/2021	Started with loud ringing in my left ear at 2pm, followed 2 hours later with complete hearing loss in left ear and then woke up the next morning at 6:30am with severe vertigo (nausea and inability to walk). Vertigo got better after lights turned on to the point that I had no nausea anymore, but needed to hold onto things while walking. Ringing Went to urgent care at 10am to get assessed and after speaking with an ENT they prescribed Prednisone and Meclizine. Meclizine didn't help so only took for 2 days, was on Prednisone for 3 weeks .
1351197	5/26/2021	CA	45	F	5/20/2021	5/20/2021	Day 1: hearing loss in left ear, face felt sunburned, pain at surgical site (had oral surgery 4/15/21), fatigue, headache Day 2: fatigue, headache Day 3: fatigue, headache Days 4-6: headache
1352345	5/26/2021		33	F	3/24/2021	4/12/2021	Sudden hearing loss (SSNL) of left ear, onset approximately 2 weeks after vaccine
1352364	5/26/2021	PA	46	F	3/10/2021	3/1/2021	Swollen lymph nodes resulting in tonsil removal, tingling and numbness in tongue, constant ringing in ears, possible hearing loss
1348849	5/26/2021	FL	22	F	4/24/2021	4/24/2021	Immediate dizziness, nausea, and complete loss of hearing (subsided after 10-20 seconds), vomiting water. Dizziness remained for a few days along with other more common symptoms such as headache and arm soreness and pain and heavy fatigue.

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1348981	5/26/2021	CA	78	M	1/29/2021	2/2/2021	Sudden hearing loss; This regulatory authority case was reported by an other health care professional and describes the occurrence of SUDDEN HEARING LOSS (Sudden hearing loss) in a 78-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 041L20A) for COVID-19 vaccination. Concurrent medical conditions included Hypothyroidism. Concomitant products included VALACICLOVIR HYDROCHLORIDE (VALACYCLOVIR HCL), MULTIVITAMIN & MINERAL and ANTIOXIDANTS NOS for an unknown indication. On 29-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Feb-2021, the patient experienced SUDDEN HEARING LOSS (Sudden hearing loss) (seriousness criterion medically significant). At the time of the report, SUDDEN HEARING LOSS (Sudden hearing loss) had not resolved. 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. Patient reported the hearing loss happen on left ear. No treatment information for the event was provided. 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.
1346781	5/25/2021	MT	54	M	1/21/2021	1/21/2021	persistent bilateral tinnitus, interferes with hearing - began 4 hours after 2nd dose of Moderna vaccine on 1-21-21. Stopped for 6 hours after PCP initiated treatment with prednisone (on 5-17-21) but returned and has persisted since. No prior history of tinnitus or hearing problems.
1348467	5/25/2021	WA	34	M	5/25/2021	5/25/2021	Patient received vaccine, per family at vaccination site patients eyes rolled back and he looked pale. Patient is blind, deaf and nonverbal at baseline. Patient had BP 110/80, HR 84, RR 20 per patients family SpO2 98% on RA. Patient had cookies, applesauce and returned to baseline. Patient observed for 30 minutes.



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1348641	5/25/2021	MI	50	M	4/13/2021	5/23/2021	Hearing loss in left ear
1346603	5/25/2021	NY	64	F	4/10/2021	5/8/2021	After my second Pfizer covid vaccine, three weeks to the day I experienced sudden hearing loss in my left ear. Doctor stated it is idiopathic reason.
1347560	5/25/2021		67	M	5/13/2021	5/24/2021	sudden left sided sensorineural hearing loss
1346635	5/25/2021	FL	44	F	4/17/2021	4/18/2021	The day after vaccination (Day 2) she had stiffness in both upper arms and upper legs. On day 3, she had body pain. That same night she experienced extreme muscle weakness, headache, chills, night sweats, nausea, temporary loss of hearing in her right ear, and didn't want to eat or drink anything. These symptoms continued for a week.
1347676	5/25/2021	CA	56	M	4/9/2021	4/14/2021	Patient had 1st COVID vaccination on 4/9/2021. After 4 days, developed left sided tinnitus and ear pain. Recommended to use flonase for 1 week. On 4/12 he had started nortriptyline prescribed by neurology for headache, so stopped this due to side effect of tinnitus. He does feel the hearing is decreased. Subjectively states ringing got better after stopping nortriptyline and starting flonase. On 5/7/21 patient had 2nd covid vaccine. On 5/29/21 audiology shows left side with mild-moderate sensorineural hearing loss from 250-500Hz, 6000-8000 Hz patient reports 2 months of constant left side hissing tinnitus after vaccine. 5/21/21 patient prescribed prednisone oral titrating doses for 14 days.
1346710	5/25/2021	NC	39	M	5/23/2021	5/24/2021	loss of hearing in right ear and ringing sound in ear
1346828	5/25/2021	TX	66	M	5/23/2021	5/23/2021	Loss of Hearing in Left Ear - No Treatment as of now, Not sure what to do?
1347118	5/25/2021	FL	54	M	4/23/2021	4/23/2021	6 Hours after the patient had received his 2nd COVID Vaccine, the patient had suddenly experienced symptoms of sudden hearing loss, tinniutis, and vertigo out of his Left Ear

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1347170	5/25/2021	NY	34	M	5/24/2021	5/24/2021	5 min after administration, nausea, disorientation, stomach cramps, blood pressure drop, partial loss of hearing and sight, cold sweat, on the verge of losing consciousness. Reaction lasted for approximately 20 min, no medical help was administered. After 30 min, the symptoms subsided, 2 hours later were gone.
1347404	5/25/2021	CA	28	F	5/22/2021	5/25/2021	Sudden loss of hearing in one ear. Same side of body as injection arm.
1347459	5/25/2021	ND	68	M	3/24/2021	3/31/2021	I received my second dose of Moderna vaccine on 3/24/2021 and approximately one week later I experienced sudden loss of hearing in my right ear. A diagnosis of sudden severe sensorineural hearing loss was confirmed by both audiologist and MD ENT specialist. Hearing aid is no longer of benefit and treatment plan includes a future unilateral cochlear implant for my right ear.
1346639	5/25/2021	PA	36	M	5/24/2021	5/24/2021	Hearing loss in left ear discovered approximately 4.5 hours after shot. Hearing level at an estimate 20% of normal. Next morning hearing just slightly improved at an estimated 40% of normal with intense ringing in left ear only.
1343081	5/24/2021	OR	68	F	2/17/2021	2/19/2021	Beginning about 48 hours after I received my second Covid vaccination, I developed sudden hearing loss in my right ear associated with a feeling of "having a sock over my ear" and buzzing around my ear. These symptoms occurred in conjunction with the expected side effects from the vaccine with mild chills, fatigue, and aching, which lasted for 1-2 days. I did not lose the hearing in my right ear completely, but had marked decrease in hearing only in the right ear. I received no treatment for that symptom, and only had slight improvement in the right ear hearing loss over the next 2 to 3 months. I saw Dr. (otolaryngologist) on 5/19/2021 to evaluate my hearing loss, and had an audiogram the same day, showing significant decrease in hearing in my right ear.
1343721	5/24/2021	TX	90	M	2/12/2021	2/17/2021	Sudden hearing loss, tinnitus- hearing test, visit to ENT, prednisone given, no resolution

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1343412	5/24/2021	FL	18	M	5/12/2021	5/23/2021	Pulsatile Tinnitus, verigo, dizziness, nausea, vomiting. When I searched the Internet, I found hundreds if not thousands of people reporting serious problems regarding their ears shortly after receiving a Covid-19 vaccine. Total or partial hearing loss, tinnitus, vertigo, nausea, etc. This needs to be reported to the Public. I'm angry that I was not warned about this before getting the vaccine.
1343438	5/24/2021	MN	55	M	5/10/2021	5/14/2021	4 days afterwards, I developed intense tinnitus in my right ear (the one affected by Meniere's) and fullness. The ringing, deafness & fullness continues until today. I have lost a lot of hearing acuity in both ears. I felt really ill (flu like) on 5/20/21. I had full body aches and severely sore throat. The PA prescribed Methylprednisolone 4 mg dosepak. I have been taking according to instructions. Today, I developed vertigo for the first time in 14 years.
1343529	5/24/2021	ND	40	F	3/23/2021	4/3/2021	On 4/3 I woke up with Sudden Sensorineural Hearing Loss (SSNHL) in my left ear. I could not hear anything, and had tinnitus and dizziness. I was given prednisone 30mg for 5 days, Zyrtec-D, and cefdinir for 10 days. This partially cleared up, but I still cannot hear in my left ear, and have tinnitus. I went to the ENT on 5/19 and was given a transtympanic steroid injection of 24mg/ml Decadron. After a week, I don't think it has gotten any better, and I might have permanent hearing loss.
1342415	5/24/2021	WV	50	F	1/8/2021	1/26/2021	Acute unilateral (left) sensorineural hearing loss - 2 1/2 weeks after first covid 19 vaccine (Moderna). Documented moderate to severe hearing loss left ear by serial auditory testing. Treated with approx 18 days of oral corticosteroids. Hearing recovered by 2/18/21 follow up audiogram and visit.
1343587	5/24/2021	VA	45	F	4/11/2021	4/12/2021	tinnitus, partial hearing loss, vertigo
1344378	5/24/2021	NJ	22	M	4/22/2021	5/12/2021	Tinnitus (ringing) in left ear and hearing loss at higher frequencies, which developed about 19 days after my second Pfizer dose on 4/22

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1343902	5/24/2021	IN	57	F	1/11/2021	1/25/2021	Sudden Loss of hearing in Left ear. Unable to hear when talking on phone with left ear. Can hear perfectly fine with right ear. Thought it may be allergies but had been taking allergy meds, started flonase for allergies without relief. Started on antibiotic in April for 10 days no relief. Referred to ENT. Appointment on May 21. Confirmed hearing loss in Left ear.
1343782	5/24/2021	NJ	52	M	3/27/2021	4/6/2021	Hearing loss Vertigo Headaches Ringing in ears
1342450	5/24/2021	PA	41	F	2/21/2021	4/1/2021	Left ear slight hearing loss, tinnitus and ear fullness. Right ear is also ringing but not as bad as the left. The ears both have a popping sensation and the left ear feels closed at times.
1343633	5/24/2021		65	M	3/23/2021	4/15/2021	Left mild to profound sudden sensorineural hearing loss 3 weeks after COVID vaccine. Associated tinnitus.
1341725	5/23/2021	FL	94	F	2/11/2021	2/27/2021	Pt had acute ischemic stroke involving right vertebral artery 16 days after dose number one of Pfizer vaccine. She developed sudden dizziness and loss of leg strength, fell to floor. it took 7 hours until she was found and taken to hospital, so did not receive TPA. CTA on 2/27/2021 showed occluded V4 segment of rt vertebral artery. residual deficits currently include imbalance, loss of lower extremity strength (now in wheelchair), loss of hearing and discordant ocular movement.
1342106	5/23/2021	MD	15	M	5/18/2021	5/19/2021	Sudden hearing loss in Left Ear -15 db to -55 db depending on frequency. Most loss in 500Hz to 1000Hz range. Visited 2 ENT Dr for audiology tests. Recommendation/prescription 60mg daily Prednisone tablets for 7 days, 40mg daily for next 3 days, 20mg for 3 days followed by 10mg for 3 days.
1342157	5/23/2021	FL	72	F	3/16/2021	4/3/2021	Sudden total hearing loss in left ear, treated by daily transtympanic steroid injections over a period of 3 weeks. Regained much of my hearing.

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1340488	5/22/2021	TX		M	3/19/2021		<p>he is deaf in one ear; hard of hearing in the other/My hearing is not very good; his tinnitus has "sky rocketed" and gotten much worse/ringing in ears; has not even been able to sleep much; after my second shot it even got worse; This is a spontaneous report from a contactable consumer (patient). A 60-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Formulation: Solution for injection Batch/Lot number was not reported, Expiration Date was not reported), via an unspecified route of administration on 19-MAR-2021 as 2nd dose, single for covid-19 immunization. The patient medical history included Tinnitus (tinnitus -ringing of the ears) for about 25 years. Concomitant medications were not reported. The patient historical vaccination included first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) for COVID-19 Immunization taken on 26-FEB-2021. Patient stated that he has had tinnitus (ringing of the ears) for about 25 years, however, since he received both doses his tinnitus has "sky rocketed" and gotten much worse. He stated that he has not even been able to sleep much in the past 4 days because of it. This has been ongoing since March. He had seen his doctor multiple times and tried multiple treatments for his worsening tinnitus but it has not gotten any better. He stated that he does not know what to do and his doctor does not know what to do either at this point. The caller wants to know if there have been any other reports or complaints about this type of side effect after receiving the vaccine. The patient declined to be transferred to a hospital at this time. He did give consent for his information and his experience to be shared with hospital and for them to contact him via phone if necessary for any follow up questions. He stated that he was deaf in one ear and hard of hearing in the other. He also stated he was third person he had spoken with and it was hard for him to hear on the phone. Patient stated that the reason he was calling because he took his Pfizer first shot on February (26Feb2021) and second shot on March (19Mar2021) and he had taken this they going to be ringing in ears "last 35" (not clarified) and after the first shot he ended up getting headache not thinking too much about it but very highly and after his second shot it even got worse he had already been to the doctor to see if he has found out anybody having any problem with</p>

*VAERS\_ID RECVDATE STATE AGE\_YRS SEX VAX\_DATE ONSET\_DATE SYMPTOM\_TEXT*

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Covid shots concerning the ringing in ears. Are you familiar with this?" Consumer was informed about Pfizer Medical information Department. In response to further probing, consumer stated, "No, it is not. My hearing is not very good, so I am stressing right now." As consumer was not willing to proceed the call. Product details (LOT#, expiration date, NDC# and UPC#), Pharmacy details and treatment could not be probed over the call. Limited information available over the call. The outcome of the events was unknown. Information on the lot/batch number has been requested.

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1340333	5/22/2021	WA	53	F	4/30/2021	5/1/2021	<p>Blood sugar increased; no hearing in my right ear at all; ears were both stuffy; heavy pressure and could hear a loud tone in my head/ears; noise got worse and more intense as well as higher pitched/a loud tone going through my head, tinnitus; severe loud high pitched screeching noise that gave her a terrible headache; This is a spontaneous report from a contactable consumer (patient). A 53-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in arm left on 30Apr2021 11:30 (Batch/Lot Number: EW 171) as 1st dose, single for COVID-19 immunisation. Medical history included fibromyalgia, osteoarthritis (mildly), allergy: latex and Sulfa. Concomitant medication included furosemide (LASIX [FUROSEMIDE]) taken for an unspecified indication, start and stop date were not reported. Patient woke up the morning after vaccine (01May2021 07:00) and immediately noticed ears were both stuffy and it was difficult to hear. Patient had heavy pressure and could hear a loud tone in head/ears that was consistent and never stopped. Throughout the day the noise got worse and more intense as well as higher pitched. By that evening (01May2021 19:00) patient realized she had no hearing in right ear at all. Only severe loud high pitched screeching noise that gave her a terrible headache. She saw her ENT (ear, nose, throat) on Monday AM (03May2021) and they did audiology test and confirmed 100% loss of hearing in right ear! Severe tinnitus at deafening pitch and 24/7 nonstop, no silence ever since Saturday 01May2021. The Dr. prescribed her 60 mg prednisone over 7 days then taper down over 2nd week. Patient had MRI of brain on 12May2021 and follow up appoint on 18May2021. She met with her primary care doctor on 05May2021 to discuss all and she did a great deal of bloodwork and all normal. Investigation on unknown date included blood sugar increased. The events of ears were both stuffy and it was difficult to hear/ heavy pressure and could hear a loud tone in head/ears/ noise got worse and more intense as well as higher pitched/a loud tone going through head, tinnitus and no hearing in right ear at all were resulted in Physician Office Visit and received treatment included prednisone and were reported as serious with seriousness criteria: disability. Outcome of blood sugar increased was</p>

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1340341	5/22/2021	CT		F		4/5/2021	<p>unknown. Outcome of other events was not resolved.</p> <p>pain down right arm; right elbow throbbing; right hand numb; Tinnitus; pain across forehead right eye; hearing loss; pain across forehead right eye; migraine/migraine for next 24 hours; This is a spontaneous report from a contactable consumer (patient). A 55-year-old female patient (not pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on an unspecified date (Lot Number: EP6955) as 2ND DOSE SINGLE for covid-19 immunisation. Medical history included Lichen planus, 7 years before 2021, Rash on scalp, given benadryl and blue light for scalp. No recurrence, adhesive tape allergy. Historical vaccine included first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) via an unspecified route of administration, administered in Arm Left on 12Mar2021 02:30 PM (Lot Number: EN6208) as single dose for covid-19 immunisation. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication(s) included ergocalciferol (VIT D) taken for an unspecified indication, start and stop date were not reported. The patient previously took benadryl for rash, bnt162b2 for covid-19 immunisation. The patient experienced 2nd shot pain across forehead right eye migraine then pain down right arm right elbow throbbing right hand numb while sitting at (facility). Migraine for next 24 hours. Onset of Tinnitus 3 days after. Thought it would work itself out. Went to ENT on 26Apr2021 and have hearing loss. Prescribed Prednisone. No change in tinnitus. Never had tinnitus before until got the vaccine. Not on any medications, active and eat healthy. Have follow up on 11May2021. This is a problem, found a Facebook group with over 2000+ members having same symptoms. All event onset date was 05Apr2021 10:00 AM. Therapeutic measures were taken as a result of events. The outcome of events was not recovered. No follow-up attempts are needed. No further information is expected.</p>



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1340360	5/22/2021	NY	53	M	4/29/2021	4/30/2021	I woke up 12-16 hours after my 2nd dose with a loud, high pitched noise in both of my ears. (Tinnitus); This is a spontaneous report from a contactable consumer (patient). A 53-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 29Apr2021 14:30 at age of 53 years old (Lot Number: ew0172) as 2ND DOSE, SINGLE for covid-19 immunisation. Medical history included many known allergies, but did not react to vaccine. Patient was not diagnosed with COVID-19 prior to vaccination. Historical vaccine included bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 08Apr2021 14:30 PM at age of 53 years old (Lot Number: ew0172) as 1ST DOSE, SINGLE for covid-19 immunisation. After the 1st dose, patient was quite sick, suffered from exhaustion (sleeping 15-17 hrs a day) and a heavy cough, and minor sinus pressure, for the first 2.5 weeks after the 1st dose, noticed a very faint high pitch in ears a few days before the 2nd shot, but dismissed it as an aberration. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication(s) included meloxicam; omeprazole; levocetirizine, all taken for an unspecified indication, start and stop date were not reported. Patient woke up 12-16 hours after his 2nd dose with a loud, high pitched noise in both of ears (Tinnitus on 30Apr2021 05:00 AM). It has not diminished in the week since the 2nd shot. Patient can hear it while talking on the phone and when laying in bed. Serious criteria was provided as disability and with physician office visit. Patient had hearing tested by an audiologist 5 days after the shot and do not have hearing loss, despite the tinnitus. As a former professional singer, he was diligent about protecting hearing, wearing protection whenever near loud noises. Patient have never had symptoms of Tinnitus prior to the vaccine. The patient underwent lab tests and procedures which included hearing tested on 04May2021: no hearing loss, despite the tinnitus. Patient was not test for COVID-19 Since the vaccination. The outcome of event was not recovered and without hospitalization and with treatment given. Information on Lot/Batch number was available. Additional information has been requested.

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1340470	5/22/2021	MO		U	5/4/2021	5/4/2021	hearing loss/Unilateral sensorineural hearing loss; ringing in his ear; Tired; This is a spontaneous report from a contactable consumer (patient's wife). A 46-year-old patient of an unspecified gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE2), via an unspecified route of administration on 04May2021 09:00 (Batch/Lot Number: EW0179) as 2nd dose, single for covid-19 immunisation. The first dose was received on 13Apr2021 15:00 (lot number: ER8731) and patient experienced tired, slight fever and back pains similar to what he experienced with covid. Medical history included sinus surgery on Dec2014 and covid-19 positive on from 11Jan2021 to an unknown date. Concomitant medications included rosuvastatin for cholesterol; propranolol for blood pressure; finasteride for hair loss; and multivitamin. Patient felt tired on 04May2021. On 08May2021 07:30, patient woke with ringing in ear and hearing loss/ significant reduced hearing. Tinnitus was reported as ongoing, reported as medically significant, and resulted to physician's office visit. Prednisone 2-pac was given as treatment. ENT (Otorhinolaryngologist) performed hearing test and exam, no obvious reason for issues. Hearing test on 10May2021, High frequency SNHL Right greater than Left (Unilateral sensorineural hearing loss) muffled hearing. Patient had experienced improvement but still has tinnitus (17May2021). Outcome of the event of tired was unknown and for the remaining events was recovering. No follow-up attempts are needed. No further information is expected.

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1340416	5/22/2021		42	F	1/30/2021	3/11/2021	Sudden hearing loss and tinnitus; Sudden hearing loss and tinnitus; This is a spontaneous report from a contactable consumer (patient). A 42-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number was not reported), via an unspecified route of administration, administered in arm left on 30Jan2021 (at the age of 42-years-old) as 2nd dose, single for COVID-19 immunisation. Medical history included known allergy to Sulfa. The patient's concomitant medications were not reported. The patient previously received the first dose of BNT162B2 (Batch/Lot Number: unknown), administered in left arm on 09Jan2021 for COVID-19 immunisation. The patient experienced sudden hearing loss and tinnitus on 11Mar2021. Adverse events resulted in doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. Therapeutic measures were taken as a result of the events which included oral steroids, injected steroids and hearing aid. The outcome of the events was not recovered. Seriousness criteria of both events was reported as disabling/incapacitating. Information on the lot/batch number has been requested.

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1336281	5/21/2021	CA	67	F	4/1/2021		SORE THROAT; SHORTNESS OF BREATH; MYALGIA; FATIGUE; HORRIFIC HEADACHE; HORRIBLE PAIN IN CHEST LIKE HEART ATTACK; BONE WRACKING DRY COUGH; METALLIC TASTE IN MOUTH; FELT DIZZY; FELT LIKE HIT BY DUMP TRUCK; BODYACHE; NOT FEELING WELL; AGITATED; URINATING A LOT; BILATERAL EARACHE; WAS TOO SICK; HEART RATE WENT UP TO MORE THAN 80 BPM; This spontaneous report received from a patient concerned a 67 year old female. The patient's weight was 66.7 kilograms, and height was not reported. The patient's past medical history included tachycardia, atrial fibrillation, left periorbital ecchymosis, dry eyes, trouble focusing, headache, nausea on right side of chest, felt like gas bubble and emesis, possible post concussion symptoms, voice hoarse/raspy voice, chronic laryngitis, flare up of hemorrhoid, constipated over a weekend, increased heart rate, nontoxic uninodular thyroid goiter, atherosclerosis of aorta, fatigue, papillary thyroid cancer, right thyroid lobectomy, deep vein thrombosis, gerd, melanoma of skin, dyspnea, deep vein thrombosis, sinus pain, tooth pain, treatment non compliance, pharyngitis, stroke, vertigo, and influenza like illness, and concurrent conditions included non-smoker, no alcohol use, asthma, cerebral palsy, qt prolonged, chest pain when tired, diabetes mellitus, chronic kidney disease stage 3, hypertension, congenital nystagmus, hearing loss, hypothyroidism, and diabetes, and other pre-existing medical conditions included the patient had no history of abuse or illicit drug usage. The patient was previously treated with phenoxymethylpenicillin, guaifenesin for sore throat, calcium carbonate, famotidine, simeticone, promethazine, cefalexin, diphtheria vaccine toxoid/pertussis vaccine acellular/tetanus vaccine toxoid for prophylactic vaccination, salbutamol, ciclesonide, and polymyxin for red eyes; and experienced drug allergy when treated with atenolol, ciprofloxacin, and erythromycin. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 043A21A, and expiry: 21-JUN-2021) dose was not reported, administered on 04-APR-2021 11:15 for prophylactic vaccination. Concomitant medications included disopyramide phosphate. On 10-MAR-2014, Laboratory data included: Factor V Leiden mutation (NR: not provided) negative, and Prothrombin

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mutation G20210A (NR: not provided) HET Abnormal, coagulation. On APR-2021, the subject experienced heart rate went up to more than 80 bpm. On APR-2021, the subject experienced agitated. On APR-2021, the subject experienced urinating a lot. On APR-2021, the subject experienced bilateral earache. On APR-2021, the subject experienced was too sick. On APR-2021, the subject experienced bodyache. On APR-2021, the subject experienced not feeling well. On 04-APR-2021, the subject experienced metallic taste in mouth. On 04-APR-2021, the subject experienced felt dizzy. On 04-APR-2021, the subject experienced felt like hit by dump truck. On 05-APR-2021, the subject experienced horrible pain in chest like heart attack. On 05-APR-2021, the subject experienced bone wracking dry cough. On 05-APR-2021, the subject experienced horrific headache. On 09-APR-2021, the subject experienced fatigue. On 13-APR-2021, Laboratory data included: COVID-19 virus test (NR: not provided) Negative. On 20-APR-2021, the subject experienced sore throat. On 20-APR-2021, the subject experienced shortness of breath. On 20-APR-2021, the subject experienced myalgia. Laboratory data included: Anion gap (NR: not provided) 10 mEq/L, B-type natriuretic peptide (NR: not provided) 64 pg/dL, BUN (NR: not provided) 26 mg/dL, Blood pressure (NR: not provided) 214/91 mm Hg, Body temperature (NR: not provided) 97.8 F, CO2 (NR: not provided) 26 mEq/L, Chloride (NR: not provided) 102 mEq/L, Creatinine (NR: not provided) 0.92 mg/dL, Differential white blood cell count (NR: not provided) Normal, Glomerular filtration rate (NR: not provided) more than 60 mL/min, Glucose (NR: not provided) 328 mg/dL, Hematocrit (NR: not provided) 42.9 %, Hemoglobin (NR: not provided) 14.9 g/dL, Lab test (NR: not provided) Normal (no blood clots/thrombocytopenia), MCV (NR: not provided) 91 fL, Nucleated red cells (NR: not provided) 0 kilo per microliter, Oxygen saturation (NR: not provided) 98 %, Pain scale (NR: not provided) 1 (units unspecified), Platelet count (NR: not provided) 190 kilo per microliter, Potassium (NR: not provided) 4 mEq/L, Pulse rate (NR: not provided) 81 beats per minute, RBC count (NR: not provided) 4.73 million per microliter, Respiratory rate (NR: not provided) 18 (units unspecified), Sodium (NR: not provided) 138 mEq/L, Troponin I (NR: not provided) more than 0.02 ng/dL, WBC count (NR: not provided) 7.3

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							kilo per microliter, and X-ray (NR: not provided) Aortic atherosclerosis. Treatment medications included: hydralazine. On 20-APR-2021 17:34, Laboratory data included: Blood pressure (NR: not provided) 190/100 mm Hg, Body temperature (NR: not provided) 36.6 degree celsius, Glasgow coma scale (NR: not provided) Eye opening:4, Verbal response:5, Motor Response: 6, Total Coma Score:15, Oxygen saturation (NR: not provided) 97 %, Pulse rate (NR: not provided) 74 bpm, and Respiratory rate (NR: not provided) 16 (units unspecified). On 28-APR-2021, treatment medications included: prednisone. Additional treatment medications (dates unspecified) included: estradiol, levothyroxine, paracetamol, verapamil hydrochloride, salbutamol, diphenhydramine hydrochloride/lidocaine/nystatin, budesonide/formoterol, guaifenesin, benzonatate, chlorhexidine gluconate, ipratropium, aciclovir, fluticasone, montelukast, hydralazine hydrochloride, fluticasone propionate/salmeterol xinafoate, and famotidine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from metallic taste in mouth on 05-APR-2021, felt dizzy on 20-APR-2021, felt like hit by dump truck on 16-APR-2021, was too sick, and shortness of breath, and horrific headache on 19-APR-2021, had not recovered from bone wracking dry cough, horrible pain in chest like heart attack, sore throat, and bilateral earache, and the outcome of heart rate went up to more than 80 bpm, myalgia, not feeling well, fatigue, urinating a lot, agitated and bodyache was not reported. This report was non-serious.; Sender's Comments: V0: Medical assessment comment not required as per standard procedure as case assessed as non serious
1337505	5/21/2021	NC	60	F	4/8/2021	5/9/2021	Hearing loss
1337077	5/21/2021	CA	18	M	5/21/2021	5/21/2021	Suddenly felt dizzy and loss of hearing, sweaty and arms and legs felt tingly. He turned pale. We laid him down and placed ice pack on his forehead and neck. BP initially was 84/50 repeat in 10 min was 105/54. He felt better after 10 min. Felt back to normal at 30 min when he was released to his mother
1336940	5/21/2021	PA	42	M	5/20/2021	5/20/2021	101.8 fever Meniere's disease episode. 90% hearing loss in right ear

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1337904	5/21/2021	CA	62	M	4/3/2021	4/4/2021	The initial dose of Phizer Covid vaccine exacerbated a preexisting condition. It caused significant hearing loss and made mild tinnitus very severe. Currently being treated with Rozerum sleeping aid and was just prescribed lidocaine patches
1336543	5/21/2021	ND	70	F	4/1/2021	4/28/2021	Loss of hearing much greater than before and much ear pain (otalgia) with nothing else to account for it. Hearing loss is still ongoing.
1336153	5/21/2021	CA	43	M	5/19/2021	5/19/2021	Dizzy, full body sweat, temporary loss of hearing and sight. Symptoms came on 1 minute after injection and lasted for 20 minutes. Lingered ringing and dizziness 24 hours after.
1336132	5/21/2021	CA	34	M	5/12/2021	5/14/2021	Tinnitus, ringing in my left ear and slight hearing loss
1336119	5/21/2021	OR	37	F	2/7/2021	2/11/2021	4 days after each dose of series started having vestibular symptoms. First dose resulted in disequilibrium that was positional (up and down movements of the head) at first and then progressed to persistent the next day and ended with a migraine headache that night. Better during the weekend and then took about 2 weeks to resolve. Had almost fully resolved (would still return with ingestion of antihistamine so had to stop taking it) but then got second dose and was initially ok, but 4 days after dose started having rotator vertigo L sided. Vertigo and disequilibrium were never symptoms of known schwannoma. The schwannoma is small 3mm and intralabyrinthine. Negligible hearing loss at baseline of 25 dB at 4000 Hz. Both ENT physicians acknowledge temporal link but agree hard to tell because vaccine is so new and hard to conclude causation and none of the routine evaluation for the schwannoma fit the clinical picture.
1336915	5/21/2021	AZ	43	F	2/3/2021	2/8/2021	Sudden sensorineural hearing loss experienced- increased tinnitus, reduced hearing ability, initial onset 2/8/2021; treatment- oral steroids started on 2-11-2021; Outcome-tinnitus returned to original levels, hearing loss seems to be permanent.

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1332827	5/20/2021		60	F	4/12/2021	4/1/2021	sensitive stomach. She reports that this can happen not only with the Pfizer vaccine; significant hearing loss; ringing in the ears; This is a spontaneous report from a contactable consumer (patient). A 60-year-old female patient received first dose of bnt162b2 (BNT162B2), via an unspecified route of administration on 12Apr2021 (Lot number was not reported) as single dose (at age of 60-year-old) for covid-19 immunisation. Medical history and concomitant medications were not reported. On unknown date in Apr2021 patient experienced significant hearing loss, ringing in the ears, also reported as ear ringing like crazy and lost significant hearing. On unknown date she experienced sensitive stomach (she reported that this can happen not only with the pfizer vaccine). Patient stated that after receiving the first dose of Pfizer COVID-19 Vaccine, 10 hours later she developed a ringing in the ears (also reported as her ears started buzzing like ringing like crazy) to which she has seen her health care professional (HCP) and an ear specialist and has under gone hearing tests and states "has significant hearing loss" to which she is on steroids to help, she would like to know if Pfizer had any documented cases on this and what she needed to do about this. She has been going to an ear specialist and he said that she lost significant hearing in that ear where she heard the noise. For treatment, they are doing an injection into her ear. She is still having to go for injections but it does not sound like anything. She researched the internet and there is a whole group of people who experienced this with the Pfizer and Moderna and the other vaccine. Patient added that a doctor did not want to give an opinion or say anything. They did not know if this was permanent or will go away. Patient stated that a lot of people are out there, there are a lot of people with the same problem. She does not know which vaccines they got. She is halfway vaccinated because she is afraid to take the second one. She read comments of people who took the second, and people say it was worse. They discussed with doctors that it should go away eventually. Some say it went away in 9 weeks, some still had the hearing problem and it is uncomfortable. Patient added that it is all day ringing in the air, in her left ear. She went to the emergency room because it was so unbearable, and they did not know what to do. Patient did not take any medications like she did not have any issues, no blood pressure or nothing.



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1334942	5/20/2021	MN	46	F	4/29/2021	5/4/2021	<p>Patient said that she cannot take steroids by mouth because she has a sensitive stomach. She reports that this can happen not only with the Pfizer vaccine, it happened with people taking Moderna, Astra Zeneca and Johnson and Johnson reported that. It is all over the internet. A bunch of people are having this problem. Therapeutic measures were taken as a result of significant hearing loss and ringing in the ears. Outcome of the events was unknown. Patient skipped the second dose because she does not want to make it worse. Information on the lot/batch number has been requested.</p> <p>Sudden hearing loss in both ears 5 days after 2nd vaccination.; inflammation; This is a spontaneous report from a non-contactable consumer (patient). A 46-year-old non-pregnant female patient received bnt162b2 (BNT162B2 reported as PFIZER COVID-19 VACCINE), dose 2 at vaccination age of 46-year-old via an unspecified route of administration in the right arm on 29Apr2021 09:30 (Batch/Lot number was not reported) as 2nd dose, single for covid-19 immunisation. Medical history included meniere's disease. The patient has no known allergies. The patient was not diagnosed with Covid-19 prior to vaccination. The patient received the first dose of bnt162b2 (BNT162B2 reported as PFIZER COVID-19 VACCINE) at vaccination age of 46-year-old on 09Apr2021 at 10:30 AM in the left arm for Covid-19 immunisation. Concomitant medications included cetirizine hydrochloride (ZYRTEC); and ethinylestradiol, ferrous fumarate, norethisterone acetate (LO LOESTRIN FE), both indications and therapy dates were not reported. The patient did not have other vaccine in four weeks. The patient received the vaccine in a doctor's office/urgent care. On 04May2021 07:30 AM, the patient experienced sudden hearing loss in both ears 5 days after 2nd vaccination. The event resulted in doctor or other healthcare professional office/clinic visit and received the treatment of steroid to relieve inflammation (04May2021 07:30 AM). The patient has not been tested post vaccination. The outcome of the event sudden hearing loss was recovering while the outcome of the other event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.</p>

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1334691	5/20/2021	GA	76	F	2/18/2021	2/18/2021	Sudden Sensorineural Hearing Loss/Cochlear Hydrops
1334431	5/20/2021		25	M	4/9/2021	4/9/2021	Tinnitus in right ear only with mild loss of hearing that began on 4/9 and continues to 4/12.
1334104	5/20/2021	PA	14	F	5/20/2021	5/20/2021	Patient immediately became sweaty, dizzy, and experiencing hearing loss after receiving her first dose. Patient was seated on floor with elevated legs before she was wheeled back for observation. Patient was visually pale and sweaty. Patient denied any anxiousness before receiving her vaccine. Patient had vitals assessed and was given snacks and juice. Patient was reassessed after 15 minutes and reported feeling better and was sent home with parent. Patient and parent were advised to reach out to family doctor if any late onset of symptoms.
1333211	5/20/2021	CA	51	F	3/22/2021	4/13/2021	22/Mar/2021 1st Moderna COVID Vaccination Injection L Arm 13/Apr/2021- 23 days post first Moderna COVID vaccination Left Ear Fullness, L Ear Tinnitus, 16/Apr/2021- Patient saw ENT, Dr. MD: 30 decibel hearing loss confirmed L Ear. Started 1st L Inner Ear Steroid Injection. - Blood work for Immune disorders completed and no abnormalities found - Brain MRI concentration L Ear completed and no abnormalities found - Confirmed no vertigo associated with disorder 19/Apr/2021 2nd Moderna COVID Vaccination Injection L Arm 21/Apr/2021 Follow up visit ENT, Dr., MD - received second L Inner Ear Steroid Injection 28/Apr/2021 Follow up Visit ENT, Dr., MD - Hearing test shows hearing returns to normal, no further steroid injections. 12/May/2021 - 23 days post second Moderna COVID Vaccination, L Ear fullness, L Ear Tinnitus return, patient feels this is greater than first episode. 18/May/2021 - Return to see ENT, Dr., MD, confirm L Ear Hearing loss has returned. Started 60 mg Prednisone Oral QD x 14 days_ Diagnosis: AIED Autoimmune Inner Ear Disorder

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

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

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1332651	5/20/2021	TX	44	F	3/31/2021	4/5/2021	Tinnitus & partial hearing loss in right ear; Tinnitus & partial hearing loss in right ear; This is a spontaneous report from a contactable consumer (the patient). A 44-year-old non pregnant female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiration date were not reported) via unspecified route on 31Mar2021 as single dose for covid-19 immunization. Medical history included supplementation therapy. The patient's concomitant medications include escitalopram oxalate (LEXAPRO), Iron supplements and Vitamin D. The patient did not receive any other vaccine within 4 weeks prior to the COVID vaccine. Reportedly, patient was not diagnosed with COVID-19 prior to vaccination. Patient had not been tested for COVID-19 since the vaccination. On 05Apr2021, the patient experience tinnitus and partial hearing loss in right ear. Started 5 days after vaccine. The patient did not receive any treatment for the adverse events. The outcome of the events was not recovered. Information about lot/batch number has been requested.

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1332751	5/20/2021	WA	32	M	4/3/2021	4/4/2021	AS sensorineural hearing loss; tinnitus; This is a spontaneous report from a contactable consumer (patient). A 32-year-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 03Apr2021 15:00 (Lot Number: EN8737) as 2nd dose, single for covid-19 immunisation. The patient medical history was not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included bupropion hydrochloride (BUPROPION HCL XL) taken for an unspecified indication, start and stop date were not reported. Historical vaccine included first dose of bnt162b2 (Lot number: EN6208) on 13Mar2021 15:30, administered in Left arm for covid-19 immunisation. The patient experienced Sudden AS sensorineural hearing loss likely causing tinnitus possibly related to Covid vaccination response on 04Apr2021 08:00. Event seriousness criteria was disability. The patient presented with hearing loss for 1 month, onset after COVID vaccine which was on 03Apr2021. The adverse event resulted in Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. Treatment received for the adverse event included two separate transtympanic steroid injections, and prednisone medication (60mg then taper). Since the vaccination, the patient has not been tested for COVID-19. The outcome of event was not recovered. Information on Lot/Batch number was available. Additional information has been requested.

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1332715	5/20/2021	MD	35	F	4/25/2021	4/25/2021	entire intestines hurt her; back pain/sharp pain in the lower back; Back pain felt like nerve inflammation like sciatica; Back pain felt like nerve inflammation like sciatica; sore pain in the spine area/pain can change from day to day; it can be on both sides of spine, or tailbone; right side neck pain (felt like a pulled muscle); sharp shoulder blade pain/shooting pain in the hips when she walks; right ear, it felt swollen; hearing was muted-approximately 20% hearing loss, could not hear clear sounds/partial hearing loss/ dulled, similar to wearing a thick hat/transferred to her other ear; Feeling like a pressure on her ear; little pinkish rash/pinkish marbled rash; felt woozy; felt a little drunk or funny; felt a little drunk or funny; She currently has these symptoms, limited movement; difficulty walking, can't walk fast; felt like body could not hold her weight anymore; She can't bend over without pain and is unable to get things on the bottom of the refrigerator or pots in the kitchen; jerking muscle in the left thigh and right thigh; felt a heaviness on her face, felt like a heavy mask on it even when the mask was removed; Pain is a stabbing pain very painful and then the stabbing pains come and go and feels like a pulling pain, like a nerve pain; numbness in buttocks and central part of buttocks like tingling pins and pricks; numbness in buttocks and central part of buttocks like tingling pins and pricks/tingling sensation in both hands and both feet; pain in buttocks; This is a spontaneous report from a contactable consumer (patient). A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in right arm on 25Apr2021 at 16:15 (at the age of 35 years old) (Lot Number: EW0176, unknown expiration) as 1st dose, single for COVID-19 immunization. Medical history included ongoing penicilline allergy since at the age of 17 years old (manifested by breathing issues, tightness in neck, all swollen up) and currently the patient does not have a thyroid. Concomitant medications included levothyroxine sodium (SYNTHROID) and liothyronine sodium (CYTOMEL), both ongoing as the patient does not have a thyroid. The patient previously took codeine and experienced allergy (at the age of 17 years old). A few minutes after receiving the vaccine on 25Apr2021, the patient experienced right side neck pain (felt like a pulled muscle) and sharp shoulder blade pain. She got the

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vaccine in her right arm but had no arm pain. Then in her right ear, it felt swollen and her hearing was muted- approximately 20% hearing loss, could not hear clear sounds. Feeling like a pressure on her ear with partial hearing loss. It was dulled, similar to wearing a thick hat. Then it transferred to her other ear. Her face was feeling swollen, but it was not swollen, and she had a little pinkish rash but just under her mask. She didn't have any breathing problems. She asked the (name) staff member if these symptoms were normal. Patient was sitting in the waiting area of (name) pharmacy after administered the COVID-19 vaccine; all of these symptoms started happening around 3-4 minutes after receiving the vaccine. She would say within first 15 minutes after the COVID-19 vaccine was administered, it affected her other ear, where both ears had the muted hearing sensation which lasted about 2 hours. These side effects lasted about 1-2 hours and resolved on their own, no ointments were used. About 15 minutes after receiving the vaccine, she started having back pain, felt woozy, and felt a little drunk or funny. About 45 minutes later, she had sharp pain in the lower back, shooting pain in the hips when she walks. She currently has these symptoms, limited movement, difficulty walking, can't walk fast. After that, she was in bed all day and could barely make it to the bathroom. She previously was very healthy and regularly took long walks. Her back and hips feel sore. Back pain felt like nerve inflammation like sciatica where she got sharp pain in her lower back that felt like immediate inflammation. She got to the point where she was not able to sit straight, felt like body could not hold her weight anymore. She can't bend over without pain and is unable to get things on the bottom of the refrigerator or pots in the kitchen. She is unable to wash her hands together, she felt like her back can't support her weight. She had to wash one hand at a time. She is unable to get out of bed regularly, she has to roll out of bed. It has been 9 days from the vaccine and is still having shooting pains in her hips and jerking muscle in the left thigh and right thigh and it felt like nerves pulling string in the right leg which lasted only like 30-45 seconds. Before she went to the (name) pharmacy for the COVID-19 vaccine, she had never had any sorts of back issues, no strain, no health problems in that area. She told her husband she was going to have to lay on the



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ground or go home, so they left. She can't walk more than 10-15 minutes. She left the pharmacy, and when she got in the car about 20 minutes after she had gotten the vaccine, she felt a heaviness on her face, felt like a heavy mask on it even when the mask was removed. She felt initially that her face was swollen, like it was pressed, but there was no visual swelling that she could see in the mirror. When she took her mask off the triangular area where the mask had covered she could see a little more of a rash, like pinkish marbled rash but it would go away in about 45 minutes to 1 hour, started to slowly fade away. She felt that if it was a rash it would be all over her face; but this area was only where the face mask had been. She had no injury that could have caused that. The pain the next day was so bad, she was not able to sit or stand. She was barely rolling out of bed, had to hold on to furniture and walls to make it to bathroom. She is still not able to fully bend down. She has limit in movement. She still has pain, it did improve since the first day; but she still gets like a sore pain in the spine area, lower spine like a shooting pain from hips to connection where her legs meet bone which is still there. The pain can change from day to day; it can be on both sides of spine, or tailbone, hips, joints from where her legs attach to the hip area. Pain is a stabbing pain very painful and then the stabbing pains come and go and feels like a pulling pain, like a nerve pain but there is constant soreness in that area; on top of that still has the stabbing pain; this has been going on for the last 9 days did not have a break from this. She has tried massaging the area, tried Bengay on her back, tried ketoprofen (Ketonal), tried Capsaicin patches, Voltaren for the pain but none of those have helped the pain. Pain is a deep pain. The only thing that has helped it is like hot or thermal water bottle that you fill up with hot water which helps mute the pain to where it is manageable and helps her fall asleep at night. She still feels pain at time of call feels like a spinal injury. She experienced for 3 days; she would say on day number 3 (in 2021), the pain moved from the lower back to the half of buttocks on both sides and started getting numbness in buttocks and central part of buttocks like tingling pins and pricks feeling for maybe a day or 2 then it resolved. She still has pain in buttocks and hips and the pain can move to lower back and will hurt in lower back. Then on 04May2021,

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symptoms like entire intestines hurt her, she wasn't eating, it started at night when she was going to bed; so she is thinking maybe the pain is radiating to other parts of body to like her lower abdominal area; she used the hot water rubber bottle to relax muscles. She does not have the tingling sensation in her buttocks any longer; but does have tingling sensation in both hands and both feet that she sometimes feels, it is ongoing most of the time and is pretty severe. She feels pain getting up and down, still having pain; She is glad she can walk, because before walking was not very possible for her. She also tried a little bit of a back massage where she lay on her back and kind of wobbled on massager, but it doesn't help; the pain does not feel muscular it feels like something with the nerves. When she walks, she feels pain around her spine and lower back central part of spine, hips or lower back, like someone literally stabbed her in the back. She has seen her doctor on 03May2021 and was suggested seeing a neurologist before getting her second shot which is due 17May2021. Doctor ordered a blood panel and urine test and are still waiting for results (unknown results) taken on 03May2021. The patient asked if these are side effects of the vaccine. The patient did not know if she should or should not get the second dose relative to these events as of yet; second dose is scheduled for 17May2021. No additional vaccines administered on same date of the Pfizer suspect. No prior vaccinations (within 4 weeks). The events resulted in physician office visit. Patient was not hospitalized. The patient recovered from events right side neck pain (felt like a pulled muscle), "right ear, it felt swollen", partial hearing loss, pressure on her ear, little pinkish rash/pinkish marbled rash, and jerking muscle in the left thigh and right thigh on 25Apr2021. The patient also recovered from event numbness in buttocks and central part of buttocks in 2021. The patient was recovering from events limited movement, difficulty walking, and heaviness on face. Outcome of events "felt woozy, felt a little drunk or funny", and "entire intestines hurt her" were unknown. While the patient had not yet recovered from the remaining events. No follow-up attempts are needed. No further information is expected.

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1332518	5/20/2021	FL	61	M	3/31/2021	4/1/2021	<p>Loss my hearing in left ear; Light ringing/buzzing in right ear; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS UNILATERAL (Loss my hearing in left ear) in a 61-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. unknown) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 31-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. In April 2021, the patient experienced DEAFNESS UNILATERAL (Loss my hearing in left ear) (seriousness criterion medically significant) and TINNITUS (Light ringing/buzzing in right ear). At the time of the report, DEAFNESS UNILATERAL (Loss my hearing in left ear) and TINNITUS (Light ringing/buzzing in right ear) had not resolved. 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. Concomitant product use was not provided by the reporter. Treatment information was not provided. 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-2021-118211 (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.</p>

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1332822	5/20/2021	NE	28	F	5/1/2021	5/1/2021	slowly lose her hearing in right ear/ mild hearing loss/ she could not hear out of her right ear/ started in her left ear that she sometimes could not hear out of; It started as a pain in her right ear going down through her jaw and neck; This is the spontaneous report received from a contactable consumer (patient). A 28-year-old female patient (not pregnant) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot Number: ER8736) via an unspecified route of administration, administered in Arm Left on 01May2021 at single dose for COVID-19 immunisation at the age of 28-year-old. Medical history included mild allergy to bananas, stroke on mother's side of the family, hearing loss on Father's side of the family. There were no concomitant medications. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There was no any other medications the patient received within 2 weeks of vaccination. The patient previously received the first dose of BNT162B2 (Lot number: EW0158) on the left arm on 10Apr2021 at the age of 28-year old for Covid-19 immunization. The patient had started to slowly lose her hearing in right ear. It started as a pain in her right ear going down through her jaw and neck with mild hearing loss the first night of her second dose (01May2021) but had continued. She went through waves of times when she could not hear out of her right ear. Wednesday 05May2021 it how now started in her left ear that she sometimes could not hear out of. No treatment received for the events. The outcome of the event was not recovered.

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1332833	5/20/2021			M	5/1/2021		Multi system organ failure; Renal failure; Shock; Cardiac tamponade; Multifocal small stroke; Systemic inflammation and hyperinflammation; Hearing loss; Pleural effusion; Neo pressure; This is a spontaneous report from a contactable Physician via medical information center. A male patient of an unspecified age (Age: 20; Unit: unknown) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot/Batch number: Not reported) via unspecified route of administration on an unknown date as 1st dose single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unknown date in May2021, the patient experienced multi system organ failure, renal failure, shock, neo pressure (hypotension), cardiac tamponade, pleural effusion, multifocal small stroke (transient ischaemic attack), systemic inflammation (systemic inflammatory response syndrome), hearing loss (deafness). The outcome of the events was unknown. Physician commented: HCP wanted to know reports of similar cases such as a male patient (20 years old) experienced after the first dose of the Pfizer covid vaccine. He experienced multi system organ failure, renal failure, shock, neo pressure, cardiac tamponade requiring pericardial window, pleural effusion requiring chest tube, hearing loss, multifocal small stroke, systemic inflammation and hyperinflammation. HCP is looking for guidance on treatment as well. Informed the physician that we can do some more research on their question to see if there was any additional information available. Information related to batch/Lot no. was requested.; Sender's Comments: There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, concomitant medications, age of the patient, date of vaccine given, date on when the event started ,lab reports etc. The case will be reevaluated 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

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							to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
1330611	5/19/2021	WA	61	M	1/8/2021	1/12/2021	Sudden sensorineural hearing loss in left ear noted Jan 12 2021 (4 days after 1st dose). Spontaneous recovery of some hearing within 48 hours. High-pitched tinnitus in both ears. another episode of sudden hearing loss noted Jan 31 2021 (5 days after second dose), with spontaneous recovery. Residual low frequency hearing loss in left ear; High frequency tinnitus remains in both ears as of reporting date (5/19/2021)
1329431	5/19/2021	CA	39	F	4/12/2021	4/13/2021	<p> Ringing in my ears mostly right ear/Echo in ear; Very sensitive to sound; hearing loss; This is a spontaneous report from a contactable consumer (reporting for herself). A 39-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 12Apr2021 (Batch/Lot Number: ER8734) as 1ST DOSE, SINGLE for COVID-19 immunization. The patient medical history and concomitant medications were not reported. On 13Apr2021, the patient experienced ringing in her ears, mostly right ear, echo in ear, very sensitive to sound, and hearing loss. The event resulted in doctor or other healthcare professional office/clinic visit. The events were treated with anti-inflammatory ear drops. The outcome of the events recovering. The patient was not diagnosed with COVID-19 prior to vaccination. The patient has not been tested for COVID-19 since the vaccination. Information on the lot/batch number has been requested. </p>

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1329474	5/19/2021	NY	56	F	3/30/2021	3/30/2021	left ear felt very sore; severe intestinal cramps; Severe diarrhea; mild hearing loss/partial hearing loss; fever; chills; headache; nausea; loss of appetite; Tinnitus/new tinnitus from the vaccine was much louder; This is a spontaneous report received from a contactable consumer (patient). A 56-year-old female patient (not pregnant) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: EP7533 and expiration date: 31Jul2021), via an unspecified route of administration, in arm right, on 30Mar2021 15:45 (at the age of 56-year-old, not pregnant), at single dose, for COVID-19 immunization. Medical history included myopic degeneration/glaucoma, mild tinnitus in both ears since childhood. Patient was not diagnosed with COVID-19 prior to vaccination. No other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medications included brimonidine, timolol, latanoprost eye drops, and pramlintide. The patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: EN6202 and expiration date not provided), via an unspecified route of administration, in arm right, on 09Mar2021 15:45 (at the age of 56-year-old), at single dose, for COVID-19 immunization. Other past drugs included ciprofloxacin (CIPRO), cefprozil (CEFZIL), sulfamethoxazole, trimethoprim (BACTRIM), azelastine nasal spray. The patient experienced tinnitus in left ear started about 30Mar2021 17:00 (reported as "1 hour after vaccination"), it was much louder on 31Mar2021 (reported as "the next morning") with mild hearing loss. Patient woke up in the morning with the fever and chills, and was accompanied by headache, nausea, loss of appetite. Patient had severe diarrhea on 03Apr2021, 04Apr2021, 05Apr2021, fever and severe intestinal cramps on 07Apr2021. All symptoms improved except for severe tinnitus in left ear. Sometimes it was so loud it feels like patient's whole brain was getting affected. Patient's blood vessel in left ear was pulsing too. Pulsing tinnitus. 5 weeks in from second COVID vaccine. Patient had a very loud tinnitus, ringing in the ear and the left ear felt very sore, it was like partial hearing loss, which lasted for few days. So, now the hearing came back and my hearing was normal. Patient visited Audiological/ENT on 14Apr2021 and had hearing tests, it was normal but patient had very loud tinnitus. Patient had a severe

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tinnitus. This new tinnitus from the vaccine was much louder with additional piercing hissing/whooshing sounds. Patient was still experiencing this discomfort, it is the same, this it is not getting better, it was very loudly. The adverse events result in doctor or other healthcare professional office/clinic visit. Patient stated she was finding that so many people those who have the same side effect (further clarification unknown), it was the tinnitus, the ringing in the ears and partial hearing loss either temporary or permanent and it is a pretty big side effect and its pretty much severe lasting many weeks and months. Patient had not been tested for COVID-19 Since the vaccination. The outcome of the event "tinnitus aggravated" was not recovered; of other events was recovering.



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1329483	5/19/2021	NH	61	M	4/27/2021	5/4/2021	experienced hearing loss in his left ear/hearing loss on both ears; his right ear seems like there is water in there or it is underwater/left ear sounds like everything is echoing; immediately things were muffled; This is a spontaneous report from a contactable consumer (patient). A 61-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in right upper arm on 27Apr2021 11:00 (Batch/Lot Number: EWO171; Expiration Date: Aug2021) as 1st dose, single for covid-19 immunization. Medical history including hearing was about 80 percent in the left ear/loss of 20-30 percent which started 10 years ago when the patient was 51. The patient has no concomitant medications. No additional vaccines administered on same date of the Pfizer suspect and no prior vaccinations within 4 weeks. After receiving a dose of Pfizer Covid-19 vaccine on 27Apr2021, the patient experienced hearing loss in his left ear, it was barely noticeable but today (04May2021 12:00) there was a dramatic shift and he experienced hearing loss on both ears, it was instantaneous. The patient wanted to know if there are any reports of hearing loss and when could it go away. He has a hearing issue in his left ear that he has had, his hearing was about 80 percent in the left ear and in the right ear it was a 100 percent. Today, at noon he has almost lost his hearing in his left ear and his right ear seems like there is water in there or it is underwater. His left ear sounds like everything is echoing but, he can hear the call handler just fine. His right ear was perfect and now it is messed up. He is worried about that. The patient wonders why that happened and why did they both go. He reported that the shot may have had something to do with it and if it does, what should he do or maybe he is just getting old. He cannot hear in the left ear much; he was just testing it while on hold listening to the music to see how much he had. He felt like there is water in it, not a little, a lot of water and it echoes a little bit and seemed like it's underwater. Started 10 years ago when he was 51, he lost 20-30 percent and it stopped as far as he could tell. He did not get checked out then because he could hear clearly. Today at 12 pm, and it was not gradual, it was like turning a light on, immediately things were muffled. Even when he was putting his hands over his ears, there was like an echo. He was on the phone with his wife at

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the time. He did not know what happened, so, he went to work, and nothing is changed. He told her something just happened to his ears. He thought of doing something in the meantime and not trying to wait for it to get better. Right ear feels like it is underwater, maybe the left ear is affecting the right the or the weaker ear is being affected more. The right ear is the stronger ear over the left ear. That is what bothering him. His weaker ear is being affected more than his good ear, which his right ear has always been the stronger ear and he never had problems before with his right ear. It was a dramatic switch today at 12pm and his ears have been that way ever since. The left ear feels like its underwater, so much even if he blocks that ear with his finger or his palm. Still there is something going on in both ears. He did not notice the right ear because the other ear was such a shock and he was just dealing with that. He noticed the right side too after trying to see if he could hear out of the left. He had no baseline to go off of for sure or a history. No baseline to go from other than this hearing change of event, which may be totally him. He wanted to see if there is anything related to this because it was so dramatic. The events were not treated. The outcome of the event "experienced hearing loss in his left ear/hearing loss on both ears" was not recovered while the other events were unknown. Information on Lot/Batch number was available. Additional information has been requested.

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1329488	5/19/2021	FL		F			Hearing loss in right ear; the ringing was much louder now than ever before; the ringing was much louder now than ever before; This is a spontaneous report from a contactable consumer (patient). A 70-year-old female patient received the 2nd dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on an unspecified date in 2021 (Lot Number: EX 6200), as single dose, for COVID-19 immunisation. Medical history included ongoing tinnitus (before the 2 vaccinations). Prior to vaccination the patient was not diagnosed with COVID-19. Concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID-19 vaccine. Previously the patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech) for COVID-19 immunisation on 17Feb2021 (lot# EL9262, at 12:00 PM, in left arm). The patient experienced hearing loss in right ear (medically significant) in 2021 with outcome of not recovered, the ringing was much louder now than ever before (non-serious) in 2021 with outcome of not recovered. The patient reported to have mild to medium ringing in ears before the injections. She reported the ringing was much louder now than ever before. The tones were different in each ear. It was almost unbearable at times. She also lost some hearing in right ear, left ear was fine. Since the vaccination the patient was not tested for COVID-19.

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1329524	5/19/2021	MA	47	F	4/15/2021	4/15/2021	Within 5 hrs of vaccination, developed acute and persistent tinnitus. Also some loss of hearing acuity.; Within 5 hrs of vaccination, developed acute and persistent tinnitus. Also some loss of hearing acuity.; This is a spontaneous report from a contactable consumer, the patient. A 47-year-old female patient received bnt162b2 (PFIZER- BIONTECH COVID-19 VACCINE, Solution for injection, Lot number was not reported), dose 1 via an unspecified route of administration, administered in right arm on 15Apr2021 14:00 as 1ST DOSE, SINGLE for covid-19 immunisation. The patient medical history and concomitant medications were not reported. On 15Apr2021 19:00 within 5 hrs of vaccination, the patient developed acute and persistent tinnitus and some loss of hearing acuity. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and did not receive any other medications the within 2 weeks of vaccination. Adverse event result in doctor or other healthcare professional office/clinic visit. Patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination, patient has not been tested for COVID-19. Information on the lot/batch number has been requested
1331024	5/19/2021	NJ	50	M	4/12/2021	4/15/2021	Server headaches and head pressure. Sudden hearing loss in right ear and ringing in both ears for over four weeks. My doctor has put me on steroids. Ringing in my ears has not stopped
1331310	5/19/2021	NY	41	F	4/7/2021	4/21/2021	~~Covid toes" - purple, blistering toes persistent for over 5 weeks, persistent headaches at back of head (cerebellum area) for over 3 weeks (not getting better), hearing loss in right ear, tinnitus ringing in right ear, fatigue, intense brain fog

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1329489	5/19/2021	PA	80	F	3/18/2021	3/27/2021	Complete unilateral hearing loss right ear; This is a spontaneous report from a contactable nurse. An 80-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), in Feb2021 (Lot not reported) as 1 st dose, single then on 18Mar2021 (Lot not reported) as 2 nd dose, single; both intramuscular (at the age of 80-years-old) for covid-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, patient was not diagnosed with COVID-19 and since vaccination, patient was not tested for COVID-19. Medical history included neoplasm malignant. The patient's concomitant medications were not reported. The reported adverse event was complete unilateral hearing loss right ear on 27Mar2021. The event resulted in doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. Treatment received were PET-scan (in 2021), MRI (in 2021), hearing test (in 2021), antibiotics and prednisone. The outcome of the event was recovered with sequel in 2021. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available a causal relationship between event unilateral hearing loss right ear and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be completely excluded. The case will be reevaluated 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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1326059	5/18/2021	CT	30	F	5/14/2021	5/14/2021	Remained in waiting room for 15 minutes as per instructions from medical staff. Within approximately 10 minutes of administration, I experienced a wave of warmth that led to a feeling that I would pass out. Called out to nursing staff that I was feeling "dizzy" (didn't know what else to call it). It was not like normal dizziness. Remained seated with legs stretched out to try to combat the feeling I would pass out. Nurses checked my blood pressure and it was in the low 70's. Along with low blood pressure, I experienced temporary hearing loss in left ear, nausea (feeling I could throw up), feeling I could diarrhea/defecate immediately (but held it in for obvious reasons), mental confusion. Nurses called the Emergency Department at my local hospital and told me I should (based on symptoms) be admitted to the hospital. Nurse said my blood pressure wasn't stabilizing at a normal rate of a typical vasovagal reaction. Nurse withheld administering Epipen and monitored the course of my symptoms. EMTs arrived and checked my vitals again in the Ambulance. In the Ambulance, I recall the technician saying my blood pressure was somewhere around 140. This reading is abnormally high for me (my typical blood pressure is around 110). I declined admission to the hospital due to my horrible medical insurance and worry about exorbitant costs. Symptoms did not resolve until approximately 50 minutes after the start of the incident (approx. 9:22 AM).
1326519	5/18/2021	NC	54	F	4/21/2021	4/21/2021	Loss of hearing in right ear, sever tinnitus. Brought on by severe headache after vaccine. Headache was like a vice and my head felt so much pressure squeezing tightly
1328901	5/18/2021	CA	45	F	3/12/2021	4/17/2021	Experienced a short episode of what felt like heart palpitations and extreme fatigue, then a sudden hearing loss that has persisted for five weeks and continuing. Also experiencing, as a result of hearing loss: tinnitus, balance issues, and headaches. Possible permanent hearing loss.
1327700	5/18/2021	VA	51	F	4/12/2021	4/16/2021	3-4 days after vaccine noticed severe hearing loss in left ear, continued unabated. Also experienced ringing in left ear. Days later experienced several hours of almost total loss of hearing in that same ear. Saw primary care physician 5/10/21 and was referred to ENT. Saw ENT for hearing test on 5/17/21 and for treatment on 5/18/21.

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1327247	5/18/2021	CA	58	M	3/23/2021	5/10/2021	03/23 Sore arm after shot for three days and general soreness in left shoulder. No other side effects, Soreness fade within a weeks 05/10 /2021: Woke up with what was felt like a closed eustachian tube (right side). Teble, high end hearing muted all day. Minor post nasal drip. 05/11/2021 No nasal drip, sounded better in the morning. By 12pm, hearing in my right ear is completely gone. 05/12/2021 Visit to GP : clean out ear with not relief. Simple Test confirms hearing loss is not viral but sensorinrual loss.
1323443	5/17/2021	PA	38	M	3/26/2021	4/4/2021	Tinnitus has been consistent since April 4, 2021. Constant ringing in left ear. Feeling of fullness in both ears which is not constant. Mild hearing loss in left ear.
1323724	5/17/2021	MO	41	F	4/21/2021	4/22/2021	Tinnitus in ears, starting loudly in the right ear at 16hrs after vaccination and softer in the left ears. Left ear became louder over the next week. Called primary care doctor twice over the next couple days and saw ENT on 4/28/21 after vaccination. No hearing loss detected and no cure available for tinnitus. ENT was unable to say if tinnitus will resolve over the next few weeks/months. Considering it has been nearly 4 weeks, I consider this to be permanent damage.
1324494	5/17/2021	WA	17	M	5/11/2021	5/11/2021	Pfizer-BioNTech COVID-19 Vaccine EUA ; On 5/11/21, Patient experienced tingling in left arm minutes after the vaccine was injected (4:07pm). Patient became nauseous. While in the vehicle to go home, patient's breathing quickened. After this, patient's vision became blurry and he was unable to see. Patient also experienced hearing loss with ringing in ears. The father of the patient pulled the car over in case medical attention was needed. Patient eventually passed out for about 30 seconds (about 4:22). Patient recovered, but complained about fogginess (thinking was unclear and unfocused). The next day, on 5/12/21, the patient experienced chills and nausea without a fever. Currently, the patient is doing fine with no further symptoms.





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1325392	5/17/2021	GA	36	F	4/28/2021	5/3/2021	No known effect to baby since it is not due for a few more months. I am only aware of the hearing loss I experienced as the pregnant mother I've now had two separate bouts of hearing loss. The first started 5 days after the first vaccine and lasted around 36 hours. The second was almost two weeks after that and also lasted around 36 hours. Both times I felt a lot of pressure in my ears and had muffled hearing. I subsequently made an appointment with an ENT that alerted me this could be a vaccine side effect. I have not had my second dose of the vaccine yet.
1321925	5/16/2021	NY	50	M	4/21/2021	4/30/2021	Severe persistent dizziness, nausea, and vomiting. Taken to Emergency Room on 5/2, diagnosed with BPPV (Vertigo), discharged the same day, Severe dizziness continues for 3 more days, then additional symptoms show up - heavy pressure in the ears and in the back of the head, few days later left ear pops, and the right one clogs even further. On 5/6 visited PCP, no blood nor EKG issues detected, referred to ENT. Visited ENT doctor on 5/12, diagnosed with partial hearing loss in the right ear.

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1320059	5/15/2021	CA		M	3/30/2021	4/1/2021	his low-level chronic tinnitus and hearing loss became extreme and had stayed that way ever since, 30 days ago, with no relief; his low-level chronic tinnitus and hearing loss became extreme and had stayed that way ever since, 30 days ago, with no relief; his low-level chronic tinnitus and hearing loss became extreme and had stayed that way ever since, 30 days ago, with no relief; This is a spontaneous report from a contactable consumer (patient). A male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via unspecified route of administration in left arm on 30Mar2021 at 11:45 at single dose for COVID-19 immunization. The relevant medical history included low-level chronic tinnitus and idiopathic hearing loss from unspecified date. Concomitant medications were reported as none. On 01Apr2021 at 03:00 AM, one day after the first (AND ONLY) Pfizer injection, his low-level chronic tinnitus and hearing loss became extreme and had stayed that way ever since, 30 days ago, with no relief. Out of fear of making the tinnitus even worse, he had decided not to get the second Pfizer shot. 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 recovered. Information about Batch/lot number has been requested.
1320457	5/15/2021	NY	60	M	3/13/2021	4/7/2021	Sudden onset hearing loss in right ear

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1320244	5/15/2021	IL	59	M	3/12/2021	3/1/2021	Rheumatoid arthritis flare up; Pain in joint involving hand; Injection site papule; Bruising; Sprain; Dizziness; Loss of balance; Sickness; Vision decreased / Bilateral abnormal vision; Blurring of eyes; fatigue; bumps from the injector pen; Pain in extremity / ARM PAIN; This is a solicited report from non-Pfizer sponsored program received from a contactable physician based upon information received by Pfizer from company (21K-163-3820459-00). A 59-year-old adult make received the first dose of intramuscular BNT162b2 (solution for injection; Lot EL3248 expiry information not provided) as a single dose on 12Mar2021 (at 59-years-old) for COVID-19 immunisation. The patient also started to receive subcutaneous adalimumab (HUMIRA, unspecified formulation) 40mg at an unspecified frequency from an unspecified date for arthritis. Relevant medical history included rheumatoid arthritis, inflammation, high blood pressure, red face, red skin, used cane for walking because he could not walk (before adalimumab), and a loss of hearing in the left ear (one month prior to starting adalimumab). It was unknown if patient was enrolled in a COVID-19 Vaccine Trial. Concomitant medications included sulfasalazine for inflammation; lisinopril for high blood pressure; and another [unspecified] medication for inflammation. The patient previously received treatment for inflammation with steroids which were not good enough. On an unspecified date in Mar2021, after receiving the vaccine, the patient developed arm pain, it made him tired, he had dizziness, fatigue almost every time, and a loss of balance. The patient had bumps from the injector pen/ Injection site papule, Pain in joint involving hand, bruising, sprain, and sickness. On an unspecified date in Apr2021 the patient experienced bilateral abnormal vision/vision decreased and blurring of eyes. On 09Apr2021, patient received second dose BNT162b2 (solution for injection; Lot EL3302 expiry information not provided) as a single dose. The action taken with adalimumab was unknown. The outcome of the event Sickness was recovered on an unspecified date. The outcome of the events bilateral abnormal vision/vision decreased, blurring of eyes, and fatigue, was not recovered. The outcome of the events pain in extremity / arm pain, bruising, sprain, dizziness, loss of balance, was recovering. The outcome of the events Pain in joint involving hand, Injection site papule, and

*VAERS\_ID RECVDATE STATE AGE\_YRS SEX VAX\_DATE ONSET\_DATE SYMPTOM\_TEXT*

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bumps from the injector pen was unknown. The reporter's assessment of the causal relationship of the event with the suspect product BNT162b2 was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment. No follow-up attempts possible. No further information expected.; Sender's Comments: Based on available information, a possible contributory role of subject product, BNT162B2 vaccine cannot be excluded for the reported events of Injection site papule, Pain in joint involving hand, bruising, dizziness, loss of balance, fatigue and sickness, based on temporal relationship. Based on the information provided by the reporter, it appears unlikely that the subject product contributed to the RA flare and other reported events, which likely represent intercurrent medical conditions. There is very limited information provided in this report. This case will be reassessed upon receipt of follow-up information. 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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1320118	5/15/2021	MN		M			<p>he is in the hospital with Encephalitis due to the Pfizer vaccine; dementia like symptoms; sudden loss of hearing; Can't walk; losing his voice; urinary incontinence; trouble swallowing; loss of personality flat affect; shaking of hands/full body tremor; weakness; fatigue; loss of interest; kind of in a "stupor state";, can't stay warm; trouble responding in conversations; confusion; falling asleep constantly; This is a spontaneous report from a contactable consumer reported for her father. An 80-years-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date as single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. Historical vaccine included first dose of BNT162B2 via an unspecified route of administration on an unspecified date as single dose for covid-19 immunization. The patient had received both doses of the Pfizer Covid 19 vaccine. He was in the hospital with Encephalitis due to the Pfizer vaccine per his doctors. His symptoms were as follows: Can't walk, losing his voice, dementia like symptoms, urinary incontinence, trouble swallowing, loss of personality flat affect, shaking of hands, full body tremor, weakness, fatigue, loss of interest, kind of in a "stupor state", sudden loss of hearing, can't stay warm, trouble responding in conversations, confusion, falling asleep constantly. He had tons and tons of new symptoms and he had never had any of these problems. It had been reported to the CDC by the doctors. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.</p>

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1320105	5/15/2021	NC	41	M	4/28/2021	4/29/2021	a potential false blood pressure readings/The readings were over 200/140/took it on his wrist and measured at 215/147; the pain at the location of the lower arm got near tremble; This is a spontaneous report from a contactable consumer (patient). A 41-year-old male patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration, administered in Arm Left on 28Apr2021 16:00 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included blood pressure abnormal, blood cholesterol abnormal, deafness. The patient's concomitant medications included unspecified products received within 2 weeks of vaccination. The patient previously received the first dose of BNT162B2 on 06Apr2021 01:15 PM at arm left for COVID-19 immunization. The patient was not diagnosed with COVID-19 prior to vaccination and since the vaccination, he has not been tested for COVID-19. The patient reported a potential false blood pressure readings on 29Apr2021, a day after administered 2nd dose. The readings were over 200/140 and he took it at home using a blood pressure reading device. He took it on his wrist and measured at 215/147. In his recent doctors visit prior to administer the 2nd dose, the accurate readings was 183/136 (estimated). With the false blood pressure readings, the pain at the location of the lower arm got near tremble due to the fact of the false readings has been taken. The events outcome was unknown. Information on the Lot/Batch number has been requested.

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1320244	5/15/2021	IL	59	M	3/12/2021	3/1/2021	Rheumatoid arthritis flare up; Pain in joint involving hand; Injection site papule; Bruising; Sprain; Dizziness; Loss of balance; Sickness; Vision decreased / Bilateral abnormal vision; Blurring of eyes; fatigue; bumps from the injector pen; Pain in extremity / ARM PAIN; This is a solicited report from non-Pfizer sponsored program received from a contactable physician based upon information received by Pfizer from company (21K-163-3820459-00). A 59-year-old adult make received the first dose of intramuscular BNT162b2 (solution for injection; Lot EL3248 expiry information not provided) as a single dose on 12Mar2021 (at 59-years-old) for COVID-19 immunisation. The patient also started to receive subcutaneous adalimumab (HUMIRA, unspecified formulation) 40mg at an unspecified frequency from an unspecified date for arthritis. Relevant medical history included rheumatoid arthritis, inflammation, high blood pressure, red face, red skin, used cane for walking because he could not walk (before adalimumab), and a loss of hearing in the left ear (one month prior to starting adalimumab). It was unknown if patient was enrolled in a COVID-19 Vaccine Trial. Concomitant medications included sulfasalazine for inflammation; lisinopril for high blood pressure; and another [unspecified] medication for inflammation. The patient previously received treatment for inflammation with steroids which were not good enough. On an unspecified date in Mar2021, after receiving the vaccine, the patient developed arm pain, it made him tired, he had dizziness, fatigue almost every time, and a loss of balance. The patient had bumps from the injector pen/ Injection site papule, Pain in joint involving hand, bruising, sprain, and sickness. On an unspecified date in Apr2021 the patent experienced bilateral abnormal vision/vision decreased and blurring of eyes. On 09Apr2021, patient received second dose BNT162b2 (solution for injection; Lot EL3302 expiry information not provided) as a single dose. The action taken with adalimumab was unknown. The outcome of the event Sickness was recovered on an unspecified date. The outcome of the events bilateral abnormal vision/vision decreased, blurring of eyes, and fatigue, was not recovered. The outcome of the events pain in extremity / arm pain, bruising, sprain, dizziness, loss of balance, was recovering. The outcome of the events Pain in joint involving hand, Injection site papule, and

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bumps from the injector pen was unknown. The reporter's assessment of the causal relationship of the event with the suspect product BNT162b2 was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment. No follow-up attempts possible. No further information expected.; Sender's Comments: Based on available information, a possible contributory role of subject product, BNT162B2 vaccine cannot be excluded for the reported events of Injection site papule, Pain in joint involving hand, bruising, dizziness, loss of balance, fatigue and sickness, based on temporal relationship. Based on the information provided by the reporter, it appears unlikely that the subject product contributed to the RA flare and other reported events, which likely represent intercurrent medical conditions. There is very limited information provided in this report. This case will be reassessed upon receipt of follow-up information. 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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1320061	5/15/2021			M		4/13/2021	Sudden sensorineural hearing loss; This is a spontaneous report from a contactable physician. An 84-year-old male patient received bnt162b2 (Pfizer COVID 19 vaccine) at the age of 84 years old, via an unspecified route of administration on an unspecified date (Lot Number: Unknown) at single dose for COVID-19 immunization. The patient's medical history was not reported. The patient was not diagnosed with COVID-19 prior to vaccination. The patient's concomitant medications were not reported. The patient experienced sudden sensorineural hearing loss on 13Apr2021. Seriousness criterion was reported as disability. The event resulted in doctor or other healthcare professional office/clinic visit. The patient received high dose prednisone as treatment. The patient has not been tested for COVID-19 since the vaccination. The outcome of event was not resolved. Information about lot/batch number has been requested.; Sender's Comments: As there is limited information in the case provided, the causal association between the event sudden sensorineural hearing loss 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.
1319610	5/15/2021	NY	36	F	2/28/2021	5/5/2021	Sudden sensorineural hearing loss in right ear 1.5 months after receiving 2nd dose
1321250	5/15/2021	WA	72	F	3/13/2021	4/10/2021	By April 13, I had completely lost the hearing in my right ear. I was diagnosed with SHL, sudden sensorial hearing loss. No treatment. Permanent deafness. Use of hearing aid will not help.
1317775	5/14/2021	CT	67	F	3/17/2021	4/17/2021	Tinnitus , hissing ringing in both ears. Went to ENT and had hearing test. Minor hearing loss. Recommended earing aids to mask Tinnitus.

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1317340	5/14/2021	FL	60	F	2/2/2021	4/5/2021	I awoke on April 5th at 6 am. I was deaf in both ears except the sound of my own saliva in the right ear. Upon attempting to rise I was exceedingly dizzy/light-headed. I went to the ground and then extreme loud - extremely loud sound in head. I held my head in my hands and attempted to stand again and could not. Finally I was able to stand and get myself to the bathroom. The loud sound and deafness continued for about 20 to 30 minutes at that intensity, then lessened. Was back to "normal" about an hour later, except fullness in right ear. I really should have called 911, yet I was in a rural area with my 99 year old mother and did not want to startle her. One week later, April 13th, tinnitus, lower volume, and vertigo returned. Vertigo was intermittent; tinnitus has been 24/7 since April 13th. I saw ENT, on April 7th. He thought I either had a stroke or a vestibular migraine, yet he was not aware of the 24/7 tinnitus. He ordered MRI. Results negative for stroke or tumor. I have an appointment with ENT next week. (Was visiting my mom and family at time of initial acute onset.)

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1317177	5/14/2021	CA	55	M	3/30/2021	3/31/2021	I acquired Covid on January 13. I was sick for three days, largely with headaches. I lost my sense of smell. After approximately 7 weeks, I had recovered most of my sense of smell. I received dose 1 of Moderna on March 2. Four days later I noticed that my sense of smell had diminished substantially. I contacted my primary and was assured that it wasn't a result of the vaccine. I saw an EENT, and he too assured me it wasn't because of the vaccine. I was put on Flonase and one course of steroids (12 days). After 2 weeks, my sense of smell was returning. I received my second dose on 3/30. Within 12 hours I knew something was wrong. My sense of smell seemed to be obliterated. It felt like there was a "hole" in the center of my nose. Within 36 hours, the turbinates in my nose were hypertrophic. I have never suffered seasonal allergies and had never even heard the word "turbinate" before this. 45 days later, my left nostril is blocked. My right nostril is nearly blocked. I have fluid behind both ears, and my hearing has diminished. I feel completely let down by the medical establishment and even the CDC. There is no way that I should have been advised to have the vaccine just 40 days after contracting covid. All of the promises that the vaccine can't reduce sense of smell because there's no Covid in the vaccine are misleading. My immune system responded to the vaccine by attacking the site of the original infection, which was my nose. This has been devastating to me. I am depressed, anxious, and hopeless that this will correct itself. I will likely suffer some percentage of hearing loss. I was completely recovered from Covid, and it's only these vaccines that have ruined my health.

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1316050	5/14/2021	CA	70	F	2/17/2021		lost hearing in her right ear; mouth sores diagnosed as oral shingles; This is a spontaneous report from a contactable consumer (patient). A 70-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 17Feb2021 (Lot Number: EL9266) as SINGLE DOSE for covid-19 immunisation. Medical history included surgery from 22Sep2020 (had lab work on Sep2020 because of surgery) and blood pressure. The patient had shingle's vaccine. Concomitant medication(s) included irbesartan (IRBESARTAN) taken for blood pressure, start and stop date were not reported. Five days after the first vaccine the patient got severe sores in her mouth and then she went to the doctor, they call it she could possibly have shingles or shingles in her mouth it appeared to be canker sore (later reported mouth sores diagnosed as oral shingles). Then five days later she woke up in the night and could not hear. She lost hearing in her right ear. Actually loss of hearing 2 days before the got her second vaccine and she talked to her doctor and doctor thought the patient still went ahead and had the second vaccine but she didn't want to put the patient on the Prednisone because that will weaken her immunity but then it didn't get better and she sent the patient to Ear, Nose and throat he told the patient if she has any hope to getting her hearing back she had to start this medicine but that's what the patient was concerned about. The patient took Prednisone on 12Mar2021 for the ear treatment. For the first 2 week she was taking 60 mg and then after 3 weeks, she took 2 tablets 40 mg and then the next week she took 10 mg for 2 days. The outcome of event mouth sores diagnosed as oral shingles was recovering, others was unknown.
1315989	5/14/2021		24	F	4/14/2021	5/10/2021	Pain and loss of hearing

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1312873	5/13/2021	MI	52	M	3/11/2021	3/11/2021	Permanent hearing loss on left ear; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEAFNESS UNILATERAL (Permanent hearing loss on left ear) in a 52-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 023M20A) for COVID-19 vaccination. No Medical History information was reported. On 11-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Mar-2021, the patient experienced DEAFNESS UNILATERAL (Permanent hearing loss on left ear) (seriousness criterion disability). At the time of the report, DEAFNESS UNILATERAL (Permanent hearing loss on left ear) had not resolved. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Magnetic resonance imaging head: no infections or tumors (normal) No infections or tumors. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant medications were not reported. The patient has been evaluated by ENT several times and was given steroid treatment in response to the event.; Sender's Comments: Based on the current available information which includes a temporal association between the use of the product and onset of the reported events, a causal relationship cannot be excluded.
1313639	5/13/2021	MD	37	F	4/13/2021	4/14/2021	32 weeks pregnant at time of vaccination On the next day following vaccination, noticed sudden hearing loss in right ear. Will start steroid treatment. MRI not yet performed.

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1315843	5/13/2021	TX	54	F	1/7/2021	2/7/2021	Sudden sensorial hearing loss/Decreased Hearing; started to feel right ear fullness; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEAFNESS NEUROSENSORY (Sudden sensorial hearing loss/Decreased Hearing) in a 54-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 032L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 07-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 05-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 07-Feb-2021, the patient experienced DEAFNESS NEUROSENSORY (Sudden sensorial hearing loss/Decreased Hearing) (seriousness criterion medically significant) and EAR DISCOMFORT (started to feel right ear fullness). At the time of the report, DEAFNESS NEUROSENSORY (Sudden sensorial hearing loss/Decreased Hearing) and EAR DISCOMFORT (started to feel right ear fullness) had not resolved. Information about concomitant medication was not information provided. Treatment details included steroid with Antihistamine. Action taken with mRNA-1273 in response to the events was not applicable. Company Comment: Based on current available information and the temporal association between product date 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 date and the start date of the events a causal relationship cannot be excluded.
1315215	5/13/2021	CA	50	F	4/27/2021	4/28/2021	hearing loss, left ear, noticed 1 day after second vaccine (4/28/2021-present). Treated with 60 mg/day oral prednisone for 14 days, plus 5-day taper (50, 40, 30, 20, 10 mg). As of day 14, no noticeable improvement. Audiogram performed 5/3/2021. Second audiogram scheduled for 5/20/2021. Fever, fatigue, malaise (4/28-5/5)

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1313838	5/13/2021	VA	63	M	2/27/2021	2/28/2021	Feb 28, Sunday: went sleep around 12:45am, woke up 7:15 am, fever 100.6 F, dizziness, complete hearing loss in right ear, fatigue, stayed in bed for a few hours, fever continued through the day, 100.2 to 102.1 F Mar 1, Monday: went sleep 12:00 am, fever 100.4F. Woke up 8am, sudden hearing loss (SHL) in right ear continued, no change, and 99.6F in morning, dizziness, fever was gone by afternoon. SHL continued. Mar 2, Tuesday: SHL continued, dizziness, temperature 96.7F, body ache and soreness were less. Went to Otolaryngology for checkup and treatment at 11:40 am. Diagnose results: complete hearing loss in right ear. Received treatment: injection into right ear and prescription of Prednisone 10mg, injectio
1312997	5/13/2021	TX	46	M	3/25/2021	4/4/2021	Sudden Sensory deafness in my right ear, and severe ringing.; Sudden Sensory deafness in my right ear, and severe ringing.; This is a spontaneous report from a contactable consumer. A 46-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EP6955), dose 1 via an unspecified route of administration, administered in left arm on 25Mar2021, at 09:15 as single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. No known allergies were noted. No other vaccines or medications were noted within two weeks . Prior to vaccination, no diagnosis with COVID-19 was noted. The patient noted sudden sensory deafness in my right ear, and severe ringing on 04Apr2021. Therapeutic measures were taken as a result of the events; 60 mg of prednisone daily was administered. No COVID test was administered post vaccination. The outcome of sudden sensory deafness in my right ear, and severe ringing was not recovered. Since the vaccination, the patient has not been tested for COVID-19. No follow-up attempts are needed. No further information is expected.
1312671	5/13/2021	CA	38	M	4/14/2021	4/25/2021	Developer Tinnitus right after taking shots. At first it was very mild. But after taking my second shot, I feel like my tinnitus symptoms have worsened. I never had history of hearing problems before.
1315676	5/13/2021	NC	42	F	4/16/2021	4/18/2021	Left ear: Ringing in ear, hearing loss, tinnitus Steroid shot injection in eardrum Not resolved

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1313628	5/13/2021	PA	51	F	3/29/2021	4/18/2021	Labyrinthitis of right ear with sudden profound sensorineural hearing loss and vertigo starting 3 weeks after vaccination, resulting in total deafness of right ear despite steroid treatment.
1310911	5/12/2021	TN	43	M	4/7/2021	4/18/2021	Starting 11 days post-vaccine, I've experienced sudden hearing loss in my right ear.



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1309300	5/12/2021	MI	50	F	4/18/2021	4/21/2021	<p>This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of FACIAL PARALYSIS (left eye is not blinking completely) and DEAFNESS UNILATERAL (loss of hearing in the left ear) in a 50-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 007C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 18-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Apr-2021, the patient experienced DEAFNESS UNILATERAL (loss of hearing in the left ear) (seriousness criterion medically significant) and EAR CONGESTION (congestion feeling in the left ear, feels like its plugged up). On 29-Apr-2021, the patient experienced FACIAL PARALYSIS (left eye is not blinking completely) (seriousness criterion medically significant), HYPOAESTHESIA ORAL (left side mouth numb, does not have as much control on left side of mouth) and LACRIMATION INCREASED (left eye tearing excessively). At the time of the report, FACIAL PARALYSIS (left eye is not blinking completely), DEAFNESS UNILATERAL (loss of hearing in the left ear), HYPOAESTHESIA ORAL (left side mouth numb, does not have as much control on left side of mouth), EAR CONGESTION (congestion feeling in the left ear, feels like its plugged up) and LACRIMATION INCREASED (left eye tearing excessively) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Apr-2021, Physical examination: abnormal (abnormal) Patient was told by a physician there was fluid in the ear.. On 29-Apr-2021, Acoustic stimulation tests: abnormal (abnormal) Based on the results of a hearing test, the ENT told her that he believes her symptoms are due to a nerve issue that is affecting the muscles on the left side of the face.. On 29-Apr-2021, Ear, nose and throat examination: normal (normal) The ENT specialist's examination found no infection and no fluid in ear.. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. There are no routine concomitant prescription or over-the-counter medications. Treatment included antibiotic doxycycline hyclate 100 mg twice a day for ear symptoms, prescribed</p>

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by a physician who was seen on 23-Apr-2021. A 13-day prednisone taper was prescribed by an ENT (Ear, Nose, and Throat physician/ otolaryngologist) who was seen on 29-Apr-2021. The patient is currently still taking the antibiotic. Thursday 29Apr2021, she visited an ear, nose, and throat (ENT) specialist for her ear symptoms. The ENT specialist's examination found no infection and found no fluid in her left ear. The ENT told her that the antibiotic therapy would not have caused this type of reaction and told her the symptoms may be due to the Moderna Covid-19 vaccine dose. Based on the results of a hearing test which she was given which was ordered by the ENT because of the symptoms, the ENT told her that he believes that her symptoms are due to a nerve issue that is affecting the muscles on the left side of the face. The ENT told her that he has had other patients with similar symptoms after receiving a second dose of Covid-19 vaccine, which are referenced in the cross-linked case. The ENT prescribed a steroid, Prednisone 10 mg, for the symptoms. She started the Prednisone steroid taper on 29Apr2021, describing the Prednisone 10 mg taper to be decreasing by one tablet a day for 13 days. She is still currently taking the Prednisone taper. 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.

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1309525	5/12/2021	NJ	28	F	4/5/2021	4/9/2021	and had pain; The caller thought the patient had allergies,; SEVERE hearing loss; ringing and pressure in her ears; ringing and pressure in her ears; This is a spontaneous report from contactable consumers (including patient herself and her mother). A 28-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration, administered in left deltoid on 05Apr2021 (Batch/Lot Number: ER8733) as 1st dose, single for COVID-19 immunisation. The patient's medical history was not reported. There were no concomitant medications. Patient was not diagnosed with COVID-19 prior to vaccination. The patient had no health issues and was "perfectly healthy." The patient didn't want to get the vaccine but her mother said she needed to get it, so the patient got the shot. On 09Apr2021, four days after receiving the vaccine, the patient had ringing in her ears, then it was hard to hear, and had pain out of nowhere. She started having ringing and pressure in her ears, then lost hearing in one year. She went to the doctor and had a hearing test. She had 50% hearing loss in her left ear. The doctor ordered an MRI with contrast and without contrast and came out negative. Patient's mother thought the patient had allergies, although the patient never has allergies, so the patient took some Afrin nose spray and saline spray. They waited. Then it was the other ear. Patient started having trouble hearing/ can't hear out of ear. The patient's ears got worse then the patient started losing her hearing. Today, the patient felt that something was not right so she went to see and Ear, Nose and Throat doctor diagnosed the patient with severe hearing loss. The doctor kept asking the patient when she received the COVID vaccine because he had seen this in other patients who have received the vaccine. The doctor believes that the hearing loss was because of the vaccine because it started right after the patient received the vaccine. The doctor prescribed the patient a high dose of cortisone for 12 days and now he wants an MRI of the patient's brain with and without contrast. There was not a question that loss of hearing is a side effect of the vaccine. The doctor had seen this before and mother just wanted to know if she has to spend thousands of dollars, what happens? Does she need to go to the news? She wants to know what to do. Is the hearing loss temporary? What percentage had the reaction recovered from it? The

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patient's insurance was going to run out at the end of April and she will not be able to afford the treatment of this. What is going on? The event was so bad that the patient said she will not live like this- its a ringing and pressure in the patient's head and its driving the patient crazy, now its gone but she can't hear. The doctor had seen this before and patient's mother just wanted to know if the patient has to spend thousands of dollars, what happens? Does the caller need to go to the news? The caller wants to know what to do. She stated "I did my own research. Every time I googled hearing loss, it's everywhere about ringing in the ears. My daughter left her job and now we have medical bills and she has no insurance. Pfizer has not been very good with getting back to me. I need help for my daughter. I need financial help. They're thinking about killing themselves because of the noise in their head. This should really be out there to say that there's a good chance that you may lose your hearing and have sounds in your head that drive you crazy. People need to be educated to make the right decision for them. This should really be out there to say that there's a good chance that you may lose your hearing and have sounds in your head that drive you crazy. People need to be educated to make the right decision for them. My daughter left her job and now we have medical bills and she has no insurance." There has not been a new event. Patient had a MRI of the brain with and without contrast and it was negative. She used steroids and was not better. Outcome of hearing loss was not recovered, of ringing and pressure in her ears recovered on an unspecified date, of remaining events was unknown. The patient had not been tested for COVID-19 since the vaccination.

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1309549	5/12/2021	TX	49	F	4/6/2021	4/8/2021	<p>Tinnitus - 24 hours a day, 7 days a week. I believe I have hearing loss and an scheduled for ent visit this week.;</p> <p>Tinnitus - 24 hours a day, 7 days a week. I believe I have hearing loss and an scheduled for ent visit this week.;</p> <p>This is a spontaneous report from a contactable consumer (patient). A 49-year-old female patient (non-regnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/Lot number was not reported), via an unspecified route of administration, administered in left leg on 06Apr2021 09:30 as 1st dose, single for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient had no known allergies. Vaccine facility type was pharmacy/drug store. The patient did 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 patient experienced tinnitus - 24 hours a day, 7 days a week. that started on 08Apr2021 at 09:00. The patient believed she had hearing loss and was scheduled for ENT visit this week. The patient will have a hearing test (do not know next steps). The outcome of the events was not recovered. Events were reported as non-serious. Information on the batch/lot number has been requested.</p>

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1309559	5/12/2021	MO	51	F	4/8/2021	4/10/2021	Nerve damage; Dizziness; Lost her hearing in her right ear; This is a spontaneous report from a contactable consumer (patient, self-reported). A 51-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTEC COVID-19 mRNA VACCINE, Solution for injection, lot number: EW0162 and expiry date: Jul2021), via an unspecified route of administration, in Arm Left, on 08Apr2021, as a single dose for COVID-19 immunization. The patient's medical history included thyroid problem and seasonal allergies. The patient did not have any family medical history relevant to events. The patient did not receive any vaccine within 4 weeks prior to vaccination. Concomitant medications were not reported. The patient reported that she received the first dose of the Pfizer COVID- 19 vaccine on 08Apr2021 and one day later on 10Apr2021 when she woke up in the morning, she lost hearing on her right ear. She mentioned her doctor told her she should call. She called her physician, and she did not have any accident or anything outside, she was healthy, she only had the vaccine. It bothers her. She described noise in her ear like a dog barking and her ear feels like a big pressure and every time she heard crying or talking or a loud sound, she could not hear. Her doctor never heard of this with the vaccine. She went to see a primary doctor and her HCP said this was due to allergies and pollen, because it was April and he said that he never heard of a hearing loss for COVID vaccine and prescribed Meclizine. She did not have allergy problems and anything wrong with her sinus or a runny nose, so she decided to go to a professional doctor, ear nose and throat. Then she went to see a ear nose and throat doctor on 15Apr2021 and 21Apr2021, and he said that he heard about a couple of cases with the vaccine and he tested her by performing a hearing test and it was true that the COVID-19 vaccine caused nerve damage. She was deaf in her right ear, her test came back horrible, she could not hear. The patient (withheld) said that this was because of the COVID virus in the vaccine, that destroyed nerves in the right ear and that was why she could not hear. She was currently taking Prednisone 10mg tablets, take 6 tablets for 3 days, and then 5 tablets for 3 days, and then 4 tablets and changes every 3 days. The patient was prescribed with meclizine 25mg tablets to take 3 times a day for dizziness. She did not have the

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dizziness when she took the pills. The patient also reported that she was healthy before and she usually takes the flu shot every year and this never had happened before. She was COVID-19 positive on 06Feb2021. She had COVID on 14Feb2021. The events did not require a visit to emergency room. The events were resulted in physician office visit. She would like to verify if this has happened to someone else before and if her hearing will return. The COVID-19 vaccine destroyed her health, and second vaccine was scheduled for 03May2021. The patient would like to know if she should get the second dose of the COVID-19 vaccine after presenting side effects from the first dose. The patient got response that she should not get the Pfizer-BioNTech COVID-19 Vaccine if she had a severe allergic reaction after a previous dose of the vaccine or if she had a severe allergic reaction to any ingredient of the vaccine. The decision to receive the second dose for any other reason cannot be made by Pfizer. The patient was referred to speak to your healthcare provider about the risks of the vaccine compared to the risks of potentially not being fully protected against COVID-19 infection. The patient's healthcare provider knows your health situation and has access to information that can better help inform this decision. Follow up attempts are possible further information is expected

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1309592	5/12/2021	FL	40	M	3/31/2021	4/2/2021	low frequency hearing loss; Right Ear Fullness and Ringing/Tinnitus; Right Ear Fullness and Ringing/Tinnitus; This is a spontaneous report from a contactable consumer (patient). A 40-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), at the age of 40-year-old via an unspecified route of administration, administered in Arm Left on 31Mar2021 15:00 (Lot Number: ER8737) as 1st dose, single for covid-19 immunisation. Medical history was none. No known allergies. 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 received no other vaccines within 4 weeks prior to the COVID vaccine. The patient's concomitant medications were not reported. The patient experienced right ear fullness and ringing/tinnitus. No symptoms before and it had been constant since. Followed up with Hearing test showing low frequency hearing loss on 02Apr2021. Previous (unrelated) hearing test 3 months earlier shows no hearing loss (normal) in 2021. The events were serious disability. The events start date was on 02Apr2021. The event resulted in Doctor or other healthcare professional office/clinic visit. Therapeutic measures were taken including prednisone. The events outcome was not recovered.



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1309594	5/12/2021	TX		F			Sudden pulsatile tinnitus and loss of hearing in left ear within a week or so after 2nd shot.; Sudden pulsatile tinnitus and loss of hearing in left ear within a week or so after 2nd shot.; This is a spontaneous report from a contactable consumer (patient). A 63-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number Er8727, on unknown date at single dose in right arm for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient had no known allergies. The patient had no covid prior vaccination. The patient had not tested covid post vaccination. The patient had not received any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously received first dose of BNT162B2 Lot number En6202, on 28Feb2021 and had a blot clot discovered in lung within 2 weeks of first shot. The patient had sudden pulsatile tinnitus and loss of hearing in left ear within a week or so after 2nd shot. The patient went for ENT Dr for hear. Treatment was received for the events. The outcome of the event was unknown. The event is serious with hospitalization and disability.
1310487	5/12/2021	MO	26	M	4/20/2021	4/20/2021	Dizziness started that day, ringing in right ear started that day, pressure began to build in right ear (noticed the next day). Pressure continued to build in right ear over the 2 days. Pt. reported need to see ENT by Friday morning due to pressure in right ear and hearing loss. Saw Dr. Office on Tuesday 4/27/21
1311218	5/12/2021	CA	54	M	4/26/2021	4/26/2021	Flulike symptoms that continued to get worse. On the morning of the 29th day of April I woke up and couldn't hear. I was temporarily deaf. I fell out of bed and couldn't get up. Finally got to my phone about half an hour later and called 911. I was taken by ambulance to the hospital and put in intensive care. My organs were failing and I was close to death. It was some kind of infection and I'm still on antibiotics. Intervainious antibiotics at home.

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1311994	5/12/2021	NY	61	F	3/29/2021	3/30/2021	Day 1 dizziness, mild headache, could not get warm, no fever, diarrhea, extreme nausea, severely increased ringing of left ear. Day 2 same as day 1, day 3 - day 8 dehydration and severe ringing of ears. Day 9 sudden diminished hearing in the left ear. Ringing and hearing loss remain today 5/12/21. I saw my regular physician, an ENT PA, and Audiologist. Took hearing test which confirmed loss of hearing in left ear (compared to previous test; right ear was the same). Took 10 mg of Prednisone for 10 days to regain hearing, did not improve (2nd hearing test), had an MRI, no significant finding. I am now taking sleeping aids.
1312211	5/12/2021	NC	48	F	3/29/2021	3/31/2021	3/31/21 significant loss of hearing in left ear 4/7/21 Dr. prescribed prednisone and ciprofloxacin 4/9/21 slight improvement in hearing 4/11/21 Total loss of hearing in right ear 4/12/21 To ER 4/14/21 Back to Dr. Prescribed second round of prednisone No improvement 5/5/21 Began dexamethasone perfusion?alternate shots bilaterally over 6 weeks
1312234	5/12/2021	VA	37	M	4/27/2021	4/28/2021	Loss of hearing, Ringing in ears all day similar to riding airplane, headache. dizziness. Ear pain to loud noise.
1311739	5/12/2021	WI	42	M	3/31/2021	4/9/2021	Nine days after 2nd shot, sudden, nearly complete hearing loss occurred in right ear, which previously was within normal hearing ranges.
1309736	5/12/2021		50	F	3/29/2021	3/29/2021	Patient started to notice Rt sided hearing loss 4hrs 15mins post COVID-19 Moderna 2nd dose. Conducted Audiology hearing test 3 weeks post second shot secondary to on-going and pronounced hearing loss within right ear. Patient referred to ENT. ENT provider prescribed oral steroids for one week. Hearing loss persisted with worsening of symptoms throughout treatment with steroids and at 1-wk post conclusion of steroid treatment. ENT performed a myringotomy of the right ear on 04 MAY 21, with no improvement of hearing post-procedure. Meanwhile additional symptoms have presented with difficulty swallowing water and oral secretions on right sided, with pinpointed right-sided headaches starting on 08 MAY 21.

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1310929	5/12/2021	CO	60	M	4/19/2021	5/4/2021	About 2 weeks after Pfizer COVID 19 vaccine 1st shot, I developed significant tinnitus in both ears which still persists to this date. I have some hearing loss too. I'm not getting the second shot.
1305020	5/11/2021	NJ	59	F	4/7/2021	4/7/2021	This spontaneous case was reported by a consumer and describes the occurrence of SUDDEN HEARING LOSS (Hearing loss) in a 59-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. No Medical History information was reported. On 07-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 07-Apr-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced SUDDEN HEARING LOSS (Hearing loss) (seriousness criterion medically significant) and VACCINATION SITE PAIN (Arm hurt a bit). On 07-Apr-2021, SUDDEN HEARING LOSS (Hearing loss) had resolved. At the time of the report, VACCINATION SITE PAIN (Arm hurt a bit) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Patient takes many concomitant medications but details were not provided. Patient took Tylenol (paracetamol) for her arm pain. Reporter states that when experiencing the sudden hearing loss event, she couldn't hear a single thing. She also noted that the event had resolved before she went to bed that same day. 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.
1304854	5/11/2021	IL	38	M	3/20/2021	3/27/2021	Tinnitus left ear Hearing loss left ear Previously never had tinnitus or hearing problems. After about 1 week of 2nd Moderna dose I developed Tinnitus and loss of hearing

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1305670	5/11/2021	CA	56	F	3/24/2021	4/11/2021	Complete deafness in right ear; 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, lot number: eng199), via an unspecified route of administration, in left arm on 24Mar2021 09:00 (at the age of 56-years-old) as single dose for COVID-19 immunization. Medical history included known allergy to penicillin. The patient received other medications within two weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19, did not receive any vaccines within four weeks and was not pregnant at the time of vaccination. Patient received vaccine at the Pharmacy or Drug Store. The patient experienced complete deafness in right ear on 11Apr2021. Hearing loss was not regained with current aggressive medical care. The event resulted in physician or other healthcare professional office or clinic visit and considered as serious due to disability. Since the vaccination, patient has not been tested for COVID-19. The patient was treated with steroids, several other medications and oxygen. Outcome of the event was not resolved.

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1305811	5/11/2021	PA	68	F	3/10/2021	3/17/2021	I developed tinnitus in my left ear and some loss of hearing in my left ear.; I developed tinnitus in my left ear and some loss of hearing in my left ear.; This is a spontaneous report from a contactable consumer reporting for self. A 68-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 via an unspecified route of administration, administered in right arm on 10Mar2021 (Batch/Lot Number: EN6205) as a single dose for COVID-19 immunisation. Medical history included high blood pressure increased from 2001 ("for 20 years") and cancer (first time was in 2004 and then in 2008). The patient was receiving unspecified concomitant medications ("I am taking a lot of different medication"). The patient previously received first dose of BNT162B2 (Batch/lot number: EN6205) on 09Feb2021. On 17Mar2021, the patient developed tinnitus in her left ear and some loss of hearing in her left ear. The patient underwent lab tests including blood work on 14Apr2021 with normal results and MRI brain 15Apr2021 with normal result. The patient had not yet received any treatment for the events at the time of reporting. The patient states she doesn't know for sure, but she believed she had a side effect from receiving the Pfizer vaccine. The outcome of the events tinnitus in her left ear and some loss of hearing in her left ear was unknown.
1306347	5/11/2021	VA	46	F	4/27/2021	5/1/2021	I have had problems with my ears since my second vaccine. My ears have felt chronically clogged and I've been experiencing mild loss of hearing in one or both ears consistently since the vaccine. This has continued through today and I'll be heading to the doctors today for treatment.
1306568	5/11/2021	MA	34	M	2/3/2021	3/6/2021	Loss of hearing in left ear. Started with intense ringing, followed by vertigo and then ultimately loss of hearing

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1306680	5/11/2021		22	F	5/10/2021	5/11/2021	There was a delayed reaction starting 7 days after first dose. Symptoms included redness and soreness at the site of injection and swollen lymph nodes in the armpit of the arm where the shot was injected. 12 hours after receiving the second dose I was shaking, nauseated, dizzy, sweating one minute and freezing the next, pain all over the body, my breathing slowed down and lastly there was a loud deafening ringing in my ears. These symptoms lasted a frightening 10 or so minutes leaving behind the bodily aches.
1306820	5/11/2021	MI	47	M	4/29/2021	5/8/2021	Tinnitus, and loss of hearing in right ear.
1307901	5/11/2021	PR	42	F	4/1/2021	5/3/2021	Hearing loss
1303439	5/10/2021	TX	20	F	5/10/2021	5/10/2021	After 5 minutes of receiving the COVID-19 Vaccination J&J/Janssen, the patient began to feel warm and experience hot flashes. She reported brief hearing loss and numbness throughout her body. 911 was called and they arrived 6 minutes later. Her blood pressure and pulse was taken and she was taken to the hospital on a stretcher.

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1301823	5/10/2021		56	F	2/26/2021	4/7/2021	20% hearing loss; Ringing in the ear; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEAFNESS (20% hearing loss) in a 56-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 047A21A. and 014M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 26-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 07-Apr-2021, the patient experienced DEAFNESS (20% hearing loss) (seriousness criterion medically significant) and TINNITUS (Ringing in the ear). At the time of the report, DEAFNESS (20% hearing loss) and TINNITUS (Ringing in the ear) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment medication included Prednisone. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was not applicable. 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.
1302072	5/10/2021	VA	33	F	3/16/2021	3/23/2021	Severe ear ringing in both ears. I have experienced temporary deafness in my left ear. I had no prior issues with this before getting the vaccine.

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1302139	5/10/2021	CT	57	F	3/25/2021	4/14/2021	First 48 hours extreme/severe pain in right shoulder (person who administered dose put shot too high - almost in tendon - so that could have contributed), severe headache, diarrhea. Next two plus weeks, I felt like someone took a dump inside my body; like my body was a cesspool. I felt gross, ill, uncomfortable, out of sorts, with joint pains which migrated around my body. When that finally seemed to be resolving, I woke on April 14th (3 weeks post vaccine) with LOUD ringing in my right ear (ringing both ears, but right side worse). 2 weeks later I was diagnosed with acute neurological-sensorial hearing loss and was put on prednisone. A week later, my hearing test was back to baseline, but I am still dealing with tinnitus which seems unstable and changing (I guess thankfully, since I hope this will go away). Prior to the second vaccine I'd been feeling better than I had in years due to a new exercise program begun in late January 2021. Was feeling younger, healthier, stronger than I had in years and was pain free. My diet is super healthy (not the typical diet of a typical American) - consisting of whole, unprocessed vegetables, protein and healthy fats.
1302756	5/10/2021	WA	62	F	4/8/2021	5/5/2021	Tinnitus in left ear, marked hearing loss, continuous
1302901	5/10/2021	NY	46	M	4/21/2021	5/8/2021	Saturday, May 8th woke up with severe tinnitus and then suddenly lost all hearing in left ear. Went to urgent care and go prednisone and ENT on May 10th. Hearing loss in my left ear is totally gone. They have little to no hope of recovery. Will be doing an MRI.
1304813	5/10/2021	UT	41	F	4/26/2021	4/29/2021	Clogged feeling in ears, hearing loss, tinnitus
1303309	5/10/2021	OR	48	F	4/19/2021	4/26/2021	Acute left-sided sensorineural hearing loss occurred 7 days after vaccine. ENT visit, no improvement with prednisone. Planned follow up 5/11/21 with possible steroid injection.
1303458	5/10/2021		48	F	4/1/2021	4/10/2021	Sudden, permanent, unilateral hearing loss on same side of injection,



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1303622	5/10/2021	AK	45	F	1/13/2021	1/15/2021	tinnitus for 24 hours, loss of hearing for 48 hours, tinnitus for about 7 days. Received second dose on 2/3/21, Lot# EL3289, tinnitus restarted at about 24 hours post-vaccine. No improvement and tinnitus continues. All symptoms only in right ear.
1303006	5/10/2021	CA	35	M	4/8/2021	4/11/2021	Developed tinnitus after 2 days of vaccination. Prior to vaccination I was having mild ringing in my right ear due to moderate hearing loss caused by ear drum perforation. 2 days after vaccination I started having tinnitus on left side of my brain on and off and now it's continuous , also ringing in my right ear has increased , it is causing to me to have sleepless nights and groggy days. It has not improved even after a month. It could be a permanent damage but I am not sure.
1300718	5/9/2021	VA	59	M	3/10/2021	3/14/2021	Sudden onset of hearing loss and tinnitus in the left ear. Went through two courses of Prednisone treatment starting 4 days after the onset of symptoms. Three hearing tests were done - one before the treatments and one after each treatment. There was no significant improvement from the treatment.
1299136	5/8/2021	TX	46	M	4/19/2021	4/22/2021	clogged ears, loss of hearing acuity. Sudden onset.; clogged ears, loss of hearing acuity. Sudden onset.; This is a spontaneous report from a contactable consumer (patient). A 46-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot ER8735), via an unspecified route of administration, administered in left arm on 19Apr2021 14:00 as single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient had no known allergies. The patient had no other vaccine in 4 weeks and no other medications in 2 weeks. On 22Apr2021 20:30, the patient experienced clogged ears and loss of hearing acuity, sudden onset. There was no therapy for the events. The patient had no Covid prior vaccination and was not Covid tested post vaccination. Outcome of events was not recovered.

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1299368	5/8/2021	PA	20	M	4/19/2021	4/19/2021	worsening renal failure/kidney function continued to decline; gross hematuria; follicular conjunctivitis; a low CD3/CD4 count (CD4 91, CD347, CD8 258); a low CD3/CD4 count (CD4 91, CD347, CD8 258); The patient's unilateral tinnitus progressed to bilateral sensorineural deafness over 2 days; The patient's unilateral tinnitus progressed to bilateral sensorineural deafness over 2 days; pustular rash on his chin forehead, chest and back; nauseous; diffuse myalgia; vomited; suprapubic pain; This is a spontaneous report from a contactable other healthcare professional. A 20-year-old male patient first dose of received bnt162b2 (BNT162B2), intramuscular, administered in left arm on 19Apr2021, at the age of 20-years old, (Lot Number: EW0151) as SINGLE DOSE for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. Prior to vaccination, the patient has not been diagnosed with COVID-19. It was reported that the patient was in his usual state of good health until 19Apr2021, when he received his first dose of the Pfizer COVID-19 vaccine. Two hours after the injection he became nauseous and vomited multiple times. Overnight he experienced diffuse myalgia and suprapubic pain. On 20Apr2021, he woke up the next day to a pustular rash on his chin, forehead, chest and back. The patient describes similar previous rashes that have resolved spontaneously. On 21Apr2021, he began to experience gross hematuria and presented to the Emergency department. On the medicine floor he was initially found to have worsening renal failure, follicular conjunctivitis by skin biopsy, a low CD3/CD4 count (CD4 91, CD3 47, CD8 258) with normal complement, and bilateral tinnitus. The patient's unilateral tinnitus progressed to bilateral sensorineural deafness over 2 days. His kidney function continued to decline and hemodialysis was begun on 27Apr2021. His kidney function continued to decline on hemodialysis, becoming so he was transferred to the MICU for CRRT. The patient was hospitalized for 12 days due to the events, the events were also assessed as life-threatening. The patient been tested for COVID-19 post vaccination with unknown result. The outcome of the events was unknown. Therapeutic measures were taken as a result of the events. Information on Lot/Batch number was available. Additional information has been requested.

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1299504	5/8/2021	MI	71	F	3/17/2021	3/22/2021	Sudden Sensorineural hearing loss of right ear occurred 5 days after vaccine injection
1299524	5/8/2021	MI	50	F	4/18/2021	4/21/2021	Sudden left sensorineural hearing loss started 3 days after injection Left facial paralysis started 11 days after injection
1299587	5/8/2021	PA	51	F	3/11/2021	3/20/2021	Spike in blood pressure noticed around one week after injection; treated by doctor by adding amlodipine besylate 5 mg on 4/15/21; follow up appointment on 4/21/21 showed normal blood pressure Pulsatile tinnitus in left ear - scheduled MRI MRA for 5/13/21; referred to ENT; hearing test on 5/4/21 revealed no hearing loss in left ear and mild nerve loss in right ear; no other issues noted with nose, throat or carotid artery noise; follow up scheduled for 5/18/21 to review MRI MRA results Pulsatile tinnitus remains in left ear, along with minor episodes of dizziness and mild headaches in front and back of left side of head starting around 4/30/21
1299800	5/8/2021	FL	71	M	2/25/2021	3/25/2021	Nose bleed 4/20/21, noticed some loss of balance 5/5/2021, complete loss of hearing in right ear accompanied by balance issues and motion sickness
1300180	5/8/2021	FL	42	F	1/30/2021	3/11/2021	Sudden Hearing loss and tinnitus

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1299218	5/8/2021	IN	65	F	1/22/2021	1/26/2021	Severe dizziness, tinnitus, ear pressure, deafness in left ear. After 13 weeks dizziness is lessened but still present, ear issues still persist.; Severe dizziness, tinnitus, ear pressure, deafness in left ear. After 13 weeks dizziness is lessened but still present, ear issues still persist.; Severe dizziness, tinnitus, ear pressure, deafness in left ear. After 13 weeks dizziness is lessened but still present, ear issues still persist.; Severe dizziness, tinnitus, ear pressure, deafness in left ear. After 13 weeks dizziness is lessened but still present, ear issues still persist.; This is a spontaneous report from a contactable consumer (patient). A 65-years-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 1 via an unspecified route of administration, administered in left arm on 22Jan2021 10:00 (Lot Number: FL9262) as SINGLE DOSE (at age of 65 years old) for covid-19 immunisation. Medical history included occasional migraines from an unknown date and unknown if ongoing. The patient did not have any allergies. There were no concomitant medications. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 26Jan2021, the patient experienced Severe dizziness, tinnitus, ear pressure, deafness in left ear. After 13 weeks dizziness is lessened but still present, ear issues still persist. The patient was hospitalized for 1 day on unknown date for the event "severe dizziness, tinnitus, ear pressure, deafness in left ear. after 13 weeks dizziness is lessened but still present, ear issues still persist". The events resulted in [Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization, Disability or permanent damage]. Therapeutic measures were taken as a result of severe dizziness, tinnitus, ear pressure, deafness in left ear. after 13 weeks dizziness is lessened but still present, ear issues still persist. Treatment included IV, Medication. The patient underwent lab tests and procedures which included nasal Swab PCR in Feb2021: result COVID negative, Blood test Antibody test in Feb2021: result COVID negative , nasal Swab PCR in Mar2021: result COVID Negative. Outcome of the events was not recovered. The patient received BNT162B2 (PFIZER) dose 2, Lot number FL9267 on 12Feb2021 10: 00am in

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1299192	5/8/2021	CA	34	M	3/10/2021	3/28/2021	<p>the left arm.</p> <p>Tinnitus in right ear; Vertigo; Congestion and partial hearing loss in left ear/Congestion and partial hearing loss in right ear; Congestion and partial hearing loss in left ear/Congestion and partial hearing loss in right ear; This is a spontaneous report from a contactable consumer (patient). A 34-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 10Mar2021 10:45 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation, 34 years old. Medical history reported as none. No other vaccines in four weeks. No COVID prior vaccination. No known allergies. Concomitant medication included isotretinoin (ACUTANE) taken for an unspecified indication, start and stop date were not reported (in two weeks). It was further reported that congestion and partial hearing loss in left ear occurred on 28Mar2021 09:00 through 31Mar2021 and was resolving over time. There was vertigo in the morning of 31Mar2021, congestion and partial hearing loss in right ear starting 03Apr2021 and resolving over time. Tinnitus in right ear starting 03Apr2021. Tinnitus has still not gone away. The patient underwent lab tests and procedures which included Nasal Swab: negative on 16Mar2021, 23Mar2021, 30Mar2021, 06Apr2021, 13Apr2021, and 20Apr2021. Therapeutic measures were taken as a result of congestion and partial hearing loss in left ear/congestion and partial hearing loss in right ear, vertigo, and tinnitus in right ear (methylprednisolone). The events required physician office visit. Outcome of the events deafness bilateral and ear congestion was recovering, while vertigo and tinnitus was not recovered. The events were reported as serious (disability). Information about lot and batch number was requested.</p>

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1299188	5/8/2021	AK	59	F	3/23/2021	3/28/2021	head pressure (specifically left ear area, also mild hearing loss left ear); Headache; head pressure (specifically left ear area, also mild hearing loss left ear); Tinnitus; loss of appetite; insomnia (still have tinnitus and ear pressure as well as insomnia); insomnia (still have tinnitus and ear pressure as well as insomnia); This is a spontaneous report from a contactable consumer (patient). A 59-year-old female patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration (at the age of 59-years-old), administered in Arm Left on 23Mar2021 12:45 (Lot Number: ER8730) as single dose for COVID-19 immunization. Medical history included known allergy to penicillin. The patient was not pregnant. Not diagnosed with COVID prior vaccination. No concomitant medications received. The patient previously received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration (at the age of 59-years-old), administered in Arm Left on 02Mar2021 08:15 AM (Lot Number: EN6202) as single dose for COVID-19 immunization. The patient experienced headache, head pressure (specifically left ear area, also mild hearing loss left ear), tinnitus, loss of appetite, insomnia (still have tinnitus and ear pressure as well as insomnia) on 28Mar2021 12:00. The events resulted in Doctor or other healthcare professional office/clinic visit. The patient underwent lab tests and procedures which included SARS-CoV-2 test: negative on 30Mar2021. No treatment received for the events. The outcome of the events was not recovered. The event mild hearing loss left ear was considered as serious (medically significant). Facility type vaccine was Hospital. No other vaccine in four weeks.

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1299260	5/8/2021	MN		F	3/3/2021	4/10/2021	some hearing loss; Severe Tinnitus after the second which has not gone away; This is a spontaneous report from a contactable consumer, patient. A 63-year-old non-pregnant female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: Ew0151) via an unspecified route of administration, in the left arm on 03Mar2021 as a single dose for COVID-19 immunisation. The patient medical history was not reported. Since the vaccination, the patient has not been tested for COVID-19. Concomitant drugs were not provided. The patient previously received the first dose of BNT162b2 in the left arm on 03Mar2021 at 15:00 (Lot Number: EN6199) for COVID-19 immunisation. The patient had not received any other vaccines within 4 weeks prior to the COVID-19 vaccine. On 10Apr2021 at 03:15, the patient experienced some hearing loss and severe tinnitus after the second which has not gone away. The patient reported, she noticed ringing in the ears (tinnitus) after the first one then went away. Severe tinnitus after the second which has not gone away. Doc sent me for hearing test. Which I've had some hearing loss. No treatment was provided for the events. The patient had not recovered from the events, some hearing loss and severe tinnitus after the second which has not gone away.

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1299156	5/8/2021	CT	42	M	4/8/2021	4/17/2021	Sudden Idiopathic Hearing Loss; clogged ear feeling; Hearing whistling noises; approx. 30-50% of hearing in right ear; This is a spontaneous report from a contactable consumer (patient). A 42-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 08Apr2021 at 18:30 (Lot Number: EP6955) (at the age of 42-year-old) as single dose for COVID-19 immunisation. Medical history included eosinophilic oesophagitis, hypertension and enlarged prostate, all from an unknown date and unknown if ongoing. The patient did not test positive to COVID-19, pre or post vaccination. Concomitant medications included clonazepam; lisinopril; omeprazole and tamsulosin, all concomitants were taken for an unspecified indication, start and stop date were not reported. The patient previously took erythromycin and experienced allergy. On 17Apr2021 at 09:00, the patient was diagnosed as "Sudden Idiopathic Hearing Loss" in right ear. He woke up to clogged ear feeling. Hearing whistling noises and approx. 30-50% of hearing in right ear. The events were serious, disabling. The events required emergency room visit and physician office visit. Therapeutic measures were taken as a result of the events and included treatment with prednisone. The patient outcome of the events was not recovered.



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1299135	5/8/2021	MO	41	F		4/1/2021	<p>This is a spontaneous report from a contactable consumer reporting for the daughter. A 41-year-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration on 10Apr2021 (Batch/Lot number was not reported) as single dose maybe the right arm (reporter was unsure) at the age of 41-year-old for COVID-19 immunisation, administered through hospital. Medical history was none. There were no concomitant medications. In Apr2201 the patient experienced she can't hear right now and it won't go away, ringing in ears, she is extremely stressed out and this is affecting her life, she was so upset. The course of events was as follows: She has had ringing in her ears from this, started some time after the shot. She was extremely stressed out and this was affecting her life. She can't live like this. She recently divorced with 2 kids and trying to work. Went to the doctor twice and they sent her to ENT department. This is destroying her life. It was very stressful. Patient was having a severe problem. She had been to the doctor twice, including this week in Apr2021 and once the end of last week in Apr2021. They looked at her medications and sent her to counseling, to therapy. She had definitely not gotten better, has been persistent. She did not know on like a graph scale where it was. She received no treatment for ringing in ears. She was trying to take something for stress because this was horrible. She cannot hear right now and it won't go away. This is a serious problem. Reporter did not want her daughter to go deaf. She received a message from hospital, regarding her being scheduled for the second vaccine on Saturday and she said she was not going for that she wished she had not gotten the first one. Reporter stated she has a good friend who's daughter was a PA whom she has been corresponding to about this and she sent them links of how the Covid vaccine is linked to tinnitus. She has never had anyone report this. She sent it to her daughter and her daughter said can't read this, there is blogs with responses and she just said she can't read this, she was so upset that she can't hear right because of this with this ringing that won't go away. She had gotten a call from the Hospital Department stating that she was ready for the second shot. She was not getting the second shot and was sorry that she got the first one. The outcome of events was not recovered. Information on the lot/batch number has been requested.</p>

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1299085	5/8/2021			F	3/1/2021	3/1/2021	I also feel I have some hearing loss; Tinnitus in both ears; ear pain; I also have ear pressure; Numbness in my face and full right leg off and on; Numbness in my face and full right leg off and on; Odd sensations in the top and back of our head; 24/7 tinnitus is driving us downright mad; Odd sensations in the top and back of our head; This is a spontaneous report received a contactable consumer, the patient. This consumer reported similar events for two patients with the same product; this case is the first of two, only this case is serious. A female of unspecified age received the first dose of BNT162b2 (solution for injection; batch/lot and expiry information not provided) as a single dose via an unspecified route on an unspecified date in Mar2021 for COVID-19 immunisation. There was no medical history, concomitant or past drug history reported. The patient reported that about fifteen minutes or so after receiving the first dose of the Pfizer COVID vaccine she experienced new onset tinnitus in both ears. The patient stated that she has ear pressure, ear pain, and numbness in my face and full right leg off and on. The patient also mentioned she is experiencing odd sensations in the top and back of our head. The patient stated that she also feels she has some hearing loss though has not been able to get it checked yet. The patient exclaimed that the 24/7 tinnitus is driving her downright mad. The patient reported the she received the second dose even though she is still experiencing side effects because she wanted to do her part and get vaccinated. The outcome of the events tinnitus in both ears, ear pressure, ear pain, numbness in my face and full right leg off and on, and odd sensations on the top and back of my head, was not recovered. The outcome of the events hearing loss, and 24/7 tinnitus is driving us downright mad was unknown. The lot number for the vaccine, BNT162b2, was not provided and will be requested during follow up.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021465140 PFIZER (Same reporter/product, similar event in different patient)

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1299181	5/8/2021	CA	72	M	3/31/2021	4/3/2021	substantial hearing loss in his right ear; woke up with ringing in his right ear; This is a spontaneous report from a contactable consumer (patient). A 72-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 31Mar2021 at 10:00 (lot number: ER8737) as single dose for covid-19 immunisation, administered at the hospital. The patient received the first dose of bnt162b2 in Mar2021 at 10:00 (lot number: EN6208) for covid-19 immunisation. Medical history was reported as none. The patient's concomitant medications were not reported. The patient had no other vaccines in four weeks and no other medications in two weeks. The patient had no COVID prior vaccination and not COVID tested post vaccination. On 03Apr2021, patient woke up with ringing in his right ear at 5 AM and upon rising at 7:30 AM, he noticed substantial hearing loss in his right ear. The patient received treatment for the events. Outcome of the events were reported as recovered with lasting effects. The events resulted in doctor or other healthcare professional office/clinic visit and disability or permanent damage.

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1294672	5/7/2021	NY	39	M	2/14/2021	2/1/2021	hearing loss; bad tinnitus in his left ear; This is a spontaneous report from a contactable consumer. A 39-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Left Arm on 14Feb2021 11:30 (Batch/Lot Number: EL9266; Expiration Date: 31May2021) as SINGLE DOSE (at the age of 39-year-old years) for covid-19 immunisation. The Patient received second dose in left arm on 07Mar2021 11:45 lot number: EN6201, expiration date: Jun2021. Medical history included ongoing asthma which was diagnosed when he was 9 years old. He states the he is also susceptible to chest infections. There were no concomitant medications. The patient experienced hearing loss (medically significant) on Feb2021 with outcome of not recovered and bad tinnitus in his left ear on Feb2021 with outcome of not recovered. The patient underwent lab tests and procedures which included acoustic stimulation tests: this morning it's in his right ear on 21Apr2021 and acoustic stimulation tests: hearing loss on 2021 the hearing loss was initially only in his left ear; magnetic resonance imaging: negative on unspecified date. He is an audio engineer and sound editor and that is how he makes his money. He states that today (21Apr2021) will make the 5th hearing test in total and his hearing hasn't gotten any better. Three weeks ago it was only the left ear and as of today the right (21Apr2021) ear is also being affected. Symptoms started in Left ear and are now in the right ear as well. An MRI was done and that was negative. He thinks it is related to the vaccine. The patient went to the physician office for treatment. The patient did not have additional vaccines administered on same date of the Pfizer Suspect. The patient had no prior vaccination within 4 weeks. Follow-up attempts are completed. No further information is expected.
1294763	5/7/2021	OH	31	M	5/3/2021	5/6/2021	Severe tinnitus, some hearing loss in right ear. Lethargy.

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1294695	5/7/2021	OH	50	M	4/7/2021	4/9/2021	Hearing loss and tinnitus in ears - primarily right ear; Hearing loss and tinnitus in ears - primarily right ear; This is a spontaneous report from a contactable consumer (patient). This 50- year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE Lot number: EP7533), via an unspecified route of administration, on 7Apr2021 at 11:00 am (at the age of 50-years-old) as a single dose for COVID-19 vaccination, in left arm, at a Pharmacy or Drug Store. Historic vaccine included first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number EP6955, expiration date: unknown) via unspecified route of administration in on 17Mar2021 at 12:00 pm as a single dose for COVID-19 immunization. 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. The patient has no known allergies. Medical history included: Rheumatoid arthritis, hypothyroidism. Concomitant medications included: Thyroid medication. The patient reported hearing loss and tinnitus in ears - primarily right ear on 09Apr2021. No treatment was received. The clinical outcome of the events was not recovered. Since the vaccination, the patient has not been tested for COVID-19.
1294739	5/7/2021	NC		M	4/19/2021	4/20/2021	Sprain in leg; thinking I am deaf; had covid; had covid; had little chills; Tired; throat was painful; This is a spontaneous report from a contactable consumer (patient). A male patient of an unspecified age received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on 19Apr2021 16:45 (Lot Number: EW0169) as single dose for covid-19 immunization. Medical history included Knee arthroplasty. The patient's concomitant medications were not reported. Patient received the dose1 (lot: EP7533) for Covid-19 immunisation. The patient felt a little bit tired like the symptom when had covid and throat was painful and had little chills on 20Apr2021. had a sprain in leg but patient guessed that because had a knee replacement on unknown date. Patient stated, "Sorry, I am thinking I am deaf. I am sorry, I cannot understand". The outcome was unknown. No follow-up attempts are needed. No further information is expected.

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

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

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losing hearing before that, but the patient was not able to talk to the caller or family a lot." (as reported). The reporter did not provide details on medications administered during the patient's hospital stay. The reporter stated that the patient was just discharged from the hospital and sent home. The reporter believed that the patient needed more care and more medicine and that he was not finished with treatment. The reporter stated that the patient should have been back to normal health before having been discharged from the hospital. He did not know why the patient was discharged. The reporter stated that the patient was sent home without any medicine and was still experiencing daily headaches. The patient took Advil Migraine for his headaches which did not work, or only worked for 10 minutes and then the pain would come back. The hospital referred the patient to a different facility. The reporter stated that the patient could not get an appointment with this facility for up to 2 months from now. The patient could not wait 2 months for relief. He could not be like that with a headache and no feeling on his right side for 2 months. According to a different doctor the patient needed "more IVIG, immunoglobulin and needed to get attention from a neurologist to watch him until he got better." The patient had an appointment scheduled with a neurologist for Monday 26Apr2021 at 08:00. The clinical outcome of the event fever was recovered/resolved on an unspecified date; does not feel from his waist down on left side and weakness on left side were recovering/resolving; does not feel from his waist down on right side, weakness on right side, lost hearing on right side, pain in back, pain in neck that went up to his head and headache were not recovered/not resolved and passed out, Guillain Barre syndrome and high blood pressure were unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up



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1296278	5/7/2021	MI	64	F	3/9/2021	3/17/2021	About a week and a half after the vaccine I suddenly developed high pitched very loud tinnitus in both ears. This persisted until April 5th when I woke up with an extremely loud jet engine sound in the left ear. The hearing had diminished 97% overnight. After tests at ENT specialists I was put on Prednisone and scheduled for an MRI. After taking the course of Prednisone there is no improvement. The hearing loss was experienced on the side that the vaccine was administered. The MRI showed nothing unusual. I continue to have loud tinnitus and no hearing in the left ear.
1292708	5/6/2021	IL	20	M	5/6/2021	5/6/2021	Blurry vision, diaphoretic, hearing loss
1292955	5/6/2021	TX	65	F	3/22/2021	3/23/2021	Chronic severe head ache (uncommon), rigidity of neck, earache, dizziness , fullness of the head, tinnitus both ears more loud left side like very loud crickets sound. As time progressed now May 6, 2021 I am experiencing the same symptoms plus vertigo at night and loss of hearing in both ears. My insurance does not cover the big copay for doctor's visit
1293930	5/6/2021	IL	31	F	3/30/2021	4/22/2021	Hearing loss, tinnitus, brain fog
1294129	5/6/2021	TX	38	F	4/2/2021	4/4/2021	Started getting reduced hearing on both ears, worse on right hand side, shortly after 1st dose received on 4/2/2021. Hearing deteriorated even further after second dose received 5/4/2021. Right hand side ear worse than left. No pain associated with hearing loss, but clouded mind, and extreme tiredness due to impaired hearing. Especially if in noisy locations like a grocery store.
1294356	5/6/2021	CA	60	F	3/12/2021	3/24/2021	Ringing in Right ear, Possible hearing loss
1292380	5/6/2021	VA	69	M	3/11/2021	3/13/2021	Sudden partial deafness in right ear. Referred to ENT. Audiology indicated major loss of low frequency hearing in right ear. Doctor prescribed steroid taper (12 day) with possible minor improvement. ENT doctor offered a steroid injection into ear but thought that too much time had passed for it to be effective.
1294300	5/6/2021	MO	42	F	2/4/2021	2/24/2021	Moderate/Severe Tinnitus and hearing loss in left ear, unsuccessfully treated with medrol dose pack and 18 day course of prednisone

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1288380	5/5/2021	TN	57	F	3/10/2021	3/11/2021	moderate hearing loss; hyperacusis; tinnitus; This is a spontaneous report from a contactable consumer (patient). A 57-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EN6198 and expiration date not provided), via an unspecified route of administration, administered in Arm Left second dose on 10Mar2021 13:00 at single dose for covid-19 immunisation. The patient's medical history included hypertension. The patient was not pregnant at time of vaccination. The patient's concomitant medications included desvenlafaxine, candesartan, fluticasone propionate (FLONASE [FLUTICASONE PROPIONATE]), and azelastine. The patient historical vaccine includes bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL9264) via an unspecified route of administration, administered in Arm Left first dose on 17Feb2021 for covid-19 immunisation. On 11Mar2021 14:00, the patient experienced moderate hearing loss confirmed by doctor hyperacusiss and tinnitus. The patient was treated with oral steroids. The events cause physician office visit. The outcome of the events was not recovered. No follow-up attempts are needed. No further information is expected.

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1288118	5/5/2021	NY		F			Have experienced hearing loss after vaccination; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS (Have experienced hearing loss after vaccination) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced DEAFNESS (Have experienced hearing loss after vaccination) (seriousness criterion medically significant). At the time of the report, DEAFNESS (Have experienced hearing loss after vaccination) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Concomitant product use was not provided by the reporter. The patient is a part of a group of over 1000 patients (all vaccines, not just Moderna). No treatment information was provided. Company Comment : Very limited information regarding the events has been provided at this time. Additional information regarding date of onset, date of vaccination, medical history and concomitant medications are required for further evaluation. This case was linked to US-MODERNATX, INC.-MOD-2021-091898, US-MODERNATX, INC.-MOD-2021-092733 (E2B Linked Report).; Sender's Comments: Very limited information regarding the events has been provided at this time. Additional information regarding date of onset, date of vaccination, medical history and concomitant medications are required for further evaluation. US-MODERNATX, INC.-MOD-2021-091898:Crosslinked (MOD21-082668) US-MODERNATX, INC.-MOD-2021-092733:Crosslinked (MOD21-082695)
1291300	5/5/2021	TX	58	F	3/17/2021	3/24/2021	Severe Vertigo, profusely sweating, vomiting, severe dizziness, hearing loss (left), tinnitus.
1288473	5/5/2021	NY	60	F	4/27/2021	4/28/2021	Adverse event is HEARING LOSS in the left ear. Right now being treated with steroids orally. May have to get steroid injections in ear drum. Hearing is completely gone. No signs, just suddenly came on briefly.

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1288422	5/5/2021			M	6/2/2015		Deafness right ear; Urinary tract infection; Feeling bad; Weakness; This is a solicited report based on the information received by Pfizer. A 85-years-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscular on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation; ibrutinib (IMBRUVICA), oral from 02Jun2015 (Batch/Lot number was not reported) to an unspecified date, at 140 mg, 3x/day [(140 mg, 3 in 1 D)] for chronic lymphocytic leukaemia; ibrutinib (IMBRUVICA), oral from an unspecified date (Batch/Lot number was not reported) and ongoing, at 420 mg, 1x/day [420 mg (420 mg, 1 in 1 D)] for Chronic Lymphocytic Leuk of B-Cell Type Not Achieve Remis The patient had no known medical history The patient's concomitant medications were not reported. The patient experienced deafness right ear, urinary tract infection, feeling bad and weakness. All events involved hospitalization and were medically significant. The patient's hospitalization was prolonged as a result of deafness right ear, urinary tract infection, feeling bad, weakness. The action taken in response to the event(s) for ibrutinib was permanently withdrawn on an unspecified date , for ibrutinib was dose not changed. The clinical outcome of the events was recovering. Solicited report by a consumer of an elderly male with events of couldn't hear from right ear and urinary tract infection and non-serious feel crummy and weakened with Imbruvica (Ibrutinib) and Imbruvica (Ibrutinib). There was no reported medical history. On unknown dates, the patient experienced couldn't hear from right ear, urinary tract infection, feel crummy and weakened. Covid-19 vaccine was also considered suspect. It was unknown if patient was enrolled in a COVID-19 Vaccine Trial. On unknown date, patient received 1st dose COVID-19 Vaccine manufactured by Pfizer, lot number unknown, expiration date unknown. Patient was in hospital for a week and had lots of tests. And came out to being urinary tract infection that made him feel crummy and was weakened. Patient also reported that couldn't hear from right ear it could be from Pfizer vaccine. Which was finished a month ago. And never had much trouble with Imbruvica. Causality for Imbruvica (Ibrutinib) The reporter's causality for the event(s) of couldn't hear from right ear, urinary tract infection, feel crummy and

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weakened was not provided. Company's opinion is that there is no reasonable possibility that the event of couldn't hear from right ear is related to Imbruvica (Ibrutinib). Company's opinion is that there is a reasonable possibility that the events of Urinary Tract Infection, feel crummy and weakened are related to Imbruvica (Ibrutinib). Causality for Imbruvica (Ibrutinib) The reporter's causality for the event(s) of couldn't hear from right ear, urinary tract infection, feel crummy and weakened was not provided. Company's opinion is that there is no reasonable possibility that the event of couldn't hear from right ear is related to Imbruvica (Ibrutinib). Company's opinion is that there is a reasonable possibility that the events of Urinary Tract Infection, feel crummy and weakened are related to Imbruvica (Ibrutinib). Suspect Drug (s): Seq.No.: 1 Drug: Imbruvica (capsule) (Ibrutinib), Unknown Daily dose: 420 mg (140 mg, 3 in 1 D) Route of Admin: Oral Therapy dates/Duration: 02Jun2015-Discontinued Indications for Use: Chronic Lymphocytic Leuk of B-Cell Type Not Achieve Remis Causality Deafness right ear (Deafness unilateral) Action(s) taken with drug: Drug discontinued Causality as per reporter (Drug/Vaccine): Not Reported Causality as per Mfr. (Drug/Vaccine): No reasonable possibility Dechallenge: Unk Urinary Tract infection (Urinary Tract infection) Action(s) taken with drug: Drug discontinued Causality as per reporter (Drug/Vaccine): Not Reported Causality as per Mfr. (Drug/Vaccine): Reasonable possibility Dechallenge: Unk Feeling bad (Feeling abnormal) Action(s) taken with drug: Drug discontinued Causality as per reporter (Drug/Vaccine): Not Reported Causality as per Mfr. (Drug/Vaccine): Reasonable possibility Dechallenge: Unk Weakness (Asthenia) Action(s) taken with drug: Drug discontinued Causality as per reporter (Drug/Vaccine): Not Reported Causality as per Mfr. (Drug/Vaccine): Reasonable possibility Dechallenge: Unk Seq No.: 2 Drug: Imbruvica (Tablet) (Ibrutinib) Daily dose: 420 mg (420 mg, 1 in 1 D) Route of Admin: Oral Therapy dates/Duration: Unk-Ongoing indications for Use: Chronic Lymphocytic Leuk of B-Cell Type Not Achieve Remis Causality Deafness right ear (Deafness unilateral) Action(s) taken with drug: Dose not changed Causality as per reporter (Drug/Vaccine): Not Reported Causality as per Mfr. (Drug/Vaccine): No reasonable

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possibility Dechallenge: N/A Urinary Tract infection (Urinary Tract infection) Action(s) taken with drug: Dose not changed Causality as per reporter (Drug/Vaccine): Not Reported Causality as per Mfr. (Drug/Vaccine): Reasonable possibility Dechallenge: N/A Feeling bad (Feeling abnormal) Action(s) taken with drug: Dose not changed Causality as per reporter (Drug/Vaccine): Not Reported Causality as per Mfr. (Drug/Vaccine): Reasonable possibility Dechallenge: N/A Weakness (Asthenia) Action(s) taken with drug: Dose not changed Causality as per reporter (Drug/Vaccine): Not Reported Causality as per Mfr. (Drug/Vaccine): Reasonable possibility Dechallenge: N/A Seq No.: 3 Drug: COVID-19 Vaccine (COVID-19 Vaccine), Unknown Daily dose: Pfizer Vaccine Route of Admin: Intra-muscular Indications for Use: COVID-19 Vaccination Causality Deafness right ear (Deafness unilateral) Action(s) taken with drug: Unknown Causality as per reporter (Drug/Vaccine): Reasonable possibility Dechallenge: N/A Urinary Tract infection (Urinary Tract infection) Action(s) taken with drug: Unknown Causality as per reporter (Drug/Vaccine): Not Reported Dechallenge: N/A Feeling bad (Feeling abnormal) Action(s) taken with drug: Unknown Causality as per reporter (Drug/Vaccine): Not Reported Dechallenge: N/A Weakness (Asthenia) Action(s) taken with drug: Unknown Causality as per reporter (Drug/Vaccine): Not Reported Dechallenge: N/A The reporter assessment of the causal relationship of the events UTI, Feeling bad and Weakness with the suspect product BNT162B2 was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment. No follow-up attempts are possible; Information about lot/batch number cannot be obtained.; Sender's Comments: Based on the available information, the reported events deafness right ear, urinary tract infection, feeling bad and weakness are attributed to underlying or intercurrent medical conditions that were unlikely related to BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA 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

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1288038	5/5/2021	WA	53	F	4/30/2021	5/1/2021	any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
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I had my Covid Pfizer vaccine on 4/30 in the morning and only felt a mildly sore arm that evening. I woke up the next morning to very stuffed ears, high pitched ringing in my ears...It was difficult to hear over the loud tone in my head/ears.. My hearing declined Throughout the day by night time I have no hearing left in my right ear. I went to see my ENT specialist on Monday, 5/1/2021. I had a full audiology work up and meeting with my ENT. The exam so that I had 100% hearing loss in my right ear. I am having an MRI on Weds 5/12 and meeting again with my ENT on 5/18. I was put on a high dose of steroids, Prednisone, for the next 2 weeks. trying to get back some hearing.

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1288393	5/5/2021	IN	68	F	2/22/2021	4/11/2021	Hearing loss due to nerve damage; sudden and unexpected hearing loss in her left ear; This is a spontaneous report from a contactable consumer, the patient. A 68-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot: EN6200), via an unspecified route of administration on 22Feb2021 (at the age of 68-years-old) as a single dose for COVID-19 immunization. Medical history was not reported. Concomitant medications were reported as none. There were no other vaccines administered within 4 weeks or on the same date as the COVID-19 vaccine. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot: EL9263) on 01Feb2021 (at the age of 68-years-old) for COVID-19 immunization. On 08Mar2021, the patient had a cataract extraction in both eyes after which she started taking prednisolone acetate USP 1% (UPC: 6075811910, Lot: T0557, Expiry: Jun2023) steroid eye drops on approximately 10Mar2021 for an unspecified length of treatment. On 11Apr2021, the patient experienced sudden and unexpected hearing loss in the left ear only, which worsened. Per the appointment with the ear, nose, and throat (ENT) doctor, there was no reason for the unexpected hearing loss in her left ear, and the hearing loss was not related to anything medical. The ENT doctor started the patient on a steroid treatment (prednisone) for 10 days. On 20Apr2021, the patient had an abnormal hearing test which showed left ear hearing loss due to nerve damage (as of an unspecified date). The events did not require an emergency room visit. The clinical outcome of sudden and unexpected hearing loss in her left ear was not resolved, while of hearing loss due to nerve damage was unknown.



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1288368	5/5/2021	NY	91	M	3/16/2021	3/1/2021	<p>Felt a little off; Pneumonia; This is a spontaneous report from a contactable consumer (patient's daughter). A 91-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number and expiration date not reported) via an unspecified route of administration, administered on the left arm on 16Mar2021 at a single dose for COVID-19 immunisation. The patient's medical history included deaf. Concomitant medications were not reported. Reporter stated that a week and a half after his first vaccine he had pneumonia (Mar2021); but that they didn't think it was related to the vaccine. The patient also felt a little off on 16Mar2021 and required a visit to the emergency room and physician office. The facility where the vaccine was administered was in a clinic. There were no additional vaccines administered on same date of Pfizer suspect. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There was no family medical history relevant to events and no relevant tests done. Outcome of the event pneumonia was unknown while not recovered for the other event. The reporter mentioned that they didn't think that pneumonia was related to the vaccine. Information about the Lot/batch number has been requested.;</p> <p>Sender's Comments: Based on available information, pneumonia is assessed as unrelated to BNT162B2, this is an intercurrent medical condition. Potential contributors include patient's advanced age as the risk for infections is higher in this population. Case will be reassessed if additional information is received</p>

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1288111	5/5/2021	AR	39	F	3/19/2021	4/16/2021	Hearing loss persists; Cannot hear correctly; Right ear feels numb; Soreness in injected right arm; Fatigue; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS (Hearing loss persists) in a 39-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 013A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included ASCORBIC ACID, ERGOCALCIFEROL, NICOTINAMIDE, RETINOL, RIBOFLAVIN, THIAMINE HYDROCHLORIDE (VITAMINS [ASCORBIC ACID;ERGOCALCIFEROL;NICOTINAMIDE;RETINOL;RIBOFLAVIN;THIAMINE HYDROCHLORIDE]) for an unknown indication. On 19-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 16-Apr-2021, the patient experienced VACCINATION SITE PAIN (Soreness in injected right arm) and FATIGUE (Fatigue). On 20-Apr-2021, the patient experienced HYPOACUSIS (Cannot hear correctly) and HYPOAESTHESIA (Right ear feels numb). On 27-Apr-2021, the patient experienced DEAFNESS (Hearing loss persists) (seriousness criterion medically significant). At the time of the report, DEAFNESS (Hearing loss persists), HYPOACUSIS (Cannot hear correctly), HYPOAESTHESIA (Right ear feels numb), VACCINATION SITE PAIN (Soreness in injected right arm) and FATIGUE (Fatigue) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was not applicable. Treatment information included paracetamol. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded. This case was linked to MOD-2021-092179 (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 these events, a causal relationship cannot be excluded.

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1291329	5/5/2021	UT	26	F	4/13/2021	4/13/2021	hearing loss; muffled hearing; echoing in ear; it got worse; This is a spontaneous report from a contactable consumer. This 26-year-old female consumer (patient) received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 13Apr2021 14:45 (Batch/Lot Number: EIM0162) as SINGLE DOSE for covid-19 immunisation. Medical history included covid-19 from an unknown date and unknown if ongoing. Historical vaccine included BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 1 (lot number= ER8727) on 22Mar2021 at 02:45PM on right arm and experienced ringing and pulsing in left ear. The patient's concomitant medications were not reported. After second shot on 13Apr2021, the patient reported "it got worse, hearing loss, muffled hearing and echoing in ear" with outcome of not recovered. Therapeutic measures were taken as a result of reported events included over the counter medications. The patient was not tested positive for COVID post vaccination.

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1288130	5/5/2021	OH	75	F	1/13/2021		Hearing loss in right ear; Blocking of both the ears; Sounds as of ocean in right ear; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS UNILATERAL (Hearing loss in right ear) in a 75-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 011M20A and 013L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included ATORVASTATIN CALCIUM (LIPITOR) and LEVOTHYROXINE SODIUM (SYNTHROID) for an unknown indication. On 13-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced DEAFNESS UNILATERAL (Hearing loss in right ear) (seriousness criterion medically significant), EAR DISCOMFORT (Blocking of both the ears) and TINNITUS (Sounds as of ocean in right ear). At the time of the report, DEAFNESS UNILATERAL (Hearing loss in right ear) and TINNITUS (Sounds as of ocean in right ear) outcome was unknown and EAR DISCOMFORT (Blocking of both the ears) had resolved. Treatment medications included flu nose, allergy pill, nasal spray and prednisone. Company Comment: Based on the current available information and temporal association between the use of the product and the onset of the events, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-098399 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the onset of the events, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-098399:First Dose Case

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1284777	5/4/2021	UT	29	M	4/16/2021	4/17/2021	Loss of hearing in left ear; Dizziness more than 24 hours after; loud tinnitus; Deep pain in left side upper abdomen/ lower ribcage.; Deep pain in left side upper abdomen/ lower ribcage.; This is a spontaneous report from a contactable consumer (patient). A 29-year-old male consumer received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 16Apr2021 at 14:15 at single dose in left arm for COVID-19 immunisation at the age of 29-year-old. Medical history and concomitant medications were unknown. Historical vaccine included first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 24Mar2021 at 13:00 in left arm for COVID-19 immunisation at the age of 29-year-old. On 17Apr2021 at 16:00, the patient experienced loss of hearing in left ear, loud tinnitus, deep pain in left side upper abdomen/ lower ribcage, dizziness (also reported as more than 24 hours after). The patient was no treated due to the events. On 19Apr2021, nasal swab resulted negative. The patient did not recover from the events. Prior to vaccination, the patient was not diagnosed with COVID-19; since the vaccination, the patient has not been tested for COVID-19. Information on the lot/batch number has been requested.

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1284746	5/4/2021	TX	53	F	3/19/2021	4/10/2021	Sudden hearing loss in right ear; This is a spontaneous report from a contactable consumer (patient). A 53-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in left arm on 26Feb2021 13:30 (Lot Number: EN6198) at a single dose, and the second dose via an unspecified route of administration in left arm on 19Mar2021 13:30 (Lot Number: EN6199) at a single dose for covid-19 immunization at the age of 53 years old. Medical history included hypertension and known allergies to sulfa, both from an unknown date and unknown if ongoing. The patient did not have covid prior vaccination. The patient was not pregnant at the time of vaccination. Concomitant medication included irbesartan taken for an unspecified indication, start and stop date were not reported. The patient experienced sudden hearing loss in right ear on 10Apr2021 12:00. The event resulted in doctor or other healthcare professional office/clinic visit, and caused disability or permanent damage. The patient underwent lab tests and procedures which included covid-19 virus test (nasal swab): negative on 14Apr2021. Therapeutic measures were taken as a result of sudden hearing loss in right ear included steroid injection series into eardrum. The outcome of the event was not recovered.
1284817	5/4/2021			F			bilateral hearing loss 10 days after; This is a spontaneous report from a contactable consumer (the patient is reporter's mother). A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced bilateral hearing loss 10 days after receiving the Pfizer vaccine. Hearing returned in one ear. Hearing remained intermittent in the other ear. Patient did not have inflamed auditory nerve. Patient is currently undergoing testing for Meniere's disease. The outcome of event was recovering. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

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1284935	5/4/2021	NC	52	F	2/10/2021	2/10/2021	<p>Sudden hearing loss; feeling cold; Nausea; Fatigue; Muscle aches; Fever of 101; Began violently shaking and it was so bad was scared; Ringing in right ear; Headache; This spontaneous case was reported by a nurse (subsequently medically confirmed) and describes the occurrence of SUDDEN HEARING LOSS (Sudden hearing loss) in a 52-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 016M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included COVID-19 on 20-Dec-2020 and Transient ischaemic attack (Right patient foramen ovale). Concurrent medical conditions included Penicillin allergy, Drug allergy (Lisinopril), Blood pressure high since 2010 and Arthritis. Concomitant products included METOPROLOL for Blood pressure high, ACETYLSALICYLIC ACID (ASPIRIN (E.C.)) for Transient ischaemic attack, VITAMIN D3 for Vitamin deficiency, FISH OIL and PNEUMOCOCCAL VACCINE for an unknown indication. On 10-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Feb-2021, the patient experienced HEADACHE (Headache). On 11-Feb-2021, the patient experienced TREMOR (Began violently shaking and it was so bad was scared), TINNITUS (Ringing in right ear), PYREXIA (Fever of 101), FATIGUE (Fatigue) and MYALGIA (Muscle aches). On an unknown date, the patient experienced SUDDEN HEARING LOSS (Sudden hearing loss) (seriousness criterion medically significant), FEELING COLD (feeling cold) and NAUSEA (Nausea). On 14-Feb-2021, TREMOR (Began violently shaking and it was so bad was scared), PYREXIA (Fever of 101), FATIGUE (Fatigue) and MYALGIA (Muscle aches) had resolved. At the time of the report, SUDDEN HEARING LOSS (Sudden hearing loss) and TINNITUS (Ringing in right ear) had not resolved and FEELING COLD (feeling cold), HEADACHE (Headache) and NAUSEA (Nausea) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Dec-2020, SARS-CoV-2 test: positive (Positive) Positive. On 11-Feb-2021, Body temperature: 101.8 (High) Temperature of 101.8. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273</p>

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(Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication, fish oil was used for heart health. On 11 Feb 2021, patient woke up with severe shaking which felt different from fever and chills. Patient shook so hard and was not able to open the bottle of ibuprofen and had to ask for help. Patient was totally alert during the severe shaking and was continued to shake for about four hours. Along with it patient experienced temperature of 101.8 about two hours, fatigue, muscle aches nausea and ringing in right ear. The ringing in right ear continued since. Three weeks after the vaccination, patient went to an ENT and was diagnosed with sudden hearing loss probably related to a virus. Patient was given tapered dose of steroids to take for 2 weeks and returned to the office for follow up. Nothing had changed. Patient made another appointment with another ENT who wants patient to have a magnetic resonance imaging done next week.. Treatment information included ibuprofen 600 mg, tylenol 650mg and steroids. 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 23-Apr-2021: Follow up was received included reporter information, patient demographics, historical conditions, laboratory data, concomitant medications, vaccine information, additional events (sudden hearing loss, ringing in right ear, fatigue, muscle aches, nausea) and upgraded to serious case due to the medically significant event sudden hearing loss.; 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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1284939	5/4/2021	NY	60	F	1/6/2021	3/14/2021	<p>Asthma; Hearing loss(felt clogged, electronic vibration, white noise, crackling sounds); Weird noises in her left ear; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS UNILATERAL (Hearing loss(felt clogged, electronic vibration, white noise, crackling sounds)) in a 60-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 010M20A and 012L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 06-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 14-Mar-2021, the patient experienced TINNITUS (Weird noises in her left ear). On 15-Mar-2021, the patient experienced DEAFNESS UNILATERAL (Hearing loss(felt clogged, electronic vibration, white noise, crackling sounds)) (seriousness criterion medically significant). On an unknown date, the patient experienced ASTHMA (Asthma). On 22-Mar-2021, DEAFNESS UNILATERAL (Hearing loss(felt clogged, electronic vibration, white noise, crackling sounds)) had resolved. At the time of the report, TINNITUS (Weird noises in her left ear) and ASTHMA (Asthma) outcome was unknown. Concomitant information not provided On 14/Mar/2021, she had weird noises in her left ear. The next day she had hearing loss (felt clogged, electronic vibration, white noise, crackling sounds). On 17/Mar/2021 she went to ENT who told her she was not the first patient of the day that came in with hearing loss due to vaccination. She was diagnosed with hearing loss of 60 percent in left ear for word recognition. Her speech reception threshold in left ear was AIR 30 decibels (dB), pure tone average left Air 28 decibels Hearing Level (dB HL), bone 25 dB HL. Her right ear was normal at Air 17 dB HL. She saw a specialist the same day and was examined. He gave her 60 mg/day of prednisone for 7 days. She went back a week later, and her results were word recognition at 100%, but she still has clicking and white noise in the ear. Speech recognition air 20dB pure tone average air was 18 dB HL, bone 17 dB HL. Tympanogram diagnostics done on 17/Mar/2021 showed ear canal</p>

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volume left 1.25, right 2.27. A week later it was 1.66 in left, right was 1.43. Action taken with mRNA-1273 in response to the events was not Applicable. 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. This case was linked to MOD21-082695, MOD21-082690, US-MODERNATX, INC.-MOD-2021-092733, US-MODERNATX, INC.-MOD-2021-092583 (E2B Linked Report).; 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. MOD21-082695: MOD21-082690: US-MODERNATX, INC.-MOD-2021-092733: US-MODERNATX, INC.-MOD-2021-092583:Crosslinked (MOD21-082668)

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1284941	5/4/2021	NV	64	M	3/22/2021	4/22/2021	loss of hearing on the right ear; ear ache; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS UNILATERAL (loss of hearing on the right ear) in a 64-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 037B21A and 038A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Ear infection (had a major ear infection back in 2003) in 2003. On 22-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 22-Apr-2021, the patient experienced DEAFNESS UNILATERAL (loss of hearing on the right ear) (seriousness criterion medically significant) and EAR PAIN (ear ache). At the time of the report, DEAFNESS UNILATERAL (loss of hearing on the right ear) and EAR PAIN (ear ache) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment information included Ear washing. 1 percent Neomycin and 3.5 mg Polymyxin Suspension, 3 drops 4 times a day. Action taken with response to the events are not applicable. 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.
1286241	5/4/2021	MI	59	M	3/20/2021	4/16/2021	The patient developed a blood clot in the left calf 2 weeks after the first dose of Moderna COVID vaccine, which required treatment with Eliquis 5 mg twice daily. The patient also reported hearing loss that needed treatment with a tapering steroid protocol. The sense of hearing did not recover after the most recent loss event.
1286738	5/4/2021	NY	62	M	4/8/2021	4/8/2021	Sudden sensorineural hearing loss

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1284719	5/4/2021	CA	72	F	1/29/2021	2/6/2021	Left ear hearing loss; unilateral vision loss; Brain fog; Hot; Swelling in her arm that is the size of a baseball; COVID Arm; Itchy; Red circle around injection site; Tired; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS UNILATERAL (Left ear hearing loss) and BLINDNESS UNILATERAL (unilateral vision loss) in a 72-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 042L20A and 010A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Dairy intolerance. Concomitant products included DOXYCYCLINE from 01-Jan-2020 to an unknown date for Rosacea, DEXLANSOPRAZOLE (DEXILANT) and FAMOTIDINE for Stomach discomfort, ROSUVASTATIN for Stroke, LEVOTHYROXINE for Thyroid disorder NOS, CLOPIDOGREL, CALCIUM, ACETYLSALICYLIC ACID (BABY ASPIRIN), LEVOCETIRIZINE DIHYDROCHLORIDE (XYZAL) and MAGNESIUM OXIDE for an unknown indication. On 29-Jan-2021 at 9:15 AM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Mar-2021 at 9:15 AM, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 06-Feb-2021, the patient experienced FEELING ABNORMAL (Brain fog), VACCINATION SITE WARMTH (Hot), PERIPHERAL SWELLING (Swelling in her arm that is the size of a baseball), VACCINATION SITE REACTION (COVID Arm), VACCINATION SITE PRURITUS (Itchy), VACCINATION SITE ERYTHEMA (Red circle around injection site) and FATIGUE (Tired). On an unknown date, the patient experienced DEAFNESS UNILATERAL (Left ear hearing loss) (seriousness criterion medically significant) and BLINDNESS UNILATERAL (unilateral vision loss) (seriousness criterion medically significant). On 13-Feb-2021, VACCINATION SITE REACTION (COVID Arm) had resolved. At the time of the report, DEAFNESS UNILATERAL (Left ear hearing loss), FEELING ABNORMAL (Brain fog), VACCINATION SITE WARMTH (Hot), PERIPHERAL SWELLING (Swelling in her arm that is the size of a baseball), VACCINATION SITE PRURITUS (Itchy), VACCINATION SITE ERYTHEMA (Red circle around injection site) and

<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>
							FATIGUE (Tired) outcome was unknown. Treatment information not provided. The patient received both scheduled doses of mRNA-1273 prior to the events, therefore action taken with the drug in response to the events was not applicable. 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 21-Apr-2021: Case upgraded to serious based on event update. Con meds added. Prior event outcome updated. Medical history updated based on information; 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.
1282729	5/3/2021	OH	52	M	3/10/2021	3/11/2021	Tinnitus - ringing in ears and loss of hearing, nerve damage - proven by a Hearing test
1281750	5/3/2021	AL	63	M	4/21/2021	4/21/2021	Patient described a cold sweat and chills, then he lost consciousness and his neighbors called EMS. He was seen at Hospital. In the aftermath, the patient complains of hearing loss.
1282155	5/3/2021	CA	47	F	3/15/2021	3/26/2021	Woke up on 3/26/21 with hearing loss in right ear. No warning just woke up that way
1282756	5/3/2021	LA	39	M	5/3/2021	5/3/2021	Almost vasovagal syncope. Vaccine administered at 11:00. Vasovagal symptoms present at 11:03. Profuse sweating, decreased ability to see (tunnel vision), ringing in the ears (subsequent hearing loss). Fainting did not present, and symptoms completely subsided at 11:08.
1284438	5/3/2021	CA	37	M	3/1/2021	3/8/2021	Hearing Loss/Tinnitus/Coclear Hydrops
1282147	5/3/2021	AZ	84	F	2/26/2021	2/28/2021	sudden complete loss of hearing in left ear received 2 shots in ear and was put on antibiotics and antibacterial pills for 10 days No return of hearing at all
1280876	5/2/2021	CA	33	F	3/29/2021	4/22/2021	Extreme Pulsatile Tinnitus started in the right ear after the vaccine. Then loss of equilibrium and vomiting that led to overnight hospitalization. Hearing loss in right Ear and vertigo still present.

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1280344	5/2/2021	CA	37	F	4/27/2021	4/29/2021	48 hrs after the vaccine, I experienced intense pressure in my head and then hearing loss in my left ear. By the evening on April 29, I had lost almost all hearing in my left ear and was experiencing intense ringing in my left ear and pressure in my right ear. Woke up April 30th and the symptoms were worse and had lost all hearing in my left ear.
1276769	5/1/2021	PA	78	F	4/14/2021	4/16/2021	Hearing loss; Vertigo; Tinnitus; This spontaneous case was reported by a patient family member or friend and describes the occurrence of DEAFNESS (Hearing loss) in a 78-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. no medical history was provided by the reporter. On 14-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Apr-2021, the patient experienced DEAFNESS (Hearing loss) (seriousness criteria disability and medically significant), VERTIGO (Vertigo) and TINNITUS (Tinnitus). At the time of the report, DEAFNESS (Hearing loss), VERTIGO (Vertigo) and TINNITUS (Tinnitus) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was not provided by the reporter. Patient went to audiologist and was given a hearing aide. Treatment information was not provided. 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.

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1278954	5/1/2021	CA		F	4/15/2021	4/16/2021	loss of hearing in my hearing impaired ear; sore arm; tinnitus; slight redness; This is a spontaneous report from a contactable consumer reporting for herself. A 55-year-old female patient received the second dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot #EW0153) via an unspecified route of administration in left arm on 15Apr2021 04:15PM for COVID-19 immunization. The patient took first dose of BNT162b2 (Lot number ER8730) on 25Mar2021 03:00PM in left arm. Relevant medical history included previous cancer history and two stem cell transplants. The patient had no known allergies. Concomitant medications included metoprolol, pravastatin, levothyroxine and cetirizine hydrochloride (Zyrtec). On 16Mar2021 at 09:30PM the patient experienced loss of hearing in her hearing impaired ear, sore arm, tinnitus and slight redness. Clinical course was described as follows. Standard sore arm and slight redness, but the day after the second vaccine sudden onset tinnitus and loss of hearing in my hearing impaired ear. The patient noticed recent increase in tinnitus that may have started after the first vaccine, but this was very sudden after the second vaccine. Much better but tinnitus was ongoing. No treatment was given for the events. The patient had no COVID prior vaccination and was not tested for COVID post vaccination.

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1278773	5/1/2021	MT	67	M	3/31/2021	4/3/2021	Sudden hearing loss in left ear; worsened tinnitus; hearing had decreased by 20 percent; This is a spontaneous report from a contactable consumer (patient). A 67-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EP7533), dose 1 via an unspecified route of administration, administered in Arm Right on 31Mar2021 14:15 (at the age of 67years) as single dose for Covid-19 immunization. Medical history included eosinophilic esophagitis, degenerative disc disease, and food and environmental allergies, and as reported " previously lost hearing in my right ear and partial in my left ear"; all from an unknown date and unknown if ongoing. Concomitant medications included meloxicam, omeprazole, azelastine, and triamcinolone acetonide (NASACORT); all taken for an unspecified indication, start and stop date were not reported. The patient previously took Codeine, Cipro (ciprofloxacin), and Percocet and experienced drug allergy. The patient was not diagnosed with COVID-19 prior to vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. It was reported that the patient experienced sudden hearing loss in left ear beginning within a week of taking vaccine. Inability to recognize words and sounds was most apparent, in addition to worsened tinnitus. The patient stated, "I previously lost hearing in my right ear and partial in my left ear in earlier sudden hearing losses, so I was aware of what was happening and scheduled an ENT visit. The patient had a hearing test on an unspecified date, and it showed that hearing had decreased by 20 percent. The ENT started her on the injectable steroid treatment in her left ear. The start date of adverse events was 03Apr2021 (as reported). The adverse events resulted in Doctor or other healthcare professional office/clinic visit. The patient was treated with interaural steroid injections. The patient has not been tested for COVID-19 since the vaccination. The outcome of events was not recovered.



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1278706	5/1/2021	NY	49	F	2/2/2021	2/8/2021	<p>idiopathic sudden hearing loss on left ear; severe headache on my left head for full 3 days after the 2nd Vaccine; tinnitus on my left ear on and off; felt extreme fatigue and tired; This is a spontaneous report from a contactable other healthcare professional (reporting for herself). A 49-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection; Batch/Lot number was not reported), dose 2, via an unspecified route of administration, administered in left arm on 02Feb2021 10:00 A.M. at the age of 49 years old, as a single dose, for COVID-19 immunization. The patient's medical history included hypertension. The patient had no known allergies and no prior COVID vaccination. The patient was not also tested with COVID post vaccination. Concomitant medications were not reported. The patient previously received first dose of BNT162B2 vaccine for COVID-19 immunization and experienced minor headache. On 08Feb2021, the patient reported that she experienced severe headache on her left head for full 3 days after the 2nd Vaccine. The patient had a minor headache when she had the first vaccine, but it lasted only a day and it was mild one. About 1 week after the 2nd vaccine, the patient had a tinnitus on her left ear on and off. She thought it was because she was tired. For some reason after the 2nd shot, the patient felt extreme fatigue and tired. The left ear ringing was happening more frequently and getting loud. The patient went to urgent care and also went to ENT, and there it was found out that she was having an idiopathic sudden hearing loss on left ear. The patient was treated with oral steroid and injection but the hearing sensory was not coming back yet. The outcome of the events was not recovered. Information about lot/batch has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on idiopathic sudden hearing loss 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>

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1278687	5/1/2021	NY	42	M	4/5/2021	4/14/2021	Left ear sudden hearing loss; This is a spontaneous report from a contactable physician (patient himself). A 42-year-old male patient received his second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in left arm on 05Apr2021 13:30 (Batch/Lot Number: Er8734) as a single dose for COVID-19 immunisation. Medical history included asthma. Allergies were unknown. The patient's concomitant medications were not reported. The patient previously received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in left arm on 15Mar2021 12:00 PM. The patient experienced left ear sudden hearing loss on 14Apr2021 20:00. Event resulted in Doctor or other healthcare professional office/clinic visit, Disability or permanent damage. Treatment received included high dose steroids. The patient underwent PCR COVID Nasal swab test: negative on 14Apr2021. Outcome of event was recovering.; Sender's Comments: Based on temporal association, a contributory role of BNT162B2 to the event left ear sudden hearing loss cannot be excluded completely. The case will be reassessed once more 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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1278494	5/1/2021	IL	53	M	4/2/2021	4/9/2021	Sudden loss of hearing; This is a spontaneous report from a contactable consumer. A 53-year-old male patient received the 1st dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 02Apr2021 (Batch/Lot number was not reported) as SINGLE DOSE for COVID-19 immunization. Medical history and concomitant medications were not reported. On 09Apr2021 (one week after taking the vaccine), the patient experienced sudden loss of hearing. The patient went to the doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care due to the event and received steroids as treatment. The patient was recovering from the event. No follow-up attempts are possible, information about lot/batch number cannot be obtained.
1278452	5/1/2021	CA	36	M	3/30/2021	3/30/2021	hearing loss; Tinnitus; This is a spontaneous report from a contactable consumer (patient). A 36-year-old male patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration (at the age of 36-years-old), administered in Arm Left on 30Mar2021 (Lot Number: ER8730) as single dose for COVID-19 immunization. The patient's medical history was not reported. The patient had no known allergies. There were no concomitant medications. The patient previously received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration (at the age of 36-years-old), administered in Arm Left on 02Mar2021 04:00 PM (lot number: EN6205) as single dose for COVID-19 immunization. The patient experienced hearing loss and tinnitus on 30Mar2021. No treatment received for adverse events. The outcome of the events was not recovered. The event hearing loss was considered as serious (medically significant). Facility type vaccine was Pharmacy or Drug Store. No other vaccine in four weeks. No other medications in two weeks. Not diagnosed with COVID prior vaccination. Not COVID tested post vaccination.

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1278415	5/1/2021	MO	70	M	4/1/2021	4/13/2021	listening to a slow ceiling fan motor whooshing and constantly hears it in both ears; began experiencing hearing loss, noise disappeared suddenly in both ears; very deadening sound in both ears; This is a spontaneous report from a contactable consumer (patient). A 70-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8733), via intramuscular route of administration on 01Apr2021 at 09:30 (at the age of 70 years) at a single dose in the left arm for COVID-19 immunization. Medical history included blood clot in leg almost 10 years ago. Concomitant medications included rivaroxaban (XARELTO, strength: 20 mg) taken for blood clot in leg and other unspecified medications. The patient previously took silodosin (RAPAFLO) a number of years ago for urination and he broke out in hives. Patient had no family medical history. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient had first shot done on 01Apr2021 at 09:30. On the evening of 13Apr2021 at 19:30, he kind of got a very deadening sound in both ears and then began experiencing hearing loss, noise disappeared suddenly in both ears. He woke up the next day (14Apr2021 at 05:00) with what he described as listening to a slow ceiling fan motor whooshing and constantly hears it in both ears. He called his doctor because he thought it may disappear but his doctor instructed him to see an ear and throat doctor about this (for clarification). He called to report the events and to know if it's safe to get the second dose of the vaccine. The outcome of the events was not recovered.

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1277549	5/1/2021	TX	20	M	4/19/2021	4/19/2021	Initial presentation Patient was in his usual state of good health until 4/19 when he received his first dose of the Pfizer COVID-19 vaccine. Two hours after the injection he became nauseous and vomited multiple times. Overnight he experienced diffuse myalgia and suprapubic pain. He awoke the next day to a pustular rash on his chin, forehead, chest and back. The patient describes similar previous rashes that have resolved spontaneously. The next day he began to experience gross hematuria and presented to the ED with a temperature of 98.9, blood pressure of 100/69mmHg, heart rate of 110bpm, respiratory rate of 18 breaths per minute and an O2 saturation of 97% on room air. On examination, patient was ill-appearing with diffuse pustules on his face, chest and back, periorbital edema, and leukoplakia of the tongue and buccal mucosa. His abdomen was soft and tender to palpation in the suprapubic area and at both costovertebral angles. Hospital course In the ED the patient was found to have a metabolic acidosis of pH 7.33 with an anion gap of 16, lactate 2.6, neutrophilic leukocytosis (22k), acute renal insufficiency with a BUN of 45 and creatinine 3.81 (baseline is 0.76). The patient?s urine demonstrated packed RBCs and 5-10 WBCs. He was admitted to the medicine service for further management. On the medicine floor he was initially found to have rhabdomyolysis (CK 584), worsening renal failure (Creatinine 8), follicular conjunctivitis by skin biopsy, a low CD3/CD4 count (CD4 91, CD3 47, CD8 258) with normal complement, and bilateral tinnitus. CT A/P without contrast showed increased attenuation of renal pelves and ureters consistent with hemorrhage, but no renal stones or hydronephrosis was seen. The patient was treated with pulse dose 500mg IV Methylprednisilone for 3 days and then transitioned to 60mg Prednisone. The patient?s pustular rash and oral leukoplakia greatly improved while on pulse dose steroids, but his kidney function continued to decline (Creatinine rising from 8 to 11), and the patient?s bilateral tinnitus progressed to bilateral sensorineural deafness over 2 days. Bilateral hearing loss prompted an MRI of the brain which identified several punctate infarcts across multiple vascular territories in bilateral cortices and left cerebellum. The patient?s kidney function has continued to decline, with progressive hyperkalemia and

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1279053	5/1/2021	MI	70	M	2/17/2021		<p>left arm hurts real bad occasionally; permanently damaged nerve endings in his ears; it's hard to fall asleep as he hears it all the time; the tinnitus interferes with his hearing/hearing loss; noise in his ears/tinnitus in both of his ears; This is a spontaneous report from a contactable consumer (patient). A 70-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: EN6201 and expiration date not provided), via an unspecified route of administration, in arm left, on 17Feb2021 (at the age of 70-year-old), at single dose, for COVID-19 immunization. Medical history included cholesterol issues (not bad) and diabetic type 2, and patient had been taking the same medication for diabetes and cholesterol for 5 years. No prior vaccinations within 4 weeks. Concomitant medications included medications for diabetes and cholesterol. The patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: EL9268 and expiration date not provided), via an unspecified route of administration, in right arm, on 27Jan2021 in the morning (at the age of 70-year-old), at single dose, for COVID-19 immunization. The patient experienced the tinnitus interferes with his hearing/hearing loss in 2021; mini stroke; noise in his ears/tinnitus in both of his ears in 2021; left arm hurts really bad occasionally; permanently damaged nerve endings in his ears (treatment received); it's hard to fall asleep as he hears it all the time. Patient stated he had the 2nd vaccine about 2 months ago and a month later he got tinnitus in both of his ears. Patient stated he didn't think it was the vaccine. Patient stated his hearing was perfect but the tinnitus interferes with his hearing. Patient stated it was a month and a half when the tinnitus came on, he woke in the morning and had noise in his ears and thought what was that he must be getting old and found that it didn't do that, it happened in one ear or the other it's never both ears equal amounts. Patient relayed that his left arm hurts really bad occasionally. It's been going on since it was put out with tinnitus and losing hearing since the beginning. Patient stated he contacted doctor about hearing loss and tinnitus and something going on. Patient stated when he lays down he had it too. Patient stated he was assuming the worse and he has permanently damaged nerve endings in his ears. Patient stated he saw a doctor, a</p>

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specialist for a second opinion. Doctor stated he can't explain either why both ears at the same time and that doesn't work in nature, patient don't lose his hearing in both ears at the same time. Patient stated he had the CT and the hearing test and one doctor said he thought he had a mini stroke and the other doctor said no there would be more evidence of that and can't explain it. Patient stated the medication did it and damaged the nerves. Patient stated it was persisting and annoying, it was day and night and when he was talking he can hear it still and it's very bad. Patient stated it was after 27Feb2021 and he doesn't know the date. Patient stated his ears plug easily and he got them drained and had a hearing test done and he had noise in his ears and then went back to the doctor and was ordered a CT scan. Patient stated he thought it was age and it came on and he didn't know tinnitus doesn't come in both ears at the same time and he did research and found it doesn't, it's never at the same time, it's impossible. Patient stated he was told the CT looked great for his age and doctor said his hearing was real good and both doctors said his hearing was real good and they don't have a reason to explain it. Patient stated he would not take the vaccine if he knew about hearing loss and can't reverse the damage that is done. Patient stated he was not happy his hearing was screwed up and it's hard to fall asleep as he hears it all the time. Patient stated he got a B12 shot and the nerve endings required B12 and the doctor gave him an injection 2 weeks ago and it didn't help. The patient underwent lab tests and procedures in 2021, which included hearing test revealed hearing was really good; CT scan looked great for patient's age. The outcome of the events "the tinnitus interferes with his hearing/hearing loss", "noise in his ears/tinnitus in both of his ears" was not recovered; of other events was unknown.



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1276777	5/1/2021	NY	31	M	4/12/2021	4/13/2021	Hearing Loss; Extreme ringing in the Ears/ buzzing all the time/tinnitus got worse as of today; Dizziness; Vertigo; Headache; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS (Hearing Loss) in a 31-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Ringing in ears. On 12-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Apr-2021, the patient experienced DEAFNESS (Hearing Loss) (seriousness criterion medically significant), TINNITUS (Extreme ringing in the Ears/ buzzing all the time/tinnitus got worse as of today), DIZZINESS (Dizziness), VERTIGO (Vertigo) and HEADACHE (Headache). At the time of the report, DEAFNESS (Hearing Loss), DIZZINESS (Dizziness), VERTIGO (Vertigo) and HEADACHE (Headache) outcome was unknown and TINNITUS (Extreme ringing in the Ears/ buzzing all the time/tinnitus got worse as of today) had not resolved. 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. No concomitant medications reported. No treatment information provided. 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, a causal relationship cannot be excluded. Headache is consistent with the product 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, a causal relationship cannot be excluded. Headache is consistent with the product safety profile

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1279155	5/1/2021		22	F	4/14/2021	4/15/2021	This is a spontaneous report from a non-contactable consumer (patient). A 22-year-old female patient received bnt162b2 (COVID 19 Pfizer), dose 1 via an unspecified route of administration, administered in right arm on 14Apr2021 15:00 (lot unknown, reason: misplaced/discarded) as single dose for COVID -19 immunization. Medical history included known allergies: penicillin. The patient's concomitant medications were not reported. The patient experienced complete loss of hearing in left ear. White noise sound only. Less than 24 hours after administration on 15Apr2021 with outcome of unknown. The patient is not pregnant. No treatment was given for events. The patient has not received other vaccine in four weeks. The patient was not diagnosed with covid prior vaccination has not been tested for covid post vaccination. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.

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1276759	5/1/2021	IL	42	M	3/17/2021	4/16/2021	hearing loss; Ears popping; tinnitus/wavy sounds; headache; joint pain; This spontaneous case was reported by a pharmacist and describes the occurrence of DEAFNESS (hearing loss) in a 42-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 032B21A and 038A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 17-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 14-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 16-Apr-2021, the patient experienced HEADACHE (headache) and ARTHRALGIA (joint pain). On 18-Apr-2021, the patient experienced DEAFNESS (hearing loss) (seriousness criterion medically significant), EAR DISCOMFORT (Ears popping) and TINNITUS (tinnitus/wavy sounds). At the time of the report, DEAFNESS (hearing loss), EAR DISCOMFORT (Ears popping), TINNITUS (tinnitus/wavy sounds), HEADACHE (headache) and ARTHRALGIA (joint pain) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications reported. No treatment information provided. The patient received both scheduled doses of mRNA-1273 prior to the event, therefore action taken with the drug in response to the event is not applicable. 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. However, Further information has been requested.; 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. However, Further information has been requested.

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1276722	5/1/2021	CA	65	F	4/13/2021	4/14/2021	<p>contemplated suicide; She lost 55 decibel in left ear/ was diagnosed with sensorineural hearing loss; left ear felt like I am in the plane and need to pop my ear; She had tinnitus/ringing in her ear; Headache; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEAFNESS NEUROSENSORY (She lost 55 decibel in left ear/ was diagnosed with sensorineural hearing loss) and SUICIDAL IDEATION (contemplated suicide) in a 65-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 046B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history reported by the reporter. The patient's past medical history included No adverse event (No Historical Condition reported). Concomitant products included CALCIUM and COLECALCIFEROL (VITAMIN D [COLECALCIFEROL]) for Bone disorder NOS. On 13-Apr-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 14-Apr-2021, the patient experienced EAR DISCOMFORT (left ear felt like I am in the plane and need to pop my ear), TINNITUS (She had tinnitus/ringing in her ear) and HEADACHE (Headache). On 15-Apr-2021, the patient experienced DEAFNESS NEUROSENSORY (She lost 55 decibel in left ear/ was diagnosed with sensorineural hearing loss) (seriousness criterion medically significant). On an unknown date, the patient experienced SUICIDAL IDEATION (contemplated suicide) (seriousness criterion medically significant). At the time of the report, DEAFNESS NEUROSENSORY (She lost 55 decibel in left ear/ was diagnosed with sensorineural hearing loss) was resolving, SUICIDAL IDEATION (contemplated suicide), EAR DISCOMFORT (left ear felt like I am in the plane and need to pop my ear) and HEADACHE (Headache) outcome was unknown and TINNITUS (She had tinnitus/ringing in her ear) had not resolved. Not Provided Treatment medications included prednisone 60 mg for 10 days. 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</p>

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1276714	5/1/2021		38	F	3/8/2021	4/6/2021	<p>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> <p>Lost little bit of hearing; Tinnitus in both his ears; Inflammation in his inner ear; eustachian tubes draining; Discomfort; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEAFNESS (Lost little bit of hearing) in a 38-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 08-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 06-Apr-2021, the patient experienced DEAFNESS (Lost little bit of hearing) (seriousness criterion medically significant), TINNITUS (Tinnitus in both his ears), INNER EAR INFLAMMATION (Inflammation in his inner ear), EUSTACHIAN TUBE DYSFUNCTION (eustachian tubes draining) and DISCOMFORT (Discomfort). At the time of the report, DEAFNESS (Lost little bit of hearing), TINNITUS (Tinnitus in both his ears), INNER EAR INFLAMMATION (Inflammation in his inner ear), EUSTACHIAN TUBE DYSFUNCTION (eustachian tubes draining) and DISCOMFORT (Discomfort) outcome 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. However, Very limited information regarding these events has been provided at this time. Further information has been provided.; 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. However, Very limited information regarding these events has been provided at this time. Further information has been provided.</p>

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1276421	5/1/2021	WV		M		4/1/2021	SEIZURES; DID NOT SLEEP WELL; IRRITABILITY; ANGER; CRYING; BAD RASH ON HIS BOTTOM; This spontaneous report received from a consumer concerned a 32 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included quadriplegia, deafness, and seizures. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805022 expiry: UNKNOWN) dose was not reported, administered on 06-APR-2021 on left arm for prophylactic vaccination. Concomitant medications included unspecified seizures medications. On 06-Apr-2021, after receiving the vaccine the patient did not sleep well, since then extra seizures. The patient has had an inaudible seizure for several years. On 21-APR-2021, the patient slept through the night, irritability. The patient was totally different, angry, crying a lot, had rash, one on his bottom and bad one there. The patient took seizures medicine three times a day. The patient did not have any further information. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the did not sleep well, seizures, irritability, anger, crying and bad rash on his bottom was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 : - Covid-19 vaccine ad26.cov2.s-SEIZURES- This event is considered not related. The event 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 than the drug. Specifically: MEDICAL HISTORY, UNDERLYING DISEASE

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1276382	5/1/2021	MA	51	M		4/8/2021	BOTH EYES HAVING PRESSURE-TYPE PAIN, NOW LOCALIZED TO LEFT EYE; HEADACHE; INJECTION SITE PAIN SPREAD IN LEFT ARM; BODY ACHES; CHILLS; This spontaneous report received from a consumer concerned a 51 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included diabetes ii, insomnia, neuropathy, tinnitus, vertigo, acne, chronic back pain (bulging discs), seasonal nut allergies, anxiety, smoker, non alcohol user, depression, hearing loss, and cholesterol. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 043A21A, expiry: not reported) dose was not reported, administered on 08-APR-2021 12:00 for prophylactic vaccination. Concomitant medications included atorvastatin for cholesterol, bupropion, lamotrigine, metformin hydrochloride, montelukast, and sertraline. On 08-APR-2021, the subject experienced body aches. On 08-APR-2021, the subject experienced chills. On 08-APR-2021 12:00, the subject experienced injection site pain spread in left arm. On 08-APR-2021 15:00, the subject experienced headache. On 09-APR-2021, the subject experienced both eyes having pressure-type pain, now localized to left eye. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from injection site pain spread in left arm, body aches, chills, headache, and both eyes having pressure-type pain, now localized to left eye. This report was non-serious.

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1274290	4/30/2021	MA	33	M	4/9/2021	4/17/2021	1 week after vaccine (rec'd vaccine 4/9, sx start 4/16) developed acute onset nausea, disequilibrium, and vomiting which was stable and patient was able to work. Then on 4/23 developed severe N/V and disequilibrium - could not move his head or stand up without needing to vomit. Received prednisone, antibiotics, and had ENT evaluation without notable results; no hearing loss/tinnitus. Eventually referred to hospital by ENT. Found to have lesion on CT head and subsequently had brain MRI (4/27/21) that showed multiple enhancing white matter lesions concerning for MS vs ADEM. LP was essentially normal (2 WBC, normal protein, normal glucose) with infectious serologies/PCR pending at time of submission. Received pulse dose steroids (1000 mg) per Neurology.
1273503	4/30/2021	MI	50	F	4/18/2021	4/21/2021	Some hearing loss-ongoing treatment with Doxycycline Hyclate 100 mg and Prednisone 10 mg tabs for 13 days Left side facial weakness-ENT thinks it's due to nerve damage possibly caused by vaccine-has seen others with similar symptoms-symptoms ongoing
1273045	4/30/2021	AL	20	F	4/29/2021	4/29/2021	Systemic: Dizziness / Lightheadness-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Hypotension-Medium, Systemic: Nausea-Medium, Systemic: Tachycardia-Medium, Additional Details: Loss of hearing for a few minutes. EMTs came to store monitored pt and BP for additional 15-20 mins. BP increased to over 100. PT had water, crackers and chocolate. Pt felt fine and refused to be taken by ambulance but had a friend pick her up. I explained situation to friend and pt was told to take it easy for the rest of the day.
1274167	4/30/2021	KY	39	M	4/9/2021	4/12/2021	Constant Tinnitus (mainly left ear), Ear fullness and pain (both ears), ear popping (both ears), dizziness, possible hearing loss.
1274055	4/30/2021	FL	46	F	4/2/2021	4/20/2021	Sudden idiopathic hearing loss, right ear



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1269522	4/29/2021	GA	52	F	3/23/2021	3/24/2021	hearing loss in the right ear; This is a spontaneous report from a contactable consumer, the patient, and a non-contactable consumer, the patient's sister. A 52-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscular in the left arm on 23Mar2021 between 13:00 and 13:30 (at the age of 52-years-old) as a single dose for COVID-19 immunization. Medical history includes ringing in ears, problem with hearing out of the other (left) ear. Concomitant medications were none. There were no additional vaccines administered on the same date, or within 4 weeks of BNT162B2. On 24Mar2021, the patient experienced hearing loss in the right ear and sometime between 19:00 - 20:00, the patient could not hear out of the right ear for a day. The patient never had a problem with this ear. No emergency room or physician's office visit was required. The patient got up the next morning and her hearing was back. The clinical outcome of hearing loss in the right ear and could not hear out of the right ear was resolved on 25Mar2021. Information on the lot/batch number has been requested.
1270591	4/29/2021	OH	68	M	4/7/2021	4/9/2021	sudden right sensorineural hearing loss--pt has complete hearing loss in right ear and did not respond to treatment.
1271083	4/29/2021	NV	26	M	4/20/2021	4/20/2021	After my initial Covid vaccine shot, I had a strange sensation of tinnitus in my right ear. Sounds felt slightly deafened, like I was hearing at 75% efficiency out of that ear, but there wasn't any ringing sound for me like typical tinnitus. After my second Covid vaccine, this symptom got worse and I became more sensitive to loud noises and sounds, as well as being able to hear my heartbeat in my right ear which felt like a throbbing or pulsing sensation. This leads me to believe it is pulsatile tinnitus. The feeling comes and goes with various frequency and intensity throughout the day.

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1269739	4/29/2021	AZ	81	M	3/11/2021	3/26/2021	<p>Lost hearing in left ear; This is a spontaneous report from a contactable consumer (patient). An 81-year-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot: EN6199), via an unspecified route of administration in left arm on 11Mar2021 11:00 (at the age of 81-years-old) as single dose for covid-19 immunisation. No additional vaccines administered on same date of bnt162b2. No prior vaccinations (within 4 weeks). The patient received first dose of bnt162b2 (Batch/lot number: EL1283) in left arm on 18Feb2021 (at the age of 81-years-old) for Covid-19 immunization. Medical history included ongoing borderline diabetes (had that for years; has always been the same; His last test was 6.7 which was pretty good); 2 stents in leg (at least 5 years ago; takes a blood thinner (ongoing)); partial knee replacement (a couple years ago, that came out fine) and shots (when he was in the military, he got all the shots and had no problem). Concomitant medications included clopidogrel bisulfate (PLAVIX) as blood thinner from an unspecified start date and ongoing and just takes his normal medications that the doctors prescribe. He has been taking them for quite a few years so he didn't think they have anything to do with it. He never knows, it could be a mixture. But no, he didn't think any medications he takes were relevant. The patient previously took only one flu shot last Sep2020. No events following prior vaccinations. The patient experienced lost hearing in left ear on 26Mar2021 at 07:00, he woke up and that was it, he had no hearing, it was complete hearing loss. Then he thought maybe it would come back during the day. He heard something and picked his head off of the pillow. His partner was talking, but his right ear was buried in the pillow. When he raised it he could hear her talk. That's when he noticed. The next day he went to same day care and they put him on an antibiotic. He took 2 of the antibiotic the first day and then 1 each day. He didn't know if he has it. He did not have information for the antibiotic or remember the name of it. The event did not require emergency room visit but a visit to the physician's office. went to the same day clinic on 27Mar2021, the day after his hearing loss. He had thought maybe it might come back. The antibiotic didn't work, so he went to his primary doctor on 01Apr2021 and made an appointment with an ENT on 07Apr2021. On 07Apr2021 the hearing test with</p>

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							result of the bottom was completely dead on his left ear, everything else was dead. His right ear was great for his age. What they did was put a needle in his ear drum and shot it with a steroid. They said a couple of treatments sometimes brings back the hearing and sometimes doesn't. They called it sudden hearing loss. He could hear out of his right ear okay. He had good hearing before and had no problems. The patient wanted to know if there had been any problems with loss of hearing after the Covid vaccine. He wished that he would have some improvement. There was no one in his family that lost their hearing, so he would say probably not. No one in his family has any problems or lost hearing or anything. He didn't know of any other problem that would be significant. The outcome of the event was not recovered.
1272061	4/29/2021	TX	63	M	3/6/2021	3/29/2021	Sudden deafness in right ear with constant ringing. Tinnitus symptoms. Completed a hearing test today, April 29, 2021 and results show loss of hearing in right ear.
1269971	4/29/2021			F			UNEXPECTED THERAPEUTIC BENEFIT; This spontaneous report received from a patient via a company representative concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's past medical history included neural hearing loss. 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. No concomitant medications were reported. The batch number was not reported. Per procedure, no follow-up will be requested for this case On an unspecified date, the subject experienced hearing restored in right ear. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of hearing restored in right ear was unknown. This report was non-serious.
1266443	4/28/2021	VA	50	F	4/9/2021	4/16/2021	Fullness in ear and headache that led to ear pain and ringing and now told have hearing loss and constant ringing

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1266060	4/28/2021	FL		U			Hearing loss in the right ear; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number and Expiration Date were not reported), intramuscular, on an unspecified date, at a single dose, for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had the second COVID-19 shot and had developed hearing loss in the right ear on an unspecified date. The patient was trying to get information on this effect. The patient asked if the company had any data on hearing loss, duration, remedy, etc. The patient also advised to feel free to contact him/her to help the patient and/or use him/her to help others. The outcome of the event was unknown. Information about lot number and expiration date for the suspect product will be requested in follow-up attempts.
1266048	4/28/2021	OH	24	F	4/6/2021	4/7/2021	tinnitus and slightly hearing loss; tinnitus and slightly hearing loss; This is a spontaneous report from a non-contactable consumer (patient). A 24-year-old female patient received bnt162b2 (BNT162B2, Solution for injection, Lot Number: ER87 30), via an unspecified route of administration on 06Apr2021 (received at 24-years-old) as single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient was not pregnant. She did not have COVID prior to vaccination. The patient experienced tinnitus and slightly hearing loss on 07Apr2021. The outcome of the events was not recovered. She was not tested for COVID post vaccination. No follow up attempts are possible. No further information is expected.

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1265976	4/28/2021	CO	71	M	3/26/2021	3/27/2021	He is shrinking a little; patient has gained weight; completely deaf in his left ear/hearing loss; wife thinks the patient is not hearing well out of his right ear; he had walked straight into half of a wall because he was so off kilted; This is a spontaneous report from a contactable consumer (patient's wife) via the Pfizer sponsored program. A 71-years-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EP6955), via an unspecified route of administration on 26Mar2021 09:00 as SINGLE DOSE for covid-19 immunization (Age at vaccination: 71 years). Medical history included transidential Global Amnesiac Episode from Mar2021, blocked carotid artery on his left side and tinnitus (had a history of Tinnitus in his left ear for about 4 years but he could hear). Concomitant medication included acetylsalicylic acid (BAYER ASPIRIN) for carotid artery blockage. The reporter stated that the patient was completely deaf in his left ear and had hearing loss on 10Apr2021. The reporter also stated that he had walked straight into half of a wall because he was so off kilted on 27Mar2021 . The wife thinks the patient is not hearing well out of his right ear on 10Apr2021. The reporter also stated that he is shrinking a little and the patient has gained weight on an unspecified date. The reporter also says that she thought that her husband's side effects started a little late after the vaccine date, has that been reported? Her husband had made the mistake of getting on the internet even though she said not to do that. She jokingly says that her husband is like a medical manual and he thinks that he is going to die from everything. The patient underwent lab tests and procedures which included height: shrinking and weight: gained on an unspecified date and CAT scan and MRI: Transidential Global Amnesiac Episode on Mar2021. Outcome of the event deafness and hearing decreased was not recovered while outcome of the remaining events was unknown.

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1265947	4/28/2021	MA	73	M	3/22/2021	3/22/2021	Sudden Hearing Loss; 1st dose 16Mar2021, 2nd dose 22Mar2021; This is a spontaneous report from a contactable consumer (patient) reported that a 73-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in arm left on 22Mar2021 10:30 (at the age of 73-years-old) as a single dose for covid-19 immunisation. The patient medical history included diabetes from an unknown date. The patient had no covid-19 prior vaccination. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), administered in left arm on 16Mar2021 2:30 PM (at the age of 73-years-old) for covid-19 immunization. The patient experienced sudden hearing loss on 08Apr2021 17:00 with outcome of unknown. The event resulted in doctor or other healthcare professional office/clinic visit. The patient did not received any treatment for the event. The outcome of the event was unknown. Not covid-19 tested post vaccination. Information on the lot/batch number has been requested.

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1265919	4/28/2021	TN	50	F	3/19/2021	3/1/2021	severe tinnitus/tinnitus was reported as worsened; This is a spontaneous report from a contactable other healthcare professional (patient). A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose via an unspecified route of administration, administered in the left upper arm on 19Mar2021 (batch/lot number: EN6207; expiration date: 31Jul2021) as a single dose for COVID-19 immunisation. Medical history included ongoing arthritis, ongoing intermittent tinnitus - she has a history of noise exposure and intermittent tinnitus in the past but was certainly unremarkable, she shrunk before the vaccine - she was five seven her whole life and then thinks she was only five six. Family history included hearing loss in her mother, grandmother, and uncle but that was with advanced age. There were no concomitant medications. Historical vaccine included BNT162B2 first dose on 26Feb2021 via injection in her left upper arm (lot number: E and then either I or 1 9266; expiration date unknown) for COVID-19 immunisation. The patient experienced severe tinnitus on Mar2021, tinnitus was reported as worsened. She received the second dose of the Covid vaccine on 19Mar2021 and reported a day or two later, she started experiencing tinnitus. She stated that she has been on and off steroids for the tinnitus. She asked if there has been a correlation identified between the vaccine and tinnitus. She asked was this a side effect of the vaccine. She was asking for any information such as studies, articles, awareness and frequency, regarding tinnitus being experienced after the vaccine. She was calling about the COVID 19 vaccine. She stated she was formally a retired audiologist she was calling because she was wondering what information Pfizer has about the onset of tinnitus. She stated after the second vaccine, she has developed significant tinnitus and as an audiologist she has trained people about tinnitus. She asked was this a symptom of the vaccine. She stated she knows tinnitus was a side effect of the COVID virus but was unsure if it was a side effect of the vaccine. She stated as a matter of fact she went to the national adverse reaction to report her reaction but not the particular Pfizer website. She stated she turns 51 next week and was currently 50. She stated she was five six as she has shrunk. She clarified she shrunk before the vaccine and stated she was five seven her whole life and

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then thinks she was only five six. She stated her doctor does not know she has this side effect. She stated she was going to see an ear nose throat friend but she was waiting. Severe tinnitus: She stated this started between 1 and 2 days after she received the vaccine which was on 19Mar2021 so either 20Mar2021 or 21Mar2021. She stated it may have got worse she had taken a short round of steroids and the tinnitus got better after the first two days and then the tinnitus returned and had no response to the steroids and she has done this twice. She stated the first two days of steroid usage she feels relief then the tinnitus comes back and she said to heck with it and stopped the steroid. She stated the tinnitus was a constant bilateral high frequency pure tone just very high pitch. She stated this was medically significant because it was a significant finding but not life-threatening. First dose was an injection in her left upper arm and received on 26Feb2021 unknown NDC number and expiry date. She stated the lot number was E and then either I or 1 9266. She stated it was actually not her turn in to get the vaccine but School System had extra doses and opened it up to anyone and everyone not just 1A or 1B. She stated she was 50 with no medical significant comorbidities other than arthritis and since the vaccine was opened up to the general public she was also eligible to get the second dose. She stated she believes the COVID 19 vaccine was related to the severe tinnitus because the onset was immediate and she has had tinnitus from other noise exposure but this was very different and not intermittent and does not come and go it was a different pitch too. She stated there has been no changes, no medication changes so everything else remained steady almost immediately after the vaccine her ears started ringing and she sort of ignored it and her ears were screaming loud a significant very loud even in the presence of background noise just a constant high pitch noise. She stated the tinnitus was impacted only 2 days from the steroids and then no impact after. She stated she considered taking a third dose and was still doing experiments. She stated was this something Pfizer was aware of and was there any information about monitoring people. She stated she knows there has not been a vaccine for that long and there may not be long term resolution but she wanted to report and ask what information Pfizer may already have. She stated the first



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							steroid she started approximately 9 days after the onset and she had Medrol left over from her knee. She clarified the name as Medrol dose packs. She stated she thinks it was a 6, 5, 4, 3, 2, 1 Medrol dose pack that she had left over and she was able to set a series of 4, 3, 2, 2, and 1 but she threw packaging away and it was not a current medication as it was dated a couple years ago but she figured she would see if it would work and the first couple days it did but then not so much. Medrol dose packs unknown manufacturer, NDC number, lot number, expiry date. She stated moving forward her husband was a doctor and wrote Prednisone 10 mg and she was supposed to take 30 mg twice a day for 10 days and she took 30 mg once a day since she did not read the bottle and so she took 30 mg once a day for 5 days. She stated the same thing happened the first two days resolved and then nothing. Prednisone unknown manufacturer, NDC number, lot number, expiry date. She stated so she was actually considering taking 60 mg for 10 days and try to hit the tinnitus to see if she has an impact. She stated her concern/whole point to take the vaccine was to get antibodies and the body can recognize it but now a week and 2 weeks out she has taken a steroid which was suppressing her immune system and what does that do to the immune system. She stated the tinnitus was significant and she does not have a quiet moment and it was a cruel injustice as she used to train people and spent hours and hours counseling and now she was experiencing it. She stated it was significant enough to call and see if there was anything Pfizer knows more. She stated the first dose was given at 12:30 to 13:00 and the second dose was around 11:45 to 12:00. The adverse event did not require a visit to the emergency room and physician's office. No prior vaccinations (within 4 weeks). The outcome of the event was not recovered.
1265653	4/28/2021	GA	35	F	4/22/2021	4/24/2021	clogged ears, hearing loss, ear pressure, ear pain
1267460	4/28/2021	CA	28	M	4/15/2021	4/22/2021	My left ear is mostly deaf. I feel a bit of pressure in the affected ear. No tinnitus.

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1269157	4/28/2021			F			RESTORED HEARING; UNEXPECTED THERAPEUTIC BENEFIT; This spontaneous report received from a patient via a company representative concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's concurrent conditions included neural hearing loss. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 206A21A expiry: 23-JUN-2021) dose, start therapy date were not reported for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, the subject experienced restored hearing, and unexpected therapeutic benefit. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the restored hearing and unexpected therapeutic benefit was not reported. This report was non-serious.
1266567	4/28/2021	FL	59	F	3/26/2021	3/27/2021	tennis and possible hearing loss
1268190	4/28/2021	AZ	67	F	2/1/2021	2/18/2021	SUDDEN ONSET OF TINNITUS, BOTH EARS, L>R, WITHIN 60 MINUTES OF VACCINE ADMINISTRATION, LASTING ABOUT 4-8 HRS, THEN RESOLVING. APPROXIMATELY 2 WEEKS POST-VACCINATION, ABRUPT ONSET OF MILD HEARING LOSS, LEFT EAR. DIAGNOSED WITH 20 DB SENSORINEURAL HEARING LOSS IN 2 HIGH FREQUENCIES IN LEFT EAR AFTER AUDIOMETRY DONE ON 04/26/2021.
1267844	4/28/2021	TX	87	M	2/21/2021	3/10/2021	I suddenly experienced sudden hearing loss in my left ear. Thinking it may be ear wax or fluid contributing to this issue, I went to an urgent care and they cleaned both ears. They found no fluid or infection, but I still could not hear in my left ear. I made an appointment with an ENT. He also did not see any physical issues and ordered an MRI.
1269427	4/28/2021	UT	35	F	4/9/2021	4/14/2021	Sudden hearing loss and tinnitus in right ear

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1269137	4/28/2021	VA	57	F		4/11/2021	<p>TIREDDNESS; UNEXPECTED THERAPEUTIC BENEFIT; FEVER; This spontaneous report received from a patient concerned a 57 year old female. The patient's height, and weight were not reported. The patient's past medical history included sensory neural hearing loss, tinnitus, and inner ear sepsis, and concurrent conditions included hearing aid user. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown and expiry: UNKNOWN) dose was not reported, administered on 11-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 11-APR-2021, the subject experienced fever. Laboratory data included: Body temperature (NR: not provided) 101.8 F. On 12-APR-2021, the subject experienced unexpected therapeutic benefit. On 14-APR-2021, the subject experienced tiredness. Laboratory data (dates unspecified) included: COVID-19 virus test negative (NR: not provided) Negative, and Hearing test (NR: not provided) Unknown. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fever on 12-APR-2021, was recovering from tiredness, and the outcome of unexpected therapeutic benefit was not reported. This report was non-serious.; Sender's Comments: V1: Medical Assessment Comment not required as per standard procedure as case assessed as Non serious.</p>

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1261793	4/27/2021	MI	73	M	2/17/2021	2/17/2021	Spinal meningitis; Shingles; severe pounding headaches; migraine; pain in his back; wobbly, very off balance; dizziness; stomach pain; stomach felt hard; has not had a correct bowel movement since then; ringing in his ears; hearing loss; drive his blood pressure up/his blood pressure goes up; This is a spontaneous report from contactable consumers (patient and wife). A 73-year-old male patient received bnt162b2 (BNT162B2 reported as PFIZER COVID SHOT), dose 2 via an unspecified route of administration (reported as injection) at vaccination age of 73-year-old in the left arm (reported as left shoulder) on 17Feb2021 09:15 (Lot Number: EL3247) as a single dose for covid-19 immunisation. The patient had no medical history and concomitant medications. The patient received the first dose of bnt162b2 (BNT162B2 reported as PFIZER COVID SHOT) via an unspecified route of administration (reported as injection) at vaccination age of 72-year-old in the left arm (reported as left shoulder) on 26Jan2021 09:00 (Lot Number: EL9262) as a single dose for covid-19 immunization. The patient's historical immunizations were reported that the patient never had a flu vaccine in his life before this one and the only other vaccines has ever had were the pneumonia shots and that was years ago. The patient did not receive other vaccine four weeks prior to the first administration of the bnt162b2. The patient received the vaccine in a military facility. The patient reported that he started having (after the second shot) dizziness on 18Feb2021 and pain in his back on 12Mar2021 that kept accelerating until he was admitted in the hospital. The dizziness was ongoing, and he was shaking all the time now, he has had never had the shakes. He added that if he stands up, he gets very dizzy, wobbly, very off balance and starts to drive his blood pressure up on 18Feb2021. He has been checking that twice a day and if he's up at all and walking around, his blood pressure goes up and his head starts pounding. It's the same and it's just wrong. The patient stated that they ran a series of tests, did a spinal tap and found out he had viral spinal meningitis and shingles which he is still experiencing. The wife reported that one of the side effects is that the patient has lost some hearing, so she stated that she was going to help a little. The dizziness began, he's got it marked down on the day he got his second shot on the 17Feb2021 but further stated he has a note on his sheet that he was busy all

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day, he believes it was the day after (18Feb2021 but also reported as 17Feb2021), that he began having dizziness. On 13Mar2021, the patient began to have stomach pain and stomach felt hard. The patient stated that his stomach felt hard and has not had a correct bowel movement since then. He added that his stomach and digestive system were not any better, it's persisting. He mentioned that it started just progressing from his back to his stomach. It started going up and getting in his head and having severe pounding headaches. He has never had a headache, never had a migraine, these were severe. He added that he had to be in a dark quiet room to get any peace and that continued until he got out of the hospital. He also mentioned that he was still having severe pounding headaches from 17Mar2021 they are not as severe as those were. He added that he went to the emergency room on 18Mar2021 because of the severe head problems and lower back problems. They checked him for kidney stones and had x-rays (they were ultrasonic) which they thought maybe he had passed a stone, but there was no evidence of it, other than a distressed left kidney. They scheduled him for another ultrasound on 23Mar2021. He mentioned that his migraines still persisted since 17Mar2021 and when he went back in on the 23Mar2021 for the ultrasound (unknown result), they went back to the emergency room and checked in. They did more tests and they said his white blood count went up to 17,000 and it was obvious his body was fighting something and that's when they admitted him to the hospital. The reporter stated that after they did the spinal tap on the 26Mar2021 and determined that he had the shingles and the spinal meningitis, they gave him a super dose of some medicine and discharged him home with 10 days-worth of medications that they said would help with his symptoms, but the virus would have to run its course. On Mar2021, the patient also mentioned that he has such hearing loss, ringing in his ears, that's a factor. The ringing is so loud that it does cut down on the quality of his hearing. He couldn't hear at all when he got out of the hospital but that has subsided. He stated that the tinnitus, that's what he thinks it's called, it's just non-stop and heavy in his ears. It started while he was in the hospital. He couldn't hear but didn't pay much attention to it. It was all muffled, so then when he came out of the hospital, he

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paid more attention that is was non-stop ringing which was about the same and it hasn't worsened. The adverse events required emergency room and physician office visit (virtual consult). The patient underwent lab tests and procedures which included blood pressure measurement up on an unspecified date in 2021, had multiple computerized tomogram (CAT) scan and magnetic resonance imaging (MRI) but they couldn't find any problems on an unspecified date in 2021, spinal tap showed spinal meningitis and shingles on 26Mar2021, white blood cell count was 17,000 on 23Mar2021 and x-ray (they were ultrasonic) with results of distressed left kidney on 18Mar2021. He had multiple CAT scans and multiple MRI's and the MRI was absolutely miserable with his pounding headache, an hour in that machine. Basically, that's why they had to do the spinal tap because they couldn't find any problems. The reporter stated that through the blood work they could see it, but with the CAT scans, x-rays, ultrasounds, MRI's, they all came back with basically nothing on them on an unspecified date in 2021. With the spinal tap, they knew within an hour, they found spinal meningitis and he did have the shingles. There is a big shingles spot on his chest, it was the only obvious thing and the only rash was on his chest. The patient doesn't remember when he first got the rash on his chest, he had so many electrodes on his body monitoring him, he thought it was one of those sticky things that was irritating him. When someone came in at the hospital, that's when they saw it. They said oh you have got shingles. The patient stated that it wasn't painful, he was in enough of other pain. It was about the size of a silver dollar and there's a little bit of stuff on his back, it goes around like a belt. They saw some little spots on his back, but it never bothered him. The patient reported that it's a lot better, its healing. He can still see the whole thing, it feels kind of rough and bumpy, but it's not painful, it's healing and its improved. The reporter agrees it started sometime in Mar2021 and it is ongoing. The patient mentioned that he was unsure if they did any urine testing, but they took so much blood and stuff, they didn't tell him anything about that. The events dizziness, back pain, headache, gait unsteady, migraine, meningitis, shingles resulted in hospitalization. The outcome of the events back pain, meningitis and blood pressure orthostatic increased were unknown, as for the

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1265459	4/27/2021	CA	46	F	3/11/2021	4/4/2021	<p>events headache and shingles were recovering, while the outcome of the other events was not recovered.</p> <p>I had sudden sensorineural hearing loss first in my left ear and then in my right. I still have distorted hearing in my left ear and my right ear is still muffled. It happened a little under 3 weeks after the vaccine. The doctor performed a hearing test in my left ear and it showed moderate sensorineural hearing loss compared to the hearing test I had last August. 2 weeks later my right ear showed decreased hearing. I was put on 60 mg of steroids for 2 weeks and given doxycycline for 2 weeks. The dr also had me do a CT scan. I also had an elevated D-dimer test for clots.</p>

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1264698	4/27/2021	OH		F	2/9/2021	3/11/2021	<p>Lost hearing; Machine noise, that is now a softer noise as of today; Ringing in the ear/tinnitus; Chills; Slight headache; More tired than normal; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS (Lost hearing) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 022M20A and 026L70A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 09-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 11-Mar-2021, the patient experienced DEAFNESS (Lost hearing) (seriousness criterion medically significant), TINNITUS (Machine noise, that is now a softer noise as of today), TINNITUS (Ringing in the ear/tinnitus), CHILLS (Chills), HEADACHE (Slight headache) and FATIGUE (More tired than normal). At the time of the report, DEAFNESS (Lost hearing), TINNITUS (Machine noise, that is now a softer noise as of today), CHILLS (Chills), HEADACHE (Slight headache) and FATIGUE (More tired than normal) outcome was unknown and TINNITUS (Ringing in the ear/tinnitus) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Mar-2021, Acoustic stimulation tests: normal (normal) normal. No concomitant medications were reported. Her healthcare provider felt her symptoms were related to the vaccine. As of 22-Mar-2021 she still has ear symptoms that she describes to be "like a machine noise, that is now a softer noise". The patient is not pregnant and takes no routine medications. To treat her vaccine symptoms she took ibuprofen and aspirin as a treatment. Ear, nose, and throat doctor and had a hearing test that had normal results. Sinuses were checked and were also clear. When asked was this present after her first dose which was on 9Feb2021 Lot Number:026L70A, she indicates no and that she only had a sore arm then. Both vaccine doses were given by the county health department and was given in her left upper arm. Second dose Lot Number: 022M20A. Based on the current available information and temporal association between the use of the product and the start</p>



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1264693	4/27/2021	NC	58	M	4/13/2021	4/15/2021	<p>date of the events, a causal relationship cannot be excluded. This case was linked; 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> <p>can't hear out of left ear; Ringing in both ears; Ringing in the other ear that did not last long; Ringing in one ear that didn't last long; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS UNILATERAL (can't hear out of left ear) in a 58-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 13-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 TINNITUS (Ringing in one ear that didn't last long). On 16-Apr-2021, the patient experienced TINNITUS (Ringing in the other ear that did not last long). On 18-Apr-2021, the patient experienced TINNITUS (Ringing in both ears). On 20-Apr-2021, the patient experienced DEAFNESS UNILATERAL (can't hear out of left ear) (seriousness criterion medically significant). On 15-Apr-2021, TINNITUS (Ringing in one ear that didn't last long) had resolved. On 16-Apr-2021, TINNITUS (Ringing in the other ear that did not last long) had resolved. At the time of the report, DEAFNESS UNILATERAL (can't hear out of left ear) and TINNITUS (Ringing in both ears) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant products were reported. No treatment information was provided. 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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1263967	4/27/2021	AZ	36	F	3/1/2021	4/2/2021	Hearing loss (right ear), ringing in ear, vertigo, dizziness, numbness in my head, pins and needles in my face, arms and legs Diagnosis: Labyrinthitis, Sensorineural hearing loss, BPPV Recommendations: VRT with physical therapy, steroid treatment
1263628	4/27/2021	OH	66	F	12/23/2020	12/28/2020	I had a sudden onset of a loud pitch sound in my R ear that woke me up then it was intermittent but after getting the 2nd dose it is almost constant. I have seen by ENT 3x and had hearing test done 2x. Hearing showed mild hearing loss that I was already aware of as self discovered 2 years ago. Can only sleep because I started back taking prozac 40mg, and clonazepam 1mg at bedtime. Xanax 1mg taken during the day to help me relax. These are Rx'd.
1262434	4/27/2021	AZ	69	F	3/1/2021	4/6/2021	Developed intense tinnitus on April 6th, partially debilitating accompanied with headaches, difficulty sleeping, aches in ear and occasional shooting pain. On April 7th I had a NEGATIVE Covid test to rule out the disease. Ear Nose and Throat exam ruled out causes other than vaccine induced ototoxic impact to the ear nerve. audiology exam for hearing loss scheduled. It is now a month with no improvement and no proven treatment available.

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1262200	4/27/2021	CO		M		3/1/2021	SEVERE TINNITUS ATTACK OF RIGHT EAR; LOST 15-20 LBS IN TWO WEEKS; DID NOT SLEEP FOR THREE WEEKS; This spontaneous report received from a patient via a company representative concerned a male of unspecified age. The patient's height, and weight were not reported. The patient's concurrent conditions included tinnitus, and hearing loss. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805020, and batch number: 1805020 expiry: UNKNOWN) dose was not reported, administered on 05-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 17-MAR-2021, the subject experienced severe tinnitus attack of right ear. On an unspecified date, the subject experienced lost 15-20 lbs in two weeks, and did not sleep for three weeks. Laboratory data (dates unspecified) included: Diagnostic ultrasound (NR: not provided) Negative, and MRI (NR: not provided) Negative. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from lost 15-20 lbs in two weeks, had not recovered from severe tinnitus attack of right ear, and the outcome of did not sleep for three weeks was not reported. This report was non-serious.; Sender's Comments: V0: Medical assessment comments not required as per standard procedure as the case is assessed non serious.
1265572	4/27/2021	CA	58	F	4/2/2021	4/14/2021	Onset of tinnitus between the first and second dose. Hearing test showed minimal hearing loss. No treatment given yet.

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1261930	4/27/2021			F	2/22/2021	2/22/2021	Sudden hearing loss; Ear ringing; This spontaneous case was reported by a consumer and describes the occurrence of SUDDEN HEARING LOSS (Sudden hearing loss) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 004M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 22-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Feb-2021, the patient experienced TINNITUS (Ear ringing). On 10-Mar-2021, the patient experienced SUDDEN HEARING LOSS (Sudden hearing loss) (seriousness criterion medically significant). At the time of the report, SUDDEN HEARING LOSS (Sudden hearing loss) and TINNITUS (Ear ringing) had not resolved. Concomitant medications were not reported. Treatment received in response to the events was not reported. Company Comment Based on current available information and the temporal association between product 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 and the start date of the events a causal relationship cannot be excluded.

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1261309	4/27/2021	CA		F		4/1/2021	FEELS LIKE DEAF ON BOTH EARS; FEELS NUMB IN HEAD; EARS FEEL NUMB; This spontaneous report received from a patient concerned a female of unspecified age. 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: 202A21A expiry: UNKNOWN) dose was not reported, administered on 10-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On APR-2021, the subject experienced feels numb in head. On APR-2021, the subject experienced ears feel numb. On 14-APR-2021, the subject experienced feels like deaf on both ears. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the feels like deaf on both ears, feels numb in head and ears feel numb was not reported. 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.
1261263	4/27/2021	CA		M		4/1/2021	RIGHT EAR FEELING DEAF; COUGH; BODY ACHES; JOINT PAIN; RIGHT LEG HURTING; FEVER; This spontaneous report received from a patient concerned a male of unspecified age. 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: 1808980, and expiry: UNKNOWN) dose was not reported, administered on 12-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On APR-2021, the subject experienced right ear feeling deaf. On APR-2021, the subject experienced cough. On APR-2021, the subject experienced body aches. On APR-2021, the subject experienced joint pain. On APR-2021, the subject experienced right leg hurting. On APR-2021, the subject experienced fever. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the cough, fever, joint pain, body aches, right leg hurting and right ear feeling deaf was not reported. 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.

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1262122	4/27/2021	AR	39	F	4/16/2021	4/22/2021	For almost a week now I've experienced a slight hearing loss, seems to be in my right ear!! There is a constant slight numb like feeling in the right ear! At times out of no where there is a ringing sound in my ear!! This concerns me!! Other effects like soreness in the arm ,fatigue, and joint pain went away within a few days! I took tylenol for that!! I was told that you all could give me no answers!! I waited to see if this would pass!! I'm trying to see my MEDICAL PROFESSIONAL about this issue!! I have questions! How long will this last and is this normal!! I've called your hotlines, what's the use if they can't answer questions!! I'm a Substitute Teacher, this makes me uncomfortable!! What should I do!!
1259513	4/26/2021	SD	75	F	4/1/2021	4/5/2021	loss of hearing on left ear
1260067	4/26/2021	IL	41	M	4/14/2021	4/16/2021	Moderna Vaccine - 2nd dose 4/14: ~3PM administered vaccine 4/15: Headache and Joint Pain 4/16: Ear started popping. Loss of hearing -- > Ringing in Ear -- > Vertigo
1259670	4/26/2021	PA	17	F	4/26/2021	4/26/2021	After vaccination patient described stomach hurting, nausea, sweating, and loss of hearing. Patient felt immediately better after moving up from chair and being transferred to Med OBVs at 17:18. First set of VS were taken at 17:21, HR:83, RR:20, BP: 121/68, SPO2: 98. Patient then stated that she had not eaten a meal before the vaccine, only a chewy bar. Second set of VS were taken at 17:28, HR: 89, RR: 20, BP: 116/67, SPO2: 98. Patient stated she felt fine and was comfortable heading home, last set of VS were taken at 17:45, HR: 82, RR: 20, BP: 112/63, SPO2: 98. Patient was released at 17:45 with her father.
1259331	4/26/2021	NY	63	M	4/3/2021	4/10/2021	Loss of hearing in my left ear along with chronic tinnitus which all started days after the injection.

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1257388	4/26/2021	HI	59	F	3/3/2021	4/3/2021	3/3/21 2nd shot 3/25/21 started a cough and runny nose, asked Dr. for cough medication due to chronic coughing causing rib pain 4/3/21 woke up with both ears plugged. Called Dr and over the phone he said it sounds like an allergy which caused blocked eustachian tube and prescribed nasal spray and allergy medication with instruction to immediately stop blowing my nose. 4/19/21 left ear worse and could barely hear anything at work so drove to Urgent Care to get it looked at. Dr. there said since there is liquid behind the ears it is Acute serous Otitis and to continue taking the meds my Dr. prescribed. 4/25/21 L ear is no better and unable to hear from it, today woke up with R ear getting plugged. Also, before the hearing problem, I woke up with a rash on the entire front of my neck that itched, lasted for a week with minimal rash around my eyes and ear area.
1257351	4/26/2021	NC	51	M	3/27/2021	4/10/2021	Tinnitus, sudden hearing loss.
1257678	4/26/2021	IL	49	F	4/6/2021	4/22/2021	Slight headache and sore arm day after Woke up on 4/22 with hearing loss and loud tinnitus in right ear, moderate tinnitus in left ear, tingly feeling extending from top of head down right side of face into neck. Scheduled appointment with an ENT for later in the day. Ear canals looked fine. She placed me on prednisone, symptoms have diminished (tingling sensation gone) vibrating sensation of eardrum reduced, hearing loss still persistent and still have tinnitus.
1254856	4/25/2021	NY		M	4/1/2021	4/1/2021	profound hearing loss; This is a spontaneous report from a contactable consumer via a Pfizer-sponsored program. A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration on 01Apr2021 (Batch/Lot number was not reported) as single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. On 01Apr2021, the patient experienced profound hearing loss. The patient stated that he was deaf in his left ear. The patient was not taking prednisone and he was not sure what else the doctor can do as far as an MRI. The outcome of the event was unknown. Information on the lot/batch number has been requested.

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1256795	4/25/2021	CA		M	3/25/2021	3/26/2021	On 3/26/2021 I woke up in dire uncontrollable pain, level 10. I almost went to ER, but I called Medical Center and asked if I could come down for a pain shot, at 9:30 am. They told me to take Tylenol. I told her I have GERD and Tylenol is OFF the table. They then said they would call me back, but didn't call me back until 11:50 am. The RN again told me to take Tylenol, and I told her again I have GERD and Tylenol is OFF the table. She told me I couldn't come down to see them. I was left in dire pain, laying flat on my back, standing, or sitting. It was the most appalling experience I've ever had. I have already tried contacting CDC, and the lady kept sending me an automated reply saying I needed to go to the VERS site. I finally emailed her and told her to NOT REPLY again. I told her all the information I have stated here, but the lady didn't want to enter it into the system, purposely. What a total failure of the CDC, totally incompetent and ignorant. This just caused a public informative response failure on CDC's end. I also called the 800 number before sending all those emails to CDC, requesting a return call. They never returned my call !! Another CDC failure. I am deaf and use a captioned phone. The stupid recording went too fast for my caption phone to print out and I had to call that 800 number 3 times to understand the stupid menu. This is discrimination of the deaf. I'm sick and tired of it all. I explained this to the lady that sent me several emails, but she didn't want to hear it. More discrimination. Where does it end? So HOPEFULLY this information gets into your system. Don't send me a reply stating I didn't fill out this form correctly, or I will permanently BLOCK your emails. Thank you
1256318	4/25/2021	CO	16	M	4/17/2021	4/24/2021	Sudden hearing loss
1256121	4/25/2021	IA	43	F	3/5/2021	4/13/2021	Vestibular symptoms, hearing loss, vertigo, balance problems. Started 4-13-21. Treated in patient at hospital. Released 4-15-21. Currently under care of primary care dr, ent, pt, and waiting neurologist consult.



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1255557	4/25/2021	VA	47	M	4/5/2021	4/8/2021	Experienced momentary loss of hearing (seconds duration) in each ear, which seemed to resolve; have persistent tinnitus in both ears; This is a spontaneous report from a contactable consumer (patient himself). A 47-years-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, lot number: EP7533) via an unspecified route of administration on 05Apr2021 at 11:45 am as a single dose for COVID-19 immunisation. The patient's medical history included Allergy and GERD. The patient's concomitant medications were not reported. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient's 2 weeks prior vaccines included omeprazole, daily vitamin B-12, D3. Prior to vaccination, patient was not diagnosed with COVID-19. COVID vaccination was none. Since the vaccination, patient had not been tested for COVID-19. COVID tested post vaccination was none. On 08Apr2021 at 11pm, the patient reported that she experienced momentary loss of hearing (seconds duration) in each ear, which seemed to resolve, but currently she has persistent tinnitus in both ears. The patient reported that she did not take any treatment for the events and the events led to physician visit. Outcome of events was not resolved.

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1255339	4/25/2021	AZ	57	F	4/5/2021	4/6/2021	deafness; Tinnitus; ear pressure; This is a spontaneous report from a contactable consumer (patient). A 57-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: EW0105) via an unspecified route of administration into the right arm on 05Apr2021 15:45 (at the age of 57-years-old) as single dose for COVID-19 immunisation. Medical history included Hashimoto's disease, hypothyroidism and asthma. Patient was not pregnant. Concomitant medications included simvastatin (SIMVASTATIN), quetiapine (QUETIAPINE), magnesium (MAGNESIUM), acetylsalicylic acid (ASPIRIN (E.C.))and bepotastine besilate (POTAS). Historical vaccine includes first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: EP7534) into the right arm on 16Mar2021 01:00 PM (at the age of 57-years-old) for COVID-19 immunization. On 06Apr2021, patient experienced deafness, tinnitus and ear pressure. The patient did not receive treatment for the events reported. Outcome of events recovered on Apr2021.
1255232	4/25/2021	NY	32	F	4/5/2021	4/6/2021	Sudden hearing loss; This is a spontaneous report from a contactable consumer (patient). A non-pregnant 32-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in left arm on 05Apr2021 at 18:00 (6:00 PM) (at the age of 32 years old) (Batch/Lot number was not reported) as a single dose for COVID-19 immunisation. The patient medical history was not reported. Concomitant medications included spironolactone and atomoxetine. The patient experienced sudden hearing loss on 06Apr2021. The patient did not receive treatment for the event. It was unknown if the patient has COVID prior to vaccination and was not tested for COVID post vaccination. The patient did not receive other vaccine in four weeks. Outcome of the event was unknown. Information on the lot/batch number has been requested.

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1257065	4/25/2021	NJ	70	M	1/21/2021	1/22/1921	Vertigo, fatigue, sudden increase in hearing loss in right ear accompanied by tinnitus and reverberation. Occurred about 24 hours after 1st injection in January. Patient seen by audiologist on Monday, Jan. 25th and then referred to and treated by ENT with course of steroids soon after with no improvement. Fatigue lasted a few days. Hearing loss and tinnitus continue.
1255185	4/25/2021	IL	43	F	4/3/2021	4/3/2021	Experienced significant increase in pre-existing tinnitus in right ear, and new onset of tinnitus and possible sudden hearing loss in left ear following vaccination; Experienced significant increase in pre-existing tinnitus in right ear, and new onset of tinnitus and possible sudden hearing loss in left ear following vaccination; This is a spontaneous report from a contactable consumer (patient). A 43-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration, administered in arm left on 03Apr2021 10:30 (Batch/Lot Number: ED7533) as single dose for covid-19 immunisation. Medical history included AV block, colitis, optic neuritis, previous hearing loss in right ears and pre-existing tinnitus in right ears all from an unknown date and unknown if ongoing. Concomitant medications included montelukast; clarithromycin (CLARITIN) and bisacodyl (DULCOLAX); all taken for an unspecified indication, start and stop date were not reported. The patient previously took amoxicillin and vancomycin and experienced allergies. The patient experienced experienced significant increase in pre-existing tinnitus in right ear, and new onset of tinnitus and possible sudden hearing loss in left ear following vaccination on 03Apr2021 13:00. Contacting doctor, the patient was hesitant to receive second vaccination. No treatment was received for the events. The patient did not recover from the events.

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1255533	4/25/2021	MD	60	F	4/5/2021	4/5/2021	possible hearing loss; episodes of elevated tinnitus (pre-existing); vertigo; dizzy; hands felt like vibrating; nauseous; threw up; diarrhea; chills; This is a spontaneous report from a contactable consumer (patient). A 60-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) (at 60 years of age), dose 2 via an unspecified route of administration, administered in arm left on 05Apr2021 13:00 (Batch/Lot Number: EP7533) as a single dose for COVID-19 immunisation. Medical history included tinnitus and penicillin allergy, both from an unknown date and unknown if ongoing. Concomitant medications included ciclosporin (RESTASIS) and vitamin d nos (VITAMIN D NOS), both taken for an unspecified indication, start and stop date were not reported. Historical vaccine included PFIZER BIONTECH COVID 19 VACCINE (lot number: EL9629) (at 60 years of age), dose 1 in the left arm on 08Mar2021 13:00 for COVID-19 immunisation. The patient was not pregnant. The patient did not receive any other vaccine in four weeks prior to covid vaccine. The patient had no covid prior to vaccination. The patient has not been covid tested post vaccination. The patient experienced repeated night time episodes of elevated tinnitus (pre-existing), possible hearing loss, vertigo, dizzy, hands felt like vibrating, nauseous, threw up, diarrhea, and chills, all on 05Apr2021 14:00 PM with outcome of recovered/resolved with Sequel. The events resulted to Emergency room/department or urgent care. No treatment received for the events.

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1254798	4/25/2021	OH	43	M	3/24/2021	3/26/2021	High frequency hearing loss; High pitch ear ringing; This is a spontaneous report from a contactable consumer (patient). A 43-year-old male patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot number: ER26L3), via an unspecified route of administration, administered in the left arm on 24Mar2021 at 17:45 as a single dose for COVID-19 immunization. The patient had no medical history and had no known allergies. The patient did not have COVID prior to the vaccination. There were no concomitant medications and the patient did not have other vaccines in four weeks and did not have other medications in two weeks. The patient has not been tested for COVID post vaccination. The patient experienced high frequency hearing loss and high pitch ear ringing on 26Mar2021 at 05:00. The patient did not receive treatment for the events. The outcome of the events was not recovered. The events were reported with a seriousness criteria of disability.

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1254746	4/25/2021	TX	46	M	1/18/2021	3/22/2021	Loss of hearing in left ear; tinnitus/echoing; numbness around area of left ear; This is a spontaneous report from a contactable health care professional (patient). A 46-year-old male patient received the second dose BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot number: EI3248), via an unspecified route of administration, administered in the left arm on 18Jan2021 as a single dose for COVID-19 immunization. Medical history included Hashimoto's disease, high cholesterol and is prediabetic all from an unknown date and unknown if ongoing. The patient has no known allergies. The patient did not have COVID prior to vaccination and has not been tested for COVID post vaccination. Concomitant medications included empagliflozin (JARDIANCE); levothyroxine (manufacturer unknown); metoprolol (manufacturer unknown); rosuvastatin (manufacturer unknown) and fish oil (OMEGA 3 [FISH OIL]), all taken for an unspecified indication, start and stop date were not reported. The patient previously received the first dose of bnt162b2 (lot number: Es1685) on 28Dec2020 at 12:00 PM via intramuscular route on the right arm for COVID-19 immunization. The patient experienced loss of hearing in left ear, tinnitus/echoing and numbness around area of left ear all on 22Mar2021 at 12:00. The ENT prescribed prednisone 10mg as treatment for the events. The outcome of the events was not recovered.; Sender's Comments: Based on the information currently available, a causal association between the reported events and BNT162B2 cannot be fully 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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1254720	4/25/2021	FL	25	M	4/7/2021	4/7/2021	Temporary hearing loss; ringing of the ears; Extreme cold sweats; Blurred vision; This is a spontaneous report from a non-contactable consumer for a 25-years-old male patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in right arm on 07Apr2021 14:00 (Batch/Lot Number: EP7533) as SINGLE DOSE for covid-19 immunisation. Medical history included Covid-19 (Covid prior vaccination: Yes). Concomitant medications included sulfamethoxazole, trimethoprim. The patient previously took a tetanus booster on left arm. The patient had a Covid prior vaccination and not Covid tested post vaccination. On 07Apr2021 at 14:00, the patient experienced temporary hearing loss, ringing of the ears, extreme cold sweats, and blurred vision. The patient did not receive treatment for the events. The outcome of events was recovered on 07Apr2021. No follow up attempts are possible. No further information is expected.
1254642	4/25/2021	MI		F	3/22/2021	3/22/2021	hearing loss in her right ear; Vertigo; Lightheadedness; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in right arm on 22Mar2021 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. On 22Mar2021, the patient experienced hearing loss in her right ear, vertigo, lightheadedness. The clinical course was as follows: Patient says she received her first dose of the Pfizer COVID-19 vaccine the 22Mar2021 and she has some questions. She says she had hearing loss in her right ear after the first shot which she got in her right arm. She says she also had vertigo, is that a side effect? She says she is still feeling lightheaded, and she has been taking Tylenol, and she doesn't know why her hearing went away. She says she also used some sweet oil that she sometimes used years ago like her mom used to use, to see if it would clear up. She asks is this a side effect and should she get the second dose? The outcome of the events was not reported. Information on the lot/Batch number has been requested.

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1254614	4/25/2021	MA	20	F	4/5/2021	4/5/2021	<p>Dystonic reaction beginning in right hand then spreading up arm to eventually involve most of upper body.;</p> <p>Dystonic reaction beginning in right hand then spreading up arm to eventually involve most of upper body.;</p> <p>This is a spontaneous report received from a contactable consumer (patient). A 20-year-old female patient (not pregnant) received bnt162b2 (Pfizer BioNTech Covid 19 vaccine), dose 1 via an unspecified route of administration, administered in Arm Right on 05Apr2021 13:00 (Batch/Lot Number: Unknown) at single dose for covid-19 immunization. Facility where the most recent COVID-19 vaccine was administered was in Hospital. Medical history included Premature, Myoclonus-Dystonia, Hearing loss, gastroparesis, vocal cord paresis/dysfuntion/dystonia, hemiplegic migraine, loss of taste and smell unrelated to COVID. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medications within 2 weeks of vaccination included gabapentin taken for an unspecified indication, start and stop date were not reported; ethinylestradiol, norethisterone (NORETHIN 1/35) taken for an unspecified indication, start and stop date were not reported; propranolol (PROPANOLOL) taken for an unspecified indication, start and stop date were not reported. The patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously used Propofol, Fentanyl, Reglan, and experienced allergies. The patient experienced dystonic reaction beginning in right hand then spreading up arm to eventually involve most of upper body. Event started from 05Apr2021 and resulted in doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. Treatment received for the adverse event included Benadryl and Ibuprofen w/ note to follow up neuro. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the event was recovering. Information on the lot/batch number has been requested.</p>



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1254540	4/25/2021	NJ	71	F	3/2/2021	3/22/2021	<p>diagnosed with sudden sensorineural hearing loss (SSHL); tinnitus; 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 VACCINE, solution for injection, lot number: EN6205), via an unspecified route of administration, in right arm, on 02Mar2021 (at the age of 71 years old) at a single dose for covid-19 immunisation. Medical history included fibromyalgia, blood pressure (abnormal), blood cholesterol (abnormal). Concomitant medications included duloxetine hydrochloride (CYMBALTA) for fibromyalgia, metoprolol for blood pressure; atorvastatin calcium (LIPITOR) for cholesterol; vitamin d3 for vitamin; ubidecarenone (COQ10) for vitamin; aspirin [acetylsalicylic acid]; and calcium carbonate (CALTRATE). The patient had no history of previous immunizations and no additional vaccines administered on the same date. The patient had no prior vaccinations within four weeks. The patient developed an adverse event from the vaccine, in which her doctor prescribed her to receive steroid injections in her ear drum to help with tinnitus and hearing loss experienced from the vaccine on 22Mar2021. The patient is two weeks post second vaccine administration and asked if she can take a steroid orally rather than having to get it injected into her ear drum. The patient stated that she can't be absolutely sure that this adverse event was from the vaccine. She further reported that she had the first dose of the vaccine on 02Mar2021. On 22Mar2021, she woke up completely deaf in one ear and it was diagnosed with sudden sensorineural hearing loss (SSHL). Stated that along with that, she had had severe ringing in the ear, like tinnitus type of condition. Stated that she went to the doctor on 22Mar2021 to the ear, nose, throat (ENT) doctor and stated that he was not absolutely sure. Stated that in the ENT industry is looking at the fact that they are having many patients coming in with this condition. They don't know if this is because of the vaccine or the fact that so many people are getting the vaccine. They are seeing an up rise in this condition and are dealing with it. Stated that the doctor didn't want to give oral steroids, which is the recommendation because, she was having the second dose of vaccine on 23Mar2021. Decided to inject steroid into ear drum instead of doing it orally because he didn't want to kind of cancel out the vaccine.</p>

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States that she still does not know if the ringing, tinnitus is from the vaccine or not. Stated that she has now had 3 injections of this steroid directly into her ear. Further, ringing in ear started as mild ringing and she woke up completely deaf in that ear. The patient got the third injection on 02Apr2021. After the first injection, started getting some hearing back, not much, but is a little improved. Stated that it is slightly improved. She does not know the name of the injected steroid. States that currently, as recommended by her doctor, is undergoing HBOT therapy, which is hyperbaric oxygen therapy. Stated that it is known to be helpful in this SSHL condition. Stated that she has had 5 treatments and is going to continue until 20 treatments. The event required a visit at physician office. The patient underwent magnetic resonance imaging (MRI) on unspecified date to make sure, there are two things in the brain that could cause loss of hearing; 1 is a tumor and one is something else and the patient don't have either. Therapeutic measures were taken as a result of the event. Outcome of the event was recovering.

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1254339	4/25/2021	MI	70	F	3/15/2021	3/1/2021	<p>           achy; not feeling well, overall feeling unwell; flu symptoms; nausea; joint pain; arm is a little sore; This is a spontaneous report from a contactable consumer, the patient. This 70-year-old female patient of received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EN6205), via an unspecified route of administration on 15Mar2021 "between 12:20 - 12:30" (at the age of 70-year-old) as single dose for COVID-19 immunization. Medical history included thyroid removal due to thyroid cancer when she was 32-34 years old, shingles, broken rib on chest X-ray, and hearing problem. The patient also stated that she doesn't have a spleen, so she is very sensitive to ASPIRIN (acetylsalicylic acid). Concomitant medications included valaciclovir hydrochloride (VALTREX S) 7 days treatment for shingles, and levothyroxine (manufacturer unknown). The patient previously took the influenza vaccine on 28Nov2020, then 9 days later (Dec2020) she thought she was having a heart attack and went by EMS to the hospital where they checked her for a heart attack but it was negative and she also got an echocardiogram that was negative. She was diagnosed with costochondritis ten days after getting the Flu shot. She took ibuprofen (MOTRIN) about a month for costochondritis and it made her blood pressure go up, so she was off it. On 15Mar2021, the patient reported that she was feeling fine after her first dose of COVID vaccine. She stated even her arm is a little sore (in Mar2021). Until 14:00 on 17Mar2021, the patient reported not feeling well, experiencing overall feeling unwell, flu symptoms, nausea and joint pain. Later, she also stated feels like she is coming down with the flu now and has joint pain, though she doesn't have a fever, and she is achy. The clinical outcomes of the feeling unwell, flu symptoms, nausea, joint pain, achy and arm is a little sore were not reported.         </p>

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1254223	4/25/2021	VA	60	F	2/27/2021	2/28/2021	it felt like my head would pop off at one point; hearing muffled; left ear was clogged and ringing; This is a spontaneous report from a contactable consumer. A 60-year-old non-pregnant female patient received dose of bnt162b2 (PFIZER BIONTECH COVID mRNA VACCINE, solution for injection, Lot Number: EN6205), via an unspecified route of administration, administered in arm Left on 27Feb2021 at 12:00 as SINGLE DOSE for covid-19 immunization. Medical history included Acid Reflux and known allergies to Bananas. The patient had no other vaccine in four weeks. Concomitant medication(s) in two weeks included rabeprazole (RABEPRAZOLE) taken 20 mg dose for an unspecified indication, start and stop date were not reported. The patient reported that about 28 hours after the vaccination her left ear was clogged and ringing and then both ears were clogged, and it felt like her head would pop off at one point. The patient was literally thought that she was going deaf. This had never happened to her before. It has gotten better at about 34 hours in, but left ear still feels clogged and hearing muffled. On 28Feb2021 at 16:00, the patient experienced hearing muffled and it felt like my head would pop off at one point and left ear was clogged and ringing. The patient not had covid prior vaccination; not tested covid post vaccination. The patient did not receive any treatment for the events. The outcome of the events is recovering. No follow-up attempts are possible. No further information is expected.

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1255228	4/25/2021	OH	59	F	3/15/2021	3/1/2021	Right ear started popping; patient started to feel fullness in her right ear; right ear started high pitched ringing (tinnitus); She then lost hearing in her right ear; This is a spontaneous report from a contactable consumer (patient). A 59-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration, administered in left arm on 15Mar2021 15:00 (lot number: EN6207) at the age of 59 years old, as single dose for COVID-19 immunization. Medical history reported as none. The patient was not pregnant at the time of vaccination. Concomitant medications included hydrochlorothiazide, metoprolol tartrate (METOPROLOL TARTRATE AND HYDROCHLOROTHIAZIDE); losartan; levothyroxine sodium (LEVOTHYROXINE); all taken for an unspecified indication, start and stop date were not reported. 2 days after 1st dose (17Mar2021 04:00), the patient started to feel fullness in her right ear. She thought at first perhaps it was water, but feeling continued. Right ear started popping a few days later. She called her primary care physician and made appointment to come in. Primary care could see nothing wrong, no inflammation in ear or fluid. That following weekend (Mar2021) after primary care visit, her right ear started high pitched ringing (tinnitus). She then lost hearing in her right ear. She went to urgent care who also saw nothing but referred her to ENT doctor. 2 days later at ENT audiologist reported significant hearing loss in her right ear. She is currently prescribed prednisone with no change. She never had a reaction to any shot ever previously. She also have never had any hearing issues or tinnitus ever in her life. The only time she had anything is from the Pfizer shot. She has been advised by her doctor to hold off on second dose. The events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, disability or permanent damage. The patient was not diagnosed with COVID prior and after vaccination. The patient has no known allergies. No other vaccines received four weeks prior to COVID vaccine. The patient has not recovered from the events.

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1255277	4/25/2021	GA	42	M	3/22/2021	4/3/2021	Loss of hearing in right ear followed by tinnitus; Loss of hearing in right ear followed by tinnitus; This is a spontaneous report from a contactable consumer (patient). A 42-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration, administered in Arm Left on 22Mar2021 12:00 (Batch/Lot number was not reported), age at vaccination of 42-years-old, as single dose for covid-19 immunisation. Medical history was none. Concomitant medication included esomeprazole sodium (NEXIUM [ESOMEPRAZOLE SODIUM]) taken for an unspecified indication, start and stop date were not reported. The patient experienced loss of hearing in right ear followed by tinnitus on 03Apr2021. The events resulted in emergency room/department or urgent care; it was unknown if treatments were given for the events. No other vaccine given in in four weeks. The patient was not tested for covid prior vaccination. The patient underwent lab tests and procedures which included sars-cov-2 test negative on 08Apr2021. The patient had not recovered from the events. Information on the lot/batch number has been requested.
1253936	4/24/2021	NY	94	F		3/19/2021	BLACK AND BLUE MARK AT SITE OF INJECTION; SHE FELT PAIN DURING THE INJECTION OF THE VACCINE; This spontaneous report received from a patient concerned a 94 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included deaf. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown and expiry: unknown) dose was not reported, administered on 17-MAR-2021 for prophylactic vaccination on left arm. The batch number was not reported and has been requested. No concomitant medications were reported. On 19-MAR-2021, the subject experienced black and blue mark at site of injection. On 19-MAR-2021, the subject experienced pain. The action taken with covid-19 vaccine ad26.cov2.s was not reported. The patient had not recovered from black and blue mark at site of injection, and the outcome of pain was not reported. This report was non-serious.

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1253185	4/24/2021	TX		F		3/18/2021	HARD TO BREATHE; DIZZY; RASH; NAUSEA; This spontaneous report received from a vaccine facility concerned a 52 year old female. The patient's height, and weight were not reported. The patient's past medical history included covid-19 infection, and concurrent conditions included uti diagnosis, alcohol use, non smoker, and loss of hearing in left ear, and other pre-existing medical conditions included no known drug allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029, expiry: UNKNOWN) dose was not reported, administered on 10-MAR-2021 09:45 on right arm for prophylactic vaccination. Concomitant medications included sulfamethoxazole/trimethoprim for uti. On MAR-2021, Laboratory data included: Blood pressure (NR: not provided) 136/76 mmHg, 168/95 mmHg, and Heart rate (NR: not provided) 127 BPM. On 18-MAR-2021, the subject experienced hard to breathe. On 18-MAR-2021, the subject experienced dizzy. On 18-MAR-2021, the subject experienced rash. On 18-MAR-2021, the subject experienced nausea. Laboratory data (dates unspecified) included: Blood pressure (NR: not provided) 192/117 mmHg, and Heart rate (NR: not provided) 129 BPM. Treatment medications (dates unspecified) included: diphenhydramine hydrochloride. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from nausea, dizzy, and hard to breathe, and had not recovered from rash. This report was non-serious.
1251441	4/24/2021	TX	71	F	3/5/2021	3/12/2021	Complete hearing loss of my right ear. A sudden zero percent hearing left after 7 days of taking the vaccine.
1251403	4/24/2021	OH	71	M	2/2/2021	2/12/2021	Patient developed vertigo and hearing loss in his right ear on 2/12/2021. He was evaluated by urgent care, and ED visit, PCP, and an ENT. The ENT performed a hearing test on 3/24/2021 which showed clinically deaf in his right ear. An MRI was completed on 4/14/2021 and showed no signs of abnormality.

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1251291	4/24/2021	OH	50	M	3/13/2021	3/24/2021	Experienced Sudden Sensorineural Hearing Loss (SSNHL) in the left ear beginning in early morning on March 24, 2021. Hearing loss occurred over the course of approximately 1 hour. Initial care sought through an urgent care on March 24, followed by my primary care physician on March 26, and then emergency room on March 27. Emergency room consulted with Dr and began treatment with oral course of prednisone, 50mg tablet once per day for a total of 6 days. Referred to Dr, ENT, on an emergent basis. Full audiological testing performed on March 29 at Dr office showed profound hearing loss (80-110 db) across all frequencies in left ear, with a speech recognition of 0%. Also experienced aural fullness and tinnitus in left ear. Received intratympanic injections of dexamethasone at Dr office on March 29, April 6 and April 15. I began to notice extremely gradual improvement of ability to hear starting on March 30, with slow incremental improvement continuing to date, but so far only partial recovery has occurred. A second full audiological assessment was performed on April 15 at Dr office, and results showed left ear hearing had improved to "asymmetric mild sloping to profound" hearing loss (25 -95 db from low to high frequencies), speech recognition improved to 48%. Complete recovery has been described as unlikely, but final recovery level is unknown and will be assessed in the coming months - most recovery from SSNHL occurs in the initial month following onset. Next appointment will be in 6 months to assess final hearing level in left ear and discuss amplification (hearing aid) if necessary.



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1254037	4/24/2021	TX	81	F	2/5/2021	2/13/2021	10 days after COVID VACCINE had soreness, itching, warmth and red area size of orange at injection site on right arm; 10 days after COVID VACCINE had soreness, itching, warmth and red area size of orange at injection site on right arm; 10 days after COVID VACCINE had soreness, itching, warmth and red area size of orange at injection site on right arm; 10 days after COVID VACCINE had soreness, itching, warmth and red area size of orange at injection site on right arm; This is a spontaneous report from a contactable nurse (patient). A 81-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Formulation: Solution for injection, Lot: EM9810 Expiration date:unknown) first dose intramuscular on right arm on 05Feb2021 08:30 AM (at age of 81-year-old) at single dose for Covid-19 immunization. Medical history included emphysema, ruptured eardrum partial deafness, arthritis from unspecified date. Prior to vaccination, the patient was not diagnosed with COVID-19. Patient has not tested COVID post vaccination. No other vaccine was taken in four weeks. Patient was allergic to Zyban. Concomitant medications included ASA 81 mg, MVI, Biotin, Vitamin C, Stiolto inhaler from unspecified date and unknown if ongoing. Patient previously 18 months ago got surgical glue in vein procedure, 10 days later patient experienced warmth, redness, itching, tenderness at site after COVID VACCINE had soreness, itching, warmth, and red area size of orange at injection site on right arm on 13 Feb2021. No treatment received for the adverse event and the patient asked should I take the second dose of the vaccine. The outcome of events were recovering.
1248605	4/23/2021	NC	18	M	4/21/2021	4/21/2021	10 Minutes after injection, passed out Headache for 2 days Fatigue for 2 days Vomiting for 1 day Hearing loss left ear currently Loss of appetite currently shortness of breath currently
1249617	4/23/2021	NJ	42	M	4/4/2021	4/6/2021	Terrible loud ringing in ears and buzzing in head, hearing loss (high frequency ), fatigue, insomnia, fever, chills, brain fog

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1249615	4/23/2021	WA	61	F	4/3/2021	4/4/2021	I am deaf in my right ear (pre-existing). Since vaccinated, I have so much noise in my deaf/right ear that I'm having trouble hearing with my left ear. It started the day after the vaccine, then let up for a couple days before returning and seems to get a bit louder each day.
1248417	4/23/2021	CA	34	M	3/10/2021	3/28/2021	Congestion and partial hearing loss for 4 days in left ear starting the morning of 3/28/21; increased congestion and hearing loss in left ear evening of 3/30/21; vertigo the morning of 3/31/21 resolving mid afternoon; improvement in congestion and hearing of the left ear the evening of 3/31/21; tinnitus and congestion in right ear 4/3/21; congestion resolved a week later; tinnitus in right ear since 4/3/21. Doctor prescribed short course of methylprednisolone, 4mg pills. No improvement in tinnitus.

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1245468	4/23/2021	NY		F	4/13/2021	4/13/2021	<p>~~I lost hearing in both ears for 20 min, on and off ever since"; "my vision doubled in size"; "It sounds like a buzzing nose, and feels like I'm on a plan and my ears need to pop."; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS TRANSITORY ("I lost hearing in both ears for 20 min, on and off ever since") in a 27-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 042B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Sore throat (Patient reported that her throat was no longer sore at the time of vaccine just "scratchy."). Concomitant products included CODEINE PHOSPHATE, GUAIFENESIN, PHENIRAMINE MALEATE (ROBITUSSIN A-C) from an unknown date to 13-Apr-2021 for Sore throat. On 13-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Apr-2021, the patient experienced DEAFNESS TRANSITORY ("I lost hearing in both ears for 20 min, on and off ever since") (seriousness criterion medically significant) and DIPLOPIA ("my vision doubled in size"). On an unknown date, the patient experienced TINNITUS ("It sounds like a buzzing nose, and feels like I'm on a plan and my ears need to pop."). On 13-Apr-2021, DIPLOPIA ("my vision doubled in size") had resolved. At the time of the report, DEAFNESS TRANSITORY ("I lost hearing in both ears for 20 min, on and off ever since") and TINNITUS ("It sounds like a buzzing nose, and feels like I'm on a plan and my ears need to pop.") had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Apr-2021, SARS-CoV-2 test: negative (Negative) Patient had received a negative COVID test on the day of the vaccination.. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Patient denies any treatment related to 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</p>

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							cannot be excluded.
1245253	4/23/2021	MI	34	F	4/14/2021	4/20/2021	Partial hearing loss, tinnitus. Both ears feel "muffled" and "stuffy" and are ringing loudly. First, the left ear started feeling that way, and then the next day, the right ear started feeling it and the left ear got worse.
1243737	4/22/2021	WI	79	M	2/7/2021	2/9/2021	loss of hearing in right ear after first shot and loss of hearing in left ear after second shot. two other males in our small community have same issue that I know of
1243484	4/22/2021	OK	62	M	12/29/2020	1/13/2021	Severe Tinnitus and hearing loss from 1/13/21 to the present.

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1242571	4/22/2021	KS	45	M	3/6/2021	3/15/2021	Janssen/J&J COVID-19 Vaccine EUA Miller-Fischer Variant GBS - See continuation page #1 facial diplegia and ataxia 45-year-old male with history of schizophrenia presented with 6-day history of facial diplegia initially evaluated at outside facilities and transferred over here for further management. There is a concern for Miller Fischer variant GBS. No history of tick bite no signs of systemic infections. Patient had a recent COVID-19 vaccine March 6th. On exam patient has pretty severe bilateral facial weakness in the lower motor apparent without any other cranial nerve involvement. There is numbness in the lateral toes of the right foot and sensory ataxia on exam. Patellar reflex and Achilles tendons were absent. Remaining reflexes were present. Multiple labs are pending lumbar puncture is pending. MRI brain is negative for enhancing lesions of the cranial and intra-articular portions of the facial nerve. After lumbar puncture will probably start the patient on IVIG if there was no signs of infection planning for 5-day course. Recommend artificial tears and supportive management to prevent corneal ulcers from facial weakness. OT and speech to see the patient. Assessment: 1. Acute facial diplegia with bilateral peripheral cranial nerve VII dysfunction concerning for AIDP. Symptoms started about 1 week ago. House Brackmann scale 5 bilaterally. Patient with metallic taste of tongue, pressure in his ears with some pain behind the ears. Unable to close his eyes, raise his forehead, puff out his cheeks, or purse his lips. No vibration sense to his chin. Also noticing new numbness of his right toes and has absent R patellar reflex. No recent noted infections although possible left mandibular tooth abscess noted on CT imaging and he reports a chronic "rotten tooth". Patient had a COVID-19 Johnson & Johnson vaccine on March 4. MRI brain with and without contrast is negative without noted enhancement of the facial nerve root. Planning lumbar puncture today and then will discuss further treatment. Will add moisture for his eyes and gabapentin for pain. 2. Neutrophilic leukocytosis. Unclear etiology. May need to have the dentist look at his tooth and consider removal. Will discuss further. 3. History of schizophrenia. Patient denies any acute complaints with this but is anxious to restart his lithium which is okay from our standpoint. 4. Tobacco use 5. Hypothyroidism. Continue home

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levothyroxine. Plan: - LP, see orders - motor sensory neuropathy panel, b12, ANA, ACE, EBV Ab panel, RPR, Lyme reflexive panel, HIV, TSH, UA -Eyedrops and ointment to bilateral eyes -Gabapentin 100 mg 3 times daily -SLP to see History of Present Illness: 45-year-old male with a history of schizophrenia and tobacco use who presents with facial diplegia for the last 6 to 7 days. On Saturday night a week ago he had a fullness in his bilateral ears and thought he may have an ear infection. He woke up Sunday morning (March 21) with bifacial weakness and dysarthria. He has a metallic taste in his tongue. He feels somewhat swollen and sore in the posterior area. He still has a full feeling in his ears but no hearing loss. He cannot completely close his eyes. He has no movement of his forehead he cannot puff out his cheeks. He has had difficulty getting food to back of his mouth to swallow. His eyes are watering. He has some occasional stabbing, ice pick pains behind his ears, mild at present. He feels numb in his perioral area. Since occurrence this is not worsened or improved. He denies any illnesses in the last month or 2. He has had some diaphoresis at home since this occurred. No palpitations. No bowel or bladder issues. No difficulty walking. Denies shortness of breath. After transfer here and when he is asked he has noted some numbness in his third through fifth toes on the right foot which is new. He had a Johnson & Johnson COVID-19 vaccination on March 4. He has been on lithium since he was a child and recently was placed on Zoloft. He denies any new mental health issues but stopped his medications when the symptoms occurred as he was concerned there might be a potential side effect. At the outside hospital he had a CT of the neck which did note lucency around the root of his remaining left mandibular molar suspicious for abscess as well as large dental caries. He reports knowing he has had a rotten tooth on the back left for a long time. He is missing most of his upper teeth except a couple molars ("from bad decisions in his young years"). He had gone into the local ED about 3 days ago and they gave him a prescription for amoxicillin, prednisone, Zyrtec and Benadryl. He had a couple doses of amoxicillin and prednisone before he went back to the ED yesterday with ongoing symptoms. Medical History Past Medical History: Diagnosis Date o Anxiety o Paranoid schizophrenia o Smoking status: Current Every

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Day Smoker Packs/day: 0.50 Years: 30.00 Pack years: 15.00 Substance and Sexual Activity o Alcohol use: Yes Frequency: 2-4 times a month o Drug use: Not Currently o Sexual activity: Defer Patient is allergic to geodon [ziprasidone hcl]; haldol [haloperidol]; abilify [aripiprazole]; and latuda [lurasidone]. Review of Systems he has a history of low back pain with right leg radiculopathy for which she had a radiofrequency ablation done in the past. Physical Exam: Current Vital Signs: BP 139/77 (BP Location: Left arm, Patient Position: Lying) | Pulse 89 | Temp 36.6 °C (97.9 °F) (Oral) | Resp 18 | Ht 1.702 m (5' 7") | Wt 110 kg (241 lb 6.5 oz) | SpO2 97% | BMI 37.81 kg/m² Labs: Sodium 137 Potassium 4.4 BUN 16 Creatinine 1.05 Glucose 109 Lithium level 0.2 WBC 16.64 Hemoglobin 14.5 DISCHARGE SUMMARY Hospital Course: 45-year-old male with a history of schizophrenia who had 6 to 7 days now of complaints of upper forehead/facial weakness, eyes watering leading to blurry vision until he wipes away the excess and numbness of his lips and mouth and tongue feeling thick. He noticed that his speech was a little different and he felt muffled and cottonmouth. He had a little bit of issue eating as he states that he had to put his food in the back of his throat so that his tongue would not push the food out of his mouth. He denies any numbness around his maxilla or mandible or cheeks. He stopped all of his medications abruptly when he had the symptoms as he thought it may be a side effect from something. He denies any recent environmental or insect exposure. No fevers or chills. No URI symptoms. No ear pain. No nausea or vomiting. Patient was ultimately diagnosed with Miller Fisher variant GBS secondary to Johnson & Johnson COVID-19 vaccine. Neurology evaluated and started IVIG treatment for 5 total doses. He progressively improved with his symptoms throughout the 5 days of hospitalization. He completed IVIG therapy on 4/1/2021. I personally evaluated the patient on the day of discharge he was doing well and had no complaints. He is to follow-up with neurology in 1 to 2 months. FMLA paperwork was filled out. He was discharged with eye ointment solution and told to protect his eyes. It was neurology recommendation that he take at least 2 months off of work in order to do so. I had no changes in my physical exam—significant cranial nerve deficits associated with

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							primary diagnosis. Otherwise no focal neurologic deficits observed in the upper and lower extremities. Heart was regular rate and rhythm lungs are clear. Abdomen had normal bowel sounds and was nontender. He has no peripheral edema to speak of. Miller-Fischer Variant GBS - F/u with neuro in 1-2months
1242331	4/22/2021	TX	43	M	4/5/2021	4/8/2021	Patient had tinnitus for 3 days following Pfizer vaccine, and then sudden sensorineural hearing loss ~ 4 days after the Pfizer vaccine.
1240223	4/22/2021	MO	25	M	4/16/2021	4/17/2021	Tinnitus on right ear and partial hearing loss on same ear.
1241633	4/22/2021	TX	49	F	3/13/2021	3/13/2021	sudden onset profound sensorineural hearing loss in right ear on 3-15-21
1242344	4/22/2021	MI	74	F	4/1/2021	4/7/2021	On march 4th 1st dose, high fever fatigue chills 2-3 days, left armpit lymphonode tender pain for about 1 week. on april 1st, 2nd dose,felt worse,but no armpit pain. on the 7th day suddenly ear ringing, noise hearing loss. can hear louder sound with noise can not hear the word. She used to have hearing problem but never has diffeculty for communication ,never use hearing aid. she had hearing test done. The fever and bodyn ache was treated with tylenol. hearing loss treated with methylprednisonlone for 6 days. no obvious effect.
1243475	4/22/2021	IL	49	F	4/7/2021	4/12/2021	Severe hearing loss left ear Tinnitus Ear fullness/pressure



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1235769	4/21/2021	CA	28	M	4/6/2021	4/6/2021	seizures/Convulsions; weird metal or acidic taste in my mouth; felt heavy; feel shaky; back spasms; blood pressure spiked to higher than normal levels; nauseous; weakness on my left side; pain at the injection site; pain at the injection site, my back, and neck; pain at the injection site, my back, and neck; feel super tired; This is a spontaneous report from a contactable consumer (patient). A 28-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in arm left on 06Apr2021 11:15 (Batch/Lot Number: EP7533) as single dose for COVID-19 immunisation. Medical history included axenfeld reigers, bilateral congenital iris coloboma, bilateral glaucoma, hearing loss. Known allergies: peanut, albuterol, amoxicillin-pot clavulante, doxycycline, fentanyl, levosalbutamol (LEVALBUTEROL), oxycodone-acetaminophin, sedation. Concomitant medications in two weeks: cryofood (unspecific), folic acid, cyanocobalamin (B12), timolol and dorzolamide hydrochloride/timolol, all from unknown date for unknown indication. First, patient had a weird metal or acidic taste in mouth. Following that, patient felt heavy. Next, began to feel shaky having back spasms. His blood pressure spiked to higher than normal levels and started feeling shakey dropped. Patient was laid down by nursing staff and blood pressure dropped. After being laid down, patient started having seizures/convulsions, paramedics were called and patient was given midazolam hydrochloride (VERSED, anti-seizure meds) and was taken to the ER (emergency room). Once patient arrived at the ER, he felt nauseous and was given anti-nausea medication, after about 4 hours patient was released. But he was experiencing weakness on left side and pain at the injection site, back, and neck, and felt super tired. AEs onset at 11:30 of 06Apr2021. Outcome of the events was resolving. Patient had no COVID prior vaccination and had no COVID tested post vaccination.

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1235519	4/21/2021	NY	84	F	3/8/2021	3/8/2021	<p>Sinus infection got worse; Headache; Lost hearing; Had bothering tinnitus; All her body feels sick; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEAFNESS (Lost hearing) in an 84-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. Unknown) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Allergy (Allergy to Vaccine NOS). Concurrent medical conditions included Diabetes. On 08-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 08-Mar-2021, the patient experienced DEAFNESS (Lost hearing) (seriousness criterion medically significant), TINNITUS (Had bothering tinnitus), MALAISE (All her body feels sick) and HEADACHE (Headache). On an unknown date, the patient experienced SINUSITIS (Sinus infection got worse). At the time of the report, DEAFNESS (Lost hearing), TINNITUS (Had bothering tinnitus), MALAISE (All her body feels sick), SINUSITIS (Sinus infection got worse) and HEADACHE (Headache) outcome was unknown. No concomitant medicines reported. Treatment information included unspecified antibiotic, diphenhydramine and prednisone. Based on the current available information and the temporal association between the product use and the start date of the events a causal relationship cannot be excluded. Action taken with the drug in response to the events was not applicable.; Sender's Comments: Based on the current available information and the temporal association between the product use and the start date of the events a causal relationship cannot be excluded.</p>

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1235684	4/21/2021	IL	71	F	2/5/2021	3/8/2021	<p>If not 100 % sure but she may had an ischemic stroke,This is not normal; viral meningitis; chills; vision problems,vision problem was bad; hearing problems; This spontaneous case was reported by a consumer and describes the occurrence of ISCHAEMIC STROKE (If not 100 % sure but she may had an ischemic stroke,This is not normal) and MENINGITIS VIRAL (viral meningitis) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. QQ2A21 and 038K20A) 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.). On 05-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 07-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 08-Mar-2021, the patient experienced VISION BLURRED (vision problems,vision problem was bad) and HEARING DISABILITY (hearing problems). On an unknown date, the patient experienced ISCHAEMIC STROKE (If not 100 % sure but she may had an ischemic stroke,This is not normal) (seriousness criterion medically significant), MENINGITIS VIRAL (viral meningitis) (seriousness criterion medically significant) and CHILLS (chills). At the time of the report, ISCHAEMIC STROKE (If not 100 % sure but she may had an ischemic stroke,This is not normal), MENINGITIS VIRAL (viral meningitis), VISION BLURRED (vision problems,vision problem was bad), HEARING DISABILITY (hearing problems) and CHILLS (chills) outcome was unknown. Action taken with mRNA-1273 in response to the events was not Applicable. Treatment medication includes: Blood thinner Rosuvastatin, 81mg aspirin. Additional information:After second dose had chills but she hear from people who had fever, chills and etc. Woke up on Monday March 8 with vision problems, hearing problems. She waited 8 days until she went to the doctor because everybody says had a reaction but this was getting worse. Went to eye doctor because of vision problem was bad, on March 18 4 weeks after first symptoms appears, optometrist send to her internist and after consultation, on March 23 had 2 MRI head and brain. March 26 had contrast MRI brain, send her for a carotid study in her neck. Went to</p>

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1235761	4/21/2021			F	3/22/2021	3/23/2021	<p>the internist again, April 2 send to spinal test. April 5 echocardiogram, yesterday went to first appointment with her vision therapeutics. This morning went to the neurologist send her for 2 more brain MRI. If not 100 % sure but she may had an ischemic stroke, doctor will confirm it with the studies. Neurologist confirm she has viral meningitis and the symptoms are similar with ischemic stroke, but that is not confirmed yet. 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. Further information is requested.; 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. Further information is requested.</p> <p>experiencing right ear losing/hearing loss; vertigo; My head is cloudy; I have headaches also; This is a spontaneous report from a contactable consumer (patient) via medical information team. A 63-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: unknown), via an unspecified route of administration on 22Mar2021 at a single dose for COVID-19 immunization. The patient's medical history was not reported. There were no concomitant medications. On 23Mar2021, the patient was experiencing right ear losing/hearing loss in volume. She had vertigo and her head was cloudy. She had headaches also. Patient was suggested to consult with her doctor/healthcare provider about what you have experienced/are experiencing. The outcome of the events was unknown. Follow-up attempts are possible; Information about lot/batch number is requested.</p>

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1235771	4/21/2021	CA	70	M	1/15/2021	1/1/2021	noticeable rapidly deteriorating hearing loss experienced; This is a spontaneous report from a contactable consumer (patient). A 70-year-old male patient received first dose of BNT162B2, (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Formulation: Solution for injection; Lot Number: EL8982) via an unspecified route of administration on 15Jan2021 16:30 (at the age of 70-year-old) as single dose for COVID-19 immunization. Medical history included diabetes, high blood pressure. Concomitant medication(s) included valsartan; nicametate dihydrogen citrate (NICAMETA); dipyridamole. It was reported that around the time of the 1st Pfizer Covid-19 vaccine shot, patient experienced noticeable rapidly deteriorating hearing loss in Jan2021. It was reported that patient was not diagnosed with COVID-19 prior to vaccination. The patient underwent lab tests and procedures which included RT-PCR: negative on 01Apr2021. Therapeutic measures were taken as a result of deafness unilateral included oral steroids, steroid injections into ear drum. Outcome of event was not recovered. Follow up attempts are completed. No further information is expected.

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1235777	4/21/2021	CA	70	M	2/5/2021	2/20/2021	2 weeks after 2nd dose, sudden profound hearing loss in left ear on 2/20/21; This is a spontaneous report from a contactable consumer (patient). A 70-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration on 05Feb2021 18:00 (Batch/Lot Number: EM9809) as single dose for covid-19 immunisation. The COVID-19 vaccine was administered at health facility. Medical history included diabetes, high blood pressure. Prior to vaccination, the patient was not diagnosed. Concomitant medications included valsartan taken for an unspecified indication, start and stop date were not reported; nicametate dihydrogen citrate (NICAMETA) taken for an unspecified indication, start and stop date were not reported; dipyridamole taken for an unspecified indication, start and stop date were not reported and 'Novartis' product. The patient received the first dose of bnt162b2 (lot number: EL8982) on 15Jan2021 04:30 PM and around the time of the 1st shot, noticeable rapidly deteriorating hearing loss experienced, declining more in right ear according to audiometry test on 12Feb2021. The patient experienced 2 weeks after 2nd dose, sudden profound hearing loss in left ear on 20Feb2021 08:30 AM. 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 oral steroids, steroid injections into ear drum. The patient underwent lab tests and procedures which included Covid-19 RT-PCR test: negative on 01Apr2021. The outcome of the event was not recovered.

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1235787	4/21/2021	VA	41	M	3/16/2021	3/16/2021	lost hearing in right ear; everything sounds muffled; constant buzzing; felt foggy, like brain fog; tired, really tired; This is a spontaneous report from a contactable consumer (patient). A 41-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration at age of 41-years, at single dose in left upper arm on 16Mar2021 at 12:00 (Lot Number: EP6955) for covid-19 immunisation. The patient medical history was none. Weight was 99.79 kg and Height was 191 cm. There were no concomitant medications. The patient previously received tetanus vaccine for immunisation when he was a kid. The patient reported that he had his first shot and was scheduled to take second shot today (on 06Apr2021). He stated that two days after the first shot, on 18Mar2021, he didn't have any arm pain, nausea, vomiting, or headaches. He lost hearing out of right ear. He already went to the physician about it. He was scheduled to go to Ear Nose and Throat doctor on 12Apr2021. He stated they checked his ear and everything. The hearing loss was not related to any kind of ear wax or anything. He went to urgent care, so they were limited to what they can do, and he was referred out to Ear Nose and Throat. He said everything sounded muffled and liked a constant buzzing in that ear. He had never had this problem. That doctor was going to check his ears and would do a hearing test on 12Apr2021. He confirmed that the hearing loss started on 18Mar2021. He also confirmed that the hearing loss was still ongoing and it was about the same, or persisting. The patient also reported that after the first one he didn't have the side effects that they claim to have. He hadn't died from it. He was just tired really tired, two to three hours after the shot, he got the shot at 12 noon, so about 2 to 3 o'clock. He laid down to rest and went to sleep. He woke up the next morning, went to work and was fine. He stated that other than that no headache, no arm pain, no diarrhea, no vomiting. He just felt foggy like brain fog the following morning after the vaccine till about mid-day and it went away. It only lasted four or five hours. He confirmed that was on 17Mar2021, as well as, that he had recovered completely. The patient received treatment and included that prescription medication for ear: Ofloxacin 0.3%. Instill five drops in the right ear two times a day for seven days. There was no additional vaccine administered on

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							same date of the Pfizer Suspect. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Event outcome for Hearing loss, Muffled hearing in both ears and Ear buzzing was not recovered, while for Tiredness and Foggy feeling in head was recovered on 17Mar2021.
1236721	4/21/2021	PA	67	M	3/26/2021	3/28/2021	Loss of hearing in right ear/ringing-noise in right ear
1237262	4/21/2021	MS	48	F	4/15/2021	4/15/2021	Patient complains of hearing loss in left ear since receiving vaccine-referred to ENT
1237484	4/21/2021	GA	69	F	2/16/2021	2/1/2021	Hearing loss



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1235686	4/21/2021	NE	78	F	2/27/2021	4/7/2021	Hearing loss in both ears, worse in left; This spontaneous case was reported by a patient and describes the occurrence of DEAFNESS BILATERAL (Hearing loss in both ears, worse in left) in a 78-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 025A21A and 016B21A) for COVID-19 vaccination. The patient's past medical history included No adverse event (Medical history was not provided). Concomitant products included PROBIOTICS NOS, VITAMIN D3, VITAMIN B12 NOS and BIOTIN for an unknown indication. On 27-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form(s). On 27-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form(s). On 07-Apr-2021, the patient experienced DEAFNESS BILATERAL (Hearing loss in both ears, worse in left) (seriousness criteria disability and medically significant). At the time of the report, DEAFNESS BILATERAL (Hearing loss in both ears, worse in left) outcome was unknown. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 12-Apr-2021, Acoustic stimulation tests: hearing loss (abnormal) Hearing loss. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant medications also included Thyroid medicine. Patient experienced hearing down on the right side of the ear. It was buzzing at first. Patient started taking Prednisone on 13-Apr-2021 and had to take it for 18 days. Company comment: Based on the current available information and temporal association between the use of the product and the start date of this 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 this event, a causal relationship cannot be excluded.
1237628	4/21/2021	TX	51	F	3/6/2021	3/7/2021	Bell's palsy, tinnitus, and hearing loss

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1235585	4/21/2021	TX	55	F	3/30/2021	4/5/2021	On April 5th I was sitting, watching TV. Suddenly, it felt as though I needed to pop my left ear and I couldn't. I also couldn't hear out of that ear. It was a roaring sound like the ocean and intermittent buzzing and ringing in my ear. The next day was no better and I started getting dizzy. By April 5th I had a very bad case of Vertigo and had to go to the hospital. I was given an IV with motion sickness meds and nausea meds, as well as antibiotics and I think a steroid shot. I still couldn't hear. I was sent home with prescriptions. The vertigo gradually got better over the following days, but I never regained my hearing. On the 12th of April, still feeling the affects of the vertigo, and out of nausea meds, I went to my primary doctor. I received another steroid shot and more meds. On the 19th I went again and got a hearing test. I am deaf in my left ear and will see a specialist.
1237775	4/21/2021	TX	52	M	3/20/2021	3/22/2021	the morning after my 2nd pfizer vaccine dose --3/21-2021 - i experienced hearing loss and non-stop tinnitus. after 29 days of 24/7 ear-ringing I finally went to an ear specialist on 04/19/2021. i was administered a hearing test and an ear exam. was told i have lost 'approximately 35% of my hearing in both ears.' the ear specilist did not discuss the fact that i had ZERO hearing loss and ZERO tinnitus prior to my 2nd vaccine dose. The ear speciaalist simply advised me to either purchase hearing aides or download some white noise apps to play overnight. there was no advice or insight as to how the vaccine did this to me.
1239797	4/21/2021	AL	42	F	4/5/2021	4/8/2021	I had the vaccine on 4/5 and on 4/8 I experienced sudden sensorineural hearing loss, unilaterally left ear... I am now profoundly deaf in my left ear. Suffering tinnitus and vertigo.

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1235755	4/21/2021	TX	64	F	3/22/2021	3/26/2021	Hearing loss on left ear; This is a spontaneous report from a contactable consumer (patient). A 64-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 22Mar2021 13:30 (Lot Number: ER8782), age at vaccination of 64-years-old as single dose for covid-19 immunisation. Medical history included thyroid disorder from an unknown date and unknown if ongoing, hypertension from an unknown date and unknown if ongoing (high blood pressure). Patient was not pregnant and was not pregnant at the time of vaccination. The patient previously took naproxen and experienced drug hypersensitivity; patient received fist dose of bnt162b2 for covid-19 immunisation on an unspecified date (Lot Number not available). The patient experienced hearing loss on left ear on 26Mar2021 14:30, that resulted in emergency room/department or urgent care. Therapeutic measures were taken as results of the event and included administration of steroid injection, prednisone and Meclizine. The patient did not receive other vaccine in four weeks; covid prior vaccination: No; Covid tested post vaccination: No. Outcome of the event was not recovered.

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1235642	4/21/2021	CT	49	F	3/11/2021	4/10/2021	Loss of hearing in left ear; Ringing in left ear; This spontaneous case was reported by a non-health professional and describes the occurrence of DEAFNESS (Loss of hearing in left ear) in a 49-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 037B21A and 040A21A) 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 recorded medical history). On 11-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 10-Apr-2021, the patient experienced DEAFNESS (Loss of hearing in left ear) (seriousness criterion medically significant) and TINNITUS (Ringing in left ear). At the time of the report, DEAFNESS (Loss of hearing in left ear) and TINNITUS (Ringing in left ear) outcome was unknown. Concomitant product use was not provided by the reporter. Treatment information was not provided. The patient received both scheduled doses of mRNA-1273 prior to the event; therefore, action taken with the drug in response to the event is not applicable. Company Comment - Based on the current available information and temporal association between the use of the product and the onset date of the reported 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 onset date of the reported events, a causal relationship cannot be excluded.
1233590	4/20/2021	CT	63	F	4/17/2021	4/18/2021	About a day after getting my second Pfizer COVID vaccine, I started hearing a ringing in my ears -- high in pitch. It is fairly constant during my waking hours and slightly louder or more dominant in my right ear. There is no external sound making this noise. Moreover, I do not have hearing loss.

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1235187	4/20/2021	CA	48	F	4/1/2021	4/1/2021	I had just finished my menstrual bleeding two days before the shot. I started bleeding again after getting the vaccine. Breast tenderness. Hearing loss on day 3 that went back to normal two days later, followed by the most excruciating headache I have ever had that hasn't subsided for 48 hours straight until I went to a migraine clinic. Relief now, 5 hours later., maintaining excederine doses and migraine medication when migraine headache returns.
1234832	4/20/2021	FL	73	M	2/23/2021	3/15/2021	Hearing loss ...right ear one morning when I woke up. ...Then left ear a day later. My first doctors apt. was on 3/18/2021. They thought cleaning the ears would do. Not so. To schedule next apt on 3/6/21 was harder to get apt. I was put on 50mg of Prednisone daily for 10 days. I saw the doctor again today and he gave me a second type of steroid which was thru the ear drum into the nerve. I go back on 4/27/21. I have got back hearing in the left ear but I am only 30% in the right ear.
1234443	4/20/2021	CO	16	F	3/31/2021	3/31/2021	After the first dose, mild dizziness and nausea followed by massive inflammation in joints and face, severe fatigue and loss of hearing in right ear. Hearing returned in 3 days, general malaise until a week before 2nd shot when she started having severe bloody noses and EXTREMELY heavy period. After the second dose, 45 minute nose bleed soaked through two wash cloths, so many blood clots it clogged the sink.
1234227	4/20/2021	FL	69	F	2/22/2021	2/23/2021	Patient awoke the morning after vaccination with severe tinnitus, worse in the left ear. She was evaluated by ENT approximately 2 weeks after symptom onset. At that time, there was no improvement in the symptoms. Audiogram was performed. Patient was found to have high frequency hearing loss. No baseline audiogram was available for comparison. She had no known hearing loss history. Patient was re-evaluated approximately 2 months s/p vaccination, with persistent symptoms. No improvement to date.
1234189	4/20/2021	FL	48	F	12/30/2020	1/3/2021	After 3 days of receiving 1st dose. I started having left side facial spasms. Symptoms continued with chronic left ear pain, vision loss, hearing loss and speech which lead to left side facial paralysis. ( Bell's Palsy).

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1235432	4/20/2021	MT	72	F	2/12/2021	3/12/2021	Sudden hearing loss in both ears about equally from 40% to 70%; Hearing was normal before with no problems
1233686	4/20/2021	CA	58	M	4/5/2021	4/6/2021	I received my J&J vaccine on 04-05-2021 at 11am and on 04-6-2021 around 6pm I experienced a plugged white ear. The sound in my right ear was completely deformed, I had muffled hearing. I saw an ENT doctor, on 04-07-2021 at 4pm and he performed an audiology test but by that time my hearing had degraded. I have cohesive hearing loss, age related and my hearing has worsened since last appointment. My symptoms lasted less than 24 hours and I did not receive medicine treatment. On the other hand, I also had secondary symptoms to my left ear, similar to what I experienced in my right ear. I experienced a pulsating drum beat hearing to my left ear and I also did not receive care or treatment. These symptoms lasted temporarily and again I did not receive any medicine for my right and left ear.
1232360	4/20/2021	VA	50	F	2/4/2021	2/9/2021	Sudden and significant hearing loss in left ear several days after second dose.
1233455	4/20/2021	FL	55	F	4/11/2021	4/12/2021	The patient had the COVID 19 vaccine on 4/11. The following day, she developed severe nonpositional vertigo and sudden deafness and tinnitus in the right ear. She went to an urgent care and was given methylprednisone dose pak and meclizine with some relief of the vertigo, however the deafness persisted. I saw her in clinic on 4/16 and obtained a hearing test which confirmed a profound sensorineural loss in the right ear. This along with the vertigo symptoms was suggestive of labyrinthine injury to the right ear. The patient was started on high dose steroids and will follow up with a repeat hearing test in 2 weeks.
1233083	4/20/2021	VA	81	M	2/22/2021	3/23/2021	Hearing loss and then additional hearing loss one week after initial ENT dr appointment to diagnose.
1233002	4/20/2021	NE	59	M	4/1/2021	4/1/2021	Patient developed tinnitus approximately 2 hours after receiving the Covid vaccine. He noted loss of hearing the same night. The following day he had dizziness and would vomit with certain movements. As of 4/20 hearing test shows severe loss of hearing in his left ear. Unsure at this time if hearing will return.

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1232356	4/20/2021	MA	34	F	3/6/2021	3/23/2021	Tinnitus, hearing loss in left ear, and vertigo all happened on 3/23/2021 at 3:05pm. By 3:30, the vertigo attack had become severe with vomiting lasting until 8:30pm. Tinnitus is still present today (4/20/2021). Hearing loss in left ear resolved after a second severe vertigo attack on 4/13/2021 (vomiting lasting 10 hours). Saw PCP and referred to ENT for further testing (upcoming) after first vertigo attack.
1231437	4/20/2021	AZ	36	F	3/27/2021	3/27/2021	Constant Tinnitus began in left ear the night I received the Covid-19 Vaccine shot. After a couple of days more symptoms appeared, including: Left ear fullness/pressure/inflammation feeling, left ear numbness, left outer ear tightness, shooting nerve pain in into left ear (outside and inside ear), shooting nerve pain towards the scalp on left side, extreme cramping inside and outside left ear. The tinnitus alternates between loudness of 2-7, at worst its a high pitched ringing noise, at best its a hissing noise. Often also a whistling noise, crackling noise, sleigh bell noise, occasionally pulsatile. Also have increased anxiety due to the tinnitus. Audiologist confirmed unilateral hearing loss in left ear in the Ultra high frequency hearing range (35db at 10K Hz, 60 dB at 11.2K Hz, 50 dB at 12.5K Hz, 40 dB at 14K Hz, and 35 dB at 16K Hz). Audiologist recommended practicing Mindfulness and listening to classical music, so as to not be in quiet environment, where I might focus more on the ringing in my ear. Taking supplements including: Multi-Vitamin, Iron supplement, Vitamin D3, Vitamin B Complex, Alpha Lipoic Acid, Bio-Flavonoids, Systemic enzymes, Benfotiamine, Turmeric. Currently 3.5 weeks later, I still have tinnitus, but it is usually at a volume of 3 or 4. It more often is hissing noise with alternating high pitched ringing. The ear fullness, numbness and nerve pain is less, but still there. ENT PA prescribed Methylprednisolone 7 day tapered dose on 4/15/2021 to take if painful symptoms of nerve shooting continue or get worse. Nerve shooting pains improved slightly, so as of yet have not begun the methylprednisolone. Anxiety has improved with use of Classical Music and Mindfulness. Also found a Facebook Group of those suffering tinnitus after the Covid-19 vaccine, and have found support there to cope.

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1233817	4/20/2021	CT	51	F	3/30/2021	3/31/2021	Sever hearing loss and tinnitus. Day after shot clogged ear and fullness, noise. Went to ent hearing test showed severe hearing loss was put on round of steroids.
1231558	4/20/2021	VA	67	F	4/5/2021	4/15/2021	Sudden hearing loss, Right ear only. Ruled out physical blockage of external ear canal. No medical history for SHL. Onset was textbook: Overnight development, Acute onset, Nearly total hearing loss in R ear. Accompanied by minor tinnitus / low frequency. No recent history of injury or illness.
1230392	4/19/2021	CA	67	F	3/12/2021	3/14/2021	1) Kidney infection - horrible pain; 2) Lost all hearing in left ear. First shot - February 11, 2021. Second shot - March 12, 2021. Two days after second shot - horrible pain in lower right side. Kidney infection. Lab tests confirmed. Treated. One month after Second shot, April 11 - lost all hearing in my left ear: Sudden Sensorineural hearing loss, or SNHL. Still no resolution. Trying everything. I am deaf.
1227478	4/19/2021	FL	63	F	3/26/2021	3/27/2021	The day following my injection I experienced escalated Tinnitus. Different tones and pitches. Occasional ear pain. Feeling of fullness in the ears that was not present before vaccine. Neck and shoulder pains. 1 week away from second dose and I am still experiencing escalated tinnitus. Slightly improved from initial response but escalated from level before injection. I feel I have had some hearing loss.



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1227887	4/19/2021	DC	26	F	4/1/2021	4/1/2021	<p>sensorineural hearing loss; tinnitus followed by sensation of ear fullness; tinnitus followed by sensation of ear fullness; This is a spontaneous report from a contactable other healthcare professional (patient). A 26-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EM9809 and expiration date not provided) via an unspecified route of administration administered in the left arm on 01Apr2021 10:00 as a single dose for COVID-19 immunization. Medical history included Gilbert syndrome. The patient is not pregnant at the time of vaccination. The patient had no known allergies to medications, food, or other products. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient's concomitant medications were not reported. The patient did not receive any other vaccine within 4 weeks prior to the COVID vaccine. The patient took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6204) via an unspecified route of administration in the left arm on 10Mar2021, 08:30 for Covid-19 immunization. On 01Apr2021 17:00, the patient experienced 2 hours of tinnitus followed by sensation of ear fullness. She woke up the next day, 02Apr2021 with sensorineural hearing loss for which she was given a course of high dose steroids and requiring follow up with ENT and otoneurologist. The events resulted in Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. Treatment received for the adverse events includes 60 mg prednisone in emergency department and was prescribed 10 days. The outcome of the events was not recovered. The reporter assessed the events as serious (disabling/incapacitating).; Sender's Comments: Based on the close temporal relationship, A possible contributory role of the suspect product to the development of Tinnitus, sensation of ear fullness and Sensory Neural Hearing Loss 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</p>

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							Investigators, as appropriate
1228225	4/19/2021		28	F	4/9/2021	4/18/2021	On 19 April 2021 patient developed left-sided facial weakness in the afternoon, seen in the ER that evening and diagnosed with left-sided Bell's palsy. No associated loss of hearing or taste. No other symptoms of weakness or diplopia. Does have a history of multiple sclerosis (on disease modifying treatment).
1228757	4/19/2021	NY	46	F	4/13/2021	4/14/2021	Resting heart rate of 116 bpm (standard ~55-60). (Also, ongoing exacerbated tinnitus/hearing loss - 5 weeks post first shot)
1229310	4/19/2021	CA	40	F	4/5/2021	4/10/2021	- Sudden loss of hearing in left ear on April 10 (5 days after second COVID shot) upon waking up in the morning around 8:00 am. - Loss of hearing was becoming more pronounced, so I went to the doctor for an exam on 4/14. Dr. could not determine cause of hearing loss. Scheduled an audiology exam and appointment with ENT for 4/15. Doctor prescribed oral steroids to try and save hearing. While I was at the pharmacy waiting for my Rx, I suddenly developed vertigo around 5:30 pm, which resulted in being sent to the ER. I could not stand, felt faint, and was vomiting excessively. - At the ER, was given lots of anti-nausea medication. Eventually, the tests determined that there was nothing obviously wrong in my brain (aneurysm, stroke, tumor, etc.), and the medication stopped the vomiting such that I was able to be discharged around midnight.
1229357	4/19/2021	IL	32	M	3/11/2021	3/22/2021	Sudden sensorineural hearing loss in my right ear. No improvement. Tinnitus- Severe

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1229875	4/19/2021	MN	27	F	4/1/2021	4/12/2021	I received my first Moderna shot on April 1, 2021. On April 12th, I began experiencing what felt like air pressure issues in my right ear on and off throughout the day until April 14th, then I felt like I was loosing hearing on my right ear. On April 15th, exactly two weeks after recieving my first Moderna dose, I completely lost hearing on the right side of my ear and had awful ringing in my ear. I went to see a PCP and they could not diagnose me. On Monday, April 19th I went to see an ENT specialist, they did not find an infection or ear wax built up and said I may have Sudden Sensorineural Hearing Loss (SSHL) and prescribed me Prednisone. They were not 100% sure if the vaccine could be the cause but said it is a possibilty, especially as the number of people keeps increasing. My left hearing is perfect but my right is almost nonexistent. I am 27 year old, female, petite and healthy. I have never had any hearing problems in my life and this occured within 2 weeks of my vaccination. It is difficult to hear and my quality of life just in the last week had diminished as it is overwhelming to drive, be in meetings, or even listen to music.
1230604	4/19/2021	CA	66	F	2/7/2021	2/10/2021	Several days after the vaccination I developed pulsatile tinnitus. No apparent hearing loss. It seems to be resolving in that the tinnitus is less loud and somewhat less frequent.

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1230958	4/19/2021	VT	72	F	3/5/2021	3/1/2021	teeny weeny buzzing sound in right ear , different sound in ear; woke up during a night, and could not hear/could not hear for a week; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SUDDEN HEARING LOSS (woke up during a night, and could not hear/could not hear for a week) in a 72-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 19B21A and 30A21A) 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 not provided). On 05-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 10-Mar-2021, the patient experienced TINNITUS (teeny weeny buzzing sound in right ear , different sound in ear). In March 2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced SUDDEN HEARING LOSS (woke up during a night, and could not hear/could not hear for a week) (seriousness criterion medically significant). In March 2021, SUDDEN HEARING LOSS (woke up during a night, and could not hear/could not hear for a week) had resolved. At the time of the report, TINNITUS (teeny weeny buzzing sound in right ear , different sound in ear) outcome was unknown. Concomitant product use was not provided. Treatment included a visit to the patient's Primary Care Physician (PCP) who checked her ear and said her ear looks good, there was no wax. An appointment was scheduled for an Ear Specialist Doctor. The patient stated there are still different sounds in her right ear. Over a period of time it is getting better but still not there.; 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. Further information has been requested.

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1230960	4/19/2021	WI	58	F	3/25/2021	3/25/2021	could not hear with my left ear at all; hearing lots of noise in left ear; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS UNILATERAL (could not hear with my left ear at all) in a 58-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 016B21A) 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). On 25-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Mar-2021, the patient experienced DEAFNESS UNILATERAL (could not hear with my left ear at all) (seriousness criterion medically significant) and TINNITUS (hearing lots of noise in left ear). On 04-Apr-2021, DEAFNESS UNILATERAL (could not hear with my left ear at all) was resolving and TINNITUS (hearing lots of noise in left ear) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Mar-2021, Acoustic stimulation tests: abnormal (abnormal) she has 90% of hearing lost. According to the patient, 3 hours after receiving vaccine, she started hearing lots of noise in her left ear. She plugged her right ear and found that she could not hear with left hear at all. She went to emergency room where she was given a low dose steroid. She was prescribed a high dose steroid. No relevant concomitant medications were reported. Based on the current available information and temporal association between the use of the product and the start date of these 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 these events, a causal relationship cannot be excluded.

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1231262	4/19/2021	NM	41	F	4/7/2021	4/8/2021	A day after receiving my first vaccine, the onset of ringing in my ears began and my ear felt full and I had dizziness. I went to my primary Doctor and she ruled out ear infection and referred me to an ENT doctor and an audiologist. They gave me an audiogram and then the ENT doctor could not give a definite diagnosis except that I now have hearing loss in both my ears and tinnitus could be a chronic issue. I continue to suffer hearing loss and tinnitus in my ears since I received my vaccine and it continues to this day.
1229631	4/19/2021	TX	23	F	4/14/2021	4/19/2021	Ringing in my right ear, small amount of hearing loss in right ear as well.
1225750	4/18/2021	MD	52	F	4/15/2021	4/16/2021	Left arm pain Fatigue/foggy Headache Reason for reporting: Tinnitus (ear swooshing and ringing) developed in left ear, slight hearing loss aabout 12 hours after vaccine
1227303	4/18/2021	VA	32	F	4/12/2021	4/16/2021	Received dose on Monday 4/12 at 7:15am. Low grade fever, neck ache and chills developed that evening and went away by next morning. On 4/16, woke up with almost no ability to hear out of my left ear and there was a very loud ringing sound in my ear. Happened off and on throughout the day but by evening, I only heard a ringing noise. I went to the urgent care and they said my ear had no sign of ear infection or allergies. Next morning, I couldn't hear almost anything out of my ear with a very loud ringing noise. Was consistent through 4:30pm that day. Went back to the urgent care and a different nurse practicing confirmed my ear looked completely normal. I've never experienced deafness or ringing in my ear before. Since this morning (4/18) I have had a low ringing sound in my left ear, but no more deafness.
1227168	4/18/2021	CO	66	M	3/23/2021	3/26/2021	Increased tinnitus and increased hearing loss, no treatment

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1227161	4/18/2021	PA	62	F	3/16/2021	3/20/2021	Dramatic loss of hearing in both ears; Tinnitus; This is a spontaneous report from a contactable consumer (patient). A 62-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration, administered in left arm on 16Mar2021 13:30 (Batch/Lot Number: EP 7534) as single dose for covid-19 immunisation at a clinic. Medical history included depression and high blood pressure. The patient has no allergies to medications, food, or other products. The patient was not diagnosed with COVID-19 prior to vaccination. Concomitant medications included duloxetine hydrochloride (CYMBALTA), losartan potassium (COZAAR) and lamotrigine. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced tinnitus and dramatic loss of hearing in both ears on 20Mar2021. The events resulted in emergency room/department or urgent care visit. The events were not treated. The patient has not been tested for COVID-19 since the vaccination. The outcome of the events was not recovered.
1226688	4/18/2021	FL	63	M	3/17/2021	3/27/2021	Moderate to severe sudden hearing loss and tinnitus starting on March 27th - 10 days post-vaccination.
1226457	4/18/2021	OH	69	F	2/12/2021	2/19/2021	Extreme pounding in left ear. Woke me from a sound sleep. Fullness and hearing loss in left ear
1226387	4/18/2021	DE	67	F	2/26/2021	3/12/2021	Ringing and slight hearing loss in left ear.
1227335	4/18/2021	VA	81	F	2/26/2021	4/11/2021	98% Hearing Loss

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1226089	4/18/2021	OH	64	F	3/27/2021	4/15/2021	(1) Triggered migraine headaches. I have had migraines starting around age 4, through age 53 (with a brief respite during pregnancy in 1998/90). I have had none since menopause. Starting 2 weeks after my first dose (3/06/21 - Pfizer EN6206) I have had migraines most days, including two severe ones. They have been continuous since my second dose, requiring medication with aspirin and ibuprofen, but seem to be near the end of active migraines 3 weeks after my second dose. (2) Three days ago I noticed that my tinnitus was dramatically worse. I have had tinnitus for more than 20 years (single frequency, corresponding to frequency at which I have a hearing loss). This may be a response to the aspirin needed to address the migraines, but the worsening began several days after my last aspirin (or ibuprofen) dose.
1225624	4/18/2021	NY	17	M	4/8/2021	4/11/2021	On the evening of 4/11/21, pt. suddenly had trouble hearing and had tinnitus in his left ear. He reports it felt clogged/stuffy "like being on an airplane" as well. He saw an ENT the morning of 4/12/21. The doctor cleared wax from pts. ear and an audiologist performed a hearing test. The results showed a loss of 50% of hearing in his left ear along with tinnitus. His diagnosis was sudden sensorineural hearing loss. Pt. was given an Rx for prednisone, valtrex and N-Acetyl-L-Cysteine for two weeks, which he started on 4/12/21. Dr. ordered an MRI with contrast of pts. internal auditory canals which will be performed on 4/21/21. Dr. referred pt to another ENT who pt. saw on 4/16/21. Drs. audiologist performed another hearing test which showed some improvement in hearing in the left ear but no improvement in the tinnitus. Dr. injected steroids through pts. left eardrum to the space behind it. Pt. will have additional injections on 4/23/21 and 4/30/21. As of today, 4/18/21, pt. reports that his hearing is worse and the tinnitus has not improved.



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1225475	4/18/2021	NY	17	M	4/8/2021	4/11/2021	Hearing loss and a clogged, stuffed feeling in the left ear. Significant level of tinnitus in the left ear. It came on suddenly in the evening 3 days after receiving the vaccine. Saw an ENT the following morning (April 12, 2021) who cleared the ears of wax and performed a hearing test. Diagnosed 50% loss of hearing in the left ear. No fluid in the ear or any explanation readily available. He diagnosed sudden sensorineural hearing loss. He prescribed Prednisone, Valtrex and N-Acetyl-L-Cysteine to begin immediately. He referred patient to a specialist who patient saw on 4/16/21 at 4pm. Doctor performed another hearing test that confirmed hearing loss and tinnitus in the left ear. The test showed perhaps slight improvement in hearing but not in level of tinnitus. Doctor injected steroids directly behind patient's left eardrum during the visit and Patient is scheduled for follow up injections on 4/23/21 and 4/30/21. patient was directed to continue taking all the medications prescribed by doctor on 4/12/21 (prednisone, valtrex and N-Acetyl-L-Cystine) Patient is scheduled for an MRI of his internal auditory canals on 4/21/2021 which was ordered by doctor.

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1224882	4/18/2021	WA	58	M	3/30/2021	4/2/2021	Right ear Hearing loss; more tinitas in ear; This is a spontaneous report from a contactable consumer (patient) reported for himself. A 58-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 30Mar2021 at 12:15 PM (Lot number: er8734) on the left arm as single dose for COVID-19 immunization. Medical history was not provided. There were no allergies to medications, food, or other products. Patient had unspecified concomitant medication(s). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient did not diagnose with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. On 02Apr2021 at 03:00 AM, the patient experienced right ear hearing loss, and more tinitas in ear, happened 4 days after injection; events also resulted in Doctor or other healthcare professional office/clinic visit. Treatment received for the adverse events including took Sudafed for 5 days. The outcome of events was not recovered. No follow-up attempts are needed. No further information is expected.

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1224531	4/18/2021			F	3/1/2021	3/8/2021	loss of hearing; Right arm sore; Tinnitus; Fatigue; Muscle aches; Hot and cold; High blood pressure.; This is a spontaneous report from a non-contactable consumer (patient). This female adult patient received bnt162b2 dose 2 via unspecified route of administration in right arm in Mar2021 02:00 PM (Lot number unknown) at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not provided. 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. The patient previously received bnt162b2 dose 1 via unspecified route of administration in right arm in Feb2021 02:00 PM (Lot number unknown) at single dose for COVID-19 immunization and experienced right arm sore. The patient received the second dose in Mar2021 and experienced loss of hearing, right arm sore, tinnitus, fatigue, muscle aches, hot and cold, high blood pressure on 08Mar2021 17:00. The events resulted in Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. The patient received Injection of steroid for ear as treatment. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the event events was recovered. Information on the lot/batch number has been requested.

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1224420	4/18/2021	WA	44	F	3/3/2021	3/15/2021	Became deaf in her right ear after receiving the 1st vaccine; This is a spontaneous report from a contactable consumer (patient). A 44-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot Number: En 6205), via an unspecified route of administration, administered in arm left on 03Mar2021 19:30 at single dose for COVID-19 immunisation. Medical history and concomitant medications were both reported as none. No known allergies. No other vaccine in four weeks, and no other medications in two weeks. There was no COVID prior vaccination. There was no COVID tested post vaccination. The patient became deaf in her right ear after receiving the 1st vaccine on 15Mar2021 12:00 with outcome of not recovered. The event resulted in doctor or other healthcare professional office/clinic visit. Treatment received for the event that included steroid injections. The patient underwent lab tests and procedures in 2021 which included hearing tests: unknown results, magnetic resonance imaging (MRI): unknown results. The patient received the second dose of BNT162B2 (Lot number: Ep 7534) in the right arm on 24Mar2021.

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1224416	4/18/2021	MD	63	M	3/20/2021	3/20/2021	severe Sudden Sensineural Hearing Loss in his left ear; Vertigo; loud tinnitus developed in both ears; This is a spontaneous report received from a contactable consumer (patient). A 63-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER2613) via an unspecified route of administration at left arm on 20Mar2021 at 13:15 (63-year-old at time of vaccination), at single dose, for COVID-19 immunization. The patient's medical history included epilepsy and chronic urticaria. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient had no known allergies to medications, food, or other products. Concomitant medications received within 2 weeks of vaccination included lamotrigine, hydroxyzine, and omalizumab (XOLAIR). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Within 8 hours of receiving vaccine (at 21:15 on 20Mar2021), loud tinnitus developed in both ears. Next morning (on 21Mar2021) he had severe sudden sensineural hearing loss in his left ear and vertigo. Seriousness criteria was reported as disability. Receiving steroid injections and oral steroids. Vertigo and tinnitus continue. Adverse events result in doctor or other healthcare professional office/clinic visit. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was not recovered. Information on the lot/batch number has been requested.
1224245	4/18/2021	WA	63	M	3/31/2021	4/17/2021	Nausea and dizziness 4/14 - 4/17. Sudden hearing loss and tinnitus in right ear on 4/17 (no prior tinnitus and previously only mild hearing loss in both ears).
1224227	4/18/2021	KS	26	M	4/15/2021	4/15/2021	Tinnitus and minor hearing loss in right ear, on and off, for last 2 days. No treatment taken so far.
1226303	4/18/2021	PA	34	F	4/15/2021	4/18/2021	Tinnitus and hearing loss in right ear. Stuffed sinus. Headache. Mussel ache.

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1222482	4/17/2021	OR	29	M	4/16/2021	4/16/2021	The patient is a 29-year-old adult male with severe intellectual/developmental disabilities, is Deaf and blind, and doesn't communicate with words. Since oral sedation was unavailable at the time of vaccination, extra precaution was needed to ensure that he was calm and relaxed before administration. Various distracting techniques were used, and being in his own environment mitigated stress that he might have experienced had he been in an unknown facility. Unfortunately, due to the nature of how quick the dose needed to be administered before he noticed that something was wrong, only about three fourths of the dosage (0.5 ML) was administered, possibly around 0.3 or 0.4. The provider is going to attempt to compensate for this in the second dose series after they are able to order an oral sedative from his primary care provider. No adverse reactions are noted at this time.
1223743	4/17/2021	CA	53	F	1/26/2021	3/6/2021	On day #39 after receiving the 2nd dose of the Moderna COVID 19 vaccine, I woke up with hearing loss, tinnitus and pressure in my left ear. I saw an ENT on 3/8/2021 and was given a 13 day regimen for Prednisone.
1223691	4/17/2021	FL	29	F	4/16/2021	4/16/2021	Dizziness, nausea, seeing black spots, loss of hearing, having difficulty speaking, neurological disorientation for roughly 25 minutes. (Unable to answer nurses questions or understand the questions being asked)
1223580	4/17/2021	ME	63	M	12/24/2020	3/1/2021	hearing loss
1219692	4/16/2021	MA	68	F	3/18/2021	3/23/2021	Five days after the first dose of the vaccine I experienced a sudden onset of tinnitus in my left ear. When it continued for more than a few days I did some research and found that others have experienced the same side effect. I started taking fish oil and a decongestant as suggested treatments for tinnitus but the ringing is still constant with only mild improvement. I have not experienced a hearing loss at this time. It has been 29 days since I had the first vaccine and 24 days since the onset of tinnitus.
1219139	4/16/2021	MA	59	M	4/15/2021	4/16/2021	My dad woke up this morning with partial hearing loss to his right ear. Other normal symptoms he has is back pain and a little small rash at injection site.

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1218664	4/16/2021	WY	49	M	3/22/2021	3/26/2021	SUDDEN SENSINEURAL HEARING LOSS
1218082	4/16/2021	CO	44	F	4/7/2021	4/15/2021	Woke up with hearing loss and sensitivity to loud sounds.

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1217466	4/16/2021	CA		F			<p>PATIENT LOST HEARING IN HER EAR; HAD A REALLY BAD EAR INFECTION; This spontaneous report received from a health care professional concerned a female of unspecified age. The patient's concurrent conditions included primary pulmonary hypertension. The patient received macitentan (tablet, oral, batch number: ZM021B0101 expiry: 30/NOV/2023) 10 mg, every 1 day, frequency, and therapy dates were not reported for primary pulmonary hypertension. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose, start therapy date were not reported for prophylactic vaccination. Concomitant medications included tadalafil. On an unspecified date, the subject experienced subject lost hearing in her ear, and had a really bad ear infection. The action taken with covid-19 vaccine ad26.cov2.s was not applicable; and dose of macitentan was not changed. The outcome of the patient lost hearing in her ear and had a really bad ear infection was not reported. This report was serious (Other Medically Important Condition). Version created to amend previously reported information on 16-Mar-2021: upon review Opsumit (macitentan) updated from concomitant to co-suspect, labeling and causality for co-suspect assessed.; Sender's Comments: V1 Additional information received in this version is regarding amendment of co-suspect. 20210341336-Covid-19 vaccine ad26.cov2.s -Hearing loss. This event(s) is considered not related. The event(s) has an unknown/unclear 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: UNDERLYING DISEASE 20210341336-Macitentan -Hearing loss. Follow-up received regarding Other Information: Amended co-suspect. This event(s) is considered not related. The event(s) has an unknown/unclear 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: UNDERLYING DISEASE</p>



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1218674	4/16/2021	MO	62	M	4/8/2021	4/9/2021	On 04/09/2021, day after 2nd Pfizer vaccine, woke up with stuffy head/chills. As day progressed towards work, changed to loss of hearing in right ear with phase shifting and ringing. Very disorienting and dangerous to work in busy kitchen. Made through weekend now little to no hearing in right ear with whirring, roaring, chirping. Saw Dr on 04/13 and started treatment for ear infection. Steroids and nasal spray for 3 days to no relief. Started antibiotics on 04/15. As of now at 10:36am on 04/16 no let up in all symptoms!
1216616	4/16/2021	CA	23	M	4/15/2021	4/15/2021	About 5 minutes after receiving the shot, patient complained of being light headed, hot, patchy vision, loss of hearing, pale color and almost passed out at the pharmacy contour. He had been helped to have a seat and drink some water, about 5 minutes later he felt much better but only experienced tingling in his fingertips. He stayed for another 20 minutes in pharmacy and mentioned he felt totally alright before leaving the pharmacy area.

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1221051	4/16/2021	NH	79	M	1/26/2021	2/11/2021	lost most the hearing in the left ear; had a bad day generally; This spontaneous case was reported by a patient and describes the occurrence of DEAFNESS UNILATERAL (lost most the hearing in the left ear) in a 79-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 013L20A and 022M20A) 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). On 26-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 11-Feb-2021, the patient experienced DEAFNESS UNILATERAL (lost most the hearing in the left ear) (seriousness criterion medically significant) and FEELING ABNORMAL (had a bad day generally). In April 2021, DEAFNESS UNILATERAL (lost most the hearing in the left ear) was resolving. At the time of the report, FEELING ABNORMAL (had a bad day generally) outcome was unknown. No relevant concomitant medications were reported. The patient confirmed lost most of the hearing in the left ear by a visit to the clinic after a hearing exam was done. The patient stated that he can hear better now but the left ear was not usable and could not use a telephone. It was better now but still not ok and was still "metallic." The patient does not know if 2nd dose had influenced the hearing and stated that he did not have prior history of hearing issues. Action taken with mRNA-1273 in response to events was not applicable. No treatment information was provided. Based on the current available information and temporal association between the use of the product and the onset date of the reported 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 onset date of the reported events, a causal relationship cannot be excluded.

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1219680	4/16/2021	CA	35	F	4/13/2021	4/15/2021	Loss of Hearing on left side. Right side was tremendous pressure. "Whoosing" sounds for 24 hours. Finally has day progressed hearing came back on left side but still feel pressure feeling on right side. Never had any ear problems before.
1221121	4/16/2021	TX	51	F	3/26/2021	3/29/2021	Bruise approximately 1.5? in diameter at injection site & swelling, very sore shoulder muscle for next 2-3 days; Pulsating tinnitus in right ear started 3/29/21; dizziness started 3/31/21 or 4/1/21; headaches and constriction of facial muscles around right eye began 4-5 days after injection; 4/4/21 dizziness was accompanied by feeling of nausea and loss of appetite Visited ENT on 4/5/21. Audiologist assessed loss of hearing in both ears
1219824	4/16/2021	MA	56	F	3/28/2021	4/3/2021	Profound hearing loss in L ear with slow improvement on high dose steroids
1219827	4/16/2021	NC	35	M	4/7/2021	4/14/2021	Increased ringing in both ears. Gradual but significant hearing loss in left ear. Started maybe on 4/12, but is noticeable on 4/14 and has gotten worse since.

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1220981	4/16/2021	MO	73	F	3/12/2021	3/13/2021	loss of hearing; Body aches; Diarrhea; shortness of breath; Loss of tastes; loss of attention; loss of memory; Breaking of the hair; Blurry vision; Nausea; chills Life Threatening; Fatigue; muscle aches; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS (loss of hearing) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 011A21A) 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). On 12-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Mar-2021, the patient experienced DEAFNESS (loss of hearing) (seriousness criterion medically significant), PAIN (Body aches), DIARRHOEA (Diarrhea), DYSPNOEA (shortness of breath), AGEUSIA (Loss of tastes), DISTURBANCE IN ATTENTION (loss of attention), AMNESIA (loss of memory), TRICHORRHEXIS (Breaking of the hair), VISION BLURRED (Blurry vision), NAUSEA (Nausea), CHILLS (chills Life Threatening), FATIGUE (Fatigue) and MYALGIA (muscle aches). At the time of the report, DEAFNESS (loss of hearing), PAIN (Body aches), DIARRHOEA (Diarrhea), DYSPNOEA (shortness of breath), AGEUSIA (Loss of tastes), DISTURBANCE IN ATTENTION (loss of attention), AMNESIA (loss of memory), TRICHORRHEXIS (Breaking of the hair), NAUSEA (Nausea), CHILLS (chills Life Threatening), FATIGUE (Fatigue) and MYALGIA (muscle aches) had not resolved and VISION BLURRED (Blurry vision) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. Treatment included were, acetaminophen (Tylenol) and an inhaler. Company comment:Very limited information regarding these events has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.
1220347	4/16/2021	MD	59	M	4/13/2021	4/13/2021	Severe tinnitus with mild hearing loss

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1220484	4/16/2021	PA	60	M	3/18/2021	4/2/2021	Sudden onset of tinnitus with hearing loss in right ear. Starting at 0200 on 01 April 2021. Tinnitus and hearing loss is ongoing. Tinnitus has decreased in intensity, but there was a sudden increase of tinnitus the evening of 08 April 2021, the same day that I received the 2nd vaccine dose. Hearing loss in right continues. Minor hearing loss in left ear was detected with audiology testing also.

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1220947	4/16/2021		73	U			<p>Loss of hearing in the left ear; Sore throat; Ears clogged; SEVERE muscle spasms; All of my muscles in my arms, legs, and cheeks were trembling constantly; One hard, tiny, tiny mucous ball from each cough; Tremendous sweats; I slept for 1 day; Headache; SEVERE chills; Fever; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS UNILATERAL (Loss of hearing in the left ear) in a 73-year-old patient of an unknown gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Asthma and Hypoglycemia. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced DEAFNESS UNILATERAL (Loss of hearing in the left ear) (seriousness criterion medically significant), OROPHARYNGEAL PAIN (Sore throat), EAR DISCOMFORT (Ears clogged), MUSCLE SPASMS (SEVERE muscle spasms), TREMOR (All of my muscles in my arms, legs, and cheeks were trembling constantly), PRODUCTIVE COUGH (One hard, tiny, tiny mucous ball from each cough), HYPERHIDROSIS (Tremendous sweats), HYPERSOMNIA (I slept for 1 day), HEADACHE (Headache), CHILLS (SEVERE chills) and PYREXIA (Fever). At the time of the report, DEAFNESS UNILATERAL (Loss of hearing in the left ear), OROPHARYNGEAL PAIN (Sore throat), EAR DISCOMFORT (Ears clogged), MUSCLE SPASMS (SEVERE muscle spasms), TREMOR (All of my muscles in my arms, legs, and cheeks were trembling constantly), PRODUCTIVE COUGH (One hard, tiny, tiny mucous ball from each cough), HYPERHIDROSIS (Tremendous sweats), HYPERSOMNIA (I slept for 1 day), HEADACHE (Headache), CHILLS (SEVERE chills) and PYREXIA (Fever) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Body temperature: 103.3 (High) 103.3. Very limited information regarding these events has been provided at this time. Further information has been requested. This case was</p>

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1219192	4/16/2021	CA	17	M	4/14/2021	4/14/2021	linked to MOD-2021-072199 (Patient Link).; Sender's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.
							Patient c/o dizziness, temporary loss of hearing, weakness, nausea and sweating . Took vital signs B/P was low 104/47. After 9 minutes B/P was up to 110/70 and patient's symptoms were resolved. He refused to be transported to ER to be evaluated and was taken home by his friend. Parents were notified of the event.

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1215762	4/16/2021	NC		F		3/19/2021	CHILLS; SHOULDER PAIN; HEADACHE; NAUSEATED; PASSED OUT; HEARING LOSS GETTING WORSE; CHEST PAINS; SWELLED UP; RINGING IN LEFT EAR; TREMBLING; BRAIN FOG; This spontaneous report received from a patient concerned a 74 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included type 2 diabetes and arthritis in the lower back. The patient was not pregnant. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: 1805018, and expiry: unknown) dose was not reported, administered on left arm on 19-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 19-MAR-2021, 30 minutes post-vaccination, the patient passed out and was rushed to the hospital and later she recovered. On the same day, the patient also experienced chest pains, chills, brain fog, trembling, nausea, shoulder pain that was shooting up and down between shoulder and elbow, ringing in left ear, developed swelling; headache and hearing loss in left ear that got worse. Electrocardiogram (EKG) was performed for chest pains (result unknown). At the hospital, she was given treatment that included Benadryl (diphenhydramine hydrochloride), many different shots (unspecified) and 'intravenous' (IV). The patient was at the hospital for about 8 hours. The patient was sent to a hearing specialist for her hearing loss. On 21-MAR-2021, the patient recovered from the events chest pains, chills, 'swelled up', nausea and trembling. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from chest pains, chills, swelled up, nauseated, trembling and passed out, and had not recovered from brain fog, shoulder pain, headache, left ear hearing loss, and ringing in left ear. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210409641- covid-19 vaccine ad26.cov2.s - passed out. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.



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1218135	4/16/2021	MA	60	M	3/31/2021	4/2/2021	Notes severe tinnitus starting 2 days after receiving the vaccine. No hearing loss noted
1214088	4/15/2021	NC	77	F	2/15/2021	2/27/2021	Sudden onset hearing loss, dizziness and two falls
1216073	4/15/2021	MA	43	M	4/10/2021	4/12/2021	Tinnitus, slight loss of hearing in left ear
1215392	4/15/2021	GA	46	F	3/31/2021	4/6/2021	Tinnitus in left ear and sudden mild hearing loss. I've had it for 9 days straight and it hasn't gone away. I saw my ENT specialist and primary care doctor. The only explanation that could of caused this is the shot. I've never had issues with my ear until I got the vaccine.
1215346	4/15/2021	CA	72	M	1/20/2021	1/25/2021	SSHL (Sudden Sensorineural Hearing Loss) in right ear.
1215100	4/15/2021	WI	64	F	3/12/2021	4/6/2021	4-2-2021 acute sinusitis symptoms onset (rhinitis, mild tinnitus, sore throat, Right ear fullness 4-7-2021 progression of above symptoms; 2 a.m. right ear "crackling sounds" with 2 short episodes of sharp pain in right ear (like toothpick jabs), followed with complete fullness, and full loss of hearing 4-7-2021 seen in retail clinic; Dx sinusitis with Rx Augmentin po BID x 10 days 4-9-2021 seen in Urgent Care; Dx otitis media; Rx added ear drops Cipro/dexamethasone 4 gtts BID x 7 days; referral to ENT 4-13-2021 ENT and audiologist Dx: left ear mild hearing loss; right ear severe hearing loss complicated by sinusitis, possible neuro etiology (NONE prior) I now have no hearing in my right ear.
1215085	4/15/2021		72	M	3/29/2021	3/29/2021	I received Moderna vaccine. After 1st dose I had slight headaches; after 2nd dose I have significant hearing loss, like someone put sound attenuating ear muffs over my ears, this occurred about 4 hours after the 2nd dose (March 29). This feeling went away but now I have constant buzzing in both ears, constantly. Did not have these problems before the vaccine.

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1214537	4/15/2021	WA	44	F	3/31/2021	4/8/2021	vaccinated 3/31/2021 w/o any problem. on 4/8/2021 about 6 pm she had ?allergic reaction? with sudden severe bilat eyelid swelling and swelling both external ears with "weeping" (transudate) and bilat ear pain. no swelling lips/tongue, no wheeze, no SOB, no hives. Seen at a Urgent care on 4/9/2021 diagnosed with bilat otitis media, bilat otitis externa, started on Augmentin and ciprofolxacin drops. seen by me 4/15/2021 with ear pain, congestion, hearing loss. exam shows bilat suppurative otitis media. I switched her to DS Septra and have asked her to follow up with ENT if not improving. she has never had an ear infection nor allergic reaction like this before.
1214195	4/15/2021	AZ	63	M	3/4/2021	3/11/2021	Loss of hearing in my Left ear. I have had recent hearing test that documented sudden loss and f/u appt with ENT doctor confirming loss. He put me on high dose prednisone for the past week and no changes to date.
1216490	4/15/2021		45	F	4/13/2021	4/14/2021	Unilateral hearing loss, tinnitus- began within 24 hours of vaccine, still ongoing 2 days later
1214092	4/15/2021	SC	58	F	1/5/2021	1/6/2021	Sudden hearing loss in left ear, occurred within 24 hours after first COVID vaccine received. Not sure if coincidence or if an adverse reaction. Treated by Dr and had two audiology test preformed. Currently wearing hearing aid's.

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1216146	4/15/2021	IA	32	F	4/9/2021	4/10/2021	Janssen COVID-19 Vaccine EUA Patient received Janssen vaccine 4/9/2021. Patient presented to ED 4/14/2021. Patient is a very pleasant 32-year-old female, with past medical history significant for taking bromocriptine for prolactin issues as well as metformin for type 2 diabetes, presents to the emergency department for evaluation of continued headache over the last 1 week. Patient also reports chills, sweats, body aches ever since receiving the Johnson and Johnson coronavirus vaccination 1 week ago. The headache started after receiving the vaccination and has been continuing ever since. It does not fluctuate in intensity. It is caused her blurred vision and difficulty focusing. No tinnitus or hearing loss. No slurred speech, vomiting, numbness or weakness or tingling to the extremities or any facial droop. No history of strokes or aneurysms. She is not on blood thinning medication at all. No upper nor lower extremity swelling or redness. No abdominal pain, nausea, vomiting or diarrhea. She reports the continued subtle shortness of breath and body aches since the vaccination as well. No rapid heart rate, long flights, long car rides, surgeries nor oral contraceptive use. Patient started on heparin drip. Neurologist recommended transferring patient to higher level of care. emergency department physician is willing to accept the patient at their facility. Patient transferred to the facility.
1213520	4/15/2021	PA	17	F	4/15/2021	4/15/2021	Dizziness, mild sweating, and a temporary loss of hearing a few minutes after the shot before brief LOC. Mother reported "eyes rolling up" and a respiratory gasp. Rapid recovery with fully orientation on the floor. VS stable in observation. No nausea or visual changes reported by the patient. No orthostasis.
1213376	4/15/2021	AR	44	M	2/26/2021	4/1/2021	Slightly over a month after receiving my second COVID vaccination (1st vaccination January 29, 2nd vaccination February 26) I awoke with markedly worse tinnitus in my left ear and noticeable hearing loss.
1213031	4/15/2021	PA	22	F	4/15/2021	4/15/2021	Warmth, dizziness, temporary loss of hearing shortly after vaccination. No nausea, diaphoresis, or tunnel vision. Near syncope prevented by lying down quickly. Typical vasovagal reaction for her. Rapid recovery with all normal vital signs. No orthostasis.

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1212776	4/15/2021	OH	47	F	2/2/2021	3/15/2021	Tinnitus and significant hearing loss in my left ear.
1212773	4/15/2021	WI	56	F	4/1/2021	4/8/2021	Extreme ringing in the ears woke me up at 4 am on day 7 after vaccination. Shortly after, I lost hearing in my left ear. Went to the ER where I was prescribed prednisone. I have been on it for a week now with no relief thus far. I am very dizzy, still have extreme ringing, and hearing loss in the left ear.
1212511	4/15/2021	TX	59	M	2/10/2021	3/1/2021	Symptoms: Ringing in left ear and mild vertigo (date of onset shown previously is approximate) Diagnosis: Sudden hearing loss diagnosed by hearing test; Dr. stated likely a side effect of COVID vaccine (said they had seen a few other cases) Treatment: Tapered dosing of Prednisone (10 mg) over two weeks. Outcome: Slight improvement in hearing but not enough to state full recovery
1212172	4/15/2021	IN	67	M	3/3/2021	3/24/2021	Bilateral tinnitus (ringing in ears), hearing loss
1212096	4/15/2021	NC	42	F	4/9/2021	4/11/2021	Sudden hearing loss in left ear
1214120	4/15/2021	NC	75	M	1/25/2021	2/2/2021	Total deafness in right ear

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1215750	4/15/2021	FL		F		3/16/2021	<p>DIZZY; FALLS; SHAKING; NEUROLOGICAL DISORDER; DIFFICULTY IN WALKING; LEGS STIFFENING; LOWER BACK PAIN WORSE; BACK OF LEG AND BACK OF ARM PAIN; FEVER RUNNING CONSTANTLY; BODY ACHES/PAIN ALL OVER BODY; This spontaneous report received from a patient concerned a 43 year old female. The patient's height, and weight were not reported. The patient's past medical history included failed neck and back surgery, and car accident, and concurrent conditions included hashimoto's disease, high cholesterol, high blood pressure, type 2 diabetes, glaucoma, arthritis in back, herniated disc, bulging disc, upper back scoliosis, severe hearing loss, irritable bowel syndrome, sulfa and sulfate drugs allergy, upper/lower back pain, and neck pain. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 1805018 expiry: UNKNOWN) dose was not reported, administered on 16-MAR-2021 for prophylactic vaccination. Concomitant medications included hydrocodone for neck pain, and upper/lower back pain. On 16-MAR-2021, the subject experienced body aches/pain all over body. On 16-MAR-2021, the subject experienced legs stiffening. On 16-MAR-2021, the subject experienced lower back pain worse. On 16-MAR-2021, the subject experienced back of leg and back of arm pain. On 16-MAR-2021, the subject experienced fever running constantly. On 17-MAR-2021, the subject experienced difficulty in walking. On an unspecified date, the subject experienced dizzy, falls, shaking, and neurological disorder. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from difficulty in walking, back of leg and back of arm pain, legs stiffening, and lower back pain worse, and the outcome of body aches/pain all over body, fever running constantly, dizzy, falls, neurological disorder and shaking was not reported. This report was non-serious.; Sender's Comments: V0: Medical assessment comment not required as per the standard procedure as the case is assessed as non-serious.</p>
1209569	4/14/2021	CA	73	M	3/18/2021	3/22/2021	hearing loss in left ear

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1209669	4/14/2021	PA	78	M	2/26/2021	2/28/2021	Sudden, unilateral sensorineural hearing loss developed 02/28/2021 0630.. Oral prednisone taper, trans-tympanic steroid injection. No improvement in hearing to date.
1210459	4/14/2021	TX	29	F	4/9/2021	4/9/2021	patient fainted, loss of hearing in ear, had a brief seizure
1208635	4/14/2021	CT	61	F	3/1/2021	3/19/2021	Stroke- hearing loss in right ear, extreme headache left temple lobe, nausea, dizziness, diarrhea, inability to move legs. Hospitalized for 5 days Continued weakness left side of the body
1210768	4/14/2021	CA	56	M	4/7/2021	4/9/2021	The first shot of Pfizer is taken at 1 pm April 7 at stadium . I had sudden hearing loss COMPLETELY for my Right ear at 6pm April 9. I went to urgent care around 7 pm April 9. The doctor at urgent care gave me AMOXICILLIN 500 mg for 7 days. 10:30 am of April 10, a doctor from Medical Center starts to treat me with PREDNISONE for 10 days. 4:30 pm of April 12, Dr., ENT, examines my ears and order audiology test. 11 am of April 14, I got audiology test which shows I completely lose my hearing for my right ear.
1211132	4/14/2021	TX	44	F	4/10/2021	4/14/2021	Ringling in left ear, loss of hearing in left ear, extreme sensitivity to loud noises.

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1202572	4/13/2021	CA	63	M	3/13/2021	3/13/2021	63 year old male with progressive weakness at bilateral faces and extremities, LEs > UEs, absent DTRs throughout x 2 weeks. Received J&J vaccine at 3 weeks ago. His current neurological examination and clinical history is suggestive of GBS NEUROLOGICAL EXAM: MSE: A+Ox 3 Language: no aphasia CRANIAL NERVES: 2nd CN: bilateral pupils are equal round and reaction to light, visual field-full 3rd,4th and 6th CN: EOM- I 5th CN: no sensory deficite 7th CN: face: symmetric, not able to smile or blowing air or holding water 8th CN: hearing loss: no 9, 10th CN: no dysarthria, palate movement:normal 11th CN: no neck weakness 12th CN: tongue: middle, no atrophy MOTOR EXAM: Tone: normal Strength: 4+/5 at bilateral UEs, 4 Pt symptoms started very early. Narrative from family below: "Day 1 (The day he took the vaccine): My father was complaining of very heavy chest pressure (said he felt like his chest was being pushed down with force.) He felt really tired and had a nasty headache. Day 2 He began to feel tingles in his legs and arms. Said he felt sore and had mild pain around his back, feet, legs, hands, and arms. The headache came in and out. Day 3 He began feeling more severe pains in both legs + headache. More tingling around his face, lips, and jaw. Day 4 Severe pain continued around his entire body. Had an episode where he lost vision from 1 eye (he described it as blurry vision) felt like he was going blind from one eye. Day 5 Could barely stand on his two feet and could no longer go to work. He stayed in bed and then hospital visits began. My mom took him to emergency for the first time. I was able to get details of the location where he was vaccinated and onsite contact information. The info is below:
1200467	4/13/2021	FL	36	F	4/12/2021	4/12/2021	Random bouts of hearing loss followed by loud ringing in the ear. It subsides fairly quickly but has happened 3 times in less then 24 hrs of receiving the shot. Never dealt with this before
1201148	4/13/2021	VA	54	F	3/12/2021	3/17/2021	6 days after receiving vaccine, experienced sudden onset of vertigo, vomiting. ENT determined unknown nerve damage of left ear, hearing loss probably due to interruption of blood flow. No apparent injury.

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1201191	4/13/2021	MA	78	F	2/8/2021	2/14/2021	SNHL. Hearing loss in left ear,
1201539	4/13/2021	KY	62	F	2/12/2021	3/17/2021	Sudden Hearing loss and tinnitus in right ear.
1201822	4/13/2021	UT	21	F	4/9/2021	4/10/2021	I had the typical soreness about 12 hours after the injection. No worries there. The next morning, on the 10th, around 11:40 AM, I started feeling extremely dizzy. The room started spinning. I was standing at the time, and I kept standing, but other than that, I had no control. My hearing starting going fuzzy, starting with ringing in my ears until it sounded like I was underwater. My vision started blurring, as well, eventually going completely black. For a solid 5-10 seconds, I could neither hear clearly nor see at all. I was conscious, because I could think relatively clearly, and I could feel my eyes blinking and could wiggle my fingers, but that was it. Once the episode passed, I immediately sat down. About a minute later, I started having excruciating abdominal pain. The pain was wracking my whole body, causing me to go pale (as I later saw once I could hobble to the bathroom) and making me sweat. After about twenty minutes, the whole thing passed and I was left with minor dizziness and slight nausea. Now, three days later, I still have some of the dizziness, but none of the blindness, deafness, or pain has returned. All other side effects, such as soreness, have completely left.



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1202170	4/13/2021	NY	32	F	3/31/2021	4/1/2021	<p>Tinnitus in both ears noticed on 2am of the night after the shot was administered. Never experienced tinnitus before. Consistent ringing in both ears that has not changed, on top of it more pitches that appear randomly and loudly. gets worse with stress. adds stress anxiety and interrupts sleep and work. Visit to ENT concluded no hearing loss and ears look normal. Acupuncture and jaw massages help calm and relieve symptoms but still persisting. Full journal: Scale (1 - non existent, 10 - very bad) 01/04/2021 02:00am - white noise and pressure in ears : 2 9:00am - headache: 3, ears: 2, intermittent ticking on right ear (heard once or twice in the morning) 10:00am - + nausea :2 2pm - ear pressure and ringing more noticeable with headphones: 3 02/04/2021 2am - ear pressure went down, ringing on right ear high B: 3 4pm - ringing on right ear not noticeable unless i focus hard on it. 03/04/2021 9pm - ringing on right ear high Cish - not noticeable unless it is quiet : 3, pressure in both ears - 3 04/04/2021 12pm - ringing on right ear \- 3 pressure in right ear - 3 trying to put focus away all day. tried 10min ear exercises 04/05/2021 9am - did 10 min ear exercises 10am - pressure plus ringing in both ears - 1.5-2 6pm- acupuncture 04/07/2021 5-6pm - walk in city, still more sensitive to traffic and street noise, need to cover my ear frequently, friend noticed. 11pm - stressful conversation with partner, resolved 12am - ringing in right ear phased in louder volume (5/10) for 2 seconds and stopped. 7am - ringing in left ear phased in louder volume (7/10) for a second and resumed to normal volume, new pitch - high A - left ear - 3 (intermittent), right ear - 2 04/08/2021 2am - left ear high A 5/10 goes up and down in volume mainly 4-5. took a long bike ride yesterday (90 mins), walked in the cold for 30 mins in the evening - was not dressed enough. EST visit - washed left ear to take out wax. no hearing loss - hearing looks high normal. no more info on 2nd shot. 6pm - acupuncture 04/09/2021 5am - no high A anymore. left ear- 1.5, notice only when block my ear, right ear 2-3.5 (phasing in and out) high F# and maybe C too 04/10/2021 8am - left ear - 2-3 only high Bb, right ear - 2-3 no high f#, only high C , white noise in both - 2 4pm - stressful conversation with partner, resolved 5/10 04/11/2021 morning - barely noticeable 7pm - after being out all day and a little cold - high F# appeared again 3/10. no pressure in ear anymore 04/12/2021 9am - high</p>

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							C added to both again 3/10 10am - work virtual meeting - high C goes 5/10 9pm - after acupuncture feeling better overall, high F# again 2-3/10, no high C 04/13/2021 2:56am, 3am, 7am - woke up from bad new pitch - G 7/10. massaging jaw at 7am helped relief.
1202217	4/13/2021	MA	52	F	3/29/2021	4/3/2021	Bilateral tinnitus 5 days after vaccine administration, imbalance and vertigo started after in combination with hearing loss. Patient stated quality of life is dramatically affected since. It is still unresolved and patient has appointment for check up.
1205840	4/13/2021	NY	59	M	3/21/2021	3/26/2021	Six days after receiving the 1st dose of the Pfizer vaccine, I experienced a sudden, total loss of hearing in the left ear. This was accompanied by extreme vertigo and loud tinnitus which has not abated. I have visited an ENT specialist and had three audiology tests, which has confirmed that there is no hearing function in the left ear. ENT diagnosed as labyrinthitis due to viral infection. Tried to reduce inflammation and potentially restore hearing function by injecting steroids directly into the ear. These treatments have not worked. I received the 2nd dose of the vaccine on 4/11/21 as scheduled.
1203294	4/13/2021	TX	37	M	4/1/2021	4/8/2021	Dizziness, nauseous tinnitus hearing loss - diagnosed with SSHL (sudden sensorial hearing loss)
1204007	4/13/2021	TN	63	F	4/6/2021	4/7/2021	Approximately 12 hours after receiving the first vaccine I experienced a headache and congestion in my face and especially my ears. The ear pressure was very uncomfortable and I had noise like wind in both ears. Sounded like I was shouting and echoing when speaking. Took allergy meds and Tylenol. No relief. Finally Sudafed provided some relief from the pressure. Felt like I needed to pop my ears. Definitely worse on the left side. This has continued for a week. This morning I was so unbalanced I had to hold on to the wall to get to the bathroom. Had sweats and chills for a few hours. Also quite fatigued which is very rare for me. Very concerned about hearing loss if this does not resolve soon,
1204177	4/13/2021	CO	54	F	3/1/2021	3/31/2021	Tinnitus, and hearing loss

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1204290	4/13/2021	CA	65	F	1/4/2021	1/6/2021	After vaccine, Sore arm around 2 pm and at night time very painful; fever and chills; next day - muscle pains; body aches; headache and I threw up a little bit. It was about three days of these symptoms. The worse was on January 6, I couldn't hear on my left ear. I had a hearing test - they said my hearing was really weak on my left side. They gave me Prednisone for a week and it didn't go away; still had hearing loss after prednisone. There was a little bit of sound - sound of ringing - it was hard to understand people around me. I still have hearing loss today since January 6 in my left ear. I can hear with my right ear - but not on left.

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1204769	4/13/2021	CA	62	M	3/13/2021	3/14/2021	<p>Lost hearing in the left ear; Tinnitus (ringing in the left ear); This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEAFNESS (Lost hearing in the left ear) in a 62-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) 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 LOSARTAN, AMOXICILLIN and PREDNISONE for an unknown indication. On 13-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 14-Mar-2021, the patient experienced TINNITUS (Tinnitus (ringing in the left ear)). On an unknown date, the patient experienced DEAFNESS (Lost hearing in the left ear) (seriousness criterion medically significant). At the time of the report, DEAFNESS (Lost hearing in the left ear) and TINNITUS (Tinnitus (ringing in the left ear)) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Acoustic stimulation tests: abnormal (abnormal) Hearing loss. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. The patient was taking other unspecified concomitant medications. On an unknown date, the patient went to an urgent care ear throat specialist with a chief complaint of tinnitus and had a hearing test. The patient was diagnosed with hearing loss in the left ear and was given a steroid prescription. Based on the current available information and the 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 the 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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1204780	4/13/2021	MA	87	F	3/20/2021	3/21/2021	Right side hearing loss; Dizziness; Nausea; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEAFNESS (Right side hearing loss) in an 87-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 038A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On 20-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Mar-2021, the patient experienced DEAFNESS (Right side hearing loss) (seriousness criterion medically significant), DIZZINESS (Dizziness) and NAUSEA (Nausea). At the time of the report, DEAFNESS (Right side hearing loss), DIZZINESS (Dizziness) and NAUSEA (Nausea) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 21-Mar-2021, Magnetic resonance imaging: normal (normal) normal. Action taken with mRNA-1273 in response to the event was not applicable. Concomitant product use was not provided by the reporter. No treatment information was provided.; 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.
1204837	4/13/2021	NY	19	F	4/10/2021	4/11/2021	Left middle ear effusion with conductive hearing loss

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1204904	4/13/2021	VA	21	M	3/8/2021	3/8/2021	4/8/21: Vaccine Received - 6:00pm By 9:00pm, patient begins suffering from intense headache, hearing loss in both ears, and blurred vision. For the ears, it was as if someone had taken ear plugs and coated the ear drum with them, making it hard to hear. Headache was treated with an ice pack on the temple for immediate site relief. Began to feel tired and worn out while in bed, loss of vision begins to occur as well. Body aches begin. 4/9/21: Patient is woken up from intense body spasms throughout the entire body. Once awake, the entire body was spasming, causing the patient to be unable to control his body, and all extremities. After sipping some water for about an hour, the spasms subsided in all areas of the body except for the legs and shoulders. 4:00pm patient begins to feel extremely nauseous, begins having increased bowel movements including rapid diarrhea, and extreme stomach cramping. Deep body aches and pain continue. 4/10/21: 10am: patients body begins to become covered in hives all across his skin, inside his mouth, under his feet, and in his hair. Hives continued to grow, with no reddening of the skin however. This was treated with Benadryl for the remainder of the day; hives subsiding around 6:15pm. Dehydration also occurred, and hospital treatment for IV saline bag was soon to be utilized had the patient not been able to rehydrate himself. Body aches continue

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1205159	4/13/2021	FL	95	M	3/20/2021	3/22/2021	loss of hearing two days after vaccine; up for 48 hours after the vaccine; This is a spontaneous report from a contactable consumer (patient). A 95-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; Lot Number: EN6208) via an unspecified route of administration, administered in Arm Right, at the age of 95-year-old, on 20Mar2021 11:30, as SINGLE DOSE for covid-19 immunisation. Medical history was not reported. Concomitant medications included atenolol; dutasteride; apixaban (ELIQUIS); and methenamine. The patient received amoxicillin and experienced allergy and first dose of of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; Lot Number: ENF6200) via an unspecified route of administration, administered in Arm Right on 27Feb2021 11:45, as SINGLE DOSE for covid-19 immunisation. It was reported that the patient received other vaccine (unspecified) four weeks before receiving the COVID vaccine. The patient was up for 48 hours after the vaccine on 22Mar2021, then loss of hearing two days after vaccine on 22Mar2021. The patient did not receive any treatment in response to the events. The event loss of hearing two days required emergency room visit. The patient was not diagnosed with COVID before vaccination and was not tested since vaccination. Outcome of the events was not recovered.
1205588	4/13/2021	NY	66	F	1/21/2021	1/22/2021	I have sensorineural hearing loss in my left ear. Following the vaccine, the next day I had an increase in tinnitus and a decrease in speech recognition. i also had fever, chills and fatigue. My arm was very sore and bright red. It was very hot to the touch.

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1205239	4/13/2021	FL	64	M	3/1/2021	3/1/2021	bladder and urinary tract infection/ first one was E.coli; bladder and urinary tract infection/ first one was E.coli; This is a spontaneous report from a contactable consumer (patient). A 64-year-old male patient received the first dose of bnt162b2 (BNT162B2, lot number: EN6205), via an unspecified route of administration on 01Mar2021 (received at 64-years-old) as single dose for covid-19 immunization. Medical history included diabetes mellitus (patient takes Metformin and Insulin), blood cholesterol (patient takes Lipitor for cholesterol), partially deaf. Concomitant medications included isosorbide mononitrate (ISOSORBIDE MONONITRATE) taken for an unspecified indication, start and stop date were not reported; metformin (METFORMIN) taken for diabetes mellitus, start and stop date were not reported; insulin (INSULIN) taken for diabetes mellitus, start and stop date were not reported; atorvastatin (LIPITOR [ATORVASTATIN]) taken for blood cholesterol, start and stop date were not reported; metoprolol (METOPROLOL) taken for an unspecified indication, start and stop date were not reported. The patient stated that in his whole life, he never had a bladder or urinary tract infection and each time after getting the shot he got a bladder, urinary tract infection. He was hospitalized once, the second time they treated him in ER (emergency room). The patient explained that he took the first dose of the Pfizer vaccine on 01Mar2021 while he took the second dose on 23Mar2021. He got hospitalized two days after he got the first shot (03Mar2021). He first went to the hospital because his symptoms were gone and were already up going on for two days (since 01Mar2021) when he checked. They checked him and they were wondering why he was getting fever and chills and they find out that he had a bladder and urinary tract infection. When probed for second dose and causes after that, the patient stated that on 23Mar2021, he got some symptoms but the result was from a urinary track and bladder infection, the first one was E.coli and the second one they did not tell him what kind of infection it was. The patient was hospitalized for three days, from 03Mar2021 to 06Mar2021 due to the bladder and urinary tract infection. Outcome of the events was unknown.



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1202205	4/13/2021	IL	69	F	2/2/2021	2/16/2021	Tinnitus (ongoing), hearing loss right ear (ongoing), headache, fatigue, muscle and joint pain, dizziness, sinus and head congestion (ongoing).
1205184	4/13/2021	FL	76	F	3/10/2021		hearing loss in high frequencies; developed tinnitus; She was very depressed; This is a spontaneous report from a contactable consumer (patient) via Medical information team reported for herself. A 76-years-old female patient received bnt162b2 (BNT162B2, Solution for injection), dose 1 intramuscular, administered in Arm Right on 10Mar2021 09:22 (at the age of 76-years-old) (Batch/Lot Number: EN6206) as SINGLE DOSE for covid-19 immunization. Medical history included immunodeficiency, respiratory disorder, cytogenetic abnormality, endocrine disorder, diabetes mellitus, obesity from an unknown date and unknown if ongoing. There were no concomitant medications. Patient had first shot of vaccine on 10Mar2021 and was due for her second on 01Apr2021. Within 2 days of receiving it, she got Tinnitus and was still experiencing ear ringing. She had already spoke to HCP. She was very depressed that she may have this side effect forever. She asked if anyone else had reported this side effect. She doesn't know if it was a side effect. She was wondering if she should get second shot or will anything worse happen. There was no prescriber. It was either 12Mar2021 or 13Mar2021, that she noticed it. For tinnitus she did not pay a lot of attention until Sunday, so she knew she got it on Saturday, or Friday, unknown time. No ER or physician's office required. She did make an appointment with an ENT and audiologist on 24Mar2021. Patient did not know if it had anything to do with the vaccine. No infection. Somewhat of hearing loss in high frequencies, but she did not need a hearing aid. There were no prior Vaccinations (within 4 weeks) and no lab tests reported. Outcome of event tinnitus was reported as not recovered and outcome of event deafness and depressed mood was unknown.
1197075	4/12/2021	CA	50	F	1/27/2021	1/28/2021	Headache, shortness of breath, loss of hearing, fever of 100.5 F, bodyaches, chest tightness, swelling of my face
1199288	4/12/2021	IL	63	F	2/9/2021	2/21/2021	Severe head congestion settling in right ear. Hearing loss found during visit to Ear, Nose and Throat dr. Some tinnitus.

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1199186	4/12/2021	AZ	37	M	3/26/2021	4/6/2021	Went to urgent care on the 9th said it was EDT, decided to go to an ENT as hearing reduced significantly and was not getting better. Tinnitus and sudden sensorineural hearing loss in right ear.
1199002	4/12/2021	NJ	36	F	4/11/2021	4/12/2021	Tinnitus (ringing in my ears), suspected hearing loss, full and popping ears
1198918	4/12/2021	TX	47	F	3/10/2021	3/19/2021	Sudden sensorineural hearing loss (SSNHL) in left ear, beginning 8-9 days after vaccine on March 19th Friday. Symptoms of fullness, muffled hearing, sensitivity to sound. This was coupled with increased/exacerbated tinnitus in both left and right ears. Hearing test and physical exam done by ENT on March 22 Monday showed a loss of hearing in low frequencies in left ear of up to 40 DB. Treatment with steroids was initiated (prednisone 50 mg for 7 days, 30 mg 1 day, 25 mg 1 day). Follow-up visit to ENT on March 31 showed improvement in hearing nearly back to levels prior to the SSNHL; however tinnitus remained elevated. Prednisone was continued at 40 mg for 1 week with taper.
1197970	4/12/2021	FL	63	M	4/5/2021	4/6/2021	Around 330 on 4/6, I started feeling bad and arrived home around 530pm and had a slight Temperature (99) with hearing loss in both ears. But the right one had complete hearing loss. Thinking it would be a short term side effect, but realizing on Thursday am with was not, I called my physician office on Thursday and they called back on Thursday for a Friday 9am appt with the PA. She said it was sinus related , fluid in the ears was pushing the ear drum back and gave me a prescription for Fluticasone and to take my Zyreth and Sudafed. Call her in a week if symptoms did not away. On 4/12/21, I still have massive hearing loss and pain, so called a ENT for an appt and received a 1:15pm on the same day. This was the first day I had balance issues.
1199522	4/12/2021	NJ	77	M	3/25/2021	4/1/2021	After about a week, started hearing ringing in both the ears. Now I have suffered some hearing loss.
1197166	4/12/2021	NC	62	M	3/13/2021	3/31/2021	I had a sudden hearing loss in my right ear still present as of 4/12. I went to the ENT had hearing test which showed 90% loss, MRI(no tumors) and prescribed Prednisone.

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1199094	4/12/2021	TX	20	F	4/12/2021	4/12/2021	Patient fainted and had seizure like symptoms with eyes rolling back in head, clamminess, sweating, severe stomach cramps, blurred vision, and temporary loss of hearing
1196575	4/12/2021	FL	32	F	4/11/2021	4/11/2021	Immediate nausea, left arm pain, tingling in left arm, sweating, loss of vision, loss of hearing, stomach pain, tingling in fingers after approx. 10 minutes.
1196468	4/12/2021	MA	63	M	4/8/2021	4/9/2021	The day after his second Pfizer vaccine, he developed hearing loss and had a CT scan of head that showed a large temporal lobe intracranial hemorrhage
1196152	4/12/2021	AZ	59	M	3/29/2021	4/8/2021	Developed hearing loss and tinnitus. Symptoms are worse on right side.
1195936	4/12/2021	WI	49	F	4/1/2021	4/5/2021	I had my first Moderna shot in my right arm on March 4th. I got a bad headache the next day. After that a very low ringing in my ears started. I barely noticed it. On April 1st, I had my second shot in my left arm. By that night I was very sick with splitting headache, fever, chills, fatigue. After three days I got better. The ringing in my ears increased from then on getting louder every day. It is now a high pitched ring tone that does not subside that is loud enough to be heard all day and night no matter what I am doing. Nothing I do changes the loudness or tone. I have never had tinnitus before or any hearing loss or hearing issues. I am in good health with no underlying medical conditions.
1195694	4/12/2021	GA	34	F	4/7/2021	4/7/2021	Site: Pain at Injection Site-Severe, Systemic: Body Aches Generalized-Severe, Systemic: Chills-Severe, Systemic: patient experienced hearing loss for 24 hours- hearing has now returned-Severe
1195549	4/12/2021	MI	34	F	4/6/2021	4/8/2021	Tinnitus, hearing loss in left ear, vertigo,
1197678	4/12/2021	KY	54	M	4/6/2021	4/12/2021	sudden onset hearing loss on the left
1198995	4/12/2021	NY	80	M	3/4/2021	3/9/2021	Total loss of hearing in left ear. Steroids by mouth-13 days Steroids injections in ear -once a week for 3 weeks
1193537	4/11/2021	NY	52	M	2/28/2021	3/14/2021	Severe ringing in left ear, sudden full deafness in left ear and continues tinnitus

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1195382	4/11/2021	VA	47	M	4/5/2021	4/8/2021	Experienced intermittent, temporary loss of hearing ( seconds duration) in ears during 4/8 and 4/9 (approximately 3 times per ear) Each ear was was affected individually, not simultaneously. Subjectively, hearing seemed to recover, but hearing test has not been performed, yet . Since 4/9, have persistent tinnitus in both ears. Had telemedicine visit on 4/11 and will schedule evaluation with ENT specialist.
1195220	4/11/2021	MD	50	F	3/15/2021	3/23/2021	Adverse events: -Sudden sensorineural hearing loss (SNHL) of right ear -Tinnitus Treatment: -Prednisone 60 mg/day for 2 weeks

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1194126	4/11/2021	NY		F	3/18/2021	3/18/2021	Bell's palsy on right side; Numbness of face on right side; Hearing loss in right ear; Buzzing in both ears; Flu like symptoms for 4 days; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEAFNESS (Hearing loss in right ear) and FACIAL PARALYSIS (Bell's palsy on right side) in a 65-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 037A21B) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Multiple sclerosis, Blood pressure and Cholesterol. On 18-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 18-Mar-2021, the patient experienced INFLUENZA LIKE ILLNESS (Flu like symptoms for 4 days). On 25-Mar-2021, the patient experienced DEAFNESS (Hearing loss in right ear) (seriousness criterion medically significant) and TINNITUS (Buzzing in both ears). On 27-Mar-2021, the patient experienced FACIAL PARALYSIS (Bell's palsy on right side) (seriousness criterion medically significant) and HYPOAESTHESIA (Numbness of face on right side). On 22-Mar-2021, INFLUENZA LIKE ILLNESS (Flu like symptoms for 4 days) had resolved. At the time of the report, DEAFNESS (Hearing loss in right ear), FACIAL PARALYSIS (Bell's palsy on right side), TINNITUS (Buzzing in both ears) and HYPOAESTHESIA (Numbness of face on right side) outcome was unknown. She was taking blood pressure and cholesterol medicine as concomitant. Treatment included steroid infusion.; Sender's Comments: Limited information regarding these events has been provided at this time and a causal relationship cannot be excluded
1193700	4/11/2021	TX	69	F	3/29/2021	4/2/2021	total hearing loss in right ear
1193534	4/11/2021	MI	62	M	4/9/2021	4/9/2021	1st day, and 2nd day, slight hearing loss particularly to mens speaking voice on TV. Now gone. 1st night frquent night time urination, now gone.
1193375	4/11/2021	GA	42	M	3/22/2021	4/4/2021	Loss of hearing in right ear. Came back but now there is tinnitus in both ears

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1193305	4/11/2021	TN	64	F	3/11/2021	3/11/2021	Tasted vaccine in throat, throat closed briefly, ringing in ears began immediately, hearing loss/stuffiness in right ear occurred immediately, foggy brain occurred immediately. The tinnitus is constant and persists along with the hearing loss .
1193273	4/11/2021	WA	50	F	4/2/2021	4/10/2021	Left ear plugged, then a few hours later right ear, with minimal hearing loss
1193196	4/11/2021	CA	41	F	3/16/2021	3/17/2021	Tinnitus, loss of hearing, pressure in ears.
1193105	4/11/2021	MA	59	F	4/5/2021	4/9/2021	Loss of hearing in right ear and some in left ear.
1192691	4/11/2021	WI	38	F	1/19/2021	2/5/2021	Acute onset of tinnitus and hearing loss.
1193755	4/11/2021	CA	46	M	3/24/2021	3/30/2021	Tinnitus. Continuous ringing in ears that will not go away. I was perfectly healthy before the shot.. then several days after developed an ache in my right abdomen, fatigue and constant ringing in ears that will not go away. I'm also having a very hard time sleeping.. sometimes only being able to get 2 or 3 hours a night regardless of how tired I am. I'm very disappointed and not sure if I should get the second shot or not given how I'm feeling now. Before the shot I was perfectly healthy. I eat well, exercise and have never in my life experienced tinnitus or any type of hearing problem. This shot was the ONLY thing that could have caused this. I'm not sure what to do next or if I should get the second shot which could make it worse. I'm very worried because the ringing and aches have been constant for 10 days.. some days worse than others.
1189878	4/10/2021	MD	63	F	3/25/2021	3/26/2021	I'm estimating that it was in the late afternoon the day after my vaccination, the tinnitus in both ears became much louder, with the left ear particularly loud. It makes it difficult to sleep, even with a sound conditioner. On March 28, I sent a message to my primary physician, indicating the increased level of tinnitus and wondering if I should not take the 2nd dose in four weeks. He replied that tinnitus was not a side effect of the vaccine based on clinical trials and he would like me to get the 2nd dose. He said I could run it by an ENT. I saw an ENT, on April 8. She determined that I have minor hearing loss typical for my age and said that is likely the cause(cont.)

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1188850	4/10/2021	IA	69	M	2/13/2021	3/15/2021	loss of hearing right ear; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS (loss of hearing right ear) in a 69-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 044A21A and 031L20A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No reported medical history). On 13-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 15-Mar-2021, the patient experienced DEAFNESS (loss of hearing right ear) (seriousness criterion medically significant). At the time of the report, DEAFNESS (loss of hearing right ear) had not resolved. Additional information: On 15MAR2021 I went to the Emergency room. I then went to see an Ears Nose and Throat Doctor on 17MAR2021. The Doctor put me on Prednisone 60mg daily times one week. I then went to go see the Ears Nose and Throat Doctor again today 01APR2021and he gave me a steroid injection into my right ear.At this point the hearing has not returned to my right ear Based on the current available information and temporal association between the use of the product and the start date of this event, a causal relationship cannot be excluded. This case was linked to MOD-2021-065921 (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 this event, a causal relationship cannot be excluded.
1192185	4/10/2021	CA	73	F			Very bad head ache. Achy and tired for 1.5 days. Vomited twice the day after vaccine. Lost of hearing, ringing, and noise in R. ear. All have subsided, except the the hearing loss. I can not even hear someone talking on the phone. The noise and the ringing have gone, but I truly cannot hear except very very faint sounds.

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1188829	4/10/2021	OH	55	F	3/18/2021	3/19/2021	dizzy; pukey; deaf in her left ear; water sounds in her ear; This spontaneous case was reported by a patient and describes the occurrence of DEAFNESS (deaf in her left ear) in a 55-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) 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). On 18-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-Mar-2021, the patient experienced DEAFNESS (deaf in her left ear) (seriousness criterion medically significant) and TINNITUS (water sounds in her ear). On an unknown date, the patient experienced DIZZINESS (dizzy) and NAUSEA (pukey). At the time of the report, DEAFNESS (deaf in her left ear), TINNITUS (water sounds in her ear), DIZZINESS (dizzy) and NAUSEA (pukey) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Magnetic resonance imaging: not provided (Inconclusive) 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 these events, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-062183 (E2B Linked Report). This case was linked to MOD-2021-062183 (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 these events, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-062183:
1190364	4/10/2021	TX	40	M	4/9/2021	4/10/2021	Ringling in ears , loss of hearing , tinatus
1192441	4/10/2021	TN	22	F	4/8/2021	4/8/2021	chills, uncontrollable shaking, fever, fever dreams, headache, dizziness, nausea, loss of vision (momentarily), loss of hearing (upon waking up)



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1191799	4/10/2021		35	F	3/18/2021	3/1/2021	pressure in her ears; right ear was burning; almost passed out; dizzy; hot; couldn't hear everything sounded really far away; had impaired thinking, couldn't think straight; no concentration for two days straight; had buzzing in her ears and heightened sounds; pins and needles sensation in her feet that went up to her legs/on day 9 the pins and needles sensation seems to be in her hands and arms as well; This is a spontaneous report received from a contactable consumer (patient). A 35-year-old female patient received 1st dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, LOT/Batch number and expiration date unknown) via an unspecified route of administration on 18Mar2021 at age of 35-year-old at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient stated she received the first dose of the Pfizer COVID vaccine on 18MAR 2021. She stated ten minutes after the vaccine on 18Mar2021 she became dizzy, hot, almost passed out, couldn't hear everything sounded really far away. Patient stated this lasted for 20 minutes. Patient stated she also had impaired thinking, couldn't think straight and no concentration for two days straight. She stated she also had buzzing in her ears and heightened sounds for three days. She stated she had pins and needles sensation in her feet that went up to her legs. She stated on day 9 the pins and needles sensation seems to be in her hands and arms as well. Patient stated yesterday (26Mar2021) her right ear was burning and today (27Mar2021) she has pressure in her ears in addition to the pins and needles sensation. Events were reported as non-serious. Patient would like to know if her symptoms have been reported or are normal. She would like to know how long will her symptoms last and if they are permanent. She would like to know if she should receive the second dose of the vaccine. She would like to know what treatment she should have for her symptoms. She would like to know if there were any reports of autoimmune diseases being diagnosed after receiving the vaccine. She would like for someone to notify her if any information or data becomes available regarding the side effects she has mentioned that were not mentioned in the FactSheet. No information in PI regarding impaired thinking, loss of hearing, heightened hearing, pins and needles in extremities, and burning and pressure in ears.

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							There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic or neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine. Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination. No information in PI regarding autoimmune disorders being diagnosed after receiving Pfizer COVID vaccine. Outcome of dizzy, hot, almost passed out, couldn't hear everything sounded really far away was recovered on 18Mar2021, of had impaired thinking, couldn't think straight, no concentration for two days straight, buzzing in her ears and heightened sounds for three days was recovered in Mar2021, of the other events was unknown. Information on the lot/batch number has been requested.
1191819	4/10/2021			F			loss of hearing in one ear; This is a spontaneous report from a non-contactable consumer. An adult female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient experienced Loss of hearing in one ear. The patient received treatment for the event: Steroid. The patient was not diagnosed with COVID-19 prior to vaccination. The outcome of the event was not recovered. No follow-up attempts are possible; information about lot/batch number cannot be obtained.
1191987	4/10/2021	NC	64	M	4/1/2021	4/4/2021	Received vaccine on Thursday evening at 6:00pm. On Saturday, I felt that something has changed with my hearing. On Sunday morning I was deaf in my left ear.
1191491	4/10/2021	OH	51	F	2/12/2021	3/5/2021	Total / Sudden Sensorineural Hearing Loss - Right Ear, Tinnitus

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1190996	4/10/2021	AZ	61	F	3/20/2021	3/20/2021	feels a little dizzy; Noticed her voice is not quite right; feels kind of wierd; significant loss of hearing in right ear; when she eats fruit, she notices blocked feeling in her ear. When she talks she notices an echo in her ear; muscle pain in injection site the first night after her dose; Sore Arm Left; This is a spontaneous report from a contactable consumer (patient). A 61-year-old female patient received first dose bnt162b2 (PFIZER COVID VACCINE), via an unspecified route of administration, administered in Arm Left on 20Mar2021 (Batch/Lot Number: ER2613) as single dose for COVID-19 immunization. There were no medical history and concomitant medications. The patient received first dose of PFIZER COVID VACCINE last Saturday 20Mar2021. On 26Mar2021 the patient reported muscle pain in injection site the first night after her dose but it only lasted one day. Today 26Mar2021 noticed significant loss of hearing in right ear and feels a little dizzy. Noticed her voice was not quite right. She stated she felt kind of weird. When she eats fruit, she notices blocked feeling in her ear. When she talked she noticed an echo in her ear. She stated she was typically healthy. had this been reported and wondering when it will go away. On 29Mar2021 she stated she called last Friday and reported it because she was so frightened that she had lost her hearing in her right ear. She stated that after one day, her hearing half recovered and after two days, her hearing completely recovered. The patient experienced hearing loss in right ear from 26Mar2021 and sore arm left from 20Mar2021. She stated that she was 61, almost 62 and was very healthy, no medications, not sick. She stated her last vaccine that she had was in childhood. She stated that she doesn't get the flu shot and doesn't get the flu, nothing really. She stated that she had this vaccine for other people, for their concern, she was not worried. She stated the first night, she felt muscle pain in her arm and then she forgot about the vaccine, until Friday. She stated she realized when she searched sudden loss of hearing. She stated that it was all gone. She stated she thought should she have the second one, She stated she thinks it was fine. Clarifies that the first morning she noticed it when she got up it was a little weird, She stated she couldn't hear something, so she started searching this and said she better check it out because it said she needed to get treated sooner. She

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1192495	4/10/2021	IL	18	F	4/10/2021	4/10/2021	<p>stated she thought what should she do and was in a panic and that was how she went on the internet and make the link. She stated she wanted to let Pfizer know that everything was back to normal. The outcome of event 'significant loss of hearing in right ear' and 'when she eats fruit, she notices blocked feeling in her ear. When she talks she notices an echo in her ear' was recovered on 28Mar2021, of event 'muscle pain in injection site the first night after her dose' and 'Sore Arm Left' and was recovered on 21Mar2021, of other events was recovered on an unspecified date.</p> <p>Initially: Severe arm pain at the site immediately and then within minutes of vaccine: hearing loss and then tunnel vision to vision loss to feeling that could pass out: Hearing and vision came back in about 5-10 min and with taking off sweatshirt at that time 12 hours later: 101 fever and chills</p>

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1188817	4/10/2021	WV	54	F	3/17/2021	3/17/2021	hearing loss from right ear; muffled hearing on right ear; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS UNILATERAL (hearing loss from right ear) in a 54-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 006B21) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Renal impairment NOS. On 17-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Mar-2021, the patient experienced DEAFNESS UNILATERAL (hearing loss from right ear) (seriousness criterion medically significant) and PRESBYACUSIS (muffled hearing on right ear). At the time of the report, DEAFNESS UNILATERAL (hearing loss from right ear) and PRESBYACUSIS (muffled hearing on right ear) 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. Concomitant medications were not reported. The patient was evaluated at the urgent care and found a wax plug in her ear. The patient was told it was a coincidence that it started at the same time after getting a shot and is not related to vaccine. Treatment for the events was not reported.; 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.
1191534	4/10/2021	IL		U			Received the first vaccine on January 2. Developed URI symptoms/sinus infection. On January 29th went to medical clinic related to ringing in the right ear. Was placed on Amoxicillin-Clav and told to visit ENT if ringing did not stop. Ringing did improve but never went away. Received second dose of vaccine on Feb. 2nd, 2021. Tinnitus increased after second vaccine. Went to ENT received prednisone for 21 days. Hearing test showed mild hearing loss on first ENT visit and worsening hearing loss on second visit. Currently, in treatment with ENT to investigate all cause of tinnitus and hearing loss.

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1190061	4/10/2021	CA	16	F	4/9/2021	4/9/2021	vomited w/ tunnel vision- temporary hearing loss
1189820	4/10/2021	MO	54	M	4/2/2021	4/5/2021	After vaccine, had sore arm and joint/muscle pain, tiredness for 24 hours. I have had very mild to mild tinnitus most of my life. Noticed 2x increase in tinnitus loudness on April 5. Tinnitus is louder in right ear, and there seems to be 20% hearing loss in right ear.
1189619	4/10/2021	FL	49	F	4/1/2021	4/2/2021	She can't hear at all from her right ear; Her right ear was numb; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS UNILATERAL (She can't hear at all from her right ear) in a 49-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 No adverse event (Medical history not reported.). On 01-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Apr-2021, the patient experienced DEAFNESS UNILATERAL (She can't hear at all from her right ear) (seriousness criterion medically significant) and HYPOAESTHESIA (Her right ear was numb). At the time of the report, DEAFNESS UNILATERAL (She can't hear at all from her right ear) and HYPOAESTHESIA (Her right ear was numb) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No treatment information was provided. No relevant concomitant medications were reported. Based on the current available information and temporal association between the use of the product and the onset date of the reported events, a causal relationship cannot be excluded. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported events, a causal relationship cannot be excluded. Further information has been requested.

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1189612	4/10/2021	NC	52	M	3/25/2021	3/28/2021	lost hearing in his left ear; felt like something entered into his ear; [felt like something entered into his ear] and went down his throat; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS (lost hearing in his left ear) in a 52-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Insulin-requiring type II diabetes mellitus (insulin -dependent). Concomitant products included DOXYCYCLINE for an unknown indication. On 25-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Mar-2021, the patient experienced DEAFNESS (lost hearing in his left ear) (seriousness criterion medically significant), EAR DISCOMFORT (felt like something entered into his ear) and OROPHARYNGEAL DISCOMFORT ([felt like something entered into his ear] and went down his throat). At the time of the report, DEAFNESS (lost hearing in his left ear), EAR DISCOMFORT (felt like something entered into his ear) and OROPHARYNGEAL DISCOMFORT ([felt like something entered into his ear] and went down his throat) 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 these 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 these events, a causal relationship cannot be excluded.

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1189569	4/10/2021	OH		U			Losing their hearing after getting the vaccine; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS (Losing their hearing after getting the vaccine) 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 medical history was reported.). On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced DEAFNESS (Losing their hearing after getting the vaccine) (seriousness criterion medically significant). At the time of the report, DEAFNESS (Losing their hearing after getting the vaccine) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Concomitant product use was not provided by the reporter. Treatment information was not provided. Very limited information regarding this event has been provided at this time. Further information has been requested. This case was linked to MOD21-065420, US-MODERNATX, INC.-MOD-2021-062192 (E2B Linked Report).; Sender's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested. MOD21-065420: US-MODERNATX, INC.-MOD-2021-062192:
1188489	4/10/2021	CO	35	F	3/12/2021	3/25/2021	Tinnitus, sporadic hearing loss, whooshing sound in ears occurring at various times through each day
1189009	4/10/2021	WA	30	F	3/30/2021	3/30/2021	I'm having spells of dizziness, hearing loss, and headaches.



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1190894	4/10/2021	FL	61	F	3/22/2021	3/22/2021	swelling of tongues and upper inside plate; upper inside palate in her mouth was also kind of swelling; upper lip tingling/numbness and swelling of tongues and upper inside plate; muscle soreness near the injection site; injection site was painful; couldn't move her arm behind her or up and was limited with that arm; This is a spontaneous report from a contactable consumer (patient). A 61-year-old female patient received first dose BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in arm left on 22Mar2021 10:15 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included she was in generally good health besides being hard of hearing and she got hit by a car at age 2 and after she got older her HCP said she would be completely deaf by age 60 and she was now classified as being profoundly deaf. There were no concomitant medications. She had never gotten the flu shot in her life. The patient experienced had muscle soreness near the injection site, injection site was painful, couldn't move her arm behind her or up and was limited with that arm on 22Mar2021, numbness and swelling of tongues and upper inside plate, upper inside palate in her mouth was also kind of swelling and upper lip tingling, all on 22Mar2021 19:00. There was no treatment received. She had physician office visit to ask the HCP to see if there was anything she can take before she takes the 2nd dose to prevent this. The clinical course was reported as follows: She had the 1st dose of the Pfizer Vaccine on 22Mar2021 at 10:15am and for the most part where the injection site was and some in the muscle it was very painful and she was told this is very common; the vaccine was given in her left arm into the muscle and the injection site was painful for a while and then the muscle below it felt painful and throughout the day and yesterday she couldn't move her arm behind her or up and was limited with that arm on 22Mar2021. Today the pain was getting better and the muscle and injection site still are kind of sore but she was sure that would get better in time. Around 7:00pm(22Mar2021 19:00) in the evening she had another reaction that was not listed in the severe reactions and that was she had some numbness and swelling in her tongue and then the upper inside palate in her mouth was also kind of swelling and her upper lip was tingling; states this swelling and tingling

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							<p>began on 22Mar2021 and was not ongoing fortunately she slept sitting up and did not want to lie down and suffocate herself; when she woke up at 4:30am the swelling and tingling went away so she does not know what time the symptoms went away because she was asleep. She had no treatment and tries to avoid medicine as much as possible and did not go to the emergency room but following yesterday she went to the walk in clinic last night because she wanted to ask the HCP to see if there was anything she can take before she takes the 2nd dose to prevent this, and the HCP said there is nothing he can do. Case were assessed as non-serious by reporter. Outcome of muscle soreness near the injection site, injection site was painful, couldn't move her arm behind her or up and was limited with that arm was recovering, of other events was recovered in Mar2021. Information on lot/ batch number has been requested.</p>
1189730	4/10/2021	FL	18	M	4/9/2021	4/9/2021	tunnel vision, feeling faint, loss of hearing
1192566	4/10/2021	IN	39	F	2/9/2021	3/30/2021	Acute idiopathic loss of hearing in left ear, not related to acute injury
1186240	4/9/2021	NJ	53	F	1/6/2021	4/2/2021	Sudden Sensorineural hearing loss, profound left ear

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1183802	4/9/2021		53	M	2/23/2021	3/23/2021	Sensory hearing loss; hearing problem and could barely hear; This spontaneous case was reported by a consumer and describes the occurrence of HYPOACUSIS (hearing problem and could barely hear) and DEAFNESS NEUROSENSORY (Sensory hearing loss) in a 53-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 001B21A and 024M20A) for COVID-19 vaccination. The patient's past medical history included No adverse event. On 23-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 23-Mar-2021, the patient experienced HYPOACUSIS (hearing problem and could barely hear) (seriousness criterion medically significant). On 27-Mar-2021, the patient experienced DEAFNESS NEUROSENSORY (Sensory hearing loss) (seriousness criterion medically significant). At the time of the report, HYPOACUSIS (hearing problem and could barely hear) and DEAFNESS NEUROSENSORY (Sensory hearing loss) outcome was unknown. Treatment was provided with Prednisone and Valtrex 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 Reporter did not allow further contact; 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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1183804	4/9/2021	IL	33	M	3/12/2021	3/12/2021	ringing in my right ear; experienced numbness in his right ear.; complete deafness in my right ear; This spontaneous case was reported by a consumer and describes the occurrence of TINNITUS (ringing in my right ear), HYPOAESTHESIA (experienced numbness in his right ear.) and DEAFNESS UNILATERAL (complete deafness in my right ear) in a 33-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 001B21A) for COVID-19 vaccination. The patient's past medical history included No adverse event (no reported medical history). On 12-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 12-Mar-2021, the patient experienced TINNITUS (ringing in my right ear) (seriousness criterion hospitalization), HYPOAESTHESIA (experienced numbness in his right ear.) (seriousness criterion hospitalization) and DEAFNESS UNILATERAL (complete deafness in my right ear) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 14-Mar-2021 to 15-Mar-2021 due to DEAFNESS UNILATERAL, HYPOAESTHESIA and TINNITUS. At the time of the report, TINNITUS (ringing in my right ear), HYPOAESTHESIA (experienced numbness in his right ear.) and DEAFNESS UNILATERAL (complete deafness in my right ear) outcome was unknown. Patient mentioned Within 45 min after the injection, there was ringing in his right ear. 2 hrs after injection, he experienced numbness in his right ear. 3 hrs after injection, he experienced complete deafness in his right ear. 13Mar2021: He went to Urgent Care. 14Mar2021: He went to the Emergency Room. He stayed there under observation from 14Mar2021-15Mar2021. He saw neurologists, Internal medicine doctors, & a bunch of other doctors. No one could diagnose the problem.; 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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1184219	4/9/2021	FL	62	F	3/25/2021	4/1/2021	On the 7th day after receiving the vaccination I experienced a sudden onset of severe Vertigo. I could not walk or open my eyes due to the sensation of the room tilting and moving which resulted in severe uncontrollable vomiting. The severe vertigo lasted 24 hours. However, I continue to have intermittent bouts of dizziness, nausea and loss of hearing that occurs 10-15 times a day lasting 5-10 minutes. Although I am able to walk about now, I still can not drive due to safety concerns. My biggest fear, of course being if this is going to be permanent or if it will resolve. Item 21 can not be addressed at this time as it is still unresolved.
1184539	4/9/2021	CO	62	F	3/23/2021	3/24/2021	Nausea, headache, stiff neck six hours later. Muscle pain, elevated blood pressure, severe ringing in ears occurred 15 hours (3am) after injection. Saw PCP on 3/25- prescribed blood pressure medication (never taken before) and referred to ENT. Saw ENT on 3/29 and 3/30. Prescribed high dose Prednisone for two weeks. Hearing test shows hearing loss in left ear. Received injection in left arm. Shrill high pitched ringing in both ears with no improvement. See Audiologist on 4/20 for hearing recheck to see if hearing has improved in left ear.
1185160	4/9/2021	IN	22	F	4/7/2021	4/7/2021	At 15 min mark after receiving vaccine: sudden loss of hearing (extremely muffled, underwater sounding), profuse sweating, and then lost vision and passed out entirely when attempted to stand up for help. After laying down, quickly regained consciousness and felt better. After effects and soreness have been minimal. Have not fainted during/after vaccine before.

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1185345	4/9/2021		62	M	4/9/2021	4/9/2021	<p>Patient seen at the Vaccination Center on 4/9/2021. He had just received his first dose of COVID-19 vaccine. He was feeling dizzy and felt like he was going to pass out. He was transported by EMT to the Adverse Reaction Area and then moved. Representative served as sign language interpreter via tablet. His wife was also present and is deaf. Patient stated that his heart rate was very slow, and he felt dizzy, hot, and sweating. He also felt very weak and it appeared that was going to pass out. He was also shaking. Ambulance was called due to the above symptoms. Patient also stated that he thought he may need to go to the ER. Vital signs: 9:53 am: Blood pressure was 143/71, heart rate was 71. Patient was given an ice pack. He also took sips of water. He then noted that he felt better, after laying down. Ambulance crew arrived and he declined to go to the ER. He got up and walked around stated that he felt better. He notes that his head feels like it's slightly buzzing, so he lay down again. Vitals signs: 10:25 am: Blood pressure 138/63, heart rate is 64, temperature is 98.1 Patient felt better and noted no more buzzing in his head. He also walked around and felt normal. Patient notes that he blacked out as a child whenever he got shots/injections. He was not surprised that this happened to him today. He wanted to know whether he should get the second vaccine injection. It is recommended that he get his second vaccine injection and we also discussed that he may have the same reaction as today. He should allow for extra time and be well-hydrated. He felt safe to go home and his wife would be driving him home. Should he feel worse, then he should go to the ER. The patient and his wife understand this. All questions were answered.</p>
1186132	4/9/2021	NV	68	F	3/20/2021	3/23/2021	<p>Tinnitus developed suddenly. Very loud, very constant. No hearing loss noticed. No previous experience with tinnitus.</p>

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1186697	4/9/2021	PA	55	M	4/7/2021	4/8/2021	Developed severe tinnitus and subsequent hearing loss in right ear. 4 weeks after testing positive (asymptomatic) for COVID-19 (early December 2020), tinnitus and hearing loss was experienced over a 3-4 day period. This hearing loss and tinnitus improved after 8 days. Hearing loss and tinnitus gradually improved (estimated 90-95% return in hearing with tinnitus varying). Hearing loss after receiving the vaccine was more rapid (severe loss of hearing in right ear over a two day period).
1186863	4/9/2021	CO	36	F	4/7/2021	4/7/2021	Beginning approximately 2 minutes after receiving shot, experienced the following in sequential order: - Mild but Sharp pain (2-3 on pain scale) in my right elbow (same side as injection) - Slight lightheadedness - Sweating Profusely - Extremely blurred vision - Muffled hearing/Deafness I recovered within 10-15 minutes and was sent on my way by the paramedics. Was not particularly nervous about getting the shot, and I don't have any history of fainting. Felt perfectly fine the rest of the evening.
1186945	4/9/2021	WV	53	M	3/18/2021	3/19/2021	Complete hearing loss in right ear on March 26th , 8 days after vaccination. Upon vaccination he first felt congestion in the right ear the next day. Congestion progressed to what we thought was an ear infection or sinus infection that had gone to the ear. Was treated on March 28 with Prednisone dose pack. On March 30th Z-pack antibiotic was added. On April 2, PCP changed antibiotic to doxycycline and upped the Prednisone. On April 5th referred to ENT specialist. On April 8th appointment with ENT, extensive hearing tests performed and diagnosis of complete hearing loss. Loss presented similar to "viral hearing loss.~~
1187965	4/9/2021	IA	35	M	3/26/2021	3/27/2021	Hearing loss
1186110	4/9/2021	IN	43	F	1/11/2021	1/12/2021	Tinnitus, hearing loss left ear
1179860	4/8/2021	OH	44	M	4/5/2021	4/6/2021	Sudden loss of hearing in left ear
1182971	4/8/2021	NH	34	F	4/8/2021	4/8/2021	Lightheadedness, dizziness, loss of hearing, then laid down before I fainted.

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1182918	4/8/2021	TX	31	M	3/4/2021	3/5/2021	was diagnosed with high-frequency hearing loss and tinnitus BEFORE vaccine. My tinnitus was not bad the day of or had flared up before taking the vaccine. 1-2 days after having the first dosage of the vaccine I noticed my tinnitus was a lot worse, more noticeable, extremely high pitched, and unbearable for most of the time, on top of the "sickness" and "sore arm" symptoms. This lasted a couple of days (about 3-4 days) after the vaccine. This also happened for the second dose I received on 4/1/21. I did check in my symptoms on the v-check application (first dose only).
1182733	4/8/2021	CA		U			acute hearing loss in the left ear; This is a spontaneous report from a contactable physician. A patient of unspecified age and gender received the second dose of BNT162B2 (Pfizer-BIONTECH COVID-19 Vaccine), via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient experienced acute hearing loss in the left ear about ten days after getting the vaccine. The physician was wondering how common this was and if there was any advice for re-treatment or further testing. Outcome of the event was unknown. Information about the lot/batch number has been requested.; Sender's Comments: Based on temporal association, a contributory role of BNT162B2 to the event hearing loss 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.
1182559	4/8/2021	IL	18	F	4/8/2021	4/8/2021	Immediate ringing and loss of hearing in ears, blurred/starry vision, excessive sweating, nausea, and faintness.
1182308	4/8/2021	CA	32	M	4/8/2021	4/8/2021	Patient reported feeling dizzy, nauseated, Loss of hearing and lightheaded ness Patient seen by medical team, refused medical transport, stated symptoms improved, signed AMA form



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1181929	4/8/2021	PA	66	F	2/22/2021	2/24/2021	I have severe tinnitus 24x7 and sleep with a cochlear implant to lessen the noise so I can sleep. I remove it when I awaken. When I took it off THIS TIME, the noise was so loud and profound that I fell back on my bed, put my hands on my head, grabbed a hearing aid (near the bed) that allows some sound. If that had no effect, I would've been non-functional. I didn't report it at the time. When I saw my internist for a yearly exam, I told her and did a follow-up in an email. I wanted her to understand it how incapacitated I was. I have a profound hearing loss (hence, the cochlear implant). I have no doubt this was due to ototoxicity of the vaccination.
1181821	4/8/2021	TX	47	F	1/22/2021	1/24/2021	I had a goose egg on the left arm at the site of the injection. It went away after 24 hours. 1/24/2021 - ringing in my right ear high pitched ringing at 06:00 pm. Never experienced it before. I took OTC allergy medication, and it didn't go away. I saw Dr. 1/27/2021 and the Dr. did not find any fluid or anything wrong, but she gave me-antibiotic and drops Cipro. Those did not help with the ringing. About 2 weeks later, the ringing had not gone away after finishing the meds. At this appt, doctor recommended I go to an ENT. February 17th or so I saw Dr. I met with an audiologist that did a hearing test. And they confirmed that in my right ear that I had mild hearing loss associated with Tinnitus. Then when I saw the ENT, he did a complete exam didn't find an infection or fluids or anything in my outer ear that would create tinnitus. He ordered an MRI. Had the MRI done the last week of February. I still have the ringing it never stops. No other treatment after initial treatment from first Dr appt. I did have the second vaccine - 2/25/2021.
1180179	4/8/2021	CA	32	F	4/1/2021	4/1/2021	Patient reported feeling dizziness and loss of hearing in the left ear. First blood pressure taken was low at 73/36. Retaken 3 minutes later and was within normal range at 121/83. Symptoms resolved 10 minutes later.
1183190	4/8/2021	FL	34	F	4/8/2021	4/8/2021	Immediately after injection, I became light headed, clammy, increased heart rate, tingles over entire body and loss of hearing. After a few minutes the symptoms decreased. The tinkling feeling in the fingers lasted longest. After 15 minutes the symptoms had ended. The pharmacist kept me there for over 30 minutes for observation.

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1179734	4/8/2021	OH	43	M	3/24/2021	3/26/2021	- 36 hours after vaccine administration I start to experience loud ear ringing; - few hours later the ringing reduced in intensity and stays constant until now; - it is a high frequency noise in both ears; - audiogram revealed high frequency hearing loss and ENT found the external ears to be normal; - I have received no treatment or any other type of care;
1179392	4/8/2021	TX	46	M	3/25/2021	4/4/2021	On 04/04/21, I lost all hearing in my right ear and can only hear a ringing (tinnitus). This might not be COVID Vaccine related, but I have not taken any other medications and overall feel healthy. Went to the emergency room on 04/04/21, CT scans performed with no issues found. They gave steroids and antibiotics to take. I Saw ENT on 04/06/21 and a hearing test was performed and it was determined that I had Sudden Sensory Deafness in my right ear. Taking 60mg Prednisone each morning and 500mg Valacyclovir twice daily. The symptoms have not changed (improved or worsened) as of today.
1179373	4/8/2021	OH	69	F	2/10/2021	2/13/2021	Tinnitus and hearing loss right ear

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1179194	4/8/2021	AZ		F	3/11/2021	3/11/2021	tinnitus; head is still cloggy; woke up with plugged ear; ringing in left ear; Swollen glands with whole neck side; 50% hear loss; sore arm; tender to touch; headache; This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS (50% hear loss) in a 63-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 003A21) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 11-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1. On 11-Mar-2021, the patient experienced PAIN IN EXTREMITY (sore arm), TENDERNESS (tender to touch,) and HEADACHE (headache). On 13-Mar-2021, the patient experienced TINNITUS (tinnitus), LYMPHADENOPATHY (Swollen glands with whole neck side), DEAFNESS (50% hear loss) (seriousness criterion medically significant), HEAD DISCOMFORT (head is still cloggy), EAR DISCOMFORT (woke up with plugged ear) and TINNITUS (ringing in left ear). At the time of the report, PAIN IN EXTREMITY (sore arm), TENDERNESS (tender to touch,), HEADACHE (headache), TINNITUS (tinnitus), LYMPHADENOPATHY (Swollen glands with whole neck side), DEAFNESS (50% hear loss), HEAD DISCOMFORT (head is still cloggy) and TINNITUS (ringing in left ear) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown.; 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.
1179037	4/8/2021		20	F	4/7/2021	4/7/2021	Felt pain in left arm immediately followed by difficulty breathing, sweating, nausea, loss of hearing and vision. No treatment given. Suddenly felt ok after a few moments. Went home, got full body aches, chills, tiredness, inability to sleep, and diarrhea

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1178954	4/8/2021	CA	62	F	4/1/2021	4/2/2021	The day after my second dose of Moderna COVID-19 vaccine, I had sudden onset tinnitus in both ears. It persists one week later. Never louder, never softer. Always there. No OTC medicine helps. The noise level is moderate (6 out of 10). I also have stuffy sinuses since the vaccination, but relieving sinus pressure using cold medicine does not stop the tinnitus. My blood pressure is now measuring "low hypertension," whereas before it was reliably normal. The soonest an ENT doctor can see me is in 3 weeks. I'm very concerned about possible hearing loss, but at this time, I would guess any hearing loss is mild.
1180586	4/8/2021	TX	50	M	2/6/2021	2/10/2021	3 Days after first vaccine (2/6/21) I had ringing in ears. Also, had slight loss of hearing 6 days after first vaccine. Ringing in ears has gotten worse after 2nd vaccine (2/27/21).
1173928	4/7/2021	FL	65	F	3/13/2021	3/17/2021	Hearing loss in left ear for three days.; Ringing in both ears.; This is a spontaneous report from a contactable consumer (patient). A 65-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration, administered in the left arm on 13Mar2021 18:00 (lot number: En6199) as single dose (at the age of 65-years-old) for COVID-19 immunisation. Medical history included atrial fibrillation (Afib) and shrimp allergy. Concomitant medication included diltiazem hydrochloride (DILTIAZEM [DILTIAZEM HYDROCHLORIDE]) taken for an unspecified indication, start and stop date were not reported; and multiple vitamins (unspecified). No other vaccine was given in four weeks. The patient did not have COVID prior vaccination. On 17Mar2021 at 08:00, the patient experienced ringing in both ears, hearing loss in left ear for three days. The patient was concerned about taking second shot on 03Apr2021. No treatment was received for the events. The patient was not tested for COVID post vaccination. The patient has not recovered from the events.

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1178022	4/7/2021	FL	47	F	4/3/2021	4/3/2021	Slight loss of hearing, vision completely whited out, blood pressure dropped to 60/40. I felt very sleepy. This started about 2 or 3 minutes after the vaccine was injected. Medics started me on oxygen and elevated my feet. Attempted to start an IV (not successful because I have hard to find veins), checked blood sugar (normal) and did EKG (normal). After about 15 minutes my blood pressure returned to normal and I felt fine except for a headache. They wanted to send me to the hospital but I refused. My primary care physician advises me to not take the second dose of this vaccine.
1178168	4/7/2021	TX	58	F	4/1/2021	4/7/2021	woke up on 4/7/2021 unable to hear at all in right ear, after having NO symptoms since original vaccine on 3/11/2021 except for a dull headache on most days, which subsided on 4/3/2021. There were no prior indication that hearing loss was imminent, such as pain, ringing in the ear, redness, itching, fever, crackling, popping, muffled hearing, etc. I saw my primary doctor on 4/7/2021 to rule out ear wax or infection. She started me on Prednisone and referred me to ENT. Appointment with ENT is on 4/8/2021 for his evaluation.
1175270	4/7/2021	CA	73	M	3/1/2021	4/4/2021	Pfizer vaccinated on 3/1/2021. On 4/4/2021, I suddenly found hearing loss of left ear. When listening to music with headphones, the sound in the left ear is so weak that almost no sound can be heard. I am really frightened and worried it's going to be permanent.
1176017	4/7/2021	GA	60	F	2/23/2021	2/25/2021	Tinnitus and whooshing sound , stuffiness in both ears and feeling of ears being blocked , bilateral hearing loss, symptoms more severe in left ear since last week of February. It took me a few weeks to get an ENT appointment scheduled. ENT surgeon consulted , Bilateral hearing loss as evidenced by two audiograms, ENT surgeon advised more tests including another audiogram. Saw ENT on March 24 ,2021, next appointment scheduled for April 9th No history of any hearing problems before this event started, no history of any health problems , no chronic diseases or on any medication.

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1176178	4/7/2021	WA	66	F	1/25/2021	1/25/2021	severe tinnitus that started a few hours after the vaccine and lasted for 2 weeks after. The tinnitus has persisted and is intermittent but occurs daily for long periods. I also have experienced a noticeable hearing loss. I have difficulty hearing what people are saying and all sounds are muffled. I did not have this problem or the tinnitus prior to receiving the vaccine.
1176280	4/7/2021	TN	65	M	3/29/2021	3/31/2021	Have had increase in Tinnitus. Have had partial loss of hearing in left ear, across all frequencies, and particularly at low frequencies. I test my hearing at home. Have had hearing loss in both ears from 2013 thru 2017 but that resolved in 2018 and 2018 thru now hearing has been excellent.
1176469	4/7/2021			U		3/25/2021	LOSS OF HEARING FOR A BIT; DIZZINESS, COULD NOT HOLD HEAD UP; VISUAL DISTURBANCE; SWEAT; SORE ARM; NAUSEA; This spontaneous report received from a patient via a company representative concerned a patient of unspecified age and 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 was not reported, administered on 25-MAR-2021 for prophylactic vaccination. The batch number was not reported. We are unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 25-MAR-2021, the subject experienced loss of hearing for a bit. On 25-MAR-2021, the subject experienced dizziness, could not hold head up. On 25-MAR-2021, the subject experienced visual disturbance. On 25-MAR-2021, the subject experienced sweat. On 25-MAR-2021, the subject experienced sore arm. On 25-MAR-2021, the subject experienced nausea. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from loss of hearing for a bit, dizziness, could not hold head up, visual disturbance, sweat, and nausea on 25-MAR-2021, and had not recovered from sore arm. 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.

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1176831	4/7/2021	IN	36	F	4/1/2021	4/1/2021	Headache lasting 17 hours, nausea, intense itching at vaccination site, large red rash at vaccination site and loss of hearing acuity for 6 days.
1177009	4/7/2021	WI	78	M	3/11/2021	3/19/2021	Patient went to ER on 3/19/21 for sudden idiopathic hearing loss, right ear. was given prednisone and meclizine and followed up with Dr. on 4/6/21. pt is now receiving ongoing treatment from ENT specialist for steroid injections in ear to try and regain hearing.
1177294	4/7/2021	CA	40	M	3/19/2021	3/20/2021	Tinnitus in left ear and possible hearing loss
1177610	4/7/2021	IN	20	F	4/2/2021	4/2/2021	Within 5-6 minutes after receiving vaccine profuse sweating was noted, loss of hearing and impaired vision. Also felt extremely nauseous

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1173864	4/7/2021	TN	83	F	1/30/2021	2/19/2021	severe sudden onset hearing loss; This is a spontaneous report from a contactable consumer. This consumer reported similar events for two patients. This is the first of two reports. An 83-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in arm on 30Jan2021 10:00 (lot number: EN5318; Expiration Date: May2021) as a single dose (at the age of 83-years-old) for covid-19 immunisation. Medical history included a little discomfort in her hands and arthritis both from an unknown date. Concomitant medication included paracetamol (TYLENOL ARTHRITIS) taken for a little discomfort in her hands and arthritis, start and stop date were not reported. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899, expiry date: Mar2021) on 09Jan2021 (at the age of 83-years-old) for covid-19 immunisation and flu (at the age of 83-years-old) for flu vaccine on an unspecified date in 2020. It was reported that two weeks later (19Feb2021), she had developed severe sudden onset hearing loss. The hearing loss occurred in both ears and that it has basically stayed the same. They have gone to the ENT and already had steroid injections. The patient was also prescribed Valtrex. The patient had finished the 10 day course of Valtrex that was prescribed just in case there were any viral or fungal issues causing the hearing loss. The patient has had 3 hearing tests performed and there has been no improvement in her hearing. The patient was scheduled for her 4th hearing test this week on 22Mar2021. The patient has had 3 rounds of steroid injections into her ears. The patient underwent lab tests and procedures which included hearing test: unknown result on 01Mar2021, hearing test: not improving, unchanged on 08Mar2021 and 15Mar2021 and magnetic resonance imaging: normal on 12Mar2021. The outcome of the event was not recovered.; Sender's Comments: Linked Report(s) : 2021315404 Same reporter/vaccine/event, but different patient



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1175407	4/7/2021	TN	57	F	3/10/2021	3/11/2021	About 6 hours later flu like symptoms, body aches, fever. The next day having tinnitus type symptoms and sensitivity to sounds. That lasted about another day and seemed to go away. Then the same hearing symptoms came back on April 5. I went to my Ear, nose and throat doctor and they said I had moderate sudden hearing loss in my left ear. I have gone before and they had a baseline test to compare it to. They have prescribed a steroid, prednisone to try to help. They said there is a possibility the hearing loss could be permanent.
1175942	4/7/2021	TX	58	F	3/30/2021	3/31/2021	Pt presented to clinic for eval for severe vertigo, nausea, vomiting, diarrhea, dizziness, hearing loss, loss of balance. Symptoms started the evening of 3/31/21 and she presented to the clinic for eval on morning of 4/1/21. Was diagnosed with labyrinthitis by ENT.
1175229	4/7/2021	ME	78	M	3/22/2021	4/4/2021	Hearing loss left ear
1177672	4/7/2021	TX	27	M	2/27/2021	2/27/2021	16:30 Problem : dizziness loss of hearing and vision, clammy & sweaty skin, SOB, unsteady gait, feeling very hot. 27 year old male received first Moderna vaccine, Moderna lot# 012a21a, Exp. 08/17/21, to left deltoid. 16:32 patient began experiencing dizziness, loss of hearing and vision, clammy and sweaty skin, SOB, unsteady gait. 16:37 patients hearing and vision returned. VS: 77-100/60, O2 sats 99% room air. Encouraged deep breathing for SOB. Applied cool cloth to back of patient?s neck. Ice chips given. Offered bottle water and snack 16:45 staff assisted patient to observation table. Patient ambulated without any issues. 16:50 asked patient how was he feeling, patient states, ?he is feeling better and he is no longer experiencing any symptoms. Observed patient for an additional minute. Reassessed vitals: VS: 86- 106/62, O2 sats 97%, room air. 17:10 Patient left facility. No other complaints voiced.
1175221	4/7/2021	PA	66	M	4/5/2021	4/5/2021	DIZZINESS AND VERTIGO AND APPEAR TO SEE FLOATERS / HAVE NOT HAD THIS AFFECT SINCE I WAS FIRDT DIAGNOSED WITH TINNITUS AND COMLETE RIGHT EAR HEARING LOSS vestibular disorder in 1985

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1178234	4/7/2021	TX	64	M	3/16/2021	3/20/2021	<p>Shingles; Sore throat; Swelling of the left side of his face; Ear infection; Rash on the side of his face, inside his ear, and on his scalp; Loss of hearing; Drooping of his left lip; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEAFNESS (Loss of hearing) and FACIAL PARALYSIS (Drooping of his left lip) in a 64-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 002B21A) 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 recorded medical history). Concomitant products included AMOXICILLIN SODIUM (AMOXICILLIN [AMOXICILLIN SODIUM]) for Laceration. On 16-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Mar-2021, the patient experienced DEAFNESS (Loss of hearing) (seriousness criterion medically significant), FACIAL PARALYSIS (Drooping of his left lip) (seriousness criterion medically significant), OROPHARYNGEAL PAIN (Sore throat), SWELLING FACE (Swelling of the left side of his face), EAR INFECTION (Ear infection) and RASH (Rash on the side of his face, inside his ear, and on his scalp). On 27-Mar-2021, the patient experienced HERPES ZOSTER (Shingles). At the time of the report, DEAFNESS (Loss of hearing), FACIAL PARALYSIS (Drooping of his left lip), HERPES ZOSTER (Shingles), OROPHARYNGEAL PAIN (Sore throat), SWELLING FACE (Swelling of the left side of his face), EAR INFECTION (Ear infection) and RASH (Rash on the side of his face, inside his ear, and on his scalp) had not resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Patient went to urgent care center for the events experienced. Treatment for the events included ciprofloxacin 0.3%, dexamethasone 0.1% suspension and cefdinir. Treatment for shingles included valacyclovir 1mg, gabapentin 300mg, and prednisolone 4mg. Most recent FOLLOW-UP information incorporated above includes: On 30-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, a causal relationship cannot be excluded.</p>

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1175029	4/7/2021	IA		M	3/13/2021	3/16/2021	Deafness unilateral; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEAFNESS UNILATERAL (Deafness unilateral) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 13-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Mar-2021, the patient experienced DEAFNESS UNILATERAL (Deafness unilateral) (seriousness criterion medically significant). At the time of the report, DEAFNESS UNILATERAL (Deafness unilateral) had not resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment included steroids; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of this event, a causal relationship cannot be excluded.

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1175010	4/7/2021	CA		M			<p>unilateral loss of hearing; white noise; This spontaneous case was reported by a health care professional (subsequently medically confirmed) and describes the occurrence of DEAFNESS UNILATERAL (unilateral loss of hearing) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) 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 medical history reported). On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced DEAFNESS UNILATERAL (unilateral loss of hearing) (seriousness criterion medically significant) and TINNITUS (white noise). At the time of the report, DEAFNESS UNILATERAL (unilateral loss of hearing) and TINNITUS (white noise) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.; 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>
1173992	4/7/2021			U			<p>severe sudden onset hearing loss/ another person who is experiencing the same; This is a spontaneous report from a contactable consumer. This consumer reported similar events for two patients. This is the second of two reports. 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 (Batch/Lot number was not reported) as 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 severe sudden onset hearing loss/ another person who is experiencing the same. The event was assessed as serious (medically significant). The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021314158 same reporter/similar AE/drug and different patient.</p>

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1173959	4/7/2021	RI	67	F	2/20/2021	2/21/2021	<p>Rash in her mouth/break out on her lips and her ear;  Rash in her mouth/break out on her lips and her ear;  Shingles; Pain; Ramsay-Hunt syndrome; Loss of hearing;  Itchy on the left side of the face; Blisters on face, temple,  ear; Left side of her face is scorched bright red and  painful; Left side of her face is scorched bright red and  painful; Numbness; no feeling in her mouth on the left,  cheek, temple; Numbness; no feeling in her mouth on the  left, cheek, temple; Blisters in her mouth; Pain, teeth  started hurting went to her temple; Pain, teeth started  hurting went to her temple; This is a spontaneous report  from a contactable consumer (patient). A 67-year-old  female patient received the first dose of BNT162B2  (PFIZER-BIONTECH COVID-19 VACCINE, Lot number  and expiration date were not reported) on the left arm on  20Feb2021 (09:30) as a single dose, with route of  administration unspecified, for COVID -19 immunization  at the pharmacy/drug store (not a military facility).  Medical history included shoulder surgery in Aug2020;  ongoing abnormal blood pressure; ongoing heart  disorder; and was in a pacemaker and defibrillator.  Concomitant medications included carvedilol for  abnormal blood pressure from 2012 and ongoing;  losartan for heart disorder from 2012 and ongoing; and  furosemide from 2017 and ongoing. On 05Mar2021, the  patient had Ramsay-Hunt syndrome and loss of hearing.  On 21Feb2021, the patient had pain/teeth started hurting  and went to her temple. On 22Feb2021, the patient had  blisters in the mouth; left side of the face was scorched  bright red and painful; and numbness/no feeling in the  mouth on the left, cheek and temple. On 23Feb2021, the  patient had blisters on face, temple and ear. On  25Feb2021, the patient was itchy on the left side of the  face. On an unspecified date, the patient had rash in her  mouth/broke out on her lips and ear; shingles; and pain.  The events, 'pain/teeth started hurting and went to her  temple', 'blisters in the mouth', 'blisters on face, temple  and ear' and 'pain', had resulted into physician's office  visit. The patient's ENT had the patient put on treatment  with valaciclovir (VALTREX) and prednisolone for the  'blisters in the mouth', 'blisters on face, temple and ear';  treatment for 'pain/teeth started hurting and went to her  temple', 'left side of the face was scorched bright red and  painful', 'itchy on the left side of the face', 'rash in her  mouth/broke out on her lips and ear', 'shingles' and 'pain';</p>

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1175605	4/7/2021	MS	59	F	2/2/2021	2/4/2021	<p>and unspecified ear drops for 'loss of hearing'. The outcome of the events was not recovered for 'Ramsay-Hunt syndrome', 'loss of hearing', 'pain/teeth started hurting and went to her temple', 'left side of the face was scorched bright red and painful', 'numbness/no feeling in the mouth on the left, cheek and temple' and 'itchy on the left side of the face'; was recovered on 04Mar2021 for 'blisters in the mouth' and 'blisters on face, temple and ear'; and was unknown for 'rash in her mouth/broke out on her lips and ear' and 'pain'. The patient had received the second dose of vaccination on 20Mar2021. Information about batch/lot number has been requested.</p> <p>Received Covid vaccination/injection in right arm on 2/2/21. For the 1st four days, had occasional heart palpitations that lasted first 4 days then stopped--heart returned to normal with no more episodes. On 2/4/21, that night when I went to bed, I noticed a ringing in my left ear that became louder &amp; louder as the next several days went by. I then noticed substantial hearing loss in my left ear. Also 2 days later, I started having a dull ache around my left ear along with the loud, high pitched ringing. I kept thinking it would get better but a week before my next vaccine, I called my ENT who monitors a small lesion &amp; hearing in my left middle ear. I already had slight conductive hearing loss from this lesion and my last appointment/check up with her was in September 2020. Dr. had me come to the hospital on 3/11/21 and a hearing test was performed and my left ear hearing had declined 15 decibels since my last hearing test in Sept 2020. I was prescribed a Medrol Pak (steroids) for 1 week and returned on 3/23 for a 2nd hearing test with no improvement in my hearing or the loud ringing (tinnitus). The Dr. told me that my hearing test showed damage to the left ear nerve. I had also developed an inflamed, painful large sore under the left side of my tongue &amp; was prescribed Triamcinolone Acetonide Dental Paste to use 2 x daily on the sore. The Dr. ordered an MRI of my brain &amp; left ear to make sure the lesion in my ear had not grown. I had the MRI on 3/29/21 and returned to my Dr. on 3/30/21 for results. The lesion was stable, no growth. I made my own decision and did not return for my 2nd Covid vaccine because it appears the 1st vaccine either inflamed the nerve in my ear or caused an auto immune response.</p>

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1177427	4/7/2021		64	M	3/11/2021	3/13/2021	I have suffered from tinnitus for 20 years however 2 days after taking the first vaccine my hearing loss increased and the ringing in my ears got much louder. It is currently 4 weeks later and it is still very loud. I just received my second shot to day and am praying that it doesn't get worse.

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1178261	4/7/2021	CA	59	F	1/5/2021	1/5/2021	head aches; chills; weird feeling on head; left hand from elbow to finger tips began to numb then few seconds right hand fingers began to numb, numbness to both hands; started feeling sweaty; shortness of breath; light headed; nausea; blood pressure drop to 40; The initial was missing the following minimum criteria: Unspecified AE. Upon receipt of follow-up information on 23Mar2021, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable consumer (patient). A 59-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose at the age of 59-years-old via an unspecified route of administration, administered in arm left on 05Jan2021 (Batch/Lot Number: EL1284) as single dose for covid-19 immunisation. Medical history included atrial fibrillation, thyroid problem, hearing problem from an unknown date and unknown if ongoing, Stroke like paralysis from 2014 to an unknown date, gallbladder removal in 2018. Concomitant medications included sotalol, taken for atrial fibrillation from Dec2019 and ongoing; levothyroxine taken for thyroid disorder from 2017 and ongoing; cyanocobalamin (B-12) taken for an unspecified indication from 2014 and ongoing; aspirin [acetylsalicylic acid], taken for an unspecified indication from 2014 and ongoing. The patient experienced 3-5 minutes after the first dose on 05Jan2021, started feeling sweaty, shortness of breath, light headed, nausea, numbness to both hands. Next day 06Jan2021, wake up with numbness to left hands, head aches, chills, weird feeling in head (back left side of head). This went on for about 2 weeks lasted 1 month got better as days went day. It was also reported that she experienced that her left hand from elbow to finger tips began to numb then few seconds right hand fingers began to numb for period of 2 weeks. Her blood pressure drop to 40 on 05Jan2021. The patient underwent lab tests and procedures which included blood pressure measurement: drop to 40 on 05Jan2021, sars-cov-2 antibody test: 0 (came out 0 antibodies on my blood work had never been expose to anyone with Covid 19) on 24Nov2019, sars-cov-2 test: negative on 08Jan2021. The patient also reported that on 05Jan2021, she received the dose and had a reaction to it, but that same day her mother was taken to the hospital because she wasn't breathing well and she came out positive to Covid, she passed away 14



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							days after the patient took a test on Covid 08Jan2021 tested negative. She don't know if it was soon to be tested but other family member tested positive. The patient did not receive treatment for the events and was hospitalized due to the events. The patient did not recover from nausea, headache, chills while the outcome of the other events was unknown.
1178641	4/7/2021	FL	71	F	2/9/2021	2/15/2021	I started having tinnitus in both ears after serveral days of having the first vaccination. I have a hearing problem from birth but when the tinnitus started I had noise and more hearing loss. I have not had treatment yet but I have an appoinment for my physical next month. I will have it checked out then if I can stand the loss.
1178337	4/7/2021	IL	41	M	3/31/2021	4/1/2021	The next day I noticed tinnitus (high pitch mild ringing in both ears) . Therefore it has been a total of 7 days with ringing in both ears and it has not gone away. It has been constant, no pulses, no frequency changes, etc. Just constant high pitch ringing in both ears. Sometimes by inner ear feels funny, slightly tingle feeling that is related to the tinnitus. The tinnitus is most noticeable in quiet settings, sleeping, reading, watching TV, I do not noticed it as much in office environments, listening to music, walking outside. I have experienced tinnitus in the past after loud music band or rock concert but do not attend live loud music often and try to avoid it because it hurts my ears. I do not have any known hearing problem, I try to protect my ears and use hearing protection often to avoid damage. When I cut my lawn I wear hearing protection, when I am working on shop floor I wear hearing protection. I am thinking the vaccine is related somehow. I never had COVID-19 in past. I use to be able to be in quiet settings and not have any tinnitus before vaccine.

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1178292	4/7/2021	PA	33	M	3/24/2021	3/24/2021	hearing loss in his right ear; This is a spontaneous report from a contactable consumer (patient). A 33-year-old male patient received bnt162b2 (BNT162B2), at the age of 33-years at vaccination, dose 2 via an unspecified route of administration, administered in Arm Left on 24Mar2021 15:15 (Batch/Lot Number: EL3248) as SINGLE DOSE, dose 1 via an unspecified route of administration on 02Mar2021 13:00 (Batch/Lot Number: EN6203) as SINGLE DOSE for covid-19 immunisation. Prior to vaccination, the patient was not diagnosed with COVID 19. The patient's medical history and concomitant medications were not reported. On 24Mar2021 22:00, patient experienced hearing loss in his right ear with outcome of not recovered. Since the vaccination, the patient has not been tested for COVID 19. Information on Lot/Batch number was available. Additional information has been requested.
1170609	4/6/2021	PA	43	M	4/1/2021	4/1/2021	extreme fatigue that went away after 48 hours I now have a hearing problem that I did not have prior to the vaccine , I am not sure if it is a eustacean tube disorder but everything sounds muffled and it is like when you need to get your ear to pop but it wont. This has been going on for 5 days now and I plan to see a doctor to see if anything can be done, I am hoping that this is not a permanant issue. I have read of other people having hearing loss from the vaccinees from all 3 manufacturers
1171365	4/6/2021	PA	55	F	4/5/2021	4/6/2021	About an hour an a half after the shot - I started to feel nauseous due to inner ear issue. I could not hear well out of my right ear. There was no ringing - things just sounded like they were in a tunnel. Even when I was in bed I still did not have full hearing back. I felt like I had to lay very still do to the nausea. I had once had a bout of vertigo and I also knew that a sudden movement can feel awful. The vertigo incident resulted in some hearing loss in my right ear. Anyway, I finally fell asleep and by 9 a.m. was fine. It is 11:30 and everything seems fine. I am only writing this as I googled hearing loss with vaccine and it seems like quite a few people are reporting this as well as tinnitus. I think this is gone but too early to tell.

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1171528	4/6/2021	CA	47	F	3/19/2021	3/21/2021	Sudden, complete hearing loss in left ear - still complete hearing loss today after Prednisone taper and two hearing tests with audiologist and ENT Vertigo - Resolved in one week, treated with Meclizine Vomiting - Resolved in four days, treated with Zofran Nausea - Continues to today. Still cannot eat full meals or proteins Dizziness - Continues to today.
1172780	4/6/2021	OH	64	F	4/2/2021	4/3/2021	Hearing loss in right ear - from 2:30 am to midnight 4/3/21 Racing heart and serious PVCs - from 2:30 am to 9:00 pm 4/3/21 Dizziness, fever, horrible body aches, headache, mild nausea all day 4/3/21 Complete exhaustion from 4/3/21 to 4/4/21 all day
1174183	4/6/2021	OH	61	M	3/11/2021	3/13/2021	Tinnitus, hearing loss
1172986	4/6/2021	OR	48	F	4/4/2021	4/4/2021	Within ten minutes of the shot in the left arm, I experienced paresthesia (numbness, burning, and tingling) of Cranial Nerve VII as well as a feeling as if a cotton ball had been inserted toward the front of my ear (no hearing loss or pain, just an odd feeling of fullness). As this was not a reaction I had been told to watch for, I thought I must be imagining it, and did not report to onsite personnel. When it was still happening fifteen hours later, I called the OHSU COVID line for advice.
1173385	4/6/2021	CA	70	M	1/15/2021	2/20/2021	Around the time of the 1st dose of Pfizer Covid-19 vaccine, noticeable deteriorating hearing loss, more rapidly in right ear. Then 2 weeks after 2nd dose, sudden profound hearing loss in left ear occurred.

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1173607	4/6/2021	MA		M	3/3/2021	3/4/2021	there was no fluid in ear; suspected an ear infection.; he woke up with his ear blocked and he couldn't hear; This spontaneous case was reported by a nurse (subsequently medically confirmed) and describes the occurrence of SUDDEN HEARING LOSS (he woke up with his ear blocked and he couldn't hear) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) 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.). On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Mar-2021, the patient experienced SUDDEN HEARING LOSS (he woke up with his ear blocked and he couldn't hear) (seriousness criterion medically significant). On 05-Mar-2021, the patient experienced EAR DISCOMFORT (there was no fluid in ear) and EAR INFECTION (suspected an ear infection.). At the time of the report, SUDDEN HEARING LOSS (he woke up with his ear blocked and he couldn't hear), EAR DISCOMFORT (there was no fluid in ear) and EAR INFECTION (suspected an ear infection.) 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. Reporter did not allow further contact
1174082	4/6/2021	AZ	56	F	4/2/2021	4/4/2021	Acute hearing loss in left ear. Began approximately 36 hours after injection.

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1174173	4/6/2021	MN	79	M	3/10/2021	3/31/2021	When I woke up on March 31, I discovered I had lost total hearing in my right ear. I went immediately to see my doctor. There was no wax buildup, and the outer ear was clear. I went the same day to see my Audiologist (since I wear hearing aids), and upon testing discovered there was a total loss of hearing in the right ear. The left ear was the same as test results in October, 2020. On April 2 I went to see dr. He determined that I had suffered SSNHL, Sudden Sensory Neural Hearing Loss. Dr. prescribed Prednisone, 10 mg tablets: 6 at one time for 4 days, then 4 at one time for 4 days, then 2 tablets for 4 days, then 1, then 1/2. As of this date, April 6 there is yet no improvement
1172502	4/6/2021	PA	70	F	3/22/2021	3/29/2021	Gradual loss of hearing acuity. Realized tv was at highest audio and couldn't decipher dialogue
1171655	4/6/2021	WA	0	F	4/6/2021	4/6/2021	Hearing loss and tinnitus in my left ear since getting the first dose of covid vaccine Moderna.
1170213	4/5/2021	NC	62	M	4/1/2021	4/3/2021	Severe Tinitus and hearing loss in one ear.
1168515	4/5/2021	NY	58	M	3/21/2021	3/29/2021	Asymmetric Sensorineural Hearing Loss (SNHL) in right ear, Profound deafness. Tinnitus,
1168717	4/5/2021	CA	22	M	4/3/2021	4/3/2021	nausea, shortness of breath light headedness loss of vision loss of hearing tingling fingers to right hand.
1169221	4/5/2021	AZ	58	F	3/23/2021	3/25/2021	First injection on 3/2/21 I developed Eustachian tube dysfunction with significant hearing loss in bilateral ears. Treated with Rx ear drops. No infection noted on exam findings. Symptoms nearly resolved w/in 2 weeks. Second injection on 3/23/21, I did not have any reaction or adverse symptoms until 2 days after. The ETD restarted. I was treated with Prednisone with a positive response w/in 2-3 after treatment, while tapering the Prednisone my ETD got more severe. I am scheduled for an ENT visit on 4/6/21. My symptoms are progressing to the point of inability to tolerate hearing my voice or any other noises.
1169745	4/5/2021	OH	32	M	3/26/2021	4/1/2021	Piercing tinnitus. Hearing became a bit muffled after a few days and turned into full blown, piercing, debilitating tinnitus within a week. Never had any hearing problems before in my life and my senses have always been acute.

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1170153	4/5/2021	OH	72	F	3/8/2021	3/10/2021	Patient said two days after her first dose she experienced "profound hearing loss" in her right ear, as well as tinnitus. Joint pain started about 5 to 6 days after the hearing loss. She has visited her doctor, ENT specialist, and surgeon, who has been giving her cortisone shots in her ear.
1170308	4/5/2021	NH	44	F	4/5/2021	4/5/2021	Temporary hearing loss and ear discomfort. Felt like ear pressure when changing altitude quickly, but added with warm burning sensation. Mostly return to normal 6 hours later. Also experienced warmth and uncomfortable tight feeling in right side of neck. Neck discomfort mostly resolved 6 hours later.
1170492	4/5/2021	MD	52	F	3/31/2021	4/2/2021	I feel pain and weakness on my whole left side. Nausea Intermittent deafness on the left side Ears popping at times Numbness at times Headache Fatigue Sleeping Napping Lost trains of thought Lightheadedness
1169877	4/5/2021	TX	87	F	3/5/2021	3/6/2021	30 hours later , profound sensorineural hearing loss in right ear. Treated by steroid, hearing returned in one week . Black tarry stools . INR increased from 2 to 12 ER visit , admitted to hospital on March 23. TIAs
1166637	4/4/2021	IN	65	F	1/22/2021	1/27/2021	4 Days after vaccine, mild to increasing dizziness, vertigo, ringing in ears (tinnitus), resulting in going to hospital 1 week after first vaccine with extreme dizziness, vomiting, tinnitus. Loss of hearing in left ear going from no hearing to minimal hearing over 10 weeks. 2 hospital visits (one 7 days after first vaccine, 2nd one 4 weeks after 2nd vaccine. Prescribed Meclizine. 10 weeks since first vaccine. Still experiencing extreme dizziness, vertigo, tinnitus, loss of hearing in left ear. First vaccine 01/22/2021 Second vaccine 02/12/2021
1166392	4/4/2021	FL	63	M	3/11/2021	3/11/2021	Severe loud high pitched continuous tinnitus in both ears with some hearing loss.
1166327	4/4/2021	CO	51	M	4/3/2021	4/3/2021	Tinnitus and partial hearing loss in right ear

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1166093	4/4/2021	FL	40	M	2/20/2021	3/24/2021	Initial symptoms first 48 hours first dose; Headache; Joint pain- hips and below (left knee locked up and could not bare weight on it). Tiredness; Second dose 48 hours; Fever 101.8; Tiredness; Severe headache; Sore Arm; Approximately 1 month after 2nd dose unknown if related. Sudden hearing loss left ear; Tinnitus; Lightheaded.
1166967	4/4/2021	VA	59	M	4/3/2021	4/4/2021	At 5:30 pm on April 4, one day subsequent to my 2nd dose, I lost hearing in my left ear accompanied by a feeling of pressure and severe tinnitus. No other known factors occurred prior to onset of deafness and tinnitus. I am not experiencing any sinus symptoms, or am I aware of any blockage of my ear canal. Attempts to clear the eustachian tube are unsuccessful, no crackling, popping, etc. I have had light to moderate tinnitus in both ears for decades, but the sudden (instantaneous) onset of deafness accompanied by a very severe ringing is unprecedented. It is now 6:36 pm and the pressure is subsiding but the ringing and deafness continues.
1167211	4/4/2021	NY	63	M	4/1/2021	4/2/2021	Loss of hearing in one ear
1163064	4/3/2021	CA	70	F	2/5/2021	2/5/2021	Sudden sensorineural (?inner ear?) hearing loss Moderate to severe hearing loss. Words sound fuzzy. Some things I can't hear. Onset a few days after 1st shot.
1165042	4/3/2021	OH	59	F	3/11/2021	3/13/2021	Severe Tinnitus, slight hearing loss, accompanying severe headache - tinnitus has persisted for three weeks, unabated.
1164976	4/3/2021	TX	36	F	3/30/2021	3/30/2021	Per EMT report, approximately 5 minutes after vaccination, client had seizure lasting approximately 3 minutes. Client is hearing impaired and has a history of epileptic seizures. Spouse reports last seizure event x3 weeks ago. Per EMT/Paramedic, airway was maintained. EMS was called, after seizure event, client was awake, respirations even and unlabored, skin warm and dry, client was incontinent of urine, no acute distress. Spouse answered EMS questions on behalf of client as client is deaf. Client refused transport to hospital, but was transported to vehicle without further incident.

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1164933	4/3/2021	AL	40	F	3/5/2021	3/6/2021	After second dose high fever for 36 hours, sore arm, ringing in ears. Ringing in ears has been persistent. 4 weeks later had significant hearing loss in right ear.
1164709	4/3/2021		49	F	3/8/2021	3/8/2021	Tinnitus and Hearing Loss
1164643	4/3/2021	WA	42	F	4/1/2021	4/2/2021	Ringing in left ear and hearing loss in left ear started on 4/2 and continues to persist. For the first 24 hours after receiving vaccine I sweated and had severe muscle cramps which have now resolved. The ringing ear and hearing loss hasn't stopped and is very concerning.
1163130	4/3/2021	OH	59	F	3/15/2021	3/19/2021	Tinnitus and severe hearing loss in right ear. Scheduled for an MRI by ENT doctor to rule out anything else. Audiologist checked hearing. Normal on left ear , severe hearing loss and tinnitus right ear. Scheduled for 2nd dose on April 6, 2021. Probably going to at least delay second dose as I am now terrified hearing loss will get worse! Just to note, I have NEVER had anything wrong with my hearing ever until I got this shot!
1163032	4/3/2021	AZ	57	F	3/17/2021	3/20/2021	3 days after I received the first shot of the Moderna vaccine I developed terrible tinnitus. I already had mild tinnitus but this was 10 times worse. It hasn't gone away. when I researched it online I realized many other people had also gotten tinnitus from the vaccine. I went to an ENT today April 2nd to get my hearing checked. My hearing is not registering as damaged but the audiologist told me several other people had been coming in because they got tinnitus from the covid-19 vaccine. I'm very worried about getting the next vaccine especially because I have been reading reports of people going deaf from it and people whose tinnitus has not resolved in several weeks. My tinnitus has not resolved either and I'm worried the damage to my ears could come later. I can't sleep because of the ringing and I'm really scared.



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1163019	4/3/2021	HI	38	M	1/11/2021	1/22/2021	I am a board certified physician in gastroenterology and internal medicine and work for the Medical Center. I have no hearing or ear history. Received Pfizer vaccine from work on 12/21/20 L arm IM, no side effects, sore arm for < 24 hours, second dose 1/11/21 L arm IM, no side effects, sore arm for < 24, however, on 1/22/21 work up with muffled hearing and bringing in the left ear only. Called colleague Doctor who started prednisone 50 mg immediately on 1/23/21 and continued for 4 weeks without improvement. Audiometry testing 1/25/21 demonstrated moderate high-frequency hearing loss suggestive of sudden sensorineural hearing loss (SSHL). Emergent CT head and MRI brain and ear were unrevealing. 20 session of hyperbaric oxygen therapy from 1/21-2/21 without substantial improvement. Vasculitis workup negative with normal ANA, CRP, ESR, ANCA, CBC, CMP. 3/21 COVID-19 antibodies test for exposure negative. 4/21 noting more public event reporting of hearing loss and tinnitus associated with vaccines. reports-grow-amid-covid-19-vaccinations/) while I understand there is not causal evidence yet linked, I feel that there is a temporal relationship and odd correlation that needs to be recorded and accounted prospectively further. Vascular surgeon, Hematologist who are treating me for a PE and DVT post ankle fracture and surgery do not correlate the SSHL with my DVT, PE, or anticoagulation. To date 3 audiometry tests demonstrate persistent left-sided moderate high-frequency hearing loss.
1164363	4/3/2021	FL	36	F	3/29/2021	3/29/2021	The first day about 10 minutes after I got the shot I had hives on both arms and an instant migraine. The hives went away after an hour or two but the migraine was present for 3 days. On March 31st I started having jaw and ear pain and April 1st hearing loss. On April 3rd, I went to the ER due to my ear canal closing completely, swelling and lots of pain. I was put on amoxiciclan and ear drops to treat outer ear infection. I still cannot hear.
1164332	4/3/2021	NJ	41	M	3/13/2021	4/3/2021	Sudden onset sensorineural hearing loss In left ear.

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1164226	4/3/2021	WV	39	F	1/12/2021	1/18/2021	I have never had a history of hearing loss or ringing in my ears. Within 1 week of receiving my first dose of the COVID vaccine, I began experiencing horrible tinnitus, dizziness and nausea.
1164110	4/3/2021	MI	52	F	3/17/2021	3/18/2021	Hearing loss in left ear, pressure in both ears, slight ringing in ears
1163874	4/3/2021	DC	26	F	4/1/2021	4/2/2021	tinnitus and hearing loss in left ear
1163667	4/3/2021	WI	46	F	3/24/2021	3/30/2021	* Vaccinated on 3/24/21 * Suddenly suffered tinnitus and hearing loss at my left ear on 3/30/21 * Tinnitus and hearing loss got better on 4/2/21 * Took Methy1PREDNISolone treatment starting 4/2/21 after seeing ENT doctor * As of 4/3/2021, the tinnitus at my left ear went away but still experiencing a small degree of hearing loss.
1163360	4/3/2021	PA	62	F	3/16/2021	3/20/2021	Tinnitus and loss of hearing in both ears
1164650	4/3/2021	WA	77	M	3/31/2021	3/31/2021	tinnitus, which I have had for 20 years, was worsened. Today (3 days after shot) seems better. Purchased ear buds day after shot to mask extra tinnitus noise for sleep. Part of the associated ear bud app has a hearing test. (Who knew?) Anyway, this hearing test showed hearing loss for maybe 40% of their test I told primary care doc about it and she said should see ENT doc asap. Have not noticed any hearing loss, just "failed" the test. Appt with ENT is 3 days away. On prednisone in the interim per the rec of pcp.

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1158703	4/2/2021	ND	59	F	1/20/2021	1/20/2021	Hearing loss with tinnitus to right ear; Hearing loss with tinnitus to right ear; This is a spontaneous report from a contactable nurse (patient). A 59-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 20Jan2021 11:30 (Batch/Lot number was not reported) as SINGLE DOSE for COVID-19 immunisation. The patient was not pregnant at time of vaccination. Medical history included DM (diabetes mellitus) and HTN (hypertension) from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. 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 20Jan2021 11:30, the patient experienced hearing loss with tinnitus to right ear. The events resulted in doctor or other healthcare professional office/clinic visit and disability or permanent damage. The events was treated with hyperbaric oxygen therapy. The outcome of the events was not recovered.; Sender's Comments: Based on the information provided and plausible temporal association, the causality between the suspect drug and the event hearing loss with tinnitus cannot be completely excluded. This 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 to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
1160588	4/2/2021	PA	60	M	3/12/2021	3/12/2021	Symptoms: hearing loss and tinnitus. States he had an evaluation by PCP and an ENT was treated with a steroid shot. Unknown if symptoms related. Plans to continue to follow up with MD's.

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1161990	4/2/2021	OH	71	M	2/1/2021	2/1/2021	Some hearing loss; Tinnitus; A spontaneous report was received from Consumer concerning himself, a 71 years old male patient who received Moderna's COVID-19 vaccine(mRNA-1273) and experienced some hearing loss/deafness and tinnitus/tinnitus. The patient's medical history was not provided. Concomitant product included Warfarin. On 1 Feb 2021, prior to onset of events, the patient received their first of two planned doses of mRNA-1273 (Batch Number: 007m20a) by intramuscular route for prophylaxis of COVID-19 infection. On 01 Feb 2021 he had some hearing loss and tinnitus. Patient stated he canceled second Moderna vaccine until he receives more information on his side effect. Patient was concerned about scheduling second Moderna vaccine. Treatment was not reported. Action taken with mRNA-1273 in response to the event was withdrawn. The outcome of the event some hearing loss and tinnitus was unknown.; Reporter's Comments: Very limited information regarding the events has been provided at this time. Further information has been requested.

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1162010	4/2/2021	WI	79	M	1/28/2021	1/28/2021	Significant hearing problem in left ear / loss of hearing in left ear; Gets loud ringing in the ear; Amplified sounds after taking first dose; A spontaneous report was received from a consumer concerning himself, 79-year-old, patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced significant hearing problem in left ear, loss of hearing in left ear/deafness unilateral, gets loud ringing in the ear/tinnitus, amplified sounds after taking the first dose of the moderna vaccine/ ear disorder. The patient's medical history was not provided. Concomitant medications reported included acetylsalicylic acid, simvastatin, vitamin D, multivitamin and levothyroxine for product use for unknown indication. On 28 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 007M20A) via unknown route in the left arm for prophylaxis of COVID-19 infection. On 25 Feb 2021, the patient received their second of two planned doses of mRNA-1273 (Lot number: 007M20A) via unknown route for prophylaxis of COVID-19 infection. Patient reports that he was scheduled for a brain scan. On 28 Jan 2021, the patient experienced significant hearing problem in left ear, loss of hearing in left ear, gets loud ringing in the ear, amplified sounds after taking the first dose of the moderna vaccine. Treatment information was not provided. The patient received both scheduled doses of mRNA-1273 prior to the event(s); therefore, action taken with the drug in response to the event(s) was not applicable. The outcome of the event(s), significant hearing problem in left ear, loss of hearing in left ear, gets loud ringing in the ear, amplified sounds after taking the first dose of the moderna vaccine was unknown.; 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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1162094	4/2/2021	WI	38	F	1/19/2021	2/4/2021	Severe bilateral tinnitus; Hearing loss; This is a spontaneous report from a contactable nurse reporting for self. A 38-years-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, administered in left arm on 19Jan2021 (at the age of 38-years old) (Batch/Lot Number: EL1293) as a single dose for COVID-19 immunization. The patient had not received any other vaccines in the 4 weeks prior. Medical history included postural orthostatic tachycardia syndrome (POTS) from an unknown date. The patient had not experienced COVID prior to vaccination. The patient's concomitant medications were not reported. The patient previously received first dose of BNT 162b2 on 29Dec2020 at 12:00 PM, in left arm for COVID-19 immunization; and previously received CECLOR and experienced allergy. The patient developed severe bilateral tinnitus and hearing loss on 04Feb2021 at 2:00am, 2 weeks after vaccination with 2nd dose. The event resulted in a doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care visit, and Disability or permanent damage. As treatment for the events, the nurse reported "multiple visits to doctors and medications hearing." The outcome of the events severe bilateral tinnitus and hearing loss were not recovered. The patient wasnot COVID-tested post vaccination.; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 vaccine can not be excluded for the reported events of tinnitus and hearing loss due to temporal relationship. Case will be re-assessed upon the additional information provided. 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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1162122	4/2/2021			F			became deaf in one hair; became extraordinarily sick; This is a spontaneous report from a contactable consumer reported for his wife. A 72-year-old female patient received her 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 immunization. Medical history and concomitant medications were not reported. Historical vaccine included polio vaccination at six years of age for immunization. Patient was to receive second dose on 26Mar2021. She had a concern with polio vaccination at six years of age. She went to get her teeth cleaned and the dentist reported that his wife became extraordinarily sick, became deaf in one hair. Had spoken to HCP. She was asking if there was a website that she can search adverse reactions. Outcome of events was unknown. Information on the lot/batch number has been requested.
1162564	4/2/2021	SD	67	M	3/25/2021	3/28/2021	2 days after first inj. developed cold sore upper lip treated normally and went away after week or so. 3 days after second dose another sore on bottom lip felt and looked like a burn, used vaseline and better after week and a half. 3 days after second dose extreme tinnitus started in left ear, 4 th. day hearing loss in left ear, stuffy plugged feeling, no pain. Continues to this day. Also feeling fatigued.

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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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1158803	4/2/2021	NC	44	F	3/12/2021	3/23/2021	<p>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.</p> <p>Acute vertigo lasting for three days with some lessening after 3 days but but normal activity has not resumed. It is not accompanied by tinnitus or hearing loss.</p>

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1159941	4/2/2021	OH	48	M	4/2/2021	4/2/2021	pt is deaf. as soon as shot was administered pt was holding his heart and made a motion that he had chest pain. pt became diaphoretic. he wrote on a piece of paper that he had chest pain. plain twp ems assessed him. he did have elevated blood pressure of 130/90 as well. squad took him to the hospital.
1159239	4/2/2021	KY	43	F	4/1/2021	4/2/2021	Pfizer-BioNTech COVID-19 Vaccine EUA I was vaccinated yesterday and woke up with morning with tinnitus in both ears, although it appears to be worse in the left ear than the right. I also think I've got a bit a hearing loss, but that may just be the interference of the high pitched tone. Everything sounds a bit muffled today, though, as well.
1160463	4/2/2021	VT	80	F	3/18/2021	3/19/2021	Vertigo, nausea, dizziness, vomiting, hearing loss. All symptoms lasted 48 hours. Went to Urgent care and was given Meclizine 12.5mg and Ondansetron 4mg. Dizziness and nausea lessened over the next 3 days. Went to ENT doctor - Hearing test on 3/29/21 revealed total loss of hearing in right ear. Hearing in left ear was diminished before vaccination and that was about the same after the vaccination. ENT injected steroid into right ear on 3/31/21. Second steroid injection on 4/2/21. No improvement in hearing so far. Dizziness continues off and on. Still unstable and needs to use a walker.
1159311	4/2/2021	TN	66	F	2/1/2021	3/1/2021	The only immediate reaction to the vaccine was soreness in my arm. On March 11, I woke at 3:30 AM and had almost total hearing loss in my right ear along with some unsteadiness. I have also experienced unusual neurological symptoms like burning, tingling and numbness in my right foot, leg, hand and face. My second vaccine was delayed because I was taking steroids to help with hearing loss. I had my second shot on March 31 with no side effects to date.
1159323	4/2/2021	KS	58	M	3/12/2021	3/17/2021	Noted upon awakening that hearing decreased in left ear - progressed to total hearing loss over course of the day. OTC remedies attempted - ear cleaning, peroxide in ear. Some hearing resolved after several days, pt still describes feeling such as water in hear re: decreased hearing.
1159431	4/2/2021	NC	74	M	2/12/2021	2/19/2021	98% loss of hearing in Right Ear

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1159516	4/2/2021	CA	52	M	1/8/2021	3/1/2021	I hear a High pitched tone heard in both ears. Constant, day or night. No change with head position, or when clearing ears, or when plugging one ear or the other. Very annoying, I hear it with everything I do. I do not think I have any hearing loss. And I may get my hearing checked but unfortunately I don't have a baseline audio gram to be able to compare.
1158340	4/2/2021	TX	24	F	3/17/2021	3/17/2021	I am suffering from hearing loss in my left ear. I feel like swimming in the deep pool.
1162779	4/2/2021		51	M	2/25/2021	3/21/2021	Total hearing loss in right ear

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1158695	4/2/2021	AZ	61	M	3/3/2021	3/1/2021	<p>Lost hearing on my right ear, same side the shot I had; Tinnitus and still I have ringing in my right ear; This is a spontaneous report from a contactable consumer (patient). A 61-year-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6203), via an unspecified route of administration in right arm on 03Mar2021 as a single dose for COVID-19 immunisation. Medical history included high blood pressure and cholesterol. Concomitant medications included amlodipine besilate/ valsartan for blood pressure high, hydrochlorothiazide, atorvastatin for cholesterol, and alprazolam. The patient stated "I had a really bad side effect from my 1st (dose) Pfizer vaccine for Covid shot. I probably got it 16 days ago on Wednesday, the date I got it, I received it on Wednesday 03Mar2021 of this year. It was the Wednesday, this Saturday I was feeling great, feeling fine and I became, I lost my hearing on my right ear, my right ear at the same side as the shot and I still have tinnitus then I have taken steroids (prednisone) for it (treatment). Four days later, I experienced low hearing in my right ear, low hearing, I lost my hearing in my right ear. I have tinnitus, still I have ringing in my (right) ear. Yes, I want them to follow up because I don't know if I should take the 2nd shot. I am not sure if I am going to take the 2nd shot because I will just the "affect" (not clarified), I don't want to get deaf. I got, my hearing, my hearing is back. I don't know what extend, I am going to the doctor next week to get a hearing test. I have been taking prednisone, a steroid for my hearing; 10 mg tablet, I started off of it's 6 tablets 3 times a day and decreased to 5 tablets 3 times a day, 60 mg for 3 days in a row then 50 mg for 3 days in a row and then 40 mg for 3 days in a row, I got a table at time, so I was getting a bad reaction to the prednisone, So my doctor told me to stop it. (Dosage further not clarified) I was getting super anxiety, I couldn't, I can't sleep at night and can't sleep at all. I am on antibiotics and steroid (treatment), I am on steroid to regain my hearing and now next weekend I am supposed to do for my second shot and I don't to take it but I "still" (not clarified) have tinnitus and I lost my hearing in my right ear, I don't know what to do, so I just waited at home let's see what happened this. Are those side adverse effects or what, I don't know?" Outcome of lost hearing was recovered and of tinnitus was not recovered.</p>

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1155138	4/1/2021	WA	60	M	3/26/2021	3/27/2021	severe tinnitus, hearing loss along with body aches the day following 2nd dose of Moderna. The body aches cleared after one day, the tinnitus and hearing loss has not. The symptoms are more pronounced and severe in the morning and clears to more manageable levels by mid-day
1153882	4/1/2021	MO	87	F		3/11/2021	HEARING LOSS; CHILLS; VISION LOSS TO BOTH EYES; This spontaneous report received from a patient concerned an 87 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included polyethylene glycol (peg) allergy, and propylene glycol allergy. 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, 1 total, administered on 11-MAR-2021 for prophylactic vaccination on left arm. No concomitant medications were reported. On 11-MAR-2021, patient experienced vision loss that lasted for an hour. Subject attributed it to the PEG and propylene glycol allergy. Later on the same day, she experienced chills that lasted until 14-MAR-2021. The subject also began having some hearing loss and further probing reveals she was referring to her ears feeling "stopped up" and it "sounded like she was in a deep well". She had not sought medical care at this time. Subject was encouraged to seek medical treatment for issues that won't resolve, would seem serious, or, would be bothersome. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from vision loss to both eyes on 11-MAR-2021, and chills on 14-MAR-2021, and the outcome of hearing loss was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210328836-Covid-19 vaccine ad26.cov2.s-Vision loss to both eyes, Hearing loss. This events is considered unassessable. The events has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the events.

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1153972	4/1/2021	FL		M	2/12/2021	3/12/2021	<p>hearing loss in left ear; All the other symptoms too; A spontaneous report was received from a consumer, concerning a male patient of unspecified age, who received Moderna's COVID-19 vaccine and experienced hearing loss in the left ear. The patient's medical history and concomitant product were not reported</p> <p>On 12 Feb 2021 date, prior to the onset of events, the patient received their first of two planned doses of mRNA-1273 (lot number unknown) via unknown route for COVID-19 infection prophylaxis. On 12 Mar 2021, prior to the onset of events, the patient received their second of two planned doses of mRNA-1273 (lot number unknown) via unknown route for COVID-19 infection prophylaxis. On 12 Mar 2021, patient had experienced other symptoms too but did not elaborate the same. On 15 Mar 2021 patient started noticing hearing loss in his left ear. The patient had not treated his ear loss. Action taken with mRNA-1273 in response to the event was not applicable. The outcome of the events were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded.</p>

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1154008	4/1/2021	PA	77	M	1/21/2021	1/1/2021	Loss of hearing; Tinnitus; A spontaneous report was received from a consumer concerning a 77-year-old, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced deafness/hearing loss and tinnitus. The patient's medical history, was not provided. Concomitant medications reported included prednisone. On 21 Jan 2021, prior to the onset of the events, the patient received their dose of two planned doses of mRNA-1273 (Lot number: 012L20A) intramuscularly in an unknown location for prophylaxis of COVID-19 infection. Approximately two days after vaccination the patient developed hearing loss in his left ear. He consulted doctor but was unable to find the medical reason for his loss of hearing. Also, the patient reported tinnitus. The patient has another appointment with ENT on 06 Apr 2021. The patient is going for a blood work for to confirm for the antibodies after the vaccination. The event deafness was considered as serious and medically significant. The treatment information was not reported. Action taken with mRNA-1273 in response to the events was not reported. The events, loss of hearing and tinnitus was not reported.; 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 events, a causal relationship cannot be excluded.
1154154	4/1/2021		89	M	2/8/2021	2/24/2021	death Narrative: 88 yo male with PMH CAD, aortic valve stenosis, sensorineural hearing loss, impaired fasting glucose, thrombocytopenia, obesity, GERD, and mixed hyperlipidemia was found to have passed away when staff did an outreach on 3/8/2021 for patient to come back for his second vaccine dose. Per family member, patient passed away on 2/24/2021. Patient has no prior positive for COVID19, no recent hospitalization (none found within the facilities record). Patient received the vaccine on 2/8/2021 with no complications. We have no other records to review. Pt was not hospitalized prior to vaccination or post vaccination. Possible cause of death unknown, no death note found in chart.
1154496	4/1/2021	FL	69	M	1/25/2021	1/27/2021	Buzzing tinnitus of left ear. long standing history of left worse than right hearing loss- tinnitus started 2 days after first Moderna vaccination



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1155471	4/1/2021	OH	66	F	3/24/2021	3/29/2021	3/25 - soreness at injection site. 3/29 - Extreme fatigue, body aches. 3/30 - Fatigue, body aches, headache, sudden loss of hearing and tinnitus in right ear, dizziness with vomiting. 3/31 - Family physician recommended taking Zyrtec for tinnitus, still having fatigue but seemed to be improving, bad headache returned. 4/1 - Able to hear just a little in the right ear after 2 doses of Zyrtec but tinnitus and loud ringing in the ear this morning with headache. Fatigue seems a little better this morning.
1155666	4/1/2021	NC	55	F	3/17/2021	3/17/2021	Severe tinnitus starting in left ear then 1 week later the tinnitus is in both ears. Very loud, low, roar causing vertigo, nausea and hearing loss. Horrific headaches.
1155995	4/1/2021	ME	66	F	3/18/2021	3/19/2021	Pfizer--severe ear pain, discharge from ear, ringing in ear, nerve pain across cheekbone, jawline and neck, then hearing loss--started the morning after the first shot. I've been to GP twice--treated with topical antibiotic, but still a lot of pain two weeks later. Pain across cheek, jaw, etc. has let up, but ear still oozing. Don't meet with ear, nose, throat MD until this coming Monday. The outer ear feels "burned" and is crusty. Pus in the ear canal. No fever. Jaw extremely painful (hard to talk and/or eat)
1156065	4/1/2021	OH	68	M	3/25/2021	3/27/2021	received call from patient's wife. reports received 2nd COVID 10 vaccine on 3/25/21 and 2 days later husband went deaf at 5pm on 3/27/21. Went to the ER, then regular physician. Was referred to audiology. Wife states all physicians informed that cause of deafness was caused by the vaccine. Patient may or may not get full hearing back. Reports left hearing has partially returned and right hearing has not.

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1157088	4/1/2021	CA	23	M	4/1/2021	4/1/2021	Patient was waiting for a 15 minute observational period. During the observation he started experiencing dizziness, light headedness and loss of hearing. Patient stood up to notify observation staff of his symptoms and had a syncopal episode and was moved to a cot. Patient soon regained consciousness and observational staff took a first set of vital signs with BP 128/72, O2 97% and strong pulse of 108 Bpm. Patient continued having dizziness for approximately 10 minutes after the event occurred. Onsite medical staff offered an ambulance transport to a nearby medical facility and patient reused against medical advice. Medical staff took a second set of vital signs with BP 124/76, O2 99%, strong pulse 78 BPM. Medical staff took patient out on a wheel chair and patient had a relative drive him home.

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1157551	4/1/2021	CA		M	2/1/2021	2/2/2021	they found yellowish fluid which they thought was an infection, ear pain in his right ear, slight dizziness; overall had manageable energy level to work and appetite; flu-like symptoms; stomach problems; slight diarrhea; sweating; spent more of the day sleeping; had no appetite just drinking fluids; nausea; chills; experienced hearing loss in his right ear; soreness; A Spontaneous report from was received from a Healthcare professional, concerning a 65-year-old male patient, who received Moderna's COVID-19 vaccine experienced multiple symptoms. Patient had a history of cholesterol and high blood pressure. It was reported that patient used Lipitor, Fish oil, cholesterol medications and high blood pressure medications as concomitant product. On 01Feb2021, prior to the onset of events, the patient received his first of two planned doses of mRNA-1273 (unknown lot number) via unspecified route on left arm for COVID-19 infection prophylaxis. On 02Feb2021, within 24 hours, he had right ear pain and following day, he developed hearing loss, slight dizziness but overall had manageable energy level to work and appetite. On the 04 FEB 2021, he had flu-like symptoms, light headed, G.I discomfort, nausea, slight diarrhea, sweating, chills, with continuous hearing impairment, spent most of time sleeping, had no appetite and was just drinking fluids. Next few days slowly gained energy and appetite back. On the 08 FEB 2021, felt really uncomfortable in his ear, still feeling nausea. At urgent care to yellowish discharge from the ear was assumed as infection and treated with Amoxil and Flonase. He recovered the flu-like symptoms except his hearing loss. He was referred to an ear specialist by primary to evaluate the hearing loss. Action taken with mRNA-1273 in response to the events was unknown. The outcome of the events was considered to be unknown at the time of this report.; Reporter's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.

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1157553	4/1/2021	SC		M	2/24/2021	2/25/2021	hearing is gone, cotton in his ear; A spontaneous report was received from a consumer, concerning a male patient of unspecified age, who received Moderna COVID-19 vaccine (mRNA-1273) and experienced hearing loss. The patient's medical history was not provided but it was reported he sees a dialysis doctor. concomitant product use was not provided by the reporter. On 24-FEB-2021, prior to the onset of the symptoms, the patient received his first vaccination of mRNA-1273 (lot/ batch number unknown) via intramuscular route for COVID-19 infection prophylaxis. On 25-FEB-2021, the patient's wife reported his hearing was gone, seems like the patient had cotton in his ear. No treatment medication was reported. Action taken with mRNA-1273 in response to event was unknown. The outcome of the event was considered to be unknown at the time of this report.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.
1158222	4/1/2021	OR	68	M	3/23/2021	3/26/2021	Hearing loss in one ear.
1154159	4/1/2021	MD	63	M	3/20/2021	3/20/2021	Within 8 hours of injection, developed loud tinnitus. Woke up the next morning with almost total hearing loss in left ear and vertigo to the point where I was in bed except to go to the bathroom. Called Tele Doc but was unable to assists. Was able to g appointment with ENT for March 23. Diagnosed with profound Asymmetrical Sensorineural Hearing Loss in left ear, tinnitus and vertigo. Elected treatment to include intratympanic steroid (24mg) injections and oral prednisone. Receiving PT for vertigo. Tinnitus is unchanged as of the date of this report. Hearing test on 3/31 noted a slight change in ability to comprehend speech (2 words vs 0 words).

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1152072	3/31/2021	OH	65	F	3/5/2021	3/6/2021	First day sore arm and slight headache, next day approximately 22 hours later, chills and slight body aches, then highly congested and fever of 101degrees. Fever broke about 3 am in the morning and I noticed that I could not hear out of right ear. Left and right face was tender and made metal drum like sounds in right ear. Went to urgent care on Friday and received a steroid shot and anti-biotics. Relieved sensitive face symptoms, but still had hearing loss and high tinnitus. Went to ENT was put on high dose of steroids, no difference, Hearing test, loss of 70% hearing in right ear. Hearing test one month prior 12% hearing loss. Sensitivity to touch ear yet.

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1153479	3/31/2021	CA	70	F	3/10/2021		<p>This is a spontaneous report from a contactable consumer (patient) received from a Pfizer-sponsored program. A 70-years-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE: Solution for injection, Batch/Lot Number: EN6204), via an unspecified route of administration, administered in Arm Left on 10Mar2021 as single dose for COVID-19 immunization. Medical history included blood pressure abnormal from an unknown date and unknown if ongoing, surgery from 22Sep2020 to an unknown date (I had surgery on 22Sep), ongoing deafness (so actually loss of hearing 2 days before I got my second vaccine/five days later she woke up in the night and could not hear). Historical vaccine included at the age of 70 years patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE: Solution for injection, Batch/Lot Number: unknown), via an unspecified route of administration, on 17Feb2021 as single dose for COVID-19 immunization cause severe sores in my mouth, possibly have shingles or shingles in my mouth and it appears to be canker sore and shingles vaccine. Concomitant medication included Irbesartan 75 mg, orally for blood pressure abnormal. On an unspecified date, the patient reported I had loss of hearing in my ear, in my right ear, sores in her mouth. Reporter stated, I am, I have called because I got my COVID-19 Vaccine just last Wednesday, my second one and I had loss of hearing in my ear, in my right ear and then middle of night it just went away and went to my doctor and she sent to me eye, nose and throat doctor and Friday after the vaccine, I had to be put on Prednisone and that lower your immune system, so when I talk with the Pharmacist I asked her is that would appear with the shot, I had on Wednesday and she was unable to tell me because she said it was so new, so I was just wondering is that going to affect me on my immunity of the second vaccine, that I had start taking prednisone on Friday after day after I got the vaccine. When paraphrased the above concern, Patient stated, I actually I had my first vaccine on 17Feb and then 5 days after that I got severe sores in my mouth and then I went to my doctor, they call it I could possibly have shingles or shingles in my mouth it appears to be canker sore but I had the shingles vaccine then after I got back 5 days later that's when I woke up, so actually loss of hearing 2</p>

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1153400	3/31/2021	CA	61	M	3/30/2021	3/31/2021	<p>days before I got my second vaccine and I talk to my doctor and she said, she thought I still go ahead and have the second vaccine but she said she didn't want to put me on the Prednisone because she said that will weaken my immunity but then it didn't get better and she sent me to Ear, Nose and throat he told my if I have any hope to getting my hearing back I had to start this medicine but that's what I am concerned about, so I took it but I was wondering if it interfere all with the second dose of giving me protection. The mouth sore that is improved, the hearing I still dealing with it, like I said I have been taking the medicine the Friday and then this Thursday the doctor said to come in and he is going to do some testing on my ear but it just come on, so it just middle of the midnight, persisting. patient stated, For my ear its like Prednisone. For the first 2 week I am taking 60 mg and then after 3 weeks, I take 2 tablets 40 mg and then the next week I take 10 mg for 2 days. Reporter stated that five days after she got mouth sores diagnosed as oral shingles after the first dose and then five days later she woke up in the night and could not hear. She thinks she has another reaction. This reaction occurred between the first and second dose of the vaccine. Reporter reported that she lost hearing in one ear. Reporter had the second vaccination on Wednesday and put on prednisone on Friday. Reporter was concerned about not having immunity because of taking prednisone so soon after her second dose. The patient underwent lab tests and procedures which included laboratory test: unknown results on Sep2020. Therapeutic measures were taken as a result of i had loss of hearing in my ear, in my right ear. The outcome of event i had loss of hearing in my ear, in my right ear was not recovered while for sores in her mouth was recovering.</p> <p>Deafness in the left ear, tinnitus in the right ear. Slight dizziness. Started 28 hours after the injection.</p>

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1153266	3/31/2021	MI	44	F	2/15/2021	2/22/2021	6 days after receiving 2nd dose, sudden hearing loss and tinnitus in Right ear. Severe vertigo 8 days after. Prescribed high dose steroids from doctor, still suffering from hearing loss and tinnitus; 6 days after receiving 2nd dose, sudden hearing loss and tinnitus in Right ear. Severe vertigo 8 days after. Prescribed high dose steroids from doctor, still suffering from hearing loss and tinnitus; 6 days after receiving 2nd dose, sudden hearing loss and tinnitus in Right ear. Severe vertigo 8 days after. Prescribed high dose steroids from doctor, still suffering from hearing loss and tinnitus; This is a spontaneous report from a contactable nurse. A 44-year-old non-pregnant female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EN6201) at the age of 44, intramuscularly, administered in the left arm on 15Feb2021 at 15:30 as a single dose for covid-19 immunization. Medical history included covid-19 (If covid prior vaccination: Yes) from an unknown date and unknown if ongoing. Patient has no known allergies. Concomitant medications included levothyroxine sodium (SYNTHROID); liothyronine sodium (CYTOMEL); and ibuprofen (ADVIL [IBUPROFEN]) all taken for an unspecified indication, start and stop date were not reported. The patient received the first dose of BNT162B2 at the age of 44, given intramuscularly in the left arm on 25Jan2021 at 03:30 PM for Covid-19 immunisation. On 22Feb2021, 6 days after receiving the 2nd dose, patient experienced sudden hearing loss and tinnitus in right ear and severe vertigo 8 days after (24Feb2021). Patient was prescribed high dose steroids from doctor. It was reported that the events resulted in doctor or other healthcare professional office/clinic visit, Disability or permanent damage. The patient was still suffering from hearing loss and tinnitus 3 weeks later. The patient underwent lab tests and procedures which included multiple hearing tests and Magnetic resonance imaging (MRI) both on unknown date with unknown result. The outcome of the event was recovering at the time of the report.; Sender's Comments: Based on known drug profile it is unlikely that the reported sudden hearing loss, tinnitus and severe vertigo were causally related to bnt162b2. These are intercurrent medical conditions. Case will be reassessed if additional information is received. The impact of this report on the



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1153176	3/31/2021	TX	45	F	3/4/2021	3/23/2021	<p>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>Sudden deafness; A spontaneous report (United States) was received from a 45-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sudden deafness/sudden hearing loss. The patient's medical history, was not provided. Products known to have been used by the patient, within two weeks prior to the event, included prednisone, mycophenolate mofetil, hydroxychloroquine sulphate and lisinopril. On 04 Mar 2021 prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Batch number:0271921a ) via unknown route in the left arm for prophylaxis of COVID-19 infection. On 16 Mar 2021, after receiving the first dose, the patient experienced complete hearing loss all at once in right ear. She was diagnosed with sudden deafness on 23 Mar 2021. Treatment medication included unspecified steroid shots in the ear drum. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the event sudden deafness was not resolved 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 event, a causal relationship cannot be excluded.</p>

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1154635	3/31/2021	WA	53	M	3/23/2021	3/24/2021	1st dose administered 2/23/2021 with only mild arm pain and no side effects. 2nd dose 3/23/2021 caused significant arm pain in the evening. By morning feeling a little unwell and right ear congestion as well as continued arm pain. No nasal congestion or signs of allergies. By 2nd morning ear congestion was significant. By 3rd morning 3/26/21 right ear hearing seriously impaired. Saw General Physician on 3/27 and found no problems with ears physically and diagnosed with Sudden Sensorineural Hearing Loss. Dr. declined to file as possible vaccine side effect. On Monday 3/29 audiologist confirmed 35-40db loss above 750Hz, and board certified Otolaryngologist ENT confirmed idiopathic SSHL with possible cause of vaccination. Prescribed 60mg prednisone and 1gm Valacyclovir daily. Hyperbaric treatment indicated.
1152597	3/31/2021	DE	76	F	2/1/2021	2/3/2021	2/1 midnight woke up with fever, chills. 2/1 No reaction to vaccine but sore arm. 3/3 went to orthopedic dr for shoulder, put on meloxicam. Began noticing that I couldn't hear well, keep saying excuse me, trouble hearing tv, tinnitus began (Never had this problem before. (Husband could hear better than me without his hearing aids.) (3/18 went to doctor ). He thought I had fluid in my ears. Put me on fluticasone Propionate Nasal spray, stopped meloxicam. Called Dr. and he put me on antibiotic (10 days) thinking I had ear infection. Still couldn't hear well. On 3/1 at 11:45 am had 2nd Moderna vaccine shot. By midnight I had fever, chills. 3/2 fever, chills am, very tired. 3/2 in the evening I thought I would watch tv. I turned it on and the mouths were moving but I couldn't understand anything they were saying. 3/8 Went to ENT and had a hearing test. I still had tinnitus. Test results showed that I have a moderate to severe hearing loss in conversation area in both ears. 3/9 Went to ENT who prescribed prednisone beginning with 60 mg. 3/30 Had another hearing test at ENT. Test results showed no improvement, hearing still as on 3/8. So end results I have tinnitus all the time and a hearing loss that I did not have before taking the vaccine.

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1153500	3/31/2021	ME	35	F	2/11/2021	2/17/2021	<p>developed left sided facial paralysis; some findings of inflammation on the 8th nerve; developed unilateral left ear symptoms such as muffled hearing, mild pain, pressure, tinnitus; developed unilateral left ear symptoms such as muffled hearing, mild pain, pressure, tinnitus; developed unilateral left ear symptoms such as muffled hearing, mild pain, pressure, tinnitus; ear discomfort; ear discomfort that worsened; progressed to mild hearing loss; This is a spontaneous report from a contactable healthcare professional (patient). A 35-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date: EN5318), via an unspecified route of administration, administered in the left arm on 11Feb2021 08:15 at a single dose (at the age of 35-years-old) for COVID-19 immunisation; vaccinated in a hospital. Medical history was not reported. No known allergies. Concomitant medication included escitalopram. The patient had no other vaccine in four weeks. The patient did not have COVID prior to vaccination. Six days after the vaccine (17Feb2021), the patient developed unilateral left ear symptoms such as muffled hearing, mild pain, pressure, tinnitus, which then progressed to mild hearing loss. After about 7 days of ear discomfort that worsened (2 weeks exactly after first dose of vaccine), the patient developed left sided facial paralysis. The patient was seen by ENT, had a full workup including hearing test and head MRI with contrast. Came back normal aside for some findings of inflammation on the 8th nerve. The patient was placed on acyclovir 500mg 3x a day for 7 days and 60 mg of prednisone for 7 days with a 9 day taper. The facial paralysis completely recovered after 2-3 full weeks. The ear was mostly recovered with some residual tinnitus. The patient was not COVID tested post vaccination. The patient required a visit to the doctor and emergency room for the events. The patient recovered from left sided facial paralysis in Mar2021. The patient was recovering from the remaining events.;</p> <p>Sender's Comments: Considering plausible temporal association and lack of alternative explanations, the events left ear hearing loss, inflammation on the 8th nerve, and left sided facial paralysis are possibly related to 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</p>

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							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.
1152064	3/31/2021	NY	22	F	3/30/2021	3/30/2021	Nausea, blurred vision, loss of vision, loss of hearing, out of it, heart racing, body became hot, ice packs were placed all over my body, in a couple minutes my vision came back and my heart rate started to slow
1151906	3/31/2021	SD	69	M	3/11/2021	3/18/2021	One week after second Moderna covid vaccination patient developed tinnitus and hearing loss in both ears, right worse than left. I saw him in clinic on 3/31 about 13 days after onset of symptoms. Normal ear examination. His hearing is reduced even with hearing amplification. Sense of ear pressure is lessening but the tinnitus and hearing loss are still present to the same extent.
1151557	3/31/2021	IN	62	F	3/26/2021	3/31/2021	Starting when I woke up this morning, I had what I'd call mild hearing loss. It varied, moving back and forth between the two ears, throughout the day. It is now 1:30 and is a little better but still there.

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1151463	3/31/2021	TN	64	F	3/10/2021	3/1/2021	<p>she found out later it was an allergic reaction to the vaccine; blotches/rash all over right side of face; She had pain, but she didn't feel that it will kill her, it was sort of burns where the red spots/blotches are.; swelling of the face; throat was a little swollen but not bad; little bit of weakness; didn't feel all that great; She isn't sure if she had muscle pain or joint pain, she may have had a little bit of that.; She isn't sure if she had muscle pain or joint pain, she may have had a little bit of that.; This is a spontaneous report from a contactable consumer (patient). A 64-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on 10Mar2021 (Lot Number: EN6208) (at the age of 64-year-old) as single dose for COVID-19 immunisation. The patient medical history included hearing problem from an unknown date and ongoing. Concomitant medications were not reported. On Mar2021, the patient reported that she started getting blotches all over her face, clarified on the right side of her face, she found out later it was an allergic reaction to the vaccine. 2 days later, she had a few blotches on the left side of her face. She clarifies the blotches have not gone away completely. She had pain, but she didn't feel that it will kill her, it was sort of burns where the red spots/blotches were. The symptoms that she had were swelling of the face, her throat was a little swollen but not bad. She had a rash on her face. She had a little bit of weakness. She didn't feel all that great. She wasn't sure if she had muscle pain or joint pain, she may have had a little bit of that. Therapeutic measures were taken as a result of the events and included treatment with NEOSPORIN (formulation: cream, Lot: 164012, Expiry date: May2022) and BENADRYL (formulation: cream, Lot: 3290LZ, Expiry date: Oct2022) and she mentioned she also took BENADRYL tablets. The patient outcome of the events was unknown.</p>

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1149916	3/31/2021		60	F	3/8/2021	3/15/2021	Potential hearing loss; Dizziness about one week after receiving which lasted about 3 hours; More intense tinnitus symptoms than usual; 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, solution for injection, lot: EL9629), via an unspecified route of administration, administered in left arm on 08Mar2021 13:00 (at the age of 60-years-old) as single dose for covid-19 immunisation. The patient was not pregnant at the time of vaccination. The vaccination facility type was a pharmacy/drug store. No other vaccine in four weeks. The patient did not have COVID prior vaccination and was not COVID tested post vaccination. Medical history included tinnitus, allergy to PCN and "Thygeson's Disease". Concomitant medication included ciclosporin (RESTASIS). The reported adverse events were dizziness about one week after receiving which lasted about 3 hours; more intense tinnitus symptoms than usual and potential hearing loss, all on 15Mar2021 at 17:00. The events resulted in doctor or other healthcare professional office/clinic visit. There was no treatment for the events. The outcome of the events was recovering.
1149337	3/31/2021	IN	57	M	3/30/2021	3/30/2021	Slight imbalance and my ears feel under high pressure and hearing loss with ringing in my ears.

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1153137	3/31/2021		33	M	3/13/2021	3/13/2021	Deafness in the right ear; Ear ringing; Numbness on the ears; A spontaneous report was received from a 33-year-old male consumer who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced numbness in ears/hypoesthesia, ears ringing /tinnitus, and deafness in right ear/deafness unilateral. The patient has no known medical history. No relevant concomitant medications were taken during vaccination. On unknown date, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: if reported or unknown) for prophylaxis of COVID-19 infection. The patient did not experience any adverse events after the first dose. On 13 Mar 2021, prior to the onset of the events, the patient received the second of two planned doses of mRNA-1273 (lot/batch: 001B21A) intramuscularly in left arm for prophylaxis of COVID-19 infection. On 13 Mar 2021, 45 minutes after the second dose, the patient experienced ringing in ears and 2 hours later numbness in ears. Approximately 3 hours after vaccination, the patient experienced deafness in his right ear, which was considered as medically significant event. The event deafness persisted, and the patient went to emergency room for consultation. The patient was treated with prednisone for the events. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the events ringing in ears and numbness in ears were considered as unknown. The outcome of the event deafness in his right ear was considered as not recovered.; 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.
1153404	3/31/2021	NC	42	M	3/30/2021	3/30/2021	Loss of hearing to last less than 5 min. followed by ringing ears through the following day. Uncontrolled palsy for head and neck intermittently through the injection day. I lost my voice and had spasms in my larynx. For several hours I had a hard time choosing my words and speaking which was the scariest. I could not focus enough to even wash my hands on injection day and had to be driven home from work. I got dehydrated because water tasted horrible. The next morning I am better on all fronts except the ringing in my ears wont stop

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1149258	3/30/2021	CA	44	M	3/17/2021	3/19/2021	Patient with no prior otologic history presented to clinic 2-3 days after first dose of vaccine with bilateral tinnitus and aural fullness. No associated hearing loss or vertigo.
1147531	3/30/2021	UT	38	F	3/10/2021	3/15/2021	Sudden hearing loss in left ear
1147325	3/30/2021	CO	56	F	3/25/2021	3/25/2021	both ears were ringing consistently. I have prior "slight" hearing loss and thought that by cleaning my ears over and over again my hearing would improve. Drove up one of the streets that was a hill and ear "popped" and hearing improved, but then went back to the same ringing constantly and hearing loss as before. My arm was sore, but that went away in about a day and no adverse signs were noticed in the arm, no fever, just the ringing and loss of hearing. I can hear if someone talks loudly enough and I have to have the TV up to the loudest volume level. I am concerned now if I get the second vaccine that the loss will be permanent. It has been 5 days since the first dose and the ringing and hearing loss has not improved.
1147215	3/30/2021	NC	70	F	3/26/2021	3/27/2021	Next morning ringing in left ear Discovered 2 days later hearing loss



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1146741	3/30/2021		57	F	1/5/2021	1/6/2021	first dose of BNT162B2:19Dec2020 ; second dose of BNT162B2: 05Jan2021; first dose of BNT162B2:19Dec2020 ; second dose of BNT162B2: 05Jan2021; hearing loss; This is a spontaneous report from a non-contactable consumer (patient). A 57-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EJ1686), via unspecified route of administration on 05Jan2021 (at the age of 57 years) at a single dose in the left arm for COVID-19 immunization. Medical history included 'hypothyroid'. Concomitant medication included levothyroxine. The patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK5730) on 19Dec2020 at 11:00 AM (age: 57-years) in the left arm for COVID-19 immunization. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior vaccination. The patient was not pregnant at the time of vaccination. On 06Jan2021 at 16:00, the patient had hearing loss. The event resulted to physician office visit. The patient received steroids as treatment. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the event was not recovered. No follow-up attempts are possible. No further information is expected.
1148196	3/30/2021	NJ	37	F	3/1/2021	3/2/2021	headache, hearing loss, rash, fatigue
1149265	3/30/2021	CA	53	F	3/10/2021	3/1/2021	Patient with previously stable autoimmune inner ear disease noticed L > R hearing loss after 1st dose of vaccine. Undergoing intertympanic steroid injections.
1146661	3/30/2021	NC	63	F	3/28/2021	3/29/2021	I got my vaccine and was ok (normal mild side effects). I went to bed and awoke around 2:20 a.m. with tinnitus. I have had it in the past but never more than a few hours. It's ongoing and I am concerned after reading prolonged tinnitus can cause hearing loss. I also found an online group of others having this issue (worse and louder than me) from all 3 Covid-19 vaccines). I have no pain, no itching, just the high pitched ringing and it seems to be "louder" or felt as louder in my right ear. All the mild symptoms are resolved and I'm left with this. My other concern is should I take the 2nd shot? Some on the group board skipped it.

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1149250	3/30/2021	CA	72	F	2/28/2021	3/1/2021	Patient with no prior otologic history noted sudden onset of bilateral non-pulsatile tinnitus after second dose of vaccine. No associated hearing loss
1149244	3/30/2021	CA	48	M	2/3/2021	2/5/2021	Patient with no prior otologic disorders noted sudden hearing loss on left 2-3 days after vaccine.
1149103	3/30/2021	WA	30	M	3/26/2021	3/28/2021	Right ear hearing loss - 2 days since vaccination until present (4 days since vaccination) Right ear ringing - 2 days since vaccination until present (4 days since vaccination) Right wrist joint ache - 1 day since vaccination until 2 days since vaccination
1149084	3/30/2021	CT	29	M	3/21/2021	3/29/2021	The tinnitus in my left ear has worsened and I have slight hearing loss in that same ear.
1148928	3/30/2021	CA	65	M	2/11/2021	2/12/2021	Tinnitus in left ear with sudden hearing loss
1148817	3/30/2021	VA	66	F	3/25/2021	3/27/2021	Saturday 03/27/ 2021, suddenly loss my hearing in both ears after 6 hours recovered rt ear hearing somewhat not fully, left ear complete hearing loss.no pain just complete loss in left ear
1149277	3/30/2021	CA	58	F	2/1/2021	3/1/2021	Patient with no prior otologic history notes onset of bilateral hearing loss ~ 10 days after first dose of vaccine. She notes associated non-pulsatile tinnitus and aural fullness AU. Currently treated with oral steroids

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1146662	3/30/2021	IN	84	F	3/1/2021	3/1/2021	Cannot hear; A Spontaneous report was received from a caregiver concerning a 84-year-old, female patient, who received dose of Moderna's COVID-19 vaccine (mRNA-1273) and experienced cannot hear (deafness transitory). The patient's medical history included melanoma, anxiety, pain, edema and a non-specific heart/cardiac condition. Concomitant medications included medications for anxiety, pain, heart and edema. No specific drug names/doses were reported. On 01 MAR 2021 prior to the onset of events the patients received first dose of their two planned doses of mRNA-1273 (Batch N0:022M20A) via unknown route for prophylaxis of Covid-19 infection. On 01 Mar 2021, the patient cannot hear since she got vaccinated. It was reported that, it seems to come and go, hearing has been failing. The event, Deafness was medically significant. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the event, cannot hear (deafness transitory), 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 event, a causal relationship cannot be excluded.
1148338	3/30/2021	WV	43	F	2/15/2021	3/10/2021	Worsening Tinnitus, development of pulsatile tinnitus, acute loss of hearing in left ear, loss of female menstruation (first vaccine)
1147554	3/30/2021	NH		U			Ringling and partial hearing loss in left ear.
1144461	3/29/2021	TN	32	M	3/12/2021	3/12/2021	Initial: 12 hours following - fever, chills, nausea, diarrhea, dizziness Following (since vaccination): extreme dizziness, eye pressure and blurry vision, tingling in scalp and face, back pain, hearing loss, and tinnitus

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1143554	3/29/2021	NY	60	M	3/18/2021	3/20/2021	Received the first COVID vaccine on March 18 and two days later I suddenly lost hearing in my left ear. This was near total hearing loss. I could only hear a slight buzz when putting a phone to my ear and listening for the dial tone. Went to my health care provider a couple of days later. They cleaned both ears and examined for any obvious problems. This seemed to improve the hearing in the ear slightly. Physician's Assistant said the hearing loss was most likely a reaction to the vaccine and advised giving it two weeks to see if it improves. Hearing didn't improve much (if at all) throughout the remainder of the week. Over the weekend of March 27-28 hearing seemed to be improving. This morning, March 29, hearing has noticeably improved and I can carry on a phone conversation using my left ear. Hearing is not back to normal yet but it is much better than a few days ago.
1143242	3/29/2021	NY	43	F	2/9/2021	2/9/2021	2/9/2021 Almost instantly had nausea, dizziness, blurred vision. Lower extremities hot to touch, almost sweating. Upper extremities cold. R hip pain to the point I almost thought I broke my hip. Urgent care; steroid shot for hearing loss. ENT; stated I have Meniere's disease. Will have the rest of my life. Weeks zero appetite, diarrhea.
1143064	3/29/2021	NY	43	F	2/9/2021	2/9/2021	2/9/2021 Almost instantly again, started to experience dizziness. Followed by nausea. I was extremely fatigued. The joint pain, hip, came when I got home; R hip; felt like I almost broke my hip. Lasted for at least a month. Diarrhea started same day and lasted for 3 weeks. Into the first night, entire bottom half of bottom was all hot to the touch; only bottom half. Top half was cold. So much heat was coming off my body; sweating, uncomfortable. 3/2021 Ringing in ears. My ears, I woke up and couldn't hear; roaring. I couldn't hear at work. Went to Urgent Care; steroid shot. 60% hearing loss. Went to ENT. Stated that this has been happening with COVID patients. But I never had COVID. He extended the steroids and weaned them down. Told I will have rest of my life; Meniere disease. Due for follow up.

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1144566	3/29/2021	IL	50	F	1/8/2021	1/16/2021	<p>On 16Jan2021, both ears were clogged but I couldn't hear well out of left ear and there is a constant hum in it. On 17Jan, I had pain in left ear but it went away. My left ear still is clogged; has decreased hearing/decreased hearing of lower register; On 16Jan2021, both ears were clogged but I couldn't hear well out of left ear and there is a constant hum in it. On 17Jan, I had pain in left ear but it went away. My left ear still is clogged; On 16Jan2021, both ears were clogged but I couldn't hear well out of left ear and there is a constant hum in it. On 17Jan, I had pain in left ear but it went away. My left ear still is clogged; On 16Jan2021, both ears were clogged but I couldn't hear well out of left ear and there is a constant hum in it. On 17Jan, I had pain in left ear but it went away. My left ear still is clogged; This is a spontaneous report from a contactable nurse (patient). A 50-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 administered in left arm in the hospital on 08Jan2021 07:30 as SINGLE DOSE for COVID-19 immunisation. The patient had no other vaccine in four weeks. The patient had unspecified medical history and concomitant medications in two weeks. The patient had no known allergies. The patient had no COVID prior vaccination and was not tested for COVID post vaccination. Historical vaccine includes first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EK5730) administered in left arm on 18Dec2020 at 06:30 PM for COVID-19 immunisation. On 16Jan2021, both ears were clogged but patient couldn't hear well out of left ear and there was a constant hum in it on 16Jan2021 at 06:00 AM. On 17Jan2021, the patient had pain in left ear but it went away. Her left ear still was clogged, has constant hum and has decreased hearing on 17Jan2021. Right ear hearing was always fine and clogged feeling went away in two weeks. The patient saw ear, nose, and throat (ENT) on 19Jan2021, patient was started on steroids. The patient had magnetic resonance imaging (MRI) and several types of hearing tests on 19Jan2021. MRI was normal. Hearing tests showed decreased hearing of lower register. One doctor thought she should mention it since it happened within 8 days of receiving her second vaccination. The events resulted in doctor or other healthcare professional</p>

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office/clinic visit. Therapeutic measures were taken as a result of all events which includes MRI, steroids, and hearing test. The patient recovered from ear pain on an unspecified date while outcome of the rest of the events was not yet recovered.; Sender's Comments: Based on the information provided, and on plausible temporal association, the Company assessed that a reasonable possibility could not be completely excluded that the reported event Hearing loss (both ears were clogged but I couldn't hear well out of left ear and there is a constant hum in it) was related to the PFIZER-BIONTECH COVID-19 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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1144562	3/29/2021	IN	66	M	2/17/2021	3/3/2021	developed coryzal sxs of nasal stuffiness; developed coryzal sxs of nasal stuffiness; ear fullness; decreased hearing L ear; unilateral hearing loss without dizziness or pain; sensorineural dysfunction; This is a spontaneous report from a contactable physician (patient). A 66-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; batch/lot number and expiration date unknown), intramuscular, administered in left arm on 17Feb2021 09:15 as single dose for covid-19 immunisation at a hospital. Medical history included allergies to sulfa-urticaria, hypertension (HNT), hyperlipidemia, hypothyroidism, GERD, osteoarthritis, and coronary artery calcification per cardiac CT scan. Concomitant medications included levothyroxine sodium (SYNTHROID), atorvastatin, metformin hydrochloride (METFORMIN ER), hctz, famotidine, ergocalciferol (VIT D), and melatonin. The patient had no other vaccine in four weeks. The patient previously took fenofibrate and experienced allergies: photosensitivity. The patient received IM injection on 17Feb2021 with no sequelae initially. On or about 03Mar2021 at 13:00, the patient developed coryzal sxs of nasal stuffiness and ear fullness. The patient used Flonase and Z pack and Afrin. The patient also developed decreased hearing L ear confirmed yesterday by ENT doc. This was unilateral hearing loss without dizziness or pain. Hearing has improved but is still abnormal. Tympanograms are normal. Exam was consistent with sensorineural dysfunction. The patient was reluctant to receive the second dose scheduled for Wednesday, 17Mar2021. The events were assessed as serious due to disability or permanent damage and resulted in doctor or other healthcare professional office/clinic visit. The patient was not tested for Covid post vaccination. The outcome of the events was recovering. Information about lot/batch has been requested.; 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

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Investigators, as appropriate.



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1144574	3/29/2021	CA	51	F	1/29/2021	1/29/2021	lost hearing of the right ear; ear infection; sinus infection; couple of hours later she started hearing like a buzzing sound, hollow sound; she couldn't hear very well; This is a spontaneous report from a contactable consumer. This consumer reported for a 51-year-old female patient (Reporter's sister-in-law) that she received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number; EL3247;solution for injection), dose 1 via an unspecified route of administration on 29Jan2021 at single dose for covid-19 immunization. Patient's age was 52 years old at the time of vaccination with weight 76.644 kg, height; 154.94 cm. Patient's medical history included diabetes. Patient's concomitant medications included Metformin at 1000 mg for diabetes, Lisinopril at 10 mg for blood pressure, Insulin at 100 units, Atorvastatin at 40 mg (therapy dates unspecified). Reporter stated, "This is regarding my sister-in-law, it's in regards to, I had called few weeks ago and they had told me to call back I need to know who do I speak to as I need to send some paper work. She had a reaction to the Covid injection and I have all the paper work here. They told me that we needed to send also that they are going to try and see how she can get compensated back because she had to go to the hospital, she had to go to the urgent care twice, she had to see specialist and things like that." Reporter stated, "On 29Jan2021 (Later corrected), she got it done at work and couple of hours later she started hearing like a buzzing sound, she end up she couldn't hear very well and then the next day she (word incomprehensible) out of her right ear. It's been like the longest time. Pfizer EL3247." Treatment: Reporter stated, "Well she went to the urgent care twice although she had, one doctor said she had sinus infection the other doctor said she had ear infection. So, she went to a specialist ENT and he said she had none of those infections. He did put her on Prednisone because she lost hearing of the right ear so, he gave her 10 mg of Prednisone, gave 6 tablets 5, 4, 3 like that." She did not take the 2nd vaccine. She had loss of hearing, a buzzing sound, hollow sound, still has loss of hearing in right ear. Reporter was provided with the number of Pfizer Medical Information as # and was requested to select option 3, timings as 8 am to 8 pm Monday to Sunday as per (EST). Investigation assessment; no. The outcome of events was not recovered for lost hearing of the right ear and for other

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							events were unknown.
1144669	3/29/2021	CA	66	M	3/8/2021	3/18/2021	03/18/2021 Woke up with hearing loss, fullness and loud tinnitus in left ear; fullness and increased level of tinnitus in right ear. Had small amount of ear wax removed from left ear with no improvement. Erratic blood pressure and pulse rate. Doctor started me on Amlodipine which I have now discontinued as BP has returned to normal. Fullness and high level of tinnitus continues in both ears with some intermittent improvement.
1144789	3/29/2021	OH	40	F	3/10/2021	3/10/2021	On 3/10/2021 Migraine headache started at 6:15pm Ear ringing (tinnitus) started at 7:00 pm 3/11/2021 Additional hearing muffled was noticeable 3/16/2021: severe migraine, throwing up, nauseous 3/17/2021: facial rash prominent **hearing loss deemed permanent, ringing continuous
1144958	3/29/2021	NH	57	M	3/27/2021	3/29/2021	Woke up with a consistent ringing in both ears (4:00 am Monday 3/29/2021 - vaccine received 11:50 am Saturday 3/27/2021) No previous history of tinnitus or hearing loss.
1145438	3/29/2021	PA	45	F	2/6/2021	2/11/2021	Tinnitus started intermittently approximately 5 days after the vaccine. It then became constant on 3/5/2021 (approximately 4 weeks after the 2nd dose of the vaccine). No previous history of hearing loss or hearing issues. It has not yet resolved.
1145773	3/29/2021	FL	62	M	1/4/2021	1/4/2021	Loss of hearing in L ear, tinnitus in L ear, Fullness in L ear, Episode of Vertigo resulting in an emergency Room visit.
1143712	3/29/2021	AR	73	M	3/4/2021	3/18/2021	Patient noted extreme hearing loss in right ear beginning two weeks after 2nd Pfizer Covid Vaccine dose. The next day hearing loss was total in both ears. Patient reports he cannot even hear himself talk.

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1143484	3/29/2021	MD	33	F	3/5/2021	3/7/2021	hearing loss; Tinnitus in left ear/Crackling sound and ringing in ear; dullness; This is a spontaneous report from a contactable consumer (reporting for herself). A 33-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6204, expiration date: unknown), via an unspecified route of administration in left arm on 05Mar2021 at 14:00 as SINGLE DOSE for COVID-19 immunization. The patient's medical history included Crohn's Disease, anxiety, and penicillin allergy. Concomitant medication included amitriptyline and celecoxib (CELEXA), both for unspecified indication. On 07Mar2021, the patient experienced tinnitus in left ear, crackling sound and ringing in ear, dullness and some hearing loss. The outcome of the events was not recovered.

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1140661	3/28/2021	NY	30	F	2/19/2021	2/20/2021	complete hearing loss in my left ear for about four hours/ noticed but undocumented hearing loss; headache; chills; hangover feeling; incredibly loud ringing in left ear/ intermittent throughout the day, lasting for several hours at some points/ constant dull ringing/ tinnitus/ ringing in both ears; The initial safety information received was reporting only non-serious adverse drug reactions. Upon receipt of follow-up information on 22Mar2021, this case now contains serious adverse reaction. Information processed together. This is a spontaneous report from a contactable Other Health Professional (patient). A 30-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot EN6201) via intramuscular at left deltoid on 19Feb2021 at 14:30 (30-year-old at time of vaccination), at single dose, for COVID-19 immunization. The patient's medical history included bipolar disorder, ADHD, depression, and low Vit D. The patient had no COVID prior vaccination. There were no known allergies. Concomitant medications included lamotrigine (LAMICTAL) from 2016 and ongoing for bipolar, sertraline hydrochloride (ZOLOFT) from 2020 and ongoing for Bipolar, amphetamine/dexamphetamine (reported as amphetamine/dextroamphetamine salt extended) from 2015 and ongoing for ADHD and depression, Vitamin D3 from 2020 and ongoing for low Vit D, and cyanocobalamin (VITAMIN B12). The patient did not receive other vaccine in four weeks. Facility type was school or student health clinic; vaccine was administered at military facility. On 20Feb2021 at 21:00, patient had the normal headache, chills, "hangover feeling" in addition to an incredibly loud ringing in her left ear after her first dose. The ringing was intermittent throughout the day, lasting for several hours at some points. The intensity of it has subsided but there seems to be a constant dull ringing in her left ear now. She also had some weird effects with her medications the two days following her first dose. Not entirely sure if they're related but her medication seemed to be ineffective on Saturday and have little effect on Sunday. Severe tinnitus began around 10:00 (as reported) following her first vaccination, resulting in complete hearing loss in her left ear for about four hours. After that the severe ringing was intermittent for about five more hours. She now has ringing in both ears since, with noticed but

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							undocumented hearing loss. There were no further complications after the second dose. The second dose (batch/lot number EN6205) was received via Intramuscular at left deltoid on 12Mar2021 at 14:00. The adverse events did not result in emergency room visit or physician office visit. The patient did not test COVID post vaccination. No therapeutic measures were taken as a result of the events. The outcome of tinnitus was not recovered; outcome of other events was recovered with sequel.
1141214	3/28/2021	MD	50	F	3/27/2021	3/27/2021	Pain radiating from injection site to shoulder and neck. Patient stayed for 45 minutes after injection and states that after the initial intense pain the pain has remained the same and has gotten no worse. Advised patient to apply heat and ice and take an anti inflammatory to help with pain and to seek medical attention in pain worsens, she loses movement in neck, or loss of hearing.
1141480	3/28/2021	AZ	42	F	2/1/2021	2/1/2021	Extreme tinnitus beginning the day following vaccine and lasting about 48 hours. Within two days, tinnitus reduced but has remained persistent for now well over a month. For last 3 weeks, experiencing intermittent extreme tinnitus in left ear followed by muffled hearing/hearing loss. Overall tinnitus volume now seems to be increasing/worsening.
1142041	3/28/2021	MN	86	F	2/11/2021	2/13/2021	Hearing loss in left ear (complete loss). Right ear hearing is diminished. This was confirmed by two hearing tests. Not gradual but sudden onset. Was told it is permanent.
1142341	3/28/2021	CA	66	M	2/1/2021	3/4/2021	Sensorineural hearing loss (SNHL) of left ear. Started on morning of 3/4/2021. On-going - Sudden idiopathic hearing loss, left ear On-going - Tinnitus of left ear Dr. Notes - 3/26/2021 No subjective improvement in hearing loss and nonpulsatile noise since completing oral steroids and having undergone 3 intratympanic injections Is interested in completing the fourth injection as discussed before reassessing, this was done today without any issues Independently reviewed MRI IAC results. Shows inflammation of the left cochlear nerve without mass lesion. Radiology also felt that there was inflammation of the 7th cranial nerve as comparison with the right. Discussed these findings with patient and provided copy of report.

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1140178	3/27/2021	CA	71	M	1/22/2021	2/2/2021	Sudden onset of right sided hearing loss and tinnitus on 02/02/2021
1139499	3/27/2021	TN	73	M	2/10/2021	3/12/2021	Left sudden hearing loss several days after vaccine. Hearing nearly completely recovered 5 weeks later after transtympanic steroid injection.
1139380	3/27/2021	FL	65	F	2/1/2021	3/1/2021	Relapsing Polychondritis woke up and I'm deaf now in right ear.

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1139726	3/27/2021	AR	45	M	3/8/2021	3/10/2021	Right ear pain started on the Wednesday afternoon, two days after Vaccine shot. By Friday evening the ear pain was intense and it had moved below the ear to lymphnode area. Saturday, his ear was really swollen and red. He went to the Urgent Care and they prescribed an antibiotic Cephalexin thinking it could be some sort of ear infection or insect bite. Sunday morning he woke up with his face droopy. We tried to get an appt. with Urgent Care, but they sent us to the ER. The ER did a physical assessment and concluded he had an ear infection and Bells Palsy. The prescribed another antibiotic Doxycycline, an antiviral Famciclovir and a steroid of prednisone. By Monday he was extremely nauseas and had started having vertigo. We went to Urgent Care and they prescribed him Ondansetron for nausea and made the assessment that he had Shingles in his ear. We saw PCP on Wednesday and he assessed that this was a zoster ear infection causing facial paralysis and vertigo, also known as a rare condition called Ramsay Hunt Syndrome and that it was most likely attributed to his Covid vaccine shot and not to get the second vaccine shot. The Dr. took him off the antibiotics and put him on a higher dose of prednisone, a different antiviral (valacyclovir) and Meclizine for vertigo symptoms. He sent referrals for Neurology, ENT and Eye Dr. He saw the Neurologist that Friday and he concurred Ramsay Hunt Syndrome, most likley from Covid Vaccine and do not get the second vaccine shot. The neurologist referred him to Physical Therapy to treat his vestibular issues. He ordered an MRI and some blood work. We are still waiting for the results. We saw an ENT an he had him have a hearing test which showed moderate high frequency hearing loss. The ENT prescribed Gabapentin for the ear and face pain. He started to see a physical therapist this week, he had his MRI on Wednesday and we see the ENT again on Monday. He has no improvement yet, other than the nausea has subsided.
1138925	3/26/2021	AZ	64	M	3/25/2021	3/26/2021	Right ear feeling like there is a pressure in my ear like it is plugged and there's some hearing loss. These symptoms are continuous.
1137859	3/26/2021	MI	67	M	3/24/2021	3/24/2021	Tinnitus/ hearing loss

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1137383	3/26/2021	MT	45	F	1/6/2021	1/7/2021	Within an hour I had quite a bit right sided swollen lymph nodes. Another hour or two later I started having tinnitus in my right ear. I've seen a Provider and an Audiologist. The Provider they couldn't see anything structure wrong with my ear. The Audiologist told me I had mild hearing loss on the right side. I will do a re-check in 6 weeks.
1136293	3/26/2021	FL	62	M	3/8/2021	3/14/2021	Tinnitus - Left Ear - plus some hearing loss . The tinnitus comes and goes, and seems to also be related to my neck position
1135485	3/25/2021	FL	75	F	3/20/2021	3/21/2021	Awoke 7:30 am day after vaccination (16 hrs later) unable to hear R ear. Unable to access medical care because it was Sunday. Contacted primary physician who said he would try to get me ENT appointment ASAP, but suggested I get audiology evaluation ASAP, which I did, on Monday afternoon, 3/22/2021. Eval confirmed hearing loss with problem in R middle ear. Developed mild flu-like symptoms on Monday evening that persisted for about 30 hours...mild nausea, headache, malaise. Appointment with Dr. ENT scheduled for 3/25/2021. He said I was about the 5th vaccine related hearing loss he had seen, and has prescribed a course of Prednisone, in hopes hearing will return.
1136164	3/25/2021	SD	21	F	3/24/2021	3/24/2021	Immediately after injection: dizziness, nausea, light headedness, temporary loss of hearing, blurred vision, abdominal cramps, fever. 1+ Hour after injection: severe abdominal cramps, nausea, severe headache (severe pain behind eyes specially when eyes were open), chest pains, upper back pain, pain in all joints (primarily hips), muscle aches over whole body, fatigue, chills, fever, trouble breathing, light headedness Morning After Injection: full body ache, severe fatigue, trouble sleeping, fever, chills, body sweats, slight chest pains, even more severe headache. 24 -36 hours after Injection: reduced muscled aches, fatigue, headache, pain at the sight of injection.
1131984	3/25/2021	PA	53	F	3/9/2021	3/17/2021	Constant moderate tinnitus started about 1 week after vaccine. Never had tinnitus or hearing loss before this. Did test COVID positive in September 2020 and lost sense of smell and taste but that has since recovered. Tinnitus is new and constant....just since vaccine. Not going to get second dose.



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1134602	3/25/2021	PA	70	F	2/17/2021	2/25/2021	Started with violent sneezing in week after 2nd Moderna Vaccine. Then on Friday, March 5, left ear started to feel clogged. Totally clogged on March 6. On Sunday March 7th, lost hearing in left ear around 7 PM. On Monday , March 8, I was seen as an emergency visit at Ear Nose and Throat Dr. Hearing test was performed and doctor injected steroid into my inner left ear canal. I was given a prescription for oral prednisone, which was started on Tuesday, 3/9. I continued this medication until Monday, 3/22. Since seeing him on 3/8 I have received three injections in my left ear and two hearing tests, the last one being told I have profound hearing loss in my left ear and continue suffering with ringing in the left ear. My next appointment is tomorrow 3/25. I pray that my hearing returns.
1134275	3/25/2021	KY	66	M	3/10/2021	3/14/2021	ringing in the right ear and hearing loss
1134193	3/25/2021	TX	64	M	3/5/2021	3/19/2021	Dose 1 on 2/5/2021 Dose 2 on 3/5/2021 Symptom of loss of hearing in my right ear resulting in tinnitus in the right ear (ringing)
1134014	3/25/2021	OH	24	F	3/25/2021	3/25/2021	Patient stated she began to have heart palpitations a couple mins after sitting down then followed by vision and hearing by the time nurse arrived. Patient stated feeling like she going to pass out then asked nurse to hold her hand. EMT arrived checked vital signs all within normal limit per patient. Patient then states that everytime she is in a medical setting she pass out or has vision and hearing loss due to panick and anxiety attack. Stated everytime to gives blood she has this is sure. Patient also refused homecare.
1133657	3/25/2021	MT	52	M	3/4/2021	3/23/2021	Immediate hearing loss/ heavy ringing...I was sitting on my couch watching TV. I went from hearing to non-hearing in an instant. I noticed there is a feeling of pressure in the ear area. I now have a heavy ringing with some random "ticking" in the ear. I am not able to hear anything short of really loud noises that sound like metallic screeching.

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1133649	3/25/2021	FL	51	M	1/5/2021	1/6/2021	After covid second shot I had fever i took Tylenol, fever gone. 01/08/2021 I went to work. Next morning 01/09/2021 . I was stroked out taken to er. Still I have weakness on left , hearing loss, loss taste, even I drink water taste bitter. Loss smell. I am doing physical and speech therapy. Still not recovered.
1133494	3/25/2021			M			hearing loss; This is a spontaneous report from a contactable Pharmacist. A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced hearing loss on an unspecified date after the first dose in one of his ears. Outcome of the event was not recovered. Information on lot number/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 vaccine can not be excluded for the reported event of hearing loss due to temporal relationship. Case will be re-assessed upon the additional information provided.

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1133480	3/25/2021	CA		F	2/9/2021	2/18/2021	<p>passing out; almost like I was deaf for a second; couldn't talk; couldn't get off the couch; red spots over it; arm was swollen; low grade fever; A spontaneous report was received from a consumer concerning a 65-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced hearing decreased, speech impairment, NOS, loss of consciousness, gait inability, vaccination site erythema, vaccination site swelling and pyrexia. The patient's medical history was not provided by the reporter. Concomitant medications were not reported. On 09 Feb 2021, about 10 days prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (Lot number: 027L20A) through unknown route in the right arm for prophylaxis of COVID-19 infection. Nine days after the shot (18 Feb 2021) she had the following symptoms: arm was swollen, red spots over it, low grade fever, passing out, couldn't talk, couldn't get up off the couch and hearing decreased for a second. She had ibuprofen 2 tablets on 18 Feb 2021 and 19 Feb 2021. Action taken with mRNA-1273 in response to the events was not applicable. The events, hearing decreased, speech impairment NOS, passing out, couldn't get off the couch, vaccination site erythema, vaccination site swelling, low grade fever, and were considered recovered on 19 Feb 2021.; 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.</p>

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1133028	3/25/2021	NJ	86	M	2/8/2021	3/2/2021	uncontrollable sneezing; runny nose; tired; allergies; calcium was very high; creatine high; This is a spontaneous report from a contactable consumer (patient). An 86-year-old male patient received the second dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot number: em9809) via an unspecified route of administration, administered in left arm on 08Feb2021 at 08:15 at a single dose for COVID-19 immunization. Medical history included being deaf, glaucoma, left bundle branch block and osteoarthritis all from an unknown date and unknown if ongoing. The patient had no known allergies. The patient was not tested for COVID prior to vaccination. The patient had unspecified concomitant medications. The patient previously received the first dose of BNT162B2 (lot number: el38982) on 18Jan2021 at 08:15 AM on the left arm for COVID-19 immunization after which the patient could not hear anything. It was reported that on an unspecified date in 02Mar2021, about 2 and 1/2 weeks after receiving the second dose, the patient had uncontrollable sneezing and runny nose and was very tired. The doctor said it was allergies. The patient had a nasal swab test for COVID on 27Feb2021 and flu test on 02Mar2021 which were both negative. The patient's blood work was taken and his calcium was very high and creatine was high on 02Mar2021. The events required an emergency room visit and a physician office visit. The patient was admitted to the hospital on 02Mar2021 to Mar2021, for 5 days due to the events. They took bone biopsy and the patient was waiting for the results. It was reported that the patient was fine after the first injection and now this. The patient wanted to inform Pfizer since it may be connected. It was unknown if the patient received treatment for the events. The outcome of the events was unknown.
1132319	3/25/2021	OH	45	M	3/23/2021	3/24/2021	Ringling in left ear and loss of hearing. The symptom is mostly gone after about 24 hours.

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1131744	3/25/2021	NV	52	F	2/9/2021	2/9/2021	Tinnitus for past 6 weeks starting the night I received the second Moderna vaccine shot. The tinnitus was accompanied by a migraine and 101.8 fever and some nausea and dizziness. While the migraine and fever subsided, the tinnitus has remained constant for the past six weeks. Also had rash on back of left hand after the first shot - was advised at the site for the second shot that rashes are common and it came back with the second shot though not as bad as with the first shot. The vaccine shot was on left arm, rash on left hand, and tinnitus and hearing loss on left side as well.
1136207	3/25/2021	CA	38	M	3/11/2021	3/14/2021	Initially, it started with some odd headaches exclusive to the right side of my face - near my sinus cavity extending to my right temple and around my right ear. On day 10, March 20, 2021, at approximately 5:00 pm, I lost all hearing in my right ear. I was turned away as a possible ear infection, but due to the complete loss of hearing, I followed up on Tuesday, March 23, 2021. After being seen by an ENT, I was diagnosed with Sudden Sensorineural Hearing Loss in my Right ear. I have started treatment with my first injection into the eardrum and am currently on day 3 of oral steroids (predniSONE - 20mg Tablets, 3x first 7 days, 2x days 8-9, 1x day 10). No improvement or recovery as of yet, if at all.
1128151	3/24/2021	CA	70	M	2/1/2021	2/1/2021	New onset left sided tinnitus without associated hearing loss shortly after vaccination. Of note patient was diagnosed with prostate cancer 2 months ago and was started on hormone therapy 1 week prior to our clinic visit. He was also vaccinated with Pfizer vaccine ( about 2 weeks prior) and the tinnitus may have started around the time of second vaccine.
1129765	3/24/2021		45	M	3/5/2021	3/23/2021	Sudden hearing loss; Tinnitus. ENT doctor prescribed Prednisone for 2 weeks (80mg per day for the first week, then a progressively decreasing dose for the second week).

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1129671	3/24/2021	CA	59	M	2/17/2021	2/23/2021	He suddenly totally lost his right hearing; A spontaneous report was received from a consumer concerning a 59 years old male patient who suddenly had a total loss of his right hearing (deafness). The patient's medical history was not provided. Products known to have been used by the patient, within two weeks prior to the event, included montelukast sodium, hydrochlorothiazide, atorvastatin, losartan potassium and potassium. On 17 Feb 2021, at 4:45 PM approximately six days prior to the onset of the event, the patient received their first of two planned doses of mRNA-1273 (lot: 030M20A) intramuscularly for prophylaxis of COVID-19 infection. On 23 Feb 2021, the patient suddenly totally lost his right hearing and patient went to emergency room (ER) and specialist doctors. Treatment for the event included meclizine 25 mg, lorazepam 0.5 mg, amoxicillin 875-clavulanate 125 mg, prednisone 5 mg. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event of patient suddenly totally lost his right hearing was 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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1129667	3/24/2021	FL	65	F	2/11/2021	2/18/2021	Sudden sensorial hearing loss; A spontaneous report was received from a consumer who of 65-years-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and had sudden sensorial hearing loss/ deafness. The patient's current conditions included high blood pressure, gastric issue- acid reflux and cholesterol unspecified. Products known to have been used by the patient, within two weeks prior to the event, included medications for high blood pressure, gastric issue- acid reflux and cholesterol unspecified. On 11 Feb 2021, approximately 8 days prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number: 0104M20A) in the right arm for prophylaxis of COVID-19 infection. On 12 Feb 2021, the patient was diagnosed with an ear issue. Later on, 18 Mar 2021, a week after vaccination the patient had sudden sensorial hearing loss. Treatment for the event included steroids for ear issues. The seriousness criteria for the event deafness was assessed as serious. Action taken with mRNA-1273 in response to the event was not provided. The outcome of the event was not reported.; 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.
1129049	3/24/2021	KY	92	F	3/6/2021	3/19/2021	13 days post vaccination patient wakes up with a slight itch in here ears. By 4pm she reports a sudden hearing loss in her right ear. On day 14 she proceeds to get very weak with vertigo, nausea, and anorexia. No temp or other signs of illness. On day 15 we take her to ER and work up was negative. On day 16 we take her to ENT no explanation of the sudden hearing loss but is told she is totally deaf in the right ear and needs a hearing aid in the left. She did not have this prior to the vaccination and it was a sudden onset.
1128163	3/24/2021	CA	76	M	2/27/2021	3/1/2021	Patient without prior otologic diagnosis. Presented to clinic with left sudden hearing loss. He received second dose of Moderna vaccine and noted hearing loss 7-10 days after. Currently completed oral steroids and receiving intratympanic steroid injections.

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1129914	3/24/2021	WA	36	M	3/20/2021	3/20/2021	near immediate cold sensation in left arm, nausea, and light headedness approx 3-5 minutes later hearing loss and blacked out
1128157	3/24/2021	CA	60	M	2/1/2021	2/1/2021	Patient with longstanding history of bilateral exostosis. Noted to have left sudden hearing loss, unsure about timing ~ 1-2 weeks after. Treated with oral and intertympanic steroids
1128134	3/24/2021	CA	74	F	1/1/2021	2/1/2021	Patient has history of autoimmune inner ear disease. She has a left cochlear implant and noted hearing loss on right ear compared to her baseline approximately 1 week after first dose of covid vaccine.
1128149	3/24/2021	CA	25	M	3/1/2021	3/1/2021	Patient with longstanding bilateral non-pulsatile tinnitus without associated hearing loss. No dizziness, ear pain, hearing loss or vertigo. He received Moderna vaccine on 3/2 and his tinnitus got much louder. It improved but has not become louder again. He is currently treated with trial of niacin.
1128143	3/24/2021	CA	54	F	2/10/2021	3/1/2021	Patient noted non-pulsatile tinnitus couple weeks (unable to specify) after 2nd dose of Covid vaccine 2/10 (moderna) She did not not associated hearing loss or vertigo
1128138	3/24/2021	CA	64	M	1/1/2021	2/1/2021	Patient without prior otologic history noticed left sided hearing loss and tinnitus 1-2 weeks after second dose of Moderna vaccine. No vertigo.
1128131	3/24/2021	CA	73	M	1/10/2021	2/1/2021	Patient has history of bilateral Meniere's disease which has been managed medically. The hearing loss is sudden. Patient received COVID-19 vaccine in late December 2020 Moderna. Did notice mild change in hearing with first vaccine. Bad systemic reaction to second dose. Has progressed significantly since. The change in hearing was about 2 to 4 weeks after second vaccine.
1130231	3/24/2021	IL	64	F	3/17/2021	3/17/2021	Meniere's Disease- increased symptoms of ear congestion, hearing loss, tinnitus, right ear



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1128053	3/24/2021			F	3/14/2021	3/15/2021	Lost hearing in one ear; A spontaneous report was received from a consumer concerning an age unspecified, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced loss of hearing in one ear. The patient's medical history was not provided. Concomitant medications were not provided. On 14 Mar 2021, approximately a day prior to the onset of the events, the patient received their first of the two planned doses of mRNA-1273 (Batch number: unknown) intramuscularly for prophylaxis of COVID-19 infection. On the morning of 15 Mar 2021, the reporter states that her sister had no hearing in one ear. Treatment information was not provided by reporter. Lab tests were not provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, lost hearing in one ear, was considered unknown.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.
1128160	3/24/2021	CA	39	M	3/1/2021	3/1/2021	Patient with no prior otologic history. Patient notes vaccination about 2 weeks ago, received first dose of Moderna. He notes this last Wednesday he noticed muffled hearing on the right along with sound distortion. Diagnosis of right sided sudden hearing loss with tinnitus. No vertigo. Currently on oral steroids

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1128058	3/24/2021	MO		F	2/24/2021	2/25/2021	about to lose her mind; Ringing in the ears, a tinnitus thing; Ringing in the ears, a tinnitus thing; hard of hearing, I have hearing loss, conductive hearing loss; hard of hearing, I have hearing loss, conductive hearing loss; lymph nodes were painful; Ear, side of face and neck on right side hurting really bad; ear, side of face and neck on right side hurting really bad; Ear, side of face and neck on right side hurting really bad; This is a spontaneous report from a contactable consumer (patient). A 39-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 24Feb2021 (Batch/Lot number was not reported) as a single dose for COVID-19 immunization. Medical history included tinnitus from 2006 to an unknown date, 15 years ago and she needed to go to the hospital and get IV steroids. The patient's concomitant medications were not reported. The patient previously received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 2021 (Batch/Lot number was not reported) as a single dose for COVID-19 immunization and did not experience any side effects. This patient was administered the second dose of Pfizer COVID-19 Vaccine last Wednesday, 24Feb2021. Starting Thursday, 25Feb2021 she had pain in like the lymph nodes on her right side really bad which was the side she got the Pfizer COVID-19 Vaccine second dose in; conductive hearing loss; her ear, side of face and neck on right side hurting really bad. Ear pain is really bad. She took Ibuprofen and it was better but the events continued through Thursday the 25Feb2021, Friday the 26Feb2021 and Saturday the 27Feb2021. Starting Saturday the 27Feb2021 she got ringing in the ears, a tinnitus thing which has been ongoing ever since. Patient also stated, "After the second Covid shot lymph nodes were painful, especially in my ears, I am hard of hearing, I have hearing loss, conductive hearing loss and when the pain went away I had ringing in the ears for 4 days now and it won't go away." She is not a healthcare professional, but she works in the field of deaf and hard of hearing. She saw that in the beginning people who get COVID can get those symptoms like hearing loss; but she did not know if the tinnitus and conductive hearing loss is associated with the Pfizer COVID-19 Vaccine. She has had no other symptoms like that of a cold that

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would have caused the hearing loss and tinnitus. She called the Pharmacist and ENT and everyone thinks her events are Pfizer COVID-19 Vaccine related; but the ENT was only able to tell her that they have only seen people that have COVID that have hearing loss which is considered long term; but the providers have not actually had anyone report hearing loss or tinnitus with the Pfizer COVID-19 Vaccine. No one really knows if these events are going to go away. She is about to lose her mind because events won't stop. The ENT read some articles where COVID could affect hearing but did not have information on if Pfizer COVID-19 Vaccine could affect hearing. She called to ask for more information about these events relative to the Pfizer COVID-19 Vaccine. The patient had read comments for side effects for actually Covid but patient haven't had Covid. Patient had been at home for a year so she has not been exposed to anything, so this is just from the vaccine. She read an article that Covid can affect hearing. Wanted to know if we had reports of that with the vaccine and if it will go away? HCP had seen the article and they know that Covid infection itself can cause it and it is long term but that still being studied so nobody really knows. She could not find any information specific to vaccine as far as the symptoms it comes as a Covid general and then it says long-term and whatever your ear condition is it can worsen. Patient stated that the last time it (ringing) lasted this long was 15 years ago and she needed to go to the hospital and get IV steroids. Therapeutic measures were taken as a result of ear, side of face and neck on right side hurting really bad which included ibuprofen. The outcome of the event ringing in the ears, a tinnitus thing was not recovered, Pain in ear was recovering, while for the other events was unknown. The reporter assessed the events as non-serious. Information on lot/batch number has been requested.

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1126361	3/23/2021	WI	79	M	2/25/2021	2/25/2021	I received the first dose Moderna, and it started off with left ear being plugged up and it wouldn't clear subsequently I get a strong solid tone, I've gotten amplified sounds out of the left ear, If I'm watching tv the voice comes through in a burbling way and at times I'm watching tv straight ahead and the left ear hears the sound from the side and the right ear hears the tv. I have no other known reasons to suspect anything else to have caused the problems, the only thing I can relate the change to is having the two vaccinations. I saw ENT and did a hearing test with significant loss of hearing in left ear and that was followed up with a basil endoscopy and no determination could be made from that. I'm scheduled for a brain scan on March 30th.
1125205	3/23/2021		34	M	3/18/2021	3/20/2021	Hearing loss ('muffled') affecting right ear 48h post vaccine.
1125316	3/23/2021	NJ	59	M	3/18/2021	3/18/2021	The Patient presents with cricket sound and high pitch Tinnitus in both ears that began 4 days ago. Additional information:2nd dose of pfizer covid vaccine friday at noon. 3 hours later pt got ringing in ears. Noted B/L high pitched chirping in ears about 3 hours after receiving 2nd Pfizer vaccine 5 days ago, no hearing loss, no dizziness or HA feels fatigued and has L arm soreness that has improved
1125526	3/23/2021	VA	74	F	3/3/2021	3/18/2021	12 days following my second Moderna vaccination I woke with dizziness, increased tinnitus, decreased hearing, fever and chills, nausea, and headache. After 2 1/2 days, the fever and chills, headache, and nausea had subsided. The tinnitus is the same as it's been since 3/17 (meaning worse than it's been over the past several decades), dizziness is mostly okay, some hearing loss is still noticeable when I am speaking with people who are wearing masks.
1125982	3/23/2021	OH	49	F	1/23/2021	1/25/2021	Loss of hearing in right ear on 3/25/21, ringing in ear on 3/25/21, Vertigo on 3/26/21

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1126461	3/23/2021	FL	93	U	3/13/2021	3/14/2021	Caller is pt's son, reporting side-effects/reaction of the father, to Janssen COVID-19 Vaccine. All information collected was by the caller (pt's son) and not by the pt. The pt received the Janssen COVID-19 Vaccine Lot# 1805029 at facility 03/13/2021, time unknown. The following day, 03/14/2021 the pt was speaking incoherently, easily agitated, wasn't speaking to gf. The pt's history of ministrokes lead to the family calling 9-1-1. Pt was admitted to Medical Center on 03/14/2021. Pt vomitted, aspirated, was put on a ventilator, admitted to the ICU for 2-3 days and discharged 03/19/2021. Pt takes Atorvastatin (Eliquis) 2.5mg bid, Furosemide 20mg qd, Lisinopril 40mg qd, Metoprolol tartrate 12.5mg bid, and Folic Acid 1mg qd. Pt has a pacemaker and hypertension. Caller denies pt has any allergies. Currently the pt is only experiencing a loss of hearing. Caller was advised to take pt to primary doctor to have ears and hearing examined. Agent was consulted and Dr. was notified.
1127434	3/23/2021	CA	50	M	3/15/2021	3/16/2021	March 15: 2:45pm Pfizer COVID vaccine 1 March 16: 6am - severe headache: treated with two Excedrins at 8am and then two more Excedrins at 6pm. March 17: 10am - severe headache: treated with two Excedrins at 10am March 18: Upper neck and shoulder pain: untreated March 19: Upper neck and shoulder pain and hearing loss (approximately 50% hearing loss): untreated March 20: Upper neck and shoulder pain: treated with Arnica Cream, hearing loss continues, untreated March 21 - 22: Upper neck and shoulder pain: treated with Arnica Cream: hearing loss continues. March 23: Upper neck and shoulder pain improved. Hearing loss continues. Notified Dr. (my primary physician)
1127634	3/23/2021	MA	60	F	2/25/2021	3/28/2021	sudden hearing loss
1128120	3/23/2021	CA	68	M	1/23/2021	1/23/2021	Patient with previously stable Meniere's disease noted to have new onset bilateral hearing loss, vertigo spells and Meniere's exacerbation. Currently, treating with oral steroids.

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1125916	3/23/2021	FL	71	M	3/4/2021	3/21/2021	Waking up with severe tinnitus in both ears and echo sounding in L ear. Head sounds like inside a bucket or down at bottom of a pool. Sometimes there is a repeat echo from inside the L ear. Extreme loss of hearing this morning. The first time this happened it cleared up after an hour or so last Sunday but this morning it is not getting better. I have had tinnitus for many years but never this bad or severe sounding where hard to hear everything and this horrible echo sound.
1124759	3/22/2021	SC	51	F	2/28/2021	3/1/2021	Tinnitus in both ears; some temporary hearing loss in left ear (happens in short bursts)
1121601	3/22/2021			M			lost hearing in one ear; This is a spontaneous report from a non-contactable consumer. A 60-year-old male patient received the second 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 immunization. The patient's medical history and concomitant medications were not reported. After the second Pfizer COVID vaccine, patient was in bed for 3 days, and lost hearing in one ear about 3-4 days after the shot. Doctor put him on steroids. ENT said that for people who had COVID the cytokine release could be very damaging to the auditory nerve. It's been about a week since the hearing loss and he has not yet recovered. No follow-up attempts are possible, information about batch number cannot be obtained. No further information is expected.
1121661	3/22/2021	CA	43	F	3/15/2021	3/19/2021	Extreme itching little bumps everywhere including earm ear swollen loss of hearing . 2nd day still hurt. Hearing is fine still swollen
1121946	3/22/2021	IN	46	F	3/19/2021	3/19/2021	Hearing loss. Feels like pressure in ears. Like they need to pop. Noticed I can't hear as well when in the car listening to radio.
1122382	3/22/2021	NE	28	M	12/29/2020	2/28/2021	Became deaf in my left ear on Feb 28th.
1122625	3/22/2021	CO	66	F	3/12/2021	3/15/2021	Extreme tinnitus, deafness

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1123241	3/22/2021	AZ	63	M	2/5/2021	3/7/2021	Tinnitus followed by acute hearing loss left side approximately 4 weeks after second COVID 19 dose. Currently treated with Prednisone with little improvement. Scheduled for MRI 3/25
1123962	3/22/2021	VA	57	F	3/20/2021	3/21/2021	Saturday, within 6-8 hours started with fatigue. Then later that evening chills, headache, fever, and aches. During the first night my ear started kind of ringing and feeling in a funnel or clogged or something (different from anything experienced before). Sunday, continued with fatigue, headache, fever, body aches, generally not feeling well, and ear continued to get worse with some hearing loss. Now today (Monday) I can't hear as well in my left ear and it's a type of ringing and still feeling clogged or in tunnel or something like that. Hard to describe... but I can't hear as well in that ear.
1124354	3/22/2021	CT	46	F	3/5/2021	3/7/2021	Muffled hearing in left ear for a little over a week. Hearing test resulted in sudden hearing loss. Prescribed prednisone and within days it was better and hearing test showed improvement.

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1124525	3/22/2021	GU	24	M	3/18/2021	3/18/2021	I kept a log of the events that occurred. Notes: 25mg amitriptyline taken nightly for the last month, 200mg motrin I've never taken pain killers before this, time is in military. Mar 18 1430 (1 hour 30 mins after my shot) i have a compressing headache toward the back of my head so i take 1 motrin. 1700 i head home, take 1 amitriptyline and head straight to sleep. ( i have no apatite so no dinner ) Mar 19 0100 The pain starts, it?s unbearable. I am sweating heavily and im also shivering cold. i have a high fever I have body aches which turns my shivering into shaking which keeps my wife up all night. In my dreams i feel pain. I talked to my deceased mother, i hold my deceased cat and i relive some of my most regrettable moments. 0700 I wake up, the bed is soaking wet. I take a motrin and get dressed. it takes me an hour longer to get ready for work because, the pain has sapped my energy. My supervisor sends me home seeing how horrible I look. 0900 I take an amitriptyline and lay down. I ask me wife to close to the storm shutters to darken the room. They are normally pretty quiet to close but, this time they are deafeningly loud. I struggled to get 1 hour of sleep. 1500 I wake up due to shaking so bad that i hit my head on the wall. I then take 2 motrin and about 30 mins later i notice theres a tightness in my chest. i take 1 tums. I know that my body is exhausted from the pain and my mind is clouded but i really wanted to do all of the tasks that i was planning on doing this weekend. All of the tasks end up failing. 2100 i try the tasks again and end up failing again. 20 Mar 0100. I eat a pear and 2 cheetos. i do not take a amitriptyline and i lay down. i have no pain or fever. (Dream start) The dream i had is of me watching myself get thrown around by a ghost. The ghost possesses my body for a short time. I grab some kittens (cats are a comfort to me so im guessing that my subconscious trying to reel me back in) I then wake my sleeping wife and tell her theres a ghost and we need to leave. We walk outside and im in an old neighborhood that i grew up in, everything darkens and im in pitch black feeling my way around a room. I open my eyes and im in a hotel. The front desk staff will not let me take the kittens up to my room so i leave them. When i walk into the room, it?s full of kittens (dream end) and i wake up 21 Mar 0900 I wake up and I have a sore throat and tightness in my chest. The soreness prevents me from going back to sleep and the tightness in my chest



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							causing some anxiety. Once I calm myself down and convince myself that im not having a heart attack I take 2 motrin and some tums and the pain goes away from the day. These could be some withdrawals from not taking amitriptyline since 19 mar in the morning. This is still happening as I write this report. (23 March 2021)
1124574	3/22/2021	ME	75	M	2/5/2021	2/5/2021	hearing loss right ear after 1st Covid vaccine, within 2 hrs. subjectively lost 80% of right side hearing. after 4+ has somewhat recovered hearing approx half of subjective loss. Of note: 20+ year ago lost hearing on LEFT "from a virus" and that was permanent.
1120510	3/21/2021	MA	72	F	3/17/2021	3/19/2021	Sudden hearing loss. Head feels like I'm in an airplane, but ears won't "unblock." Taste loss as well.
1121115	3/21/2021	KS	45	M	3/5/2021	3/12/2021	Got much louder Tinnitus starting about one week after 1st dose of pfizer vaccine. Had preexisting Tinnitus in same ear for 5 years as well as 35db hearing loss.
1120699	3/21/2021		20	F	3/18/2021	3/18/2021	Patient received the Pfizer Vaccine around 4:00 PM. Patient proceeded to sit at the observation area for monitoring then patient flagged down staff with c/o dizziness, blurred vision, hearing loss, slight pallor noted. Patient was noted sitting at the observation area with LVN next to her side. Patient was offered to lay down. Ice pack was placed on the back of patients neck, patient ate a candy bar, Nurse encouraged fluids. VS were taken and noted to be stable. Patient was monitored for 30 mins before departure. Patient stated having needle anxiety in the past. Nurse instructed patient and patient mother on signs, Symptoms of Severe Adverse Reactions to report to health care provider or to go to the emergency room. Patient/Family verbalized understanding.
1119233	3/20/2021	NV	33	M	3/20/2021	3/20/2021	Minor hearing loss in right ear. Fees like I can?t pop my ear.
1118614	3/20/2021	CT	74	F	2/19/2021	2/19/2021	Whooshing tinnitus and intermittent, temporary hearing loss, lasting 3-18 hours, 5 episodes between 2-19-21 and 3 16-21. Hearing tests were administered during period of loss and showed significant hearing loss. Hearing is normal today, 3-20-21.

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1118515	3/20/2021	MD	83	M	3/1/2021	3/3/2021	<p>I lost the hearing in my left ear on March 4 three days after receiving the 2nd shot of Moderna vaccine, See details below: Report of adverse reaction (hearing loss) following second injection of COVID-19 vaccine on March 1, 2021. I believe I have had a bad reaction from the second COVID-19 vaccination, which occurred on March 1 at Three days after the injection I could not hear through my left ear. The vaccine identification is: Moderna vaccine, 2nd dose, 3/01/21, Lot#: 006M20A The sequence of events to date (3/14/21) is as follows:</p> <p>Mar 1, Mon: I received the second Moderna vaccination at Retirement Community. No reaction. Ran 2 miles in the afternoon. Mar 2, Tues: Felt slightly ill. Headache. No energy. Vaccination arm very sore. Did not feel well enough to work at my desk or to run. Mar 3, Wed: Felt better. Worked as volunteer at vaccination clinic, but tired easily. Did not run afterwards. In the evening, noticed some hearing difficulties in left ear, including greatly increased tinnitus. Mar 4, Thur: Awakened in morning with no hearing in left ear, and growing diminishment of hearing in right ear. No running. Mar 5, Fri: No hearing in left ear and diminished hearing in right ear. Tinnitus level high. Called my otolaryngologist; doctor not available; scheduled appointment for March 16. Visited Urgent Care; physician assistant found no obvious problem. Visited Clinic; (my primary care physician) not available; nurse practitioner advised me to wait to see Dr. on Mar 8 at my scheduled annual wellness checkup. Ran 2 miles. Mar 6, Sat: No hearing in left ear. Right ear continues to lose hearing. Ran 2 miles. Mar 7, Sun: Left ear deaf. Right ear hearing is poor and distorted. No running Mar 8, Mon: Left ear deaf. Right ear hearing is deteriorating. Had difficulties understanding speech. Reported hearing problem to Dr. at my annual wellness exam. She said I should report it to FDA. I requested that she do so because I had some difficulty in trying to make the report. She prescribed Mirtazapine for several concurrent health issues. Ran 2 miles. Mar 9, Tue: Met with Dr. (otolaryngology) and Dr. (audiologist). A hearing test showed left ear functionally deaf and right ear poor as before. Given order for a head MRI and prescription for prednisone and instructed to return in two weeks. Dr. urged me to report problem to the CDC. Ran 2 miles. Mar 10, Wed: Hearing problems as before. Deaf in left</p>

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							ear and hear with difficulty in right ear. Tinnitus very loud. No running. Tried to send report to CDC/VAERS (email not successful). Mar 11, Thur: Started 20 mg of prednisone; within 6 hours hearing began to slowly return in left ear. Ran 2 miles. Mar 12, Fri: Hearing in left ear returned to 70-80% of normal and right ear improved also. Had head MRI in evening. No running. Mar 13, Sat: Hearing continued to improve in both ears. Tinnitus remained loud. Ran 3 miles. Mar 14, Sun: Hearing has plateaued in both ears, although TV audio seemed a bit muffled. No running. Mar 15 onwards: Awaiting lab results of head MRI. Next appointment with Dr. is March 23. (End of report)
1118112	3/20/2021	MD	79	M	3/15/2021	3/15/2021	Five to six hours after the shot, tinnitus began in my right ear. Two days after the shot, I experienced complete hearing loss in my right ear. To date (five days after the shot), I still have complete hearing loss in my right ear.
1117952	3/20/2021	NC	45	F	3/17/2021	3/20/2021	Tinnitus in left ear. Fullness in both ears and sense of hearing loss
1117657	3/20/2021	OR	47	F	2/1/2021	2/1/2021	I had both vaccines injected on the left arm. The first one was on Feb 5th. My arm got very sore at the site of injection the next day for about 24 hr. I started to notice pulsation on my ears. Then as the days went by, this turned into hyperacusis and I consulted about it on Feb 26th. the day of the second shot.. My physician referred me to an ENT. I saw the ENT on Feb 29 and had a hearing test the same day, they found no signs of hearing loss or abnormal conditions. I was diagnosed with pulsation tinnitus and hyperacusis. After the second dose, I had a skin reaction. I had redness at the site of the injection and developed a blister the same day. Then, two days later I noticed a swollen lymph node on the left side of the neck. My arm was very sore from the injection again. I noticed that the joints on my right arm are in acute pain.
1117140	3/19/2021	NJ	42	M	1/1/2021	1/20/2021	Sudden sensoneural hearing loss

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1115428	3/19/2021	FL	58	F	1/4/2021	1/10/2021	mild dizziness lasting <1min became more frequent over the course of a few days. Became extremely ill on 01/19/21 nausea, vomiting, unable to eat or drink, constant dizziness, hearing loss and tongue numbness on right side, unable to get out of bed. Went to ER 1/21/21. Dizziness has been constant and unchanged since.
1113935	3/19/2021	PA	39	F	2/24/2021	3/3/2021	some hearing loss in left ear; Ear ringing; This is a spontaneous report from a contactable other health professional (patient). A 39-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration at the age of 39-years-old on 24Feb2021 18:00 (Lot Number: EL8982) as a single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient had no known allergies. The patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration on 03Feb2021 6:00 PM (Lot Number: unknown) as a single dose for COVID-19 immunization. The patient experienced some hearing loss in left ear (medically significant) and ear ringing on 03Mar2021 19:00. Unknown if patient received treatment. The outcome of the events was not recovered. The patient was not pregnant. Facility type vaccine was Hospital. No other vaccine in four weeks. No COVID prior vaccination. Not COVID tested post vaccination.; Sender's Comments: Based on chronological connection to the vaccine a causal relationship between reported events and BNT162B2 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.
1115817	3/19/2021	VA	51	F	3/16/2021	3/16/2021	Immediate pain right side of neck and hearing loss than ringing in both ears

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1117061	3/19/2021	LA	72	F	2/10/2021	2/15/2021	complete loss of hearing in left ear; vertigo; This is a spontaneous report from a contactable consumer (the patient). A 72-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in arm left on 10Feb2021 (at the age of 72 years) (Batch/Lot Number: EN6201) as single dose for covid-19 immunisation. The patient previously took the first dose of bnt162b2, Lot number=EN3249, on 20Jan2021 at 13:00 (at the age of 72 years), in left arm for covid-19 immunisation. Vaccination was administered at Doctor's office. Medical history included high cholesterol, blood pressure increased, hypothyroidism, allergy to egg, spices, and ace inhibitors, all from an unknown date and unknown if ongoing. The patient received unspecified other medications administered in two weeks. No other vaccine administered in four weeks. No covid prior vaccination. Covid was not tested post vaccination. On 15Feb2021 at 14:30 the patient experienced complete loss of hearing in left ear and vertigo. The events required emergency room visit. Therapeutic measures taken as a result of the events included anti-nausea medications and medication for dizziness. The outcome of the events was not recovered.
1117437	3/19/2021	NY	36	M	2/26/2021	2/27/2021	Severe 90 % hearing loss of the right ear which started the morning after the vaccine. Distorted sound in the right ear which has not improved in 3 weeks!
1115614	3/19/2021	MI	74	M	3/13/2021	3/17/2021	Total loss of hearing in right ear. Sudden on set. Went to bed fine. Woke up total deaf in right ear.
1112802	3/18/2021	CA	66	M	3/1/2021	3/11/2021	Loss of hearing in right ear
1111506	3/18/2021	MA	85	F	2/14/2021	2/14/2021	2/14/21-Immediately after 1st covid vaccine experienced pressure sensation in chest and breast. Great on the right side, went up to the back to neck. The shock sensation went over the top of the head onto face with tingling bilateral. Resolved on 3/3/21. 3/3/21- Severe vertigo-hospitalized for 3 days. On day 1 of vertigo sudden hearing loss.
1110426	3/18/2021	NY	26	M	2/17/2021	2/22/2021	Persistent ringing in ears. I checked with my primary care and ENT, and I don't any hearing loss or ear damage.

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1111655	3/18/2021	NY	41	F	1/8/2021	2/27/2021	Sudden hearing loss 02/27/2021
1112598	3/18/2021	NJ	66	F	3/18/2021	3/18/2021	About a week after my first shot on 2/18/21 I noticed a ringing in my ears. I checked for side effects and did not see it listed. I thought it was just a coincidence. I saw my oncologist and she said that it may be a sign of hearing loss. So I scheduled an upcoming hearing test and ENT visit. Then today I had my second shot and within an hour the ringing in my ears increased significantly. I did further research and found that there are others who have experienced the onset of tinnitus or worsening tinnitus after receiving the vaccine.
1112532	3/18/2021		60	F	3/8/2021	3/15/2021	Week after receiving vaccine: Extreme bout of dizziness Aggravated existing tinnitus (left ear only) Appeared to be further hearing loss in left ear Sensations in face
1107872	3/17/2021	DE	62	F	3/9/2021	3/12/2021	Tinnitus, hearing loss, joint pain, sore at injection
1109717	3/17/2021	AZ	91	F	3/10/2021	3/11/2021	Extremely loud noises and hearing in ears. She had to take her hearing aids out and still extremely loud noises and words. She is deaf in one ear and barely hears from the other. When she woke up the next morning it was gone.
1109739	3/17/2021	IN	54	M	3/12/2021	3/14/2021	Tinnitus in right ear. Loss of hearing in right ear. Was put on flonase. Just treated.
1107822	3/17/2021	AZ	24	F	3/15/2021	3/15/2021	Loss of hearing/ hearing acuity in right ear

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1107524	3/17/2021	NY	77	F	3/1/2021	3/10/2021	I was fine with no noticeable reaction until sometime around 4:00 am when I felt my arm was itchy. Then upon getting up about 6:00 am, my arm was swollen and warm and I had a red rash at the shot site. It get more and more painful to touch but then after three days the swelling started to go down but i also notice that my neck glands and under my arm were also feeling discomfort. I thought it was almost gone except for the glands in my neck but then, last night, March 16th I realized I still had or that a new rash was again on the same area and is still a bit swollen and sore but not as bad as on the 10th. I am really worried about taking the 2nd shot I have a daughter who is having a heart transplant and deaf and she needs me to be in the hosp. with her to interpret for her.
1107752	3/17/2021	ME	49	F	1/25/2021	2/1/2021	Sensorineural hearing loss in right ear which now may be progressing to left ear.
1108094	3/17/2021	CT	58	F	3/17/2021	3/17/2021	Pt received her first dose of the COVID19 vaccine and within minutes she began to feel light headed. Pt had a near syncopal episode where she reported brief hearing loss. Pt reports this happens to her with injections often. EMS called and came to evaluate pt. BP 90/60 HR 66 O2 Sat 98% Repeat BP 153/90 HR 69 98% Sitting up BP 140/78 HR 70 97% Pt reported feeling better and signed refusal for transport to the hospital EMS. Pt was advised to contact her PCP and given the information for the high risk clinic for her 2nd dose.

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1109349	3/17/2021	PA	25	M	3/17/2021	3/17/2021	About 5 minutes after getting the vaccine, patient started to have tunnel vision, loss of hearing, change in LOC unable to answer where he was, he was pale, diaphoretic and unable to respond to signals patient stated he was going to pass out he was removed from the chair and placed on the floor with his legs in the air, his pulse via palpation was slow, he stated that he does not like needles and he had a similar reaction to the H1n1 vaccine . He was placed on a back board and lifted to a litter and taken to the medical obs, vital signs on arrival were 134/75, pulse72 and oxygen 100 in the right arm, @ 1830 , and at 1834 vital 148/88 HR 75 pulse ox 99 on room air. patients skin was now warm and dry, he reported that he was feeling better, at 6:35 bp 133/81, patient was then placed in a sitting position and blood pressure with position change was :143/92, pulse 68 and 99% on room air, standing after 1 minute patient was 145/87 and heart rate 78 and pulse ox 99%. Patient reported feeling better. His color had returned, he was given water and monitored for another 5 minutes.
1109493	3/17/2021	DC	34	F	3/14/2021	3/17/2021	Tinnitus and hearing loss in left ear 2 days after shot. Hoping this goes away as it is very bothersome. I have not experienced this before.
1109614	3/17/2021	NC	70	M	3/12/2021	3/16/2021	Presented with *acute sudden sensorineural hearing loss*, dehydration, poor appetite, and hypovolemic shock. Admitted to ICU for blood pressure support unresponsive to IV fluids. Given IV fluids and blood pressure support medicines in ICU, significant medical improvement after about 24 hours. His sensorineural hearing loss recovered after about 24 hours of rehydration. Workup for infection unremarkable.
1107529	3/17/2021	NY	70	F	12/1/2020	3/5/2021	When I woke up on 3.5.21 i was unable to hear out of my right ear. I went to ENT and had an exam and hearing test and was profoundly deaf in that ear. Left ear is fine. I have been experiencing loud tinnitus in the right ear, also. The Dr is treating me with a large dose of prednisone for 2+ weeks. He has ordered an MRI. The hearing after 2 weeks is starting to come back-now I am at 50% hearing.
1105130	3/16/2021	OH	59	M	3/12/2021	3/16/2021	Modern a Covid-19 Vaccine ERA Hearing loss and high pitched Tinnitus in right ear



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1104091	3/16/2021	NJ	48	M	3/13/2021	3/14/2021	Primary Adverse Event: Tinnitus in right ear, slight loss of hearing in right ear. First noticed 3/14 at approximately 3:00pm (28 hours after vaccination) and has continued through time of this report. Additional side effects: Fever and chills started approximately 10 hours after vaccination and persisted for approximately 7 hours. Fatigue began approximately 4 hours after vaccination and has gradually become less as of the timing of this report.
1104733	3/16/2021	TN	66	F	3/4/2021	3/6/2021	Initial back pain 2 days after shot which lead to nausea, then fever and vertigo. Back pain worsened considerably. Didn't eat for 3 days, and was not hungry. Had to force myself to drink and was not thirsty. 3 days after initial fever had hearing loss. Fever subsided after 5 days, nausea after the first day, vertigo after the second day, back pain became manageable after a week. Hearing loss recovery after 5 days.
1106197	3/16/2021	PA		F	12/31/2020	1/1/2021	post injection moderate increase in tinnitus noted about 5-7 days later and currently unresolved; increase in hearing difficulty due to tinnitus ongoing; This is a spontaneous report from a contactable nurse (patient herself). A 51-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot number: EL1284) via unknown route of administration on 31Dec2020 08:30 AM at single dose in right arm for COVID-19 immunization at Hospital. Medical history included hearing loss and ongoing tinnitus. Allergies to medications, food, or other products included penicillin, sulfa, levoquin. The patient was not pregnant at time of vaccination. No other vaccines have been administered within 4 weeks prior to the COVID vaccine. Prior to vaccination, patient was not diagnosed with COVID-19. Concomitant other medications the patient received within 2 weeks of vaccination included multivitamin. It was reported as post injection moderate increase in tinnitus noted about 5-7 days later in Jan2021 and currently unresolved. Also increase in hearing difficulty due to tinnitus ongoing in Jan2021. Since the vaccination, the patient has not been tested for COVID-19. No treatment received for the adverse events. The outcome of events was not recovered. No follow-up attempts are possible. No further information is expected.

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1106287	3/16/2021	GA	50	M	2/24/2021	2/24/2021	diarrhea worsened 2 hours after receiving the vaccine; Ringing in my ear; was already having a flare; Hearing loss was already there and the vaccine actually exacerbated the situation; This is a spontaneous report from a contactable consumer, the patient. A 50-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot EN6201, first dose) solution for injection intramuscular in the right arm on 24Feb2021 at 17:00 (at the age of 50-years-old) as a single dose for COVID-19 vaccination. Medical history included ongoing irritable bowel syndrome from Mar2020 and acid reflux (esophageal). Concomitant medication included ongoing lansoprazole (PREVACID) for acid reflux (esophageal) from Nov2020. The patient stated his diarrhea worsened 2 hours after receiving the vaccine (24Feb2021 at 19:00) and had diarrhea again around 10 pm. The patient stated hearing loss was already there and the vaccine actually exacerbated the situation in 2021. The patient also experienced ringing in my ear in 2021. The patient's nurse, primary care doctor, and gastroenterologist stated it was okay to receive the vaccine as the patient was in the middle of a flare up with his IBS (inflammatory bowel syndrome) in 2021. Treatment for the event hearing loss exacerbated included unspecified steroids and has been working. The outcome of the events diarrhea worsened and ringing in my ear was unknown. The outcome of the events hearing loss exacerbated and having a flare was recovering.

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1106296	3/16/2021	MA	82	F	2/24/2021	2/26/2021	hearing loss in left ear; tinnitus; This is a spontaneous report from a contactable consumer (patient). A 82-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number/expiration date: unknown), on 24Feb2021 (at the age of 82 years old) as a single dose in the left arm for COVID-19 immunization. Relevant medical history included known allergies: Keflex. Historical vaccine included: first dose of BNT162B2 lot number=en9581, administration date=03Feb2021 at 02:00 PM, Right arm. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included warfarin sodium (WARFIN), Spironolactone, Torsemide. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 26Feb2021at 14:00 AM, the patient experienced Hearing loss in left ear, and tinnitus. No treatment was received for the events hearing loss in left ear and tinnitus. The outcome of the events hearing loss in left ear and tinnitus was not recovered. Since the vaccination, the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.
1106844	3/16/2021	PA	56	F	3/15/2021	3/16/2021	Sudden hearing loss/tinnitus in right ear.
1104722	3/16/2021	NY	68	M	3/11/2021	3/16/2021	Less than 2 days after vaccine Tinnitus has developed in both ears with a constant buzzing sensation and feeling of inflammation. Also feels like hearing ability is affected due to tinnitus sensation that is continuous 24/7. It has not diminished and is not getting better as of date of this report. I do not know if I should ghet another shot as do not want to lose my hearing. Will schedule an appointment with my ENT. I do not want to go deaf from this vaccine.
1103535	3/15/2021	HI	55	F	2/20/2021	3/8/2021	Impaired hearing started on 3/8/2021 in left ear only. Ringing in ear all day on 3/11/2021. Loss of hearing progressed each day in left ear. Had doctor appointment on 3/15/2021. Per Doctor, PCP, both ears look clear. Gave referral to see a specialist to check middle ear.

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1100473	3/15/2021	MI	57	M	1/27/2021	1/29/2021	hearing loss; Ringing in ears; This is a spontaneous report from a contactable other hcp. A 57-years-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 27Jan2021 13:00 in left arm at single dose for covid-19 immunisation. Facility type vaccine was hospital. No other vaccine in four weeks. Medical history were none. No COVID prior vaccination. No COVID tested post vaccination. Known allergies: No known drug allergies (NKDA). Concomitant medication included omeprazole (PRILOSEC [OMEPRAZOLE]), zolpidem tartrate (AMBIEN CR), diazepam (DIAZEPAM) as needed. Historical vaccination included first dose of BNT162B2(lot number: ELO142) on 06Jan2021 01:00 PM in right arm for covid-19 immunisation. The patient experienced ringing in ears and hearing loss that is continually worsening on 29Jan2021 12:00 with outcome of not recovered. AE resulted in doctor or other healthcare professional office/clinic visit. it is unknown whether treatment was received.; Sender's Comments: Considering the plausible temporal association, and lacking any reported alternative explanations, a causative role of BNT162B2 vaccine for the reported worsening of ringing in ears and hearing loss 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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1100498	3/15/2021	GA	77	M	2/8/2021	2/11/2021	hearing loss; This is a spontaneous report from a contactable consumer reporting for self. A 77-years-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN9581), via an unspecified route of administration in right arm on 08Feb2021 (Age at Vaccination was 77 years old) 13:00 at single dose for covid-19 immunisation. The patient medical history was not reported. Patient stated overall in good health. Concomitant medication included finasteride, gabapentine. From 11Feb2021 12:00, patient almost a total hearing loss right ear. He wore hearing aids and they were checked to be working properly. He was concerned about this hearing loss and went to urgent care today. He was given a prescription for PredniSone and also a prescription for Neomycin-Polymyxin-hc (ear drops). 2- For the first time in 77 years, he had been given a prescription for glasses this week. Outcome of event was not recovered.
1100829	3/15/2021	NY	90	M	2/17/2021	3/3/2021	Sudden partial hearing loss with tinnitus, right ear, confirmed as SSNHL by ENT specialist and audiogram. Started on 15 day tapered therapy, starting with 10 mg of oral dexamethasone. Hearing loss subsiding slowly improving over subsequent 10 days of therapy. Tinnitus persists so far.
1101291	3/15/2021	NC	71	M	2/15/2021	3/1/2021	16 days after immunization, I started having increased Tinnitus and hearing loss. These condition s still exist today(3/15/2021)
1102393	3/15/2021	TN	62	M	2/3/2021	2/20/2021	Loss of hearing and hearing acuity in both ears
1102448	3/15/2021	TN	83	F	1/31/2021	2/18/2021	Severe bilateral sudden onset hearing loss hearing 2/18/2021

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1102854	3/15/2021	PA	54	F	1/15/2021	2/20/2021	On that day I woke up with hearing loss in my right ear, feeling of fullness and pulsatile tinnitus. I was seen by my Primary doctors office and given Amoxicillen for days with a Medrol dose pak. After 5 days this did not improve and was seen by ENT. Audiology testing was done and I was diagnosed with Sudden Sensorineural Hearing Loss of my right ear of moderate degree. MRI testing was done on 3/12/2021 and revealed no reason for these symptoms. Prednisone 30 mg was taken for 7 days tapering to 20 mg for 3 days and then to 10 mg for 3 days. Follow up is on April 6 to ENT. Hearing may not return and pulsatile tinnitus may remain.
1102559	3/15/2021	VA	66	M	3/15/2021	3/15/2021	I had the Pfizer vaccine in my left arm on Jan. 23rd. I had no side effects at the time, other than a sore arm, as with any shot. However, two days later I lost all hearing in my left ear. I had no history of ear infections or other ear or hearing problems, except for wax buildup two or three times. On Jan. 26th, I saw an ENT. To my dismay, there was no wax. He prescribed the standard treatment of Prednisone for Sudden Idiopathic Hearing Loss. No change after the first round, so I had a second round, and also had the series of three ear injections with Dexamethasone. Had an MRI, as well, which was normal. A couple of weeks into all this, I began to have a bit of sound-generated static in my ear, and this continues today. (Fortunately, I've only had the most minor of tinnitus in that ear, and even it is pretty much gone now.)
1099429	3/14/2021	NJ	39	M	2/1/2021	2/12/2021	First Pfizer shot on 02/01. Flu like symptoms for 3 days. Followed by overall fatigue. The. 10 days after shot ear symptoms began. Complete hearing loss in right ear. Began as 3 days of tinnitus. Then complete hearing loss. Put on steroid blast (60mg of Prednisone) by my primary. Referred to ENT. ENT ran hearing test and concluded that the hearing loss was complete. 12 days of complete hearing loss. Then repeated hearing test. Slight improvement. ENT delivered shot of steroids directly into my right ear. Hearing test repeated 10 days later. Slight improvement again. Now currently about 90% of hearing had returned to my right ear.

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1099283	3/14/2021	MD	50	F	1/14/2021	1/15/2021	Transcription of a text I sent to my colleagues: Hi all--I'm not sure who has received the second vaccine, but I wanted to update as to my experience. I got sick with the first one from about 4ish hours after until the next mid morning maybe? Then I felt bad again that second night. I had my vaccine (second) yesterday at 4 PM, and I felt OK going to bed but had a pretty pitiful night. I woke up at 5 AM and I felt horrible. That felt like someone took a pair of metal cymbals and slammed them together on my head. The tinnitus was strong. I also had body aches and joint pain and felt like I had the flu. I felt a little better around 1 PM, but felt bad again around 330. Now I'm miserable again with terrible body aches and chills (this was at 7:38 PM). I'm sure I will feel better in the morning, just wanted to share my experience." Sadly, since then, I have had tinnitus with a metallic ringing in both ears along with hearing loss. I had some vertigo one day but unsure if this was related. The tinnitus makes me very sad. I am a hospitalist and am happy to have been vaccinated, still. It has been 2 months today, and it remains, unrelenting. It is worse in the morning and at night. The hearing loss is difficult.
1099151	3/14/2021	MI	70	F	1/31/2021	2/16/2021	12-14 days after my first dose of the Pfizer vaccine I experiences severe increase in what has been very mild tinnitus (from hearing loss) After the second dose (lot EN6200) on Feb 21, 2021 tinnitus became unmanageable causing insomnia, anxiety and blood pressure spike to 155/80. Was treated with Amlodipine -- pressure came down but tinnitus not resolved.
1098368	3/14/2021	ME	38	M	2/9/2021	2/10/2021	Experience sudden sensorineural hearing loss and tinnitus in left ear that caused complete deafness approximately 17 hours after second dose. Treated with oral prednisone and intratympanic injection of dexamethasone. Have since recovered hearing approximately one month post-vaccine.
1099478	3/14/2021	CA	43	F	3/6/2021	3/11/2021	Tinnitus in right ear Partial hearing loss Feeling of fullness in right ear Fatigue

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1097136	3/13/2021	NC	51	F	3/4/2021	3/5/2021	Triggered menieres, it took me a few days to realize what was going on but now recognize it. This has been dormant for about 18 months, except for hearing loss. My right ear has been the problem but since shot left ear has also been hurting and ringing as well
1097764	3/13/2021	IN	66	M	2/17/2021	3/3/2021	I received the Pfizer COVID 19 vaccination on the morning of 2/17/21 with no resulting initial sequelae other than injection site tenderness. Approximately 2 weeks post-injection, I developed coryzal symptoms of nasal stuffiness and congestion without fever, chills, headache, or myalgias. On, or about, 3/3/21, I noticed diminution of hearing in the left ear without signs of drainage, fever, or dizziness. This was treated with a Z Pac, nasal and oral decongestants, and nasal steroids. Over the course of 10 days, the hearing decline had improved, but a clinical exam and testing by an ENT on 3/12/21 confirmed evidence suggestive of sensorineural hearing loss, with asymmetric impairment in the affected (left) ear.
1097731	3/13/2021	HI	91	F	2/11/2021	3/3/2021	3/3/2021 CHF, hearing loss
1097725	3/13/2021	AZ	53	M	3/12/2021	3/13/2021	I have a sudden loss of hearing on my left ear. It feels like it is full of water. I am also experiencing mild dizziness and off balance while walking.
1097323	3/13/2021	AL	50	F	1/6/2021	1/6/2021	Almost passed out after injection. Had immediate disorientation, head pressure, ear ringing, and slight hearing loss. I stayed 1 hour after at facility. The next day disorientation was better. The head pressure was better after 2 weeks. The hearing loss has slightly improved. The ear ringing worsened significantly and is still going on now, 9 weeks later. It has improved some now after seeing an ENT ear specialist. I have been taking medicine to try to help the ear ringing for about 7 weeks. The severity of the ear ringing has gone from an 8 out of 10 in loudness to about a 2. It is not gone and may never go away.
1096713	3/13/2021	PA	54	M	3/5/2021	3/5/2021	Sudden hearing loss in left ear.



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1096354	3/13/2021	NY	44	F	2/4/2021	2/11/2021	Acute hearing loss unilaterally (right ear) beginning D7 after dose 1, peaking at D10-13 after dose 1 with moderate recovery by D15. Again, acute hearing loss after second vaccine (R>L) beginning on D7, peaking on D11-16. Today is D16 with no recovery whatsoever.
1096249	3/13/2021	CA	73	M	3/10/2021	3/10/2021	Partial hearing loss in right ear. Moderate tinnitus.
1096145	3/12/2021		33	M	3/12/2021	3/12/2021	Ringing in the right ear, which progressed to numbness of the inner and outer ear, and then progressed to hearing loss in the right ear. This progressed over 2 hours and has not resolved as of now, 10 hours post the second dose of the vaccine.
1096062	3/12/2021	CA	47	F	1/13/2021	2/2/2021	Sudden sensorineural hearing loss that developed over the course of 3 days. Severe to profound hearing loss in left ear. Responded well to intratympanic dexamethasone and oral steroids. Hearing fully recovered within 2 weeks.
1093541	3/12/2021	TX	20	M	3/11/2021	3/11/2021	Systemic: Dizziness / Lightheadness-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Nausea-Mild, Systemic: Tingling (specify: facial area, extremities)-Mild, Systemic: Tinnitus-Mild, Systemic: Visual Changes/Disturbances-Mild, Additional Details: Pt nearly fainted/passed out. Had some tunnel vision/nausea/loss of hearing. Recovered after water and sitting for 15 minutes. Had some numb/tingling hands/arms.
1095601	3/12/2021	PA	56	F	2/21/2021	3/6/2021	Loss of hearing in right ear. After hearing test completely deaf in right ear.
1092223	3/11/2021	TX	69	M	3/5/2021	3/10/2021	5 days after injection I experienced sudden severe hearing loss in right ear at 5:30 am

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1091055	3/11/2021	VA	57	F	1/21/2021	1/21/2021	Within minutes of receiving second dose of the vaccine, I had a severe pain in the right side of my neck. I waited 15 minutes, but felt I could not leave as I was diaphoretic and dizzy when I stood up. I waiting up to 45 minutes until I could manage to leave after receiving bottled water and orange juice. About 5 days later, I experienced tinnitus in my left ear (swooshing sound 24/7 that beat to my pulse.) I went to an ENT appointment several weeks after and was examined. Anatomically there was no findings. The audiology report showed moderate hearing loss in my left ear. High dose steroids were prescribed. I am on day 9 of the Prednisone without any relief of the tinnitus or improvement in my hearing.
1090333	3/11/2021	CA	68	F	2/1/2021	2/1/2021	This is my second report. I have continued to have traveling headaches, tingling, nausea, joint pain, intense fatigue and brain fog. I now have constant tinnitus and am having my hearing checked next week because I feel I have hearing loss. The fatigue is debilitating. I start to feel better and another wave hits me. I was advised by my doctor to not take the second dose. The tinnitus is getting louder. It causes anxiety. I don't know how I am going to live with it.
1088464	3/10/2021	FL	74	F	3/1/2021	3/2/2021	loss of hearing, patient has hx of wearing hearing aids, hearing worsened after vaccination. Patient went to ENT doctor today, was advised to call CDC per ENT doctor. Spoke to pt's daughter because mom has lost 80% of her hearing and she is taking all of her calls. They went to audiologist for hearing test, then to ENT who prescribed Prednisone for 10days but was unsure about her situation and told her to call the CDC. Their main concern is does she take her 2nd shot and risk loosing more or all of her hearing if it was a result of the vaccine. The daughter said that they received new hearing aids a week before the vaccine. I told her that we will follow up with her in about a week to see if the steroids are helping and to find out the results from her ENT follow up appt.
1087393	3/10/2021		42	M	2/13/2021	3/5/2021	Unilateral sudden hearing loss, left ear. Normal tympanogram, normal temporal CT. No headache, visual change, dizziness, otalgia, tinnitus. Symmetrical facial movements. Exam was consistent with conductive hearing loss. Was referred to ENT, started on corticosteroids. Outcome undetermined.

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1088372	3/10/2021	ME	38	M	2/9/2021	2/9/2021	On 2/9 this employee received 2nd COVID immunization, woke up on Wednesday, found that his hearing was muffled in left ear. On Thursday, the employee reports he had no hearing in left ear, with some tinnitus. On Friday, he went to see primary care, primary care thought she saw fluid behind both ears, put him on flunase and mucinex; after consulting with his sister who is a NP, he went to see the doctor audiology, they saw him on 2/16, he was diagnosed with sudden "sensireoneural hearing loss". He was prescribed a two week course of prednisone to treat this condition by the doctor. Has begun taking the prednisone. States that he is still without hearing in his left ear, continues to have tinnitus in that ear.
1089813	3/10/2021	MD	83	M	3/2/2021	3/4/2021	Patient felt very tired on the day following administration of the vaccine, with subsequent rapid total loss of hearing in the L ear and partial loss of hearing in the R ear. Hearing loss was preceded by intense tinnitus. Subsequently patient was seen by physician and audiologist on March 9th, hearing loss was confirmed. Patient was started on prednisone by physician.
1088599	3/10/2021	CA	66	M	3/6/2021	3/6/2021	My right ear has been fluttering . About 10 hours last night, and continuing now. I had a concussion around 1990 from a bike accident with no helmet. I hit the ground on the right side of my head which effected my left ear and a lot of hearing loss. I?m theorizing that the moderna vaccine has triggered something and now my inner or middle right ear is pulsating. I?m thinking it?s blood flow I?m hearing. But whatever it is, it?s annoying

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1088884	3/10/2021	KS	74	F	3/3/2021	3/3/2021	<p>Progress Notes APRN (Nurse Practitioner) Family Medicine Cosigned by: MD at 3/4/2021, 8:45 AM Expand All Collapse All COVID VACCINE CLINIC 3/3/2021 Patient Date: 3/3/2021 Subjective Patient is a 74 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 right deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience diaphoresis. She denied rash, hives, difficulty breathing, difficulty swallowing, wheezing, throat tightness, 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 , collapse, drooling, hypotension, rapid progression of symptoms, respiratory distress, skin changes and tongue swelling. Past Medical History: Diagnosis Date ? Allergy all year ? Anxiety ? Arthritis ? Asthma exercise induced ? Calculus of gallbladder without mention of cholecystitis or obstruction Cholelithiasis; ? Diabetes mellitus ? Diabetes mellitus, type 2; ? Diverticulosis of colon (without mention of hemorrhage) Diverticulosis without Hemorrhage ? Esophageal reflux GERD; ? Hearing loss ? Hypertension ? Irritable bowel syndrome Irritable Bowel Syndrome ? Past Hospitalization Diagnosis: Chest Pain, atypical; at: Health Center; Approximate Date: 18000101; ? Nextgen Comments Palpitations/SVT; Anxiety disorder; HRT; Microscopic hematuria ? Osteoarthritis, unspecified whether generalized or localized, unspecified site Osteoarthritis; ? Other and unspecified hyperlipidemia Hyperlipidemia, Pure; ? Pancreatitis ? PONV (postoperative nausea and vomiting) ? Type II or unspecified type diabetes mellitus without mention of complication, not stated as uncontrolled; DM type II w/o comp; ? Unspecified essential hypertension Hypertension ? Unspecified hemorrhoids without mention of complication Hemorrhoids; ? Unspecified tinnitus ALLERGY REVIEW OF SYSTEMS: Patient complains of headaches (frontal, reports from using her hearing aids and is loud in the expo center. Present prior to vaccine today. ). Patient denies chills, fever and malaise/fatigue; Previous</p>

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Reactions: none Pt reports she last ate around 10 am. She declines any food/snacks from bay today.

Objective Vitals Vitals: 03/03/21 1355 BP: (!) 115/99 Pulse: 73 Resp: 16 SpO2: 97% Blood Sugar 134 collected at 1354 Physical Exam Constitutional:

General: She is not in acute distress. Appearance: Normal appearance. She is well-developed. She is not diaphoretic (no visual diaphoresis. ) 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: 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 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) Flushed sensation Pt observed for 15 minutes. t Symptoms resolved. BG good and pt able to ambulate w/o dizziness, lightheaded, sob, cp. Follow up with pcp if not improving or worsening. Continue to monitor BG and BP at home. Pt and pt's husband voices appreciation of care today. APRN Electronically Signed 3/3/2021 1:57 PM Division of Health.

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1089134	3/10/2021	KS	74	F	3/1/2021	3/1/2021	<p>Progress Notes APRN (Nurse Practitioner) ? ? Family Medicine Cosigned by: Dr at 3/1/2021 10:50 AM Expand AllCollapse All COVID VACCINE CLINIC 3/1/2021 Subjective 74 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 lightheadedness. She denied difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, 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 , hypotension, rapid progression of symptoms and respiratory distress. PMH: currently on ciprofloxacin for an UTI. Past Medical History: Diagnosis Date ? Allergic rhinitis, cause unspecified Allergic Rhinitis; NG PMH ? Allergy ? Awareness under anesthesia Pt was hard to wake when had anes in 1970's ? Carpal tunnel syndrome ? Colon polyps ? Coronary artery disease ? H/O heart artery stent 2005 ? Hearing loss bilateral hearing aids ? Iritis ? Iron deficiency anemia ? Lumbosacral spondylosis without myelopathy ? Osteoarthritis, unspecified whether generalized or localized, unspecified site Osteoarthritis; NG PMH ? Osteopenia osteopenia, MVA with whiplash injury that caused servical spondylosis 60's, s/p laminectomy 75, 88 ? Other and unspecified hyperlipidemia Hyperlipidemia, Pure; NG PMH ? Pain, chronic ? Peripheral vascular disease, unspecified (HCC) ? Tinnitus ? Unspecified essential hypertension Hypertension; NG PMH ? UTI (urinary tract infection) ? Wears hearing aid in both ears 2017 ALLERGY REVIEW OF SYSTEMS: Patient denies chills, 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, joint pain, dizziness and headaches + lightheaded: Previous Reactions: none Objective Vitals Vitals: 03/01/21 1025 03/01/21 1040 BP: (!) 144/56 132/61 Pulse: 93 70 Resp: 20 14 SpO2: 99% Physical Exam Constitutional: General: She is not in acute</p>

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distress. Appearance: Normal appearance. She is well-developed. She is obese. She is not ill-appearing or diaphoretic. Eyes: General: Right eye: No discharge. Left eye: No discharge. Conjunctiva/sclera: Conjunctivae normal. 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. 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. Mental status is at baseline. Gait: Gait abnormal (walks with a cane. ). Psychiatric: Mood and Affect: Mood is anxious. Behavior: Behavior normal. Thought Content: Thought content normal. Judgment: Judgment normal. Assessment/Plan Treatment included: water 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) Observed in the medical bay for approx 15 minutes. Pt responded well with water and rest. She was able to demonstrate ambulation in the bay w/o reoccurrence of lightheaded. Pt reports she feels a lot better. Pt encouraged to monitor bp at home and follow up with pcp if noted to be 140/90 consistently. Pt walked out by RN accompanied by pt's husband. Pt voiced appreciation for today's care/visit. APRN Electronically Signed 3/1/2021 10:32 AM

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1089382	3/10/2021	CA	59	M	2/17/2021	2/23/2021	2/17/21 - Moderna vaccination taken at approximately 4:45pm 2/23/21 - Approximately 3:30 pm right ear is stuffed, ear and nasal passages feel pressure, 5:00 pm right hear has lost hearing, 10:00pm experiencing severe vertigo, 10:30 admitted to Emergency Department, 11:30pm CT Scan taken, prescribed Meclazine 25mg tab and Lorazepam 0.5mg tab, 5:00 am released with instructions to see family physician and ENT 2/25/21 appointment with family physician, prescribed Amoxicillin-clav 875-125mg 3/5/21 appointment with Dr., ENT , informed of profound hearing loss in right ear, prescribed Prednisone 10mg tab 3/9/21 appointment with Dr., ENT, confirms total hearing loss of right ear 3/11/21 pending appointment for an MRI 3/12/21 pending appointment for 2nd audiology test
1088274	3/10/2021	CA	24	M	1/26/2021	1/27/2021	Loss of hearing in both ears; Fatigue; Joint pain; Headache; A spontaneous report was received from a Healthcare Professional concerning a 24 years old male patient who received Moderna COVID-19 vaccine (mRNA-1273) and experienced fatigue, joint pain, headache and loss of hearing in both ears. The patient's medical history was not provided. Products known to have been used by the patient were Tylenol and Ibuprofen. On 26 Jan 2021, prior to the onset of the events the patient received their first of two planned doses of mRNA-1273 (lot/batch: 041L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 27 Jan 2021, the patient experienced the events fatigue, joint pain and headache. On 28 Jan 2021, the patient experienced the loss of hearing in both ears. The patient was treated with Tylenol and Ibuprofen. No relevant laboratory details were included. Action taken with mRNA-1273 in response to the events was unknown. The outcome of events include fatigue, joint pain and headache were unknown. The outcome of the event loss of hearing in both ears was not recovered.; Reporter's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.
1087204	3/10/2021	NV	46	F	1/23/2021	2/9/2021	Complete left ear hearing loss two weeks after vaccine #1



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1088304	3/10/2021		73	F	2/25/2021	2/26/2021	1st Pfizer vaccine given Feb 4th; 2nd Vaccine received 9:30 a.m. March 25; Side effect 1: Never having had nose bleeds I had 8 minor nosebleeds after the 1st vaccine. (chalked it up to "ND dry air). March 24 at 1:30a.m. I awoke to a nose bleed my husband and I could not stop; went to ER and a catheter was placed in my nose after an hour after they could not get it stopped. Catheter was removed next day. Blood pressure 184/96 unusual for me range 120/80. Side effect 2: 10 days after the 2nd vaccine I noticed loss of hearing in my right ear. That has persisted but I have not taken any action on it. My head is tender and I feel more "off balance than normal". Not sure if this coincidence or side effect.
1086510	3/9/2021	WI	65	F	2/27/2021	2/27/2021	Fever of 3 degrees, muscle aches and pains, chills, some loss of hearing, brain processing slowness, headache, loss of appetite, dizziness.rash and itchiness of arm.
1086109	3/9/2021	AZ	61	M	3/3/2021	3/6/2021	Loss of hearing in right ear with a buzzing noise same side of the injection
1085559	3/9/2021	CA	40	M	1/21/2021	1/22/2021	Acute hearing loss in right ear. Muffled, ringing sound one day after vaccine administered. Was sleeping and heard a high pitched sound from right ear. Waited several weeks for it to clear up. Finally went to my PCP and was started on steroids. That did not help. Saw an ENT specialist and restarted on another round of steroids.

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1086031	3/9/2021	FL		F	1/29/2021	1/30/2021	<p>Hearing loss; Virus in ear; Arm was sore; A spontaneous report was received from a consumer, concerning a 73-year-old, female patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed arm sore, hearing loss and virus in my ear. The patient's medical history was not provided. Products known to have been used by the patient, within two weeks prior to the events included losartan, fluticasone, escitalopram, esomeprazole sodium, simvastatin, cetirizine hydrochloride, alpha lipoic acid, chromium, cinnamon oil, ascorbic acid, folic acid, nicotinic acid, pyridoxine hydrochloride, retinol, riboflavin, vitamin b1 nos, vitamin b12 nos, vitamin d nos, vitamin e nos, turmeric [curcuma longa rhizome], vitamin B complex, vitamin D3, levothyroxine;liothyronine, fish oil, probiotics nos, ascorbic acid, melatonin, calcium, ubidecarenone, vitamin e nos, magnesium and polycarbophil calcium.</p> <p>On 29 Jan 2021, approximately 1 day prior to the onset of symptoms, the patient received the first of two planned doses of mRNA-1273 (Batch number: 012M20A) intramuscularly in the right deltoid for prophylaxis of COVID-19 infection. On 30 Jan 2021, the next day, after the first dose of vaccine, the patient woke up with arm sore which had lasted for two days. On 25 Feb 2021, the patient experienced hearing loss which was from a virus in her ear. Treatment for the events included high dose of prednisone tablets. Action taken with mRNA-1273 in response to the events were unknown. The event of arm sore was considered resolved on 01 Feb 2021. The outcome for the events of hearing loss and virus in my ear were 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.</p>

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1083948	3/9/2021	TX	22	M	3/8/2021	3/8/2021	Site: Pain at Injection Site-Mild, Systemic: Dizziness / Lightheadness-Medium, Systemic: Hypotension-Medium, Systemic: Nausea-Medium, Systemic: Shakiness-Medium, Systemic: Tinnitus-Medium, Systemic: Visual Changes/Disturbances-Medium, Additional Details: Near fainting episode. Pt did not lose consciousness but blacked out (visual disturbances, tinnitus/temporary hearing loss, nausea) occurred within 2-3 minutes of administration. First attempt to read BP was low (~80/60). Pt is an athlete, so I waited until after water was consumed to take BP again. 2nd reading was ~106/65. Pt felt better after drinking water and after sitting for 15 minutes under observation.
1084281	3/9/2021	OH	37	M	3/3/2021	3/5/2021	He began to have some severe pain in his ears to the point of 8/10. He went to the hospital, saw a doctor and they gave him some medication Amox/clav that he took. He did not help the pain. After 2 days he went back to the ER on 3/7/21, they gave him another antibiotic called Ofloxacin ear drops. He found out that he had a hole in his ear drum. He has never had an issue like this before, and he was fine when he got the vaccine and feels it's related to that. He has had no problems other than the regular side effects which only lasted for 1 day and then went away. Yesterday, 3/8/21 the problem shifted to the other ear. He is beginning to feel pain on his left ear as well now. He has terrible hearing loss due to this issue.

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1085189	3/9/2021	MA	46	F	2/9/2021	2/9/2021	Hearing in her right ear is now muffled; Places her finger in her right ear, it feels numb; Couldn't get off the couch; Vomiting; Dizziness; Vertigo/Felt spinning all day long; No hearing in right ear; Left earache; Beeping noise right ear; Nauseated; Neck and shoulders were also achy; Head felt like it would explode; Ears were full of pressure; Neck and shoulders were also achy; Chills; Body aches; A spontaneous report, was received from a consumer (patient), a 46 years-old female patient, unknown race and ethnicity, who was administered Moderna's COVID-19 vaccine (mRNA-1273), and experienced no hearing in right ear (deafness unilateral), ears were full of pressure (ear congestion), neck and shoulders were also achy (neck pain), left earache (ear pan), beeping noise right ear (tinnitus), hearing in her right ear is now muffled (hypoaacusis), place her finger in her right ear, it feels numb (hypoaesthesia), body aches (pain), dizziness, couldn't get off the couch (asthenia), vertigo/felt spinning all day long (vertigo), chills, neck and shoulders were also achy (arthralgia), head felt like it would explode (headaches), nauseated (nausea), and vomiting. The patient's medical history included ear infection as a child, hysterectomy (5 years ago) and knee surgery (8 years ago). The patient was allergic to penicillin and sulfa drugs. Concomitant medications were not reported. On 09 Feb 2021, prior to the onset one events, the patient received the second of planned doses of mRNA-1273 (Lot number: 001A21A), intramuscularly in the left arm for the prophylaxis of COVID-19 infection. On 09 Feb 2021, after administering the vaccine, at night she started experiencing a bad reaction which includes body aches and chills. On 10 Feb 2021, in the morning, the patient head felt like it would explode, reported headaches, and her ears were full of pressure. She stated that her neck and shoulders were also achy. The patient stated that she took acetaminophen as treatment medication. On 11 Feb 2021, in the morning, the patient had a left earache and no hearing in right ear except a beeping noise. The patient also stated that she was feeling nauseated and called her primary healthcare professional and was advised to go to urgent care on the same day. The patient stated that she was prescribed prednisone (one tablet three times a week) and ear infection was ruled out. On 13 Feb 2021, the patient experienced vertigo, dizziness, but body aches were mostly gone. On 14 Feb

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1083396	3/8/2021	IN	81	M	2/17/2021	2/18/2021	<p>2021, the patient stated that it was the worst day, as she couldn't get off the couch, felt spinning all day long, and was vomiting. On 15 Feb 2021, the patient reported that she threw up in the morning and was nauseated and dizzy. The patient stated that she then went to see ear nose throat (ENT) specialist. It was reported that the findings from ENT Specialist was hearing loss in right ear and was prescribed a prednisone dose pack and unknown anti-nausea medication. On 23 Feb 2021, the patient stated that the hearing in her right ear was now muffled and can't hear high pitch in right ear. The patient stated that the hearing loss was ongoing and was still experiencing headaches. The patient stated that she currently isn't working and can't drive. The patient also stated that if she places her finger in right ear, it feels numb. The patient stated that she was scheduled to have a magnetic resonance imaging (MRI) done on 10 Mar 2021, if her hearing doesn't return. Action taken with second dose of mRNA-1273 in response to the event was not applicable. The outcome of the events, no hearing in right ear, ears were full of pressure, left earache, hearing in her right ear is now muffled, place her finger in her right ear, it feels numb, head felt like it would explode, were considered as not recovered; that of event body aches was considered as recovering/resolving; that of events neck and shoulders were also achy, beeping noise right ear, dizziness, couldn't get off the couch, vertigo/felt spinning all day long, chills, neck and shoulders were also achy, nauseated and vomiting, were considered as 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.</p> <p>Day after second vaccine woke to complete loss of hearing in left ear. Next day balance was off and still is- and hearing in left ear is still gone.</p>

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1083495	3/8/2021	AZ	33	F	1/10/2021	1/22/2021	I don't know if this is related, but reporting just in case. I began losing hearing in my left ear about 2 weeks after receiving my first shot. When it continued to get worse, I went to the dr about 3 weeks after my first shot and was diagnosed with labyrinthitis. My symptoms continued to worsen, and I now have severe hearing loss as well as 75% loss of vestibular function (diagnosed by ENT and audiologist) with constant vertigo. My current diagnosis is labyrinthitis, however I'm also getting an MRI in 2 days to rule out other possibilities.
1082511	3/8/2021	NJ	37	U	1/27/2021	2/4/2021	Right sided sudden hearing loss on day 8 after first vaccine. Treated with prednisone 20 mg tablet tapering dose. Symptoms resolved, then recurred on day 8 after vaccine # 2. Being treated with prednisone 20 mg tablet tapering dose, dexamethasone sodium phosphate 4 mg/mL injection syringe.
1082136	3/8/2021	IN	58	M	1/6/2021	2/23/2021	Acute sensory neural hearing loss of hearing in left ear starting about 8 weeks after vaccination. Started approximately 2/24/21 and became progressively worse. Audiogram demonstrated marked change. Subjectively lost about 50%. Treated with 10 days prednisone 60 mg/day with improvement to about 15% loss. MRI scheduled but not completed. COVID PCR negative. COVID Ab negative. Assessed relationship to vaccine--possible but not probable.
1081973	3/8/2021		69	F	2/26/2021	2/27/2021	Extreme fatigue, dizziness that resulted in 2 falls and complete loss of hearing. Dizziness started about 10 AM on Saturday morning (2/27) following the vaccination and continued until around 2 AM on Wednesday morning (March 3). Loss of hearing was gradual and started Sunday (2/28), but did result in complete loss of hearing which is slowly returning. She called in to the clinic to have adverse effects addressed.
1080983	3/8/2021	CA	44	M	1/15/2021	1/22/2021	1 week following my vaccine I (1/21/21) started experiencing a clogged sensation in my right ear. My symptoms have continued to escalate. I have suffered from hearing loss, consistent dizziness/off balance, and blurred vision.

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1080955	3/8/2021	KS	88	F	2/26/2021	2/26/2021	<p>Progress Notes APRN (Nurse Practitioner) ? ? Family Medicine Pt called to follow up on covid-19 vaccine done on 02/26/21. She states she did develop chills, fatigue and blood pressure was up and down (from baseline, "not of any concern"). Slight elevation of temp, under 100 F. This was on Friday. Then over the weekend, she slept a lot. Today she feels well and "ready to get dose #2". Denies any further questions or concerns. Pt is appreciative of phone call. APRN Progress Notes APRN (Nurse Practitioner) ? ? Family Medicine Cosigned by: MD at 2/28/2021 7:37 AM Expand AllCollapse All COVID VACCINE CLINIC 2/26/2021</p> <p>Patient: DOB: Date: 2/26/2021</p> <p>MRN: Subjective Patient is a 88 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 headache. She denied rash, hives, welts, difficulty breathing, difficulty swallowing, wheezing, throat tightness, hoarseness, stridor, itching, lightheadedness, dizziness, facial swelling, lip swelling, tongue swelling and weakness face, arms/legs. 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 and rapid progression of symptoms. PMH: Past Medical History: Diagnosis Date ? Allergy year round ? Cardiac pacemaker in situ 10/26/2017 ? Chronic kidney disease, stage III (moderate) (HCC) 7/17/2020 ? Coronary artery disease ? Diverticulosis ? Esophageal reflux ? Esophageal stricture ? Hearing loss ? Hiatal hernia ? Hypothyroid ? Osteoarthritis ? Palpitations ? Perennial allergic rhinitis 5/22/2017 ? Postablative ovarian failure ? Proteinuria Hypertensive ? Rheumatic fever ? Rotator cuff tear, left Nonsurgical treatment ? Sciatica ? Skin cancer nose X2 ? Unspecified cataract removed ? Unspecified essential hypertension ALLERGY REVIEW OF SYSTEMS: Patient complains of headaches Patient denies chills, fever, malaise/fatigue, facial swelling, ear pain, sinus</p>

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pain, sinus pressure, frequent throat clearing, eyes itching, puffy eyes, eye redness, cough, chest tightness, shortness of breath, wheezing, rash, hives, eczema, itching of skin, abdominal pain, muscle aches and dizziness Denies vision changes. L eyelid with droop. Chronic. Unchanged. : Previous Reactions: none  
Objective Vitals Vitals: 02/26/21 1408 02/26/21 1414 BP: (!) 156/66 (!) 145/56 Patient Position: Sitting Pulse: 60 SpO2: 99% Physical Exam Vitals and nursing note reviewed. Constitutional: General: She is not in acute distress. Appearance: Normal appearance. She is well-developed. She is not ill-appearing, toxic-appearing or diaphoretic. Eyes: Comments: Slight drooping of L eyelid, chronic, unchanged per pt and pt's granddaughter, Otherwise no facial drooping or asymmetry. Neck: Thyroid: No thyromegaly. 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. 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 present. Mental Status: She is alert and oriented to person, place, and time. Gait: Gait (walks with steady gait. ) normal. Psychiatric: Mood and Affect: Mood normal. Thought Content: Thought content normal. Judgment: Judgment normal. Assessment/Plan Treatment included: water 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) Pt monitored for approx 30 minutes. She has improvement of bp on observation along with headache has subsided. She is encouraged to monitor her bp at home and follow up with pcp if bp stays above 140/90. Granddaughter had requested pt to be evaluated. She is appreciative of this evaluation. APRN Electronically Signed 2/26/2021 2:47 PM

1080905	3/8/2021	WV	46	M	2/3/2021	2/5/2021	Low frequency hearing loss LT ear treated with HIGH dose prednisone
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1083343	3/8/2021	NY	67	M	1/21/2021	1/25/2021	Ringing in left ear and brain area (tinnitus) Received hearing test, MRI and sinus exams Nothing found other than age related normal hearing loss
1079153	3/7/2021	WA	50	F	2/2/2021	3/3/2021	Sudden unilateral hearing loss. Undergoing treatment with prednisone at this time.
1080062	3/7/2021	CT	43	M	1/28/2021	1/30/2021	Within 48 hours of receiving the COVID vaccine, I began having extreme pressure and discomfort in my right ear. Symptoms included dizziness, fullness in the ear and hearing loss. This persisted for several days. As a first course of action, I took Tylenol and antihistamines. I saw my PCP a few days later and he misdiagnosed my condition and suggested that I continue with antihistamines and Flonase. Two weeks later my condition had improved only slightly and I became more concerned. I asked my PCP whether a short course of steroids was warranted (at the suggestion of my mom and wife, who are both health care professionals). He prescribed a "dose pack," which I started on or about Monday, Feb. 22. Later that week, I connected with an ENT who is a friend of a friend. When I told him my story and symptoms he was extremely concerned and got me an immediate appointment on Friday, Feb. 26. At that visit I was diagnosed with acute and severe Sensorineural hearing loss (SNHL) that had resulted in 92% hearing loss in my right ear. Additional symptoms continue to include fullness, tinnitus and other discomfort. None of these issues existed prior to my COVID vaccine shot. I am currently undergoing a treatment of high dose prednisone and steroid injections in my ear. I am scheduled for another visit with doctor on Friday, March 12.
1079683	3/7/2021	NY	66	F	2/21/2021	3/5/2021	Sharp pain in one ear and great loss of hearing.

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1076055	3/5/2021	OH	78	M	1/27/2021	1/30/2021	<p>There was a significant drug interaction with Efudex Cream that I was applying topically to a pre-cancerous 2-cm-diameter lesion on my left shin. On the day of my first Pfizer shot, the Efudex treated lesion was progressing normally from the desquamation (scabbing and shedding of epithelial scales) to the erosion stage (starting to form a shallow 2.5-cm-diameter ulcer). Starting about Saturday 30 January (three days after the first Pfizer shot) and slowly increasing for the next four days, the Efudex-treated ulcer became deeper, the peripheral 12-cm-diameter skin became redder, and the left foot and ankle became increasingly swollen. My RN-wife and I (a former medical-research physicist) began research andChronic health conditions: nasal polyps, precancerous bleeding actinic keratoses, Cramp-Fasciculation Syndrome (leg &amp; foot cramps), early macular degeneration bilateral, hearing loss bilateral. Chronic health conditions: nasal polyps, precancerous bleeding actinic keratoses, Cramp-Fasciculation Syndrome (leg &amp; foot cramps), early macular degeneration bilateral, hearing loss bilateral.DVERSE EFFECTS, TREATMENT, AND OUTCOME: discovered that Efudex should not be given concurrently with any of a long list of immunizations. This is an Efudex problem that should gain another immunization onto that list. Being within a week of finishing the Efudex regimen, we monitored the Efudex-treatment area and the peripheral area carefully. On Thursday 4 Feb (eight days after the first Pfizer shot), the ulcer began unusual drainage, the 12-cm-diameter peripheral area became inflamed, and swelling of the left ankle and foot increased to almost skin-tight - I can upload photos if you need. Time for immediate action. My excellent Dermatologist stopped Efudex and started me on Bactrim by mouth for 10 days, and Gentamicin topical antibiotic on the ulcerated central area and Triamcinolone topical corticosteroid on the peripheral and swollen areas for three weeks. Good choices. Improvement was immediate and continued improving for the next three weeks. By the time of the second Pfizer shot on 24 February, the central area was healing well, in the late-reepithelialization stage (regrowth of epithelial tissue that now formed a completely-covering scar tissue with no oozing), and with all inflammation and swelling completely gone. After the second Pfizer shot (taken 20 days after stopping Efudex), there were zero</p>

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							adverse effects of any kind. NOTE: There were absolutely zero other adverse effects of any kind throughout the entire series: no chills, fever, headache, nausea, vomiting, diarrhea, change in pulse or blood pressure (120/70 range), loss of taste or smell, sore throat, cough, lung congestion, fatigue, feeling of being unwell, shortness of breath, injection-site swelling or redness, hives, swelling of face, decreased kidney function, or other adverse cardiovascular, neurological or pulmonary effects. There was no additional joint pain above my normal osteoarthritis. After both shots, I felt a slight normal-range injection-site soreness for the next few hours, but no site swelling, rash, redness, or other problem. We recommend that this immunization be added to the Efudex 'proscribed or warned' list.
1075566	3/5/2021	TX	63	F	2/10/2021	2/23/2021	I WOKE UP ON 2/23/2021 TWO WEEKS AFTER MY 2ND COVID SHOT WITH DIZZINESS, NAUSEA AND LOSS OF HEARING IN MY RIGHT EAR.
1076130	3/5/2021	KS	63	F	2/12/2021	2/15/2021	Started having loss of hearing in my L ear, made appt with ENT doctor who gave me a steroid injection in ear as well as prescribing steroids to take by mouth. After 2 weeks my hearing is much worse and ENT doctor is certain this is due to Covid #2 shot.
1071612	3/4/2021	MN	51	F	12/23/2020	12/28/2020	Ringing in the ear. Hearing loss. Prescribed prednisone Take 40 mg day 1-2, 30 mg on day 3-4, 20 mg on day 5-6, 10 mg on day 7-8, 5 mg on day 9-10. Prescribed on 1/20/2021. Then on 3/3/2021 prescribed prednisone 20 mg tablets TAKE 1 TABLET 3 TIMES A DAY FOR 7 DAYS, THEN 1 TABLET 2 TIMES A DAY FOR 4 DAYS, THEN 1 TABLET D FOR 4 DAYS, THEN 1/2 TABLET D FOR 4 DAYS. Currently still has hearing loss and ringing in the ear.
1074127	3/4/2021	CO	40	F	2/3/2021	2/5/2021	After 1st dose, had some hearing loss due to fullness in ears, took 2 weeks for symptoms to subside. Since 1st dose, have had 4 HSV1 cold sores come about. After 2nd dose experiencing severe heartburn. Also continue to have HSV1 cold sore outbreaks.
1073335	3/4/2021	MA	92	M	2/4/2021	2/10/2021	Sudden Loss of Hearing from Left Ear

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1072791	3/4/2021	CA	49	M	2/24/2021	2/27/2021	Given second shot on Wed 2/24 at 12pm -- Had flu like symptoms for one day. Woke up on Sat 2/27 with sudden hearing loss in left ear. Hearing loss was accompanied by a loud static sound and pressure. Saw ENT specialist on Tue 3/2 -- no evidence of any wax buildup. She immediately sent me for hearing test; showed 70% loss. Both doctors feel this is a Viral infection and that it may have occurred due to my strong immune response I had to the COVID vaccine. Was prescribed 60mg of Prednisone for two weeks; am on day 3 as of writing this. Am going to see another specialist tomorrow, 3/5/21. I am a healthy 50yr old male with no previous hearing problems. The only change in my life was getting the vaccine. I think this important to report, although I have yet to find any link between vaccine and SSHL. I have been tested over the last year a few times (mouth swab) and all test were negative. I have not been tested since my hearing loss, though I don't feel sick at all. I have read that some people who actually had COVID experienced new or increased tinnitus but did not find anyone who had actual hearing loss -- this was just doing some online reading; not actual study reports.
1072748	3/4/2021	ME	75	M	2/5/2021	3/2/2021	Pt states he received his vaccine and a few days later was diagnosed with COVID. Pt was asymptomatic at time of vaccine. Pt quarantined for 10 days and continues to feel poorly, Head and sinus congestion, "my head feels like a brick", fatigue, head ache and worsening hearing loss

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1072540	3/4/2021	MA	78	F	2/14/2021	2/15/2021	100% deaf, she couldn't hear a thing/ by 11 or 12 that same day, her hearing started to come back; This is a spontaneous report from a contactable consumer. This consumer reported for self that the 78-year-old female patient received first dose of bnt162b2 (BNT162B2, Pfizer-Biontech Covid-19 Vaccine, Lot#: EL9266) via an unspecified route of administration on 14Feb2021 via injection into left arm at single dose for covid-19 immunization (COVID Protection for herself and so that she won't give COVID to anyone else). Medical history was none. There were no concomitant medications. The patient experienced 100% deaf, she couldn't hear a thing (medically significant) on 15Feb2021 with outcome of recovered. The patient underwent lab tests and procedures which included blood pressure measurement: good the consumer did not have a stroke , body height: 5'3- 5'4 states that she has been shrinking , body temperature: good the caller did not have a stroke, blood test: blood work done in the fall but it was all fine. The consumer says, "I no problems with it. I came home, went to bed, I guess sometime during the night it happened. I got up at 6am- 100% deaf!" The consumer says she was unable to couldn't hear gas stove turn on, couldn't hear the fridge shut, couldn't hear the microwave go off, couldn't head the phone ring. The consumer went to walk in-clinic. Hearing started coming back while being seen by the PA. The consumer was given "5 prednisone pills to take if hearing doesn't come back, and was told to have them on hand in case you get the 2nd shot and it comes back". The consumer says, "I can hear perfect now". "It was a matters of hours". The consumer "searched it" and read that this is very rare side effect, but temporary. The consumer asking if she should I get the 2nd shot in 2 weeks, because she heard the side effects with 2nd shot, could be worse. Caller asks, "If I get the 2nd dose, will the hearing loss be temporary again or will it be permanent?" The consumer states that last Sunday, she had her first dose of the COVID vaccine. The consumer states that she had no aches, no pains, no anything. The consumer states that sometime in the night, she got up, and was 100% deaf, she couldn't hear a thing, not one thing. The consumer states that in the morning she was standing in the kitchen and saw her phone blinking and she couldn't hear it ring. The consumer tested her hearing by putting half a cup of

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water in the microwave for 30 seconds, and she didn't hear the beep when it was done, she heard nothing, it was zero hearing at all. The consumer couldn't call anyone cause she knew she would not be able to hear them, and it was 6AM. The consumer states that she waited until she knew her daughter would be up, and the consumer texted her daughter and explained what happened, and the consumer's daughter tried to call, the caller's primary care doctor, but they put the consumer's daughter on hold and then hung up on her. The consumer states that her daughter texted someone at Pfizer, and they did not answer, so by that time it was 1030 or 11AM, and the caller drove herself to the walk in clinic. The consumer states that slowly but surely, her hearing came back. The consumer has some questions including, should she get the second dose of the product? Caller also states that she heard on TV that the second dose has stronger side effects than the first, and so she is wondering if that is true, and if she can expect this side effect to come back again with the second dose? Height: The consumer is 5'3- 5'4, and states that she has been shrinking. The consumer states that she read some of the side effects include, nausea and fatigue, she did not have any of those, and her arm was not even sore. But, caller states that this even scared her. The consumer states that by 11 or 12 that same day, her hearing started to come back. The consumer had driven to the walk in clinic, and at first could not hear what the staff said, but it started to come back while she was there, and she did not see a doctor, she saw a PA who gave the caller a prescription for 5 pills of Prednisone, and told the caller to not take them unless the deafness comes back, or gets worse. The consumer has not taken them because her hearing did come back. The consumer wants to say that she has recovered completely, but she does not know if it will come back with the second dose of the product, so she is unsure. The consumer states that she has not seen her grandkids in a year and a half, because they were afraid to come visit her because they did not want to give her COVID. The consumer confirms that she received no other vaccines on the same day. The consumer states that she did have a flu shot in the fall, but that is all. The consumer also had blood work done in the fall but it was all fine. The consumer states that when she went to the

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walk in clinic, the staff took her blood pressure and temperature and asked her to squeeze the PA's hands and stuff, and the PA said, good the consumer did not have a stroke.

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1072537	3/4/2021	NJ	71	M	2/10/2021	2/1/2021	noticed diminished hearing in the right ear/couldn't hear a tick at all; he felt fullness in his right ear; sore left arm where he got injection; This is a spontaneous report from a contactable physician (patient). A 71-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EM9809, expiry date: unknown), via an unspecified route of administration on 10Feb2021 12:30 (at 71-year-old) at single dose (left arm) for COVID-19 immunization. Medical history included hypertension (mild hypertension and it is well controlled, it was diagnosed 5-6 years ago), hyperlipidemia (mild hyperlipidemia and it is well controlled, it was diagnosed 5-10 years ago). He stated in Aug, he tested positive for antibodies through Lab and was still positive a month later. He wondered how that might effect the decision of if he should get the second dose, if he is potentially immune. He had no symptoms but tested negative with PCR test. His girlfriend who he lives with tested negative for antibodies. Height was reported as 6 feet to 6 feet one inch tall. Weight was reported as 176-178lbs, he thought he may have gained a few pounds. There were no concomitant medications. The caller had the first dose of the vaccine 10Feb2021 12:30. 5 days later he felt fullness in his right ear (Feb2021) and noticed diminished hearing in the right ear (Feb2021), maybe 20-30% less. He was comparing how much he could hear the ticking of his watch in his left and right ear and couldn't hear a tick at all. He went to an ENT and they found that it was reduced in the right ear secondary to a nerve problem and wasn't secondary to anything else. The doctor read online on an ENT site, a couple of people had acute bouts of decreased hearing. They were treated with steroids and resolved. His provider prescribed him with a high dose of steroids, 70 mg. He was going to take it after dinner but all of the sudden he could hear the ticking better. He held off on taking the steroid and the next morning his hearing was fine. He went back and they retested and it was back to normal. He had taken Naprosyn and is not sure if that played a part in improving things. It resolved not even 24 hours after the initial symptoms. It resolved on its own. He asked, is this a side effect that has been reported? Are there any cases of this happening in one ear rather than 2? Could it be a contraindication getting the second dose? His doctor is researching it and he is supposed to



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call early next week about this. He asked how many people were in the clinical trials that the side effect data is based on. The caller stated he heard someone report that he doesn't believe that people getting the vaccine necessarily need both doses of the vaccine. They are finding after a week after the first dose they have relative immunity and might not need the second dose. The caller asked how effective this vaccine might be on new variants, how effective just one dose of the vaccine is, if Pfizer is looking into mixing the vaccines- whether it will be something that can be interchanged with other Covid-19 vaccines, asked where he could find updates on medical information about this in the future. The caller stated he wanted to thank Pfizer for developing the vaccine as quickly as they did. Retired psychiatrist calling about Pfizer COVID-19 vaccine who says he got his first dose on 10Feb in (State name), and had a sore left arm where he got the injection (Feb2021) then 5 days later had fullness in his right ear with his hearing diminished. He says he called his otolaryngologist because he had had a hearing test a few months ago, and was tested again now and there was a moderate decrease of hearing in his right ear. He says he would like to know if this could be a possible side effect, since he has read of reports and his otolaryngologist knew of two reports where people did report hearing loss. He says that he was treated acutely with steroids at high dose of 70mg for which he filled the script, then called his internist who was ambivalent with him taking a high dose. Caller says then within a few hours, his hearing was better, and by the next morning it was normal, and he went back to the ENT and his hearing was the same as it was a few months ago. He says he did not take the steroid he was prescribed, the Prednisone, he took Naproxen, and since it may have been a nerve problem with hearing diminished related to auditory nerve, it seemed to get better in a number of hours. He says he has reported this already to VAERS. Caller says his right ear is better now, it got better within a few hours after he saw his doctor, then it was completely better by the next morning. He says that after they tested his hearing due to the fullness in his ear and hearing being diminished it got better on its own. He says on the next hearing test his hearing was exactly back to normal. He says he did take Naproxen once or twice during that time period, 20 or less hour

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period, more like 12 hours, one 220mg tablet each time, he doesn't know whether that contributed to helping. Naproxen (EXP Jan2022, LOT: ODRO445). He says that the reason he is calling is to see whether Pfizer has had similar reports. He says that he saw on a website that 12 people were reporting deafness or blindness, but it seemed to be an (name), so he took it with a grain of salt. He says he would like to know whether people have been reporting with issues for hearing, unilaterally or bilaterally, or what results have been with some people. Caller says unfortunately the website he mentioned was obviously anti vaccine and claimed to be with the (name) or version of the CDC and said that they were reporting they had 12 people reporting deafness and blindness from COVID vaccine and made it sound like the most dangerous vaccine in the world, but it was a conspiracy website that claimed it was with the equivalent of CDC. Caller does not have website addresses to provide or details about reports on that site. Caller says he looked at the (name) and it said nothing about this kind of possible side effect. He says he doesn't know if his could be related to getting the vaccine, or if he should still get a second dose of the vaccine. The outcome of the event "noticed diminished hearing in the right ear/couldn't hear a tick at all" and "he felt fullness in his right ear" was recovered in Feb2021, while for other event was unknown.; Sender's Comments: Based on available information the reported unilateral deafness was unlikely related to bnt162b2. This was an intercurrent medical condition. Case will be reassessed if additional information is received. 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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1072150	3/4/2021	SC	54	F	1/12/2021	1/19/2021	Received vaccine on the specified date, had a mild reaction of rash/hives around the left arm injection site and on abdomen. Clinic gave me antihistamines for the day and it cleared up within 24 hours. The specific issue at hand is about 3-4 days after the injection I begin having some hearing loss in my left ear. As of this date it has not improved.

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1071568	3/4/2021	GA	84	M	1/28/2021	2/1/2021	<p>loss of hearing/hearing completely gone in right ear; Ringing in left ear; probably vertigo; Extreme dizziness; blood pressure was 214/113; vomitng; Weakness; nasal drip; dry scaly rash on his temples, neck, shoulders, belt line, and back of his right knee; diminished hearing in left ear/sounds like listening through a drum; pressure in temples like a hammer on each side of head; headache in back of head; A spontaneous report was received from a consumer who was also an 84-year-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced extreme dizziness, nausea ,vomiting, nasal drip, weakness, loss of hearing/hearing completely gone in right ear (deafness unilateral), diminished hearing in left ear/sounds like listening through a drum (hypoacusis), blood pressure was 214/113 (blood pressure increased), pressure in temples like a hammer on each side of head (head pressure), headache in back of head, and dry scaly rash on his temples, neck, shoulders, belt line, and back of his right knee. The patient's medical history was not provided. Concomitant product use was not provided. On 28 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: 020L20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. The patient reported he felt fine for about one week after the vaccination. Then, in the early morning of 05 Feb 2021, right after midnight, he experienced extreme dizziness, vomiting, weakness, nasal drip, and loss of hearing including ringing in his left ear and no sound in his right ear. He also started to notice a dry scaly rash on his temples, neck, shoulders, belt line, and back of his right knee. The patient was taken by ambulance to the hospital. In the ambulance, he vomited and his blood pressure was 214/113. He was placed the COVID-19 wing of the emergency room (ER) and given tests including a COVID-19 test, sonogram, "echogram", MRI, and EKG (results not provided). The patient reported he was admitted to the hospital. He was told he probably had vertigo. After his ER visit, the patient had appointments with his general practitioner, an ear nose and throat specialist, and a hearing specialist. He was told his hearing was completely gone in his right ear and diminished in his left ear. The patient could still somewhat hear out of his left ear but it sounds like listening through a drum. He states</p>

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he has to have his television up very loud to be able to hear it. At the time of this report, the patient continued to feel extremely weak, dizzy, and he had pressure in temples like a hammer on each side of his head, a headache in back of his head, and the hearing changes. Treatment for the events included unspecified medications in the ER. Action taken with mRNA-1273 in response to the events was not reported. The events of dizziness, weakness, loss of hearing/hearing completely gone in right ear, vertigo, weakness, diminished hearing in left ear/sounds like listening through a drum, pressure in temples like a hammer on each side of head, and headache in back of head were not resolved at the time of this report. The outcome of the events of blood pressure was 214/113, nausea, nasal drip, vomiting, and dry scaly rash on his temples, neck, shoulders, belt line, and back of his right knee was unknown.; Reporter's Comments: This case concerns an 84 year old, male patient, who experienced a serious unexpected event of Deafness (unilateral) among others, 9 days after receiving 1st dose of mRNA- 1273 (Lot# 020L20A). Very limited information regarding this event has been provided at this time. Further information has been requested.

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1071125	3/4/2021	IA		M			Complete hearing loss; A spontaneous report was received from a physician concerning a male patient of unknown age who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced complete hearing loss. The patient's medical history was not provided by reporter. Concomitant product use was not provided by the reporter. On an unknown date, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Batch number not provided) intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, the patient experienced complete hearing loss after receiving COVID-19 vaccine. Laboratory details were not provided. Treatment information was not reported. Action taken with mRNA-1273 in response to the events was unknown. The outcome of the event, complete hearing loss, was unknown.; Reporter's Comments: This case concerns a male patient, who experienced a serious unexpected event of Deafness, after receiving 1st dose of mRNA-1273 (Lot# unknown). Very limited information regarding this event has been provided at this time. Further information has been requested.

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1068250	3/3/2021		30	M	2/8/2021	2/13/2021	Fainting episode; Loss of hearing; Left collar-bone lymph node enlarged noticeable swelling to area and left lower neck near carotid artery/lymph nodes; Soreness in area; Cold sweats; Light-headedness; This is a spontaneous report from a contactable consumer, the patient. A 30-year-old male patient received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration in the left arm on 08Feb2021 at 07:00 (at the age of 30-years-old) as a single dose for COVID-19 immunization. The patient did not have any relevant medical history. The patient did not have any allergies to medications, food, or other products. 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 patient's concomitant medications were not reported. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient had no symptoms until 5 days post vaccination. On 13Feb2021 at 12:15, the patient experienced fainting episode, loss of hearing, left collar-bone lymph node enlarged (noticeable swelling to area and left lower neck near carotid artery/lymph nodes), soreness in area, cold sweats, and light-headedness. The events required a visit to the physician's office and emergency room (as reported). The clinical outcomes of the fainting episode, loss of hearing, left collar-bone lymph node enlarged, soreness in area, cold sweats, and light-headedness were unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

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1068291	3/3/2021	IL	69	F	1/29/2021	1/29/2021	Complete left sided deafness; This is a spontaneous report from a contactable physician. A 69-year-old female patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), intramuscular, on 29Jan2021, at single dose, for COVID-19 immunisation. Medical history included type 2 diabetes mellitus, hypertension and diverticulitis. Patient had no known allergies. Concomitant medications included several prescription medications. Patient did not receive other vaccine in four weeks. The patient experienced complete left sided deafness (disability, medically significant) on 29Jan2021 with outcome of not recovered. Therapeutic measures were taken as a result of the event and included treatment with steroids. The event required physician office visit. The reporting physician could not say that the vaccine definitely caused the event. But as the event happened shortly after the vaccine, the physician felt that it was reportable. The patient was not tested for COVID-19 after vaccination. The information on the lot/batch number has been requested.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the event deafness unilateral 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.
1069083	3/3/2021	WV	86	F	2/4/2021	2/17/2021	Left sided numbness, tingling of face, arm and leg. Loss of hearing in left ear. Called 911. Air rescue to Hospital. Workup labs, CT, MRI and carotid ultrasound. Symptoms resolved 5 hours.
1066267	3/2/2021	CA	73	M	1/30/2021	2/4/2021	Awoke 02/04/2021 with sudden hearing loss of left ear. He had "static" type noise and pressure in left ear. Static noise resolved after a few hours but left with hearing loss.



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1066557	3/2/2021	NJ	56	M	2/24/2021	2/26/2021	nerve related hearing loss that came on 24 hours after injection and progressed to total hearing loss in one ear after 72 hours
1067044	3/2/2021	SD	74	M	2/26/2021	2/26/2021	By 6:00pm I had severe tinnitus in both ears. Noticed hearing loss next morning which has continued to date: 03/02/2021. Tinnitus also continues but not as severe.
1062004	3/1/2021	WI	78	F	1/25/2021	1/27/2021	she has a hearing problem; Constant chills; Cramps; Diarrhea; Nausea; This is a spontaneous report from a contactable consumer (patient). A 78-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot number: EL3248) via an unspecified route of administration on 25Jan2021 10:30 on the left arm at a single dose for COVID-19 immunization. The patient had no medical history. There were no concomitant medications. The patient stated that she did not experience any problems until 27Jan2021 around noon, in which she started experiencing chills, cramps, and diarrhea all afternoon. She would like to know if these reactions have been reported and if they continue to persist, can she take something like Imodium. She didn't have any effect at all from it on Monday or Tuesday, and at noon on 27Jan2021, she had nausea and constant chills and diarrhea, she doesn't think this was a side effect, but wanted to check and see. She was not terribly ill, just uncomfortable, is this something she should be reporting? Stated she has a hearing problem, wished for DSU agent to speak slower. Nausea: was off and on all the time since noon today, it is better, the main thing is diarrhea, and the nausea is connected Constant chills: improving, it came and went all afternoon, she doesn't know if it has gone away, she thinks it is still here, but she is not constantly bothered, it has been periodically since noon today. Diarrhea: better since she has nothing left; nothing was getting worse, she was reporting it because she thought it may be a side effect. Outcome of the events constant chills and nausea was recovering, diarrhea was recovered on an unspecified date while unknown for the other events.

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1062193	3/1/2021			U			Mild soreness at injection site; Myalgia; Tinnitus; This is a spontaneous report from a contactable physician (patient). A patient of unspecified age and gender received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date (also reported as day 30 following dose 1) at a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously took first dose of bnt162b2 on 29Dec2020 (at the age of 79 years old) at a single dose in the left arm for covid-19 immunization and experienced neurosensory deafness in Rt ear./ total hearing loss in right ear; arm soreness; headache; myalgia; tiredness/episodic fatigue; mild cold intolerance; frontal headache (sinus like); stuffiness/Nasal congestion; postnasal drip and tinnitus in Right Ear. On unspecified date, the patient experienced mild soreness at injection site, myalgia 3/10 on day 1 and tinnitus (bilaterally, left more than right) on day 3 which was persisting but no hearing loss. The patient is scheduled to have an appointment with ENT on 18Feb2021 and will also have antibodies checked. Outcome of the event tinnitus was not recovered while outcome of all the other events was unknown. No follow-up attempts are possible. Information about batch/lot number cannot be obtained.
1062224	3/1/2021			F		1/25/2021	loss of hearing; ear pains; This is a spontaneous report from a contactable consumer, the patient. This female patient of unknown age (reported as (age: 80 unit: unspecified) received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: unknown), dose 1, single dose via an unspecified route of administration on 25Jan2021 for COVID-19 vaccination. Medical history was not reported. Concomitant medications were not reported. On an unknown date in 2021, the patient had ear pain and loss of hearing. The events were reported as non-serious. The clinical outcome of ear pain and loss of hearing was unknown. The reporter was unsure if the events were related. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

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1062491	3/1/2021	OH	69	F	2/1/2021	2/1/2021	11 days after shot, I woke up in the middle of the night and my hearing was gone in left ear. Tested last Tuesday and compared to previous tests showed catastrophic hearing loss. Prescribed Prednisone. After 6 days, notice slight improvement in hearing but still not right.
1061415	2/28/2021	NY	48	M	1/20/2021	1/22/2021	Dose Given 1/20/21, sore arm after 1/20/21. Migraine headache developed evening 1/21 Intermittent tinnitus developed 1/21/21. Woke up with subjective hearing loss/fullness Left ear and mild vertigo with nystagmus on morning of 1/23/21.
1060214	2/27/2021	WA	75	F	2/27/2021	2/27/2021	Some loss of hearing and bad pressure in ears and jaw.
1056667	2/26/2021	FL	78	F	1/20/2021	2/1/2021	hearing totally gone/complete hearing loss in left ear; tinnitus in ears and feeling of pressure; tinnitus in ears and feeling of pressure; Didn't make a real issue out of it and thought it was just congestion; This is a spontaneous report from a contactable consumer. A 78-year-old female consumer received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 20Jan2021 in left arm at 11:15 at single dose for COVID-19 immunisation at the age of 78-year-old. Lot number was E18982. Medical history and concomitant medications were unknown. Historical vaccination included flu in Jan2021 for immunization. On 08Feb2021, the patient woke up with complete hearing loss in left ear, hearing totally gone, tinnitus in ears and feeling of pressure. In Feb2021, the patient did not make a real issue out of it and thought it was just congestion. On 08Feb2021, the patient saw ENT. On 08Feb2021, the patient performed a hearing test: complete hearing loss. On unknown date, blood work was performed, and the results were unknown. The patient did not recover from woke up with complete hearing loss in left ear/ hearing totally gone, tinnitus in ears and feeling of pressure, the outcome of nasal congestion was unknown.

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1056185	2/26/2021	FL	65	F	2/3/2021	2/4/2021	Next day lost hearing in left ear and getting worse; Feels pressure and ringing in her ear.; Feels pressure and ringing in her ear./ ringing was worsening; Next day lost hearing in left ear and getting worse; This is a spontaneous report from a contactable consumer (patient). A 65-year-old female patient received the 2nd dose of bnt162b2 (BNT162B2, Batch/lot # EL3246) at single dose at right arm on 03Feb2021 16:30 for covid-19 immunisation, because of her age and she had asthma and to protect her elderly and sick parents. Medical history included ongoing ongoing asthma all of her life, ongoing tinnitus 10 years approximately, allergies to everything, environmental allergies, medication, food allergies, contact allergies, ongoing fibromyalgia a decade, ongoing gastrooesophageal reflux disease (GERD) 10-15 years. Family history: father had bladder cancer and going through bowel resection surgery, mother was immunocompromised with polymyalgia rheumatica. Concomitant medication included gabapentin (GABAPENTIN) 200 mg, 1x/day at bedtime) for Fibromyalgia, famotidine (PEPCID) OTC dose in morning and night FOR GERD. After vaccination, towards 04Feb2021 evening, she started losing hearing in her left ear. That was late afternoon. It started with some pressure, and some loss of hearing. By 05Feb2021 it got worse. So she gave herself Sudafed because she was thinking it was normal allergies. By 06Feb2021, it wasn't better. The Sudafed did not seem to help. She went to the Urgent care on 06Feb2021, who told her to go to ENT. She has an ENT appointment on 09Feb2021. The Urgent care prescribed her a short dose of prednisone by mouth 10mg twice a day. She has looked, and not find loss of hearing as a side effect. She hasn't called the doctor yet. The hearing loss has persisted or worsened. It is not constant all day long, but it is there all day long. As of on 09Feb2021, it was pretty bad. On 04Feb2021 she was also experiencing ear ringing. It was a high pitched ring in the same ear. She had tinnitus in both ears, but it was usually low. This one since the pressure started building in her ear, the ringing was louder and bigger. The ringing was worsening. The outcome of events was not recovered.

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1058799	2/26/2021	MT	46	F	1/27/2021	2/17/2021	Sudden unilateral hearing loss on the left ear. Currently taking a 14 day dose of oral predisone, had one transtympanic injection of steroids, have had 2 audiograms. Plan to start hyperbaric oxygen treatments and have more injections and audiograms. No improvement to date.

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1056641	2/26/2021	OH	93	M	1/22/2021	1/25/2021	cranial nerve 3 palsy. Ptosis of the left eye, it was completely shut; cannot hear; This is a spontaneous report from a contactable physician. A 93-years-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Jan2021 at a single dose for COVID-19 immunization. Medical history included atrial fibrillation, hypertension, hyperlipidaemia, diabetes, and chronic kidney disease. Concomitant medications were not reported. No additional vaccines administered on the same date of the vaccine and no prior vaccinations within 4 weeks. The reporter is the family's physician, who stated that the patient received the first dose of the Pfizer COVID vaccine on 22Jan2021 and three days later (25Jan2021), his left eye had ptosis - he was unable to open his left eye and it was completely shut. The patient came to him and when he would try to lift the eyelid up, it would just drop down. He then called a neuro ophthalmologist, he thought to himself that the patient could be having a stroke. The patient was sent to the Emergency Room and kept overnight to do CT of brain, MRI of brain, CT of orbits and MRI of neck. All tests came back normal, there was no stroke. The patient was discharged and was told to go see an ophthalmologist; the eye doctor diagnosed him with Cranial Nerve 3 Palsy. The reporter had read the consultation notes; the eye doctor "wrote 1-2 days after he had COVID and had this happen". The reporter clarified that the patient never had COVID, maybe this was a misunderstanding or typo with the doctor, but the patient just had the vaccine. The point is that the patient was diagnosed. The reporter further added that the patient can't hear, and so he will provide the patient's son's phone number. The reporter would like to know if this is a possible side effect of the vaccine and if he should receive the second dose of the vaccine as he is due in two days (Friday at 8:30AM on 12Feb2021). It was also reported that the ptosis has not gotten worse and has not resolved. The reporter added that the patient was admitted to the hospital for a full day. The patient underwent lab tests and procedures which included computerized tomography (CT) of the brain, CT of the neck, magnetic resonance imaging (MRI) of the brain and MRI of the orbits-all of which resulted normal in Feb2021. The events cranial nerve 3 palsy and 'Ptosis of the left eye, it was completely shut' had not resolved

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							while the outcome of the rest of the events was unknown. Information on the batch/lot number has been requested.; Sender's Comments: By close temporal relationship, the company cannot completely exclude that the reported cranial nerve 3 palsy' is related to BNT162b2 administration, even though medical history including atrial fibrillation, hypertension, hyperlipidemia, diabetes, and chronic kidney disease, in the setting of elderly age, can be considered confounding factors in the overall clinical evaluation of this event occurred three days after the vaccination. Conversely, even though cannot be excluded as reportable event based on the information provided, the company deems there is not a reasonable possibility that the reported deafness is related to BNT162b2 administration, but, at the present time, evaluated as an intercurrent condition that cannot be also excluded as already present before the vaccination. The impacts 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.
1057052	2/26/2021	AL	49	M	2/17/2021	2/20/2021	Sudden complete hearing loss in left ear. Severe leg cramping (both right and left thighs).
1057071	2/26/2021	IA	69	F	2/6/2021	2/11/2021	On the morning of 2/11/2021, I woke up with SUDDEN HEARING LOSS IN MY RIGHT EAR, was dizzy, had balance issues, and was nauseous. I went to the ER. I had a CT in the ER which also was negative for stroke. My hearing loss has NOT returned, and I still have some balance issues as well for which I am receiving PT.
1058454	2/26/2021	CA	78	M	1/27/2021	1/30/2021	3 days after the first Pfizer COVID vaccination, the patient had nausea, vomiting, dizziness, hearing loss and loss of equilibrium. These symptoms slowly resolved, but recurred 3 days after the second dose of the Pfizer COVID vaccine.

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1056511	2/26/2021	NC	62	F	2/3/2021		lost hearing in right ear; ringing in the ear; A spontaneous report was received from a 62-year-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced ringing in the ear and loss of hearing in the right. The patient's medical history was not provided. Products known to have been used by the patient were not included. On 03 Feb 2021, prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly for prophylaxis of COVID-19 infection. On an unspecified date, the patient experienced ringing in the ear and lost hearing in the right ear. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events, ringing in the ear and lost hearing in the right ear was not reported.; Reporter's Comments: Very limited information regarding this events has been provided at this time. Further information has been requested.
1055194	2/25/2021	OH	68	F	2/17/2021	2/20/2021	Profound hearing loss in left ear



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1053592	2/25/2021	NY	34	F	1/27/2021	1/28/2021	Fever; headache; body aches; This is a spontaneous report from a contactable other healthcare professional (patient). A 34-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot number: EL8983) intramuscular on the left arm on 27Jan2021 08:30 at a single dose for Covid-19 immunization. Medical history included allergies, sinus (disorder), hearing loss and allergies: shellfish and sulfa. The patient previously received first dose of BNT162B2 on 04Jan2021 for COVID-19 immunization (first dose, 04:00 PM Intramuscular on the left arm lot number: EL 0142). Concomitant medication included nigella sativa (black seed oil), turmeric [curcuma longa rhizome] and multivitamins. On 28Jan2021 05:00 AM, the patient experienced fever, headache and body aches. Events were reported as non-serious: did not result in death, was not life-threatening, did not cause/prolonged hospitalization, was not disabling/incapacitating and did not cause congenital anomaly/birth defect. Patient was not pregnant. The facility where the vaccine was administered was in a hospital. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Since the vaccination, the patient has not been tested for COVID-19. Prior to vaccination, the patient was not diagnosed with COVID-19. Outcome of the events was unknown.
1053715	2/25/2021	NJ	35	F	1/14/2021	2/21/2021	Developed Bell's Palsy - started on 2/21/21 w/ ear pain and stiff neck, progressed to numbness and tingling in face and lips on 2/22/21, then hearing loss and left sided facial paralysis. Went to ED, r/o stroke, neck/facial trauma. Given course of prednisone and acyclovir. No improvement noted to date.
1053898	2/25/2021	CA	83	F	2/12/2021	2/13/2021	We did not immediately recognize a connection between hearing loss and vaccine. next day??? we noticed drastic drop in her hearing..I had to speak loudly, almost shouting.. Local ear doctors were not taking new patients so we did nothing.. wait and see! we are 99% sure vaccine was cause of hearing loss...hope it is not long lasting...we approach our second shots on 03/05/2021 with some trepidation. (there has been no change in her hearing to date..

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1054024	2/25/2021	MD	64	F	1/11/2021	1/11/2021	Patient suffered sudden sensorineural hearing loss in right ear within hours of vaccination. On audiometry, right ear pure tone average declined from baseline of 31 dB to 64 dB, word recognition score from 88% to 44%. No vertigo.
1055029	2/25/2021		70	F	2/19/2021	2/20/2021	Right sided ear pain and hearing loss, and ptosis of right eye that started 1 day after vaccine administered. Hearing loss has improved after 3 days, yet still diminished.
1054066	2/25/2021	MD	66	F	1/21/2021	2/21/2021	Sudden sensorineural hearing loss in right ear with pure tone average of 72 dB and word recognition score of 24%, from baseline of normal hearing. No vertigo.
1052467	2/24/2021	KS	41	F	2/10/2021	2/10/2021	Onset of ringing to R ear 30min post vaccination. Developing into tinnitus R ear, dizziness with motion over next 24 hrs. Significant hearing deficient on 2/12 on R ear. PCP seen on 2/15, identified normal auditory exam, high dose predisone started. ENT/Audiologist scheduled 2/16 - diagnosed neuro hearing loss to R ear, not related to covid virus or etiology with normal eardrum mechanics, recommended continue steroid taper x3 weeks. Next audiology appt 3/9 for re-eval. Unknown disability or permanent damage at this time.

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1051002	2/24/2021	IL	86	M	2/3/2021	2/4/2021	<p>hard on hearing/lost his hearing; pain in his right ear; Chills; headache; Fever; Weakness; lacking appetite; This is a spontaneous report from a contactable consumer (patient's wife). An 86-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EM9810, expiration date was not reported) (at 86 years of age), via an unspecified route of administration in the left arm on 03Feb2021 15:00 at a single dose for COVID-19 immunization. Medical history included ongoing chronic lymphocytic leukaemia, ongoing blood pressure abnormal and ongoing thyroid disorder. Concomitant medication included hydrochlorothiazide which he was taking for years, ibrutinib which he was taking for 7 years, levothyroxine which he was taking for 10 years and losartan which he was taking for 8 years. The patient had no any other vaccine prior to covid vaccine. It was reported that the patient received the Pfizer covid vaccine on 03Feb2021. 24 hours later (04Feb2021), he experienced pain in the ears, headache, chills, and fever up to 101.5 for almost a week now, and currently is hard on hearing and had been feeling weak and lacking appetite. It was added that a week ago he received the first dose of the Pfizer COVID 19 vaccine on 03Feb2021 at 1500PM in the left arm. Within 24 hours the side effects started. He had a pain in his right ear and a headache. Since then he has gradually lost his hearing in that ear and they are following up with an ear nose and throat doctor. On 04Feb2021, he got a fever of 101.5, chills, weakness and no appetite. Since then in the evening he had been having kind of a fever of 100 to 100.5 and she has treated with TYLENOL. The fever comes and goes. In the morning he was normal. Adds his appetite was better but he still has to force himself to eat. She queried if should the patient get the second dose of the vaccine. Patient is scheduled to receive the second dose on 04Mar2021. The patient did not visit the ER. The patient underwent lab tests and procedures which included body temperature: up to 101.5, fever of 100 to 100.5, and 101.5 on 04Feb2021. The outcome of the event loss of hearing, fever, weakness, and pain in his right ear was not recovered; headache and chills are recovered on 05Feb2021; while recovering for lacking appetite. The loss of hearing was reported as worsened. Therapeutic measures were taken as a result of fever</p>

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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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						<p>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.</p>
1053386	2/24/2021	CA	84	F	1/20/2021      2/12/2021	Hearing loss, auditory hallucinations
1052988	2/24/2021	CA	33	F	2/10/2021      2/21/2021	Sudden sensorineural hearing loss in the left ear. 60 MG prednisone seems to have improved symptoms so far

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1051911	2/24/2021	PA	64	F	1/14/2021	2/7/2021	Moderna COVID-19 Vaccine: 02/07/2021 Total loss of hearing in right ear and diminished sense of taste. 02/10/2021 Hearing test and prednisone 60mg for 10 days. 02/19/2021: Hearing test Hearing did not improve, but further declined. Blood work, steroid injection into middle ear 02/26/2021: MRI, hearing test
1049509	2/23/2021	MN	64	F	2/18/2021	2/19/2021	(L) ear Hearing Loss: hearing loss occurred after both vaccinations. After Vaccination #1-1/28/2021: Hearing loss occurred on Friday 1/29/2021 about 0200-0300 then returned 100% by Saturday afternoon. Then after vaccination #2 - 2/19/2021: hearing loss occurred on Friday 0200-0300 as of 2/22/2021 hearing loss is approximately 90% returned.
1049341	2/23/2021	PA	64	F	1/27/2021	1/28/2021	Tinnitus-especially in Left ear. Previously had a very mild Tinnitus in both ears prior to vaccine. Woke up after 2nd vaccine with extreme tinnitus in left ear. Extreme ringing and muffled hearing in left ear. Right ear remains mild tinnitus. Went to ENT physician and saw NP and had hearing test performed. Mild hearing loss noted but no previous ear testing performed to compare results to. No other interventions available at this time.

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1048209	2/23/2021	IN	89	M	2/1/2021	2/6/2021	Bleeding from right kidney; Bleeding from right kidney; Left kidney is shrunken and function at about 10%; Left kidney is shrunken and function at about 10%; This is a spontaneous report from a contactable consumer (patient). An 89-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EL8982), via an unspecified route of administration on an unspecified date in Feb2021 (19:00) at single dose (at the age of 89-year-old on Left arm) for COVID-19 immunization. Medical history included arthritic knees and shoulder, prostate cancer, macro degeneration, hearing loss, congestive heart failure, Last right kidney bleed one a year ago (2020 to 2020). The patient's concomitant medications were not reported. Facility where the most recent COVID-19 vaccine was administered: Hospital. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Patient had no known allergies to medications, food, or other products. Patient had Bleeding from right kidney into nephoscimy bag. No noticeable bold from bladder. Left kidney is shrunken and function at about 10%. All events from 06Feb2021 04:00. No treatment was received in response to the events. The outcome of the events was recovering.
1050195	2/23/2021	FL	43	F	1/9/2021	2/13/2021	Acute sensorineural hearing loss right ear
1050287	2/23/2021	WA	81	F	1/21/2021	1/23/2021	Partial deafness, right ear, noted two days after the vaccine was administered. A ten-day course of Prednisone begun, and hearing PARTIALLY returned two days later. Unknown if the inflammatory reaction expected of the Moderna vaccine caused the deafness. Also unknown if the the dosage of Prednisone reduced the effectiveness of the vaccine. (My history of Meniere's disease does cloud the issue, but I decided to report the inflammatory response to the vaccine as likely relevant.)



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1050328	2/23/2021	CA	65	M	2/1/2021	2/2/2021	Vaccine - Moderna COVID-19 EUA, dose 1. Patient received the first dose on 2/1 around 6PM PST in his left arm. By 2/2, the patient experienced arm soreness, and by 9PM, he felt pain in his right ear. On the morning of 2/3, the patient woke up with hearing loss in his right ear, slight dizziness and nausea, but was able to work and eat with normal appetite. On 2/4, the patient woke up with general malaise, dizziness, lightheaded feeling, GI discomfort (minor diarrhea and vomiting), sweating, and chills. The patient still experienced hearing loss. The patient was fatigued, and had no appetite; stayed hydrated and slept most of the day. The patient gradually became less fatigued and gained appetite from 2/5-2/8. On 2/8, the patient visited urgent care for his ear. The NP on site observed yellow fluid in the patient's right ear and prescribed amoxicillin and flonase generic. The patient took the amoxicillin for 10 days and flonase generic for 14 days. On 2/22 (D21 post vaccine), the patient saw his PCP, still reported hearing loss, but the doctor did not report any findings. The patient received a referral for the ear specialist. To date, 2/23, the patient has hearing loss in his right ear.
1049726	2/23/2021	VA	32	F	2/13/2021	2/13/2021	Sudden ringing in the ear- hearing loss

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1045551	2/22/2021	DE	65	F	1/14/2021	1/14/2021	severe headache; blurriness; liquid behind her cornea; 2 leaks in the eye; extended artery in left side of head; hearing loss in left ear; arm pain; A spontaneous report received from a Consumer concerning, 65-year-old female patient who has received both doses of the Moderna COVID-19 vaccine and experiencing arm pain, sever headache, blurriness, liquid behind her cornea, 2 leaks in the eye, extended artery in left side of head and hearing loss in her left ear/MedDRA PT: [Sever Headache]. The patient's medical history was not included/ unknown. Patient's concomitant was not included/ unknown. On 10-FEB-2021, the patient received their second of two planned doses of mRNA-1273 (Batch #: 013L20A) intramuscularly for prophylaxis of COVID-19 infection. On 11-FEB-2021 Patient Husband reported, that his wife received the Moderna COVID-19 vaccine on 14JAN2021 in her left arm and on the same day experienced arm pain that lasted for 3 days. On 16JAN2021 the patient reported that she had a severe headache and shortly after experienced blurriness. The patient got medical attention and it was reported that she has liquid behind her cornea and 2 leaks in the eye, extended artery in left side of head and hearing loss in her left ear. Symptoms are ongoing and HCP consent was obtained. Patient was not hospitalized. Treatment information was not provided/ unknown. Action taken with mRNA-1273 in response to the event was not provided/unknown. The outcome of the event was unknown/not reported.; Reporter's Comments: Very limited information regarding this events has been provided at this time. Further information has been requested.

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1045620	2/22/2021			F	1/16/2021		She experienced a sudden deafness in her right ear in between receiving both her shots.; This is a spontaneous report from a consumer (patient). A 65-year-old female patient received first dose of bnt162b2 (BNT162B2 also reported as PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date not reported), via an unspecified route of administration on 16Jan2021 at SINGLE DOSE for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced a sudden deafness in her right ear in between receiving both her shots. Her second dose was on 06Feb2021. The outcome of event was unknown. Information about batch/lot number has been requested.
1047318	2/22/2021	TX	71	F	2/14/2021	2/15/2021	About 18 hours after 2nd COVID vaccine, patient developed sudden loss of hearing in the right ear, accompanied by tinnitus and vertigo and feeling of fullness in the right side of her head.
1046094	2/22/2021	CA	28	F	12/28/2020	1/5/2021	First dose 12/28/2020. On 01/05/21 patients states arm was throbbing at injection site, and that same night and next day her joints started hurting. On 01/06 she states her hands were swollen the size of sausages. She consulted a MD who is rulling out RA. Lab work ordered and a specialist consulted who thinks it is covid vaccine related. Patient also states numbness in both hands. Patient received 2nd dose on 01/25/21 with a remarkable reaction of fever of 102 for 3 days, sore throat, headache, dizziness, loss of appetite, loss of taste and loss of hearing in right ear. After further consultation, patient tested negative for COVID. Patient states she continues to wake up with sore hands and slight swelling.
1045898	2/22/2021	RI	81	F	2/14/2021	2/16/2021	Site: Pain at Injection Site-Mild, Systemic: loss of hearing in one ear-Medium
1044160	2/21/2021	OH	73	M	2/8/2021	2/10/2021	The 2nd day after the injection, I got severe tinnitus. I've had tinnitus before this for a couple years, but it was at a minimum very tolerable level until the covid shot. It's been 2 weeks and it's very difficult to sleep because of the unbearable increase in loudness in my tinnitus since the 2nd day of my shot. I got a hearing test this week (Friday Feb 19th) and my audiologist said I had NO loss of hearing from the shot.

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1042712	2/20/2021	CA	39	M	12/22/2020	1/2/2021	On January 1 and 2nd, approximately 10 days following administration of Moderna vaccination, I began to experience both hearing loss and tinnitus in my right ear. The hearing loss and ringing noise in my right ear came on rather slowly, and progressed over a week's time. There was no illness otherwise, and no trauma. The ringing continued, and I sought out medical care from both Neurology and Otolaryngology. My otolaryngologist could not find any cause and speculated that it could in fact be from the vaccination. I underwent oral steroid treatment as well as a series of 3, sequential weekly steroid injections into my middle ear space, though my tympanic membrane. I also started taking oral L-Lysine at the recommendation of my neurologist as well as other herbals including oral flavonoids to help reduce tinnitus. None of the above treatments have made any improvement in my symptoms. I had my hearing rechecked every week at ENT office and the same degree of hearing loss is evident. None of which has returned to date. I have most recently just last week begun to pursue hearing aid device at the recommendation of my ENT physician. I am currently scheduled for brain MRI to make sure there is not another physiologic cause such as a tumor or hemangioma on my nerve that would possibly explain my new symptoms in the right ear. That study is not completed yet. The hearing loss and tinnitus is constant, and unchanged, now nearly 7 weeks. The noise is significant and disturbs my sleep, and much of my daily function.
1040821	2/19/2021	NC	81	F	2/1/2021	2/2/2021	Sensorineural sudden hearing loss. Treated with Prednisone for 10 days. Hearing returned to normal. Physician will monitor in 3 months.

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1040674	2/19/2021	NY		M	1/29/2021		Completely lost hearing; Scratchy throat; A spontaneous report was received from a consumer (patient's wife), concerning an 80 years-old male patient, unknown race and ethnicity, who received Moderna's COVID-19 vaccine (mRNA-1273), and experienced completely lost hearing and scratchy throat". The patient's medical history included had partial hearing loss before the Moderna dose. Concomitant medications reported included were losartan, pantoprazole, unspecified prostate medication, cholesterol medication, heart disease, and arrhythmia medication. On 29 Jan 2021, prior to the onset of events, the patient received their first of two planned doses of mRNA-1273 (batch number: 012L20A), administered in the left arm for the prophylaxis of COVID-19 infection. On an unknown date, the patient experienced scratchy throat and completely lost hearing (had partial hearing loss before the Moderna dose) and was beginning to hear a bit. The patient did not take any medication to treat symptoms. The consumer was very much concerned because of hearing loss and asked if patient should receive the second dose of Moderna vaccine. Action taken with second dose of mRNA-1273 in response to the events was not reported. The outcome of the events completely lost hearing is resolving and scratchy throat were reported as unknown.; Reporter's Comments: Very limited information regarding the reported events has been provided at this time. onset duration is lacking for the events Further information has been requested.
1041167	2/19/2021	FL	77	M	2/13/2021	2/14/2021	I had the shot late afternoon on Saturday and woke up Sunday morning with a major ringing and I would guess 90% loss of hearing in my left ear, to day is Friday and I still am unable to hear anything in my left ear I saw my Docter on Monday and she indicated my ear was a little swollen and gave me a prescription for Methylprednisolone 4 MG and after two days on it I still am unable to hear anything in the left ear
1041375	2/19/2021	PA	58	F	2/12/2021	2/13/2021	Hearing loss, Tinnitus, Headache

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1040562	2/19/2021	PA	33	F	1/20/2021	1/21/2021	Sudden never hearing loss; This is a spontaneous report from a contactable other healthcare professional (patient). A 33-year-old female patient received the first dose of bnt162b2 (Pfizer-Biontech COVID-19 Vaccine, Lot number: EJ1685), via an unspecified route of administration at the left arm on 20Jan2021 10:00 at single dose for COVID-19 immunization. The vaccine was administered in the hospital. The patient medical history was not reported. The patient was not pregnant. There was no other vaccine in four weeks. Prior to vaccination the patient had no COVID. The patient has not tested for COVID post vaccination. Concomitant medication included fluoxetine hydrochloride (PROZAC) and hctz. On 21Jan2021, the patient experienced sudden never hearing loss. It was reported that the event resulted to doctor or other healthcare professional office/clinic visit and Disability or permanent damage. The patient received an oral steroid as treatment. The outcome of the event was not recovered.; Sender's Comments: Based on the compatible temporal association and in absence of strong confounding factors, a possible contributory role of the suspect BNT162B2 in triggering the onset of sudden never hearing loss cannot be excluded. Additional information regarding relevant medical history, etiologic and diagnostic work-up will aid in comprehensive assessment of the case. 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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1037872	2/18/2021			F			deafened her for ten minutes; This is a spontaneous report from a contactable consumer patient. A female patient of an unspecified age started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. Medical history and concomitant medication were not reported. The patient got the vaccine on an unspecified date and it deafened her for ten minutes. She was not sure if that was a side effect that she should be worried about. The patient recovered from the event on an unspecified date. Information on the lot/batch number has been requested.
1038586	2/18/2021	NJ	71	M	1/14/2021	2/16/2021	loss of hearing in left ear, under going treatment with steroid injections once week 3 times at present, with MRI w/wo contrast, blood tests. Treatment still in progress as of 02/ 18/2021
1037815	2/18/2021			F	1/28/2021	1/30/2021	She almost instantly completely lost hearing in her right ear / loss of hearing; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number and expiry date were not provided) solution for injection, 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. Patient reported she had the first shot of the vaccine on 28Jan2021, then on 30Jan2021 she reported that she almost instantly completely lost hearing in her right ear. She said it hasn't changed since. She already had a CT scan and MRI scan with her doctor, and she wanted to eliminate the vaccine shot as the cause of her loss of hearing. Outcome of the event was not recovered. Information on the lot/batch number has been requested.
1039170	2/18/2021	MN	51	M	2/2/2021	2/4/2021	SSHL in the left ear. 100% hearing loss in the left ear, very loud tinnitus, vertigo and loss of balance.

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1038864	2/18/2021	OH	67	M	2/5/2021	2/6/2021	Lost hearing in right ear the day after, 2/6/2021, my first Pfizer Covid vaccine. Saw Doctor on 2/11/2021 for ear examination and full hearing test, showing pretty much full loss of hearing in right ear. She prescribed 60mg oral steroid dosage with taper down. Followup examination with Dr Pate on 2/18/2021 which showed minor hearing improvement, she administered a steroid shot into my right ear.
1035814	2/17/2021	AR	49	F	1/6/2021	1/7/2021	About 3am the next morning I woke up to a loud ringing in both my ear. When I sat up I was very very dizzy. I got up and showered and my feet swelled very bad. I did not feel well but I went to work but the feelings never got better. So on 1/10 Sunday I went to the medical center because I jjust didnt not feel well. The swelling in the lower legs was still there so I was prescribed 20 mg of presnisone for 5 days. The sound changed during the time of the antibiotics but after I stopped taking the prednisone the ringing sound came back, my left foot is still numb and my eyes are constantly red and burning even after putting drops in my eyes, I still suffer from headaches and if I turn my head too far left or right I get dizzy still to date. On 1/14 I was given a 60 mg dose of tapered predinosone for 2 week to help elevate the symptoms but it did not work. On 2/12 I saw an ENT specialist who performed a hearing test which did produce minor hearing loss and was diagnosed with having Tinnitus.
1036568	2/17/2021	NJ	36	F	2/9/2021	2/9/2021	became unresponsive after receiving her first dose of Pfizer Vaccine . Smelling salts were applied and patient quickly became responsive. Patient was given 4 oz of apple juice which she tolerated well. Also complained of loss of hearing/smell and feeling flushed. Patient had no difficulty breathing and or rash. 911 was called and patient subsequently was sent to ER for further evaluation.



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1034995	2/17/2021	NJ	67	F	1/24/2021	1/27/2021	hearing loss/Cannot hear in right ear very well; This is a spontaneous report from a contactable consumer. A 67-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9262), via an unspecified route of administration in left arm on 24Jan2021 10:00 at a single dose for COVID-19 immunization. Medical history included ongoing blood pressure high. Concomitant medication included levamlodipine besilate for blood pressure high. On 27Jan2021, the patient experienced hearing loss in the right ear, she started to feel like she could not hear very well in her right ear. It was like she was underwater or something. Patient went to see the family doctor on 31Jan2021 because of her ear and the doctor looked in ear and did not see anything wrong. The doctor prescribed an allergy medication, something basic that could be picked up over the counter.

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1034986	2/17/2021	IL	71	M	1/19/2021	1/19/2021	<p>Ringing in left ear; Hearing loss in right ear; Ear ringing in right ear; Mild soreness at the site of injection; A spontaneous report was received from a consumer, a 71 year-old male patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced hearing loss in right ear/deafness unilateral, ear ringing in right ear/tinnitus, ringing in left ear/tinnitus, and mild soreness at the site of injection/injection site pain. The patient's medical history included a kidney transplant. Concomitant product use was not provided. On 19 Jan 2021, prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (Batch number: 029L20A) in the left arm for COVID-19 infection prophylaxis. The patient had some mild soreness at the site of the injection which lasted one to two days. On 21 Jan 2021, he experienced some ear ringing in his right ear which was followed by hearing loss that lasted six hours. Both the ear ringing and hearing loss resolved by the next morning. On 24 Jan 2021, the patient had ringing in his left ear, but it was not associated with hearing loss. The patient stated he thinks the tromethamine hydrochloride in the vaccine may have induced his hearing loss. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not provided. The events, hearing loss in right ear and ear ringing in right ear, were considered resolved on 22 Jan 2021. The event, mild soreness at the site of injection, was considered resolved on an unknown date Jan 2021. The outcome for the event, ringing in left ear, was unknown.; Reporter's Comments: This case concerns a 71- year old male patient who experienced hearing loss in right ear/deafness unilateral, ear ringing in right ear/tinnitus, ringing in left ear/tinnitus, and mild soreness at the site of injection/injection site pain, all within 4 days after administration of Moderna's COVID-19 Vaccine (mRNA-1273). 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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1035000	2/17/2021	NJ	62	F	1/13/2021	1/14/2021	16% loss of hearing; Fullness in ear on the injection side (left); This is a spontaneous report from a contactable consumer. A 62-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL8982), via an unspecified route of administration on 13Jan2021 at 11:30 at a single dose on left arm for COVID-19 immunisation. Medical history included breast cancer, lymphedema (right arm) and asthma from an unknown date and unknown if ongoing. Concomitant medications included montelukast sodium (SINGULAIR). The patient experienced 16% loss of hearing and fullness in ear on the injection side (left) on 14Jan2021 at 17:00. The patient underwent lab tests and procedures which included acoustic stimulation tests: 16 % (16% loss of hearing) on 14Jan2021. Therapeutic measures were taken as a result of 16% loss of hearing and fullness in ear on the injection side (left). The outcome of the events was not recovered.
1036432	2/17/2021	GA	49	M	2/5/2021	2/11/2021	Sudden hearing loss on left ear accompanied by fullness in the left ear and muffled sounds.

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1035515	2/17/2021	MD	61	F	1/13/2021	1/1/2021	<p>almost like she also had some mild hearing loss; nausea; exacerbation of migraine with paresthesia and tinnitus/ headaches/migraines; exacerbation of migraine with paresthesia and tinnitus; exacerbation of migraine with paresthesia and tinnitus/ increased tinnitus; some abdominal tightness; This is a spontaneous report from a contactable pharmacist (patient herself) via Medical Information team. A 61-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number: EL3302, NDC number/expiration date was unknown), via an unspecified route of administration on the left arm (also reported as upper left arm) on 13Jan2021 at 09:00 at a single dose for COVID-19 immunization; the patient was a healthcare worker and was trying to protect herself. The vaccination facility type was reported as a drive thru site. Relevant medical history included previous neurological problems, which included history of underlying migraine with paresthesia/chronic paresthesia (ongoing) and tinnitus. The patient had no family medical history relevant to the adverse events (AEs). There were no concomitant medications. The patient had no other vaccine received on the same day of the Pfizer suspect or 4 weeks prior. She never had any problems with vaccines in the past. History of all previous immunization with the Pfizer vaccine considered as suspect was reported as none. Initially, the patient was asking if there were any reports of paresthesia, serious neurologic adverse events, tinnitus, hearing loss, or abdominal tightness in the studies for the Pfizer-Biontech Covid-19 vaccine. After the patient received the first dose of the Pfizer-BioNTech COVID-19 vaccine on 13Jan2021, she experienced an exacerbation of migraine with paresthesia and tinnitus. She also reported experiencing some abdominal tightness on an unspecified date in Jan2021. The patient reported she was scheduled for her second dose of the Pfizer COVID-19 vaccine, but had concerns because she was still experiencing tinnitus and it was "almost like she also had some mild hearing loss" on an unspecified date. The patient further reported that she was due for the next dose the following day at the time of the report (03Feb2021). She had previous neurological problems and did not know if this did exacerbate things or not. She had migraines, tinnitus, and paresthesia and was wondering how many other</p>

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patients with neurological problems reported this and was this a common side effect or adverse event reported. One doctor told her not to get the second dose and another one told her to get it and she wanted to know what she should do. The patient had headaches/migraines on the evening of vaccination on 13Jan2021 that were fairly mild and 3 days after that on 16Jan2021, they got bad and was accompanied with nausea with increased tinnitus. The migraines and nausea had gone, and the chronic paresthesia was the same as she always had, but the tinnitus was a lot louder and worse. The patient also mentioned that her migraines usually go away, but this one had lingered. The AEs did not require any visit to an emergency room or a physician office. There were no investigation assessment. The patient recovered from the event "nausea" on an unspecified date, she was recovering from the event "exacerbation of migraine/ headaches/migraines," she was not recovered from the events "exacerbation of paresthesia and tinnitus/increased tinnitus, while the outcome of the events "almost like she also had some mild hearing loss and some abdominal tightness" was unknown. The reporter assessed the events "migraine, tinnitus, paresthesia, and nausea" as serious, other medically important conditions. The relatedness of drug to the reactions/events "migraine, tinnitus, paresthesia, and nausea" was unknown as per the reporting pharmacist (Method of assessment: Global Introspection).; Sender's Comments: The 61-year-old female had relevant medical history included previous neurological problems. The reported neurological events and partial hearing loss were more likely due to pre-existing conditions, and less likely related to the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE). Event nausea was likely due to the first dose of bnt162b2. 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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1035520	2/17/2021	PA	56	F	1/12/2021	1/12/2021	<p>tinnitus/she had 2 seconds of a very high pitch and then the following morning, she began having a low level, not high pitched, background low level type hum that was unresolved; This is a spontaneous report from a contactable pharmacist (patient). A 56-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot: EK9231), via intramuscular on 12Jan2021 17:30 at single dose on left arm for prevention. Medical history included hashimoto's hypothyroidism. Concomitant medication included levothyroxine sodium (SYNTHROID) and liothyronine sodium (CYTOMEL), both for Hashimoto's Hypothyroidism; cyanocobalamin (VIT B12), selenium, VITAMIN D3, ascorbic acid (VITAMIN C), calcium + magnesium, all for many years for vitamin supplementation. She also had a hormone replacement therapy patch that she had been taking for 5 years. She had experienced some tinnitus on 12Jan2021 21:00 and it had not resolved. She went to ENT (ear, nose and throat) for an ear exam. They were fine. They did not think it was the vaccine but did not know. After she received the vaccine, she had 2 seconds of a very high pitch and then the following morning, she began having a low level, not high pitched, background low level type hum that was unresolved. It started the evening of around 9pm. She went after work at 17:30 to get the vaccine. It was further reported that tinnitus started at 21:00 for just 2 seconds and then hearing was normal. However, the following morning, she woke up with this low level like if you leave TV on the like a hum. Very mild. This started at 06:00. No ER (Emergency Room) or physician's office required. On 29Jan2020, patient did an ear exam and hearing exam. Ear exam was perfect. Hearing exam revealed slightly hearing loss consistent with age. It was pretty normal. The part of the hearing that goes first as the age. Outcome of the event was not resolved. This case was reported as serious with seriousness criteria: medically significant.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the event tinnitus 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</p>

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1035533	2/17/2021	AR	74	F	1/28/2021	1/30/2021	<p>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>she lost total hearing in one ear inside of five minutes/went totally deaf in her right ear; This is a spontaneous report from a contactable consumer reported for herself. A 74-years-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3247 and expiry date: May2021), via an unspecified route of administration on left arm on 28Jan2021 16:00 at SINGLE DOSE for covid-19 immunisation. Medical history included chronic lymphocytic leukaemia, anaemia. The patient's concomitant medications were not reported. The patient previously took morphine and experienced drug hypersensitivity. The patient received the first dose of the Pfizer COVID 19 vaccine on 28Jan2021. On the 30Jan2021 04:00 PM, she lost total hearing in one ear inside of five minutes/she went totally deaf in her right ear. She has had tests done including a CT and MRI but she is still waiting for the results, which reported as under treatment. Adds she doesn't have an appointment yet, but she is supposed to get the next dose 18Feb2021. The event reported as serious with disability, result emergency room/department or urgent care. Outcome of the event was not recovered. Patient is not pregnant at the time of vaccination. No Covid prior vaccination. No covid tested post vaccination.</p>

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1033857	2/16/2021	CA	68	M	2/3/2021	2/4/2021	Hx of vertigo, migraine associated, 5 days after 1 vaccine 1/4/2021 had an episode of vertigo 1/18, later in January had another episode of vertigo. Last night was the 3rd episode. #1 Moderna 12/30/20. Reports acute episode of vertigo 1/4 (5 days post vaccine). A second episode 1/18 (19 days post vaccine). Decided to delay getting #2 Moderna by one week. Received #2 Moderna on 2/3. c/o mild fatigue 24-48 hrs post vaccine. Reports a 3rd episode of acute vertigo 6 days post #2 Moderna on 2/9. Each episode of vertigo lasted 2-5 hrs associated with n/v/diarrhea. No meds taken to treat sx. vertigo following a URI 11/2017. Complete w/u by physician 3/2018 with audiology testing and brain imaging. Found to have some sensorineural hearing loss in left ear. Poss vestibular migraines vs Meniere's Disease. Remote hx headaches and ocular migraines with aura. No episodes of vertigo since 2018 until these recently described episodes in the 1-2 week period following vaccine administration.
1029839	2/15/2021		34	F	1/23/2021	1/24/2021	Arm soreness 2hrs after shot administered; subsided by hour 36 Fatigue 24hrs after shot administered lasting at least 24hrs Slight loss of hearing in left and then right ear 48hrs later, restored 12hrs later



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1030014	2/15/2021	NJ		M	1/28/2021	1/28/2021	Upper frequency hearing loss; Ringing in my ears; Really tired; Little bit spaced out; A spontaneous report was received from a consumer concerning a 75-years-old, male patient who received Moderna's COVID-19 Vaccine, and who experienced "ringing in my ears", upper frequency hearing loss, really tired and little bit spaced out. The patient's medical history was not provided. Concomitant medication included Clopidogrel bisulfate, Bromelain, Pantoprazole sodium, Atorvastatin, low dose aspirin and Vitamin C. On 28 Jan 2021, approximately 2-3 hours prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 28 Jan 2021, the patient reported that after the injection he noticed ringing in his ears with upper frequency hearing loss. He felt tired and a little bit spaced out. Treatment information was not provided. On 29 Jan 2021, the patient reported ringing was a little better, but the upper frequency hearing loss was still there along with feeling spaced out. Action taken with mRNA-1273 in response to the events was not provided. On 29 Jan 2021, the patient was recovered from really tired. The outcome of the events "ringing in my ears", upper frequency hearing loss, and little bit spaced out was unknown.; Reporter's Comments: This case concerns a 75-year-old, male, who experienced serious unexpected event of deafness, non-serious unexpected event of tinnitus, feeling abnormal and, non-serious expected event of fatigue. The events occurred 1 days (2-3 hrs) after mRNA-1273 (Lot# Unknown). Concomitant medications included Clopidogrel bisulfate, Bromelain, Pantoprazole sodium, Atorvastatin, low dose aspirin and Vitamin C. Treatment details were not provided. 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.
1031908	2/15/2021	CA	75	M	2/5/2021	2/5/2021	Acute sudden hearing loss in right ear 4 hours after being vaccinated with Pfizer Covid vaccine
1032054	2/15/2021	CA	88	M	1/20/2021	1/24/2021	Loss of hearing in right ear. Treated with oral prednizone protocol. No noticeable improvement.

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1032126	2/15/2021	CA	33	F	2/12/2021	2/13/2021	Chills, no fever, pulled my back in the morning with blinding pain/hearing loss, mostly recovered by next day (14th) now feels like a regular pulled muscle
1032335	2/15/2021	CA	72	F	2/15/2021	2/15/2021	Pt reports feeling "dizzy." Denies SOB, chest pain, palpitations, no blurred vision, denies nausea, states, "feel more lightheaded than dizzy." Skin pink warm dry, speaks in clear complete sentences, no redness or swelling to the injection site. No allergic reaction noted. Hx of vertigo, trigeminal neuroma. H- No facial drooping, no deformity noted. E- Pupils equal, denies blurred vision. E- Denies hearing problems or deficit. N-WDL. T- No deviation, no swelling, able to swallow secretions. Lungs CTA. Heart rate, WDL, denies palpitations. Vitals WNLs.
1029319	2/14/2021	KY	77	F	2/13/2021	2/14/2021	RECEIVED BOTH DOSES OF PFIZER VACCINE. (01/23/21 & 02/13/21) AFTER 1 DAY (02/14/21) WENT TO ICC REPORTING SUDDEN HEARING LOSS IN RT EAR, LIGHT-HEADEDNESS, AND FEELING UNBALANCED. DIAGNOSED WITH HEARING LOSS OF RT EAR AND HYPERTENSION AND INSTRUCTED TO GO TO ER. WENT ER ON 02/14/21 AND WAS DIAGNOSED WITH ACUTE HEARING LOSS OF RT EAR.
1027816	2/13/2021	KS	51	F	2/6/2021	2/7/2021	2nd COVID vaccine 2/6/21 @10:02am. Episode of vasovagal syncope 2/7/21 @5:00a. Also side effects of fever, N/V, diarrhea and weakness of approx. 1 hour. Unable to eat/drink. Presented to the ED 2/8/21 @1:30p. Rec 1L LR, Tylenol, benadryl and compazine @5:25p. CT head @6:00p. I was d/c from the ED 2/8/2021 @7:47p. Severe vertigo 2/7 @5:00a-2/9 @4:00p. Profound hearing loss noted @11:30a 2/10/21. Appt with audiologist 2/12/2021 @8:00a, ENT 2/12/2021 @1:50p. Hearing test X2 shows near 100% hearing loss in R ear. Rec steroid injection behind R eardrum 2/12/21 @2:30p. PO steroid taper 2/12/21 @5:30p.
1028112	2/13/2021	NY	42	M	2/11/2021	2/13/2021	I suffer from mild tinnitus and high frequency hearing loss. Approximately 45 hours after receiving injection, my tinnitus and hearing loss in my left ear became significantly worse. I would say 20-40% worse.

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1028352	2/13/2021	FL	45	F	1/1/2021	1/31/2021	Only had sore arm with each dose but 3 weeks later lost my hearing overnight in my left ear. Profound deafness on audio gram.
1027265	2/12/2021	FL	55	M	2/2/2021	2/8/2021	Sudden onset of unilateral sensorineural hearing loss with tinnitus, 6 days post injection. No other precipitating factors or prior history.
1026117	2/12/2021	CA	75	F	1/22/2021	2/2/2021	Sudden Loss of hearing right ear
1026363	2/12/2021	AZ	53	M	1/14/2021	1/14/2021	Sudden onset of severe tinnitus and some hearing loss.
1026345	2/12/2021	NJ	65	M	2/9/2021	2/9/2021	caller states the pt lost hearing in his right ear. pt went to his audiologist and his test shows his hearing is 0-5 percent hearing loss. He was referred to Doctor and his appt is in 2 weeks. He is on high dose of prednisone taper meds.
1022812	2/11/2021		65	F	2/2/2021	2/2/2021	Approximately 30 minutes after receiving the vaccine I lost complete hearing in my left ear. I waited until the next morning to see if hearing would return. It did not and I contacted my doctor at the Clinic and was referred for an audiology test on Thursday at 9:30am followed by a appointment with an ENT. My hearing loss was profound and I was started on high dosages of steroids for a 14 day course of action. I also had a head MRI done on Monday February 8 with no significant findings. My hearing has begun to improve but at this point is not back to normal and it may never be the same. My biggest question is whether or not I should take the second vaccine. I also have a significant bruise at the injection sight that I still have 10 days later.

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1022023	2/11/2021	OR	58	F	1/21/2021	1/1/2021	<p>Right sensory neural hearing loss; Bilateral increased auditory fullness; Tinnitus; This is a spontaneous report from a contactable physician (patient herself). A 58-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection (lot number: EL8982 and expiry date unknown) intramuscular at the left arm on 21Jan2021 15:00PM at a single dose for COVID-19 immunization. The patient's medical history included osteoarthritis and exercise-induced asthma, both from an unknown date and unknown if ongoing. Concomitant medications included celecoxib, paracetamol (TYLENOL), and Vitamin D (NOS); the patient received these medications within 2 weeks of vaccination. The patient is not pregnant at the time of vaccination. She received the first dose of BNT162B2 (lot number: EK9231, expiry date unknown) intramuscular at the left arm on 30Dec2020, 8:30AM at a single dose for COVID-19 immunization. The patient previously took metronidazole from an unknown date and had allergy. The patient did not receive any other vaccines within four weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient had not been tested for COVID-19. Five days after the second vaccine, on 26Jan2021, 6:00AM, the patient had a sudden onset of right sensory neural hearing loss. Leading up to the sudden loss of hearing, bilateral increased auditory fullness and tinnitus began one to two days after vaccine. The patient received intratympanic steroid injection as treatment for the adverse events. Outcome of the events was not recovered. The case report was assessed as Serious since the events were reported as disabling/incapacitating.; Sender's Comments: A contributory role of BNT162B2 to reported events cannot be fully excluded based on the temporal relationship. Case will be reassessed if additional information is received. 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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1022990	2/11/2021	MI	73	M	2/1/2021	2/3/2021	Sudden sensorineural hearing loss in the right ear. Initially hearing loss was profound and has recovered partially to a moderate hearing loss. Hearing has not recovered to baseline as of 2/10/21. Pt also had tinnitus in the right ear which has improved but still bothersome. Patient was started on prednisone on 2/10 at date of initial consultation. Will return for follow-up audiogram in 2 weeks.
1023104	2/11/2021	IN	56	F	2/8/2021	2/9/2021	Rt side body swelling. Rt eye swelled shut. Hearing loss Rt. ear. Headache

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1023358	2/11/2021	CA		F	12/19/2020	12/19/2020	encephalitis-like symptoms; Hearing loss; memory loss; paresthesias; visual disturbances; taste disturbances; dizziness; L-sided chest pain; staggering; elevated SBP 190-200; severe L-sided chest tightness; pre-syncope; elevated BP; DDimer was elevated; fell; intermittent memory lapses; nausea episodes; can't smell that last 1-2 hrs; L neck /head pain; L neck /head pain; Left axilla lymphadenopathy; rhinitis; lightheaded/lightheadedness; had an episode of pain all over; SOB; This is a spontaneous report from a contactable physician (patient). A 46-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number and expiration date were unknown), via an unspecified route of administration from on 19Dec2020 at a single dose for COVID-19 immunization. Medical history included ovarian cancer at age 29, food allergy to clams and escargot, and allergy to sulfa. The patient's concomitant medications were not reported. The patient previously took bactrim and experienced allergies. On 19Dec2020, immediately after vaccine had rhinitis, lightheaded, given Zyrtec and water and observed for a duration of 30 min. Three hours postvaccination on 19Dec2020, at home had an episode of pain all over and SOB (shortness of breath). 3 days later (22Dec2020), patient had L (left) neck /head pain and left axilla lymphadenopathy. On 23Dec2020, she fell in the shower. On the same day (23Dec2020) the patient had intermittent memory lapses, lightheadedness, nausea episodes, can't smell that last 1-2 hours a few times a day. Symptoms worsened on 03Jan2021, with severe L-sided chest tightness, pre-syncope, was seen in the ER with elevated BP. DDimer was elevated, CT Scan of Chest/Abdomen showed L axilla lymphadenopathy, negative for PE. CBC, Electrolytes WNL (within normal limits), still on 03Jan2021. Observed in ER for 7 hrs. and then discharged home. Intermittent symptoms continued. On 08Jan2021, patient had another severe episode while at work. She was noted to be staggering, and again was complaining of left-sided chest pain. She was taken to the ER by her colleagues on 08Jan2021 and noted to have elevated SBP 190-200. On 08Jan2021, patient underwent CT head negative, MRI negative, w/u (workup) for pheochromocytoma negative and COVID negative. She was started on prednisone and Norvasc

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and discharged home. She continues to have intermittent episodes however they have decreased in intensity and last for about 1 hour. She described her symptoms as encephalitis-like symptoms. These include memory loss, paresthesia, visual disturbances, hearing loss, taste disturbances, and dizziness. These symptoms when severe have been incapacitating. She had been hospitalized for a neurological and infectious work up (including Brain MRI and multiple COVID tests) but no diagnosis has been yet identified. This symptom kcomplex (unspecified) has persisted to now. She has not received the second dose of vaccine. She is asking how long mRNA, the lipid nanoparticles and the protein spike lasts in the body. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the limited information currently available, a possible contributory role of the suspect drug in the reported events cannot be completely excluded given the implied temporal association. However, underlying medical conditions may provide the alternate explanations. 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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1018978	2/10/2021	MA	57	F	1/9/2021	1/10/2021	sore arm (briefer than with #1); malaise; fatigue; Pulsing tinnitus, eased off now; bad headache (preexisting but markedly amplified-still; chills (no fever, 3 days for real, now fading); mild nausea/loss of appetite (largely resolved.); mild nausea/loss of appetite (largely resolved.); This is a spontaneous report from a contactable Physician reported for herself. This 57-year-old female patient (not pregnant) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an 09Jan2021 09:00 AM on Arm left at single dose (Lot # EK9231) for covid-19 immunisation. Medical history included Pacemaker, Insomnia, and some preexisting hearing loss, due to effusion. No known allergies. No covid prior vaccination. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 19Dec2020 16:45 PM on Left arm at single dose (Lot # EH9899) for covid-19 immunisation. Covid test after #1 (December) due to sore arm, chills, aches and malaise. Was negative. No other vaccine in four weeks. Concomitant medications included other medications in two weeks. The patient experienced pulsing tinnitus, eased off now, also sore arm (briefer than with #1), malaise/fatigue (still but better), bad headache (persisting but markedly amplified-still, chills (no fever, 3 days for real, now fading), mild nausea/loss of appetite (largely resolved.) Events all on 10Jan2021 06:00 AM. Lab data included covid test (Nasal Swab) on 22Dec2020: negative. No treatments were received for the events. Outcome of events mild nausea/loss of appetite, malaise, fatigue was recovering. Outcome of the event chills (no fever, 3 days for real, now fading) was recovered. Outcome of the events was unknown.



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1018979	2/10/2021	MA	57	F	12/19/2020	12/1/2020	sore arm; Chills; aches; malaise; This is a spontaneous report from a contactable physician reported for herself. A 57-years-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EH9899), via an unspecified route of administration in left arm on 19Dec2020 16:45 at single dose for COVID-19 immunization. Medical history included pacemaker, insomnia and some preexisting hearing loss, no known allergies. Concomitant medications included unspecified medication received in two weeks. The patient was no pregnant. There was no other vaccine received at the same date of the product and in four weeks. The patient had no COVID prior vaccination. The patient experienced sore arm on an unspecified date, chills, aches and malaise in Dec2020. COVID test (Nasal Swab) post vaccination on 22Dec2020 due to chills, aches and malaise was negative. No treatment received for the events. The outcome of the events was unknown.
1016234	2/9/2021	TX	61	F	2/5/2021	2/5/2021	10 minutes after receiving vaccine I had sudden sharp pains in my right ear. I have had extensive surgery in and around that ear due to cholesteatoma and perilymph fistula, and I have had some nerve damage to the balance nerve. The bones of hearing have been removed and replaced with titanium artificial bones that do not work, so I am deaf in that ear. These pains were severe, as if a number of steak knives were stabbing me at once, but the pain only lasted about a minute and subsided. 3 or 4 minutes later the pain recurred exactly as before but lasted a shorter duration and at a lower level of pain. The ear felt congested the rest of the day and I avoided driving after getting home. I have had no further problems, except that I went for more dental work on 2/8, and had a dizzy spell after getting anesthetic, maybe a little heart racing for just 5 minutes or so.

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1017887	2/9/2021	AR	65	M	1/12/2021	1/31/2021	2021 ICD-10-CM Diagnosis Code H90.41 Sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side. Onset of right side diminished hearing the morning of Sunday Jan. 31st, 2021. More pronounced by Wednesday am Feb. 3rd, 2021. Seen at the University for Medical Sciences in the outpatient clinic. No significant wax in either canal. Bilateral type A tympanograms. Markedly abnormal audiogram compared to base line obtained by same facility approx. 8 months earlier. 60 DB loss across all hearing ranges right ear only. Left unchanged.
1016599	2/9/2021		77	M	1/21/2021	1/23/2021	Hearing loss in left ear; A spontaneous report was received from a 77-year-old, male, patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced hearing loss in the left ear. The patient's medical history was not provided. No relevant concomitant medications were reported. On 21 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 23 Jan 2021, the patient started to experience hearing loss in the left ear. Tinny sound in left ear. Treatment for the events was not provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome for the event, hearing loss in the left ear, was unknown.; Reporter's Comments: This case concerns a 77 year-old, male patient, who experienced event of hearing loss in the left ear. The event occurred 2 days after the first and last dose of mRNA-1273 vaccine administration. 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 and the events are assessed as possibly related.
1011908	2/8/2021	NJ	41	M	1/8/2021	1/28/2021	Sudden Sensoryneural Hearing Loss with associated Tinnitus

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1014645	2/8/2021	NY	71	F	1/16/2021	1/23/2021	Sensorineural hearing loss Right side : moderate to severe confirmed by an audiogram February 4,2021 Left side: NOT noticed subjectively - but audiogram done on February 4,2021 confirmed mild to moderate Seen by ENT 2.4.2021: started on prednisone 60mg daily for 2 weeks with the plan to taper. Received first intratympanic steroid injection by ENT

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1012376	2/8/2021	MO	68	F	1/22/2021	1/22/2021	her arm was red, swollen, and growing; her arm was red, swollen, and growing; She had numbness in parts of the ear and is now able to feel parts of the ear, but she is not sure if the numbness will go away; Caller mentioned that she can feel her ear "closing up" and by Saturday-Sunday had lost hearing on the right ear; This is a spontaneous report from a contactable consumer via Pfizer sponsored program. A 68-year-old female patient received her 1st bnt162b2 (Pfizer-Biontech Covid-19 Vaccine; Batch/lot number: EK9231) single dose on 22Jan2021 10:45 AM at right arm for COVID-19 immunization. Medical history included COVID on 05Nov2020 but was mild only and she was not hospitalized; No medications aside from over-the-counter drugs. The patient was given a Z-pack and vitamin C and immune stuff like Zinc. Concomitant drugs included high blood pressure medication. Around 6:00 PM on 22Jan2021, the patient can feel her ear "closing up" and by Saturday-Sunday had lost hearing on the right ear - the same side of her arm she received the vaccine. The patient stated it was better on 25Jan2021 but still not 100 percent. The patient tried calling the emergency room and has read up and no one can give her any answers. She made an appointment this morning with her doctor to see what was going on, states not being able to hear messes with her equilibrium. The patient was supposed to have another dose on 12Feb2021 and wanted to know if she should. The patient currently still had partial hearing loss and was prescribed a Prednisone that she took for 5 days. Her arm did not hurt Friday through Sunday, however, on Monday, her arm was red, swollen, and growing. She was able to get partial hearing back after taking Prednisone. She had numbness in parts of the ear and was now able to feel parts of the ear, but she was not sure if the numbness will go away. The outcome of hearing loss was resolving, of other events was unknown.

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1011193	2/8/2021	MD	46	F	1/8/2021	2/6/2021	Developed right jaw/ear pain within 5 days of first injection, mild headache x 1 day, without other symptoms, no fever/chills, no sinus pressure or drainage. Morning after 2nd vaccination developed hearing loss right ear. Sensorineural, seen at local urgent care and evaluated on 2/7/2021, no cerumen impaction, no acute otitis.
1014511	2/8/2021	AZ	75	M	1/20/2021	1/23/2021	Almost total hearing loss in left ear.
1011818	2/8/2021	PA	75	F	1/23/2021	1/27/2021	Loss of hearing
1011365	2/8/2021	MN	39	F	2/5/2021	2/6/2021	Hearing loss to certain tones/pitches Muffled and ringing in ears
1014697	2/8/2021	FL	52	F	2/4/2021	2/4/2021	This was my second dose. Fever as high as 103.4F. Fever lasted 24 hours above 100.0F Chills, Shaking for 4 hours from about 8/9 pm to 12/1am. Nausea, vomiting, bowel pain, inflamed rectum after bowel movement the next day, loss of hearing, dizziness, Trying to sleep and waking up gasping for air about 5 times though out the early morning. Sever Headache which lasted Two and a half days. About 2 pm on 2/5/21 I took some Emetrol for the Nausea, and Tylenol for headache and fever. I took Tylenol again the evening of 2/5/21. On 2/6/21 I Tylenol and then Ibuprofen then Excedrin. On 2/7/21 I took Excedrin once and my headache was finally gone.
1009817	2/7/2021	GA		F	1/11/2021	1/14/2021	Three days following the receipt of the Covid vaccine, I lost all hearing in my left ear. I was diagnosed with "sudden sensory nerve severe hearing loss" by an ENT
1009029	2/7/2021	IL	71	M	1/19/2021	1/22/2021	First reaction total loss of hearing in right ear. Returned after 6 hours. Next day partial loss of hearing in left ear. Did not return to normal hearing.
1007925	2/6/2021	MI	73	M	1/15/2021	1/16/2021	Sudden hearing loss in right ear.
1006489	2/5/2021	OH	72	M	2/3/2021	2/3/2021	sudden onset tinnitus and deafness in right ear, lasting 12 hours, resolving spontaneously.
1006294	2/5/2021	ND	57	F	1/12/2021	1/19/2021	Sudden sensorineural hearing loss, left ear.
1005523	2/5/2021	TX	44	M	1/5/2021	1/11/2021	sudden hearing loss left ear

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1005432	2/5/2021	MD	91	F			Ears blocked, pressure in head, loss of hearing. Next day -pain in abdomine followed by diahrea - general not feeling well,
1004413	2/5/2021	NY	68	F	1/19/2021	1/22/2021	have two discoloration in my right thumb one black long line and one red line side by side around 1 and a half inches long and behind it is a circular black and discoloration; This is a spontaneous report from a contactable other hcp. A 68-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 19Jan2021 12:00 at a SINGLE DOSE for covid-19 immunisation. Medical history included hypertension, supraventricular tachycardia and hearing loss from an unknown date and unknown if ongoing. Concomitant medication included amlodipine (AMLODIPINE) and metoprolol tartrate (METOPROLOL TARTRATE). On 22Jan2021 05:00 AM, the patient stated, "I have two discoloration in my right thumb one black long line and one red line side by side around 1 and a half inches long and behind it is a circular black and discoloration." No treatment was received for the events. The outcome of the event was not recovered.
1006788	2/5/2021	CA	49	F	1/15/2021	1/20/2021	Constant and prolonged ringing in the ear/tinnitus starting a few days after the vaccine was administered. I have never experienced this constant and prolonged tinnitus before and it has continued since it first started around January 20th. I thought it would go away, but it never did. It appears I may have some hearing loss at this time now as well, which I did not previously have.
1001080	2/4/2021	NY	55	F	1/6/2021	1/7/2021	Patient received Pfizer #1 on 1/6/21 and developed muscle cramps and tinnitus and was evaluated by ENT, TMJ specialist, allergist and her PCP. Hearing test revealed mild hearing loss in high frequency. 1/27/21 received the second dose of the vaccine. The following day she developed flu-like symptoms, including fever, chills, headache and fatigue and worsening of Tinnitus. Received Dupixent two weeks prior to the vaccine.

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1000161	2/4/2021	CA		M	12/25/2020	12/27/2020	Patient did not receive the 2nd dose as scheduled; Sick; Hearing loss (left ear); This is a spontaneous report from a Pfizer-sponsored program from a contactable consumer reporting for himself. A 63 (unit unspecified) male patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 25Dec2020, at single dose, for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced hearing loss (left ear) on 27Dec2020 with outcome of recovering. He only had 60% hearing. Therapeutic measures were taken as a result of the event and included treatment with unspecified medication. Now hearing was 90% back. Furthermore, the patient did not receive the 2nd dose on 16Jan2021 as scheduled as he was sick. The reporter stated that he didn't know if hearing loss (left ear) had to do with the vaccine. He asked the doctor, he didn't know either, he said it could be stress or virus. The information on the lot/batch number has been requested.
1003100	2/4/2021	TX	28	M	1/12/2021	1/14/2021	Sudden onset hearing loss started 48 hours after injection, ringing in ears, still ongoing two weeks later. Some hearing regained
1004974	2/4/2021	NJ	68	M	1/27/2021	1/29/2021	Pt developed sudden hearing loss on 1/29/2021
1003639	2/4/2021	NE	75	M	1/8/2021	1/9/2021	TOTAL HEARING LOSS IN LEFT EAR
1003422	2/4/2021	CA	78	M	1/29/2021	2/2/2021	Sudden Hearing Loss in left ear

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1000046	2/4/2021	NJ	86	M	1/18/2021	1/19/2021	I could not hear anything; This is a spontaneous report from a contactable consumer (patient). An 86-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: e18982), via an unspecified route of administration at the left arm on 18Jan2021 09:00 at a single dose for COVID-19 immunization. Medical history included hearing problem, CAD and glaucoma. The patient has no allergies to medications, food, or other products. Concomitant medication included tamsulosin, levothyroxine sodium (LEVOXYL), omeprazole, acetylsalicylic acid (BABY ASPIRIN) and astorta. On 19Jan2021, 1 day after injection around 5pm the patient reported to have taken a nap, and when he woke up, he could not hear anything. The patient has a hearing problem only have 10% hearing. He was going to see ENT. The event resulted to doctor or other healthcare professional office/clinic visit. The reporter assessed the event as non-serious, did not result in death, not life threatening, did not cause/prolonged hospitalization, not disabling/incapacitating, did not cause congenital anomaly/birth defect. 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. The patient has not been tested for COVID-19 post vaccination. The outcome of the event was not recovered
998858	2/3/2021	GA	82	F	1/27/2021	1/28/2021	The following symptoms began the day after the shot: headache, dizziness, tiredness, fever, complete loss of hearing in right ear, partial loss of hearing in left ear, Hearing loss lasted 6 hours before beginning to improve. Most symptoms were gone by end of 4th day. Tiredness remains along with occasional dizziness.
999215	2/3/2021	TX	20	F	1/29/2021	1/31/2021	Hearing loss in right ear



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998764	2/3/2021	CA	80	F	2/3/2021	2/3/2021	Dizziness, lightheadedness, sweating, diaphoretic. Patient is diabetic, had high BP, dizziness, loss of hearing, tunnel vision, emotional/crying. Patient was given juice, observation done, vital signs monitored, glucose checked, pulse ox checked. Patient improved after interventions. Patient verbalized feeling better and was discharged to home/self care with husband @ 1:15PM.
999381	2/3/2021	CT	42	F	12/16/2020	12/22/2020	She took the first Pzfier vaccine December 16 and 6 days later, she had complete hearing loss in left ear. She first noticed the loss of hearing occurred after a run. The pt had a piercing headache and the next morning she could not hear out of left ear. She recalls having a slight headache and tingling on the left side of her face, just after the vaccine. MRI of the brain normal. Prednisone taper, starting at 60 mg and received intratympanic steroid injections. The steroid did not help her regain her hearing. She was then seen by doctor and underwent a dozen hyperbaric O2 therapy. Pt is beginning to get her hearing back in left ear.

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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.
998242	2/3/2021	NY	61	F	1/23/2021	1/24/2021	Sudden total hearing loss, left ear; numbness in face and outer ear.
994688	2/2/2021	MD	76	F	1/19/2021	1/28/2021	About 10 days after receiving the vaccine, pt started to hear rings in left ear. Then she started to noticing hearing loss. As of today she has lost almost all hearing in her left ear. She has no other symptoms after receiving the vaccine.
995953	2/2/2021	CA	40	M	1/30/2021	2/1/2021	Acute left sensorineural hearing loss with tinnitus. Significant hearing impairment noted on audiometric evaluation. Symptoms began a day after receiving the second dose of the moderna vaccine.
994357	2/2/2021	PA	33	M	1/29/2021	2/2/2021	~50% unilateral hearing loss in left ear in low/mid frequency range
994151	2/2/2021	IN	50	F	2/1/2021	2/1/2021	At approximately 6 hours after receiving vaccine, I experienced extreme bilateral ear pressure and hearing loss. Similar experience to flying, ear plugging. It relieved after about 1 hour. Never a popping feeling or anything remarkable. Just as if the pressure relieved.

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993824	2/2/2021	NJ	80	M	1/18/2021	1/19/2021	loss of hearing; This is a spontaneous report from a contactable consumer. An 80-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 18Jan2021 12:00 PM at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. It was unknown if patient had COVID prior vaccination. The patient experienced loss of hearing the day after vaccination administered on 19Jan2021. It was unknown if treatment was received and unknown if patient had tested COVID post vaccination. The outcome of event was unknown. Information on the lot/batch number has been requested.
993160	2/2/2021	CA	69	F	1/31/2021	1/31/2021	Changes in hearing, faint, aches in hips and neck, tight chest. Faintness was within 10 minutes of administration of vaccine. And last about 2-3 minutes. Aches lasted 2 days. Ears felt strange next day: felt as if plugged, seemed both like a loss of hearing and exaggerated hearing at same time. Roaring in ears.

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990639	2/1/2021			U			Light-headed; Pulse rate is higher than what normally was/ from maybe 55 to 65, now, it's running into the 70's; This is a spontaneous report from a non-contactable consumer (patient). A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection (lot number and expiry date unknown) via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history included being on long time care facility, has hearing problem, and pulse rate abnormal. Concomitant medications included metoprolol tartrate for pulse rate abnormal. Patient got first dose yesterday. Patient felt very good all day long; got the dose in morning and had a good night sleep. But when patient woke up, patient felt so light-headed. Patient took blood pressure several times and it was normal. The other thing that was different a little bit was the pulse rate, which is higher than what normally was with the medication that patient takes for it. Patient takes metoprolol and usually, when patient takes it, pulse rate is anywhere from maybe 55 to 65, now, its running into the 70's. It is not great difference but patient just reporting experience when blood pressure was checked. Outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.
992753	2/1/2021	TX	95	F	1/29/2021	1/30/2021	Woke up deaf. Treatment was rest. No other treatment yet. Outcome - still deaf, day 3
992686	2/1/2021	AR	72	M	1/20/2021	1/27/2021	Patient complains of the following side effects starting 7 days post vaccination: Tinnitus, tingling sensation in ear, and deafness, no pain. Patient was seen by local physician. Prescribed methylprednisolone dose pack and iron.

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990619	2/1/2021	AZ		M	1/16/2021		he has been deaf since he got out; This is a spontaneous report from a contactable consumer (patient). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 16Jan2021 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. He has been a truck driver all his life. The patient reported that he has been deaf since he got out, on an unknown date. He stated that his heart doctor wanted him to take a nuclear test on 20Jan2021. Patient did not want to take a test if it will interfere with his shot and he wanted to know if this will interfere with his shot. The final outcome of the event was unknown. Information on the batch number has been requested.

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990494	2/1/2021	FL	77	F	1/11/2021	1/11/2021	<p>couldn't sleep; sudden hearing loss; complete hearing loss a few days later/hearing loss in right ear; constant humming in her right ear/getting hissing in my ear; arm felt tender; This is a spontaneous report from a contactable consumer (patient). A 77-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number was either: EL1283, CL1283, or LL1283) on 11Jan2021 at 11:00 at single dose in left arm for COVID-19 immunization. Medical history was none. There were no concomitant medications. Patient previously took pneumonia shot on an unknown date and flu shot in Oct2020 for immunization. Patient got the first dose of the vaccine on 11Jan2021 at 11:00 in the morning. On 11Jan2021 her arm felt tender where the needle went in. On 12Jan2021 late afternoon, she started getting hissing in her ear that was still there and had not gone away at all and she also had a constant humming in her right ear. By 13Jan2021, she still had the humming. She saw an ENT on 13Jan2021 and doctor didn't know if it was correlated to the vaccine or not; doctor took some wax out of her ear and she seemed to get relief from the hissing for about 15 minutes but about 15-20 minutes later the hissing/ humming continued. On 14Jan2021, woke up with complete deafness in right ear. Immediately called ENT doctor and did a hearing test. Patient could not hear and they confirmed she had sudden hearing loss in her right ear on 14Jan2021, she had nothing in her right ear (as reported). They put her on 40 mg a day of Prednisone (20mg tablets) and so far, prednisone hadn't done anything: originally taking prednisone 40mg for four days and was taking two a day; on 16Jan2021 when she was getting no relief and couldn't sleep due to the humming in her ear, she called doctor and was advised to take the 40mg together in the morning, she will take 40mg a day. On 19Jan2021 she took 20mg for four days and then decreased by half again. She was also advised by doctor to take 25mg Benadryl (UPC: 30048284 Lot: SPS023 Exp: Jun2022) at night. They are scheduling her for an MRI in Jan2021. Patient was also scheduled for the second dose on 01Feb2021 and will be on the prednisone until 26Jan2021; she would like to know whether the prednisone will diminish the effectiveness of the vaccine. She also asked if there was a certain amount of time she should wait to restart in case the</p>

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992377	2/1/2021	CO	70	M	1/1/2021	2/1/2021	<p>doctor decided she should not get the second dose; she also wanted to know if she should wait on the second vaccine and maybe start over in two months. She was concerned and wanted to know if she should proceed with the second shot. The patient underwent blood work on an unspecified date to see if she can receive contrast for an MRI. She never had problem with MRI contrast before. Final outcome of the events was reported as unknown.</p> <p>Got shot at 8am 22 Jan. Slight soreness in arm developed later the same day, but no problem. Everything was normal and went to bed. Woke up approximately 2-3 h later with extreme vertigo, dizziness, imbalance, completely clogged left ear, tinnitus in left hear and nausea. Within about an hour I was hyperventilating and had cold tingling sensation in hands and feet. About 2am went to hospital. They did a bunch of tests including a CT scan which revealed nothing adverse. They kept me over night and gave me an MRI the next morning. Again nothing adverse found. I was released that next day with orders to see PCP. Got an appt 2 days later. PCP immediately started me on Prednisone and referred me to ENT doctor. Got an audio test 2 days later and because of the severity of my symptoms (sudden, acute tinnitus and complete hearing loss in left ear) ENT prescribed higher dose and duration of prednisone. I am on day 5 of the 24day course prescribed by ENT with no appreciable improvement. Still have no hearing in left ear and tinnitus, imbalance and trouble focusing and walking. No causal link has been ascribed to the vaccine, but I am terrified of having the booster shot which is schedule for 12 Feb.</p>



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990364	2/1/2021	FL	73	M	1/12/2021	1/14/2021	Loss of hearing in his right ear; A spontaneous report was received from a 73-year-old, male, patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced hearing loss in right ear. The patient's medical history, as provided by the reporter, included ventriculoperitoneal (VP) shunt in his head. Concomitant product use was not provided by the reporter. On 12 Jan 2021, approximately two days prior to the onset of the event, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 14 Jan 2021, the patient had dental work done where four crowns were prepped and temporaries were put in, he then lost hearing in his right ear. Treatment information was not provided. He thinks that the loss of hearing might be due to this dental procedure as they were drilling for hours. He states that he has a VP shunt in this head which needs readjustments occasionally. He is seeing his neurosurgeon for the readjustment. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event, hearing loss in right ear, was unknown.; Reporter's Comments: This case concerns a 73 year-old, male patient with history of ventriculoperitoneal (VP) shunt in his head, who experienced event of hearing loss in right ear. The event occurred 2 days after the first and last dose of mRNA-1273 vaccine 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 and the event is assessed as possibly related. However, on the same day and prior to the onset of the event, the patient had extensive dental procedures done which may provide an alternative explanation for the event.
989359	1/31/2021	OR	62	M	1/28/2021	1/30/2021	Hearing loss in left ear about a day after shot. Ear hurt as I suspected an infection. Went away after a couple of days. Hearing returned. Now my right ear is starting the same. Almost all hearing is gone same as my left ear did. Feels like and ear infection. Hope it comes back like the left ear.

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988827	1/30/2021	NY	40	M	1/16/2021	1/20/2021	Ear ache started on 1-19-21 and started antibiotics. Rash on ear started 1-22-21 Facial paralysis on right side of face on 1-25-21 Went to ER on 1-25-21. Diagnosed with herpes zoster oticus. Started treatment of Valacyclovir and Prednisone. Treated by ENT on 1-29-21. Had hearing test and no hearing loss was detected. Prescribed stronger dose of prednisone because there was not any improvement in facial paralysis. Still experiencing facial paralysis on the right side. It?s unknown if it will be permanent.
984705	1/29/2021	UT	53	M	12/30/2020	12/31/2020	I started with ringing and buzzing in my right ear which progressed to almost total deafness in the right year
986085	1/29/2021	VA	58	M	1/11/2021	1/17/2021	Acute Unilateral Sensorineural Hearing Loss; This is a spontaneous report from a contactable physician. A 58-year-old male patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284), intramuscular in left arm on 11Jan2021 at a single dose for COVID-19 immunization. Medical history included hyperlipidemia. The patient had no known allergies and was not diagnosed with COVID-19 prior to vaccination. Concomitant medication included rosuvastatin calcium (CRESTOR). The patient previously received the first dose of bnt162b2 on an unknown date for COVID-19 immunization. The patient experienced acute unilateral sensorineural hearing loss on 17Jan2021 07:00 with outcome of not recovered. The event caused physician office visit. Therapeutic measures were taken as a result of acute unilateral sensorineural hearing loss that included prednisone. The patient was not tested with COVID-19 post vaccination.; Sender's Comments: Based on the compatible temporal association and in absence of strong confounding factors, there is a reasonable possibility that the event acute unilateral sensorineural hearing loss is related to suspect 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 Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

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984774	1/29/2021	IL	37	F	1/6/2021	1/13/2021	Sudden-onset R sided sensorineural hearing loss
985967	1/29/2021	OH	63	M	1/6/2021	1/13/2021	tinnitus; loss of hearing on Left side; This is a spontaneous report from a contactable physician (patient himself). A 63-year-old male patient received his second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231) via an unspecified route of administration on the left arm on 06Jan2021 at a single dose for COVID-19 immunization at hospital facility. Medical history included benign prostatic hyperplasia (BPH) and hypothyroidism. The patient had no known allergies and did not have COVID prior to vaccination. Concomitant medications included levothyroxine sodium (SYNTHROID), tamsulosin hydrochloride (FLOMAX), and finasteride taken within two weeks of vaccination. The patient had no other vaccine in four weeks. The patient previously received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK8330) via intramuscular route on the left arm on 16Dec2020 at 6:15AM. The patient experienced tinnitus and loss of hearing on left side on 13Jan2021, 7 days post 2nd dose. The adverse events resulted in Doctor or other healthcare professional office/clinic visit, Disability or permanent damage. Prednisone taper was given as treatment for the events. The patient had not been tested for COVID post vaccination. The outcome of the events was unknown.; Sender's Comments: Based on the information provided, the possible contribution of suspect BNT162B2 to the events tinnitus and loss of hearing cannot be totally excluded given the time association. The detailed clinical course about these events would be helpful for further assessment. 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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983200	1/28/2021	NY	47	F	1/13/2021	1/20/2021	Hearing loss in left ear. Not complete but high pitch sounds. Ear has been ringing since onset. Came on abruptly while sleeping at 5 am. There was pain initially. I am not sure if it is related as this did not occur until 1 week after I had the vaccine. However, I thought it was worth mentioning as the vaccine is so new.
983629	1/28/2021	PA	36	F	1/28/2021	1/28/2021	Tingle all over, hearing loss, diaphoretic - subsided shortly after
982971	1/28/2021	PA	33	F	1/20/2021	1/22/2021	Sudden hearing loss began the evening following the vaccination
981653	1/28/2021	MI	41	M	1/11/2021	1/12/2021	received dose 1 at 8:40am and woke up the next morning at 7am with hearing loss in left ear and constant ringing in the left ear. have never had this issue before.
982698	1/28/2021	NY	43	F	1/21/2021	1/21/2021	Pfizer-BioNTech Covid-19 Vaccine . Ringing in Right ear and loss of hearing for approximately 5 hours, fever, headache and pain on left arm where vaccine was inserted.
982460	1/28/2021	NY	35	F	1/12/2021	1/14/2021	Approx 1-3 days post Covid Vaccine @1, patient developed muffled hearing loss and dizziness.
981756	1/28/2021	OR	58	F	1/21/2021	1/26/2021	Sudden onset right sensorineural hearing loss day 5 after vaccine. Bilateral worsened tinnitus and aural fullness starting 2 days after vaccine, mildly for a few days after 1st dose of vaccine, then more intensely after second dose. Transtympanic steroid injection seems to be helping hearing loss but increase bilateral tinnitus continues to be more intense than baseline.

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980363	1/28/2021			M	1/13/2021	1/13/2021	<p>went deaf for a while; Trouble breathing; Swollen genitals; Injection site arm in severe pain; fever; A spontaneous report was received from a consumer who was also a male patient who received Moderna's COVID-19 Vaccine, and who developed trouble breathing, swollen genitals, injection site arm in severe pain, fever, and went deaf for a while. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 13 Jan 2021, approximately one hour prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (LOT unknown) intramuscularly for prophylaxis of COVID-19 infection. On 13 Jan 2021, approximately one hour after receiving the injection, he developed trouble breathing, swollen genitals and severe pain at the injection site. He had a fever, and he went deaf for a while. On 14 Jan 2021, the pain became so overwhelming that he went to the emergency department. No diagnostic information was provided. Treatment information was not provided. Action taken with mRNA-1273 in response to the events, trouble breathing, swollen genitals, injection site arm in severe pain, fever, and went deaf for a while, was not provided. The event, went deaf for a while, was considered recovered/resolved on an undisclosed date. The outcome of the events, trouble breathing, swollen genitals, injection site arm in severe pain and fever, was not reported.; Reporter's Comments: This spontaneous report refers to a male patient who experienced unexpected events of trouble breathing, swollen genitals, severe pain at the injection site, fever and went deaf for a while one hour after administration of the first dose of mRNA-1273, lot # unknown, Exp date-unknown. Based on temporal information provided and in the absence of any other etiological factors, a causal association cannot be excluded. Pain and fever are consistent with the known safety profile of the vaccine.</p>

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976836	1/27/2021	MI	41	F	1/14/2021	1/15/2021	seeing gray spots room started spinning felt nauseous collapsed on the table; loss of vision; loss of hearing; seeing gray spots room started spinning felt nauseous collapsed on the table; seeing gray spots room started spinning felt nauseous collapsed on the table; seeing gray spots room started spinning felt nauseous collapsed on the table; loss of the onion ability to stand up or walk; This is a spontaneous report from a contactable other health professional (patient), a 41-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231) at left arm on 14Jan2021 08:30 AM at single dose for covid-19 immunization in a public health facility. Medical history was none. Allergies to medications, food, or other products was No. Patient was not pregnant at the time of vaccination. the patient was not received any other vaccines within 4 weeks prior to the COVID vaccine. the patient received within 2 weeks of vaccination included amphetamine salts 15 mg. Patient woke up in the middle of the night got out of bed walk down a set of stairs started seeing gray spots room started spinning felt nauseous collapsed on the table. Had to call her husband to carry her back up the stairs. she had loss of vision loss of hearing and the onion ability to stand up or walk. He laid her back in bed to pick up his phone and call emergency services within five minutes everything had gone back to normal. adverse event start date was 15Jan2021 03:00 AM. the adverse event result in doctor or other healthcare professional office/clinic visit. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The final outcome of the events was unknown (if patient recovered: Unknown). It was reported as non-serious. Seriousness criteria Results in death, Life threatening, caused/prolonged hospitalization, Disabling/Incapacitating and Congenital anomaly/birth defect were all no.; 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

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							any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.
979442	1/27/2021	MD	76	F	1/7/2021	1/7/2021	Day 1 moderate to severe pain at site and headache treated with Acetaminophen. Extreme sleepiness for 48 hours and slept for most of the day. 2nd Day pain at site and headache continued. Treated with Acetaminophen. Extreme sleepiness slept for most of the day. Sore throat,cough and nasal congestion and drip, and metallic taste in mouth. Loss of appetite. Loss of hearing and appetite. I woke up at night at 1:00 a.m. with severe nasal discharge and had to sit upright for 2 hours till it abated a little. Day 3 Pain at site continued as did nasal congestion and discharge. Loss of appetite and hearing also continued. I still have nasal congestion and discharge on my 3rd week and also the loss of appetite and hearing loss. The loss of hearing has improved very minutely.
979014	1/27/2021	CA	86	F	1/21/2021	1/22/2021	loss of hearing in right ear
977581	1/27/2021	IA	18	F	1/21/2021	1/21/2021	Developed a fever of 102.7 at 2000 on 1/21/2021 with a headache and chills with sweating. Noticed generalized weakness. When she work up on 1/22/2021 she noted hearing loss bilaterally with a "ringing" sensation. This lasted approximately 1 minute. She has never experienced this sensation before.

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976864	1/27/2021	NC	46	F	12/28/2020	12/28/2020	tunnel vision; 2 minutes after injection Heart rate went to 138/Hr 110/elevated heart rate.; dizziness; This is a spontaneous report from a contactable nurse reporting for herself. A 46-years-old female patient received the first dose of BNT162B2 Pfizer-BioNTech COVID-19 Vaccine, Lot number Ek9231, via an unspecified route of administration in left arm on 28Dec2020 at 11:45, at 46 years of age, at single dose for COVID-19 immunization. The patient was not pregnant when she was vaccinated and received the vaccine in Hospital. She didn't receive any other vaccine in the previous 4 weeks. Medical history included Meniere's disease with sudden hearing loss in left ear from an unknown date, gastroesophageal reflux disease from an unknown date and allergy to penicillin and sulfa drugs. Concomitant medication included famotidine (PEPCID), paracetamol (TYLENOL), ergocalciferol (VITAMIN D) supplements and cetirizine hydrochloride (ZYRTEC). On 28Dec2020, 2 minutes after vaccine injection, the patient experienced tunnel vision, assessed as medically significant, her heart rate went to 138 and she experienced dizziness. The same happened again "at the 8 min mark": heart rate at 110 and dizziness. The events resolved on their own. Dizziness and elevated heart rate happened again later that evening. At the time of the report the reported events had resolved without any treatment.; Sender's Comments: Based on the compatible time association, the events tunnel vision, heart rate increased and dizziness are reasonably related to suspect BNT162B2 administration. 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.
976040	1/26/2021	IL	28	F	1/26/2021	1/26/2021	Dizziness, lightheadedness, weakness, sweating (hot/cold) and patient reported loss of hearing for 30 seconds. Patient sat for observation for 30+ minutes, feet elevated, drank water, and ice pack was provided for patient to place on forehead until patient's symptoms resolved.



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974847	1/26/2021	CA	63	M	12/25/2020	12/27/2020	left sudden sensorineural hearing loss , ear numbness. symptoms began 48 hours after vaccination. Treatment began 3 days after onset of symptoms and included high dose prednisone and trans-tympanic dexamethasone shots. The patient partially recovered after 3 weeks of treatment.
973280	1/26/2021	WA	63	F	12/30/2020	1/1/2021	Soreness at injection site for 72 hours.; Low grade fever 99.6 orally on day 3.; GI upset for 3 days; Migraine headache on day 6.; This is a spontaneous report from a contactable nurse (patient). A 63-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EK9231; expiry date: unknown) via an unspecified route of administration in the right arm, on 30Dec2020 at 11:00 A.M., at a single dose, for COVID-19 immunization. Relevant medical history included high blood pressure (BP), seasonal allergies, migraine, asthma, right sided hearing loss. The patient was taking unspecified concomitant medications. The patient is not pregnant at the time of vaccination. The patient was not diagnosed with COVID prior vaccination. The patient did not receive other vaccines within four weeks prior to COVID vaccination. The vaccine was administered in the hospital. On 01Jan2021, at 8:00 A.M., the patient experienced soreness at injection site for 72 hours. On day 3, the patient had low grade fever 99.6. On an unspecified date in Jan2021, the patient had gastrointestinal (GI) upset for 3 days. On day 6, the patient experienced migraine headache. The patient did not receive therapy for the events. Outcome of the events was recovered. The patient has not been tested for COVID-19 since vaccination.
972509	1/25/2021		21	U	1/22/2021	1/22/2021	Brief loss of hearing, vomiting x 15 min VSS

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970153	1/25/2021	MA	60	F	1/5/2021	1/1/2021	Pain through whole body and tremoring; Pain through whole body and tremoring/ whole body was sore; Things started looking funny/ Funny feeling in her ears; Deaf and couldn't hear; Leg cramps in both legs and toes curled out/ muscle spasming; Dizzy; nauseous; Threw up twice; Bruise at injection site; 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) (Batch/lot number: EL3246) via an unspecified route of administration on the arm left on 05Jan2021 around 12:00 PM at single dose for COVID-19 immunization. The patient used to get legs cramps when she was pregnant with her twins, but it was only one leg. The patient stated she delivered six children, was in car accidents, and had surgeries. And the patient stated the pain from the COVID-19 Vaccine was beyond any other pain she has experienced. The patient needed glasses to read patient card. And stated her eyesight was going. The patient was pretty healthy. There were no concomitant medications. The patient had no prior vaccinations within 4 weeks. And the patient did not receive additional vaccines on same date that administered BNT162B2. The patient experienced deaf and couldn't hear on 06Jan2021 09:00, leg cramps in both legs and toes curled out on 05Jan2021 19:00, dizzy on 05Jan2021, nauseous on 05Jan2021, threw up twice on 05Jan2021, things started looking funny on 06Jan2021 09:00, pain through whole body and tremoring on 06Jan2021 10:00, bruise at injection site on Jan2021. All the events (except for event bruise at injection site) were reported as seriousness as life threatening. Clinical course: the patient worked nightshift. Laid down that afternoon to take a nap and got up around 10:00. Around 05Jan2021 19:00 PM had sever leg cramps in both legs where her toes were curled out. Leg cramps after vaccine wouldn't go away and it was in both legs. Just wouldn't go away. Around 05Jan2021 21:00 PM it went away. The patient was dizzy, nauseous, and threw up twice on the night of 05Jan2021, and going into 06Jan2021. The patient went to the couch in the hotel room and started going deaf. She couldn't hear anything on 06Jan2021 around 09: 00 AM. Things started looking funny on 06Jan2021 around 09: 00 AM. Woke up at 09:35. Hour after that there was pain through her whole body and everything was hurting at 10:00 AM on

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06Jan2021. The patient was tremoring at 10:00 AM on 06Jan2021. Couldn't reach the phone to dial 9-11. Thought she was going to die. Last until about noon and then started to go away. Doesn't know if it is safe to take the second vaccine. Doesn't know if these are thing that should have happened to her. She started to get real concerned. Went into hotel room and started feeling dizzy again. Stopped haring things. Funny feeling in her ears. Was seeing things, got dizzy, and everything got dark. Everything lasted until 12:00 PM on 06Jan2021. Everything was good now. The patient had a bruise where injection was in Jan2021. Stated it was nothing compared to what she went through. Woke up around 10:00 AM. Then went back to sleep and got up around 18:00 PM. She felt fine. Her whole body was sore from the muscle spasming. The outcome of the event bruise at injection site was unknown, of the event leg cramps in both legs and toes curled out was recovered around 05Jan2021 21:00, the outcome of other remain events was recovered on 06Jan2021 12:00. The reporter considered (method of assessment: Global Introspection) that all the events were related to BNT162B2.; Sender's Comments: All the reported events were possibly related to the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), due to temporal relationship. However, it is worth noting that the 60-year-old female patient had car accidents history and had surgeries. All the events started when she worked nightshift, including leg cramps in both legs and toes curled out, nauseous, threw up twice, pain through whole body, tremoring and transient deafness. Patient did not get rest after vaccination may a risk factor to the onset of the events. 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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969110	1/24/2021	NC	35	F	12/28/2020	1/11/2021	12/28/20 - first dose of COVID Vacc; 1/11/21 - R sided tinnitus; 1/12/21 R sided hearing loss and loss of balance; visited ENT and diagnosed with Sudden Sensorineural Hearing Loss; 1/13/21 began 60mg Prednisone 7 days; 7 day taper off - no improvement in hearing by 1/24/21; ENT scheduled before second covid vaccine
968099	1/23/2021	CA	39	M	1/9/2021	1/20/2021	Acute sensorineural hearing loss
967519	1/23/2021	KS	52	F	1/2/2021	1/9/2021	Vaccine on Jan. 2. I had an achy arm on Jan. 3-4. No fever. Slight headache on Jan. 6-8. Feeling of sinus pressure on Jan.9 am. Could not hear out of right ear on Jan. 9 at 5:00 pm. By 7:00 pm I had excruciating pain in right ear and went to the ER. I was on Amoxicillin from Jan. 9-Jan. 22. I still had little to no hearing in right ear. On Jan. 22, the ENT diagnosed me with a moderate/severe conductive and sensorineural hearing loss with nerve damage. I had a ventilation tube placed in right ear on Jan.22 and placed on steroids to try to recover some hearing loss. I will follow up with the ENT in two weeks. Not sure yet if this is permanent damage.
966399	1/22/2021	MT	49	M	12/28/2020	12/29/2020	severe tinnitus and loss of hearing as some tones. persistent since day after vaccination and continuing through time of reporting to VAERS.
964726	1/22/2021	VI	42	F	12/30/2020	1/20/2021	12/30/2020 Four hours after vaccination - left arm soreness, mild headache above right eye. Client improved that evening. 1/20/2021 Four hours after second vaccine dose - Body aches, intense headache over right eye, The evening of the same day - Heaviness to left arm, increased pain to left arm radiating to hands, tightness to the left arm with a feeling of "electricity" in the arm. The pain increased in intensity to the left arm during the night. Unable to sleep due to intense pain to the left arm and axilla. 1/21/2021 In the morning, client experienced abdominal pain and diarrhea once (loose stool). She noted swelling to the left axilla, intense pain, swelling below the left jawline. 1/22/2021 Early morning nausea without emesis, itching of the right forearm and nape of the neck, throbbing pain to left axilla with itching, throbbing to the left ear, which has not been sensitive to pain due to deafness.

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964604	1/22/2021	CT	49	F	1/7/2021	1/10/2021	At 2 a.m. on January 10th, I woke up with a high pitched ringing sound in my head. The sound was constant and disrupts my sleep significantly. It is always present but not as noticeable during the day when there is noise in the surrounding area, however, my job requires a lot of report writing and for that I work in silence. Therefore, the ringing sound is very distracting and makes it hard to focus. I saw my general practitioner, on January 14th at 4:15 p.m.. She cleaned out my right ear and started me on a 6-day steroid. She did not clean out the left ear because it did not appear to have any wax buildup. I began taking the steroid on Saturday January 16th. The ringing is still there but it does seem to be more on my left side than my right now. I went to an ent specialist on January 19th who checked my hearing and said there was no hearing loss. Her recommendations were to call her in a week and if ringing doesn't go away, she will try another steroid. As of today, the ringing is still present and I have finished the course of steroid.

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962303	1/21/2021	MS	87	M	1/15/2021	1/17/2021	he smelled some kind of chemical; he began to feel real bad; This is a spontaneous report from a contactable consumer (patient's wife). An 87-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 15Jan2021 in left upper arm shoulder area at single dose for vaccination; glimepiride (manufacturer unknown), via an unspecified route of administration from 2020 and ongoing at 2 mg, 1x/day (once per day in the morning) for diabetes; vitamin d (manufacturer unknown, lot# 300015, expiration date: Jan2022), via an unspecified route of administration from 2019 and ongoing at 3000 iU, daily (2000 IUs in the morning and 1000 IUs nightly) for bone and immune health; acetylsalicylic acid (ASPIRIN, lot# P139558, expiration date: Aug2022), via an unspecified route of administration from an unspecified date and ongoing at 81 mg, 1x/day for helping thin his blood; apixaban (ELIQUIS, 2.5 mg), via an unspecified route of administration from 2018 and ongoing at 2.5 mg, 2x/day (morning and night) for blood thinner; simvastatin (ZOCOR, 20 mg), orally from an unspecified date and ongoing at 20 mg, 1x/day for cholesterol; metoprolol (manufacturer unknown, 50 mg), via an unspecified route of administration from an unspecified date and ongoing at 25 mg, daily (1/2 tablet once daily (25mg total daily dose)) for an unspecified indication; celecoxib (CELEXA), via an unspecified route of administration from an unspecified date and ongoing at unknown dose with daily (1-20 mg tablet once daily) for clinical depression; vitamin c (manufacturer unknown, lot# 205348, expiration date: Jun2023), via an unspecified route of administration from 2020 and ongoing at 1 DF, daily for supplement to boost immunity; famotidine (manufacturer unknown), via an unspecified route of administration from 2020 and ongoing at unknown dose with 2x/day (1-40mg tablet twice daily) for nauseated; cyanocobalamin (VITAMIN B12, 2500 mg, lot# 511333-01, expiration date: Jun2023), via an unspecified route of administration from 2020 and ongoing at 2500 mg, 1x/day for supplement; magnesium (manufacturer unknown, lot# 205340, expiration date: Jun2022), via an unspecified route of administration from an unspecified date and ongoing at unknown dose with daily (400 mg mostly every day but not strictly every day) to keep himself going; immuneti (manufacturer unknown, Capsule, NDC:

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2817636726), via an unspecified route of administration from an unspecified date and ongoing at 1 capsule taken daily for an unspecified indication. Medical history included bad hearing problem. This consumer called on behalf of her husband to ask about possible side effects he was having. She reported that these possible side effects could be from Pfizer COVID-19 Vaccine or his other medications: glimepiride; Vitamin D; acetylsalicylic acid; apixaban; simvastatin; metoprolol; celecoxib; Vitamin C; famotidine; Vitamin B12; magnesium; and Immuneti. She was concerned about the possible side effects and wanted to ask Pfizer if these possible side effects could be from the Pfizer COVID-19 Vaccine or his other medications. Caller's husband was administered the Pfizer COVID-19 Vaccine on 15Jan2021. Caller also got her Pfizer COVID-19 Vaccine on 15Jan2021. Neither patient or caller had any problems with the product initially. Then her husband had onset of possible side effects last night. Starting 17Jan2021 after patient took his usual night medications, which caller was unable to clearly define which of the other suspect products that included, patient began to feel real bad. He said he smelled some kind of chemical and caller said she did not smell anything. Patient got to feeling worse and worse and they stayed up fairly late to see if he got to feeling better. When he got up this morning: 18Jan2021, he was feeling some better. He came in the room and when he put his medications in his mouth, before he even got them swallowed, he began to feel bad again-caller was unable to clearly define which of the other suspect products that included. Patient had been on simvastatin a long time and one time they took him off of this and started it back; he had been back on this for about 1 year. Metoprolol was discarded after 10th and 9th of 2021, documented as provided by reporter. Patient started it maybe 2-3 years ago. Vitamin C was Over the counter product, start date was probably 6-8 months ago. Vitamin B12 was probably started about 6-8 months ago. Magnesium was Over the counter product and probably started about 6-8 months ago. Caller verified that there are no other relevant products/medical conditions to provide for this report. She mentioned separately that patient had a bad hearing problem so caller handled his calls for him. The action taken in response to the events for all drugs (except for bnt162b2) was dose not

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963474	1/21/2021	AZ	33	F	1/14/2021	1/15/2021	duration started on 1/15/21- current symptoms include, swollen left eye, numbness to left arm, fatigue , loss of hearing, chills

changed. Outcome of events were unknown. Information about Lot/Batch has been requested.



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962303	1/21/2021	MS	87	M	1/15/2021	1/17/2021	he smelled some kind of chemical; he began to feel real bad; This is a spontaneous report from a contactable consumer (patient's wife). An 87-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 15Jan2021 in left upper arm shoulder area at single dose for vaccination; glimepiride (manufacturer unknown), via an unspecified route of administration from 2020 and ongoing at 2 mg, 1x/day (once per day in the morning) for diabetes; vitamin d (manufacturer unknown, lot# 300015, expiration date: Jan2022), via an unspecified route of administration from 2019 and ongoing at 3000 iU, daily (2000 IUs in the morning and 1000 IUs nightly) for bone and immune health; acetylsalicylic acid (ASPIRIN, lot# P139558, expiration date: Aug2022), via an unspecified route of administration from an unspecified date and ongoing at 81 mg, 1x/day for helping thin his blood; apixaban (ELIQUIS, 2.5 mg), via an unspecified route of administration from 2018 and ongoing at 2.5 mg, 2x/day (morning and night) for blood thinner; simvastatin (ZOCOR, 20 mg), orally from an unspecified date and ongoing at 20 mg, 1x/day for cholesterol; metoprolol (manufacturer unknown, 50 mg), via an unspecified route of administration from an unspecified date and ongoing at 25 mg, daily (1/2 tablet once daily (25mg total daily dose)) for an unspecified indication; celecoxib (CELEXA), via an unspecified route of administration from an unspecified date and ongoing at unknown dose with daily (1-20 mg tablet once daily) for clinical depression; vitamin c (manufacturer unknown, lot# 205348, expiration date: Jun2023), via an unspecified route of administration from 2020 and ongoing at 1 DF, daily for supplement to boost immunity; famotidine (manufacturer unknown), via an unspecified route of administration from 2020 and ongoing at unknown dose with 2x/day (1-40mg tablet twice daily) for nauseated; cyanocobalamin (VITAMIN B12, 2500 mg, lot# 511333-01, expiration date: Jun2023), via an unspecified route of administration from 2020 and ongoing at 2500 mg, 1x/day for supplement; magnesium (manufacturer unknown, lot# 205340, expiration date: Jun2022), via an unspecified route of administration from an unspecified date and ongoing at unknown dose with daily (400 mg mostly every day but not strictly every day) to keep himself going; immuneti (manufacturer unknown, Capsule, NDC:

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2817636726), via an unspecified route of administration from an unspecified date and ongoing at 1 capsule taken daily for an unspecified indication. Medical history included bad hearing problem. This consumer called on behalf of her husband to ask about possible side effects he was having. She reported that these possible side effects could be from Pfizer COVID-19 Vaccine or his other medications: glimepiride; Vitamin D; acetylsalicylic acid; apixaban; simvastatin; metoprolol; celecoxib; Vitamin C; famotidine; Vitamin B12; magnesium; and Immuneti. She was concerned about the possible side effects and wanted to ask Pfizer if these possible side effects could be from the Pfizer COVID-19 Vaccine or his other medications. Caller's husband was administered the Pfizer COVID-19 Vaccine on 15Jan2021. Caller also got her Pfizer COVID-19 Vaccine on 15Jan2021. Neither patient or caller had any problems with the product initially. Then her husband had onset of possible side effects last night. Starting 17Jan2021 after patient took his usual night medications, which caller was unable to clearly define which of the other suspect products that included, patient began to feel real bad. He said he smelled some kind of chemical and caller said she did not smell anything. Patient got to feeling worse and worse and they stayed up fairly late to see if he got to feeling better. When he got up this morning: 18Jan2021, he was feeling some better. He came in the room and when he put his medications in his mouth, before he even got them swallowed, he began to feel bad again--caller was unable to clearly define which of the other suspect products that included. Patient had been on simvastatin a long time and one time they took him off of this and started it back; he had been back on this for about 1 year. Metoprolol was discarded after 10th and 9th of 2021, documented as provided by reporter. Patient started it maybe 2-3 years ago. Vitamin C was Over the counter product, start date was probably 6-8 months ago. Vitamin B12 was probably started about 6-8 months ago. Magnesium was Over the counter product and probably started about 6-8 months ago. Caller verified that there are no other relevant products/medical conditions to provide for this report. She mentioned separately that patient had a bad hearing problem so caller handled his calls for him. The action taken in response to the events for all drugs (except for bnt162b2) was dose not

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changed. Outcome of events were unknown. Information about Lot/Batch has been requested.

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962222	1/21/2021		39	F	12/18/2020	1/6/2021	Hearing loss; This is a spontaneous report from a contactable Nurse Anesthetist (patient). A 39-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/lot number: EL0140) on 18Dec2020 at single dose in the left deltoid for COVID-19 immunization. Medical history included ongoing anaemia. There were no concomitant medications. On 06Jan2021 at 16:00 the patient experienced hearing loss, serious as medically significant. Patient had no problems with her ears before hand. On 06Jan2021 around 4 PM, she was just walking in the store, with no loud music or anything, and all of a sudden her hearing in her left ear went lost and muffled. On 07Jan2021 she went to the Otolaryngologist (ENT doctor) to get her ears checked. They said no it looked perfectly fine. They did an audiogram and hearing test on 07Jan2021 and there was a 20% hearing loss. She had no idea what it was from. She took no other medications. She had anemia but that was it. She was wondering if hearing loss has been reported with the vaccine either in the studies or recently. She researched it, and with the COVID virus itself, back in Jul2020 and Oct2020, people reported hearing loss. So she went and had a COVID test in Jan2021 and it was negative. Patient stated it was very scary and weird. Event treatment included high dose oral steroids to see if it can be treated and the ENT doctor was also giving her steroid shots in the ear. She was due to see him again in Jan2021. The outcome of the event Hearing loss was not recovered. Patient also clarified that she did continue with her second dose of the vaccine on 08Jan2021. She had asked the ENT doctor his opinions on still getting the second dose, and he recommended it. The second dose of the vaccine was given on 08Jan2021 (lot EL3302, EXP: May2021) at single dose in the left deltoid for COVID-19 immunization.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported hearing loss 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

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Investigators, as appropriate.

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962303	1/21/2021	MS	87	M	1/15/2021	1/17/2021	he smelled some kind of chemical; he began to feel real bad; This is a spontaneous report from a contactable consumer (patient's wife). An 87-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 15Jan2021 in left upper arm shoulder area at single dose for vaccination; glimepiride (manufacturer unknown), via an unspecified route of administration from 2020 and ongoing at 2 mg, 1x/day (once per day in the morning) for diabetes; vitamin d (manufacturer unknown, lot# 300015, expiration date: Jan2022), via an unspecified route of administration from 2019 and ongoing at 3000 iU, daily (2000 IUs in the morning and 1000 IUs nightly) for bone and immune health; acetylsalicylic acid (ASPIRIN, lot# P139558, expiration date: Aug2022), via an unspecified route of administration from an unspecified date and ongoing at 81 mg, 1x/day for helping thin his blood; apixaban (ELIQUIS, 2.5 mg), via an unspecified route of administration from 2018 and ongoing at 2.5 mg, 2x/day (morning and night) for blood thinner; simvastatin (ZOCOR, 20 mg), orally from an unspecified date and ongoing at 20 mg, 1x/day for cholesterol; metoprolol (manufacturer unknown, 50 mg), via an unspecified route of administration from an unspecified date and ongoing at 25 mg, daily (1/2 tablet once daily (25mg total daily dose)) for an unspecified indication; celecoxib (CELEXA), via an unspecified route of administration from an unspecified date and ongoing at unknown dose with daily (1-20 mg tablet once daily) for clinical depression; vitamin c (manufacturer unknown, lot# 205348, expiration date: Jun2023), via an unspecified route of administration from 2020 and ongoing at 1 DF, daily for supplement to boost immunity; famotidine (manufacturer unknown), via an unspecified route of administration from 2020 and ongoing at unknown dose with 2x/day (1-40mg tablet twice daily) for nauseated; cyanocobalamin (VITAMIN B12, 2500 mg, lot# 511333-01, expiration date: Jun2023), via an unspecified route of administration from 2020 and ongoing at 2500 mg, 1x/day for supplement; magnesium (manufacturer unknown, lot# 205340, expiration date: Jun2022), via an unspecified route of administration from an unspecified date and ongoing at unknown dose with daily (400 mg mostly every day but not strictly every day) to keep himself going; immuneti (manufacturer unknown, Capsule, NDC:

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2817636726), via an unspecified route of administration from an unspecified date and ongoing at 1 capsule taken daily for an unspecified indication. Medical history included bad hearing problem. This consumer called on behalf of her husband to ask about possible side effects he was having. She reported that these possible side effects could be from Pfizer COVID-19 Vaccine or his other medications: glimepiride; Vitamin D; acetylsalicylic acid; apixaban; simvastatin; metoprolol; celecoxib; Vitamin C; famotidine; Vitamin B12; magnesium; and Immuneti. She was concerned about the possible side effects and wanted to ask Pfizer if these possible side effects could be from the Pfizer COVID-19 Vaccine or his other medications. Caller's husband was administered the Pfizer COVID-19 Vaccine on 15Jan2021. Caller also got her Pfizer COVID-19 Vaccine on 15Jan2021. Neither patient or caller had any problems with the product initially. Then her husband had onset of possible side effects last night. Starting 17Jan2021 after patient took his usual night medications, which caller was unable to clearly define which of the other suspect products that included, patient began to feel real bad. He said he smelled some kind of chemical and caller said she did not smell anything. Patient got to feeling worse and worse and they stayed up fairly late to see if he got to feeling better. When he got up this morning: 18Jan2021, he was feeling some better. He came in the room and when he put his medications in his mouth, before he even got them swallowed, he began to feel bad again-caller was unable to clearly define which of the other suspect products that included. Patient had been on simvastatin a long time and one time they took him off of this and started it back; he had been back on this for about 1 year. Metoprolol was discarded after 10th and 9th of 2021, documented as provided by reporter. Patient started it maybe 2-3 years ago. Vitamin C was Over the counter product, start date was probably 6-8 months ago. Vitamin B12 was probably started about 6-8 months ago. Magnesium was Over the counter product and probably started about 6-8 months ago. Caller verified that there are no other relevant products/medical conditions to provide for this report. She mentioned separately that patient had a bad hearing problem so caller handled his calls for him. The action taken in response to the events for all drugs (except for bnt162b2) was dose not

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962303	1/21/2021	MS	87	M	1/15/2021	1/17/2021	he smelled some kind of chemical; he began to feel real bad; This is a spontaneous report from a contactable consumer (patient's wife). An 87-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 15Jan2021 in left upper arm shoulder area at single dose for vaccination; glimepiride (manufacturer unknown), via an unspecified route of administration from 2020 and ongoing at 2 mg, 1x/day (once per day in the morning) for diabetes; vitamin d (manufacturer unknown, lot# 300015, expiration date: Jan2022), via an unspecified route of administration from 2019 and ongoing at 3000 iU, daily (2000 IUs in the morning and 1000 IUs nightly) for bone and immune health; acetylsalicylic acid (ASPIRIN, lot# P139558, expiration date: Aug2022), via an unspecified route of administration from an unspecified date and ongoing at 81 mg, 1x/day for helping thin his blood; apixaban (ELIQUIS, 2.5 mg), via an unspecified route of administration from 2018 and ongoing at 2.5 mg, 2x/day (morning and night) for blood thinner; simvastatin (ZOCOR, 20 mg), orally from an unspecified date and ongoing at 20 mg, 1x/day for cholesterol; metoprolol (manufacturer unknown, 50 mg), via an unspecified route of administration from an unspecified date and ongoing at 25 mg, daily (1/2 tablet once daily (25mg total daily dose)) for an unspecified indication; celecoxib (CELEXA), via an unspecified route of administration from an unspecified date and ongoing at unknown dose with daily (1-20 mg tablet once daily) for clinical depression; vitamin c (manufacturer unknown, lot# 205348, expiration date: Jun2023), via an unspecified route of administration from 2020 and ongoing at 1 DF, daily for supplement to boost immunity; famotidine (manufacturer unknown), via an unspecified route of administration from 2020 and ongoing at unknown dose with 2x/day (1-40mg tablet twice daily) for nauseated; cyanocobalamin (VITAMIN B12, 2500 mg, lot# 511333-01, expiration date: Jun2023), via an unspecified route of administration from 2020 and ongoing at 2500 mg, 1x/day for supplement; magnesium (manufacturer unknown, lot# 205340, expiration date: Jun2022), via an unspecified route of administration from an unspecified date and ongoing at unknown dose with daily (400 mg mostly every day but not strictly every day) to keep himself going; immuneti (manufacturer unknown, Capsule, NDC:

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961184	1/21/2021	WV	39	F	12/28/2020	1/15/2021	Sensorineural hearing loss in right ear. Currently on high dose prednisone.
957692	1/20/2021	PA	62	M	1/19/2021	1/19/2021	About eight hours after the injection, I noticed some hearing impairment in my left ear. Sounds are muffled, almost as if I have water trapped in the ear canal. I noticed this right before I went to bed, and the hearing loss is still present and similar in magnitude this morning. There is no pain, and the hearing in my right ear seems to be normal, although I can't rule out some slight loss on that side. Aside from a slightly sore arm at the injection site, I've had no other side effects (e.g., no fever) from the vaccination.
957720	1/20/2021	IN	34	F	12/23/2020	12/31/2020	Tinnitus, hearing loss in left ear started on 12/31/2020 and has not resolved. Vertigo and vomiting started on 1/12/2020 with a duration of approximately 48 hours then resolved.
959115	1/20/2021	FL	34	F	1/2/2021	1/3/2021	Tinnitus started in right ear within hour after receiving first vaccination but resolved within a couple of day. Within 24 hours of receiving second vaccination had muffled hearing, Jan 3, 2021. Symptoms were ignored thinking they would resolve. When symptoms persisted and evaluated patient was noted to have a severe right sided low frequency hearing loss with poor word recognition score. Patient was started on high dose steroids with partial recovery of symptoms.

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959293	1/20/2021	MD	68	F	1/8/2021	1/8/2021	Sudden Sensorineural Hearing Loss in left ear. Symptoms began Friday evening Jan. 8, 2021. Sounded like muffled sound in my ear, water running, ringing. Then on Saturday Jan.9, 2021 my left ear felt like it had to pop and I felt my hearing was impaired. By Sunday evening Jan. 10, 2021, I could barely hear out of my left ear. I called MD immediately Monday morning, Jan. 11, 2021 and was seen that afternoon. I was examined and had a hearing test. I was diagnosed with SSHL and started treatment of a series of steroid injections directly into my eardrum to save my hearing immediately. I have had 2 injections and hearing test since then. The doctors feel this was a side effect of the COVID vaccine due to my compromised immune system, but not an allergic reaction, but a side effect. I had the same condition about 15 years ago from a virus.
956704	1/19/2021	TX	39	M	1/6/2021	1/7/2021	Atypical ramsay hunt syndrome on right side. Vertigo started on 7JAN, tinnitus and hearing changes on 8 JAN, vertigo worsening 7-10 JAN, leading to significant headache, nausea and vomiting with complete PO intolerance, leading to ER visit on 13 JAN for fluid rehydration, medications (anti-vertigo, anti-nausea, steroids). CT Head unremarkable, CT soft tissue neck showed lymphadenopathy along with inflammation of right parotid consistent with acute parotitis. CXR normal. Labs relatively normal. Physical exam demonstrated vesicular lesions on right external ear and canal consistent with Ramsay Hunt syndrome. ENT evaluated and concurred. Audiology testing on 13 JAN demonstrated right mild-moderate sensorineural hearing loss. Patient discharged with Valtrex, PO prednisone, antivert.
955899	1/19/2021	CA	28	F	1/15/2021	1/15/2021	blood pressure drop, cold body, sweaty/clamy, dizziness, loss of hearing, shortness of breathe and unconsciousness/fainting. This happened 4 hours after vaccine was administered with a duration of 5 minutes.
955322	1/19/2021	OK	52	F	12/22/2020	12/22/2020	After 3 days 1st dose loose hearing then went to ER. They told me ears was clear no fluid given steroids' to take. I went Hearing specialist was told by doctor I have 80% right hearing loss.

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954426	1/19/2021	IL	43	F	12/29/2020	12/31/2020	Hospitalized for stroke on 31Dec two days after vaccine.; sudden loss of hearing to right ear; dizzy and lightheaded/severe dizziness/felt like fainting; difficulty breathing; vomiting; This is a spontaneous report from a contactable nurse (patient). This 43-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), (Lot number: EL1285) via intramuscular route on 29Dec2020 14:30 at single dose on the left arm for COVID-19 immunization. Medical history included anxiety. No known allergies. Concomitant medications were not reported. Patient was not pregnant. Facility type vaccine was Nursing Home/Senior Living Facility. No other vaccine received in four weeks. Patient hospitalized for stroke on 31Dec2020 two days after vaccine (Days of hospitalization: 4). Day of vaccine-6 hours after patient had dizzy and lightheaded for about 45 min then went away. On 31Dec2020 at 19:15 had sudden loss of hearing to right ear and severe dizziness, difficulty breathing, vomiting, and felt like fainting. Paramedics were called-sent to ER, had CTA which showed partial blockage and received TPA. Treatment included TPA, fluids, medications, hospital stay, outpatient follow ups, physical therapy. Patient was not diagnosed with COVID prior to vaccination. Patient has been tested for COVID post vaccination. The patient underwent lab tests and procedures which included Nasal Swab: Negative and Pixel: Negative on 08Jan2021. Outcome of the events was recovering.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported events including stroke, dizzy/lightheaded/felt like fainting, difficulty breathing, vomiting, and sudden loss of hearing to right, and the administration of the COVID-19 vaccine, BNT162B2. More information regarding the patient's underlying medical conditions, relevant lab tests would be helpful for the Company to make a more meaningful causality assessment.
956714	1/19/2021	NE	45	F	1/15/2021	1/15/2021	Vomiting 12 hours post vaccine. 24 hours post vaccine temps 104+ to 106.8 temp orally 30 hours post vaccine. Red swollen eyes 24 hours post vaccine. Ringing in ears and temporary loss of hearing comes and goes.

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953659	1/18/2021	WA	58	F	1/14/2021	1/14/2021	Within 1 hour MILD light headiness, passing headache, chills, sweating, Within 3 hours LEFT EAR HEARING LOSS about 25% to 50% have not yet resolved & ENT office recommends PCP prescribe prednisone rapid taper pack ASAP
952301	1/18/2021	CA	19	M	1/11/2021	1/15/2021	Jan 11-vaccination day. On Jan 14, in afternoon had tinnitus and muffled hearing that went away. The next morning Jan15, complete sudden hearing loss on left ear. Tinnitus and muffled hearing that has not went away.
951429	1/17/2021	IL	35	F	12/22/2020	12/27/2020	Sudden onset unilateral (left) sensorineural hearing loss and severe vertigo
951672	1/17/2021	WA	59	M	1/8/2021	1/10/2021	On 1/10/21, approximately 48 hours after the 2nd dose in the COVID vaccine series, I experienced ringing in right ear for about one hour, followed by sudden, complete, single-sided hearing loss in the right ear. The next day, some hearing was restored in the right ear but it was muffled. Examined by primary physician, and both both ears appeared normal. Referred to an otolaryngologist for an examination and hearing test which showed high-frequency hearing loss in the right ear. Prednisone 50 mg daily prescribed, with follow-up exam and hearing test schedule for 1/20/2021. No change in hearing, as of 1/17/2021, still muffled hearing with "full feeling" in right ear.
949935	1/16/2021	AR	20	F	1/15/2021	1/16/2021	Headache, fever, vomiting, slight loss of hearing in both ears, numb arm
949407	1/15/2021	CO	60	M	1/13/2021	1/13/2021	4.5 hours after receiving the COVID-19 vaccine second dose I experienced a sudden 50% loss of hearing in my right ear. I was otherwise asymptomatic. This persisted for 8 hours at which time my hearing mostly returned with perhaps only a 10% reduction. I had complete resolution after 24 hours.
944936	1/14/2021	AL	46	M	1/14/2021	1/14/2021	LOSS OF HEARING, HEART PALPATATIONS, TUNNEL VISION

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945116	1/14/2021	NY	43	F	1/4/2021	1/10/2021	I felt dizzy as soon as I got the vaccine. My heart rate increased but nothing to worry about. It took me at least 30 min to feel myself. That afternoon I felt L hip pinching pains and joints pain. A week later I had sudden vertigo , unable to walk normally with no tinnitus or loss of hearing . I took meclizine 50 mg and it helped. It?s already day 5 , vertigo has subsided , I still don?t feel myself but I am able to go around, drive and move. I only feel dizzy at times and feel vertigo when laying down
944275	1/14/2021	MI	72	M	1/6/2021	1/6/2021	complete hearing loss at the right ear, 5 hours post injection, continued till now 3 days past injection, not resolved yet prior to report; This is a spontaneous report from a contactable physician. A 72-years-old male patient started to receive bnt162b2 (BNT162B2) Lot number# ek9231 intramuscularly on 06Jan2021 12:00 at single dose for covid-19 immunisation. Anatomical Location: Arm Right. Facility where the most recent COVID-19 vaccine was administered: Hospital. Medical history included diabetes mellitus, hypertension. The patient did not received any other vaccines within 4 weeks prior to the COVID vaccine. Concomitant medication included alprazolam (AZOR [ALPRAZOLAM]), metformin hydrochloride, sitagliptin phosphate monohydrate (JANUMET [METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE MONOHYDRATE]), atorvastatin calcium (LIPITOR [ATORVASTATIN CALCIUM]). The patient on 06Jan2021 18:00 reported complete hearing loss at the right ear, 5 hours post injection, continued till now 3 days past injection, not resolved yet prior to report. The action taken was not applicable.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported hearing loss 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.
944917	1/14/2021	AL	46	M	1/14/2021	1/14/2021	LOSS OF HEARING, TUNNEL VISION, HOT, HEART PALPATIONS, ELEVATED HEART RATE, SWEATING

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942093	1/13/2021	OR	52	F	1/7/2021	1/8/2021	I had a mild headache the evening of the shot, I had a headache the next two days that was relieved by Advil. I had a very sore arm at the injection site Friday and Saturday after the shot was given. The arm pain was gone Sunday morning. I was very tired on Saturday especially and slept through the morning and early afternoon on and off until about 3:00 pm. On Friday during the day, I noticed my right ear starting to feel unusual and uncomfortable. On Saturday, the ear issue continued, I felt like I had some hearing loss and a constant buzzing and ear fullness feeling. On Sunday, the ear issue continued with the hearing loss, buzzing and fullness and has through today and hasn't stopped. I tried some nasal decongestant on Sunday afternoon, but it didn't have any effect. I made an appointment with the ENT doctor on Monday morning for Tuesday. I had a hearing test on Tuesday and saw the ENT doctor on Wednesday. He prescribed prednisone and ordered an MRI. I will be starting the prednisone later today (Wednesday) when the pharmacy has the prescription ready.
941891	1/13/2021	ND	46	F	12/22/2020	12/26/2020	Woke up on 26th and couldn't hear anything out of left ear - like I was deaf in that ear - Buzzing and constant titch in it. Went to ER and they first thought I had wax in it - couldn't hear after they flushed it with warm water. Didn't change anything . Did a brain MRI - and that was negative. Did some bloodwork - and it all came back okay. After all that - 6 hrs there: Prednisone - 60 mg a day for 10 days. After 24 hours of taking that my hearing was back - there was huge improvement. I Still have very loud ringing in my ear. Constant buzz in my ear. Had a hearing test to test and it looks pretty good. Going back in three months for hearing test.



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940811	1/13/2021	CO	36	F	1/4/2021	1/4/2021	hearing loss; ringing and pulsating in her ears; Chills; Headache; This is a spontaneous report from a contactable consumer (patient). A 36-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EK9231), via an unspecified route of administration in the left arm on 04Jan2021 at single dose for covid-19 immunization. Medical history included ongoing acid reflux. The patient had no concomitant medications. The patient previous received the flu shot. The patient experienced hearing loss, ringing and pulsating in her ears on 05Jan2021, headache on 04Jan2021, chills on 05Jan2021. Treatment was none. She had the vaccine on Monday at work and some of the symptoms that she has had have not resolved. She was having ringing in her ears and hearing loss. Went to see them and had her ears looked at. Everything was normal. Got the vaccine on 04Jan2021. Ringing in ears and hearing loss: Had been very consistent with no improvement. If anything, it had worsened. She was going to re-contact her doctor. She was also going to ask, should she go on Prednisone or something. She was worried she was going to lose her hearing. Her doctor said that a hearing test may need to be done. History: Takes one medication that she has been taking for years. She has never had an adverse event to any vaccine before. She got the flu shot every year. She was expecting the chills and headache, but they resolved fast. The next vaccine was 25Jan2021, the patient was asked whether she should get the second dose. The outcome of events for hearing loss, ringing and pulsating in her ears was not resolved, for headache and chills was resolved on 06Jan2021.
940373	1/13/2021	FL	46	F	1/5/2021	1/5/2021	Developed tinnitus the day I got first Pfizer COVID vaccine. Never had any known tinnitus nor hearing concerns nor hearing problems prior. Tinnitus is bilateral has been constant and continues now day 9 post vaccine. Did a hearing test that is showing mild sensorineural hearing loss in the high frequencies
937324	1/12/2021	NV	49	F	12/30/2020	12/31/2020	Had diminished hearing loss for 1 day, and sense of smell was affected, smelled vomit all day. This was the day after the vaccine. On Friday, I was back to normal. Thank God! No treatment needed.

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938087	1/12/2021	FL	34	F	12/16/2020	12/17/2020	<p>feeling of fullness in her ear; it felt like fluid in her right ear; Hearing loss in right ear; Soreness in the left arm; This is a spontaneous report from a contactable Other-HCP. A 34-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number # EH9899) 16Dec2020 at 07:40AM in the left arm at single dose via intramuscular for COVID-19 immunization. Medical history included seasonal allergy. Concomitant medications included fluticasone propionate for seasonal allergy. The day after vaccination she noticed soreness of the left arm. Then two days later she noticed hearing loss secondary to a feeling of fullness in her ear; it felt like fluid in her right ear which has improved and she states it was not serious after the first dose. Patient received the second dose of vaccine on 04Jan2021 at 08:00AM in the left arm. That night she experienced myalgia, fever, chills, back pain, and started with a constant ringing in her right ear and the hearing loss that worsened from before (reported under AER 2021012152. All of these effects have resolved except the hearing loss and ringing in her ear. Additionally she went to see an ENT doctor and get a hearing test. The Hearing test showed moderate hearing loss and speech clarity of 96% in her left ear compared to 52% in the right ear. They don't know if it is permanent. She was currently being treated with 80mg of Prednisone daily by mouth and getting Dexamethasone injections to her middle eardrum. Patient informed that on 17Dec2020 she was tested for COVID 19 with the PCR test due to an exposure at work. The result was negative. The patient recovered from soreness in the left arm on 19Dec2020. The patient had not yet recovered from deafness.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events ear congestion and hearing loss unilateral 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</p>

*VAERS\_ID RECVDATE STATE AGE\_YRS SEX VAX\_DATE ONSET\_DATE SYMPTOM\_TEXT*

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

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938089	1/12/2021	FL	34	F	1/4/2021	1/1/2021	constant ringing in right ear; Myalgia; Fever; Chills; back pain; Inappropriate schedule of vaccine administered; hearing loss that worsened from before; hearing loss that worsened from before; This is a spontaneous report from a contactable physician (patient). This 34-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot EH9899), via an unspecified route of administration, on 04Jan2021 at 08:00AM at single dose for COVID-19 immunisation. The first dose was received on 16Dec2020 at 7:40 AM at single dose. Vaccine location was in the left arm. The patient was vaccinated at hospital, age at vaccination was 34-years-old. No other vaccine was received in four weeks. Medical history was none. Concomitant medications included ongoing fluticasone propionate (FLONASE) for seasonal allergy taking for two years. On 17Dec2020, COVID-19 PCR test was negative. On 04Jan2021 at night, she experienced myalgia, fever, chills, back pain and started with a constant ringing in her right ear and the hearing loss that worsened from before (started on 18Dec2020 after first dose, see AER # 2021012126). Start date of constant ringing in right ear was 05Jan2021. The events resulted in Physician Office visit. Hearing loss in right ear worsened and constant ringing in right ear were reported serious as medically significant while the other events were reported as non-serious. She went to see an ENT doctor and get a hearing test. The hearing test showed moderate hearing loss and speech clarity of 96% in her left ear compared to 52% in the right ear. They don't know if it is permanent. She is currently being treated with 80mg of Prednisone daily by mouth and getting dexamethasone injections to her middle eardrum. All of these effects have resolved except the hearing loss and ringing in her ear. All the events were considered related to the vaccine per reporter.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation between vaccination and onset of 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

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							to RAs, Ethics Committees, and Investigators, as appropriate.
938209	1/12/2021	NY	36	F	1/7/2021	1/9/2021	In 2015 I developed vulvar ulcerations (approximately 5), periorbital edema, and sensorineuroal hearing loss following vaccination with Td, Hep A, Menactra, Yellow fever and typhoid vaccines. This was previously submitted as a VAERS. I was treated with high dose steroids with partial restoration of my hearing. I had these issues extensively worked up by GYN, ENT and Rheumatology. Since that time I have had spontaneous vulvar ulceration (typically 1 lesion) on 3 occasions over the past 5 years with no preceeding infections or clear triggers. Approximately 36h after second COVID vaccination I began to develop vulvar ulcerations-- currently have 4 -5 lesions. I also had body aches.
938248	1/12/2021	NY	36	F	1/7/2021	1/9/2021	in 2015 I developed 5-6 vulvar ulcerations, periorbital edema, sensorineural hearing loss following vaccination with Td, Menactra, Hep A, Yellow Fever and Typhoid-- previously reported to VAERS. I had an extensive w/u by ENT, Gyn & Rheumatology. I was treated with high-dose steroids and had near complete restoration of my hearing. In the past 5 years I have had 3 episodes of spontaneous vulvar ulcerations (typically 1 lesion) with no preceding infection or inflammation. It is possible I may have Behcet's syndrome, although there is no specific confirmatory test for this disorder. 36h after receiving my second COVID vaccination I developed 4-5 painful ulcers on the bilateral vulva. At this point I can manage with topical analgesics.
938310	1/12/2021	CO	37	F	12/31/2020	1/10/2021	Sudden hearing loss right ear accompanied by tinnitus
939132	1/12/2021	NJ	36	M	1/8/2021	1/11/2021	Tinnitus and partial hearing loss (likely sensorineural) in the left ear. No significant symptoms otherwise. Symptoms have progressed gradually since onset, and are constant. I am a physician and have not yet started any treatment nor had a specialist evaluation yet.

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933341	1/11/2021	AZ	33	M	1/4/2021	1/10/2021	Hearing loss to right ear and bad metatarsals/wrist joint pain. I worked 12 hrs night shift, around 0500, I started having joint pain on right wrist with minimal swelling. When I got home, I slept and woke up around 3PM, I started feeling my right ear can't hear, seems like I have a swimmers's ear, I have applied OTC swimmer's ear drops to help resolve it but no success.
934300	1/11/2021	NY	52	F	1/6/2021	1/7/2021	Muscle ache and tinnitus. Denies hearing loss
936453	1/11/2021	OH	63	F	1/7/2021	1/7/2021	Within 7 hours of receiving the vaccination I experienced significant hearing loss in my left ear. It felt like I could not pop my ear but I did not have a cold or allergy symptomw. Within 24 hours I could not hear well enough to use the telephone on the left side - barely heard the ring and could not hear a person talk. By the afternoon of January 9th my hearing had returned to near normal.
935956	1/11/2021	PA	17	F	1/4/2021	1/7/2021	Patient said she lost her hearing last Thursday (1/7/2021) around 6pm. She said she totally could not hear anything at all and she went to the ER at 11pm and stayed till 3am. Her hearing loss happened in her left ear and lasted for 5 days and started to hear sounds since Sunday and recovered. She described it as "there was pressure inside the ear" and she said she also went to her doctor and doctor said she had her hearing back 90% to 96%.
931380	1/9/2021	MI	72	M	1/6/2021	1/6/2021	patient received the vaccine at 12:00 pm on 01/06/2021 at the hospital. after 6 hours and at around 6:00 pm patient noticed that he has difficulty hearing in general, but didn't give it much attention since he was doubting the fact he couldn't hear. next day he noticed that all voices coming from the right side is completely dimmed. till he used his phone for a phone call he realized he couldnt hear form his right ear at all. he found out he does hear normally from his left ear. today is day 3 from receiving the vaccine, and the symptoms has not resolved. with complete hearing loss form his right ear. no improvement since the incident. no treatment or medical intervention has yet ocured prior to this report.

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931286	1/9/2021	MA	57	F	1/4/2020	1/5/2021	I am a physician and I got dose 2 at 1:30pm on Jan 4. Next afternoon, Jan 5, I got severe myalgias, fever up to 100, severe fatigue, went home after work and slept til the next morning, went to work, took ibuprofen, and the myalgias improved and felt better. But around 3 pm, Jan 6, I got mild vertigo. By about 7pm Jan 6, I noticed my L ear didn't hear well. I changed the battery in my hearing aide and cleaned it but It made no difference. I woke up on Jan 7 with severe vertigo and hearing loss. I did Epley's maneuvers with no effect. I have had similar episodes. I went to work, but gave up when I could not hear patients talking to me. I went to the Emergency Dept and got admitted. I was too unsteady on my feet. Audiogram showed profound hearing loss both ears and almost complete loss of discrimination in R ear. I was put on high dose steroids. Also having tinnitus (mostly whooshing sound of my own pulse). MRI negative. Blood work negative. Some mild improvement now, after 1 dose steroids.
931567	1/9/2021	FL	25	F	12/28/2020	1/6/2021	sudden sensorineural hearing loss in the right ear, audiology and ENT assessment, currently being treated with steroid medication
931978	1/9/2021	OH	30	F	1/3/2021	1/4/2021	Lost hearing in right ear. Developed severe tinnitus with hearing loss on the date after vaccine was administered. Initially developed rash near injection site. Rash has spread down entire right arm.
953192	1/9/2021		2	M	12/28/2020	12/28/2020	Headache, Fever & Tachycardia Narrative: Prior diagnosis of Covid-19 on 12-10-20. Reports having a headache when she received the vaccine. Later that evening her headache intensified into a migraine with blurred vision, left ear tinnitus the loss of hearing in left ear. She also reports tachycardia and temp of 100.2. She reports being treated with 2L NS, Torodal, solumedrol, and Ketamine. Treated at another facility, exact doses unknown.
930071	1/8/2021	LA	80	F	1/7/2021	1/7/2021	Patient states she had complete loss of hearing for 2-3 hours the evening after receiving the vaccination. She states that she took a Tylenol dose, and her hearing came back to normal a few hours later.

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930862	1/8/2021	LA	39	F	12/29/2020	1/2/2021	4 days after receiving vaccine, was awoken from sleep with high pitched tinnitus in right ear. I discovered in the morning that i could not hear out of that ear. My husband, a physician, examined ears and did not see any effusion. Consulted with a friend who is an ENT specialist, and he recommend initiating high dose steroids immediately. 2 days later, had audiology test in ENT office, and it revealed severe Sensorineural hearing loss in right ear. The steroids were continued, and valtrex was added. I had MRI of head on 1/7/20 which did not reveal any abnormality.
929394	1/8/2021	TX	79	M	12/29/2020	1/6/2021	Sudden onset of tinnitus followed by complete hearing loss in Right ear upon awaking from sleep (7 hours)



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925636	1/7/2021	MI	37	F	12/22/2020	12/23/2020	Moderate to severe headache 24-48 hours post injection. Complete sensorineural hearing loss in left ear 1 week after injection; Moderate to severe headache 24-48 hours post injection. Complete sensorineural hearing loss in left ear 1 week after injection; This is a spontaneous report from a contactable physician (patient). A 37-year-old female non-pregnant patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 17:15 at single dose on her left arm for covid-19 immunization. Medical history included known allergies to penicillin. The patient had no other medical history. There were no concomitant medications. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine and the patient was not received list of any other medications within 2 weeks of vaccination. 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 experienced moderate to severe headache 24-48 hours post injection. Complete sensorineural hearing loss in left ear 1 week after injection on 23Dec2020. These events resulted in doctor or other healthcare professional office/clinic visit, disability or permanent damage. The patient had received prednisone to treat the events. The outcome of the events was not recovered.; Sender's Comments: A possible contribution role of first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) to the onset of sensorineural hearing loss in left ear and headache cannot be excluded 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.
927307	1/7/2021	FL	58	M	12/28/2020	1/2/2021	ear fullness and loss of hearing on left ear, 4 days after getting vaccine

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925261	1/7/2021	TN	58	F	12/25/2020	12/25/2020	Within an hour of receiving the injection I lost 100% of my hearing in my right ear. Starting with some ringing, vertigo and then just silence. I called the Pfizer hotline, and they took down some information and then directed me to call the COVID hotline which resulted in pretty much the same. As it was Christmas day and the weekend, I waited to contact my Primary Physician on 12/30/20. She saw me immediately and sent me to a Specialist the next day to see Dr. for my hearing loss. There I was given an audiological assessment where my right ear was found to have moderately severe to profound sensorineural hearing loss in the right ear.
922680	1/6/2021	AZ	48	F	1/5/2021	1/5/2021	At approximately 18:00 on 01/05/2021 I noticed my hearing was hypersensitive. At about 20:00 I experienced hearing loss in my left ear like I had an ear infection. This morning I woke up and it is worse. I can barely hear out of my ear and I have tinnitus. I am dizzy and feel cautious.
922994	1/6/2021	MN	32	F	12/23/2020	12/25/2020	One day after vaccine (12/25/20) patient woke up with ringing in her ears, echoing, and diminished hearing. Ringing subsided 12/26/20 but diminished hearing continued. Seen by ENT 12/30/20 and diagnosed with hearing loss, right, with restricted hearing, left.
924747	1/6/2021	FL	34	F	12/16/2020	1/4/2021	Since the vaccine I have been having right sided hearing loss. Two days after my first dose I felt like I was underwater when talking to people, as their speech was distorted. I also felt pressure in my ear, as if it was filled with fluid, and was unable to "pop" my ears. I was evaluated by an ENT and there was no infection or fluid in my ear. It started to get better a little. After my second dose, the symptoms worsen. My hearing loss was back worse than the original time and this time I had tinnitus constantly. I also had chills, fevers, myalgia, back pain, and headaches.

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921049	1/5/2021	ME	40	F	12/19/2020	12/20/2020	bilateral tinnitus; This is a spontaneous report from a contactable physician (patient). A 40-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) lot number and expiration date were not reported, intramuscular in the arm left, first dose on 19Dec2020 09:30 at a single dose for Covid-19 immunization. Medical history included hypothyroidism. The patient previously took penicillin and had allergy with hives. The patient was not pregnant. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with Covid 19 nor was she tested for Covid 19. Concomitant medication included levothyroxine. The patient noticed onset of bilateral tinnitus that was constant and new since the injection. She doesn't know that it was related but it was very new in onset about 24 hrs after the vaccine and quite an obvious change. She mentioned that she is only 40 and has no known hearing loss and an ENT physician so can pinpoint no other triggers. The event resulted to a doctor or other healthcare professional office/clinic visit. No treatment received for the event. The outcome of the event bilateral tinnitus was not recovered. Information on the lot/batch number has been requested.

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918784	1/4/2021	CT	42	F	12/16/2020	12/22/2020	<p>Left sided hearing loss; This is a spontaneous report from a contactable physician who was also the patient. A 42-year-old non-pregnant female patient received bnt162b2, lot number and expiration date were unknown, via an unspecified route of administration on 16Dec2020 , 8:30 at a single dose for covid-19 immunization. The patient's medical history included antiphospholipid antibody from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. On 22Dec2020, the patient experienced left sided hearing loss. It was unknown if patient received treatment for the event. The outcome of the event was not recovered. The patient was not diagnosed with COVID prior to vaccination and has not been tested for COVID-19 since vaccination. Patient has no allergies. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Information on the lot/batch number has been requested.; Sender's Comments: As an individual case report there is not enough evidence to establish a causal relationship with the suspect vaccine. Currently there is no clear biological plausibility between the vaccine use and the even onset. More information such as complete medical history and concomitant medications are needed for fully medical assessment. 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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918793	1/4/2021	NC	69	M	12/21/2020	12/1/2020	Sudden onset Acoustic Neuritis without Labyrinthitis, hyperacusis, loss of hearing, fullness in ears, dizziness and tinnitus.; Sudden onset Acoustic Neuritis without Labyrinthitis, hyperacusis, loss of hearing, fullness in ears, dizziness and tinnitus.; Sudden onset Acoustic Neuritis without Labyrinthitis, hyperacusis, loss of hearing, fullness in ears, dizziness and tinnitus.; Sudden onset Acoustic Neuritis without Labyrinthitis, hyperacusis, loss of hearing, fullness in ears, dizziness and tinnitus.; Sudden onset Acoustic Neuritis without Labyrinthitis, hyperacusis, loss of hearing, fullness in ears, dizziness and tinnitus.; Sudden onset Acoustic Neuritis without Labyrinthitis, hyperacusis, loss of hearing, fullness in ears, dizziness and tinnitus.; sore arm; nerve related hearing loss; This is a spontaneous report from a contactable physician reporting for himself. A 69-years-old male patient received bnt162b2 (BNT162B2; Lot : EKS730) vaccine , intramuscular in the left deltoid on 21Dec2020 15:30 at single dose for covid-19 immunisation . Medical history included atrial fibrillation from 2009. There were no concomitant medications. The patient stated he experienced sore arm on the same day 21Dec2020 and this was not a big deal. On 26Dec2020 the patient experienced sudden onset of acoustic neuritis without labyrinthitis, hyperacusis, fullness in ears, dizziness and tinnitus . The patient also experienced nerve related hearing loss from Dec2020. Sore arm was considered non serious events, while the remaining were considered Important Medical Events. The outcome of nerve related hearing loss was recovered, the outcome of sore arm was unknown, while the outcome of the remaining events was recovering.; Sender's Comments: Based on the temporal association, it cannot be fully excluded that the vaccination with BNT162B2 might play a contributory role in the events onset. 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.
919138	1/4/2021	HI	64	M	12/16/2020	1/3/2021	Sudden profound sensorineural hearing loss-left ear

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918387	1/4/2021	NJ	63	M	12/24/2020	12/28/2020	True vertigo - room spinning dizziness, perceived motion, made worse with changes in head position. Nausea and vomiting at extremes of vertiginous symptoms. Also generalized fatigue noted. No fever, chills, diaeresis, headache, hearing loss, loss of taste or smell, cough, or nasal congestion, muscle aches, body aches or myalgias.
916200	12/31/2020	NC	69	M	12/21/2020	12/26/2020	On Day 4 after vaccine, sudden onset of bilateral fullness in ears, tinnitus, hearing loss, hyperacusis without vertigo. Weber's test did not lateralize. Rinne's test showed Air conduction greater than bone conduction consistent with neurosensory loss. Started on dexamethasone 8 mg a day for 3 days and symptoms essentially resolved.
915639	12/31/2020	IN	64	F	12/29/2020	12/30/2020	I felt very fatigued on 12/30/2020, and noticed my hearing was decreased by evening. I woke up on 12/31/2020, with total loss of hearing in my left ear and decreased hearing in my right ear.
915074	12/30/2020	MN	32	F	12/23/2020	12/25/2020	24 hours post vaccine: 12/25: I woke up with ringing in my ears, my ears feeling plugged, loss of hearing, echoing sounds. 12/26: ringing went away. Every other symptom remained. Worked through the weekend and couldn't get seen by an ENT due to scheduling until 12/30.

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910578	12/28/2020	IL	53	F	12/19/2020	12/20/2020	ringing in the ear; unable to hear out of the right ear; This is a spontaneous report from a contactable nurse. A 53-year-old female patient (and nurse) started to receive bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EJ1685), intramuscularly in the left arm on 19Dec2020 at 08:00 at 53-year-old at a single dose for COVID-19 immunization. The vaccine was administered at a hospital. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within four weeks prior to the COVID-19 vaccine. Medical history included asthma, mitral valve prolapse, Sulfonamide allergy, and allergies to tree nuts; all from an unknown date and unknown if ongoing. Concomitant medications included atorvastatin (MANUFACTURER UNKNOWN), escitalopram oxalate (LEXAPRO), fluticasone propionate (FLOVENT); all taken for an unspecified indication from an unspecified date to an unspecified date (received within two weeks of vaccination). On 20Dec2020 at 14:00, the patient experienced: unable to hear out of the right ear (medically significant). On 21Dec2020 at 02:00, the patient experienced: ringing in the ear (non-serious). The clinical course was reported as follows: Approximately 30 hours post-vaccination, the patient was unable to hear out of her right ear. It progressively worsened; however, by 02:00, the patient's hearing returned, and the patient developed a ringing in her ear. By 14:00, all the symptoms had disappeared. There was no treatment received due to 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 clinical outcome of the event, unable to hear out of the right ear, was recovered on 21Dec2020 at 02:00. The clinical outcome of the event, ringing in the ear, was recovered on 21Dec2020 at 14:00.; Sender's Comments: A possible contribution role of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) to the onset of event deafness right ear cannot be excluded due to temporal relationship. 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

*VAERS\_ID RECVDATE STATE AGE\_YRS SEX VAX\_DATE ONSET\_DATE SYMPTOM\_TEXT*

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Committees and Investigators, as appropriate.



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907944	12/23/2020	KS	34	F	12/22/2020	12/22/2020	<p>Progress Notes PA-C (Physician Assistant) ? ?  Orthopedics Cosigned by: MD at 12/22/2020 9:48 AM  Patient: Date:  12/21/2020</p> <p>Subjective Patient is a 34 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 right deltoid muscle. During her 15 minute waiting period after the injection, the patient began to experience generalized feelings of "not feeling quite right" as well as anxiety/nervousness, nausea and chills. She denied difficulty breathing, throat tightness, dizziness, chest pain, or other GI complaints. This provider noticed her raising her hand from across the waiting area and tended to her where she noted the above complaints. she was then assessed in the emergency bay area. She was monitored for severe reaction symptoms, including rapid progression of symptoms, vomiting, hypotension, chest pain, collapse and Respiratory distress. Past medical history includes anxiety for which she takes Effexor on a daily basis as well as type 2 diabetes, diagnosed approximately seven or 8 years ago during a pregnancy. She is on oral medication during the day and insulin at nighttime. She did take her oral medication today and last ate a pasta lunch right before arriving to the vaccine clinic. Last A1c was 6.5. Patient states that she generally runs a postprandial blood glucose following a heavy meal of about 180. She reported a previous history of anxiety and nervousness following vaccinations in the past. Most recently, she experienced a 30-minute period of anxiety and nervousness following her flu vaccine this past October. These feelings passed without further incidents. Review of Systems Constitutional: Positive for chills. HENT: Negative for drooling, facial swelling, hearing loss, rhinorrhea, sneezing and trouble swallowing. Eyes: Negative for redness and visual disturbance. Respiratory: Negative for cough, chest tightness and shortness of breath. Cardiovascular: Negative for chest pain. Gastrointestinal: Positive for nausea. Negative for vomiting. Skin: Negative for color change, pallor and rash. Neurological: Negative for dizziness, speech difficulty and light-headedness. Psychiatric/Behavioral: Negative for agitation and confusion. The patient is nervous/anxious.</p>

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Objective She ambulates into the emergency treatment bay under her own power and without difficulty. She is seated on the gurney, and continues to answer questions appropriately. Physical Exam Constitutional: General: She is not in acute distress. Appearance: Normal appearance. She is not toxic-appearing or diaphoretic. HENT: Head: Normocephalic and atraumatic. Nose: No rhinorrhea. Cardiovascular: Rate and Rhythm: Regular rhythm. Tachycardia present. Pulmonary: Effort: Pulmonary effort is normal. No respiratory distress. Skin: General: Skin is warm and dry. Coloration: Skin is not pale. Findings: No rash. Neurological: Mental Status: She is alert. Gait: Gait normal. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal.

Assessment/Plan Stress reaction secondary to vaccine administration and history of anxiety and nervousness following vaccinations. Vital signs obtained at 1352 with blood pressure at 154/95, mild tachycardia at 109 and 97% O2 saturation on room air. Patient denies any chest pain, shortness of breath time. She is given a bottle of water and assisted to lie down with the head of the bed slightly elevated. She continues conversating appropriately without any acute distress. Vitals reassessed at 1359 with blood pressure of 133/76, heart rate 97% on room air. Dr. at the bedside now. Suggested obtaining a blood glucose. Blood glucose obtained at 1405, elevated at 234. She continues to deny any chest pain, shortness of breath, chest tightness, swelling in the throat, nausea/vomiting or other GI complaints. Vital signs checked again at 1406 with blood pressure 133/77, heart rate 107 and 97% on room air. Vital signs last checked at 1415 to reveal a blood glucose of 219, blood pressure 127/82, heart rate 100 and O2 saturation of 97% on room air. Patient has no additional complaints at this time and reports feeling well. Her mother has driven her to the clinic today. She felt that she was able to safely walk out with any issues. She was assisted by nursing staff and ambulated out of the treatment bay independently. Treatment included routine surveillance of vital signs at about a 5-minute intervals following notification of her feeling poorly. Vital signs continued to normalize and remained stable through the duration of her 30 minutes following her vaccination. Follow up response to treatment: excellent.

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							Patient discharge: Stable to go home and follow up with PCP. Recommend to patient that she present to the ED or call 911 should she develop any symptoms up to and including but not limited to chest pain, shortness of breath, chest tightness, signs or symptoms of angioedema, or syncope. She expresses understanding the above and has no further questions today. Orders Placed This Encounter Procedures COVID-19 MRNA PA-C Electronically Signed 12/21/2020 1:51 PM
906125	12/22/2020	PA		M	12/16/2020	12/17/2020	Hearing loss; Severe tinnitus; This is a spontaneous report from a contactable pharmacist. A male patient of an unspecified age received first dose of BNT162B2 (solution for injection, lot number: EK5730, Expiry Date: 31Mar2021, NDC number: 59267-1000-01), intramuscularly on 16Dec2020 at 0.3 mg, single in deltoid for prevention of COVID viral infection. The patient's medical history and concomitant medications were not reported. The patient's wife is COVID positive, but he has not been tested and has no other symptoms. On 17Dec2020, the patient experienced hearing loss, and severe tinnitus. There is no additional vaccines administered on same date of the Pfizer suspect. The outcome of both events was not resolved.; Sender's Comments: The reported information is limited. 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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905805	12/21/2020	KS	33	F	12/21/2020	12/21/2020	<p>Date: 12/21/2020</p> <p>Subjective Patient is a 33 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 feelings of hypoglycemia. She checked her blood glucose with her own monitor and had 77 at 1104. She chewed 1 glucose tab that she had in her purse. She noted some difficulty with swallowing it and notified clinic staff. Associated dizziness and was escorted by clinic staff to the emergency bay. This provider was notified of patient reaction and she was then assessed in the emergency bay area. She denied difficulty breathing and chest pain, history of adverse reactions with prior vaccinations or allergies to medications with the exception of spironolactone. Patient had already been given a bottle of water by clinic staff and reported that the glucose tablet went down easier following the water. She took a second glucose tab sometime before 1113. She rechecked her sugar and had slight increase of 79. She did eat breakfast this morning about 0800 and had a protein bar right before her arrival today. Monitored patient for severe reaction symptoms, including rapid progression of symptoms, respiratory distress with dyspnea and increased work of breathing, vomiting, abdominal pain, hypotension and chest pain. Review of Systems HENT: Positive for trouble swallowing. Negative for facial swelling, hearing loss, rhinorrhea and voice change. Eyes: Negative for redness. Respiratory: Negative for cough, chest tightness and shortness of breath. Cardiovascular: Negative for chest pain. Skin: Negative for color change, pallor and rash. Neurological: Positive for dizziness. Negative for syncope and speech difficulty. Psychiatric/Behavioral: Negative for agitation and confusion. The patient is not nervous/anxious. Objective Vitals There were no vitals filed for this visit. Physical Exam Constitutional: General: She is not in acute distress. HENT: Head: Normocephalic and atraumatic. Nose: No rhinorrhea. Cardiovascular: Rate and Rhythm: Normal rate and regular rhythm. Pulmonary: Effort: Pulmonary effort is normal. No</p>

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respiratory distress. Skin: General: Skin is warm and dry. Coloration: Skin is not pale. Findings: No rash. Neurological: Motor: No weakness. Psychiatric: Mood and Affect: Mood normal. Behavior: Behavior normal. Assessment/Plan Patient is a 33-year-old female who has a 15-year history of type 2 diabetes, and experienced a hypoglycemic event without complaint of chest pain or shortness of breath. Vital signs obtained at 1105 with blood pressure within normal limits at 132/88, heart rate 83 and 98% O2 saturation on room air. Patient continued to compensate appropriately and reported feeling slightly better. Glucose checks repeated by patient at 1117 was 84, vital signs were blood pressure 116/80, heart rate 89, O2 saturation of 98% on room air. She continues to deny chest pain, shortness of breath or difficulty swallowing at this time. At 1117 a 10 mg cetirizine was administered by mouth. Patient was able to swallow this with a small sip of water without any difficulty. 1121, patient continues to deny chest pain or shortness of breath. She continues to be compensating appropriately and sitting at the edge of the bed. She states that she is feeling better. Vital signs obtained at 1123 with blood glucose per the patient's own meter, continuing to elevate at 103, blood pressure within normal limits at 116/91, heart rate at 85 and 100% O2 saturation on room air. At 1126, the patient continues to feel better. She is provided a granola bar to eat. She does note feeling sleepy though attributes this to this being the first day she has had off after working 4 days last week. She notes that she has been sleepy even prior to her arrival at the vaccine clinic today. She is able to eat the granola bar and continues conversing appropriately without difficulty. She continues taking small sips of water without issues. Continues to deny chest pain or shortness of breath. Blood sugar is rechecked at 1138 and continues to elevate to 116. She reports that her meter says her sugar is "stable." Final set of vital signs obtained at 1138 revealed blood glucose within normal limits at 116, blood pressure of 119/84, heart rate 83 and 100% O2 sats on room air. Patient denied complaints of chest pain, shortness of air, nausea, dizziness or blurred vision at this time. She felt much improved and we discussed her leaving the clinic and heading home to have lunch. She had no further complaints. She was able to rise to standing on her own

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							without any further issues and ambulated out of the clinic without difficulty. She was advised with strict return precautions should she develop chest pain or shortness of breath to present to the ED or call 911. She expressed understanding of this. LPN, RN, PharmD present through this encounter and assisted as asked of the, by this provider. Follow up response to treatment:excellent. Patient discharge: Stable to go home and follow up with PCP. Orders Placed This Encounter Procedures ? COVID-19 MRNA LNP-S PF PA-C Electronically Signed 12/21/2020 11:17 AM
905499	12/21/2020	IL	53	F	12/19/2020	12/20/2020	Approximately 30hrs. post vaccine I experienced hearing loss in my right ear. I could hear very little and it became worse within the next few hours. 12hrs after this began, my hearing came back and I then acquired a ringing in my right ear. This progressively lessened, and about 24 hrs after the initial hearing loss started, all the symptoms dissipated.
904331	12/19/2020	OR	45	M	12/18/2020	12/19/2020	28 hrs after vaccine, woke up with tinnitus R ear, partial hearing loss R ear - went to Urgent care - Dr diagnosed with right sensorineural hearing loss with left side unrestricted hearing - prescribed prednisone 60mg a day x10days. Audiology test to be scheduled next week.
903344	12/18/2020	PA	50	M	12/16/2020	12/17/2020	severe, acute hearing loss and tinnitus in R ear.