

## COVID Vaccine VAERS Reports for Stroke - April 10, 2021

Notes	Vaccine Type	Vaccine Manufacturer	VAERS ID	Age	Onset Interval	Adverse Event Description
	COVID19 VACCINE	JANSSEN	1105748-1	65+ years	0 days	Thursday, March 11, 2021 (approximately 8:30 am) Patient experienced blurred vision, unbalance, and slurred speech and had an irregular heartbeat. March 11, 2021 (approximately 11:30 am) Patient was admitted to Hospital administered CT scan, MRI and multiple blood tests. Diagnosis - Ischemic Stroke
	COVID19 VACCINE	JANSSEN	1117550-1	65+ years	0 days	Stroke
	COVID19 VACCINE	JANSSEN	1149738-1	40-49 years	0 days	Patient presented to Medical center with right sided MCA stroke (proximal M1) occlusion. She underwent tPA therapy and is recovering. She has a history of breast cancer that was treated in 2017. It's unclear to us whether or not these events are related. However, given the thrombosis occurred on the same day as the vaccine was administered, we felt it was a reportable event
	COVID19 VACCINE	MODERNA	0911035-1	40-49 years	0 days	Approximately 7 hours after receiving the vaccine patient who is a L&D Nurse return to work in her area. She describes that after finishing with a C-section she felt burning in both of her eyes (she thought this feels like an allergic reaction, but I am not sweating and haven't rubbed my eyes). She went to the restroom to get a cloth to wash her eyes; afterwards she reports her vision went totally black in both eyes. She reports feeling frustrated that no one came to help and some panic in trying to figure out how to get out of the restroom. She did make it out of the bathroom. Her Staff reports she postured and turned arms inward, head going to one side and passed out. They also report ~ 10 minutes of incoherent conversation and stating ""I got the vaccine, maybe I was given the wrong thing and now I'm blind"". Upon waking, patient vision fully restored and patient does not remember incoherent conversation. Differential diagnosis- TIA vs. CVA > seizure disorder>>> complex migraine""
	COVID19 VACCINE	MODERNA	0912877-1	18-29 years	0 days	Immediately after getting the vaccine she complained of headache. She had warm feeling at injection site She H/A Thursday, Friday and Saturday at mid-day her boyfriend called and said weakness in Right arm right face droop, no speech she was taken to the ER at 1 pm approximately. She was admitted and was dx was CVA . 2 TIA on left side of brain. Stopped Birth control and physician said it could be a combination of both birth control and vaccine.
	COVID19 VACCINE	MODERNA	0941476-1	40-49 years	0 days	Patient received vaccine in afternoon of 12/28. She works in ER as housekeeper 7pm-7am. The day she received the vaccine she became ill with fever chills and nausea and left work at 2am. On 12/31 she developed hemianopia. She went to ER and they did CT scan. She was told it was complex migraine. She left and came Home. On 1/1/21 her vision was back to normal. On 1/3 she suffered bilateral cerebellum ischemic stroke. She is currently in medical center. In Trauma.
	COVID19 VACCINE	MODERNA	0943223-1	60-64 years	0 days	The night of vaccination (12/28/20), pt developed mental ""fogginess"" with impaired alertness, remained oriented x4. She saw her primary care physician who ordered bloodwork and a brain MRI. On 1/8/21 pt reported that the mental fogginess had improved but she had developed a rash at the injection site. The rash cleared by 1/14/21.""
	COVID19 VACCINE	MODERNA	0967214-1	65+ years	0 days	Within 1/2 hour of vaccination the patient was dizzy and was having a hard time remaining upright, additionally the patient was less alert and oriented. Patient was observed for a few minutes and then ambulance was called. Patient was transported via EMS within an hour of being vaccinated to local hospital. Patient was found to have had major stroke and is presently in ICU and not expected to make it.
	COVID19 VACCINE	MODERNA	0972363-1	50-59 years	0 days	1/6/21 5:30 pm Client was at her patients house and stood up to leave and was ""walking like I was drunk."" Felt like her leg was asleep. Got to her car and drove to next patients house. Noticed Rt. sided weakness and knee buckling. Drove herself home and went to bed. 1/7/21 Woke up to increased symptoms, Rt hand and Rt. leg weak, slurring speech. hospital by rescue. Admitted X 7 days. CT SCAN with and without contrast showed no bleed. Telemed Visit, MD ordered MRI to rule out Cerebellum Stroke. MRI showed cerebellum stroke. Transferred to A Rehabilitation X 7 days. Has regained most of her normal functions, continues outpatient therapy.""
	COVID19 VACCINE	MODERNA	0974040-1	65+ years	0 days	high fever, severe pain, dizziness, vomiting, internal bleeding, stroke, sepsis

COVID19 VACCINE	MODERNA	0986910-1	65+ years	0 days	L MCA stroke
COVID19 VACCINE	MODERNA	0987301-1	65+ years	0 days	My Mother was given the Covid Vaccine (1st Dose) on 12/28/2020. Later that night we received a call from the nursing facility that my Mother was having uncontrollable seizures and had to be transported to the nearby hospital. The ER doctor confirmed that my Mother had tested positive to Covid. She was treated for Covid and was on life support. A few days later we received a call that my Mother had a major stroke. She passed away on January 4, 2021
COVID19 VACCINE	MODERNA	0987423-1	65+ years	0 days	Patient received COVID vaccine #1 at 5pm. At around 9pm, she went to bathroom and noticed that she felt dizzy, shortly thereafter she noticed that her speech was slurred. Her daughter saw that her mouth was droopy and called 911. Pt took 3 baby ASA at that time as well. Patient evaluated in ED for stroke, CT/CTA normal, TPA not given. Admission diagnosis CVA vs Bell's palsy (mild). MRI consistent with changes suspect acute infarct. No arrhythmias noted. ECHO unremarkable.
COVID19 VACCINE	MODERNA	0992372-1	65+ years	0 days	This is a 73 year old female that received her 1st dose with Moderna vaccine on 1/8/21 at approximately 1600. Within one hour, the patient developed altered mental status and increasing weakness. She was transported to the hospital by the staff at her Assisted Living Facility for concern of a vaccine reaction. On admission, oxygen saturation was found to be 89% on room air, BP=137/86, HR=94. Labs were normal, with the exception of WBC=15 (leukocytes normal, chest xray clear, COVID test negative), and a detectable troponin=63. Head CT negative. Physical exam was only notable for 'slight superficial erythema over distal right forearm and dorsal hand. No significant edema.' The patient was treated for a possible allergic reaction to vaccine with NS bolus, methylprednisolone 125mg, famotidine 20mg, and aspirin 300mg PR. She was admitted for monitoring given continued altered mental status/weakness. The next day, she continued to show no improvement, so a head MRI was ordered. MRI showed "" 1. Numerous acute cerebral and cerebellar infarcts involving both anterior and posterior circulations consistent with a central embolic source. 2. Minimal right parietal petechial hemorrhage. 3. Moderate atrophy and moderate nonspecific white matter signal abnormalities compatible with chronic microvascular ischemia "" Neurology was consulted, who approved the start of aspirin and to continue DVT prophylaxis. The patient's advanced dementia and timeline preclude other intervention. The patient's status was DNR/DNI. The patient was discharged on hospice to her assisted living facility on 1/11/21 (with reports of continued somnolence). It was reported that date of death was 1/24/21.""
COVID19 VACCINE	MODERNA	0992977-1	65+ years	0 days	spoke with patient husband on Saturday 1/23 and he said that she had been in the hospital. that she had had a stroke, the MD's at the hospital told him that it was not contributed to the vaccine and that they were unsure even if the stroke had occurred prior to the vaccine or after. spoke with him again on 1-29 and he stated that she had passed away on 1/25/21
COVID19 VACCINE	MODERNA	0995419-1	30-39 years	0 days	Shortness of breath, abnormal ECGs, lack of oxygen to the heart, numbness of legs and arms, tachycardia (130-160) for over 12 hours, difficulty breathing, bilateral pin point pain in legs, dizzy, syncopal convulsions, fainting, hyperventilation, vomiting, chills, headache, heart pain, fever, kidney pain
COVID19 VACCINE	MODERNA	0997677-1	65+ years	0 days	Rapid decline in health status, Elevated BP&P, posturing, loss of consciousness, Glasgow coma Scale 4 starting 2/1/2021, Deceased 2/3/21
COVID19 VACCINE	MODERNA	1002073-1	65+ years	0 days	Extreme pain in L arm injection site immediately after injection, followed by extreme fatigue, constant L arm pain, ache in body, on Tuesday-Friday, Saturday felt weak and extremely nauseous, at 2:00 pm experienced a embolic stroke on the right side of the brain and paralysis on the left side of body, rushed to ER, administered TPA clot buster and had a removal of the clots by Dr.

COVID19 VACCINE	MODERNA	1031466-1	65+ years	0 days	Minor stroke; Weak muscles; Terrible pain in neck and lower back; Terrible pain in neck and lower back; Nerve pain; Achy; Injection site reaction; A spontaneous report was received from a consumer who was also a female patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced C, injection site reaction, and achy. The patient's medical history was not provided. Concomitant medications were not reported. On 21 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Batch number: 043L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 21 Jan 2021, after vaccine administration, the patient experienced injection site reaction. On 22 Jan 2021, she was feeling achy. On 23 Jan 2021, she had nerve pain that felt like cutting on the back, legs, and arms. On 24 Jan 2021, the patient's muscles were weak and were not working or responsive on both sides. On 25 Jan 2021, the patient could not control her left hand and weakness was more predominant on left side. The patient went to the doctor and was hospitalized with minor stroke for 24 hours. The patient stated that she was still experiencing terrible pain in neck and lower back. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of events, minor stroke, weak muscles, nerve pain, injection site reaction, and achy, was unknown. The outcome of event, terrible pain in neck and lower back, was considered not resolved.; Reporter's Comments: Based on the current available information and evidence of a temporal association between mRNA-1273 use and the onset of injection site reaction and achy, a causal relationship cannot be excluded. There is limited information to assess causality for the events of injection site reaction, and achy. Additional information has been requested.
COVID19 VACCINE	MODERNA	1036498-1	60-64 years	0 days	According to the information I have gathered, she became dizzy, nauseated, vomiting later in the day. This continued for nearly two weeks. She then presented to an emergency room and was diagnosed with a cerebellar stroke that likely started on the same day as her vaccine per that physicians report.
COVID19 VACCINE	MODERNA	1042801-1	50-59 years	0 days	"Moderna COVID-19 Vaccine EUA"" Hypersensitivity & fleeting / flowing pains spread throughout left side of body from tip of nose across face, up and down neck and left side of head out through fingers of left hand, down left side of back, down left thigh / leg and out through toes of left foot. It was as if the left side of my body was in a different time zone than the right side. I called the nurse line; they suggested a visit to the ER. My BP was way up, and I panicked just a little; but, tried to use my mindfulness practice to observe the unfolding events, rather than being consumed by them. There was a CT of my skull wherein they found indications of ""an old"" stroke; so, they decided that it was possible I had a stroke. I was transferred from the Medical Center to the Stroke Center at the Medical Center under the care of Dr. Another CT with contrast and a MRI confirmed ""OLD"" stroke, but nothing new. I was assured the vaccine had nothing to do with my symptoms, and that I most likely experienced a Trans Ischemic Attack (TIA), and that the situation was merely a coincidence as they believe the vaccine had nothing to do with the TIA. However, based on my personal experience of the events as they unfolded, it is my sincere belief that the vaccine was incidental to the effects as I experienced them. I was kept overnight for further observation, released the next day, and had a follow-up with my primary care physician at the Med Center. I am now taking an 81 mg aspirin, Plavix, and 80 MG Clopidogrel as a precaution, and my symptoms have been gradually fading away.""
COVID19 VACCINE	MODERNA	1044497-1	65+ years	0 days	Massive headache for 24 hours following the 2nd dose Mini stroke (TIA)
COVID19 VACCINE	MODERNA	1052774-1	65+ years	0 days	The patient has developed an acute ischemic stroke on the evening of receiving the COVID vaccine #1 dose. She is in the hospital with left sided weakness, facial droop and speech changes. She is receiving blood thinner and therapies.
COVID19 VACCINE	MODERNA	1053346-1	65+ years	0 days	Hemorrhagic Stroke
COVID19 VACCINE	MODERNA	1053692-1	65+ years	0 days	My mother received her vaccine at 12:40 on 2/2. She waited longer than the fifteen minutes and she seemed fine. We left the facility and on the way home, approximately 45 after she received the vaccine, she began slurring her words and was confused. The slurring lasted for 2-3 minutes The confusion continued. I brought her the ER where she was immediately taken in for a CT Scan. She later had an MRI, and met with a Cardiologist. She later had an EEG at the request of a Neurologist. She spent three nights in the hospital. All tests showed no acute signs of stroke, etc.

COVID19 VACCINE	MODERNA	1058028-1	60-64 years	0 days	Moderna COVID-19 Vaccine EUA adverse event. Approximately 7 hours after the 1st COVID vaccination on 2/22/2021, patient developed symptoms of fatigue, aches, chills & fever. Her symptoms worsened into 2/23/21 with increasing shortness of breath. On arrival in the emergency center on 2/23/21, she was hypoxic with SpO2 81% on room air. Oxygen supplement via nasal cannula was given which improved her oxygenation. Covid 19 test negative. Chest Xray shows pulmonary edema and CTA chest shows no PE. She was admitted to the hospital and provided supportive care. Pulmonary Edema and inflammatory process is likely associated with the vaccine. Patient appeared to be improving, however, on 2/26/21, she was working with Physical Therapy/Occupational Therapy and had a pulse ox reading of 75% on room air. She was on 10 liters of oxygen via nasal cannula by the time she make it back to bed and her pulse ox was 89%. Neurology exam shortly afterward the above event demonstrated an NIHSS of 21. Patient became non-verbal and stat imaging revealed an acute hemorrhage in the left occipital lobe likely representing a SAH. Patient then transferred to another hospital that could provide neurosurgical intervention.
COVID19 VACCINE	MODERNA	1060190-1	65+ years	0 days	Patient received Covid Vaccine Moderna at 1145, multiple syncopal episodes at pharmacy, sent to ER. Outcome Death
COVID19 VACCINE	MODERNA	1060313-1	65+ years	0 days	I am not 100% certain of this event being related to the vaccination with the Moderna COVID19 shot or not. However, in the interest of completeness and for investigative purposes, I am reporting to you the event in relation to the vaccination as the patient reported to me. She received the vaccination on 2/14/2021 and became very confused. She had significant left arm swelling much worse than when she had her first vaccination. Her husband brought her to the emergency room and she was eventually discharged, but she went on to develop significant hypertension and she reported that her blood pressures were normal prior to the vaccination. She had an emergency room visit in which her systolic pressures were well above 240. She revisited the emergency room and had elevated blood pressures of 240 and was diagnosed with hypertensive encephalopathy and later found to have posterior reversible encephalopathy syndrome or PRES. We have started the patient on medications, and started laboratory work-up for secondary hypertension and her blood pressures have improved with treatment. We discussed the case with the neurologist, who suggested that we repeat MRI scan to make sure that her punctate lesions noted on MRI on this admission on 2/25/2021, have resolved. It was advised that if they had not resolved that we should call neurology again. Hypertensive encephalopathy is rare and press syndrome as a result is also rare. It is for this reason that I am reporting this event as again, I am not trying to mislead anyone or distort information, but should this be an adverse effect of the vaccine I wanted to make sure that this was reported as the patient's history prior to the vaccination and developing this complication post vaccination are temporally related at a minimum. The patient is a known smoker but quit on the 14th of this month.
COVID19 VACCINE	MODERNA	1060879-1	65+ years	0 days	stroke spent 3 days in ICU and saw a neurologist
COVID19 VACCINE	MODERNA	1061909-1	65+ years	0 days	Massive stroke; A spontaneous report was received from a consumer (patient's daughter), concerning an 85-year-old female patient, who received Moderna COVID-19 vaccine and death occurred in two days. The patient's medical history was not provided. No relevant concomitant medications were reported. No information on allergies. She states that her mother was physically and mentally healthy before vaccination. On 29-JAN-2021, prior to the onset of events, the patient received her first of two planned doses of covid-19 vaccine for the prophylaxis of Covid-19 infection. There were no complaints on any side effects from the patient for 6 hours after vaccination. Next day, she was found unresponsive on her bed by her neighbor after they were sent to check on her by her daughter. Her heart was beating, and she was breathing at that time, but did not have consciousness. According to her daughter, the patient had a massive stroke in her sleep sometime between 8:pm on 29-JAN-2021 and 9:30 am on 30-JAN-2021. Her life saving measures were taken out at 1:15 am on 31-JAN-2021 and she died approximately at 1:45am. No information available on hospitalization and treatment received with this event. It is not known whether autopsy was done. Action taken with 2nd dose of Moderna Covid-19 vaccine was not applicable. The outcome of the event stroke is fatal.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the event of stroke, a causal relationship cannot be excluded. Patient's elderly age is considered a risk factor.; Reported Cause(s) of Death: Massive stroke

COVID19 VACCINE	MODERNA	1070583-1	65+ years	0 days	He complained of dizziness the evening of the shot. He went to bed and when he woke up the next morning he was having double vision. His eye drifted off to the side and he was too dizzy to get up. He was taken to the hospital. They did a CT scan which didn't give a diagnosis, and they were unable to do a MRI scan due to a medical reason, so they could not determine for sure if he had a stroke. They are assuming that he did have a stroke and he has oculomotor nerve paralysis on the right side. The nurse practitioner saw him today and she reports he is doing very well now. He had been staying in an assisted living type facility when this occurred, but he is expected to return home tomorrow.
COVID19 VACCINE	MODERNA	1074925-1	Unknown	0 days	stroke; vertigo attack; severe headaches; severe dizziness; A spontaneous report was received from a consumer who was also a male patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and who experienced severe headaches / headache, severe dizziness / dizziness, vertigo attack / vertigo, and stroke / cerebrovascular accident. The patient's medical history was not provided. No relevant concomitant medications were reported. On 13 Feb 2021, prior to the onset of the events, the patient received their second dose of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 13 Feb 2021, about 12 hours after receiving the vaccine, the patient experienced severe dizziness and severe headaches which lasted for about 4 days. On 17 Feb 2021, while driving, the patient thought he was having a vertigo attack and went to the emergency room. He had a cat scan (results not provided) and was treated with TPA (tissue plasminogen activator). After three days in the hospital, they determined he had a stroke. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the events, severe headaches, severe dizziness, vertigo attack, and stroke, was not provided.; Reporter's Comments: This case concerns a male patient, who experienced a serious unexpected event of cerebrovascular accident among others, 5 days after receiving 2nd dose of mRNA- 1273 (Lot# unknown). Very limited information regarding this event has been provided at this time. Further information has been requested.
COVID19 VACCINE	MODERNA	1075922-1	65+ years	0 days	Felt bad after vaccine, had arm pain that went up my neck to my head, on 2nd day after shot I collapsed with a stroke. Blood Pressure was sky high. I was taken by Ambulance to Hospital, as I was at work at the time of the stroke. I have perfect bmi, never had high blood pressure, no health problems at all. No heart problems.
COVID19 VACCINE	MODERNA	1076108-1	65+ years	0 days	Patient received first dose of vaccine on 2/8/2021. Was monitored properly with no adverse reaction, but had a stroke a few hours later after leaving facility. Patient is still hospitalized.
COVID19 VACCINE	MODERNA	1080075-1	60-64 years	0 days	Hemorrhagic stroke. = Death
COVID19 VACCINE	MODERNA	1080485-1	65+ years	0 days	Within 10 minutes of my dad receiving his COVID-19 vaccine he suffered a major stroke.
COVID19 VACCINE	MODERNA	1091588-1	65+ years	0 days	Developed diplopia 3 hours post vaccine
COVID19 VACCINE	MODERNA	1093414-1	65+ years	0 days	Patient received 2nd dose of Moderna COVID vaccine at approx. 10am on 03/10/21. At approx. 5pm on 03/10/21, he developed typical side effects including fever, chills, and lethargy. Additionally, he became confused. The next morning, he remained lethargic and minimally responsive. He was febrile to 106 F per daughter and somewhat hypotensive with SBP into the 80s. The afternoon of 03/11/21, he also developed right facial droop and weakness. EMS was called and he was found to have suffered a left MCA stroke. He was admitted to the hospital for this and underwent thrombectomy. Of note, he was febrile and hypotensive on admission.
COVID19 VACCINE	MODERNA	1094285-1	65+ years	0 days	Had a stroke.
COVID19 VACCINE	MODERNA	1096501-1	65+ years	0 days	Episode of ischemic colitis of proximal sigmoid colon occurring within 6 hours of receive vaccine. This required hospitalization.
COVID19 VACCINE	MODERNA	1097867-1	30-39 years	0 days	Headache, nausea, and vomiting starting about 2 hours after vaccine and got worse overnight. Patient reported intractable vomiting the next morning and feeling weak so she called EMS in the evening. She developed sudden onset of right lower extremity paralysis and numbness. In ED, stroke was called and Alteplase was given on 3/13/21

COVID19 VACCINE	MODERNA	1111269-1	Unknown	0 days	<p>chronic small vessel ischemic disease; Felt Bad; Arm pain; Headache; Body ache; Sweating; Cold Feet; Tremors; Slurred speech; Elevated blood pressure; Stuttering; A spontaneous report was received from a Healthcare professional concerning a 31 Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced non-serious events of body pain, headache, arm pain, hyperhidrosis, peripheral coldness, tremor, dysarthria, elevated blood pressure, dysphonia and serious event of exacerbation of preexisting chronic small vessel ischemic disease after the 2nd dose of Moderna vaccine chronic . 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 second dose of planned doses of mRNA-1273 batch no:028L20A intramuscularly in the Anatomical location for prophylaxis of COVID-19 infection. On the same day, The patient experienced arm pain, headache, sweating, body ache, cold feet, tremors, slurred speech, elevated blood pressure measured at 183/90., and sluttering. On 21-JAN-2021, CT brain normal. MRI was abnormal and showed flare signal regions in the brain which signified early microvascular ischemic changes, a demyelinating process, vasculitis, or sequelae for migraines. The subject was treated with intravenously with lorazepam 2mg and Benadryl. On 03-FEB-2021, the subject was referred to a neurologist and was improving. On 05-FEB-2021, another MRI was performed and showed multiple scattered punctate foci of unenhancing white matter, signal alteration which were nonspecific but unchanged in comparison to previous MRI. Report suggested that findings were most likely to reflect an early onset chronic small vessel ischemic disease, other somewhat less likely considerations in a patient of this age would include migraine syndrome, various cerebral vasculopathies, or demyelinating conditions. Action taken with mRNA-1273 in response to the events was not applicable as second dose had been administered. The outcome of the event was resolving.; Reporter's Comments: The non-serious events of pain, headache, sweating, body ache, cold feet, tremors, slurred speech, elevated blood pressure, and sluttering are temporarily associated with the mRNA-1273 use and a causal association cannot be excluded. The serious event of chronic small vessel ischemic disease is considered a pre-existing event based a diagnostic findings and thus assessed as unlikely associated with mRNA-1273 use.</p>
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COVID19 VACCINE	PFIZER\BIONTECH	0918783-1	18-29 years	0 days	<p>left sided weakness; it has weakened his heart; stutter; severe stroke like symptoms; Ventricular tachycardia/help keep his heart rate at bay; Loss of balance; extreme numbness and tingling in left hand and foot; tingling in left hand and foot; oral motor impairment; mouth weakness and not coordinated/mouth is fatigued easily; Issues finding words and trouble speaking; Issues finding words and trouble speaking; Ejection fraction down to 25%; The initial case was missing the following minimum criteria: adverse event. Upon receipt of follow-up information on 28Dec2020, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable other healthcare professional (HCP). A 29-year-old male patient received bnt162b2 (lot number: EJ1685), intramuscular (deltoid left) on 21Dec2020 at 05:30 at 0.3 mL single (first dose) for Covid. Medical history was reported as ""none"". Concomitant medications were not reported. The patient previously received Flu vaccine in Oct2020 for immunization. The patient is an Occupational Therapist, and he called to report an adverse event that he experienced with the first dose of the COVID Vaccine. He received the vaccine last Monday, 21Dec2020 at 5:30AM before his shift at work, then 20 minutes later, he was having severe stroke like symptoms. He experienced severe left sided weakness, loss of balance, extreme numbness and tingling in his left hand and foot, he had issues finding his words and he couldn't speak, and he had an oral motor impairment where his mouth was weak and not coordinated. The staff at the hospital did a neurological exam on him, and he failed, so he had to go to the emergency room (ER). The patient added that he was already in the hospital when this happened, and the ER doctors suspected that he had a CVA, and they gave him TPA to prevent any permanent brain damage and it worked. The patient then added that due to the shock of this whole event, from everything that happened, it has weakened his heart. Reportedly, he is a healthy 29 year old man, with no preexisting conditions, and he works out, and he has no heart conditions, but he had to get a cardiology follow up a few days after he got the vaccine, because he started going in to Ventricular Tachycardia, which he had never had in his life. So, the doctors at the hospital went ahead and did an Echocardiogram and an EKG, and he was told that his Ejection Fraction is down to 25%. He stated his heart is so weak, that he cannot work right now, but the structure of his heart is fine and has not had any damage. The hospital staff thought that maybe the patient had a chronic heart issue that he just did not know about, and that the stress of this event maybe made it kick into overdrive, but he states that the cardiologist said that was not the case, because the structure of his heart is fine, and the only thing they can see is that the heart is pumping weak. One physician even suggested that due to the shock of the event, he might have Takotsubo Cardiomyopathy, which is a broken heart, but because the structure of his heart is okay, it should be reversible. He stated that he is hoping he will heal up good, because he is young and has no pre-existing conditions. He added that his heart is in such a state right now; he has to wear an external defibrillator. The patient stated that all these happened about 20 minutes after he received the vaccine, and he was admitted to the hospital from 21Dec2020 to 25Dec2020. His neurological symptoms have resolved except that he has a stutter that he did not have before and his mouth is fatigued easily, so he has to slow down when he is eating, but now he can eat regular for the most part. The</p>
COVID19 VACCINE	PFIZER\BIONTECH	0929173-1	65+ years	0 days	<p>Went to ER left side of face sagging. They did MRI it showed he had stroke. happened before 4pm that same day as vaccine. Happened between 2-4 pm; Went to ER left side of face sagging. They did MRI it showed he had stroke. happened before 4pm that same day as vaccine. Happened between 2-4 pm; This is a spontaneous report from a contactable consumer (patient). A 78-year-old male patient receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EK5730), on 31Dec2020 11:00 AM via unknown route of administration at single dose for COVID-19 immunization. Medical history included high blood pressure, but went up and down and had to readjust. His BP was high and not sure how long it was that way. Concomitant medications included unspecified blood pressure medications. There were no known allergies. Patient went to ER left side of face sagging. They did MRI it showed he had stroke. It Happened before 4pm that same day as vaccine on 31Dec2020 02:00 PM. And it Happened between 2-4 pm. Patient received treatment. Patient had ER test blood, cat scan, MRI. 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 did not have been tested for COVID-19. The outcome of the events was recovering. This case was assessed non-serious by reporter. And the events did not result in death, Life threatening, Caused/prolonged hospitalization, Disabling/Incapacitating, Congenital anomaly/birth defect.</p>

COVID19 VACCINE	PFIZER\BIONTECH	0932145-1	65+ years	0 days	Patient came into the emergency department on 1/8/21 with an acute ischemic stroke with complete occlusion of her left MCA. She had acute and complete flaccid paresis of her right face, arm, and leg, complete aphasia, and neglect of the right side of her body. NIHSS of 27. Onset of deficit was between 6:30pm-7:10pm. She received her 1st COVID-19 vaccine dose that morning at 10:31am.
COVID19 VACCINE	PFIZER\BIONTECH	0944084-1	30-39 years	0 days	Vaccinated Thursday morning, later in the evening felt achy and had a fever. Headache for 2 days. Sat morning 1/9/21 woke up with left arm weakness and numbness which went up to her face. Had an MRI completed which showed a new small right parital ischemic stroke.
COVID19 VACCINE	PFIZER\BIONTECH	0944270-1	50-59 years	0 days	He collapsed with left sided hemiparesis; Stroke; Rt basal ganglia hemorrhage w/ edema and mass effect.; Rt basal ganglia hemorrhage w/ edema and mass effect.; Low platelets, 114; His bp as high as 200s/100; Hand weakness; Myalgia; Fever; Severe fatigue; This is a spontaneous report from a contactable physician. A 58-year-old male patient received first dose of bnt162b2 (Pfizer BioNTech COVID vaccine), intramuscularly on 16Dec2020 at a single dose for COVID-19 immunization. Medical history included hypertension with reported med noncompliance in the last few months due to stress. Concomitant medication included hypertension medications in two weeks. The patient was presumed neg covid status prior to vaccine. He worked as a Pulm/critical care physician. He reported fever, myalgia, fatigue on 16Dec2020. Next day (17Dec2020), he took off from work due to his symptoms. The following day (18Dec2020), he came to work. He c/o ongoing severe fatigue & hand weakness in am. Staff noted him to be evaluating his hands during clinic. At 12:15, he collapsed with left sided hemiparesis. The reporter had suspicion for stroke. He was transported to the Emergency Room (ER), head CT showed Rt basal ganglia hemorrhage w/ edema and mass effect. Labs notable for Low platelets, 114 (unknown baseline) on 18Dec2020, normal coags on an unspecified date. BP recorded as 179/101, but it was noted in trauma room his bp as high as 200s/100. He had a history of hypertension with reported med noncompliance in the last few months due to stress. Patient was transferred for further care. Full course was unknown but had rebleed there with low plts. Adverse event (he collapsed with left sided hemiparesis) resulted in hospitalization (22 days), life threatening illness (immediate risk of death from the event), disability/incapacitating or permanent damage. Treatment was received for adverse events. Results of tests and procedures for investigation of the patient: on 18Dec2020, Nasal Swab test: negative. The outcome of events was not recovered. Unknown if 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 was not tested for COVID-19. Information on the lot/batch number has been requested.; Sender's Comments: Collapsed with left sided hemiparesis/suspicion for stroke are as consequences of basal ganglia hemorrhage with edema, which is caused by worsening of hypertension. Low platelet also contributes to brain hemorrhage. All these serious events are unrelated to the vaccine use. 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.
COVID19 VACCINE	PFIZER\BIONTECH	0958327-1	50-59 years	0 days	Headache and stoke
COVID19 VACCINE	PFIZER\BIONTECH	0958389-1	65+ years	0 days	Stroke-like symptoms approximately 2-3 hours after receiving shot (aphasia), BP bottomed out, was transported by EMS and is currently on a ventilator in hospital. CT scan clear; MRI pending.
COVID19 VACCINE	PFIZER\BIONTECH	0960714-1	50-59 years	0 days	Pt received vaccine and developed HA with left hemianopsia, left upper ext and left lower ext weakness. Stroke Code activated at clinic where she works CT head neg TPA administered, transferred to ED for CTA and stroke care CTA neg MRI pending but clinically improved
COVID19 VACCINE	PFIZER\BIONTECH	0968846-1	65+ years	0 days	Within 15 minutes of the injection, the individual became aphasia and stroke like symptoms. She was taken to the ER where she was later diagnosed with a cerebral hemorrhage and passed away.
COVID19 VACCINE	PFIZER\BIONTECH	0978959-1	65+ years	0 days	Presented with stroke like symptoms at 10:30, right sided weakness and slurred speach. 911 was call, patient was transported to hospital. Per ED note, patient experienced TIA which resolved, actue exacerbation of CHF. Patient was admitted. Discharge summary on 1/22 indicates same diagnosis, plan was home with hospice. Family notified hospital on 1/25 that patient had expired on 1/23 at home.



COVID19 VACCINE	PFIZER\BIONTECH	0979255-1	65+ years	0 days	Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.
COVID19 VACCINE	PFIZER\BIONTECH	0993695-1	65+ years	0 days	Couldn't speak, slurring words, stuttering, couldn't formulate a sentence; stroke; This is a spontaneous report from a contactable consumer. A 97-year-old female patient received first dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 16Jan2021 14:15 at single dose for covid-19 immunization. Medical history included ongoing atrial fibrillation(A-fib), took medication for that. Concomitant medication included acetylsalicylic acid (BABY ASPIRIN), rosuvastatin calcium (CRESTOR). Additional vaccines administered on same date of pfizer suspect reported as no. Prior vaccinations within 4 weeks, AES follow prior vaccinations and family medical history all reported as no. The patient got her first dose on 16Jan2021 and that evening she began to have a stroke. The patient was on blood thinners (apixaban(ELIQUIS) and questor). Event reported as ""Couldn't speak, slurring words, stuttering, couldn't formulate a sentence"" with onset date 16Jan2021. Event was serious as hospitalization from 17Jan2021 to 18Jan2021. The outcome of the events was not recovered/not resolved. Patient was caller's mother. Four hours later, patient couldn't speak and was slurring words. Ambulance was called, vitals were checked, and patient was told she was ok. Next morning patient was the same. Ambulance was called again and patient had a stroke. Caller stated the stroke was very coincidental. Patient had the COVID-19 Vaccine at about 2PM. Patient had A-fib. Stroke affected patient's speech, but not terribly. Patient was on a blood thinner at the time of the report because of MRI and CT scan results. The patient was taking acetylsalicylic acid (BABY ASPIRIN), but that was taken away at time of the report. The patient was on rosuvastatin calcium (CRESTOR) 0.5 at time of the report. Next appointment for second COVID-19 Vaccine was 06Feb2021. Caller was concerned. Patient never had a stroke before. The reporter wanted to know if this had been previously reported. Saturday night was when patient's speech began slurring. The patient had the Pfizer COVID-19 Vaccine that afternoon. EMS didn't take patient to the hospital on Saturday night, just took vitals and left. Patient's speech was going in and out. Caller reached out to patient Sunday morning and patient was having the same speech issues. Patient was stuttering and couldn't formulate a sentence. Ambulance was called and patient was transported to (health center). CT scan and MRI showed patient had a stroke in the area of the brain that affect speech. Patient had an echocardiogram. Clarified patient's speech symptoms began on Saturday, 16Jan2021. · Information of lot/batch number has been requested.""
COVID19 VACCINE	PFIZER\BIONTECH	0994113-1	65+ years	0 days	Daughter contacted the clinical location for vaccination to inquire regarding if her mother was confused when at the location to receive her vaccine as she ended up in the ED 2 hours later with a diagnosis of stroke. completing VAERS due to how closely the vaccine was to the event.
COVID19 VACCINE	PFIZER\BIONTECH	1000933-1	65+ years	0 days	Pfizer-BioNTech COVID- 19 Vaccine EUA Patient experienced change in speech and jerky movements on way home from COVID-19 vaccine. Presented to ED. Patient diagnosed with Acute CVA (cerebrovascular accident). Patient discharged on 1/31/2021.
COVID19 VACCINE	PFIZER\BIONTECH	1002428-1	65+ years	0 days	1st dose of vaccine was 1/12/21, Lot number EK9231 2nd dose 2/2/21, Lot number EL8982 Patient was feeling well the day of vaccine and reports no recent illness, no adverse events to first injection in COVID vaccine series. 20 minutes later developed dizziness and nausea. Within hours noticed LUE weakness. Weakness has progressed over last two days to severe left upper extremity and left lower extremity weakness with inability to walk. No sensory deficits. Some urinary retention. Hyperreflexia on examination with upgoing toe on left. Presentation consistent with transverse myelitis. Patient remains hospitalized at this time, starting treatment with IV solumedrol for clinical transverse myelitis. Workup remains in process
COVID19 VACCINE	PFIZER\BIONTECH	1010235-1	65+ years	0 days	Stroke. Massive brain bleed right side

COVID19 VACCINE	PFIZER\BIONTECH	1011771-1	65+ years	0 days	Narrative: Patient with history advanced vascular dementia, hypertensive cerebrovascular disease and stroke, T2DM. Received her second dose of Pfizer COVID-19 vaccine at approximately 14:00 and was reported to have expired at home at 20:55. Dr. (Medical Director) spoke with patient's son/caregiver 2/4/21. Son reports that patient was in her usual health yesterday morning, deemed well enough by son to travel for vaccination. He reports she had no bothersome symptoms after either first or second vaccinations. Specifically denied rash, wheeze, and difficulty breathing. Son was with patient throughout the day. In the evening, when preparing for bed, he noted she became suddenly unresponsive in a similar fashion as she has done several times in past years. While in all previous such episodes she recovered within minutes, last evening she did not regain consciousness, experiences a brief period of labored breathing, and died. Patient's son called 911 and the patient's body was brought to the medical examiners. The medical examiner declined to proceed with autopsy. Patient's son is not interested in autopsy. Patient's son reports confidence that his mother's underlying hypertensive/diabetic cardiovascular disease is the natural cause of her death. Other Relevant Hx: Symptoms: & Death Treatment:
COVID19 VACCINE	PFIZER\BIONTECH	1012742-1	60-64 years	0 days	1/31/21 0730 am confused and low grade temp 99.5, 12 noon Temp 100.6 and sitting in recliner non responsive twitching. Sent to Hospital with EMS to rule out stroke. Admitted 1/31/21.
COVID19 VACCINE	PFIZER\BIONTECH	1014871-1	50-59 years	0 days	CENTRAL RETINAL VEIN OCCLUSION RESULTING IN LOSS OF SIGHT TO RIGHT EYE I WAS ON COMPUTER AND HAD BRIGHT FLASHES OF LIGHTS THE LOST VISION IN THE EYE ABOUT 2 1/2 HOURS AFTER RECIEVING VACCINE. CRVO IS RARE IN MY AGE WITH NO HEALTH PROBLEMS. SAW ER DOCTOR THAT NIGHT THEN OPTHAMOLOGIST THE NEXT MORNING WHO DIAGNOSED ME. I AM CURREENTLY PRESCRIBED A BABY ASPIRIN AND WILL HAVE TO GET INJECTIONS IN MY EYE WHEN MACULAR EDEMA OCCURS, AN EXPECTED OCCURRENCE WITH A BLOOD CLOT IN THE RETINAL VEIN
COVID19 VACCINE	PFIZER\BIONTECH	1018910-1	30-39 years	0 days	I am actually not certain which COVID vaccine she got but she came to our hospital having a stroke confirmed by CT
COVID19 VACCINE	PFIZER\BIONTECH	1022685-1	65+ years	0 days	Received Pfizer Covid Vaccine in the AM on 2/9/21. Arrived to emergency department later the same day complaining of nausea, weakness, fatigue, Vomiting, Diarrhea. Post operative diagnosis, Ischemic colon/toxic megacolon.
COVID19 VACCINE	PFIZER\BIONTECH	1024368-1	30-39 years	0 days	Patient received her 1st dose of Pfizer vaccine around 1810 on 2/9. Approximately 10-15 mins later her arm was shaking uncontrollably, she felt that her throat was closing and had chest pressure. Medics noted hives and a rash on her chest and administered Epi and Benadryl. She began exhibiting stroke-like symptoms of expressive aphasia and dysarthria in the medic's truck around 1850. She was crying and unable to speak. She had right sided facial droop, right sided grip weakness, and right sided arm drift. Patient was transferred to MC. Patient Update: Patient received tPA on 2/9 at 1949. CT revealed no hemorrhage or large territory stroke and no large vessel occlusion. NIHSS on admission to MC was a 3. Patient was also assessed by speech pathology. Patient appears to have been discharged home on 2/10. Patient to follow up with Outpatient Neuro PT Rehab as she is having some issues with mobility, gait, and overall functional mobility. She is using a 2 wheeled walker at this time.
COVID19 VACCINE	PFIZER\BIONTECH	1030131-1	50-59 years	0 days	Basal Ganglia sudden stroke; This is a spontaneous report from a contactable consumer (patient). A 55-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on 30Jan2021 at 13:00 (at the age of 55-years-old) at a single dose for COVID-19 immunization. The patient had no medical history and no blood pressure condition. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient had no known allergies to medications, food, or other products. Concomitant medications, taken within two weeks of vaccination, included an unspecified thyroid medication. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced basal ganglia sudden stroke on 30Jan2021 at 13:00, which prolonged hospitalization, caused disability, and was reported as life-threatening. The vaccine was received during existing hospitalization. The patient underwent lab tests and procedures which included nasal swab: negative on 03Feb2021. Therapeutic measures were taken as a result of the event, which included intensive care unit (ICU) neurocare. The clinical outcome of basal ganglia sudden stroke was unknown. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.
COVID19 VACCINE	PFIZER\BIONTECH	1034234-1	65+ years	0 days	Eye Stroke / Retinal Occlusion Lost eyesight in left eye

COVID19 VACCINE	PFIZER\BIONTECH	1035548-1	65+ years	0 days	Repetitive episodes of tingling; numbness occurring in left side of body including side of face; Possible TIA; This is a spontaneous report from a contactable consumer reporting for himself. A 73-years-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EL9262), via an unspecified route of administration in the left arm on 02Feb2021 16:00 at single dose for covid-19 immunisation. Medical history included high blood pressure. Concomitant medication included amlodipine (unknown manufacturer). On 02Feb2021 16:00 the patient experienced repetitive episodes of tingling and numbness occurring in left side of body including side of face; possible TIA with outcome of not recovered. The events resulted in Emergency room/department or urgent care visit. The patient was hospitalized for 3 days due to the events. The events were serious as life-threatening and due to hospitalization. It was unknown if the patient received treatments for the events. The patient did not have COVID-19 prior to vaccination and was not covid tested post vaccination.
COVID19 VACCINE	PFIZER\BIONTECH	1035674-1	65+ years	0 days	Within 15-minutes, the patient reported a ""pulsating sharp pain"" behind their right eye. EMS evaluated the patient on-site and they were found to be hypertensive (173/88). The patient proceeded to a emergency department. In the ED, the patient remained hypertensive with a mild generalized headache. They reported that their eye pain is constant but comes in waves of higher intensity. Differential diagnosis was possible stroke due to right-sided hemianopsia and right-sided ptosis. Patient was admitted and evaluated. Aspirin was administered and blood pressure was monitored prior to discharge. ""
COVID19 VACCINE	PFIZER\BIONTECH	1042639-1	65+ years	0 days	Pt. recieved COVID vaccine on 6 Feb @0730 and presented to the hospital with chest pain & questionable stroke. + CT and transferred to another hospital @ 1430, appears CVA (cerebral vascular accident); Cardioembolic stroke; Cerebrovascular accident (CVA), unspecified mechanism; TIA (transient ischemic attack). He was discharged on 10 Feb. Home course unknown
COVID19 VACCINE	PFIZER\BIONTECH	1046413-1	65+ years	0 days	Experienced Primary Diagnosis of Stroke to left rear side of head (Also Mixed Hyperlipidemia, Coronary Artery Disease involving Native Coronary Artery of Native Heart without Angina Pectoris, Type 2 Diabetes)
COVID19 VACCINE	PFIZER\BIONTECH	1048215-1	40-49 years	0 days	Dizziness; stoke like symptoms; lost taste; Lost smell; lost hearing; weakness; right eye droopy; This is a spontaneous report from a contactable other hcp (patient). A 44-year-old female patient receive first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EL0142), at same age, via an unspecified route of administration in left arm on 05Jan2021 10:00 at single dose for covid-19 immunisation. Medical history included high blood pressure. Concomitant medication included metoprolol. The patient previously took ampicillin and experienced drug allergy. The patient experienced dizziness, stoke like symptoms, she lost taste, smell, hearing, lost station on my whole right side. Right side weakness. Only one eye blinks right eye droopy, all on 05Jan2021 10:00. Events resulted in emergency room visit. The patient was hospitalized for 1 days for all events. It was unknown whether treatment was received for all events. Patient is not pregnant at the time of vaccination. Facility where the most recent COVID-19 vaccine was administered was hospital. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient underwent lab tests and procedures which included nasal swab/ covid test: negative on 08Feb2021. The outcomes of events were not recovered.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported dizziness, stoke like symptoms, she lost taste, smell, hearing, lost station on my whole right side, right side weakness, only one eye blinks right eye droopy, and the administration of the COVID 19 vaccine, BNT162B2, administration, 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.
COVID19 VACCINE	PFIZER\BIONTECH	1051535-1	65+ years	0 days	My mother complained of a severe headache within 1 hour of receiving the injection. 18 hours later she was rushed to the the ER with a Hemorrhagic stroke. Hospitalized for 3.5 days, cognitive impairment remains, resulting in the need for rehabilitation therapy.

COVID19 VACCINE	PFIZER\BIONTECH	1051713-1	65+ years	0 days	Covid 19 vaccine was administered at 2:45 pm on 2-21-21. By 2:55 pm patient began to experience Confusion and loss of short term memory. He suddenly did not know where is was, how he got there, or why he was there. He continuously asked those questions throughout the balance of the day. The nurses on duty in the clinic got a wheel chair and escorted us to the hospital ER in the same building. He was immediately taken to a room where a doctor met us and began asking him questions. The Dr quickly ordered a multitude of tests. Results shown in item 19
COVID19 VACCINE	PFIZER\BIONTECH	1052242-1	65+ years	0 days	Patient reported as being altered, GCS 6 with noted aphasia around 1415.
COVID19 VACCINE	PFIZER\BIONTECH	1052491-1	65+ years	0 days	brain fog immediately after vaccination, 2 hours later blood pressure and heart were elevated. Around 11:00 pm went into extreme Atrial Fibrillation and risk of stroke for 10 hours. Heart rate went from 55 bpm before vaccine to 90 bpm after vaccine. Blood pressure went from 120/70 to 145/80.
COVID19 VACCINE	PFIZER\BIONTECH	1056626-1	65+ years	0 days	Vertigo last week that stayed for five days; pain at the injection site; 2 stroke like symptoms/ like she was having a TIA (Reporter confirmed TIA as Transient ischemic attack); Blood Pressure 170/130; Fatigue; Joint ache; Nausea; Vomiting; Fever 100.1; Stress; 2 stroke like symptoms/numbness in her lip; Pervasive aching; Momentary confusion; , like she was having a TIA; Not able to answer questions; she still has not recovered her strength; This is a spontaneous report from a contactable consumer (patient's daughter). A 94-year-old female patient (mother) received 1st dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot# EL1283), via an unspecified route of administration on 23Jan2021 13:00 at a single dose for COVID-19 immunisation. The patient's medical history included ischaemic stroke, haemorrhagic stroke in Aug2019, pulmonary embolism, deep vein thrombosis (DVT), cholesterol, myalgia condition, blood pressure, thyroid, sleep and vertigo. The patient concomitant medications included amlodipine for blood pressure, calcium carbonate/colecalciferol (CALCIUM + VITAMIN D), rosuvastatin calcium (CRESTOR) for cholesterol, levothyroxine for thyroid, eszopiclone (LUNESTA) for sleep medication, ascorbic acid, cupric oxide, dl-alpha tocopheryl acetate, xantofyl, zeaxanthin, zinc oxide (PRESERVISION AREDS 2), prednisone for myalgia condition, and escitalopram. The patient experienced fatigue, joint ache, nausea, vomiting, blood pressure 170/130, fever 100.1, stress, stroke like symptoms, numbness in her lip, momentary confusion; like she was having a TIA; not able to answer questions, tired, pervasive aching, all on 23Jan2021 19:00. Events reported as follow: patient had the Pfizer vaccine on Saturday around 1 pm and Saturday (Clarified 23Jan2021) night she had severe side effects for about 4 hours. When probed for side effects, the reporter stated it increased gradually over time. So, first patient had joint achiness and then she experienced nausea and vomiting. The reporter took her blood pressure. It was 170/130 and so reporter called EMS and they came up and her blood pressure had gone back down to normal and they recorded she had a fever of 100.1. EMS believed that the combination of the 'violence' of the onset and the fever caused her blood pressure to spike but she had a history of ischemic and hemorrhagic stroke. So, the reporter was concerned that the stress and whatever that was going on the reaction, the reporter was concerned that it was going to cause her a stroke. Patient had 2 stroke like symptoms, one was that she had numbness in her lip and the second was that she had momentary confusion, like she was having a TIA (reporter confirmed TIA as Transient ischemic attack). The only symptom of that was when the reporter asked her the name of her children she gave the names of her grandchildren but that confusion cleared up quickly and she was fine for a while but not able to answer questions, sharply. By the time that EMS got there patient was sharp again, no problem. For treatment, the reporter gave patient aspirin. The reporter put some Salonpas patches on her joints. It was like the analgesic patch. It was an external patch that patient put on. Patient usually does not need them that was why she was taking the prednisone to treat that kind of pervasive aching. The reporter also gave her the fluids, Gatorade kind of stuff to replace her fluids from throwing up and that kind of stuff. One more thing, it all started with an extreme fatigue but that seem normal but it seemed to lead into the other symptoms. Like it was a big day to go out and get the vaccine. So, she was a little bit tired. This was a very deep fatigue that was part of it too.

COVID19 VACCINE	PFIZER\BIONTECH	1056656-1	65+ years	0 days	<p>blew a blood vessel under her eye lid; stroke; tasted rubber band taste in her mouth; This is a spontaneous report from a contactable consumer (patient). A 65-year-old female patient received the second dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EN5318), in a clinic, intramuscularly in the right arm on 29Jan2021 at 14:00 at 65-years-old at a single dose for COVID-19 immunization. There were no prior vaccinations within four weeks of the bnt162b2. Medical history included ongoing fibromyalgia from an unknown date, reflex sympathetic dystrophy from an unknown date and unknown if ongoing, irregular heart beat from an unknown date and unknown if ongoing, ongoing hemangioma from an unknown date, thyroid problems from an unknown date and unknown if ongoing, low white blood cell counts from an unknown date and unknown if ongoing, ongoing pinched nerves in her neck and back from an unknown date, migraines from an unknown date and unknown if ongoing, diastolic heart failure from an unknown date and unknown if ongoing (diagnosed about 5 years ago.), abdominal pains from an unknown date and unknown if ongoing, numbness in her nose, foot from an unknown date and unknown if ongoing, nausea from an unknown date and unknown if ongoing, vomiting from an unknown date and unknown if ongoing. Concomitant medications were not reported. The patient previously received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EL1283) for COVID-19 immunization on 08Jan2021 at 64-years-old and experienced metallic taste (Recovered), carbamazepine (TEGRETOL) from an unknown date to an unknown date and experienced white count was down to 1, influenza vaccine (MANUFACTURER UNKNOWN) in Jul2020 at 64-years-old for immunization. The patient experienced the following events and outcomes: stroke (medically significant) on 29Jan2021 at 14:10 with outcome of unknown, blew a blood vessel under her eye lid (medically significant) on 31Jan2021 with outcome of recovering, tasted rubber band taste in her mouth (non-serious) on 29Jan2021 with outcome of unknown. The clinical course was reported as follows: The patient reported a history of migraines/ weather migraines, that cause numbness in nose and foot as well as gastro-intestinal symptoms. The patient received her first dose of the Pfizer COVID vaccine on 08Jan2021 and felt a metallic taste in her mouth (said that the metallic taste lasted about three hours; ate to get rid of the metallic taste). On 29Jan2021, the patient received her second dose; after 10 minutes her face went numb; her nose, forehead, and under her eyes all the way up felt numb. Also, the patient's systolic blood pressure was at 150. The patient reported that she also tasted rubber band taste in her mouth. The patient's neighbor that was there with her getting the vaccine told the nurse and they called the paramedics. The paramedics stated that they thought she had a stroke. She said that her blood pressure was 150 systolic (usually 107-110/79). The patient had diastolic heart failure which was diagnosed about 5 years prior. The numbness stayed with her until about 22:00 on 29Jan2021. The patient had a history of ""migraines and gets abdominal pains, numbness in her nose, foot"", and she experienced ""nausea and vomiting and stuff with her migraines."" The patient thought the vaccine just gave her a big migraine. The patient took sumatriptan succinate (IMITREX) and it did nothing. The patient said that on 31Jan2021 her eye felt weird. The patient blew a blood vessel under her eye lid. The patient's eye looked like a blood clot in the corner of her eye then it dispersed throughout the eye</p>
COVID19 VACCINE	PFIZER\BIONTECH	1056660-1	65+ years	0 days	<p>Cardiac Event MI or Stroke; Cardiac Event MI or Stroke; This is a spontaneous report from a contactable consumer (Son in law). A 73-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at left arm on 17Feb2021 14:00 at single dose for covid-19 immunisation. Medical history included atrial fibrillation (AFib), prostate cancer Survivor. Concomitant medication included alirocumab (PRALUENT), escitalopram oxalate (LEXAPRO), apixaban (ELIQUIS), nitroglycerin and Ca channel blocker. The patient received the first dose of BNT162B2 on an unknown date for covid-19 immunisation. The patient experienced cardiac event myocardial infarction (MI) or stroke on 17Feb2021. Adverse event result in Doctor or other healthcare professional office/clinic visit. It was unknown if treatment received for the events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The patient died on 19Feb2021. It was unknown if an autopsy was performed. The outcome of the events was fatal. The reporter didn't know if this was associated or not. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Cardiac Event MI or Stroke; Cardiac Event MI or Stroke</p>

COVID19 VACCINE	PFIZER\BIONTECH	1057550-1	65+ years	0 days	<p>has sporadic a-fib (at baseline); She stated she was in real bad stroke territory; she felt like she was going to faint; Her blood pressure was 220/97; tingling in her hands and feet; felt like brain sizzling like it was frying/going to faint; This is a spontaneous report from a contactable consumer, the patient. A 79-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot EN9581, first dose) solution for injection intramuscular in the left arm on 06Feb2021 at 09:30 (at the age of 79-years-old) as a single dose for COVID-19 vaccination. Medical history included ongoing sporadic A fib (atrial fibrillation) for 6 years know about; allergy to polyethylene glycol in 1985 (she had difficulty taking birth, control pills and they found out it was the coating PEG in); cerebrovascular accident prophylaxis; in 1985 She had difficulty taking birth control pills and they found out it was the coating PEG in it. She had an allergy to this where she broke out in bumps on her fingers and mouth and had itchy eyes, a full blown allergy; and when she was 45 going through menopause. Concomitant medication included apixaban (ELIQUIS) for A fib and cerebrovascular accident prophylaxis. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On 06Feb2021, the patient had sporadic a-fib (at baseline) then put in a medical van requiring emergency room visit. The patient stated, She stated she was in real bad stroke territory, felt like she was going to faint (6 minutes after vaccination), blood pressure was 220/97, tingling in her hands (6 minutes after vaccination) and feet and felt like brain sizzling like it was frying/going to faint (6 minutes after vaccination) on 06Feb2021. Lab tests included blood pressure on an unknown date high 150s and never lower than 187, then on 06Feb2021 was 220/97, on 09Feb2021 was systolic blood pressure 180, then on 10Feb2021 had gone down. The outcome of the events atrial fibrillation and feeling unwell was recovered on 06Feb2021, after 3 hours. The outcome of the events stroke, faint and tingling of extremity was unknown. The outcome of the event blood pressure was 220/97 was recovered on 10Feb2021.</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1058150-1	30-39 years	0 days	convulsing uncontrollably; stroke; rash; chest felt really heavy like someone was sitting on it; her throat felt like it was on fire; shaking uncontrollably/ arms and legs were shaking; Her speech was slurred, she could not communicate; Stuttering; dysphagia; tongue was falling to the side/mile was droopy on the right side/right arm- she would try to move it but it would not go/right leg was almost paralyzed; This is a spontaneous report from a contactable consumer (patient herself). A 39-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EM9810), via an unspecified route of administration on 09Feb2021 18:10 at a single dose for COVID-19 immunization. The patient had no relevant medical history. She was healthy and takes no medications. The patient got the vaccine Tuesday night at 6:10 PM. She waited in the parking lot where she got it, which was through (School Name). She had a severe reaction and had to receive an Epi Pen. This reaction occurred maybe 10 minutes after she got it. She had not left the parking lot yet, so it was prior to the 15 minutes. She broke out in a rash, her chest felt really heavy like someone was sitting on it, like an elephant, and her throat felt like it was on fire which is what is started as, then it went to her ears. From there, it escalated. She had gotten out of her car and took her sweatshirt off, she thought she was just hot. As soon as she got back in the car and as soon as she got in she started convulsing uncontrollably and shaking uncontrollably. Two ladies she works with had parked next two her on both sides and they noticed this and went to get the emergency squad. She did not lose consciousness. She could still hear everything but her arms and legs were shaking, and her right leg was shaking and stuck. The emergency squad had to help her out of the car. The ambulance gave her an Epi Pen injection and the squad took her to the hospital. Her speech was slurred, she could not communicate. She was stuttering the same thing over and over. She had a CAT scan with contrast and the stroke team decided she needed TPA - the stroke medication. They administered that and admitted her to the hospital Tuesday night. Wednesday she had an MRI, echocardiogram and another CAT scan and they released her to come home last night. She is still having lingering effects. Her speech is back. Her arm movement is back. The reason they treated her as a stroke patient, they said, is because when they told her to stick her tongue out, she had dysphagia - her tongue was falling to the side, and her smile was droopy on the right side. Her right arm- she would try to move it but it would not go. And her right leg too. She could do everything on her left side and nothing on her right side. She was conscious and could hear but could not get anything to work. After receiving the TPA, Wednesday when she woke up, she was being checked on every 30 minutes throughout the night, she was able to speak and communicate. She will still stutter and have slow words but it is way better and she can communicate. Her right arm is able to move and she can use it but her fine motor is hard. Like writing stuff is a challenge. She also has a walker. Her right leg is almost paralyzed, it drags beside her as she walks. She can move but has to really concentrate to get going. She has not reached out to her doctor yet. She was admitted to the hospital and had a bunch of tests done. The Epi Pen gave her stroke like symptoms. They were not sure in the hospital if it was actually a stroke based on her 2 MRI's and CAT scans. It did not look like a stroke from those but they think that the Epi Pen and the stress it puts into your body made her body shut down. Which
COVID19 VACCINE	PFIZER\BIONTECH	1059644-1	65+ years	0 days	Pt had a stroke the night after receiving the vaccine.
COVID19 VACCINE	PFIZER\BIONTECH	1062260-1	65+ years	0 days	Developed acute facial droop and slurred speech 2h after 1st dose of the vaccine on 2/17, found with R MCA stroke. Then became unresponsive on 2/27 and was found with an acute L MCA stroke. Was transferred from another hospital, was not a candidate for intervention, and was made comfort and died on 2/28

COVID19 VACCINE	PFIZER\BIONTECH	1065123-1	65+ years	0 days	gets 102 degree fever; Could not speak much next two days; Within one hour or so after: found on floor, fell on right side; unable to speak like a TIA; disoriented; This is a spontaneous report from a contactable consumer. An 82-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 12Feb2021 at 13:00 at single dose for COVID-19 immunisation at the age of 82-year-old. Medical history included dementia, high blood pressure, allergy to drugs with sulfer. Concomitant medications included 2.5 Amlodipine, 81 mg aspirin, 0.5 clonazepam, 20 mg Escitalopram, 10 mg melatonin, 5 mg memantine, 15 mg mirtazapine. The patient was not pregnant. The patient received first dose of received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 22Jan2021 at single dose for COVID-19 immunisation at the age of 82-year-old. Within one hour or so after the vaccine administration: the patient was found on floor, fell on right side, disoriented, unable to speak like a transient ischemic attack (TIA), out of it. The patient could not speak much next two days. Don 14Feb21 at 15:00, the patient got 102-degree fever. The patient was treated for the events. The patient was recovering from the events. Information on the lot/ batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1070965-1	65+ years	0 days	right sided embolic stroke, right retinal artery occlusion occurred 8 hours after vaccination, requiring hospitalization for 2 days, he is now left with right eye visual loss as the only sequelae to the stroke
COVID19 VACCINE	PFIZER\BIONTECH	1072543-1	65+ years	0 days	Like I'm having a stroke; neck ache; nightmares; nervousness; Felt terrible with bad headache; This is a spontaneous report from a contactable consumer (patient). An 86-years-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number: EN6200) via an unspecified route of administration on 15Feb2021 13:00 at single dose in left arm for COVID-19 immunisation. She received the first dose of BNT162B2 (lot number: EL9262) on 18Jan2021 13:00 in left arm for COVID-19 immunisation. The patient medical history was not reported. The patient was not pregnant at the time of vaccination. The patient was allergic to Formaldehyde, Coumadin. Concomitant medication included levothyroxine sodium (LEVOXYL). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 15Feb2021, the patient felt terrible with bad headache. On 18Feb2021 also felt terrible. On 17Feb2021 08:00, Like she was having a stroke. Headache, neck ache, nightmares, nervousness. Blood pressure was ok. Oxygen was ok. Pulse was ok. No treatment received for the adverse events. Events outcome was not recovered.
COVID19 VACCINE	PFIZER\BIONTECH	1084427-1	60-64 years	0 days	Patient reports having slurred speech beginning 2000 the evening following vaccination. She presented to the ER on 02/11/2021 and admitted to hospital for Acute CVA. Discharged on 02/14/2021. Patient's PCP recommended completion of series.
COVID19 VACCINE	PFIZER\BIONTECH	1102935-1	40-49 years	0 days	PATIENT UNRESPONSIVE. SPOUSE REPORTING FOR PATIENT, PER SPOUSE, ""My wife felt bad after the first shot, she complained of body soreness, weakness and headaches that did not go away until she had the stroke on 03/12/2021"". Patient is now hospitalized and unresponsive.""
COVID19 VACCINE	PFIZER\BIONTECH	1108591-1	65+ years	0 days	patient experienced TMI approx 2 hours post vacc presneted with loss of balance and listed to right. diagnosed by MRI the next day.



COVID19 VACCINE	PFIZER\BIONTECH	1111271-1	65+ years	0 days	Stroke; Dose Number 1 on 08Jan2021/Dose Number 2 on 25Jan2021; This is a spontaneous report from a contactable nurse. A 70-year-old male patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3249 and expiry date unknown), via an unspecified route of administration on 25Jan2021 at a single dose for COVID-19 immunization. Patient has no medical history. Concomitant medication included tamsulosin hydrochloride (FLOMAX). Patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231) intramuscular on 08Jan2021 on the left arm. The most recent COVID-19 vaccine was administered at the hospital. On 18Jan2021 06:00, the patient experienced right foot drop. Spine MRI on 18Jan2021 was negative. Stroke confirmed on brain MRI on 28Jan2021. Patient was sent to the ED at the hospital immediately after and was admitted from the ED to the hospital. Number of days of hospitalization was 2. Adverse event result: doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. Patient has not recovered from the event stroke. Event was reported as non-serious. The patient was not diagnosed with COVID-19 prior to vaccination. Patient has been tested for COVID-19 with test type: nasal swab on 28Jan2021 with result negative. Patient has no known allergies. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine.; Sender's Comments: Based on current information available, the event stroke mostly represented intercurrent condition in this patient with advanced age, unrelated to Bnt162b2. Relevant medical history and concurrent disease are missing for a medically meaningful 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 RAs, Ethics Committees, and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1113943-1	65+ years	0 days	TIA; I felt really lousy; This is a spontaneous report from a contactable consumer (patient). A 73-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6203), dose 2 at the age of 73-year-old, via an unspecified route of administration on 26Feb2021 as single dose for COVID-19 immunisation. Medical history included high blood pressure (don't have really high blood pressure but the doctor has her on blood pressure medicine, have no diabetes or whatever, and had allergies. Concomitant medication included amlodipine besylate 5 mg, taken every morning. She takes most of her medicines in the morning and had taken that stuff at about 5 o'clock or so early in the morning. The patient was previously vaccinated with the first dose of BNT162B2 on 05Feb2021 at the age of 73-year-old and had no problem. The patient stated that when she had the first COVID vaccination she had no problem and then Friday she went to get the second one, it was 3 weeks later, when she had first one she stated that she had allergies, so they had her wait 15 minutes, no problem. When she went for the second one, thankfully someone drove her that was outside the 'game court' location. When they gave it they said, she pull up and will let her know after she pull up and will decide if she has to wait 15 minutes or 30 minutes and they asked her if she had allergies, and she said yes, they said pull over here and she has to wait 30 minutes and all she know was, it's probably 2 minutes from the time she got the vaccine until she got to the place to wait. She would say 15 minutes after she got it on 26Feb2021, she felt really lousy and told her friend, they 'said' she was having a Trans Ischemic Attack (TIA), and took me to the hospital and everything. An ambulance was called on 26Feb2021 at around 8 o'clock that morning, right after she had the vaccine and carried her straight in the hospital. She was discharged the next day 27Feb2021 at about 7 PM. The patient had a CT scan of her brain, MRI of her brain, and then cardiac, something with reference to her heart, she forgot, all with unknown results. The body weight right now was about 150 pounds. The outcome of the events was unknown.
COVID19 VACCINE	PFIZER\BIONTECH	1177384-1	65+ years	0 days	4:30pm slight nausea; arm pain; mild headache 5:00 pm headache more severe; up the back of head, described as unusual pain; thought a migraine was coming on. 5-7:00pm headache continues to worsen; chills; research on line side effects of Pfizer vaccine and they coincide with symptoms; 7:05 gets up to urinate (no assistance needed); screams out in pain 3 times while on toilet; starts to vomit; right side of face (eye and cheek and mouth droop like a stroke; left hand starts to curl. Loses consciousness immediately thereafter. 911 call; paramedics on the way; airway was swept and clear; gurgled breathing. Rushed to Hospital and assessed as having massive brain bleed. Pronounced dead at 10:22pm. Acute Hemorrhagic Stroke on Death Certificate.

COVID19 VACCINE	JANSSEN	1085779-1	50-59 years	1 day	Pt presented with AMS. History provided by father at bedside. For 2 days after vaccine pt reported not knowing what he was doing and where he was. Father brought him to ED after having breakfast together and son didn't know how to pay or what foods he liked. Was unable to recall his father's name. Treatment: DAPT with ASA and plavix x21 days and then transition to plavix 75mg daily, atorvastatin 80mg (stroke treatment) Outcome: TBD
COVID19 VACCINE	JANSSEN	1105572-1	65+ years	1 day	Initially had chills, fatigue for two days, then on 3/15 awoke with severe weakness in the right lower extremity. Presented to ER, MRI showed acute stroke ( Small acute infarction within the posterior left corona radiata). Admitted for stroke stabilization and rehab evaluation. Will be discharged to home with outpatient PT and OT
COVID19 VACCINE	JANSSEN	1108465-1	50-59 years	1 day	Heart was in A-fib, blood clot formed and had a Left Posterior Parietal Stroke
COVID19 VACCINE	JANSSEN	1127077-1	50-59 years	1 day	pt presented to ER 0230 3-17-21 pt c/o right sided weakness and numbness, tried to get out of bed and use bathroom and couldn't bear weight or move his right leg. NIH stroke scale score=2, Glasgow coma score =15 183/105, HR 103, RR 18, O2 saturation 95% RA 98.7 oral temp 0/10 pain. clonidine po tablet 0.1mg. EKG=tachycardia 106 normal P waves, normal PRI, normal QRS complex, normal ST and T waves. labs=SARSCoV2 RNA negative, CT head WO=no acute intracranial abnormality by CT criteria. UA=negative, glucose 359
COVID19 VACCINE	JANSSEN	1127237-1	65+ years	1 day	Pt developed sudden-onset of severe left-sided chest pain with heavy pressure, shortness of breath and diaphoresis; pt collapsed and had a period of unresponsiveness lasting approximately 10 minutes. EMS was called and noted significant ectopy as well as frequent NSVT on ECG. Pt was transported to the Emergency Department and subsequently admitted for observation.
COVID19 VACCINE	MODERNA	0915801-1	65+ years	1 day	Patient flushed, shivering and slow to respond to questions. Patient had decreased strength in upper extremities. Upon exam patient's symptoms suggestive of stroke. Patient transferred to ER where a CT was done which showed intracranial hemorrhage.
COVID19 VACCINE	MODERNA	0917026-1	65+ years	1 day	12/28/2020, Pharmacy staff administered Moderna COVID Vaccine. 12/29/2020, he had not eaten breakfast or lunch but did consume fluids and take his medications. BP =150/70, Temp. = 101.6, Pulse= 102, Respirations= 18 and Oxygen saturation= 97%. Tylenol 650 mg given. It was difficult for him to swallow. Also had no use of right upper extremity and unable to move lower extremity, mouth was drooping and was drooling. Physician in attendance and ordered to send to ER. 1/1/2021, received information from nurse at hospital that patient received a Peg Tube this afternoon and Clinical indication of a stroke.
COVID19 VACCINE	MODERNA	0941561-1	65+ years	1 day	Staff walked into resident's room around 10:00am and noted resident's left side of his face was flaccid. Nurse was called and upon assessment resident noted to have an unequal hand grasp with left worse. He was able to talk but was mumbled and hard to understand. Physician, hospice, and family were notified. Resident had a stroke at 10:06 am on 1/8/2020. He lost all ability to use his left side. Resident passed away on 1/11/2020.
COVID19 VACCINE	MODERNA	0942392-1	65+ years	1 day	chills ...fever....extreme weakness, not even able to get himself up from a chair NO strength what so ever, feeling he was going to faint at any minute , slurred speech. Sounded as if he was having a stroke and extreme dizziness. So we to him to ER. Once there they did CBC with Differential...Comprehensive Metabolic Panel ..Protine-Inr....Ptt....Sugar Ck....Urinalysis with Reflex Culture ....Then they did a CT Head W/O Contrast Stoke Protocol & an EKG 12-lead The report with all this information was printed out on 01/05/2021 03:03 PM
COVID19 VACCINE	MODERNA	0955231-1	65+ years	1 day	After receiving Moderna vaccine, pt became increasingly tired, withdrawn, and confused, refusing to walk at home. He has begun to have mild memory changes after suspected COVID illness (covid testing negative) in November, but daughter of patient, with whom he lives, states that his memory and orientation now significantly changed- he seems to have forgotten the last ""3 years"" of memory. Presented to ER 1/16/21 as she checked his O2 and found him to be hypoxic in 60s. He is being treated for possible CAP with underlying perviously undiagnosed ILD vs post-covid lung changes (per pulmonology), and his energy and ability to walk have returned but memory is significantly impaired, confabulating and oriented only to self despite good oxygenation on 5L O2 by NC.""

COVID19 VACCINE	MODERNA	0955247-1	65+ years	1 day	About 22 hours after the shot, I had a mini stroke that required going to the emergency room by ambulance. I was transported that evening to the stroke division that same evening for further evaluation, tests and care. I have never had a mini stroke before this. The doctors said it may have been from the vaccination, or it may not have been precipitated by it. They said they don't have enough information on the Moderna vaccine to make that call.
COVID19 VACCINE	MODERNA	0958971-1	65+ years	1 day	Hemorrhagic Stroke, Right Basal Ganglion
COVID19 VACCINE	MODERNA	0959620-1	65+ years	1 day	Eleven hours after receiving COVID vaccine, client started experiencing stroke-like symptoms legs/arm weakness, couldn't speak, shortness of breath, and throat swelling. Hospital ruled out acute stroke but could not entirely exclude a cerebellar stroke due to her dizziness with vertigo and nystagmus (per hospital report). Client was in hospital 2.5 days, per hospitalist. note-all work up including MRI and tte were negative for acute findings- symptoms have resolved. Hospitalist noted symptoms may be worse following second shot. Spoke with client 1/19/21 and she reported feeling weak and tired only.
COVID19 VACCINE	MODERNA	0959857-1	60-64 years	1 day	CVA the following day Patient had vaccine on 1/14/21 and was admitted to the hospital 1/15/21.
COVID19 VACCINE	MODERNA	0964460-1	65+ years	1 day	Sometime within 12 hours from receiving vaccine he had a stroke. He was taken to the emergency room on January 16, 2021 and tests were performed and he was transferred to Hospital on January 17, 2021. A MRI was performed on January 17, 2021 and showed that he had suffered a stroke. He was put on blood thinners and sent home on January 18, 2021. He had an appointment with MD on January 19, 2021. He has appointments with speech therapist, cardiologist and neurologist.
COVID19 VACCINE	MODERNA	0964666-1	65+ years	1 day	Patient suffered stroke morning after vaccine.
COVID19 VACCINE	MODERNA	0965323-1	65+ years	1 day	Sudden onset of expressive aphasia the next morning (0915) after vaccination. Went to emergency room and diagnosed with stroke.
COVID19 VACCINE	MODERNA	0973150-1	60-64 years	1 day	Pt had slurred speech and left-sided weakness day after vaccine he presented to ER and appears to have CVA
COVID19 VACCINE	MODERNA	0974584-1	65+ years	1 day	Stroke like symptoms; Water in lungs; A spontaneous report was received from a consumer concerning an 83-year-old, male, patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced stroke like symptoms and water in lungs. The patient's medical history was not provided. Concomitant products known to have been used by the patient included, insulin aspart, insulin glargine, ticagrelor, sacubitril valsartan sodium hydrate, furosemide, carvedilol, omeprazole, and sertraline. On 04 Jan 2021, one day prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 05 Jan 2021, the patient began experiencing stroke-like symptoms and had water in his lungs. On 06 Jan 2021, the patient was hospitalized and had a computed tomography (CT) scan and magnetic imaging resonance (MRI) scan of the brain. On 09 Jan 2021, the patient was discharged from the hospital. Treatment information for the events was not provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events, stroke like symptoms and water in lungs, was not reported.; Reporter's Comments: This case concerns an 83 year old male patient who experienced serious unexpected events of Cerebrovascular accident and Pulmonary oedema. The events occurred the next day of their first dose of their first of two planned doses of mRNA-1273. Concomitant medications included, insulin aspart, insulin glargine, ticagrelor, sacubitril valsartan sodium hydrate, furosemide, carvedilol, omeprazole, and sertraline. 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.
COVID19 VACCINE	MODERNA	0974848-1	60-64 years	1 day	Woke up the next morning with slurred speech, right side weakness, illegible writing, balance issues. Next day all symptoms worse. Went to Urgent Care, was transferred to Hospital. Diagnosed with stroke.
COVID19 VACCINE	MODERNA	0987256-1	65+ years	1 day	Had Covid vaccine Friday morning, Saturday morning at breakfast started shaking, couldn't talk. Called 911 and treated for TIA. Received blood thinners, had CT scan . MRI, and echo gram on heart. Released from hospital Monday morning, no after effects.
COVID19 VACCINE	MODERNA	0987374-1	65+ years	1 day	Patient was in distress and had a Stroke ( per his wife). Ambulance called and pt was admitted to hospital.

COVID19 VACCINE	MODERNA	0997973-1	65+ years	1 day	Received vaccine at 1100 on 1/29/21. No symptoms noted during 30 minute post-vaccine observation period. Symptom onset at 0300 on 1/30/21 (16 hours after vaccine administration). Symptoms included chest pain, dyspnea on exertion, weakness, nausea/vomiting, decreased appetite, and diarrhea. Patient presented to Medical Center Emergency Department around 1130 on 2/1/21. Found to have NSTEMI 2/2 Takotsubo's cardiomyopathy with acute congestive heart failure. (of note, coronary angiography in 11/20 showed no coronary artery disease). Patient has never had a reaction to a vaccine or component despite receiving many vaccines due to extensive travel history.
COVID19 VACCINE	MODERNA	0998725-1	65+ years	1 day	Patient daughter reported that patient was admitted to Neurology with a stroke. She has cognitive and speech impairment as well as motor impairment. She was admitted either 2-2-21 or 2-3-21. She is still in the hospital.
COVID19 VACCINE	MODERNA	0999192-1	65+ years	1 day	According to the staff at the Hospital, the patient was treated in their emergency room for a stroke this morning at approximately 730AM
COVID19 VACCINE	MODERNA	1004209-1	65+ years	1 day	Stroke like symptoms; Couldn't speak; Shortness of breath; Legs and arm weakness; Dizziness with Nystagmus; Throat swelling; Dizziness with vertigo; Dizziness with vertigo; A spontaneous report was received from a nurse concerning a 79-year-old, white, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced stroke like symptoms, dizziness with nystagmus, legs and arm weakness, couldn't speak, shortness of breath, throat swelling and dizziness with vertigo. The patient's medical history, as provided by the reporter included anemia, overactive bladder, fibroid cystic disease, allergy to fluoroquinolone, ciprofloxacin, povidone iodine, morphine and adhesive tape. The concomitant medications reported included atorvastatin, calcium, colecalciferol, metoprolol succinate, pramipexole hcl and prasugrel hcl for unspecified indications. On 07 Jan 2021, 11 hours prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 025J20-2A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. The patient experienced stroke like symptoms, couldn't speak, shortness of breath and throat swelling. It was reported that the patient was hospitalized for acute stroke. On an unknown date, while still being hospitalized, the patient developed, dizziness with nystagmus and dizziness with vertigo. The lab findings included, magnetic resonance imaging (MRI) and computed tomography (CT) scans as negative for acute findings, electrocardiography (EKG), complete blood count (CBC), X-ray and chemistries were reported as within normal limits. The patient remained hospitalized for 2.5 days while the symptoms improved. On 09 Jan 2021, the patient was discharged. On 20 Jan 2021, the reporter stated that the patient felt weak and tired without other symptoms. It was also noted that the patient's discharge summary stated the patient's symptoms may be worse following a second dose of mRNA-1273 vaccine. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events, stroke like symptoms, dizziness with nystagmus, legs and arm weakness, couldn't speak, shortness of breath, throat swelling and dizziness with vertigo. were considered as resolved on an unknown date.; Reporter's Comments: This case concerns a 79-year-old, white, female patient with medical history of anemia, overactive bladder, fibroid cystic disease, who experienced the serious, unexpected event of stroke, Aphasia, dyspnea and non-serious, unexpected events of , dizziness, vertigo, pharyngeal swelling, nystagmus and muscular weakness. The events of stroke, Aphasia, Dyspnea and pharyngeal swelling occurred 11 hours after the first dose of mRNA-1273 (Lot number: 025J20-2A) administration and the events of dizziness, vertigo, pharyngeal swelling, nystagmus and muscular weakness occurred on an unknown date while the patient was still hospitalized. 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.
COVID19 VACCINE	MODERNA	1005704-1	65+ years	1 day	Pt's son called and reported that pt had COVID vaccine on 1-25-21 and was taken to the hospital via EMS due to confusion and memory loss. Pt's son states that pt was diagnosed with ""TIA"" and stayed in the hospital x 3 days. Pt states that the physicians at facility was not sure if TIA was related to vaccine but encouraged him to report adverse event. Pt's son states that pt has short term memory loss and has since moved in with him after this event happened.""
COVID19 VACCINE	MODERNA	1009866-1	65+ years	1 day	pt was given vaccine on the afternoon of 01-29-2021. Pt was administered the moderna covid-19 shot into the deltoid muscle of this pt. Pt was observed and left pharmacy. on 2-6, pts daughter calls pharmacy, and says the night of 1-29, after recieveing the vaccine, her mother had a hemmorrhagic stroke and passed away

COVID19 VACCINE	MODERNA	1011398-1	65+ years	1 day	TIA ~ found slumped in chair, aphasic, unable to stand. sent to local hospital emergency room
COVID19 VACCINE	MODERNA	1013235-1	65+ years	1 day	Patient was transported to a local hospital, She experienced a stroke.
COVID19 VACCINE	MODERNA	1020873-1	65+ years	1 day	Cerebral stroke. Symptoms onset was documented by nursing home staff on 1/13/21. Second dose of vaccine was received on 1/12/21. I am unsure at this time if it was the Pfizer or Moderna vaccine. Patient has severe deficits at this time but the brain is still healing. Several weeks in the hospital, patient now has peg tube and picc line. Flaccid right side and speech severely impacted.
COVID19 VACCINE	MODERNA	1022260-1	65+ years	1 day	Respiratory distress, seizing, cyanotic, A-Fib with RVR occurring less than 24 hours after receiving his second dose of Moderna.
COVID19 VACCINE	MODERNA	1022513-1	65+ years	1 day	Arrived to ED with slurred speech, potential stroke, was transferred to Hospital for higher level of care.
COVID19 VACCINE	MODERNA	1026171-1	65+ years	1 day	WOKE UP THIS MORNING NOT FEELING WELL, MANAGED TO SLOWLY WALK INTO KITCHEN, FELT PROFOUNDLY WEAK, BECAME DIAPHORETIC, UNABLE TO SPEAK, SYMPTOMS LASTED FOR 10-15 MINUTES AND GRADUALLY RESOLVED OVER COURSE OF 1 HOUR.
COVID19 VACCINE	MODERNA	1028508-1	65+ years	1 day	moderately high fever, headache for two days, then three days later (Tuesday morning) Signs of TIA - slurred speech, central vision blurry, word recall difficulty
COVID19 VACCINE	MODERNA	1031033-1	50-59 years	1 day	Narrative: Patient evaluated for stroke. No bleeding. Maybe ischemia - Further testing results still pending at the time of this initial report
COVID19 VACCINE	MODERNA	1031790-1	65+ years	1 day	Received influenza vaccine 1/29 at PCP clinic. Received Moderna vaccine on 2/6 by pharmacist at her place of residence. She was taken to the ER on 2/9, unresponsive. Staff reported she wasn't acting normally since 2/7. During her hospital course (2/9-2/13) she was only able to open her eyes. Unable to follow any commands. MRI showed large right MCA stroke. She was discharged from the hospital on hospice.
COVID19 VACCINE	MODERNA	1032865-1	65+ years	1 day	4am (1/29/2021) extreme sweating to the point of soaking the hair on head; extreme dizziness with vertigo and inability to stand up or walk straight leading to nausea and vomiting 11am( out of bed) needed assistance to chair bc of vertigo and vision impairment; spent most of day seated; cont to require assistance with any walking 9pm to bed 8am(1/30/2021) Wake up and all symptoms worse. Unable to walk without assistance and had a severe body lean to left. Husband called doc and they suggested calling 911 to get to ER ASAP 1130 Arrived at hospital ER and was subsequently diagnosed and admitted with a cerebellar stroke
COVID19 VACCINE	MODERNA	1034613-1	50-59 years	1 day	For two days after receiving the first vaccination for Covid-19 I ran a temperature of 101.9 and was not able to go to work. When I returned to work on Friday February 12, 2021 at approximately 8:40am I had a stroke and was rushed by ambulance to the hospital.
COVID19 VACCINE	MODERNA	1036857-1	65+ years	1 day	patient had vaccine injected at village health facility experienced ataxic gait for several weeks brought to office by family initial impression cva seen at ER, admitted had myocardial infarction next day treated immediately with balloon and and stent placement of affected artery RCA underwent bypass coronary because of more severe disease that could not be treated by cardiologist
COVID19 VACCINE	MODERNA	1039506-1	50-59 years	1 day	Patient suffered a stroke the next day. She was hospitalized at Hospital.

COVID19 VACCINE	MODERNA	1040535-1	65+ years	1 day	Stroke (blood in the brain); heavy legs; not feeling himself; difficulty walking secondary to stroke; Bad Headache; A spontaneous report was received from a consumer concerning a 65-years-old, male patient who experienced bad headache, stroke (blood in the brain), difficulty walking secondary to stroke, heavy legs, and not feeling himself. The patient's medical history included atrial fibrillation (A-Fib) four years ago. 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 blood thinners. On 10 Jan 2021, approximately one day prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number not provided) intramuscularly in the right arm for prophylaxis of COVID-19 infection. On 11 Jan 2021, the patient experienced a headache. On 28 Jan 2021, he reported having a bad headache, heavy legs and was not feeling himself. On 29 Jan 2021, the patient was admitted to the hospital and was told he had a stroke (blood in the brain). Patient was discharged on 02 Feb 2021. He now has difficulty walking and is trying to walk with a walker and has to go to rehab. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not provided. The events bad headache, stroke (blood in the brain), difficulty walking secondary to stroke, heavy legs, not feeling himself and headache were resolved on 02 Feb 2021.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the events, a causal relationship cannot be excluded. Of note, patient's medical history of atrial fibrillation and concomitant use of blood thinners may have been contributory for hemorrhagic stroke.
COVID19 VACCINE	MODERNA	1044692-1	65+ years	1 day	Right hemisphere stroke. Currently hospitalized. Stable condition.
COVID19 VACCINE	MODERNA	1047033-1	65+ years	1 day	Had vaccine on 2/15 , then on 2/16 evening had stroke like symptoms trying to turn the TV channel and could not find numbers on remote. then her friend called and could not formulate words to her on the phone and could not say the words that she was thinking. Then she called her brother who is a doctor and he told her to go to Cardiologist and get in. She was talking normal by the time she talked to him. Adverse reaction was TIA. TIA symptoms lasted 5-10 minutes max per patient.
COVID19 VACCINE	MODERNA	1047596-1	65+ years	1 day	Stroke and seizure ( In the past he had a stroke and seizure ) So this is not his first time and we are not sure if this is related to the vaccine.
COVID19 VACCINE	MODERNA	1049432-1	60-64 years	1 day	right parietal stroke—transient left-sided hemiplegia, dysarthria, agnosia, denial
COVID19 VACCINE	MODERNA	1049814-1	65+ years	1 day	Stroke confirmed on MRI.
COVID19 VACCINE	MODERNA	1051703-1	65+ years	1 day	Patient had sore arm the first day, the second day patient had slurred speech, couldn't remember or say words, went to the hospital, CT scan and it showed a stroke, AFib came back that had been resolved, he had to be bagged for 2 minutes because he stopped breathing, MD told him the covid shot may have reacted negatively with his previous heart surgery
COVID19 VACCINE	MODERNA	1052478-1	65+ years	1 day	Patient presented to the emergency department after being found down in her home and presented with right upper and lower extremity weakness and a right-sided facial droop. Patient's presentation was consistent with an acute ischemic stroke which was confirmed on MRI.
COVID19 VACCINE	MODERNA	1052496-1	65+ years	1 day	Numbness and tingling on right side of body, onset < 24 hours after vaccine was administered. Equilibrium affected. Treated at hospital ER and admitted. Acute ischemic VBA thalamic stroke.
COVID19 VACCINE	MODERNA	1055691-1	65+ years	1 day	Massive ischemic stroke with aspiration, unable to arouse on the morning of 1/21/2021 and placed on Hospice with death 1/24/2021

COVID19 VACCINE	MODERNA	1056452-1	65+ years	1 day	<p>left sided weakness; Stroke like symptoms; Slurred speech; Pneumonia; spontaneous report received from a Consumer concerning, 79-year-old female patient who received the first dose of Moderna COVID-19 vaccine and woke up the next morning not feeling well. /PT: [Not Feeling Well]. The patient's medical history included COPD, hypertension and hyperlipidemia. Patient allergies included sleep medications. Patient's concomitant included Gabapentin, Simvastatin, Advair, Spiriva and Proventil. On 04-FEB-2021, the patient received their first of two planned doses of mRNA-1273 in left arm (Batch #: 016M20A) intramuscularly for prophylaxis of COVID-19 infection. Patient daughter called on behalf of her mother. Patient daughter stated that her mother received the Moderna COVID-19 vaccine on 04FEB2021 and on 05Feb2021 her mother woke up and wasn't feeling well. She stated her mother had weakness on her left side. The daughter stated that ambulance took her mother to hospital. The daughter stated that her mother had stroke like symptoms. The daughter stated her mother had difficulty speaking and slurred speech. The daughter stated the doctor Called it ""Neglect for sensation"". The daughter stated her mother was treated like she had a stroke. The daughter stated that the doctor gave her mother a ""Clot buster"" treatment and it started to normalize. The daughter stated the MRI was negative. She daughter that her mother was still hospitalized and now has pneumonia. Wanted to know if this has been previously reported. Treatment that was given in the hospital was a ""Clot Buster"" 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: The events developed on same day after first dose of mRNA-1372. Hemiparesis, dysarthria, and pneumonia were consistent with increased risk of cerebrovascular accidents related to high blood pressure confounded by elderly age of patient. Very limited information regarding this event/s has been provided at this time. 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>
COVID19 VACCINE	MODERNA	1061608-1	65+ years	1 day	<p>The patient had her second Moderna shot on Feb 17, 2021. At 3 am the next morning she reported to the ED c/o being ""fluish"" and short of breath. She was found to be hypoxic to the upper 80's on RA, and a CXR was consistent with CHF. She stated she had some off and on chest pain for the last few weeks, especially with exertion. Ultimately it was found that she had an elevated troponin and was felt to have had an MI. She underwent cardiac cath and a stent was placed in a 95% ostial right coronary stenosis. Although she was reported as having had a ""hyperimmune"" response to the vaccine, I can only say for certain she had flash pulmonary edema due to cardiac ischemia that was due to a stenosis in her RCA that had been there for quite some time, but possibly just happened to become critical right after her second COVID vaccine. It would be hard to blame the vaccine, but it is also impossible I guess to absolve it from any role in her MI.""</p>
COVID19 VACCINE	MODERNA	1067942-1	Unknown	1 day	<p>Stroke; A spontaneous report was received from a Consumer and Other HCP concerning a 84Years-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced event like Stroke. The patient's medical history provided no adverse event. Relevant concomitant medications were reported like atorvastatin calcium, ezetimibe, niacin, metoprolol, acetylsalicylic acid, levothyroxine sodium, and iron supplement. On 4th Feb 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: 038k20a) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On date 5th Feb 2021, The patient experienced the event like Stroke, which required hospitalization. It was noted the patient's speech was getting better, but the left side of his body was still paralyzed. There was no treatment information provided There were no laboratory details provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the event is unknown.; Reporter's Comments: Although a temporal association exist, provided information is not adequate to assess the causal association between the event and mRNA-1273. Critical details such as the medical history and diagnostic report is lacking. Causality is also confounded by the patient's advanced age and suspected cardiac related condition (patient is on antihypertensive noted in conmed)</p>
COVID19 VACCINE	MODERNA	1073412-1	65+ years	1 day	<p>Initial flulike symptoms with fever Tues -Friday. Had a right side stroke 6 AM Saturday morning . Rushed to hospital and had a procedure involving a catheter through the body to the clot in the brain. Came out of that with a weekend left side and was medicated through Sunday night. At 10:30 PM Sunday night had a second stroke on the right side. Did not wake from that. Now I?m not expected to survive.</p>

COVID19 VACCINE	MODERNA	1078464-1	65+ years	1 day	My birthfather had an adverse reaction after he got his 1st Moderna COVID vaccine. He lives alone and was doing well with some underlying conditions. The day of the shot was fine. The next AM, he had vision changes and sudden numbness in his R arm/leg and fell after getting up. ?The numbness went away pretty quickly, but the visual changes remained. He refused to go to the ER/Dr. The next week and a half, he was weak, tired, and couldn?t think as clearly. ?He was brought to the ER? on Wed, 3/3/21 at Hospital. He was found to have a low oxygen level, possible a-fib, fluid retention, emphysema, and aortic stenosis, in addition to his other health issues. ?The Dr said his symptoms the day after the vaccine were a mini-stroke.. He was released from the hospital on Friday, 3/5/21. On Saturday, Hospice came to see him, since nothing can be done for his medical conditions; however, they decided not to sign him up yet, since he I was told they didn't feel he needed to, at this time. One of my sisters is staying with him during the day until he builds his strength back up. Do you think his Mini stroke and health changes had anything to do with the vaccine? He will not be getting the second COVID shot. ?We?re all caught between a rock and a hard place as far as what to do, esp for older folks.
COVID19 VACCINE	MODERNA	1086869-1	Unknown	1 day	Stroke; A spontaneous report was received from a consumer who was also a 66-years-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and who experienced stroke. The patient's medical history was not provided by the reporter. Concomitant medications included Lisinopril, Rosuvastatin, Montelukast, Hydrochlorothiazide, Sertraline, Metoprolol, and Zyrtec. The patient received their first of two planned doses of mRNA-1273 (Batch number: 029L201A) on 12 Feb 2021, approximately one day prior to the onset of the symptoms in the left non-dominant arm for prophylaxis of COVID-19 infection. The patient experienced a stroke on the night of 13 Feb 2021- 14 Feb 2021. The patient could not speak properly due to being drowsy. On unspecified date the patient was hospitalized for the event of stroke and released on 16 Feb 2021. Treatment for the event included double cholesterol med (from 10 to 20 mg) and baby aspirin. No relevant laboratory details were included. Action taken with the drug in response to the event was not reported. 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 onset date of the event of stroke, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1088069-1	Unknown	1 day	TIA; A spontaneous report was received from a nurse concerning a 76-year-old, female patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and who experienced TIA. The patient's medical history was not provided. Concomitant medications were Lipitor 10 and metformin. On 19 Feb 2021, the patient received their first dose of mRNA-1273 (Batch number: 00620) approximately one day prior to the onset of the symptoms for prophylaxis of COVID-19 infection. On 20 Feb 2021 patient was admitted to the hospital with TIA. On 21 Feb 2021 patient went undergone for Magnetic resonance imaging (MRI) and Echo cardio. The test results were not provided by the reporter. Treatment medication upon hospitalization included blood thinners and Lipitor 80. Action taken with the drug in response to the event was not reported. On 22 Feb 2021 patient was released from the hospital. The outcome of events was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the event of TIA, a causal relationship cannot be excluded. Elderly age may have been contributory.
COVID19 VACCINE	MODERNA	1090674-1	65+ years	1 day	Acute ischemic lacunar stroke in left ligament resulting in mild left leg weakness
COVID19 VACCINE	MODERNA	1091828-1	65+ years	1 day	As reported by son and by DON of Medical Center: 02.06.2021 Son reports that patient had spoken with her daughter the morning of 02.06 via phone and that patient sounded fine. Patient's son tried to call her around 3:30 or 4 and there was no answer. Son called the facility where patient resided and staff went to check on her, where they found patient on the floor, conscious. Patient was communicating fine when they found her. It is unclear if she bumped her head when she fell, but patient deteriorated and was taken to ER where a CT was done and it was determined patient had a brain bleed as well as a UTI. Patient was admitted to hospital. Patient subsequently had a stroke while in hospital. Patient was discharged to rehab facility on 02.23.2021 and while she has regained the ability to walk with a walker and some use of her right hand, she remains unable to speak.



COVID19 VACCINE	MODERNA	1093043-1	60-64 years	1 day	The second shot was on February 19. On February 20 and 21, patient experienced a sore arm and flu-like symptoms. On February 28, he had a stroke. Hospital where the ambulance took him initially diagnosed it as Bells Palsy and prescribed prednisone and an anti-viral. After an MRI the next day on Monday, he was diagnosed correctly as a stroke. On Tuesday, he was airlifted to another hospital and was in the ICU for more than 2 days. Patient spent the next 7 days in the neuro-trauma step-down unit with the results of the debilitating stroke. He is unable to swallow and his entire left side is affected as well as vision and hearing.
COVID19 VACCINE	MODERNA	1095848-1	65+ years	1 day	Hours after receiving the 1st Moderna Vaccine patient realized left arm would not move at all and left leg was weak and dragging. Called ambulance and was transported to Hospital. No other signs of a stroke, other than paralyzed left arm and weak leg. Initial scans did not show a stroke. Patient could talk fine, smile, etc. Ran tests in ER, then admitted patient. Treated with muscle relaxers given arm was bent and stiff and would not move. After admitted, the next day an MRI was performed and indicated a stroke in the part of the brain which affects the left side. Began treatment for stroke with blood thinners, etc. Patient moved to Rehab after 4 days in hospital. Remained in Rehab until Monday, March 15th then discharged with weakness in arm and leg remaining.
COVID19 VACCINE	MODERNA	1104469-1	65+ years	1 day	Excrutiating leg pain from knee to groin began on day after first shot 1/28/2021 then after 2nd dose was given on 2/24//2021 a massive stroke ocured within 8 hours.
COVID19 VACCINE	MODERNA	1107218-1	65+ years	1 day	seizures; small stroke; A spontaneous report was received from a consumer (wife of patient) concerning a 78-year-old, male patient who developed seizure and a small stroke. The patient's medical history included seizure 4 years ago, stroke long time ago. Products known to have been used by the patient, within two weeks prior to the event, Cholesterol medicines, Blood pressure medicines and Aspirin. On 18 Feb 2021, prior to the onset of the event, the patient received their first of two planned doses of mRNA-1273 (Lot 031M20A) intramuscularly in the Right arm for prophylaxis of COVID-19 infection. On 18 Feb 2021, the patient developed seizure, small stroke. Treatment for the event was not reported. Doctors are not sure about the causality, but want to report it. They spoke to his doctor about not getting the second vaccine. Action taken with mRNA-1273 in response to the event was unknown. The outcome of the event's, seizure, stroke was considered unknown.; Reporter's Comments: The events were consistent with increased risk of complications associated with history of seizure confounded by elderly age of patient. Company assessed the events to be unlikely related to company product.
COVID19 VACCINE	MODERNA	1111266-1	65+ years	1 day	No longer has vision in that eye; Stroke; Sneezing; A spontaneous report was received from a consumer concerning a 75-years-old, male patient who experienced stroke, lost vision in one eye and Sneezing. 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 blood pressure medicines. On 31 Dec 2020, approximately one day prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 [Lot number 039K20A] intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 01 Jan 2021, the patient reported sneezing and had vision issues. He was told that it appeared he had a stroke. Treatment for the event included eye drops. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events stroke, lost vision in one eye and Sneezing were unknown.; Reporter's Comments: This case concerns a 75 year old, male patient, who experienced a serious unexpected event of blindness and cerebrovascular accident. Concomitant medication included blood pressure medication. Very limited information regarding this event has been provided at this time. Further information has been requested.
COVID19 VACCINE	MODERNA	1124826-1	65+ years	1 day	Patient had a mini stroke (TIA) approximately 14 hours after the 1st Moderna COVID vaccine which is when the doctors put him on Plavix, the blood thinner and an aspirin. The patient had a massive stroke with brain hemorrhage within 24 hours of the 2nd Moderna COVID vaccine which resulted in his death.
COVID19 VACCINE	MODERNA	1126882-1	65+ years	1 day	Patient's wife states that he reported a bad headache about 3 hours after vaccination, that had improved by the next morning. The afternoon of 1/27/21, within 24 hours of receiving the vaccine, patient suffered from a stroke.

COVID19 VACCINE	PFIZER\BIONTECH	0903638-1	60-64 years	1 day	Patient is a very pleasant 62 year old gentleman with a history of HTN, hyperlipidemia who presented with left facial numbness and left UE numbness. He states that it is worse medially on his arm. Present in upper and lower face. He states it started around 730 am this morning. He also notes intermittent ""foggy"" sensation since Monday associated with some blurred vision that comes and goes. Denies focal weakness, unsteady gait, difficulty with speech and swallow. He denies f/c, cp, sob, rash, pruritis, n/v/d, edema. He did receive the Pfizer COVID vaccine yesterday""
COVID19 VACCINE	PFIZER\BIONTECH	0932623-1	65+ years	1 day	Acute ischemic stroke, basilar occlusion
COVID19 VACCINE	PFIZER\BIONTECH	0936066-1	60-64 years	1 day	Pfizer-BioNTech COVID-19 Vaccine EUA: Soon after receiving vaccination patient became tired and experienced a headache. The next day at 2:15pm the patient reported a temperature of 99.0 degrees Fahrenheit, not being as tired, but starting at 9:30 am that morning experiencing ""tongue being tied"" and having difficulty communicating described as ""know what they want to say but it... doesn't come out"" that lasted three hours. The patient denied problems walking or being confused. The patient was immediately referred to the emergency department for evaluation. Upon arrival to the emergency department patient had clear speech speaking in complete sentences and ambulating independently with a steady gait. Physical and neurological exams both normal: no aphasia and no focal neurological deficits, normal strength and sensation throughout. Initial vital signs within normal ranges except blood pressure 149/88 mmHg. Patient remained asymptomatic and stable throughout emergency department stay. Repeat vital signs were within normal ranges and patient was discharged to home with a diagnosis of transient ischemic attack. On follow-up visit with primary care physician four days after vaccination patient reports feeling much better and no new symptoms reported.""
COVID19 VACCINE	PFIZER\BIONTECH	0944857-1	65+ years	1 day	Patient presented herself to LPN slurring words and 'not herself'. Upon evaluation, patient denied drinking alcohol, knew she was not able to speak correctly and visibly frustrated. With great difficulty she was able to communicate that she had a headache and was slightly dizzy. Failed FAST and does have a history of CVAs. EMS called and patient was taken to ER where they admitted her for observation post Stroke. Per the hosp nurse, patient received tPA treatment and will be moved to step-down unit when a bed is available.
COVID19 VACCINE	PFIZER\BIONTECH	0949555-1	65+ years	1 day	Received Pfizer vaccine, first dose on Wed. 01/13/21 between 12 and 1 P.M. Thurs. 01/14/21 in the afternoon he began to note that he had difficulty walking. Went to bed when he woke up at 5:48 A.M. he reported he had ataxia. Patient reported having to walk in tiny steps to stay upright. He went to the emergency room. Had CT scan of head and found blood clots. MRI performed. Stroke found in right PCA territory, but no loss in strength in left lower extremity. Sensation and vision intact. Strength in all four extremities is 5 out of 5.
COVID19 VACCINE	PFIZER\BIONTECH	0960006-1	65+ years	1 day	Slurred speech started morning of 1/8 and patient went to ED after dialysis appointment. Admitted for TIA (transient ischemic attack). Discharged home on 1/10 with follow up appts with Neurology.
COVID19 VACCINE	PFIZER\BIONTECH	0960018-1	65+ years	1 day	Pt reported difficulty in swallowing and wife noticed left-sided facial droop morning of 1/10. Patient admitted for concerns of TIA. Symptoms resolved prior to hospitalization. Patient had MRI brain without contrast of the find evidence of acute infarct. Neurology recommended treatment patient has TIA and having dual anti-platelet therapy for 21 days followed by monotherapy of Plavix for stroke prevention. Patient was stable discharge to home 1/12/21
COVID19 VACCINE	PFIZER\BIONTECH	0970618-1	65+ years	1 day	SON SAID PATIENT WAS FOUND UNRESPONSIVE AND CALLED 911
COVID19 VACCINE	PFIZER\BIONTECH	0976011-1	65+ years	1 day	Began experiencing left sided weakness, Evaluated in ER, Medivac'd to other facility for stroke

COVID19 VACCINE	PFIZER\BIONTECH	0978870-1	40-49 years	1 day	Heart event stopped him from breathing; stroke; lack of air; This is a spontaneous report from a contactable consumer, the patient. A 40-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EL3249), via an unspecified route of administration in the left arm on 13Jan2021 (at the age of 40-years-old) as a single dose for COVID-19 immunization. Medical history included nut allergy from an unknown date and unknown if ongoing. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included zolpidem tartrate (AMBIEN) and doxepin (MANUFACTURER UNKNOWN). The patient did not receive any other vaccines within four weeks prior to the vaccination. On 14Jan2021 at 13:00, the patient experienced heart event that stopped him from breathing and the lack of air caused a stroke; all reported as life-threatening. On 14Jan2021, the patient underwent lab tests and procedures which included COVID-19 test which was negative. The patient was treated for the events which included being put on a ventilator and sedation. The clinical outcomes of the heart event stopped him from breathing, lack of air, and stroke, were not recovered.
COVID19 VACCINE	PFIZER\BIONTECH	0979257-1	65+ years	1 day	Notified by a secondary source the following information. Patient was admitted to the hospital for a stroke. The hospital discovered the patient had a stroke a week prior to vaccination. Patient pace maker had been faulty and patient INR may have been lower than therapeutic. Unable to speak directly to patient at this time to confirm these events. Actual progression unknown. Understood patient is improving.
COVID19 VACCINE	PFIZER\BIONTECH	0986036-1	30-39 years	1 day	stroke; unresponsive; unable to move one side of her body; fell down the stairs; fever; felt groggy; This is a spontaneous report from a contactable consumer and a non-contactable consumer (patient's sister). A 37-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 14Jan2021 at single dose for an covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient was an oncology nurse practitioner working received the Pfizer BioNtech vaccine on Thursday 14Jan2021. On Friday 15Jan2021, the patient visited her family members and told them she had a fever and felt groggy. She went to sleep around 8pm-9pm that evening (15Jan2021). Around 2am-3am in the morning Saturday 16Jan2021, the patient fell down the stairs and her family member found her - unresponsive and unable to move one side of her body. Her family member moved her to the couch. Around 7am-7:30am, the patient was still unresponsive and unable to move one side of her body. Her family dialed an ambulance took her to an hospital. At present - her family reported that the healthcare professional they spoke to said the patient had a stroke. She had received multiple scans (MRI, brain scan) in the hospital and was awaiting a Neuro consult. It was unknown if treatment received. The outcome of events was unknown. Information about lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	0987737-1	65+ years	1 day	On 1-23-21, less than 24 hours after the vaccine was administered, the person developed facial numbness, slurred speech, memory difficulty. BP: 200/100. This occurred again on day 3. Hospitalized a total of 6 days. Discharged home on 1-29-21. Diagnosis: TIA, possible seizures. No history of either. Positive history for controlled hypertension.
COVID19 VACCINE	PFIZER\BIONTECH	0988533-1	65+ years	1 day	Resident per her usual health when dietary staff were into apartment at 0730 with her breakfast. Resident conversing, appropriate, with no focal deficits with ADL. Resident baseline with mild confusion, generalized weakness, using a 4 wheeled walker when ambulating. Med care manager into room at 0830 with am medications. Resident was lying partially on her bed, non responsive. EMS was called immediately and resident was transported to Hospital ER. Wellness nurse was notified later that resident was admitted for rule out CVA.
COVID19 VACCINE	PFIZER\BIONTECH	0989918-1	65+ years	1 day	Stroke
COVID19 VACCINE	PFIZER\BIONTECH	0989988-1	50-59 years	1 day	Diagnosed day after 2nd shot with ophthalmic artery thrombus causing vision loss/change in left eye. I did get shot series on 12/22/2020 #1 and 1/10/2021 and was diagnosed with Covid-19 on 12/13/2020. My internist MD did not feel the vaccine caused the thrombus /Stroke but I wanted to report it as it was associated with the vaccine administration (symptoms of vision loss within 24 hours of the vaccine #2 administration).
COVID19 VACCINE	PFIZER\BIONTECH	0994515-1	65+ years	1 day	Acute on chronic respiratory failure with hypoxemia; Acute urinary retention; Arterial leg ulcer; Cardiac rhythm disorder or disturbance or change; Chest discomfort; Chest pain; SOB (shortness of breath)
COVID19 VACCINE	PFIZER\BIONTECH	0994698-1	65+ years	1 day	Embolic stroke involving left middle cerebral artery; Impaired mobility and ADLs; Stroke

COVID19 VACCINE	PFIZER\BIONTECH	0995168-1	65+ years	1 day	Aphasia CVA Rhythm IRRegular (Cardovascular) EIEvated Troponin
COVID19 VACCINE	PFIZER\BIONTECH	0997584-1	65+ years	1 day	STROKE, ABDOMINAL ANEURYSM, FATIGUE, VOMITING, FALL, HEADACHE, BODY ACHE
COVID19 VACCINE	PFIZER\BIONTECH	1000658-1	65+ years	1 day	Stroke; leukemia; This is a spontaneous report from a contactable consumer. This consumer reported for a 68-year-old male (consumer's husband) received the first dose of BNT162B2 (PFIZER COVID-19 VACCINE, lot number: EL0140, Expiry Date: Mar2021), via an unspecified route of administration on 31Dec2020 13:30 at single dose on right upper shoulder for COVID-19 prophylaxis. Medical history included smoker for 50 years, and blockage in his carotid artery. His grandma died of a stroke and his folks, his dad died of lung cancer and his mom died of uterine cancer. Both his parents had high blood pressure. His dad had a heart attack and his mom had Parkinson's because her hands would shak. There were no concomitant medications. On the 08Jan2021 at about 8PM he had a massive stroke and they had to life flight him to hospital from 08Jan2021 to 19Jan2021. He did have a blockage in his carotid artery but they have been told. She says her husband just had his second vaccine with lot is EL1283 and exp is Apr2021 and all of this could be a coincidence but he told her to call so that was why she was calling. Also he was diagnosed with, it is 4 words and then leukemia and he had an appointment with doctor to get his blood drawn every 2 weeks. The neurosurgeon that did surgery on him on 09Jan2021 at 4 am said that his carotid artery in his neck was plugged and he went in and cleaned it out and put in a stent and he said that his carotid artery was plugged all the way to his temple and he tried to get that out and couldn't. He had his stroke at 8PM on the 08Jan2021. They had dinner at 5 pm and at 6pm they were sitting on the couch and all of sudden he started slurring his words and he said his mouth felt like someone give him Novocain and then he had his arm around her and all of sudden it felt like he was choking her so she grabbed his hand and his fingers started rolling up, started closing up tight so she started playing with his fingers and then he went out in the kitchen and then he hit the floor and she called # and the paramedics came up there. When they got there he could squeeze both hands and lift both feet by that time it was 7:30, they had just brought in a chair, by time they got done bringing in the chair they realized his left side was becoming paralyzed and so they had to go back and get the stretcher so they were there for about 30 minutes, maybe 15 minutes then they headed up the hill toward the hospital at about 8pm and they came in and gave anti-blood clotting medicine and took him for a scan with dye, they found he still had a blockage on his brain so at 2AM on the 9th they came in with a medical helicopter and flew him to (institution name withheld) in (place name withheld) and they did an MRI on and seen his carotid blockage there so he had emergency surgery at from # that morning of the 09Jan2021 at (institution name withheld) and he was in ICU from Saturday until a week ago at 3 o'clock 13Jan2021 he was placed in a regular room and on the 19Jan2021 at 7:30PM he was moved (hospital name) in (place name withheld) for 14 days having 15 hours per day of therapy for a week and then he will go to (place name withheld) (rehab name withheld) and he could be there 2-3 weeks. Wednesday right before they moved him he needed a therapist in the back and one in the front and a 6 inch belt to help him stand up. He started out 08Jan2021 and was put in (institution name withheld) on the 09Jan2021 and then he was discharged to rehab on the 19Jan2021 7:30 pm She has been told it may take up to year for recovery as much as he can. The week of his stroke they were adding on to his home and he was doing the electrical upstairs so it is not like he just sat around and ate bon bons, he was very active.

COVID19 VACCINE	PFIZER\BIONTECH	1013239-1	65+ years	1 day	double vision, little dizzy, headache - yesterday had her 2nd vaccine SYMPTOMS DURATION: 2 days. Patient states she got her first COVID vaccine on 2/5/21 and had a slight headache but no other symptoms. Today, she was sitting the car when she started to have double vision. She reports dizziness/lightheadedness that is moderate. Patient states the double vision isn't everything but random things and at random times today. Denies dehydration, fever, or injection site abnormalities. No headache today. Reports that last week at her PCP's office her BP was slightly elevated and she thinks her BP may be elevated right now but does not have a cuff with her to check. Went to the Emergency Department on 2.6.21 - admitted overnight until the 7th. DETAILS OF HOSPITAL STAY: DX: Diplopia [H53.2] Blurred vision, bilateral [H53.8] HOSPITAL COURSE: 1. Double vision post COVID vaccine. Unclear etiology or if related to vaccine reaction. Resolved. CVA ruled out. Could be migraine associated. Advised patient to talk to PCP about migraine prophylaxis and see ophthalmology as outpatient. 2. HTN 3. HLD Advised patient not to drive till cleared by ophthalmology Inpatient workup included myasthenia gravis panel which is still pending The patient is a 78-year-old right-handed woman who received her first Pfizer COVID vaccination February 5. This morning she developed double vision. Images were horizontal she does not know if they were binocular or monocular. She saw couple with 1 child and it appeared that they had 2 children. She looked at her son and saw 2 heads on 1 body. She saw 2 traffic lights. Each time she saw diplopia, it lasted for maybe 1 minute, and after blinking it went away. The double vision was not associated with headache, facial numbness or weakness, numbness or weakness in her extremities, speech change or imbalance. She recovered from each episode. She has had torn retina twice in each eye. Those were each associated with flashes of light in floaters. She did not have a fever today. She has never had double vision before. Review of systems: She admits to a history of headaches. She said she had catamenial headaches and sinus headaches.
COVID19 VACCINE	PFIZER\BIONTECH	1017156-1	65+ years	1 day	Patient had R sided facial droop and slurring of speech at 9:30 AM 1/21/2021. Sent to Hospital where he was found to have CVA, with complete occlusion of the R vertebral artery from the origin of distal V3 segment.
COVID19 VACCINE	PFIZER\BIONTECH	1019661-1	65+ years	1 day	Patient admitted to hospital evening of 2/7/21 with acute ischemic stroke and received tenecteplase. Diagnosis Left MCA stroke. Reporting event given was just over 24 hours after first COVID vaccine dose.
COVID19 VACCINE	PFIZER\BIONTECH	1022969-1	65+ years	1 day	This patient received his 2nd dose of Pfizer vaccine yesterday. Today, he had focal weakness and difficulty walking and was transferred for suspected stroke.
COVID19 VACCINE	PFIZER\BIONTECH	1023887-1	50-59 years	1 day	24 hours post vaccine developed T 100.1, headache, light sensitivity, reports headache worsened, blurred vision - went to Emergency Services at Hospital, admitted. Reports diagnosis of CVA. Reports headache has improved, continues with blurred vision
COVID19 VACCINE	PFIZER\BIONTECH	1027071-1	65+ years	1 day	Adverse reaction to the vaccine started with variable weakness beginning 1/29/2021. On 1/30/21 around 8:30pm, he needed assistance in the bathroom related to weakness and had what was later identified as a stroke with left side weakness and slurred speech. In accordance with his wishes, he had care at home. Due to his advanced age and frailty, a CT scan was not pursued. The 325 mg of aspirin that he was previously taking daily was discontinued. After the stroke, he needed total care. Hospice was established at home. Nursing assistant care was delivered by daughter. Death followed 9 days later (2/9/2021).
COVID19 VACCINE	PFIZER\BIONTECH	1028101-1	65+ years	1 day	Pt develops left leg pain The day after vaccination in AM subsequently drove approximately 150 miles On his way back stopped at his brothers place for lunch. He then collapsed coming down the steps, EMS started CPR. took him to ER Resuscitated briefly but went into CardioPulm Arrest again and PEA Resucitaion for aprox 1 hour but was unsuccessful. Noted to have Left leg more swollen than Right by 3 to 4 CM presumed to have died from massive Pulmonary embolism and inferior wall myocardial ischemia
COVID19 VACCINE	PFIZER\BIONTECH	1028452-1	65+ years	1 day	The patient suffered embolic strokes and was admitted to the hospital the day after she received her first COVID-19 vaccination. She has a history of strokes, with atrial fibrillation, but was faithfully taking her Eliquis at the time she suffered these recurrent strokes.

COVID19 VACCINE	PFIZER\BIONTECH	1029784-1	65+ years	1 day	Patient presented on 1/24 with acute onset weakness and numbness of the left leg so a stroke alert was activated. NIHSS 3. Head Ct and CTA head/neck were unremarkable. Not a candidate for tPA given on Eliquis. Initial exam was notable for weakness and sensory loss in the left leg, but a sensory level was also found to the umbilicus raising concern for a myelitis. Of note, the patient also reported that certain red colored things she looked at appeared black. Labs unrevealing- CBC, CMP unremarkable. ESR, CRP normal. UA and UCx positive for E. Coli UTI, she was treated with ceftriaxone. MRIs were done of her brain, cervical and thoracic spine which were unrevealing. On 1/25, her exam worsened including worsening weakness in the left leg and new numbness and paresthesias in the right leg. Reflexes were preserved. MRI L spine was done which was unrevealing. Lumbar puncture was done which showed 2 nucleated cells and mildly elevated protein at 50, but was otherwise unrevealing. IgG Index normal. No oligoclonal bands. She developed mild hyperreflexia in the left leg and continued to have a sensory level, now at around T5-6. Repeat imaging of her cervical and thoracic spine were completed on 1/28 which showed a contrast enhancing hyperintensity at T5. The patient was diagnosed with myelitis and she was started on IV methylprednisolone x5 days and sent to rehab. Patient is now significantly improved though continues to report some numbness in the left leg.
COVID19 VACCINE	PFIZER\BIONTECH	1033683-1	65+ years	1 day	Chills and muscle weakness that started on 2/13 PM and then mom suffered a basal ganglia stroke on 2/14 PM.
COVID19 VACCINE	PFIZER\BIONTECH	1035559-1	65+ years	1 day	Stroke; like he had a film over his eye, it was cloudy, like a cloudy day; This is a spontaneous report from a contactable consumer (patient). A 81-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot/batch number: EL1283 and expiry date: 30Apr2021) solution for injection, intramuscular in left arm on 18Jan2021 13:10 at a single dose for Covid-19 immunization. Medical history included chicken pox, measles, and mumps (had chicken pox vaccine, measles, and mumps when he was younger, and he got the flu shot for flu). The patient's concomitant medications were not reported. The next day (19Jan2021) after receiving the injection, patient reported it was like he had a film over his eye, it was cloudy, like a cloudy day. This went on for a couple of days before it improved. There was still a little bit in his left eye, but he can read and it has improved. He can see now and his eyes were improving. He found out that he had a stroke on 28Jan2021. He did not go to the hospital. He does not think the stroke affected anything else. He was supposed to have an MRI sometime this week. He went to the eye doctor and the eye doctor was the one that discovered the stroke and his eye doctor sent the report over to his primary office. He had a vision field test which was how the stroke was diagnosed. He was taking a baby aspirin and he will be put on a blood thinner called Plavix. He has not started Plavix yet, he has to go pick it up. Outcome of the event stroke was unknown while the other events was recovering. No follow-up activities are needed. No further information is expected.
COVID19 VACCINE	PFIZER\BIONTECH	1036403-1	40-49 years	1 day	Hemorrhagic stroke, abnormal platelet count, petechai. Patient had my!triple CTs, MRI and angiogram after finding brain bleed. Once released home from brain bleed patient developed petechai, weakness, shortness of breath
COVID19 VACCINE	PFIZER\BIONTECH	1037159-1	65+ years	1 day	Altered mental status; confusion; TIA (transient ischemic attack)
COVID19 VACCINE	PFIZER\BIONTECH	1040851-1	65+ years	1 day	7:30 the night after the vaccine he got very lethargic and dizzy. And about thirty minutes later he couldn't he lift his right arm or right leg. He was extremely dizzy and not completely coherent. I took him to the hospital where they ran CAT scans and labeled it a TIA.
COVID19 VACCINE	PFIZER\BIONTECH	1043570-1	40-49 years	1 day	Patient suffered ICH within 24 hours of receiving COVID vaccine. Symptoms include facial droop and mild dysarthria. Admitted to Neuro ICU for monitoring.
COVID19 VACCINE	PFIZER\BIONTECH	1043932-1	65+ years	1 day	Developed expressive aphasia TIA 15 hours post vaccination, requiring 48 hour hospitalization

COVID19 VACCINE	PFIZER\BIONTECH	1047170-1	65+ years	1 day	On January 28 around 9 am, I started feeling sick. About an hour later, I felt nauseated and then started vomiting. I vomited throughout the day, about 6 times. I assumed this was a fairly common reaction to the vaccine. The following day (Jan. 29) I felt very weak and noticed that when I signed my name, my hand felt numb and I couldn't control it very well. On Saturday, my left leg began to feel abnormal. I called a friend who is a retired doctor and he said that he had heard of some neurological reactions to the vaccine. By Sunday, I was having a difficult time walking so I called my GPs office and set up an appointment for Monday morning. As soon as she saw my face without a mask, she said that I had had a stroke. I had a slight droop on my left cheek and mouth which indicated to the doctor that a stroke had occurred. She scheduled me for a MRI the following morning, Feb. 3. As soon as the MRI was completed, my GP scheduled me with a neurosurgeon whom I was able to see the same afternoon. The diagnosis was a right medullary ischemic stroke. She ordered a number of tests to be run and scheduled me for March 9 to come back for the result of all the tests and blood work. Doctor referred me for physical therapy to help me regain the use of my left leg and hand.
COVID19 VACCINE	PFIZER\BIONTECH	1047204-1	65+ years	1 day	Acute thalamic cerebrovascular event
COVID19 VACCINE	PFIZER\BIONTECH	1047571-1	Unknown	1 day	Death after stroke .
COVID19 VACCINE	PFIZER\BIONTECH	1048688-1	65+ years	1 day	My mother had a stroke on 28Jan2021 sometime after 9:30 AM the morning after getting the first dose of the Pfizer Covid vaccine; Cerebral infarction; This is a spontaneous report from a contactable consumer (reporting for mother). A 94-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date unknown as not available or provided to reporter at the time of report completion) via an unspecified route of administration on 27Jan2021 in right arm at single dose for COVID-19 immunization. Medical history included coronary artery disease and hypertension. There were no concomitant medications. The patient was not pregnant. No other vaccine was received in four weeks. The patient did not have covid prior vaccination and not have covid tested post vaccination. The patient had a stroke on 28Jan2021 sometime after 9:30 AM the morning after getting the first dose of the Pfizer Covid vaccine and was hospitalized due to stroke for 6 days from Jan2021. The patient then experienced cerebral infarction in 2021 and died due to it on 04Feb2021. Treatment received for events stroke and cerebral infarction included tPA injection. The outcome of events stroke and cerebral infarction was fatal. An autopsy was not performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Cerebral infarction
COVID19 VACCINE	PFIZER\BIONTECH	1051522-1	65+ years	1 day	Patient brought to emergency department at 2210 with concern for stroke d/t left sided weakness. Upon arrival patient appeared to have seizure like activity and was given 2mg of ativan and keppra 1000mg. Patient remained able to converse with providers during episode. Seizure activity/muscle twitching resolved after ativan/keppra administration. At the time of filing this report the patient is being admitted to the hospital.
COVID19 VACCINE	PFIZER\BIONTECH	1053367-1	50-59 years	1 day	day after vaccination suffered from a massive cerebellar stroke with ischemic infarct and suspected embolic stroke required emergency craniectomy with cerebellar resection
COVID19 VACCINE	PFIZER\BIONTECH	1059421-1	65+ years	1 day	After the second vaccine dose she reported not feeling well with unspecified symptoms for a few days. On February 18th, 2021 she visited her doctor with numbness in her hand. They thought it may be carpal tunnel and sent her home. The morning of March 18th, 2021 she had a severe stroke and was transferred to Hospital and then to other hospital. She was in the hospital until Tuesday March 23rd when she was transferred back to her home for hospice care. She died on March 26th, 2021.
COVID19 VACCINE	PFIZER\BIONTECH	1062877-1	65+ years	1 day	Stroke like symptoms and treated for CVA with Altapace
COVID19 VACCINE	PFIZER\BIONTECH	1063702-1	65+ years	1 day	24 hours later : left-sided facial droop, limb ataxia bilaterally, and mild to moderate dysarthria.

COVID19 VACCINE	PFIZER\BIONTECH	1065436-1	40-49 years	1 day	small heart attack; myocardial/paracardial issues.; My injection location had redness, hardness; My injection location had redness, hardness; pains in chest; headache; chill; running nose; shortness of breath.; This is a spontaneous report from a contactable consumer (patient). A 44-years-old male patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in left arm on 19Feb2021 17:45 at single dose for COVID-19 immunisation at hospital. Medical history included coronary artery disease. The patient's concomitant medications were not reported. The patient previously received the first dose of bnt162b2 on unknown date for covid-19 immunisation. The patient did not have covid before vaccination. The patient experienced small heart attack and myocardial/paracardial issues on an unspecified date with outcome of unknown. These events were serious as life threatening, disability and requiring hospitalization from 21Feb2021 till 23Feb2021 at 14:00. On 20Feb2021 07:00 the patient experienced headache, chill, running nose, shortness of breath with outcome of recovering. The patient experienced also pains in chest on 21Feb2021 11:00 with outcome of recovering and injection location had redness, hardness on an unspecified date with outcome of recovering. Clinical course was as follows. 19Feb2021-5:45pm the patient went to receive vaccine shot. 20Feb2021 the patient had headache, chill, runny nose, and shortness of breath. 21Feb2021 11am still had shortness of breath and pains in chest. Went to clinic had a rapid Covid test come back negative, pain increased and he went to emergency room. The patient was admitted to the hospital with small heart attack and myocardial/paracardial issues. Inflammatory response seems to possibly triggered possible underlying issue of minor heart disease. Then induced heart attack and myocardial issue. The patient would gladly be admitted to a clinic for observation and testing to assist Pfizer in understanding this unfortunate situation. The injection location had redness, hardness. The events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The patient received treatment due to the event which included multiple lab tests, Angiogram, CR scan and pain medicine.
COVID19 VACCINE	PFIZER\BIONTECH	1065921-1	65+ years	1 day	right middle cerebral stroke due to clot in brain; right middle cerebral stroke due to clot in brain; This is a spontaneous report from a contactable consumer or other non hcp. A 87-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EL9265), via an unspecified route of administration right arm single dose on 30Jan2021 15:00 for covid-19 immunisation. First dose was received on 09Jan2021 03:00 PM, right arm, lot # EK9231. Medical history included diabetes mellitus, hypertension, hyperthyroidism, glaucoma, drug allergy (to Sulfites). The patient's concomitant medications were not reported. The patient experienced right middle cerebral stroke due to clot in brain from 31Jan2021. The patient was hospitalized from 31Jan2021 to 01Feb2021. The events outcome was not recovered.
COVID19 VACCINE	PFIZER\BIONTECH	1066835-1	50-59 years	1 day	I had my 2nd does of the Pfizer vaccine on February 27, 2021. The next morning I awoke with a very bad headache. I took and Advil. My husband was making breakfast. I came downstairs, ate, had a cup of coffee, then got a glass of water and an ice pack and sat on a recliner in the living room. I don't remember much of the rest. It was like a dream. My husband said I let out a yell, my arms flailed and my eyes were very strange. I lost muscle strength in my lift side mimicking a stroke. He called 911. I was taken to Emergency facility where I gained consciousness. I was then transferred to Hospital. So far every test has come back negative. I have an EEG scheduled for this Thursday.
COVID19 VACCINE	PFIZER\BIONTECH	1069796-1	65+ years	1 day	Right dorsal medullary stroke leading to dysphagia and left-sided sensation changes. First noticed symptoms on 2/25 but did not present to emergency room until 2/27/2021. Patient was hospitalized 2/27/2021; anticipate discharge 3/4 or 3/5 2021. Patient lost ability to swallow; requires tube feeding.



COVID19 VACCINE	PFIZER\BIONTECH	1070711-1	65+ years	1 day	stroke; Joint pain; In the palm of my hand I might jump out of my skin; ; arm was hardly sore at all; right arm at the shoulder, elbow, and fingers is hurting at the joints; This is a spontaneous report from a contactable consumer. This 67-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EL9269) single dose, dose 1 via unknown route of administration in the left arm for COVID-19 vaccination on 12Feb2021 at 14:30. There were no additional vaccines administered on the same date as the COVID-19 vaccine. Medical history included pneumonia five times on an unknown date, septicemia one time, melanoma cancer in 2015, Factor V Leiden, high blood pressure and blood thinner. Prior Vaccinations (within 4 weeks): Concomitant medications included lisinopril from 2008 and ongoing for high blood pressure and warfarin 9.5 mg daily from 2008 and ongoing for blood thinner. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. On an unknown date, the patient's arm was hardly sore at all and he had a stroke. On 13Feb2021, the patient experienced joint pain, in the palm of his hand if he presses right in the dead center he thinks he is going to jump out of the skin and right arm at the shoulder, elbow and fingers is hurting at the joints. When he first felt it in his right arm it wasn't horrible and it seemed like it got worse the next day. Then it seemed like it tapered off a little bit. On 16Feb2021, the pain woke him up in the middle of the night. The events did not require an emergency room or physician's office visit. He gets the flu shot every year and he has no symptoms whatsoever. The clinical outcome of stroke, joint pain, in the palm of my hand I might jump out of my skin, arm was hardly sore at all and right arm at the shoulder, elbow, and fingers is hurting at the joints were unknown.
COVID19 VACCINE	PFIZER\BIONTECH	1076972-1	65+ years	1 day	Monday morning I found my father lying on couch trying to tell me he couldn't walk. His speech was slurred he fell and was unable to walk good his body was pulling to one side. His left arm was numb . I called ambulance he was taken to hospital diagnosed with a stroke. Now in rehab
COVID19 VACCINE	PFIZER\BIONTECH	1086900-1	50-59 years	1 day	having a small stroke; weakness in her right hand and arm; Right arm was really sore; really tired; Headache; having issues with her right hand being numb/1st 2 fingers on her right hand were numb; The initial safety information received was reporting only non-serious adverse drug reactions, Upon receipt of follow-up information on 01Mar2021, this case now contains serious adverse reaction. Information processed together. This is a spontaneous report from a contactable consumer (patient). A 59-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EN6200, expiry date was not reported) (at 59 years of age), via an unspecified route of administration in the right arm on 20Feb2021 15:49 at a single dose for COVID-19 immunisation. The patient's medical history and family medical history were none. The concomitant medications were not reported. Historical vaccine included PFIZER BIONTECH COVID 19 VACCINE, 1st dose, lot number: EL9263, injection in right arm on 30Jan2021 (at 59 years of age). There was no other vaccines administered on same date with the Pfizer vaccine and there was no any other vaccinations within four weeks prior to the first administration date of the vaccine. The patient stated that she is not an HCP, but she does work in a mental health. She stated that she is concerned. She got her 2nd dose of the vaccine on Saturday and was having weakness in her right hand and arm. She asked if this was expected. She added that when she got up yesterday, her right arm was really sore, she was extremely tired, and she had a headache. She went to bed early that night at around 5:30pm, and she woke up around 8 or 9pm that night and tried to pick up her phone and couldn't. She stated that the 1st 2 fingers on her right hand were numb. When she got up today it was fine. They are working from home, so she was typing some notes and then it felt like her fingers went numb, it felt like her 1st finger was like rubber. She stated that the numbness comes and goes. She mentioned that she doesn't have a headache right now, but it felt like it could come back. The events did not require emergency room or physician visit. On 01Mar2021, it was reported that the patient was having issues with her right hand being numb and the representative that she spoke with recommended she follow up with her PCP, which she did, and they diagnosed her with having a small stroke and also referred her to a neurologist as well. She said that her primary care provider she saw was a nurse practitioner. She said that she also saw a neurologist. It was not reported if the patient received treatment for 'having a small stroke' while no treatment received for all other events. The outcome of having a small stroke was unknown; 'weakness in her right hand and arm' was not recovered; while 'Right arm was really sore' and 'really tired' was recovering. The outcome of Headache and 'having issues with her right hand being numb/1st 2 fingers on her right hand were numb' was recovered on an unknown date.

COVID19 VACCINE	PFIZER\BIONTECH	1100501-1	65+ years	1 day	started him on his oxygen; O2 went from 85 to 98; bp 155; notably shuffled; became non-responsive; looks like he is having a stroke; This is a spontaneous report from a contactable consumer (patient's daughter). A 94-year-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date: unknown), via an unspecified route of administration on 25Feb2021 13:45 (at 94-year-old) at single dose (Arm Right) for COVID-19 immunization. Vaccination facility type is clinic. Medical history included congestive heart failure, early stages dementia. The patient's concomitant medications were not reported. The patient previously took first dose of bnt162b2 on 04Feb2021 (at 93-year-old) on right arm for COVID-19 immunization. The patient had no covid prior vaccination. Patient has no known allergies. The patient (father) seemed to be doing fine until 19:45 on 26Feb2021 roughly 30 hours after vaccination. He has early stages dementia, so if he was feeling ill he didn't report anything, and they didn't notice anything. He got up from the table, notably shuffled the 10 feet to the bathroom, sat down on the toilet before we could ""pull down his pants"", and then became non-responsive. The reporter said to her son it looks like he is having a stroke. They got him onto the floor. started him on his oxygen concentrator (usually used only at night), O2 went from 85 to 98; bp 155 from an unspecified date. after a while he came to. he is dnr, dni, so they didn't call an ambulance. Eventually they got him up. no signs of stroke. He does have congestive heart failure. This has never happened before, and he has no history of falling. Daughter was reporting the next morning. He has not yet been awake since this occurred. it is now 8am 27Feb2021. Covid was not tested post vaccination. The outcome of the event o2 went from 85 to 98 was recovered, while for other events was unknown. Information on the lot/batch number has been requested.""
COVID19 VACCINE	PFIZER\BIONTECH	1104545-1	65+ years	1 day	stroke
COVID19 VACCINE	PFIZER\BIONTECH	1113686-1	65+ years	1 day	Pfizer vaccine injected 3:00 PM 3/10/21. The next day, 27 hours post-vaccine injection, while in a store, patient noted at 6:06 PM onset of numbness/tingling Right foot/leg with difficulty standing/lifting foot. He needed support of shopping cart to make it to car. Once in car, numbness/tingling, heaviness/clumsiness of right hand/arm noted. Then right side of lips/mouth affected with dysarthria. Wife witnessed evolution and drove directly to Hospital ER/stroke center by which time patient was vomiting and required wheelchair to enter ER. Stroke team evaluation neurologist concluded ischemic stroke and administered TPA. During TPA infusion, all symptoms resolved remarkably so that dysarthria cleared, numbness resolved and dysmetria/fine motor incoordination/right hand/arm/leg/foot symptoms were markedly improved. Patient admitted to ICU for one day and then neurocare floor for one day. MRI showed 8 mm linear diffusion weighted lesion in right centrum semiovale which was deemed c/w acute/subacute infarct. Attending neurologist in ICU and neurofloor noted that location laterality of MRI lesion did not correlate well with the right-sided patient symptoms, but could not identify other left brain lesions on review of scans. EKG, TEE and echo studies showed no cardiac lesions. Carotid studies were negative. CT and CT angio were uninformative; no hemorrhagic lesions or large vessel blockage. At discharge on 3/14/2021 around 6 PM, patient could walk, talk, and use hands essentially normally to outside observer although patient could relate intermittent brief episodes of possible numbness in lips or hands/fingers or slight heaviness of foot which is slight and decreasing. Patient discharged on atorvastatin, amlodipine, fluticasone, Loratadine, 81 mg aspirin, Ibuprofen (for headaches) for further post-stroke follow-up.
COVID19 VACCINE	PFIZER\BIONTECH	1122643-1	65+ years	1 day	Massive Hemorrhagic stroke 24 hours after receiving first Pfizer vaccination. Suffered bleeding of kidney 6 days later, followed more brain bleeds and blood in stomach area. Vessels are leaking blood, Dr's were could find no reason for the bleedings, have not seen this before.
COVID19 VACCINE	PFIZER\BIONTECH	1134252-1	65+ years	1 day	1/15 through 1/19 Pt was hospitalized for COVID symptoms and diagnosed COVID +. received remdesivir and plasma on 1/15. 1/19 discharged home and doing well until 2/12 2/11 received pfizer vaccine 2/12 readmitted to hospital after being found unresponsive at home, sats 35%, rales, temp 103.8, CXR infiltrates, placed on PR mask then BIPAP- diagnosed with cytokine storm possibly from vaccine. 2/13 sats 78% on BIPAP, sweating, rapid response called and stabilized 2/16 pt found with left sided weakness, droop and left arm flaccid. CT scan revealed ischemic stroke 2/17 6L salter lab remain weak on left side 2/19 increased to 10L salter lab 2/20 possible aspiration - worsening sats 2/21 continues to have decreased sats PR mask at 15L. then back on BIPAP 2/22 discussion with family about poor prognosis. DNR comfort. 2/23 Pt passed away

COVID19 VACCINE	PFIZER\BIONTECH	1138291-1	60-64 years	1 day	Severe headache, fatigue, very sleepy about two hours after injection. Woke about 1:00 a.m. with severe headache. Gave two Tylenol and cold wash cloth for forehead. Started tossing and turning about five minutes later. Sat up in bed, fell over and struck bedside table. EMT said he suffered stroke around 1:30 am. He passed away on the 5th.
COVID19 VACCINE	PFIZER\BIONTECH	1153527-1	Unknown	1 day	Suffered massive stroke 24 hours after Pfizer vaccine; This is a spontaneous report from a contactable consumer. This consumer reported for a (age- 86; unit- unknown) female elderly patient with no pregnant received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Jan2021 13:45 PM at single dose for covid-19 immunisation. No pregnant at time of vaccination. No illnesses or chronic health conditions, no family history of strokes, heart disease or high blood pressure, very healthy prior to vaccine. No other vaccine in four weeks. She suffered massive stroke 24 hours after Pfizer vaccine on 30Jan2021 13:00 PM. Event resulted in Emergency room/department or urgent care, Hospitalization for 27 days, Life threatening illness (immediate risk of death from the event), Disability or permanent damage, Patient died on 18Mar2021. Treatments were received for the event. Outcome of the event was fatal. No autopsy was done. lot/batch number has been requested.; Reported Cause(s) of Death: Suffered massive stroke 24 hours after Pfizer vaccine
COVID19 VACCINE	JANSSEN	1154739-1	50-59 years	2 days	Ischemic stroke right cerebellar, left thalamic
COVID19 VACCINE	MODERNA	0947129-1	65+ years	2 days	Resident received Moderna vaccine on 12/23/2020 around 5 pm. At approximately 3:35 am on 12/25/2020, resident had a CVA and died on 1/1/2021 at 3:00 am.
COVID19 VACCINE	MODERNA	0974313-1	50-59 years	2 days	Patient vaccinated on 1/22. The next morning (1/23), patient experienced diminished sensory and motor function in left arm and leg, as well as facial numbness. Presented to the hospital on 1/24, and was found to have a small stroke in pontine medullary junction. Discharged on 1/25. There is some suspicion that her COVID infection in December may have precipitated this, and patient is currently being evaluated for coagulation disorders, primarily antiphospholipid antibody testing. It is unlikely that the vaccine contributed to this, but given close timeline between the two, filing this report.
COVID19 VACCINE	MODERNA	0985015-1	65+ years	2 days	There were no signs of adverse affects from vaccine. She was admitted to hospital due to stroke.
COVID19 VACCINE	MODERNA	0994015-1	65+ years	2 days	Cardiac arrest of unknown etiology. Sudden collapse with PEA requiring CPR and intubation. Now has severe anoxic encephalopathy and expect death.
COVID19 VACCINE	MODERNA	0997081-1	65+ years	2 days	Pt suffered stroke on 1-23-21, 2 days after getting vaccine.
COVID19 VACCINE	MODERNA	1002039-1	65+ years	2 days	on 1/31/2021 she had a small stroke and she is still getting therapy.
COVID19 VACCINE	MODERNA	1005616-1	40-49 years	2 days	Stroke two days after vaccination, CVA hemorrhage, aneurysm (hospitalized ICU 08 January 2021, currently requires daily physical therapy and has walker to ambulate).
COVID19 VACCINE	MODERNA	1006566-1	65+ years	2 days	unknown if it was moderna or pfizer. Vaccine administered elsewhere so details are not known to me. Pt received vaccine on Friday and was admitted to hospital Sunday 1/17 with CVA, right sided weakness.
COVID19 VACCINE	MODERNA	1009821-1	65+ years	2 days	Ischemic stroke 2 days following vaccine administration resulting in hospitalization. Symptoms began with left lower extremity weakness. The patient also reported a low-grade fever as well as fatigue and generalized weakness following vaccine.
COVID19 VACCINE	MODERNA	1026534-1	65+ years	2 days	resident had a stroke, sent to the hospital and died 4 days later
COVID19 VACCINE	MODERNA	1028597-1	50-59 years	2 days	R thalamic stroke 2 days after 2nd dose of Moderna vaccine with L sided numbness acute in onset
COVID19 VACCINE	MODERNA	1031925-1	65+ years	2 days	On 2/9/2021 experienced headache, chills, and sore arm On 2/10/2021 still experiencing similar side effects but know light headed On 2/11/2-12: 930AM experienced a TIA . I totally believed it was a by product of the Covid shot - 1st dose. Had to go to ER and go through series of tests. Now on blood thinner. Since this occurred i know of 2 people that had similar results and experienced a stroke with 2 of them experiencing major stroke and died. people had similar results Now I don't think I will take second dose - very scared NOTE: I was in great shape prior to this vaccine
COVID19 VACCINE	MODERNA	1034192-1	65+ years	2 days	Patient presented with spontaneous IVH of small vessel origin with essentially no past medical history. She then acutely developed mesenteric ischemia. Died due to all dead small bowel which also appeared to be small vessel disease and not embolic/thrombotic. This process started one week after
COVID19 VACCINE	MODERNA	1038147-1	65+ years	2 days	Patient went into new-onset atrial fibrillation, resulting in a catastrophic stroke. Patient passed away on 2/11 as a result of the stroke.

COVID19 VACCINE	MODERNA	1040541-1	65+ years	2 days	Debilitating Stroke; Affecting the left side of her body; A spontaneous report was received from a consumer concerning an 85-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced debilitating stroke (cerebrovascular accident), affecting the left side of her body (hemiplegia). The patient's medical history was not provided. No concomitant medications were reported. On 23 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 029L20A) intramuscularly for prophylaxis of COVID-19 infection. On 25 Jan 2021, the patient experienced debilitating stroke, affecting the left side of her body. Treatment information was not provided. The reporter stated that the patient was now in hospice care. Action taken with mRNA-1273 in response to the events was not provided. The outcome for the events, debilitating stroke, affecting the left side of her body, was unknown.; Reporter's Comments: This case concerns a 85-year-old, female patient who experienced debilitating cerebrovascular accident and hemiplegia 3 days after the first dose of mRNA-1273 (Lot number: 029L20A). Very limited information regarding this event has been provided at this time. Further information regarding patient's medical history and comorbidities has been requested.
COVID19 VACCINE	MODERNA	1046628-1	65+ years	2 days	daughter stated patient was found on the floor at her facility and was transported to the hospital where she was diagnosed with a CVA. Unknown if this event was related to her COVID vaccine.
COVID19 VACCINE	MODERNA	1065706-1	60-64 years	2 days	Acute CVA with Multiple small Infarcts to left Parietal and occipital area Admitted to Medical Center Admit 02/19/2021, DC 02/22/2021
COVID19 VACCINE	MODERNA	1100962-1	50-59 years	2 days	Nursing staff was informed that the patient was having a hard time walking and was not able to speak, just mumble. Presented with rapid eye movement, lip smacking, equal grips bilaterally although difficulty lifting arms. When asked about pain, pointed to R forehead. 136/99, 79, 20, 99.6. Appears uncomfortable and continuous mumbling. To local hospital via ambulance and admitted. Presumed CVA
COVID19 VACCINE	MODERNA	1105125-1	65+ years	2 days	Patient had a hemorrhagic stroke

COVID19 VACCINE	MODERNA	1105820-1	65+ years	2 days	<p>Patient seen and evaluated by PA-C. with myself. We agreed on the clinical findings and implemented our plan together. Please see PA's note for details. All relevant procedures supervised. Patient arrived to the emergency department due to respiratory symptoms, hypoxic, reported that Wednesday he received his 2nd dose of COVID vaccine. His initial workup was concern for NSTEMI with elevated troponin and peaked T-waves, his chest x-ray concerning for COVID/pneumonia. Patient initially tolerated oxygen by nasal cannula and sepsis protocol was started including IV fluid resuscitation that was done cautiously due to the concern of COVID with respiratory failure. The biotics were given. PA-C readdressed code status with patient who confirmed that his DNR DNI, she so contacted his daughter. Patient had multiorgan failure including acute kidney injury, and pneumonia with respiratory failure +/- respiratory failure. Due to the concern of NSTEMI patient was initially going to be transfer to was hospital and transfer was started. Patient respiratory status started deteriorating and his blood pressure dropped slightly but improved after 500 cubic centimeters of IV fluid and he was also placed on a NIPPV. Around 6:00 p.m. patient has significantly desaturation and he discontinued himself NIPPV. Due to inability to intubate patient, he was ventilated with BVM, patient is slowly improved saturation levels and was opening his eyes, he was placed on a non-rebreather. At this point there is high concern of ARDS and due to inability to intubate or give for the respiratory support His daughter was at bedside and updated of current medical status and poor prognosis. Patient continued deteriorating and at this point he had agonal breathing. His daughter was at bedside and she was made aware of the futile prognosis of patient due to his respiratory failure. Patient rapidly became bradycardic and went into cardiac arrest. No CPR was done due to the DNI DNR status of the patient. · Critical Care Procedure Note Authorized and Performed by: MD Total critical care time: Approximately 30 minutes Due to a high probability of clinically significant, life threatening deterioration, the patient required my highest level of preparedness to intervene emergently and I personally spent this critical care time directly and personally managing the patient. This critical care time included obtaining a history; examining the patient; pulse oximetry; ordering and review of studies; arranging urgent treatment with development of a management plan; evaluation of patient's response to treatment; frequent reassessment; and, discussions with other providers. This critical care time was performed to assess and manage the high probability of imminent, life-threatening deterioration that could result in multi-organ failure. It was exclusive of separately billable procedures and treating other patients and teaching time. Please see MDM section and the rest of the note for further information on patient assessment and treatment. · PE: VITAL SIGNS: BP: 126/75 Pulse: (!) 122 Resp: (!) 40 SpO2: (!) 82 % Temp: 98.1 °F (36.7 °C) Height: 5' 8" (172.7 cm) Weight: 152 lb (68.9 kg) General: Alert, nontoxic, in no acute distress. Lungs: Clear to auscultation bilaterally. · CLINICAL IMPRESSION: 1. Sepsis with acute hypoxic respiratory failure and septic shock, due to unspecified organism (HCC) 2. Suspected COVID-19 virus infection 3. NSTEMI (non-ST elevated myocardial infarction) (HCC) 4. Multifocal pneumonia 5. ARDS (adult respiratory distress syndrome) (HCC) 6. Acute kidney injury (HCC) · Further care and disposition otherwise as outlined by PA. · ED on 2/14/2021 Revision &amp; Routing History Detailed Report Note filed</p>
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COVID19 VACCINE	MODERNA	1111260-1	65+ years	2 days	<p>TIA diagnosis at hospital; Conscious after fall; Dizzy/ lightheadedness; Head bump (temple area and ear caused by hit sink during fall); A spontaneous report was received from a consumer who was also a 90-years-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced transient ischemic attack, fall, dizzy lightheadedness, and a head bump. The patient's medical history, as provided by the reporter, included transient ischemic attack; the patient experienced 3 events in 2020. No relevant concomitant medications were reported. On 23 Jan 2021, prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (Lot number 030L20A) intramuscularly for prophylaxis of COVID-19 infection. On 25 Jan 2021, the patient experienced dizzy lightheadedness and a fall, resulting in a head bump in her temple and ear caused by hitting the sink as she fell. The patient was hospitalized following the fall and diagnosed with transient ischemic attack. On 26 Jan 2021, the patient received magnetic resonance imaging and a laboratory test. On 27 Jan 2021, the lightheadedness and head bump had resolved. Action taken with mRNA-1273 in response to the event(s) was not reported. The outcome of the events, transient ischemic attack and fall, was considered resolved on 25 Jan 2021. The outcome of the events, lightheadedness and head bump, was considered resolved on 27 Jan 2021.; Reporter's Comments: This case concerns a 90-years-old female patient with a relevant medical history of three TIA within last year, who experienced a serious unexpected event of Dizziness and Transient ischaemic attack and non-serious unexpected events of Fall and Head injury. The events of occurred approximately 2 days after first dose of mRNA-1273, lot # 030L20A. Treatment details were not provided. Based on the current available information and temporal association between the use of the product and onset of the events a causal relationship cannot be excluded. However, patient's advanced age and prior history of TIA are considered significant confounders.</p>
COVID19 VACCINE	MODERNA	1127860-1	65+ years	2 days	<p>Not sure if covid vaccine caused this, but this is what happened - Received covid vaccine. two days later had violent shakes in the night. Immediately went to get a covid test out of precaution. Tested negative for covid, but positive for "flu b". Went home to treat flu with fluids and rest. Got no better. Went to heart doctor out of precaution, full work up...everything checked out great. Went home, got no better. Went to primary care physician, full work up...found a "spot" on left lung. Was given antibiotics and steroids, go home and in a few days will be getting better. 3 days later became incapacitated and had to be rushed to ER. Was admitted into hospital for 6 days to treat "pneumonia". Also possible UTI and sepsis. Also while in hospital found out that a mini stroke had happened. Treatment went well, oxygen levels were good. Was released with glowing reports. 24 hours later at home had to be rushed to ER again after becoming incapacitated.. Was admitted again 7 more days. During this time everything took a nose dive in succession. Lungs were failing, multiple unexplained strokes were happening (while on blood thinners, had been on blood thinner 15 years...after first stroke they changed to another blood thinner...only more strokes). After so many strokes and compounding of strokes, his neuro function started failing. He was put on life support. While on life support his organs started failing. He had to be put on comfort mode and was dead within 8 hours. A perfectly healthy 77 year old man who had never been sick a day in his life (literally) got his 2nd covid shot, two days later he fell ill. From that point on his health spiraled out of control until his death on March 19th. Every doctor (pulmonologist, cardiologist, neurologist, and all attending doctors said that it was "atypical and abnormal" what was happening. It should not have happened. 180 degrees from normal."</p>

COVID19 VACCINE	PFIZER\BIONTECH	0954426-1	40-49 years	2 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	0963137-1	65+ years	2 days	Patient received vaccine and 2 days later suffered a CVA
COVID19 VACCINE	PFIZER\BIONTECH	0977065-1	65+ years	2 days	Pt. admitted to the hospital on 22 Jan 21 with Acute on chronic combined systolic and diastolic congestive heart failure; CHF (congestive heart failure); Chest pain, unspecified type; Coronary artery disease involving native coronary artery of native heart without angina pectoris; Debility; Ischemic cardiomyopathy; Shortness of breath; Systolic and diastolic CHF, acute on chronic Still admitted as of today
COVID19 VACCINE	PFIZER\BIONTECH	1003132-1	65+ years	2 days	Stroke within 48 hours of shot on 1/22/2021. L sided weakness, facial droop, slurred speech, confusion, . to this writing (2/4/2021), symptoms persist.
COVID19 VACCINE	PFIZER\BIONTECH	1006823-1	65+ years	2 days	Patient received her vaccine on 01/25/2021. Two days later, she presented with an acute right MCA stroke with aphasia.

COVID19 VACCINE	PFIZER\BIONTECH	1017681-1	65+ years	2 days	94 yo F presented from assist living with slur speech for 1 day, last seen well on 1/30. Pt has a PMH of dementia (Baseline, she will keep saying, ""help me, help me"", AOX3, using walker, could go to bathroom by herself), hx breast cancer (s/p lumpectomy, chemo, Tamoxifen, currently not on tx), HTN, HLD, vaginal bleeding (no further work up by family), overactive bladder (on solifenacin), hx of MI (undocumented, no PCI or CABG), spine stimulator placed. According to patient's daughter, she saw her January 30, she was doing okay after the vaccine. On 1/31 when the daughter called her on the phone, she knows she has some slurred speech, when she saw patient in the facility, she noticed her gait becomes unsteady. She decided to bring her to the hospital. 1/30, she noticed the patient has spilled up some water, otherwise denies fever, chills, shortness of breath, pain, chronically, she has constipations taking laxative. In the ED, pt was afebrile, 36.1, heart rate 85, blood pressure 130/61, respiratory rate 18, saturations 98 on room air. Labs shows, sodium 134, potassium 3.6, bicarb 28, BUN 18, creatinine 0.97, glucose 119, WBC 12.5, hemoglobin 11.8, platelet 239. PT INR 1.09, COVID negative. CT head suggestive of subacute infarct. Possible including small vessel ischemic changes. Chest xray questionable patchy left retrocardiac atelectasis or pneumonia. EKG shows atrial fibrillation's heart rate 71, QTc 610. Case was discussed with neurology in the ED, patient was not a TPA or embolectomy candidate. CT head suggestive of acute/subacute cerebellar infarct. Patient does not have any residual or sensory deficit except expressive aphasia. Neuro saw patient, mentioned patient appears to have had a stroke that by the CAT scan criteria is already subacute. The patient was admitted on the stroke pathway. The patient has new onset atrial fibrillation and therefore should be considered for anticoagulation. The patient cannot have an MRI of the brain due to her spinal cord stimulator but given that the stroke is already subacute on the CT without any signs of hemorrhagic conversion she could be started on this at this point. If she gets started on anticoagulation the aspirin should be stopped. If the patient cannot go on anticoagulation or does not want to then she might be a candidate for dual antiplatelet therapy for secondary stroke prevention. 2D echo shows normal ejection fraction of the left ventricle estimated at 70 to 75%. Regional wall motion abnormality was not observed. Right ventricle systolic function is normal. Moderate aortic stenosis. Cardio was consulted for anticoagulation, From cardioembolic prevention standpoint, anticoagulation is recommended to prevent CVA. However, she has significant risks for bleeding given recent vaginal bleeding (investigation not pursued to spare her comfort), age, comorbidities, etc. Again, further discussion between family and primary team is required regarding risks vs benefits. Was evaluated by speech-language pathology present minimal oral dysphagia no overt clinical signs of aspiration, recommended to continue with NDD 2 diet/thin liquid. Patient was discharged to ECF.""
COVID19 VACCINE	PFIZER\BIONTECH	1020284-1	65+ years	2 days	DIAGNOSIS: #1. CVA #2. Aphasia, acute Number 3. Change in mental status, acute ASSESSMENT/PLAN/DECISION MAKING: Spoke with radiologist informed me that patient had a deep ischemic or infarct change in his corona radiata area which is common in patients with covid 19 infection or vaccination, which patient had a day and a half ago after lengthy discussion with wife, she informed me that patient would not want CPR and he had a stroke in the past and does not want to go to another city as he is 91 years old and therefore not a candidate for thrombolysis and also this was a wakeup stroke and so we do not know his exact time of onset, and she states that they simply want to be treated here for comfort care.
COVID19 VACCINE	PFIZER\BIONTECH	1024643-1	65+ years	2 days	1/21/2021, 48 hours after 1st dose, collapsed at home. Possibly triggered A Fib and went to ER with BP 180/110. CVA verified by MRI of brain. Drs suggested that Pradaxa was not strong enough to prevent stroke when A Fib was triggered. Anticoagulant changed to Eliquis.
COVID19 VACCINE	PFIZER\BIONTECH	1035850-1	65+ years	2 days	Patient woke up on the morning of 2/6 with symptoms of a stroke. Rushed to hospital where clot found in brain. Recovered from initial stroke but then had another major stroke on 2/8 and never recovered.
COVID19 VACCINE	PFIZER\BIONTECH	1038403-1	50-59 years	2 days	admitted to hospital for a stroke
COVID19 VACCINE	PFIZER\BIONTECH	1038447-1	65+ years	2 days	Ischemic stroke on Saturday morning following vaccine Thursday. Symptoms were muscle weakness and inability to speak
COVID19 VACCINE	PFIZER\BIONTECH	1041784-1	65+ years	2 days	On the 25th he was home alone, he called 911 and let them know he thought he was having a stroke. EMS arrived and transported him to Hospital. It was massive stroke, he was not able to comprehend anything, he was put into Hospice the following day and passed away on the 27th. There was no autopsy preformed.
COVID19 VACCINE	PFIZER\BIONTECH	1047410-1	65+ years	2 days	Acute stroke 2 days after receiving vaccine. Second stroke 7 days after that despite being started on aspirin and statin



COVID19 VACCINE	PFIZER\BIONTECH	1054924-1	40-49 years	2 days	Ischemic stroke
COVID19 VACCINE	PFIZER\BIONTECH	1058733-1	65+ years	2 days	On 02/09/2021, the patient received his first dose of the Pfizer COVID-19 vaccine. Two days later, the patient presented to ER at Hospital on 02/11/2021 after noticing right arm weakness, slurred speech and facial droop while in the shower at home. Patient was evaluated and determined to have an ischemic stroke, treated with tPA. Patient transferred to hospital ICU for monitoring on 02/12/2021. Patient transferred to step down care on 02/12/2021 and then was discharged home on 02/13/2021 with improvement in his right sided weakness and the ability to ambulate independently.
COVID19 VACCINE	PFIZER\BIONTECH	1063195-1	50-59 years	2 days	Onset of severe nausea, emesis, and bloody diarrhea, requiring hospitalization for 8 days, infusion care for 4 days after discharge due to hypokalemia, and resulting in diagnosis L ischemic colitis and hypokalemia.
COVID19 VACCINE	PFIZER\BIONTECH	1072539-1	65+ years	2 days	Ischemic stroke; not hypertensive, but supposedly is now.; Visual disturbances; Headache; This is a spontaneous report from a contactable nurse (patient). A 66-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot: EM9810, expiry: unknown), via an unspecified route of administration in the left deltoid on 01Feb2021 14:15 at a single dose for covid-19 immunization at a Physician office. Medical history included asthma, irritable bowel syndrome, pneumonia and borderline high cholesterol. The patient's concomitant medications were not reported. The patient had no prior vaccinations within 4 weeks. The patient had her first COVID-19 vaccine on 01Feb2021 and second one is due on 22Feb2021. On 03Feb2021, the patient had a headache, but didn't think too much because it is a side effect. The headache lasted all through the weekend. Visual disturbances began 04Feb2021. She called her doctor on Monday and was seen by her doctor on Tuesday, 09Feb2021. The patient was referred to the eye center. Her headache was getting a little better. On 10Feb2021, the patient was seen at an institution, her retina and macula looked good, so she was referred to the ED. The patient was told she probably had a stroke. The patient was admitted to the hospital for an ischemic stroke. By looking at the MRI, the onset of the ischemic stroke would have been five to seven days prior, placing the onset on Wednesday, 03Feb2021, which was also the onset of her headache. There is no definitive cause of her ischemic stroke. The patient currently has an arrhythmia monitor on. MRI/MRA showed her vessels looked good. MRI showed evidence of the ischemic stroke. The patient has neurologists since being admitted to the hospital. It was thought that the headache was just because of the COVID-19 Vaccine. Causality was unknown, it was stated that they haven't found anything else as a cause. The patient's doctor stated she was borderline for high cholesterol. She was not hypertensive, but supposedly is now. The patient also had echocardiogram, EKG, manual neuro checks, and blood work but does not have the results. The outcome of the events was unknown. The has trouble reading now since the stroke.; Sender's Comments: Based on available information, the reported events are assessed as unrelated to the vaccine BNT162B2 and can be explained as intercurrent or underlying medical conditions in this elderly patient with excessive weight (BMI=29) and underlying elevated cholesterol. 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.
COVID19 VACCINE	PFIZER\BIONTECH	1074011-1	65+ years	2 days	Presented to ED 48 h after vaccine with chest pain, found to have pericarditis Develop atrial fibrillation, nSTEMI from demand ischemia
COVID19 VACCINE	PFIZER\BIONTECH	1083501-1	65+ years	2 days	Patient has nausea, vomiting, severe headache and severely increased blood pressure. She reported to the ER where it was determined she had had a stroke.
COVID19 VACCINE	PFIZER\BIONTECH	1086478-1	65+ years	2 days	TIA followed by mild stroke 10 hours later. Hospitalized for 2 days for tests and observation.
COVID19 VACCINE	PFIZER\BIONTECH	1091446-1	65+ years	2 days	74 y.o. female with a history of hypertension and hyperlipidemia who was admitted to this hospital on February 25, 2020 4 hours after the development of left-sided weakness. She was found to have an acute ischemic stroke. She has had slow progression with therapy but is now able to ambulate with a walker. She is in need of further rehab, hence the transition to swing bed. She denies any new complaints today, including headache, chest pain, shortness of breath, palpitations or feelings of tachyarrhythmias. The sensory deficits on the left side have improved in particular in her left upper extremity. She is noting some improvement as well and strength. No new focal neurological deficits

COVID19 VACCINE	PFIZER\BIONTECH	1094566-1	65+ years	2 days	abrupt onset dysarthria, left facial droop and left hemiparesis on 03/10/2020 (2 days after vaccine admin) concerning for ischemic stroke. Found to have right ICA and M1 occlusions on imaging suggestive of large vessel occlusion as etiology of stroke.
COVID19 VACCINE	PFIZER\BIONTECH	1100472-1	60-64 years	2 days	I had a stroke; This is a spontaneous report from a non-contactable Nurse. A 61-years-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number:EL3302), via an unspecified route of administration in left arm on 02Feb2021 at single dose for Covid-19 immunisation in hospital. Medical history included hypothyroid. Patient is not pregnant. Concomitant medication included levothyroxine, trazodone, famotidine (PEPCID), cyanocobalamin (VITAMIN B 12). The patient previously took codeine and experienced drug hypersensitivity. Historical vaccination included BNT162B2(lot number:EL3248) on 12Jan2021, in left arm, first dose. No other vaccine in four weeks. No Covid prior vaccination. The patient stated I don't know if it was a result of the Covid shot. But I don't have any comorbidities and I had a stroke on to four which was two days after the shot on 04Feb2021 09:30 with outcome of recovering (as reported). AE result in doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, hospitalization (2 days), disability or permanent damage. The patient underwent lab tests and procedures which included Nasal Swab, Covid test result: negative. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Despite insufficient clinical information provided, by close temporal relationship and absence of factors which may provide an alternative cause, the company deems there is a reasonable possibility that the reported stroke is related to the suspect drug Comirnaty. 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.
COVID19 VACCINE	PFIZER\BIONTECH	1102412-1	65+ years	2 days	Approximately 2.5 days following my mothers fist covid-19 vaccine dose, she had a stroke and was admitted to the emergency room. She survived the stroke and following a brief stay at a skilled nursing facility, is still undergoing physical, occupational, and speech therapy.
COVID19 VACCINE	PFIZER\BIONTECH	1111287-1	65+ years	2 days	stroke; Extensive FLAIR hyperintense signal signal in the cerebral white matter/ Mild hyperintense signal in the brain stem and medial cerebellum; This is a spontaneous report from a contactable consumer. This consumer reported for a 76-year-old female patient (reporter's mother) who received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EL3302) first dose via unspecified route of administration on 21Jan2021 at 12:00 PM in left arm at single dose for COVID-19 Immunization in the hospital. There was no other vaccine administered in four weeks. Medical history included COPD (Chronic obstructive pulmonary disease), Small Cell Lung Carcinoma with metastases to brain s/p surgery, chemotherapy and radiation in 2014, dementia. Concomitant medications included citalopram at 40mg, levothyroxine at 0.05 mg, salbutamol (ALBUTEROL). The patient previously took Codeine and experienced allergies. The patient was not pregnant at the time of vaccination. The patient did not have COVID prior to vaccination. The patient had what appeared to be a stroke on Saturday, 23Jan2021 at 12:00 PM. A CT, MRI and an Echocardiogram were all performed on 23Jan2021 and there was no acute intracranial hemorrhage, mass effect, midline shift, or extra-axial fluid collection. Extensive FLAIR hyperintense signal signal in the cerebral white matter. Mild hyperintense signal in the brain stem and medial cerebellum. Following contrast administration there is no abnormal CNS enhancement. The adverse events resulted in Emergency room/department or urgent care and hospitalization for seven days from Jan2021. Treatment given was TPA to reverse adverse effects. The patient was not tested for COVID post vaccination. The outcome of events was recovered/resolved with sequel. No follow-up attempts possible. No further information expected.
COVID19 VACCINE	PFIZER\BIONTECH	1117431-1	65+ years	2 days	Found in chair lethargic less than 48 hours after her first covid vaccine by facility staff where she lives in an independent living facility. Nursing staff felt she had a stroke with right sided weakness. Slurred speech, weak, unable to walk without two person assistance. Patient was under hospice care so hospitalization was given.

COVID19 VACCINE	PFIZER\BIONTECH	1140696-1	65+ years	2 days	Multifocal Intracerebral Hemorrhage; Disseminated Intravascular Coagulopathy; strokes, Ischemic and Hemorrhagic; strokes, Ischemic and Hemorrhagic; AML; Leukemia; Blood clot diagnosis; Sore lower leg; RDW Stand. Dev. H/RDW Coeff Var H; Platelet Count L, Platelet Vol L; Neutrophils L; Band Neutrophils H; Monocytes H; Metamyelocytes H; Myelocytes H; Absolute Neutrophils L; Other Cell Type Blast Like Cells H; This is a spontaneous report from a contactable consumer. A 70-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) lot number: EL9261, via an unspecified route of administration, administered in Arm Right on 02Feb2021 08:30 (Batch/Lot Number: EL9261) as SINGLE DOSE for covid-19 immunisation. Medical history included breast cancer (8 years ago no chemo just radiation). Historical vaccine included first dose of BNT162B2 (lot number: ELO140) on 11Jan2021 for Covid-19 immunization. Concomitant medication included vitamin c [ascorbic acid] (VITAMIN C [ASCORBIC ACID]), calcium citrate, colecalciferol (CALCIUM CITRATE + D3), glucosamine, magnesium citrate, docosahexaenoic acid, eicosapentaenoic acid, tocopheryl acetate (OMEGA 3 [DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID;TOCOPHERYL ACETATE]) and curcuma longa (TURMERIC [CURCUMA LONGA]). On 04Feb2021, the patient's blood work result showed red cell distribution width (RDW) stand. dev. high; RDW coeff var high, platelet count low, platelet vol low; neutrophils low; band neutrophils high; monocytes high; metamyelocytes high; myelocytes high; absolute neutrophils low; other cell type blast like cells high. On 15Feb2021, the patient experienced sore lower leg. On 16Feb2021, the patient was diagnosed with blood clot. On 19Feb2021, the patient was diagnosed with leukemia. On 20Feb2021, the patient was diagnosed with acute myeloid leukemia (AML). On 21Feb2021, the patient had tow types of stroke, ischemic and hemorrhagic, the patient was intubated. On 23Feb2021, the patient was extubated and died due to multifocal intracerebral hemorrhage, disseminated intravascular coagulopathy, acute myeloid leukemia with blast crisis. The patient received chemotherapy and leukapheresis as treatment. The patient died on 23Feb2021. An autopsy was not performed.; Reported Cause(s) of Death: Disseminated Intravascular Coagulopathy; Acute Myeloid Leukemia With Blast Crisis; Multifocal Intracerebral Hemorrhage
COVID19 VACCINE	PFIZER\BIONTECH	1156352-1	65+ years	2 days	Patient's wife returned for second Pfizer CoVid vaccine on 4/1/2021 she told the vaccinator, that her husband, died two days after he received the first Pfizer vaccine. Date of Death - 03/13/2021. Wife states that husband had a ""massive stroke."" EEG indicated no brain activity and it was decided to remove him from life support.""
COVID19 VACCINE	KNOWN MANUFACTUR	1058033-1	65+ years	2 days	Patient had a stroke two days after vaccine. Received TPA for treatment of stroke due to acute onset of altered mental status. Had a history of afib, not on anticoagulation, which is likely cause of stroke. Family opted for comfort measures given poor neurologic status. Passed awaiting hospice placement
COVID19 VACCINE	JANSEN	1116598-1	65+ years	3 days	Occipital stroke involving vision on 3/14/21, was seen at ophthalmologist and sent to Hospital and stroke confirmed on MRI.
COVID19 VACCINE	JANSEN	1132777-1	65+ years	3 days	They found her unconscious and rushed to ER and MRI showed mild stroke
COVID19 VACCINE	JANSEN	1134651-1	60-64 years	3 days	The patient had a hemorrhagic stroke approximately 3 days after receiving the vaccine and died.
COVID19 VACCINE	JANSEN	1160996-1	40-49 years	3 days	Patient received the J&J vaccine on 3/10. On 3/13 he developed slurred speech, unilateral lower facial droop, weakness of extremities, generalized fatigue. On 3/15 he sought medical attention and was sent to ER -> diagnosed w/ TIA. Pt sent back to jail where simvastatin -> atorvastatin, pt started lisinopril, ASA. Pt denies deficits today
COVID19 VACCINE	JANSEN	1171746-1	65+ years	3 days	Patient vaccinated by EMS on 3/29/21, EMS notified clinic that patient was taken to the Hospital for a stroke on 4/1/21
COVID19 VACCINE	MODERNA	0919546-1	50-59 years	3 days	thrombotic stroke -necessitating hospitalization; and craniotomy; required mechanical ventilator for 2 days. Patient now extubated, breathing on her own. Patient remains hospitalized with marked deficits (aphasic)
COVID19 VACCINE	MODERNA	0926433-1	65+ years	3 days	Hemorrhagic Stroke. Began with vision difficulty in the morning. Then I noticed she had left sided neglect. Went to ER. Treated with Andressa (to counteract Elaquis). In SICU for 2 nights then telemetry unit for 3 nights. Currently in Rehab.

COVID19 VACCINE	MODERNA	0956075-1	30-39 years	3 days	38 year old female - healthy with no significant past medical history. Morning of 1/15/21, pt woke up with difficulty speaking (would be talking and then unable to articulate words which were replaced by grunting sounds) and tingling to her face. No changes to breathing, no numbness/tingling to extremities, equal facial symmetry. Slow onset of symptoms. Pt went to the ED, where she received a CT, MRI (inconclusive reading), lab work reported as normal per pt, EKG and chest x-ray. Symptoms self resolved while in the ED, however MD staff wanted to admit patient for 24 hours of observation and to complete an echocardiogram. Pt left AMA the evening of 1/15/21 due to resolution of symptoms and wanting to follow up with her cardiologist for the echocardiogram. Pt told by MD staff symptoms were likely caused by either TIA, possible reaction to vaccine or migraine presentation (no report of headaches/auras). Plan was to have patient on blood thinners x 30 days then baby Aspirin thereafter. Pt still needing to follow up with PCP and cardiologist for further work up.
COVID19 VACCINE	MODERNA	0969093-1	65+ years	3 days	Pt received vaccine and within 72 hrs developed a stroke. Low platelet count. Endocarditis. Emboli to liver, spleen, kidney.
COVID19 VACCINE	MODERNA	0977362-1	50-59 years	3 days	Moderna COVID-19 Vaccine EUA On 1/9/2021 I suffered a lacunar stroke, Symptoms of left sided paralysis . The symptoms came and went. I was life flighted to Hospital. Underwent several test . CT,MRI,ECHO and labs among other test I was in patient ICU for 3 days. Discharged home. The longest event lasted 4 hours . My BP was extremely elevated. I had borderline HTN in past but never that high. Fortunately I have regained the use of my left side and minimal side effects remain. Unsure if the vaccine could have elevated my BP
COVID19 VACCINE	MODERNA	0981406-1	65+ years	3 days	Stroke, death
COVID19 VACCINE	MODERNA	0996956-1	65+ years	3 days	Positive Covid case investigation with the PA DOH. Spoke with case's daughter. States her mother recieved vaccine at clinic on 01/27/21. Had no complaints of illness or exposure to a positive case prior to vaccine. Daughter states she's independent and stays alone at night. Felt fine the day and the day after of the vaccine. Per daughter, case's last known well time was Friday 1/29/21 at 730pm. Daughter states they found her Saturday morning with stroke like symptoms and was admitted to Hospital step down unit. She was also informed by the doctor that her heart was irregular with atrial fibrillation.
COVID19 VACCINE	MODERNA	1033426-1	65+ years	3 days	Stroke with right upper extremity weakness. Weakness improved, has mild residual weakness at this time. That still may improve in the coming months.
COVID19 VACCINE	MODERNA	1038228-1	30-39 years	3 days	3 days after the second Moderna vaccine patient developed right arm and leg weakness, tingling over the whole body
COVID19 VACCINE	MODERNA	1056011-1	65+ years	3 days	My grandpa had a stroke on the 15th of February. He claimed he had been feeling ""off"" for a few days, but didn't say anything. A blood clot had formed in his brain. He was doing better and about to go to rehab to strength his right side of his body. On the 22nd he took a turn for the worst. He was having trouble breathing and they sedated and partially paralyzed him to put a tube in his mouth. I believe another blood clot had formed and oxygen wasn't properly going through his body. They could not stabilize him, and he passed away the same day. ""
COVID19 VACCINE	MODERNA	1097458-1	60-64 years	3 days	Vertigo, slurred speech, difficult swallowing, numbness on left side of face/chin area; extreme weakness in both arms and both legs but more pronounced in left arm & left leg; blurred vision, extreme fatigue
COVID19 VACCINE	MODERNA	1104254-1	Unknown	3 days	transient ischemic attack episode; A spontaneous report was received from a Physician concerning a 71 year old, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced transient ischemic attack episode. The patient's medical history and products known to have been used by the patient were not reported. The patient received the first of two planned doses of mRNA-1273 (Batch number: 029L20A) on 25 Jan 2021, approximately four days prior to the onset of the symptoms intramuscularly for prophylaxis of COVID-19 infection. On 28 Jan 2021 the patient experienced transient ischemic attack episode and was hospitalized for 24 hours and then was discharged. No treatment information was provided. No relevant laboratory details were included. Action taken with the drug in response to the events were not reported. The outcome of the event was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

COVID19 VACCINE	MODERNA	1108959-1	65+ years	3 days	Stroke resulting in death. Admitted to hospital 2/21/21 as transfer from first Hospital after found collapsed in his hotel room. Left M1 occlusion, thrombectomy performed, then had hemorrhagic transformation. Developed worsening respiratory status after extubation, was reintubated. Given poor neurologic status, was extubated and started on palliative morphine drip. Pt died 0100 3/1/21.
COVID19 VACCINE	PFIZER\BIONTECH	0938118-1	50-59 years	3 days	on 1/8/2021 17:30 patient taken to ER, cerebellar hemorrhage, stroke, aneurysm
COVID19 VACCINE	PFIZER\BIONTECH	0951101-1	65+ years	3 days	PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.
COVID19 VACCINE	PFIZER\BIONTECH	0951412-1	65+ years	3 days	Vaccine was administered on 1/12/21 at Memory Care. On 1/15/21 at 12:30 he developed slurred speech at his facility and slumped to his left side. Out of concern for stroke he was sent by ambulance to Hospital. There he was found to have no evidence of stroke on MRI or CT angiogram. He was admitted to the hospital due to fever and elevated inflammatory markers (ferritin, CRP) and transaminases. He was found to have a positive SARS-CoV-2 PCR and IgG. His symptoms resolved the following morning and may have represented a TIA. He had many markers consistent with COVID-19 and his CT pulmonary angiogram did show ground glass opacities but no pulmonary embolism. It was difficult to assess if this was a reinfection with COVID-19, persistent PCR positivity from November, or an adverse event to the vaccine.
COVID19 VACCINE	PFIZER\BIONTECH	0977593-1	65+ years	3 days	Patient is a 71-year-old female with PMH of type 2 diabetes, hypertension, hyperlipidemia, cataracts, glaucoma who was transferred from Medical Center as a stroke code after she presented there for right-sided weakness, facial droop and visual changes. Patient was given TPA in the past she was within window and she was then transferred here for further management. Patient's symptoms continue to resolve. She was admitted in the ICU and managed by neuro critical care and neurology. Further imaging including CTA head and neck, MRI brain did not reveal any stroke. An assessment of small vessel disease was made which likely resolved after TPA was given. Patient was assessed by PMR and PT/OT and deemed safe to go home with family care and no restrictions. Echo, telemetry and EKG showed no signs of cardiac involvement. Patient was started Plavix x21 days and chronic baby aspirin. She was also started on Crestor 20 mg daily. Patient is to follow-up with neurology in 3 months as she got TPA. She will also follow-up with her PCP on discharge.
COVID19 VACCINE	PFIZER\BIONTECH	0992762-1	65+ years	3 days	Basal Ganglia Stroke
COVID19 VACCINE	PFIZER\BIONTECH	1002693-1	65+ years	3 days	Sudden onset of left arm heaviness and problems working 3rd and 5th digits of left hand. Admitted overnight for suspected TIA. MRI subsequently confirmed acute to subacute right frontoparietal infarct
COVID19 VACCINE	PFIZER\BIONTECH	1008637-1	65+ years	3 days	on 2/1/21 at ~7AM pt was noted by the RN to have rt sided weakness & was sent to Hospital ED for evaluation. They felt he could have had a TIA, or extension of a prior CVA (nothing new on MRI, has small vessel ischemic disease), or a COVID vaccine reaction. Symptoms have mostly resolved, he is not always cooperative so subtle weakness is difficult to detect. He was hospitalizaed, started on ASA & increased BP meds, and returned to his home, where he has resided for several years.
COVID19 VACCINE	PFIZER\BIONTECH	1026699-1	65+ years	3 days	Had a stroke 3 days after round one of Covid vaccine and subsequently died the next week due to complications of stroke. Upon admission to hospital, was in afib.
COVID19 VACCINE	PFIZER\BIONTECH	1036647-1	65+ years	3 days	On Monday, 15 February my mother in law suffered a stroke. She has been hospitalized since the stroke at Hospital.
COVID19 VACCINE	PFIZER\BIONTECH	1043099-1	40-49 years	3 days	24-48 hours after receiving dose, had low grade fever, headache, and malaise. On Tuesday morning (3 days after vaccine), woke up with vertigo, visual changes, severe nausea, diagnosed with cerebrovascular accident
COVID19 VACCINE	PFIZER\BIONTECH	1044569-1	65+ years	3 days	THROMBOTIC STROKE IN THE DISTRIBUTION OF THE LEFT MCA DISTRIBUTION
COVID19 VACCINE	PFIZER\BIONTECH	1046909-1	65+ years	3 days	Patient was admitted for acute CVA, hyperglycemia, and mild thrombocytopenia. Patient was treated and discharged on appropriate medications

COVID19 VACCINE	PFIZER\BIONTECH	1065160-1	Unknown	3 days	Stroke; This is a spontaneous report from a contactable consumer reporting on behalf of the mother. An approximately 81-year-old female patient received the second single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EL9264) on 10Feb2021, for COVID-19 immunisation. The patient received the first dose of BNT162B2 vaccine on 23Jan2021 (Batch/lot number: EL3302). Medical history was not reported. Concomitant medications included two unspecified prescriptions. On 13Feb2021 the patient experienced stroke which required hospitalization on the same day. The reporter was not sure of the name but they did a 'CAT' where they went up and pull the clot out of the brain. Event outcome was unknown. The patient was still in the hospital at the time of report. No investigation was performed before the event.
COVID19 VACCINE	PFIZER\BIONTECH	1069829-1	65+ years	3 days	Clients spouse, called to report adverse event. She reported that Medical Center directed her to call and make a report. Her spouse experienced a stroke 3 days following booster vaccination. Is currently hospitalized at Medical Center.
COVID19 VACCINE	PFIZER\BIONTECH	1099173-1	65+ years	3 days	1/24/2021 unresponsive, sent to Hospital. Admitted with diagnosis: Acute Ischemic left MCA stroke. 1/26/2021 Transferred to Hospice care. 01/30/2021 died. I don't believe the hospital was aware of her vaccination date as it is not recorded in her records, therefore I assume that a previous VAERS report has not been submitted. My relationship to the patient is that I am her daughter.
COVID19 VACCINE	PFIZER\BIONTECH	1104607-1	65+ years	3 days	Stroke on 2/11/2021 caused by a blood clot
COVID19 VACCINE	PFIZER\BIONTECH	1122739-1	65+ years	3 days	3 days after 1st shot, I suffered a stroke; This is a spontaneous report from a contactable consumer (patient himself). This 77-year-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via unspecified route of administration on the left arm on 02Feb2021 at 09:30 AM (at the age of 77-year old) at single dose for COVID-19 immunization. Relevant medical history included type 2 diabetes, kidney disease, heart failure, cutaneous T-cell lymphoma (CTCL) and allergy to lisinopril. Concomitant medications included atorvastatin (LIPITOR), metformin, losartan, potassium and acetylsalicylic acid (ASPIRIN). On 05Feb2021 at 01:30 PM, after 3 days from the first dose of vaccine, the patient experienced a stroke that resulted in hospitalization for 4 days. Treatment included CAT scan, MRI (with unknown results) and intravenous blood thinner. The outcome of the event was recovering. The event was serious due to hospitalization and life threatening illness (immediate risk of death from the event). Information on the lot/batch number has been requested.
COVID19 VACCINE	JANSSEN	1114540-1	65+ years	4 days	Transient ischemic attack confusion, mouth droop, delay in responses
COVID19 VACCINE	JANSSEN	1126402-1	65+ years	4 days	on 3/22/2021 pt developed altered mental status, right sided weakness, right sided gaze, aphasic. Patient was administered 65 mg IVPB alteplase 3/22 1245 with last known well 3/22 1000. Received Covid vaccine 3/18/21. Pt was usual state of health prior to stroke with no illnesses. initial NIH score was 18. post tpa NIH of 12 am of 3/23.
COVID19 VACCINE	JANSSEN	1148591-1	50-59 years	4 days	Was reported by the patients primary care provider that the patient experienced a stroke approximately 4 days post vaccination.
COVID19 VACCINE	MODERNA	0913010-1	40-49 years	4 days	presented to office with a 2 day history of blurred vision of his right eye. He has been diagnosed with an acute Central Retinal Vein Occlusion of his right eye. (H34.8112). No treatment at this time.
COVID19 VACCINE	MODERNA	0974068-1	65+ years	4 days	Sudden onset of severe abdominal pain with diarrhea and bloody stool/fluid on Wednesday 1/20/21. Very weak/lightheaded. To ER on evening of 1/21 - CT noted 2 Thrombi in each branch of portal vein and ischemic colitis of descending colon. No risk factors determined. Only change in life was Covid-19 Moderna vaccine. Other side effect from vaccine was only a sore are at injection site. Seen by surgery and hematology. Rapid Covid test was negative and wife's pcr Covid test was negative. As of today is feeling significantly improved but not yet taking PO and remains on heparin drip.

COVID19 VACCINE	MODERNA	1056483-1	Unknown	4 days	cardiomyopathy; A spontaneous report received from a Healthcare Professional concerning, 72-year-old female patient who received the second dose of Moderna COVID-19 vaccine and develop cardiomyopathy. The patient's medical history was not included. Patient's concomitant was not included. On 01-FEB-2021, the patient received their second of two planned doses of mRNA-1273 (Batch #: unknown) intramuscularly for prophylaxis of COVID-19 infection. Physician called and stated that his wife received the second Moderna COVID-19 vaccination on 01-FEB-2021 and on 05-FEB-2021 she developed cardiomyopathy. He stated that he would like for someone in the medical department to call him back. 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. Company assessed the events to be unlikely related to company product.
COVID19 VACCINE	MODERNA	1056842-1	65+ years	4 days	The medical facility did not treat patient as her primary care, but were informed that she passed away on 15 February 2021 of a stroke. I do not have further information on the medical aspect of this as we were not her treating provider but did administer the vaccine on 12 February.
COVID19 VACCINE	MODERNA	1061434-1	65+ years	4 days	I am the patient's daughter as well as an RN-BSN. My mother was given the Moderna vaccine on Feb 11, 2021 and on Feb 15, 2021 she had a CVA and MI. She was found on her apt. floor unconscious. She was transferred to the Hospital by ambulance where a CT scan and other tests were done. It was determined she had a stroke and heart attack. My mother was in great health, took no medications, and lived alone in her apt. before this incident. The medical professionals determined she would not recover so she was admitted to hospice and died on Feb. 21, 2021. I believe there is a relationship between the vaccine and the CVA and MI.
COVID19 VACCINE	MODERNA	1074003-1	18-29 years	4 days	Vaccine was Moderna COVID-19 Vaccine EUA 4 days after receiving the vaccine, two hours after I woke up, I began to have mild chest pain in the center of my chest. After that, the pain started to grow and grow until it was extreme pain, at around an 8/10. The pain radiated from my chest to the undersides of my arms. After two hours of pain, it started to subside and eventually was gone. There was no pain for the rest of the day. The next day, two hours after I woke up again, the mild chest pain returned. Still in the center of my chest, the pain grew into extreme pain again. This time however, it was slightly to the right and as the pain progressed it moved right until after two hours it went away again. The treatment I got at the Urgent Care was an EKG and they told me to go to a hospital. At the hospital, I got Toradol, aspirin and propranolol. My initial Troponin levels at admission to the hospital were 900 and grew to 1300. It lowered for a time, but at the last check, it rose again to 1420 after not getting Toradol for at least 12 hours.
COVID19 VACCINE	MODERNA	1075996-1	65+ years	4 days	Hospitalized February 28, 2021 with acute cerebrovascular accident with left hemiparesis, 4 days after vaccine
COVID19 VACCINE	MODERNA	1084387-1	65+ years	4 days	Stroke/ TIA
COVID19 VACCINE	MODERNA	1123167-1	65+ years	4 days	Stroke
COVID19 VACCINE	PFIZER\BIONTECH	0916668-1	30-39 years	4 days	TIA symptoms - difficulty speaking, reports leaning towards the left side and was dizzy for about 10min.
COVID19 VACCINE	PFIZER\BIONTECH	0962764-1	65+ years	4 days	Patient did not have any adverse reaction to the COVID vaccine, but we were asked by our health dept to submit a VAERS report since the patient died between his first and second dose. Received Pfizer Dose #1 12/17/2020. No side effects or adverse events noted; lived in 24/7 care facility and monitored twice daily for reaction. Date of death 12/23/2020 from aspiration pneumonia complicated by end-stage heart failure and ischemic cardiomyopathy. Death was anticipated and not sudden.
COVID19 VACCINE	PFIZER\BIONTECH	0986749-1	65+ years	4 days	5:30 am I found husband by bed, babbling, Called 911, Had Lt Hemi Stroke. Aphasic, Rt side limp, given TPA. Sent to ICU. Recovered within 2hrs, speech, movement of extremities. It hemi clot found on ct angiogram & mri. 2nd mri found clot busted with residual. transfered to telemetry next nite. echo unclusive. 02 sats low, venogram done 3days later show lt dvt, lung ct wnl. Id asa & b/p meds were given. blood work to be drawn for baseline prior to anticoagulent therapy. possible d/c 9/30.
COVID19 VACCINE	PFIZER\BIONTECH	0994613-1	65+ years	4 days	after shot i didn't have any problems and then i came home. On Monday I slipped getting out of bed and hit my head on the floor , i couldn't move or talk, Wife called 911 and went to ER. had a Stint put in my head. Went into ICU discharged. I was diagnosed with Stroke
COVID19 VACCINE	PFIZER\BIONTECH	1009884-1	65+ years	4 days	Fell, head injury and vertebrae fractured. Probable stroke. Dizziness.

COVID19 VACCINE	PFIZER\BIONTECH	1021027-1	65+ years	4 days	Patient was brought in by ambulance on 01/28/2021 with complaints of fever, chills, myalgias, shakiness, and severe hypotension. Patient was treated for severe sepsis and acute kidney injury. Patient was given fluid resuscitation, but unresponsive to treatment; NE+ vasopressin, hydrocortisone IV, along with empiric antibiotic regimen were initiated. Patient later on developed pulmonary edema, Non-ST elevation MI with no chest pain and new onset of cardiomyopathy with EF 40-45% and clean coronary arteries shown on cardiac catheterization. Physician suspected cytokine release syndrome related to the COVID vaccine and congestive heart failure. Naranjo scale score of 2 indicates possible ADR. MD indicated vaccine reaction unlikely.
COVID19 VACCINE	PFIZER\BIONTECH	1022055-1	65+ years	4 days	Had a mild a heart attack and mild stroke; had a mild a heart attack and mild stroke; urinary tract infection; Blood infection; A1C was 6.5; there was a little blood in his urine; he fell out of bed and couldn't get up; he was flushed; he had a fever of 101; This is a spontaneous report from a contactable consumer (patient's wife). A 74-year-old male patient (husband) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number: EL1283) at 0.3 mL single on 20Jan2021 for COVID-19 immunization. Medical history included thyroid; hypertension, was under control with the medication; dementia, taking memantine as a treatment for dementia, no other impairment other than what he normally has from his dementia. Concomitant medications included levothyroxine; memantine for dementia; fish oil tablet; Vitamins. Patient had a mild heart attack and a slight stroke and he did have urinary tract and blood infection on 24Jan2021. They both had the first dose of the Pfizer covid vaccine on 20Jan2021, Saturday night into Sunday. He was a dementia patient, alert to his name. On 24Jan2021, he fell out of bed and couldn't get up, he was flushed, so patient's wife took his temperature, he had a fever of 101. Patient's wife couldn't move him, so called the paramedics and they took him to Hospital. Patient's wife just found out that he had a very mild heart attack and slight stroke, no impairment other than what he normally had from the dementia. Patient's wife was wondering should he get the second shot and what was the timing of the 2nd dose of vaccine. Reporter seriousness for mild heart attack, slight stroke, urinary tract and blood infection was hospitalization. They also have him on some sort of penicillin derivative for a urinary tract infection. Since he had been to the hospital, he had at his doctor's office about 2 weeks ago today, he had a blood test, a urine test. His A1C was 6.5, there was a little blood in his urine. For that since Sunday (24Jan2021) he was having MRI, he had a couple of PET scans, he had an electrocardiogram. The neurologist came in to check on him. He was in hospital now. Hospitalization date was 25Jan2021 early in the morning. The outcome of events was unknown.
COVID19 VACCINE	PFIZER\BIONTECH	1035529-1	Unknown	4 days	ischemic stroke; This is a spontaneous report from a contactable consumer. A 9-decade-old (reported as: ""in her 80's"" ) female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), via an unspecified route of administration, first dose on 28Jan2021 at single dose for COVID-19 vaccination. Recent medical history included GI complications. The patient's concomitant medications were not reported. On 01Feb2021, the patient experienced ischemic stroke requiring hospitalization. Event took place after use of product. The outcome of the event was recovering. Information about lot/batch number has been requested.""
COVID19 VACCINE	PFIZER\BIONTECH	1035547-1	65+ years	4 days	left parietal CVA; left popliteal DVT; This is a spontaneous report from a contactable consumer (patient). A 71-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number= el 1284), via an unspecified route of administration on 22Jan2021 17:00 at single dose at left arm for covid-19 immunization. Medical history included cholesterol. Concomitant medications in two weeks included atorvastatin (LIPITOR), esomeprazole sodium (NEXIUM), triazolam and OTC vitamin. The patient was not diagnosed with COVID-19 prior to vaccination. On 26Jan2021 05:30 AM, the patient experienced left parietal CVA and left popliteal DVT (hospitalization, life threatening) with outcome of recovering. The patient was hospitalized for both events for 5 days. The patient underwent lab tests and procedures post vaccination which included nasal swab: unknown results. Patient received TPA (Tissue plasminogen activator), blood thinners as treatment. The adverse events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event).
COVID19 VACCINE	PFIZER\BIONTECH	1045951-1	65+ years	4 days	Stroke in third branch of middle cerebral artery and intramural clot of right carotid artery



COVID19 VACCINE	PFIZER\BIONTECH	1048680-1	65+ years	4 days	Acute ischemic stroke on 02Jan2021; This is a spontaneous report from a contactable Healthcare Professional. A 78-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 28Jan2021 at single dose for COVID-19 immunisation at the age of 78-year-old. Medical history and concomitant medications were unknown. The patient was not pregnant at the time of vaccination. Patient had Acute ischemic stroke on 02Jan2021; the patient was hospitalized, and she was treated for the event. On 01Feb2021, nasal swab resulted negative. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient was recovering from the event. Patient has not tested positive for COVID-19 since having the vaccine. Information on the lot/batch number has been requested; Sender's Comments: Based on the available information there is no evidence or argument to suggest a causal relationship between the reported event of ischemic stroke and BNT162B2 administration. Event occurred prior to vaccination.
COVID19 VACCINE	PFIZER\BIONTECH	1056640-1	65+ years	4 days	Lt parietal occlusion; DVT; Right paralysis; This is a spontaneous report from a contactable Nurse reporting for her husband. A 71-years-old male patient received the first dose of bnt162b2 (BNT162B2; Lot # EL 1284) vaccine, intramuscular in the left deltoid on 22Jan2021 17:00 at single dose for Covid-19 immunisation. The patient medical history was not reported. Concomitant medication included apixaban (APIXABAN), acetylsalicylic acid (ASPIRIN) atorvastatin (ATORVASTATIN), cyanocobalamin (CYANOCOBALAMIN), metoprolol tartrate (METOPROLOL TARTRATE), pantoprazole (PANTOPRAZOLE), sumatriptan (IMITREX [SUMATRIPTAN]), triazolam (TRIAZOLAM). The patient experienced DVT (deep vein thrombosis) on 26Jan2021 with outcome of not recovered, left parietal occlusion (ischaemic stroke) on 26Jan2021 05:30 with outcome of unknown, right paralysis on an unspecified date with outcome of unknown. The patient was hospitalized for DVT (deep vein thrombosis) and stroke from 26Jan2021 to 30Jan2021. The patient underwent lab tests and procedures including blood pressure diastolic: 84 mmhg on 30Jan2021, blood pressure systolic: 141 mmhg on 30Jan2021, body mass index: 26.4684 kg/m2 on 26Jan2021, body temperature: 98.2 °F on 30Jan2021, heart rate: 55 bpm on 30Jan2021, magnetic resonance imaging: acute left parietal lacunar infarct, Lower extremity ultrasound: left popliteal vein DVT, oxygen saturation: 95 % on 30Jan2021, respiratory rate: 18 br/min on 30Jan2021. The reporter considered the reported events to be possibly related to BNT162B2 vaccine. Follow up information 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 known suspect drug profile and/or implied 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 Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1058152-1	Unknown	4 days	stroke; This is a spontaneous report from a contactable consumer, the patient. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE solution for injection, Lot unknown, first dose) intramuscular on 01Feb2021 (at an unknown age) at single dose for COVID-19 vaccination. Medical history and concomitant medications were not reported. On 05Feb2021, four days after vaccination, the patient had a stroke. The outcome of the event stroke was unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.
COVID19 VACCINE	PFIZER\BIONTECH	1059679-1	50-59 years	4 days	Stroke Bala Gangria catastrophic stroke

COVID19 VACCINE	PFIZER\BIONTECH	1066924-1	65+ years	4 days	Neurology consult 2/13/21: This is a 78-year-old female we were consulted by Dr. for possible guillian barre s/p COVID vaccine. The patient tells me that she was in her normal state of health, and she received her 1st dose of the COVID-19 vaccine 7 days ago. Subsequent to that, the next day she developed chills, fatigue that continued for approximately 2 days. She states that 3 days ago, she woke up and was unable to lift her legs or get herself out of bed on her own. She felt weak in her proximal lower extremities and her trunk. She denied any bandlike sensations or paresthesias. She cannot tell me that she developed any distal lower extremity weakness initially but felt that it was the acute onset. She needed some help out of bed when she was upright, she was able to use her walker to slowly get to the factor. She may have had some urinary incontinence, she does complain of diarrhea now. Denies any tingling sensation, no bulbar symptoms. This is a 78-year-old female who we were asked to evaluate for possible Guillain-Barre syndrome. She had acute onset of lower much greater than upper extremity weakness without any definite ascending features, of relevance, is that she received the COVID-19 vaccine 3 days prior to the onset of her symptoms. She did exhibit flu-like symptoms prior to this. Given that she does not have any specific area of intrathecal enhancement to suggest Guillain-Barre or other areas of radiculitis, I think it is reasonable to proceed with lumbar puncture to look for any other source. –Given the findings on the MRI cervical and lumbar spine including enhancement of the bilateral sacral S1 region, I would like Neurosurgery to further evaluate. – would likely benefit from CT chest abdomen pelvis to rule out any underlying occult malignancy particularly if workup remains unremarkable. – continue supportive care, monitor for shortness of breath, new vital capacities Patient remains admitted to the hospital with continued weakness at the time of this report
COVID19 VACCINE	PFIZER\BIONTECH	1068270-1	65+ years	4 days	Suffered a stroke 4 days later 06Feb2021; This is a spontaneous report from a contactable consumer, the patient. A 71-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot unknown, first dose) solution for injection intramuscular in the left arm on 02Feb2021 at 14:45 (at the age of 71-years-old) at single dose for COVID-19 vaccination. The patient was not pregnant at the time of vaccination. Medical history and concomitant medications were not reported. The patient had no known allergies. 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. The patient suffered a stroke 4 days later 06Feb2021 after vaccination. The event resulted in an emergency room/department visit and hospitalization in Feb2021 for 3 days. Treatment for the event stroke included medication and therapy. The outcome of the event stroke was recovering. Since the vaccination, the patient has not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.
COVID19 VACCINE	PFIZER\BIONTECH	1076911-1	65+ years	4 days	passed away shortly after her vaccine; started dealing with signs that are common with a stroke; developed swelling in her arms; This is a spontaneous report from a contactable consumer report for grandmother. A 101-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number=EM9809) via an unspecified route of administration in left arm on 08Feb2021 04:30 AM at single dose for covid-19 immunisation. Medical history included elderly. No covid prior vaccination. No other vaccine in four weeks; No other medications in two weeks. On 12Feb2021 12:00 AM, patient passed away shortly after her vaccine. She started dealing with signs that are common with a stroke. Event considered Life threatening illness (immediate risk of death from the event). She also developed swelling in her arms. No treatment received, patient not recovered from stroke and swelling arm. The patient died on 12Feb2021. No covid tested post vaccination. It was unknown if an autopsy was performed.; Reported Cause(s) of Death: passed away shortly after her vaccine
COVID19 VACCINE	PFIZER\BIONTECH	1081063-1	65+ years	4 days	Pfizer shot on Sunday am - my father noticed my mother c/o not feeling well and unable to explain why she didn't feel well. She woke up feeling well and then quickly became disoriented and vomited. She was then unable to walk or communicate appropriately. Emergency services was called and she was transported to Emergency room. She was diagnosed with a posterior brain CVA and was treated with tpa and now remains hospitalized in the ICU with expressive aphasia and vision loss.

COVID19 VACCINE	PFIZER\BIONTECH	1085200-1	30-39 years	4 days	Patient had 4 mm left frontal lobe stroke without any other known etiology on testing (heme, cardio, neuro consulting/workup); This is a spontaneous report from a contactable physician. A 35-year-old female patient (no pregnancy) received the first dose of BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine, lot number: EL9267), intramuscularly at site of left arm at 16:30 on 16Feb2021 at single dose for COVID-19 immunisation. Medical history included hypothyroidism and autism spectrum disorder (ASD) (closed 12 years ago with NO sequelae). Concomitant medication included levothyroxine and valacyclovir [valaciclovir], both received within two weeks of vaccine. The patient had 4 mm left frontal lobe stroke without any other known etiology on testing (heme, cardio, neuro consulting/workup) at 13:15 on 20Feb2021. The patient was hospitalized for this event for 2 days. The adverse event resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event), disability or permanent damage. The patient received treatment (Multiple MRI/MRI, TTE AND TEE, blood studies/holter study, new medicatinos) for adverse event. No covid prior vaccination. Covid was tested post vaccination. Covid test type post vaccination was blood test, covid test name post vaccination was Ig M/IgG with negative result on 24Feb2021. Covid test type post vaccination was Nasal Swab, covid test name post vaccination was Rapid with negative result on 24Feb2021. No known allergies. No other vaccine received in four weeks. The outcome of event was recovered/resolved with sequel.; Sender's Comments: Limited information does not allow a medically meaningful assessment for the event Stroke for BNT162B2. Details regarding the clinical symptoms, relevant test results, treatment medications and clinical course are not provided. At this time, the case is handled as related for reporting purposes. The case will be re-evaluated if more 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.
COVID19 VACCINE	PFIZER\BIONTECH	1123123-1	65+ years	4 days	Had stroke; This is a spontaneous report from a contactable consumer (patient). A 70-years-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: EL9269) via an unspecified route of administration, administered in Arm Right on 15Feb2021 (12:00) as SINGLE DOSE for covid-19 immunisation, at 70 years old. Medical history included Cad atrial fibrillation (atrial fibrillation), Cad atrial fibrillation (Coronary Artery Disease), CHF kidney disease (congestive heart failure), CHF kidney disease (kidney disorder) from unspecified dates. No other vaccines in four weeks. No COVID prior vaccination. Concomitant medications included verapamil; alprazolam (XANAX); allopurinol (ZYLOPRIM); furosemide (LASIX); potassium; and mirtazapine (REMERON), all taken for an unspecified indication, start and stop date were not reported. The patient previously took antihistamines and experienced allergies (Known allergies: Antihistamine). The patient experienced had stroke on 19Feb2021. The patient required emergency room visit and was hospitalized for had stroke for 4 days from 2021 to 2021. Treatment reported as unknown. The patient underwent lab tests and procedures which included investigation: SARS-CoV-2 test (Nasal Swab): negative on 19Feb2021. Event outcome was recovering.
COVID19 VACCINE	JANSSEN	1116053-1	65+ years	5 days	Exceptionally healthy Patient suffered a stroke within 5-6 days after receiving the J & J vaccine.
COVID19 VACCINE	JANSSEN	1128150-1	65+ years	5 days	STROKE 4 days after
COVID19 VACCINE	MODERNA	0976284-1	65+ years	5 days	Felt strange 5 days after getting shot, weakness in legs, fatigued. Next day started having slurred speech, weakness in bil lower ext.
COVID19 VACCINE	MODERNA	1002441-1	65+ years	5 days	On morning of 1/30/11 patient presented with confusion, unilateral weakness - diagnosed and admitted with CVA - embolism of R middle cerebral artery per CT scan. Noted to be in atrial fibrillation during admission. Discharged to rehab center on 2/3/21.
COVID19 VACCINE	MODERNA	1011517-1	65+ years	5 days	Patient reported left arm numbness. Went to the hospital for full stroke evaluation all tests returned negative. (CT scan, MRI, etc.). Patient was observed overnight and released from hospital with resolved symptoms and negative report of any stroke or mini-stroke. Patient has had follow-up appointments with PCP and Cardiologist. Received ok from PCP prior to second dose vaccination of COVID.
COVID19 VACCINE	MODERNA	1018448-1	65+ years	5 days	2/6/2021 stroke. 2/8/2021 he died

COVID19 VACCINE	MODERNA	1020859-1	65+ years	5 days	Started on Jan 24 or 25-Extreme fatigue, sleeping til late in afternoon,, unable to get out of bed,, headache, just didn't feel right. Went to primary doctor office on 29th. Ran every blood test, ekg and chest xray-mostly normal except orthostatic hypertension. Told to increase fluids. Felt a little better over the next week then same symptoms again Feb 4 and 5th. Took to ER had a seizure and vomiting. CT showed a Stoke and am currently in hospital.
COVID19 VACCINE	MODERNA	1027967-1	65+ years	5 days	Patient received vaccination on 1/15/2021. Hemorrhagic Stroke on 1/20 , then diagnosed with complicated idiopathic coagulopathy
COVID19 VACCINE	MODERNA	1042766-1	65+ years	5 days	First fever and body aches day 2. On day 5 developed a stroke and later developed Bell's Palsy. Hospitalized because of this. Currently moved to a rehab hospital.
COVID19 VACCINE	MODERNA	1042967-1	65+ years	5 days	Patient called son around 6:30am on 2/18/21. When son tried to contact patient around 8:30am, he was not able to get a hold of patient. Son sent someone over to check on patient. They found patient on the floor. He was coherent at first but then lost consciousness. It believed he experienced a stroke sometime around 8:30-9:00am of 2/18/21. Patient was taken to hospital and then transferred to another hospital. He was put in a medically induced coma. He passed between 4:00 and 4:30 pm on 02/19/21.
COVID19 VACCINE	MODERNA	1045543-1	Unknown	5 days	Mini stroke; Tingling sensation; Numbness at the right side of the body from face down to foot; A spontaneous report was received from a HCP concerning a male patient who received Modern's COVID-19 vaccine (mRNA-1273) and experienced tingling sensation and numbness at the right side of the body from face down to the foot. The patient's medical history was reported as diabetic and was taking medications for diabetes but did not provide exact name of the medication. No relevant concomitant medications were reported. 24 Dec 2020, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 29 Dec 2020, 5 days after the dose of injection, the patient experienced and experienced tingling sensation and numbness at the right side of the body from face down to the foot. The patient was taken to ER and patient was diagnosed with mini stroke at the ER. No Laboratory details provided. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. At the time of this report, the outcome of the events experienced tingling sensation and numbness at the right side of the body from face down to the foot was Unknown.; Reporter's Comments: The events developed on five day after first dose of mRNA-1372. Paresthesia, and hypoesthesia were consistent with increased risk of cerebrovascular accidents associated with history of diabetes. 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.
COVID19 VACCINE	MODERNA	1055656-1	65+ years	5 days	On Day 5 (February 21st) after receiving her 2nd COVID vaccine injection, the patient suffered a massive stroke. She was rushed to an ED, arriving within 45 minutes, immediately received TPA treatment and thrombectomy from the right side of her brain. She continues to receive acute treatment inpatient.
COVID19 VACCINE	MODERNA	1073402-1	65+ years	5 days	acute CVA, thrombolysed with TPA, with residual hand weakness
COVID19 VACCINE	MODERNA	1091544-1	65+ years	5 days	On the morning of 2/22/21 Patient was found by care staff to have signs of stroke as evidence by left sided facial drooping. EMS were called and he was taken to a local hospital where he was admitted. He then was discharge to a skilled nursing facility for rehabilitation. He is still there as of today, 3/11/2021.
COVID19 VACCINE	MODERNA	1102633-1	65+ years	5 days	Client claims she had a stroke d/t covid vaccination. She developed symptoms of weakness, nausea/vomiting 5 days after receiving first dose of Moderna (February 4, 2021). On Feb. 5th client fell 3 times while at home and on Feb. 6th her daughter took her to the ED where she was diagnosed with having a CVA. Client was hospitalized 2/6/2021 thru 2/16/21. On 2/16 she was transfered to another hospital where she had another stroke and was discharged 2/23/2021. Please note client received her second covid vaccine on 02/27/2021. Writer called client's PCP office and spoke with RN. RN verified client was prescribed medications listed in box 9 prior to stroke. RN also stated client had diagnosis of hypertension prior to stroke but did not have any record of medications to treat hypertension on file prior to stroke.
COVID19 VACCINE	PFIZER\BIONTECH	0928572-1	65+ years	5 days	Facial drooping on 1/4/2021 6 days after the vaccine suffered a mild TIA or bells palsy event. appointments for a CT scan. Has mild facial drooping on the side that is already affected by TIA / cerebral hemorrhage. The long-term or permanent outcome is unknown.

COVID19 VACCINE	PFIZER\BIONTECH	0948118-1	30-39 years	5 days	Pfizer-BioNTech COVID- 19 Vaccine EUA Received communication that patient experienced a stroke and received alteplase at a non-facility (Medical Center) 5 days after receiving COVID-19 vaccination.
COVID19 VACCINE	PFIZER\BIONTECH	1001438-1	Unknown	5 days	Stroke; This is a spontaneous report from a contactable consumer. A 92-year-old female patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot/batch number and expiry date were not provided), via an unspecified route of administration on 08Jan2021 at single dose for COVID-19 immunization. Facility type vaccine was Nursing Home/Senior Living Facility. The patient medical history was not reported. No Covid prior vaccination. Concomitant medications included unspecified other medications received in two weeks. The patient experienced stroke on 13Jan2021. AE resulted in "Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization". The patient was hospitalized from Jan2021 to Jan2021 for 2 days for stroke. Patient not received other vaccine in four weeks. Patient was not pregnant. Therapeutic measures were taken as a result of stroke. The outcome of event was recovering. Information on the lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1033768-1	40-49 years	5 days	Vaccine given 1-6-21, patient had a stroke left occluded carotid with dissection 1-11-21, no risk factors. 1-20-21 had second stroke, hospitalized for both episodes without residual symptoms.
COVID19 VACCINE	PFIZER\BIONTECH	1037842-1	65+ years	5 days	may have had a mini stroke; Bell's Palsy/developed facial drooping/her eye was drooping; fell; This is a spontaneous report from a contactable consumer (patient). A 79-years-old female patient received bnt162b2 (BNT162B2, Pfizer COVID-19 Vaccine; Batch/lot number: EL9262), via an unspecified route of administration injection to right upper arm on 22Jan2021 14:00 at SINGLE DOSE for covid-19 immunisation. Medical history included ongoing she was a fainter (She was a fainter, she just faints so she has a hard time getting shots. Pfizer COVID-19 Vaccine administered to her by nurse while she was in her car seat. She just asked the nurse to let her lay down in the car seat when injection was administered so that if she fainted she would not fall far; she was still getting the wash cloth on her head preparing when the Nurse had already finished administering the injection.); ongoing depressed sometimes (she was depressed sometimes, was stressed. She was the primary caregiver for her 96 year old mother. She had seen something about stress and COVID and shots and everything); ongoing Very tired (She was almost 80 years old so she was very tired often. She was the primary caregiver for her 96 year old mother. By the time she comes home at night around 21:30 she was just wiped.); Obesity (She was really overweight but she did not like the term obesity.); thyroid disorder; hypertension; Cataract and glaucoma in left eye; family history of ongoing facial paralysis (Dad had Bell's palsy that might have been 30 years ago. He died at age 87 years.); diagnosed allergies, compromised immune status, respiratory illness, genetic / chromosomal abnormalities, endocrine abnormalities (including diabetes). Concomitant medication included Levothyroxine at 100mcg taken once daily in the morning early before she eats with Start date unknown, but at least 10-15 years ago for Thyroid. Enalapril at 10mg taken once daily (Caller initially reported product name as Vasotec, but clarified it is not Vasotec, it is drop for eye cataract and glaucoma) for High blood pressure. Brimonidine with Strength unknown, 1 drop in both eyes twice daily, started maybe 1 year ago. Specified cataract and glaucoma in left eye; but drop was administered to both eyes; and left eye was eye affected by Bell's palsy for Cataract and glaucoma in left eye. The patient previously took codeine and experienced allergy with onset maybe about 50 years ago, she was not sure; occurred during dental procedure; had bad headaches but no lasting effects so they assumed allergy to codeine; she did not know if still has allergy but says she does if asked. The patient experienced bell's palsy/developed facial drooping/her eye was drooping on 29Jan2021 with outcome of recovering, may have had a mini stroke on an unspecified date with outcome of unknown , fell on 27Jan2021 with outcome of unknown (reported date of end of reaction was 27Jan2021), she could not blink that eye on 29Jan2021 with outcome of not recovered. Five days later she fell and developed facial drooping. HCP suggested she may have had a mini stroke causing facial drooping and the fall. She went to the ER on 29Jan2021 and the ER believed it was Bell's Palsy. She was still experiencing facial symptoms but they are improving. This consumer was administered her first dose if Pfizer COVID-19 Vaccine 22Jan2021. She reported having fell 27Jan2021. She was diagnosed with Bell's palsy in 29Jan2021 after having been seen in the emergency room. She is supposed to have the second dose/booster of Pfizer COVID-19 Vaccine on 12Feb2021. She called to ask if she should or should not still get the second dose as scheduled; and if Bell's palsy could be a reaction to the Pfizer COVID-19 stroke occurred five days after receiving vaccine. I was hospitalized overnight in General Hospital. Have had two MRI's.
COVID19 VACCINE	PFIZER\BIONTECH	1068615-1	60-64 years	5 days	stroke occurred five days after receiving vaccine. I was hospitalized overnight in General Hospital. Have had two MRI's.

COVID19 VACCINE	PFIZER\BIONTECH	1104155-1	65+ years	5 days	Five days after the vaccine she was on the phone, sitting in a chair and she lifted her arm up and it felt heavy and it just dropped. She then started to raise the arm and she was not able to do it. She then suddenly lost sensation in her left arm. She then could not control it, would raise when it wanted to but was not able to feel it or control it. (had the feeling that it was not connected to her body and it was just floating around). Then started having involuntary muscle spasms in her mid torso region. The same thing then happened again and the muscle spasms were more intense and she waited around and lasted for minutes. She never lost consciousness, but then it happened again and was spreading on her left side. It then encompassed from her hip up to her shoulder. The involuntary muscle spasms were moving from the side toward her chest to where she felt it would impact her breathing. She then went to the ER and they started doing testing, and she had more spasms, and then started having double vision. In talking with the doctor about all of this she had a CVA with complex partial epilepsy with recurrent seizures and that the double vision was related to the infarct in her brain and that the stroke triggered the seizure that she had. She did not lose any memory, loss of consciousness, no weakness or loss of sensation. These episodes only lasted minutes and a refractory time of minutes and when she got to the ER she the other episode when they were trying to test her. They were not able to do the EKG or EEG due to the involuntary movements and these resolved. She is now completely recovered other than the fatigue with no residual. She saw a neurologist on 2/24/21 who felt like that she had a stroke and put her on Keppra and is going to FU in 3 months at IU. It was ruled out that there was no relationship of her transplant to this reaction. She is now on Keppra, Atorvastatin for the swelling in her brain, and also put on aspirin 81 mg. Her blood tests that were done were all drawn and were all within normal limits except for kidney function, but is only a minor #'s for her secondary to the transplant. She then had some titers drawn for CMV and that was also negative. Then she had a COVID test that was negative. Then she had spinal tap that came back normal results.
COVID19 VACCINE	PFIZER\BIONTECH	1108267-1	65+ years	5 days	Deceased Narrative: Patient was a 79 yo male with a hx of HTN, ETOH and tobacco use, PVD, HLD with no contact with health care since 2014. Patient presented to facility on 9/30 with worsening bilateral leg pain and SOB. During that hospitalization he dx with severe decompensated HF (EF 20-25%) and cardiomyopathy. Cardiac cath with severe CAD, however unable to perform interventions. Upon goals of care discussion, patient no longer wished to go to facility or aggressive medical management. Patient was transitioned to hospice for comfort care.
COVID19 VACCINE	PFIZER\BIONTECH	1109309-1	65+ years	5 days	After vaccine was administered patient was seemingly fine until a loss of consciousness/mini stroke on Jan 16 (5 days after vaccine) causing a fall and massive stroke on Jan 22 (11 days after vaccine) that left patient unresponsive and on life support until family decided to stop services and begin hospice care with no fluids or food until death
COVID19 VACCINE	PFIZER\BIONTECH	1113869-1	65+ years	5 days	Cerebrovascular Hemorrhage (Stroke), left occipital zone; This is a spontaneous report from a contactable consumer. A 78-year-old female patient received the first dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine, Lot. EK4176) at single dose, in the left arm, on 13Jan2021, at 15:00, for COVID-19 immunisation. The patient had not received any other vaccines within 4 weeks prior to the BNT162B2 vaccine. The patient had not experienced Covid-19 prior vaccination. Relevant medical history included Sulfa allergy (Sulfonamide allergy) and drug hypersensitivity due to pethidine hydrochloride (DEMEROL) was reported as past drug event. On 03Feb2021, received the second dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine, Lot. EN5318) at single dose, in the left arm, for COVID-19 immunisation. Concomitant medications included levothyroxine sodium (SYNTHROID) and estrogens conjugated, medroxyprogesterone acetate (PREMPRO). On 18Jan2021, at 12:30 PM, the patient experienced cerebrovascular hemorrhage (stroke), left occipital zone. Hospitalization and treatment (stroke Center ICU care) were required (duration of hospitalization 4 days). Clinical outcome of the adverse event was recovering at time of this report. Post the vaccination, the patient has been tested for COVID-19 (Nasal Swab) on 18Jan2021 and resulted negative.

COVID19 VACCINE	KNOWN MANUFACTUR	0999881-1	Unknown	5 days	<p>after having the COVID-19 vaccine, she mentioned that she was very sick in the hospital and is now getting well; She had seizures after receiving the MMR vaccine; She described her adverse reaction by having stroke like symptoms which she described as she cannot speak; She described her adverse reaction by having stroke like symptoms which she described as having numbness in her hands, face and lips; She described her adverse reaction by having stroke like symptoms which she described as having numbness in her hands, face and lips; She also felt exhausted; she also has pain in her arm; She mentioned that she also has her vision affected/She couldn't drive/There were wavy lines all trough her eyes; She described her adverse raction by having intense headaches/She described her adverse reaction by having stroke like symptoms which she described as having headaches; She described her adverse reaction by having stroke like symptoms; She started to have hallucinations such as seeing people that weren't there, seeing snowstorms, and seeing things shipping throughout the wind.; This spontaneous report has been received from Pfizer Inc, and a nurse, referring to a 65-year-old female patient. The patient's pertinent medical history, previous drug reactions or allergies, and concomitant medications were not provided. On unspecified date (reported as when the patient was younger), the patient was vaccinated with measles, mumps, and rubella virus vaccine (manufacturer unknown) (dose, vaccine scheme, route of administration, anatomical location, lot number and expiration date were not provided), as prophylaxis. On an unknown date, after received the measles, mumps, and rubella virus vaccine (manufacturer unknown), the patient had seizures. She mentioned that she did not have adverse event (AEs) with other immunizations but the measles, mumps, and rubella virus vaccine (manufacturer unknown). On 30-DEC-2020, the patient was vaccinated with the first dose of included SARS-CoV-2 spike protein mRNA vaccine (PFIZER BIONTECH COVID-19 VACCINE) (dose, route of administration and anatomical location were not provided), as prophylaxis. On an unknown date, after SARS-CoV-2 spike protein mRNA vaccine (PFIZER BIONTECH COVID-19 VACCINE) vaccination, she was very sick in the hospital. On 04-JAN-2021, she stated to experience an adverse reaction described as having intense headaches, having stroke-like symptoms (cerebrovascular accident), as she could not speak (speech disorder), having headaches, having numbness in her hands, face, and lips (hypoesthesia and hypoesthesia oral). The patient also felt exhausted (fatigue), had pain in her arm (but for that event she reported that she was not very concerned). Additionally, she mentioned that her vision was affected, she could not drive, and there were wavy lines all through her eyes (visual impairment). She also started to have hallucinations, such seeing people that weren't there, snowstorms, and things shipping throughout the wind. It was reported that the patient wanted to know recommendations about the second shot of the SARS-CoV-2 spike protein mRNA vaccine (PFIZER BIONTECH COVID-19 VACCINE) because with her experience, she was not comfortable having the second shot of that vaccine. At the reporting time, the patient was getting well from the event illness. The outcome of the cerebrovascular accident, headache, visual impairment, pain in extremity, fatigue, hypoesthesia oral, hypoesthesia, speech disorder, seizure and hallucination was not reported. The causality assessment between the event seizure and measles, mumps, and rubella virus vaccine (manufacturer unknown) was not provided. The causality assessment</p>
COVID19 VACCINE	JANSSEN	1139200-1	60-64 years	6 days	<p>Six days after receiving Janssen vaccine at approximately 4:00 pm, left hand experienced numbness. As the evening wore on, weakness spread through the left side of body and speech began slurring. The next day, after no improvement, went to hospital to find from CT scan that he had suffered a stroke. He had no precursors that would lead to being prone to strokes.</p>
COVID19 VACCINE	MODERNA	0996423-1	65+ years	6 days	<p>Patient had a CVA and passed away suddenly 1/10/21</p>
COVID19 VACCINE	MODERNA	1017176-1	65+ years	6 days	<p>Patient had Covid-19 in October of 2020. He recovered. He received the vaccination on 12/30/2020 with no complaints. On 01-05-2021 it was noted to he was incontinent of urine and bilateral lower extremity edema. Lab work was completed showed acute kidney injury. He had decreased blood pressure and oxygen saturations on 01-06-2021 He was admitted to the hospital with rapid progression of symptoms and suggested multi-system failure. He had a long cardiac history. On 01-14-2021 he passed away with a diagnosis of Cardiomyopathic CHF, A.Fib contributory.</p>
COVID19 VACCINE	MODERNA	1019653-1	65+ years	6 days	<p>6 days following vaccination patient had a left sided stroke-numbness in face arm and hand. went to ER. and stroke was confirmed</p>

COVID19 VACCINE	MODERNA	1024999-1	Unknown	6 days	Admitted to the hospital with multiple small strokes; Feeling fatigue; Headache; A spontaneous report was received from a consumer concerning a 79-year-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced being admitted to the hospital for multiple small strokes, fatigue and headache. The patient's medical history was not included. Products known to have been used by the patient were not provided. On 21 Jan 2021, prior to the onset of the events, the patient received the first of planned doses of mRNA-1273 (Lot number: unknown) for prophylaxis of COVID-19 infection. On an unknown date, Shortly after the mRNA-1273 vaccine was given, the patient experienced fatigue and headache which was attributed to vaccine side effect. On 27 Jan 2021, the patient was admitted to the hospital with multiple small strokes. No other treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, fatigue, headache and being hospitalized with multiple small strokes, is unknown.; Reporter's Comments: This case concerns a 79 year-old, female patient, who experienced events of multiple small strokes, fatigue and headache. The events of fatigue and headache occurred on an unknown date after the first and last dose of mRNA-1273 vaccine administration. The event of stroke occurred approximately 6 days after the first and last dose of mRNA-1273 vaccine administration. Based on the current available limited 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.
COVID19 VACCINE	MODERNA	1027275-1	65+ years	6 days	Unknown onset of altered mental status. Last time known well was day of vaccination 2/3/2021. Found altered on 2/9/2021. Working diagnosis is encephalopathy: MRI unrevealing. CVA vs other etiology
COVID19 VACCINE	MODERNA	1044610-1	65+ years	6 days	Nausea, vomiting, dizziness, distorted vision, sore arm, fever, injection site swelling, ambulatory deficiency. Admitted to Hospital
COVID19 VACCINE	MODERNA	1047133-1	50-59 years	6 days	TPA aborted Stroke on day 5 post vaccine. Probably not related but was told I needed to report it.
COVID19 VACCINE	MODERNA	1048961-1	65+ years	6 days	Stroke; A spontaneous report was received on 09 FEB 2021 from a consumer concerning an 81-year-old, male patient who received Moderna's COVID-19 vaccine and experienced stroke. The patient's medical history provided were, Alzheimer and Parkinson's disease. No relevant concomitant medications were reported. On 28 JAN 2021, patient received their first of two planned doses of mRNA-1273(Batch number 027L20A) injection for the prophylaxis of COVID-19 infection. On 03 FEB 2021, within 7 days of receiving vaccine, patient experienced a stroke. On 03 FEB 2021, patient was admitted to hospital. Patient was due for his second shot of Moderna's COVID-19 vaccine on 26 Feb 2021. Patient's hospital can only provide Pfizer's vaccine and not Moderna's COVID-19 vaccine. But patient wanted to get Moderna's COVID-19 vaccine. Patient's wife wanted to know the way she could arrange the administration of the Moderna's COVID-19 vaccine in the hospital for her husband. Treatment for the event was not provided. Action taken the second dose of mRNA-1273 in response to the event was not reported. The outcome of the event, stroke, was not provided.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the event, a causal relationship cannot be excluded. However, patient's elderly age is considered a risk factor.
COVID19 VACCINE	MODERNA	1056972-1	65+ years	6 days	5-6 days after receiving first Moderna covid vaccine pt. began not feeling well. On 02/10/2021 she saw a provider in an office for eval of abdominal pain and diarrhea and sent home. On 02/15/2021 she presented to a local ED with continuing symptoms, transferred to Medical Center, She is currently an inpatient there with a diagnosis of multiple blood clots in abdomen and brain and antiphospholipid syndrome.
COVID19 VACCINE	MODERNA	1057844-1	65+ years	6 days	Stroke in left occipital lobe Feb 1 & Feb 2 Right peripheral vision effected in both eyes 2 heart stops on Feb 10, 2021 Pacemaker implanted after heart stops
COVID19 VACCINE	MODERNA	1070978-1	60-64 years	6 days	report of patient being admitted for a stroke after about a week after first dose of moderna vaccine
COVID19 VACCINE	PFIZER\BIONTECH	1007315-1	65+ years	6 days	Excessively tired during the week after the first vaccine. One week after an undiagnosed episodic atrial fibrillation was discovered when treating a stroke. Causation not researched.



COVID19 VACCINE	PFIZER\BIONTECH	1035544-1	18-29 years	6 days	stroke; a thunder clap headache; limbs stiffened up; eyes crossed; lost speech; She is now on day three of a coma on life support from a brain aneurysm; Mood swings; irate; Body aches; This is a spontaneous report from a Contactable Consumer, the patient. This 28-year-old non-pregnant female consumer (patient) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: Unknown), via an unspecified route of administration in the left arm on 01Feb2021 as a single dose, for COVID-19 vaccination. Historical vaccination includes BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), Dose 1. The facility in which the second vaccine was administered was a hospital. No other vaccines were given within 4 weeks. Prior to vaccination, the patient was not diagnosed with COVID-19. No Medical history reported ('No health issues, At all'). The patient has no known allergies. There were no concomitant medications. On an unspecified The Patient Experienced became irate. Mood swings. Body aches for couple days; On 07Feb2021 at 13:45, The patient experienced Stroke a thunder clap headache, limbs stiffened up , eyes crossed, lost speech, now on day three of a coma on life support from a brain aneurysm (hospitalization, disability, life threatening), Treatment was given for the events of stroke, a thunder clap headache, limbs stiffened up, eyes crossed, lost speech, and brain aneurysm. The Adverse Event resulted in an Emergency Room Visit. Treatment was given for the events. 'Patient on Life support still'. The Clinical Outcome of the events Stroke a thunder clap headache, limbs stiffened up , eyes crossed, lost speech, now on day three of a coma on life support from a brain aneurysm not recovered, while Mood Swings, Anger and Pain was unknown. Information on Lot has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1077194-1	65+ years	6 days	Six days after her first dose she had a TIA which was confirmed at the hospital.
COVID19 VACCINE	PFIZER\BIONTECH	1099335-1	65+ years	6 days	Stroke (ischemic - isolated) occurred 6 days after vaccine administration
COVID19 VACCINE	MODERNA	1034014-1	65+ years	7 days	central retinal vein occlusion involving the right eye
COVID19 VACCINE	MODERNA	1038146-1	65+ years	7 days	TIA experienced on 2/13/2021 upon rising from sleep/found lacuner infarct on MRI in ER on 2/13/21
COVID19 VACCINE	MODERNA	1038609-1	65+ years	7 days	Atrial fibrillation, ischemic stroke right internal capsule, ER, tpa, recovered much of neurologic deficit
COVID19 VACCINE	MODERNA	1040633-1	50-59 years	7 days	Death due to hemorrhagic stroke.
COVID19 VACCINE	MODERNA	1043292-1	50-59 years	7 days	I have a complete timeline of my series of events. I believe the Moderna, dose 1 may have contributed to my current medical diagnosis of severe Cardiomyopathy, EF 12, L bundle branch block. I would like for someone to look into this possibility. I am an O positive individual who has never been positive for CoVid-19. I have also been anti-body tested twice with no positive antibody results. Please call me if there is any relationship for cardiomyopathy and the Moderna vaccine. I have done a lot of research and am seeking any further information to help with my present medical condition.
COVID19 VACCINE	MODERNA	1047169-1	65+ years	7 days	jaundice->hemolytic anemia-> hemorrhagic shock->multi organ failure->death pt admitted to ICU 2/16 with Hgb=3.4, treated with steroids, supportive care , pressors, pt died 2/20/21
COVID19 VACCINE	MODERNA	1050245-1	65+ years	7 days	2/17 first occurrence: symptoms = confused speech, memory impairment diagnosis = TIA 2/20 second occurrence: symptoms = confused speech, memory impairment 2/21: symptoms = confused speech, memory impairment, cognitive difficulty understanding others 2/23: unusual behavior (perhaps due to confusion), difficulty driving (almost hit a parked vehicle and a mailbox; and ran off the right side of the road), agitation (upset, because he considered it a waste of time to visit the ER and have more tests run on 2/23; and also upset that people were ""questioning his driving""""
COVID19 VACCINE	MODERNA	1053682-1	65+ years	7 days	Stroke. I do not know if the vaccine was related or not, but the patient had a stroke and falls on 2/17/2021 and 2/18/2021 and was found to have two strokes. He does have atrial fibrillation, but with the proximity to the second vaccine, I cannot tell if they are just related temporally or if there is a true risk. Another patient at this facility had a stroke within same time frame post second Moderna vaccine, but not my patient, so I do not know if that was reported. Due to new nature of this vaccine, I felt it important to report this event for further investigation. Again, I am not sure if it is a true adverse reaction of the vaccine or not.

COVID19 VACCINE	MODERNA	1062457-1	65+ years	7 days	Patient admitted for fatigue, dry throat, generalized weakness, dyspnea on exertion. Durion hospitalization was identified to have an acute ischemic CVA – unclear time of symptom onset, possibly evening of 2/9 or morning of 2/10. Time course suspicious for possible COVID vaccine adverse event. He received his first Moderna COVID vaccine on 2/2/21 per WIR. Per PCP note on 2/9/21: Patient is here today accompanied by his wife with concerns for fatigue, headaches, head pressure and tremors. Received vaccine last Tuesday. Around 10 PM that evening he developed pressured in the head. On Wednesday morning, he states he got out of bed and was in a cold sweat - he states he pajamas were soaked in sweat and he felt chilled. He experienced brief numbness of the left arm down to his fingers. On Thursday, he felt fine - he went out to snow blow. Friday he developed headaches and head pressure. At night, he felt his breathing was labored as he was ""gasping for air."" On Saturday and Sunday, he sat and laid around all day. On Monday, he wakes up at 125 AM and his blood pressure was 165/104 and it remained elevated for 3 separate readings. Patient was then admitted on 2/10/21 with weakness and confusion, then on 2/11 MD noted ?word finding difficulty, slurred speech, possible subtle right upper lip droop, and possibly some mild right hemineglect? with MRI showing likely embolic source of infarcts and cerebral MRA with possible acute thrombus. His symptoms the day after the vaccine seem a bit suspicious for TIA. Per Drug Policy Manager call to Moderna, no current reports of TIA/stroke secondary to COVID vaccine, so time course may be incidental. Patient had echocardiogram without right to left shunt or clot identified, no known history of atrial fibrillation. Was monitored on telemetry for the duration of his hospitalization without any noted arrhythmias, discharged on e patch for 14-day outpatient monitoring.""
COVID19 VACCINE	MODERNA	1101286-1	65+ years	7 days	Large Stroke
COVID19 VACCINE	MODERNA	1102462-1	65+ years	7 days	Days of bloody stools, lightheaded, GI bleed given 2 units of blood, fluids given, hypotension tachycardia, weakness, TIA while inpatient, transferred to higher level of care
COVID19 VACCINE	MODERNA	1104222-1	65+ years	7 days	Client suffered a stroke on 02/11/21 which caused client to fall while getting into shower. Client hit his head during fall causing a brain bleed and also broke his left shoulder. Client was transferred to hospital via ambulance and admitted to hospital.
COVID19 VACCINE	PFIZER\BIONTECH	0945247-1	65+ years	7 days	Has underlying dementia and often with difficulty eating. 1 week after immunization she developed a stroke with left sided weakness and difficulty swallowing. Comfort measures instituted. Not sure if this is related to the vaccine, but thought I should report
COVID19 VACCINE	PFIZER\BIONTECH	0994107-1	65+ years	7 days	On 1/26/2021, resident had an elevated blood pressure of 183/102 and he was cold and clammy. Resident sent to ER via 911. He was sent home that same day. On 1/27/2021, resident found sitting in his apartment with a facial droop, slightly slurred speech and left sided weakness. Resident had also fallen the previous night and on the morning of 1/27/2021. Resident transported to the ER for evaluation and treatment and was admitted with diagnosis of TIA; rule out stroke.
COVID19 VACCINE	PFIZER\BIONTECH	1068268-1	65+ years	7 days	stroke; This is a spontaneous report from a contactable Pharmacist, the patient's daughter-in-law. An 84-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 05Feb2021 (at the age of 84-years-old) as a single dose for COVID-19 vaccination. Medical history included stroke and atrial fibrillation from unknown dates. Concomitant medications were not reported. On 12Feb2021, the patient experienced a stroke. The clinical outcome of the event stroke was unknown. No additional information was reported. Information about lot/ batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1073327-1	65+ years	7 days	TIA stroke like symptom went to ER hospitalized Goa a day in hospital
COVID19 VACCINE	PFIZER\BIONTECH	1093887-1	65+ years	7 days	On 3/8/2021 the patient presented to the ED with stroke-like symptoms. Reason for admission: suspected TIA. Acute CVA-has been ruled out. Incidental finding CT head 9 x 5 mm lesion possibly meningioma, but scans of CTA head and neck no lesion, MRI of the brain shows no lesions.
COVID19 VACCINE	PFIZER\BIONTECH	1104160-1	65+ years	7 days	fell, hit head, confusion, memory loss, balance disorder, tremors and shaking, vomiting, headache, high blood pressure, TIA, CVA, aneurysm
COVID19 VACCINE	MODERNA	0931558-1	40-49 years	8 days	7 day after site itching, hot swelling. Unsure if related 9 day after suffered CVA and have hyper coagulation
COVID19 VACCINE	MODERNA	1048812-1	65+ years	8 days	8 days after vaccination - stroke/full right side of body paralyzed - clot buster drug at ER

COVID19 VACCINE	MODERNA	1051268-1	65+ years	8 days	Possible Stroke; Increase pressure and numbness in fingers; Headache; A spontaneous report was received from a pharmacist concerning an 81-year old male patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced possible stroke, face numbness, startled speech, increase pressure and numbness in fingers and headache. 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 alprazolam and hydroxyzine. On 02 Feb 2021, prior to the onset of the events, the patient received his first of two planned doses of mRNA-1273 (Lot number: unknown) in the left arm for prophylaxis of Covid-19 infection. On unknown date, days after the vaccine was administered, the patient reported that he started having a headache, increased pressure and numbness in fingers. Patient had been having intermittent symptoms for 9 days. Patient was admitted to hospital on 10 Feb 2021 due to possible stroke. On 11 Feb 2021, the patient began to have startled speech and face numbness. Patient was evaluated by Neurology and an MRI was done. No further information was provided. Treatment for headache included Excedrin Migraine, ibuprofen and acetaminophen. Action taken with mRNA-1273 in response to the events were not reported. The outcome for the events possible stroke, face numbness, startled speech, headache, increase pressure and numbness in fingers, were considered as 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.
COVID19 VACCINE	MODERNA	1091269-1	65+ years	8 days	A home dialysis patient who received his first COVID-19 (Moderna) vaccine on 2/4/2021. He was screened prior to admission into the clinic and reported no signs of symptom of COVID-19. This patient was diagnosed with COVID-19 on 2/12/2021 and hospitalized on 2/16/2021 with COVID pneumonia. The patient's spouse and son (who lives with them) also tested positive for COVID-19. This patient developed COVID-19 complications while inpatient including stroke and mechanical ventilation was required. The patient was made a DNR by family and removed from mechanical ventilation and expired on 2/26/2021.
COVID19 VACCINE	PFIZER\BIONTECH	1017596-1	50-59 years	8 days	1/12/21: Pt presented to ED with L sided facial droop, L sided weakness to arm and leg, numbness to L face L arm and left leg. Presentation consistent with acute ischemic stroke. Risks and benefits discussed with the patient, who agreed to proceed with tPA. MRI brain 1/12: ""Acute infarct right MCA territory predominantly involving the right parietal/insular lobes. No acute hemorrhage or midline shift."" Started on aspirin 325 mg daily and rosuvastatin dose increased to 40 mg daily 24 hours post tPA. Patient reported a history of a-flutter many years ago for which she was on a beta-blocker, but the diagnosis remains unconfirmed. Tele reviewed during stay, no arrhythmias. ECHO, normal EF, NO PFO. Discharged to rehab on 1/15.""

COVID19 VACCINE	PFIZER\BIONTECH	1026613-1	65+ years	8 days	None of my health care providers have been able to explain the cause of my sudden loss of vision in my left eye at approx. 10:15 p.m. on 7 Feb 2021. At approx. 3:00 a.m. on 8 Feb I called my ophthalmologist's answering service and my ophthalmologist called me back shortly thereafter. She told me I should go to the ER which I did at approx. 4:00 a.m. where blood tests were done, an ultrasound of my left eye, CT scan of my head, and MRI of my head were performed all with negative results. When my vision was tested at the ER using the standard wall chart, I was unable to see the largest letter on the chart with my left eye. I saw my ophthalmologist at approx. 1:40 p.m. the same day after my 6 1/2 hour ER visit. I was diagnosed with Central Retinal Vein Occlusion. Both of my eyes were dilated and photos were taken of each eye. I was given an injection of Avastin in my left eye. As of today, 12 Feb 2021, I am still functionally blind in my left eye. I can see general large objects but am unable to see details or read written words either near or far. Prior to approx. 10:15 p.m. on 7 Feb, my vision was as it had been for several years prior with little if any degradation. I typically have an annual eye exam by my ophthalmologist but due to Covid-19 my last eye exam was 9 Dec 2019 at which time there was nothing to suggest that I would have such loss of sight in either of my eyes. I am a healthy person who takes no or very little medication when prescribed. I have never been hospitalized (other than this ER visit) or diagnosed with any significant medical condition. In late Dec 2020 following routine blood tests, I had a teleconference ""physical"" with my PCP at which time I was declared to be healthy. Upon leaving the ER at approx. 10:30 a.m. on 8 Feb my ""end of visit vitals"" were recorded as blood pressure 110/63, BMI 20.92, weight 150 lbs., height 5'11"", temperature 97.6 F, pulse 67, respiration 16, and oxygen saturation 95%. Late last year I had my usual flu vaccination without any side effects. After almost 2 weeks, I do still have a bruise at the Pfizer vaccine injection site on my left arm and I experienced mild muscle soreness the evening after my vaccination and the following morning. Normally I have no adverse reaction to vaccinations.""
COVID19 VACCINE	PFIZER\BIONTECH	1101755-1	60-64 years	8 days	On 2/16/21 I suffered an occlusive stroke. No health problems. No prescriptions meds. BP was always around 120/70's. Height: 5'4"", Weight: 126 lbs. All blood work within normal range No high cholestrol, etc. I was scheduled for 2nd vaccine on 3/1, I was advised to reschedule, which I did for 3/23. I spoke to a coule of health care professionals and asked them if they would proceed with the 2nd vaccine if it were them and was told ""no"". I am very afraid to get the 2nd vaccine. I would like to discuss this with someone.""
COVID19 VACCINE	MODERNA	1055418-1	65+ years	9 days	Patient suffered a stroke and passed away
COVID19 VACCINE	MODERNA	1073487-1	65+ years	9 days	Had a stroke; A spontaneous report was received from a caregiver concerning an 81-years-old female patient who received Moderna's Covid-19 vaccine and had a stroke. Patient's medical history included a mini stroke (5-6 years ago). Concomitant medication included blood thinners. On 02 Feb 2021 at 4:30 pm, ten days prior to onset of the event stroke, the patient received the first of two planned doses of mRNA-1273 vaccine (Lot/batch: unknown) for prophylaxis of Covid-19 infection. On 11 Feb 2021, the patient had an event of stroke for which was hospitalized. The patient was on a lot of medications (not specified). Action taken with second dose of mRNA-1273 in response to the event was not recorded. The outcome of the event stroke 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 event of stroke, a causal relationship cannot be excluded. However, patient's elderly age and prior history of TIA are considered as risk factors.
COVID19 VACCINE	MODERNA	1079768-1	65+ years	9 days	Hemorrhagic Stroke
COVID19 VACCINE	MODERNA	1082355-1	65+ years	9 days	per the EUA, cases of COVID-19 vaccination that result in hospitalization or death are to be reported. This patient received Moderna on 2/10 and 1/13. Patient is admitted for mild congestive heart failure secondary to cardiomyopathy

COVID19 VACCINE	PFIZER\BIONTECH	0984637-1	30-39 years	9 days	Rught MCA Stroke; This is a spontaneous report from a contactable nurse (patient). A 39 years old female patient (no pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EH9899), intramuscular on 16Dec2020 10:15 at the first single dose at right arm for covid-19 immunisation. Medical history included Hodgkin's disease. Concomitant medication included colecalciferol (VITAMIN D3 1000). The patient experienced rught MCA stroke on 25Dec2020 06:15. Seriousness criteria reported as hospitalization, life threatening. The patient was hospitalized for rught MCA stroke for 3 days. The patient underwent lab tests and procedures which included Nasal Swab: negative on 25Dec2020. The patient received unspecified treatment for rught MCA stroke. The outcome of event was recovered.; Sender's Comments: The subject had medical history included Hodgkin's disease. The reported stroke was more likely an intercurrent disease, and unlikely causally related to the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE). 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.
COVID19 VACCINE	PFIZER\BIONTECH	0986115-1	65+ years	9 days	Suffered a massive MCA stroke; This is a spontaneous report from a Contactable Nurse. A 65-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EJ1685), intramuscularly in left arm on 12Jan2021 16:00 at single dose for COVID-19 immunization. Medical history included covid prior vaccination. Known allergies: None. The patient's concomitant medications were not reported. The patient previously received the first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EJ1685), intramuscularly in right arm on 21Dec2020 03:00 PM at single dose for COVID-19 immunization. The patient was not pregnant while receiving vaccine. Facility type vaccine: Hospital. If other vaccine in four weeks: No. Other medications in two weeks: No. The patient suffered a massive MCA (Middle cerebral artery) stroke on 21Jan2021 08:00 after getting second covid vaccine with outcome of not recovered. No history of hypertension, elevated cholesterol or medical issues. No medication being taken. Daily BP (Blood pressure) reading normal. Covid test post vaccination: Nasal Swab-PCR on 22Jan2021 with result negative. If treatment for AE: Unknown. The event was resulted in: Emergency room/department or urgent care, Hospitalization (Number of days hospitalization: 4), Life threatening illness (immediate risk of death from the event), Disability or permanent damage.; Sender's Comments: The event middle cerebral artery stroke appeared 8 days after administration BNT162B2. The Company considers that the event is less likely related to suspect BNT162B2 injection given the weak time association. The status (bleeding or infarction) and cause of the stroke 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.
COVID19 VACCINE	PFIZER\BIONTECH	1044071-1	30-39 years	9 days	I had a major stroke on 12/25/2020, 9 days after receiving the vaccine. I had a clot in my MCA. My left arm was completely flaccid, with left facial droop and garbled speech. Thankfully I was able to receive TPA that day, which resolved all of my symotoms.
COVID19 VACCINE	PFIZER\BIONTECH	1093448-1	65+ years	9 days	CVA, confirmed by MRI
COVID19 VACCINE	PFIZER\BIONTECH	1103742-1	60-64 years	9 days	Beginning February 28, 2021 stroke, seizure, fever, headache and weakness.

COVID19 VACCINE	PFIZER\BIONTECH	1142047-1	65+ years	9 days	Patient received the injection on May 2nd. Following the injection, we noticed an increased weakness and general achiness. On the 8th she was so weak that we purchased a gait belt to assist her. We were not super concerned as we were expecting the second shot to cause body aches or flu like symptoms based on what we had heard from others who had received both vaccine shots. She continued to be unsteady and we found that she has a mild UTI which we had begun treating with prescribed antibiotics. Late afternoon on the 11th, mother suffered a major stroke. we did not take her to the hospital because we had already been told that they would not be able to do anything at her age should she suffer a stroke. On the 12th I called the doctors office and asked for them to send Hospice to the house as we could tell that she was dying. Mother died on the 13th. Just a week prior to her death I had spoken with Dr. and we had discussed how that she was declining in health but that she was not even close to needing Hospice, yet she is dead a week later. Less than 2 weeks after getting her second Covid Shot.
COVID19 VACCINE	JANSSEN	1178023-1	30-39 years	10-14 days	Admitted with ischemic stroke and multiple thrombi in extremities
COVID19 VACCINE	MODERNA	0954943-1	65+ years	10-14 days	Aphasia, ,right-sided weakness and garbled speech
COVID19 VACCINE	MODERNA	1001418-1	Unknown	10-14 days	Transient ischemic attack; A report was received from a consumer concerning a 50 year old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and developed a TIA (Transient ischemic attack). The patient's medical history was not provided. The patient current condition included ulcerative colitis, blood pressure, cholesterol and acid reflux. No relevant concomitant medications were reported. On 29 Dec 2020, approximately twelve days prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot number 026L20A) intramuscularly for prophylaxis of COVID-19 infection. The patient experienced a TIA on 10 Jan 2021. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not provided. The outcome of the event TIA was unknown.
COVID19 VACCINE	MODERNA	1013051-1	65+ years	10-14 days	On 2/6/21 at 6:00PM, resident experienced sudden left facial droop, left arm and left leg weakness. She was sent to hospital and they confirmed she had an acute ischemic stroke.
COVID19 VACCINE	MODERNA	1054353-1	60-64 years	10-14 days	10 daya after receiving Moderna vaccine: 60 year old right handed woman with migraine + chronic headaches, nephrolithiasis, who presented to the hospital with expressive aphasia and right facial weakness and was found to have at least to distal left MCA occlusions for which she received IV tPA. MRI brain shows a small left frontal cortical acute ischemic stroke. Post tPA ICU course has been notable for angioedema of the tongue now improved. TTE showed PFO. LDL 111, new diagnosis HLD.
COVID19 VACCINE	MODERNA	1060543-1	65+ years	10-14 days	Began walking on treadmill at 5:30 a.m. and left foot felt heavy and dragging, L hand tingling, and facial/neck numbness. Arrived at hospital at 8:15. Vitals, EKG, CT scan, and MRI conducted. MRI showed an acute mild stroke on R side of brain. Over-night stay was recommended. Echocardiogram was performed the following day and nothing was abnormal. I am now on a heart monitor for 30 days. Upon departure of hospital the symptoms in L leg and arm have nearly resolved but face is still numb/decreased sensation. Plan to contact PCP tomorrow.
COVID19 VACCINE	MODERNA	1065909-1	40-49 years	10-14 days	Stroke; A spontaneous report was received from a consumer concerning a 48-year-old, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced stroke (cerebrovascular accident). The patient's medical history was not provided by the reporter. Concomitant product use was not reported. On 30 Dec 2020, approximately 11 days prior to the onset of the event, the patient received their first of two planned doses of mRNA-1273 (Lot #: 037K20A) intramuscularly in the right upper arm for prophylaxis of COVID-19 infection. The reporter stated that on 10 Jan 2021, the onset of symptoms of stroke began. The patient reports that he was discharged from the hospital on 20 Jan 2021 and was later discharged from patient rehabilitation on 26 Jan 2021. Treatment for the event included apixaban, acetylsalicylic acid, and atorvastatin as advised by patient's HCP (health care provider). Action taken with mRNA-1273 in response to the events was not reported. The outcome of the event, stroke, was unknown.; Reporter's Comments: This case concerns a 48 year old male who experienced stroke 11 days after the vaccine was administered. Very limited information regarding this event has been provided at this time. Further information has been requested.
COVID19 VACCINE	MODERNA	1066556-1	65+ years	10-14 days	Stroke, Pulmonary embolism, kidney failure
COVID19 VACCINE	MODERNA	1071051-1	65+ years	10-14 days	she had TIA (a mini stroke) on 2/15/2021 put in the hospital and got released the next day, doctor said is ok to get 2nd covid 19 shot.

COVID19 VACCINE	MODERNA	1100272-1	Unknown	10-14 days	Stroke; A spontaneous report was received from a consumer who was also a 76-years-old female patient, who received Moderna's covid-19 vaccine (mRNA-1273) and who experienced stroke (stroke). The patient's medical history was not provided. Concomitant medications were not reported. On 13 FEB 2021, prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number: unknown) via unknown route for prophylaxis of COVID-19 infection. On 23 FEB 2021, the patient had a stroke leading to hospitalization. Treatment details were not provided. Action taken with mRNA-1273 in response to the events was unknown. At the time of this report, the outcome of the event stroke was unknown.; Reporter's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.
COVID19 VACCINE	MODERNA	1105218-1	65+ years	10-14 days	Stroke 11 days (2-27) after first dose (2-16), discharged the following day (2-28). Spoke to PCP's office (nurse) who states stroke was likely due to patient's own decision to discontinue his blood pressure medications without doctor's approval. Stroke unlikely related to vaccination and determined patient should receive second dose on 3-16.
COVID19 VACCINE	MODERNA	1109535-1	65+ years	10-14 days	My Father had a hemorrhagic stroke. He passed away 13 days after receiving the second Modern?s vaccine.
COVID19 VACCINE	MODERNA	1151700-1	65+ years	10-14 days	Narrative: Patient received dose 1 of Moderna COVID-19 vaccine on 3/11/21 from clinic. Vaccine was administered to patient without complications and patient was observed for 15 minutes post-vaccination without any adverse effects. No documentation as to any adverse effects following the 15 minutes post-vaccination. 11 days later on 3/22/21, EMS was dispatched to patient's home and patient was found lying supine, unconscious, and unresponsive to stimuli. Patient was noted to have shallow breathing per EMS staff, and was subsequently brought to the hospital. Per family, patient lives alone and was feeling well - they had spoken to her two days prior to the event. Per family patient did not have recent fevers, vomiting, diarrhea, or cough. Also no recent medication changes or trauma. PMH includes stroke approx. 8 years ago, gout, HLD, HTN, and RLS. BP upon admission was 126/93, HR 123, temp 37.1 degrees Celcius, RR 28. Patient noted to smell of urine. CT showed large completed right sided infarct consistent with MCA stroke. Per neurology the lesion was not recoverable and patient would be unlikely to regain any function. Family was notified and poor prognosis was discussed. Patient has been very clear in the past that she would prefer ""to go when her time came"". She had a DNR And DNI as well. Daughter requested to pursue comfort measures for patient, therefore she was transferred to hospice care. Patient passed away the following day on 3/23/21. Death very unlikely due to COVID-19 vaccination since CT imaging clearly showed cerebral infarct and patient had a PMH of stroke.""
COVID19 VACCINE	PFIZER\BIONTECH	0922673-1	65+ years	10-14 days	I woke up with tingling in my right hand and arm, my right side, and down my right leg. I went to the ER at Hospital, and was confirmed to have had a stroke in my left thalamus.

COVID19 VACCINE	PFIZER\BIONTECH	0934906-1	50-59 years	10-14 days	<p>experienced symptoms of TIA; Severe aphasia; blurred vision; confusion; short term memory loss; elevated blood pressure; This is a spontaneous report from a contactable Other-HCP(Patient). A 57-year-old female patient received first dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at right arm, on 22Dec2020 08:15 at single dose for COVID-19 immunization. The patient was not pregnant. Medical history included herpes simplex on lips, post menopause, elevated cholesterol w/lifestyle changes. Known allergies reported as no. Concomitant medication included varicella zoster vaccine rge (cho) (SHINGRIX) for immunization. On 04Jan2021 08:30, the patient experienced symptoms of transient ischaemic attack(TIA), severe aphasia, blurred vision, confusion, short term memory loss, elevated blood pressure. The patient admitted to (Hospital name) (still here, hospitalization days reported as 2). Symptoms resolved except very mild aphasia. The patient had very few risk factors for TIA but did have family history of cardiovascular(CV) disease at young age, low density lipoprotein(LDL) was 192. The patient did not have diabetes, HTN, or known heart disease. She did not have severe anxiety. She did not smoke or use any substances. She walked about five miles 4x a week. Weigh reported as 157. Events reported as serious due to hospitalization. The patient had no Covid prior vaccination. Covid(nasal swab) was tested post vaccination on 04Jan2021, Covid test result was Negative. The event resulted in emergency room/department or urgent care. Treatment received for the adverse event included clopidogrel bisulfate(PLAVIX), acetylsalicylic acid (ASPIRIN), statin; potassium, CT, MRI, ""telemet"". The outcome of the events was recovering. Information on the lot/batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported symptoms of transient ischaemic attack(TIA), severe aphasia, blurred vision, confusion, short term memory loss, elevated blood pressure and the administration of BNT162B2, 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, Agency, as appropriate.""</p>
COVID19 VACCINE	PFIZER\BIONTECH	0942237-1	60-64 years	10-14 days	<p>She got the vaccine on Dec 23, and then on Jan 4 she had a mild stroke with left sided arm and face weakness. She did recover fully. She already has known CAD and risk factors for CVD. It is possible, but by no means certain, that the vaccine was an indirect cause of the event. Since the vaccine provoked an immune response, as it was supposed to, it is possible that this inflammation may have set up a metabolic predisposition that may have contributed to the event, which was 12 days later.</p>



COVID19 VACCINE	PFIZER\BIONTECH	0964218-1	50-59 years	10-14 days	<p>Pt received dose 1 of Pfizer vaccine on 12/23/2020. Starting 1/4/2021, pt developed numbness and tingling of left arm, cheek, and tongue lasting 1.5-2 minutes. Numbness starts in elbow and radiates up and down arm. These episodes happen at various times throughout the day. Sometimes her arm feels heavy. Has had an episode involving lip numbness that affected her speaking. Sometimes gets hot flashes lasting a few seconds. She contacted PCP to re-establish care on 1/11/21 after about 2 weeks of consistent, infrequent episodes. Never experienced this before. On 1/14 pt had an in person visit where she was evaluated by PCP. At ambulatory visit, BP 174/96. Other vital signs normal. Upper extremity exam: wrist (left, Phalen's test positive, Tinel test positive, no deformity, no crepitus), wrist (right, normal range of motion, Phalen's test negative, Tinel test negative), hand grips 5/5 bicep 5/5 tricep 5/5. Differential diagnosis: TIA, carpal tunnel syndrome, transient neurological event, shingles, hypertensive urgency. Anxiety could be component as well. Pt started ASA 81 mg QD and amlodipine 5 mg QD. Plan to get carotid Dopplers to rule out TIA/stroke. Consider MRI in the future. 1/16/21: Pt developed left arm/leg numbness and tingling 0530 and reported to ED with stroke-like symptoms. During this encounter, pt states that she experiences these 1-3 minute episodes of tingling/numbness every hour or so (initially only had 1-2 per day, became more frequent in days immediately preceding 1/16). Pt reports not being able to stand that morning due to weakness in lower extremities, though the symptoms resolved after sitting down. The patient denies any weakness to the right side, along with any family hx of stroke or headache. She takes omeprazole, amlodipine, and a baby aspirin daily. She does not currently follow up with a neurologist. The patient had lab work done yesterday and also recently had a US of her carotid artery which was unremarkable. She denies any weakness, numbness, or tingling currently. There are no other concerns at this time. The onset was 3 weeks ago. The course/duration of symptoms is worsening and episodic: lasting 3 minutes and with a frequency of every hour. Location: Left face, left upper extremity, left lower extremity. The character of symptoms is weakness, tingling and numbness. SBP 182/86. Temp 97.6 F. CT head negative, bloodwork unremarkable, chest X-ray negative. Pt admitted for MRI of brain and C-spine. 1/17/21: Hospital notes note that symptoms appear to worsen when pt is stressed or she talks about it. MRI of brain w/ and w/o contrast completed and unremarkable. Pt declined C-spine MRI with and without contrast. Pt discharged. 1/19/21: Pt presented to outpatient ambulatory appointment to follow up with worsening episodes of tingling in left arm/leg, numbness and tingling in mouth - is now affecting balance. Considering testing for other diseases such as syphilis, Lyme disease, multiple sclerosis, Guillaine-Barre. Priority status on referral to neurologist.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1011317-1	65+ years	10-14 days	<p>12 days after first vaccination: Dizziness; high blood pressure; nearly passed out; right arm numbness; inability to grip or pick up items with fingers; feeling of "lopsidedness"; unsteady on feet, requiring assistance to walk. Primary care physician recommended ER visit where possible stroke was diagnosed. Hospital MRI confirmed: "Left acute arterial ischemic stroke, MCA (Middle cerebral artery)". Spent 2 days in hospital with high blood pressure, dizziness. Residual right finger numbness upon release."</p>
COVID19 VACCINE	PFIZER\BIONTECH	1012897-1	40-49 years	10-14 days	Employee reports having a stroke 2 weeks after vaccination that required hospitalization.
COVID19 VACCINE	PFIZER\BIONTECH	1014658-1	65+ years	10-14 days	Left MCA stroke, is currently in the CCU
COVID19 VACCINE	PFIZER\BIONTECH	1016111-1	65+ years	10-14 days	her arm was sore but no other adverse reactions until Saturday, February 6th 2021 she had stroke between 4 and 6pm. She died within 6 to 7 hours later.
COVID19 VACCINE	PFIZER\BIONTECH	1021215-1	50-59 years	10-14 days	On Saturday 2/6 unwitnessed fall without loss of consciousness. Gait was unstable, weakness on right side (RUE, RLE) slurred speech, difficulty with finding words. Transported by POV to ED for evaluation of stroke - same sx with onset of paresthesia in right upper arm. Stroke protocol done - received tPA with resolution of symptoms during infusion. Stayed in hospital until protocol completed. Symptoms resolved over the course of the hospitalization.
COVID19 VACCINE	PFIZER\BIONTECH	1031821-1	65+ years	10-14 days	Presented to ED with altered mental status. He became fatigued and lethargic with a brief period of unresponsiveness. Could not speak and had a gaze to his left. Could not carry on conversation or answer questions appropriately. Stroke team activated and CT completed. CT negative for bleed. Neurology ordered Alteplase to be administered. Patient then transferred for further evaluation and treatment. Patient had left MCA occlusion with TICI IIb achieved. Admitted to neurology stroke service in ICU following procedure. Started on aspirin with plavix. Rehab referral.
COVID19 VACCINE	PFIZER\BIONTECH	1042636-1	65+ years	10-14 days	Left CVA Right sided numbness vision loss 2/16/2021

COVID19 VACCINE	PFIZER\BIONTECH	1045982-1	65+ years	10-14 days	CLIENT STATES 9:15AM ON 2-5-21 SHE WAS PASSENGER IN CAR AND HUSBAND NOTICED THAT SHE HAD STOPPED TALKING AND WAS JUST STARRING X 2 MIN, THEN BECAME RESPONSIVE AND TALKATIVE AGAIN. SHE WAS 'NOT QUITE HERSELF FOR ABOUT 3 DAYS'. MRI, MRA, CT OF BRAIN & U.S. OF CAROTIDS DONE. DX WITH RT TEMPORAL/PARIETAL CVA. NOW ON PLAVIX & ASA 81MG. HAS APPT WITH NEUROLOGIST 2-17-21. REMAINS 'NOT QUITE HERSELF AND OFF BALANCE'.
COVID19 VACCINE	PFIZER\BIONTECH	1046419-1	65+ years	10-14 days	TIA 10 days after injection
COVID19 VACCINE	PFIZER\BIONTECH	1054591-1	40-49 years	10-14 days	Stroke on January 20th, 2021. Unknown cause for blood clot.
COVID19 VACCINE	PFIZER\BIONTECH	1056657-1	65+ years	10-14 days	10 days after 1st dose patient suffers ischemic stroke 4 days later the patient suffered a seizure; 10 days after 1st dose patient suffers ischemic stroke 4 days later the patient suffered a seizure; This is a spontaneous report from a contactable consumer. A 71-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) on 23Jan2021 at 08:00 at single dose via an unspecified route of administration on left arm for COVID-19 immunization. Relevant medical history included Parkinson's disease, dementia, Post-traumatic stress disorder, high blood pressure and high cholesterol. Concomitant medication were not reported. It was mentioned other vaccine on 28Jan2021, but no further information provided. On 02Feb2021 at 12:00 am, 10 days after 1st dose of BNT162B2 patient experienced ischemic stroke and 4 days later the patient suffered a seizure. The events resulted in 6 days of hospitalization. At the time of the reporting the patient was recovering from events. Information about lot/ batch number has been requested
COVID19 VACCINE	PFIZER\BIONTECH	1058892-1	65+ years	10-14 days	speech/word finding difficulty ( dysarthria ), Novocain like feeling left perioral area( perioral anesthesia ) , drooling of food occasionally
COVID19 VACCINE	PFIZER\BIONTECH	1060651-1	65+ years	10-14 days	Received 1st dose Pfizer-BioNTech vaccine Lot EN9899 exp 03/2021 on 01/18/2021 during CVS onsite clinic for Assisted Living Facility. Received 2nd dose Pfizer-BioNTech vaccine Lot EN5318 Exp 05/2021 on 02/08/2021 during CVS onsite clinic for Assisted Living Facility. On 02/10/2021 during routine employment screening, tested positive for COVID-19. On 02/12/2021 reported generalized malaise, otherwise denied symptoms. On 02/21/2021 employer notified by family friend that patient was treated at Medical Center on 02/20/2021 secondary to sudden onset difficulty swallowing, impaired speech, and facial droop. Employer later notified patient was then admitted to the ICU at aforementioned hospital secondary to dx of CVA.
COVID19 VACCINE	PFIZER\BIONTECH	1072223-1	65+ years	10-14 days	Site: Pain at Injection Site-Mild, Systemic: Stroke-Severe
COVID19 VACCINE	PFIZER\BIONTECH	1075298-1	65+ years	10-14 days	Pt had worsening altered mental status, tachypnea, and low-grade fever on 1/13/21. Pt considered terminal status previously and comfort-focus care pursued. Suspected pneumonia vs. TIA/CVA. PO meds D/C'ed as patient could no longer swallow.
COVID19 VACCINE	PFIZER\BIONTECH	1095175-1	65+ years	10-14 days	The patient presented to the ED on 3/11/2021 with fatigue for a few weeks, and recent abdomen pain. The patient was found to be hyponatremic and there was also evidence of a CVA on MRI findings.
COVID19 VACCINE	PFIZER\BIONTECH	1103510-1	65+ years	10-14 days	Patient had a stroke about two weeks after the last dose was given.
COVID19 VACCINE	KNOWN MANUFACTUR	1180587-1	65+ years	10-14 days	Acute Hemorrhagic CVA resulting in eventual death.
COVID19 VACCINE	PFIZER\BIONTECH	0975214-1	65+ years	Over 120 days	He had a stroke later that night after receiving vaccine.
COVID19 VACCINE	MODERNA	0981249-1	50-59 years	15-30 days	I had covid nov 23 2020. On jan 25 I had a stroke Couldn't talk. Couldn't move my left arm or leg. I received TPA.
COVID19 VACCINE	MODERNA	1002636-1	65+ years	15-30 days	On 1/17/2021 patient woke and began her day as usual, was found down by family member 1 hour later conscious but unable to speak and unable to move her R side. She was admitted to the hospital - Initial NIHSS was 26 and CT imaging showed no acute hemorrhage but mild hypodensity of greater than 1/3 of the MCA territory (TPA not recommended). CTA did show distal L M1/M2 occlusion and she was transferred to larger facility for thrombectomy. Unfortunately the patient had persistent severe neurological deficits after thrombectomy. Was discharged home on hospice care and expired on 1/23/21.
COVID19 VACCINE	MODERNA	1023060-1	65+ years	15-30 days	Patient developed right sided hemiparesis on 2/5/2021. He presented to hospital on 2/7/2021 with these symptoms and diagnosed with an acute CVA and internal carotid artery occlusion. He was admitted to the hospital and discharged to inpatient rehab on 2/11/2021.
COVID19 VACCINE	MODERNA	1023668-1	18-29 years	15-30 days	Headache started on 1/26. Woke up from a nap on 1/30 at 1:30pm and was having difficulty with speech. I could not say the words I wanted to and words that I could get out sounded very slurry. I went to the Emergency Room where I was stroke-activated. I was admitted to the hospital 1/30 and discharged 1/31.

COVID19 VACCINE	MODERNA	1025460-1	65+ years	15-30 days	Patient went to bed totally fine and woke up saying he could not see in one eye. I rushed him to the emergency hospital they ran cat scans, MRI, heart tests etc. He stayed overnight while they checked. The next day we went to eye doctor who told him he had a eye stroke. He would regain some of his site not all of it. Something to do with blood clot or loss of blood to the eye. I was not satisfied with that so made another drs appointment for the next day with a different eye doctor. The first eye doctor gave us some blood test to do so we did it then. Later that evening we got an emergency call form the first eye doctor to get back to the hospital right away he could lose sight in the other eye.. They found some high c-reactive protein. Normal is 8 his was over 40. They put him on heavy steroids and did biopsy on both temples of his eyes. This started last Wednesday morning. He was released from the hospital Monday Morning to see his regular doctor that afternoon. Test results for the eye would be Tuesday and all other vital tests came back fine thank goodness. On Tuesday the biopsy tests also came back negative so they are stopping steroids. I think they were looking for auto immune issues. Today we are going to Rheumatologist
COVID19 VACCINE	MODERNA	1042458-1	65+ years	15-30 days	Patient admitted with acute stroke, no prior history of same. Mild hyperlipidemia, but otherwise no clear risk factors for stroke. Unclear if anything to do with COVID vaccine.
COVID19 VACCINE	MODERNA	1049648-1	65+ years	15-30 days	I was notified on 2/22/21 that this patient passed away over the weekend. I do not know the details, nor can I confirm anything beyond what I was told. I believe the death occurred on 2/20/21 due to a massive stroke.
COVID19 VACCINE	MODERNA	1056476-1	65+ years	15-30 days	Seizures; Mini stroke; Tired; A spontaneous report was received from a consumer concerning a 73-year-old male who received Moderna Covid-19 vaccine and experienced seizures, mini stroke, confused, agitated, eyes were abnormal, memory impairment, and tired. The patient's medical history included heart attack and stent placement in 2011. His relevant concomitant medications include acetylsalicylic acid, candesartan cilexetil, clopidogrel bisulfate, diltiazem hydrochloride, ezetimibe, adenosine, gabapentin, metoprolol tartrate and rosuvastatin calcium. The patient received their first of two planned doses of mRNA-1273 on 14 Jan 2021. On 10 Feb 2021, 30 minutes prior to the onset of the events, the patient received his second of two planned doses of mRNA-1273 (Lot#010M20A) intramuscularly in left deltoid for the prophylaxis of COVID-19 infection. On 10 Feb 2021, With in 30 minutes of receiving the vaccination, the patient had a seizure. They took him to the hospital, where he had a computerized tomography (CT) scan, blood work and had a consult. After consult, they said, it's a mini stroke. They released him and told her if it happens again call 911. He felt so tired and went to sleep at home. Around 17:00 dinner time, he woke up looked very blankly, and his wife reported knowing he had another seizure. She reported he ran to his keys saying, ""I have to go"", seemed confused, agitated and didn't know where he was. She called 911 andhe was transported to the hospital in an ambulance. Around 19:00 the same day, he was admitted to do scans overnight. Around 21:00, patient's eyes were abnormal, he became agitated again and nurses confirmed he was having another seizure. 30 minutes later, he was talking to his wife and daughter as if he didn't remember anything. He mentioned some metallic taste in his mouth. On 11 Feb 2021, they did an electroencephalogram (EEG) and confirmed that he was having seizure. He was prescribed seizure medication and released him from hospital. However, the patient and his wife reported not wanting him to take the medication as they believe the events were due to the vaccine. Treatment information was not provided. Action taken with vaccine is not applicable as the patient received both the doses. The outcomes of the events, seizures, mini stroke, and tired, were recovered.; Reporter's Comments: Very limited information regarding this event has been provided at this time. The patient's medical history of heart attack and concomitant medication use can be confounding factor. Further information has been requested.""

COVID19 VACCINE	MODERNA	1066166-1	65+ years	15-30 days	Patient is an 80-year-old male that is admitted for observation status for recent TIA symptoms and bradycardia. He was seen in the emergency room this morning at approximately for complaints of posterior head and neck pressure, right arm numbness and tingling as well as a mild blurry vision in his right eye. Patient states that the symptoms from the right arm and eye blurriness lasted less than 1 hour. And has completely resolved at this time. Patient states that he still does have some posterior neck tightness. But most of this is on the left side at this point. Patient denies any increase in physical activity that he could attribute to the onset of the neck pain. Patient states that it does feel tight when he turns his head from side to side. Patient states that he no longer has a headache. He does have a history of a possible mini stroke approximately 10 years ago. He has had no other recent cardiac problems, or any other strokelike symptoms since that time. Patient takes medications for his cholesterol and a baby aspirin daily. Patient is fairly active and continues to drive a semi-5 days a week. TIA Neurochecks every 4 hours Carotid Dopplers 3/2 Bradycardia Echocardiogram 3/2 Last echo 1/4/2019, EF 60% Discharged home 3/2/21.
COVID19 VACCINE	MODERNA	1071945-1	65+ years	15-30 days	Massive stroke causing Left hemiplegia
COVID19 VACCINE	MODERNA	1085088-1	65+ years	15-30 days	Bells' Palsy, started on March 4th, right sided facial droop, and visual changes. Admitted to Hospital, worked up for CVA, and started on steroids and valacyclovir
COVID19 VACCINE	MODERNA	1086021-1	65+ years	15-30 days	Possible Stroke; Unable to speak/Lack of pronunciations; Fatigue; A spontaneous report was received from a health care professional concerning 75-years old male patient who experienced stroke (Cerebrovascular accident), unable to speak/ lack of pronunciations (Speech disorder) and fatigue (Fatigue). The patient's medical history included heart attack. Concomitant medications included included Metoprolol, HCTZ, Irbesartan, and Aspirin. On 08 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: 012L201A) intramuscularly in the Anatomical location for prophylaxis of COVID-19 infection. On 05 Feb 2021, approximately four days prior to the events, the patient received their second of two planned doses of mRNA-1273 (lot/batch: 030L20A) intramuscularly in the Anatomical location for prophylaxis of COVID-19 infection. On 06 Feb 2021, the patient experienced fatigue. On 09 Feb 2021, the patient experienced the events stroke and unable to speak/ lack of pronunciations. The events resulted in hospitalisation as seriousness criteria. The patient was admitted to the hospital on 09 Feb 2021. The patient was moved to ICU for 24 hours, and was the patient was discharged from Hospital on 11 Feb 2021. Treatment for the event included Eliquis and 80 mg chewable aspirin. The patient received both scheduled doses of mRNA-1273 prior to the events, therefore, action taken with the drug in response to the events is not applicable. The events stroke, unable to speak/ lack of pronunciations and fatigue were considered as recovered/resolved.; Reporter's Comments: Based on the current available information, a temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Of note, the patient has a pre-existing history of heart attack which is a strong confounder for the reported CVA and speech disorder. Fatigue is consistent with the known safety profile of the vaccine.
COVID19 VACCINE	MODERNA	1086926-1	Unknown	15-30 days	thought that it might be a stroke; Lip is dripping at the right side; A spontaneous report was received from a Healthcare professional which concerns 37-year-old male nurse patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced a situation where his right lip is dripping and thought that it might be a stroke. The patient's medical history was not provided. The concomitant medication included Tizanidine. On 23-Dec-2021, approximately 27 days prior to the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 037K20A) intramuscularly for prophylaxis of COVID-19 infection. On 18-Jan-2021, Patient experienced a situation where his right lip are is dripping and thought that it might be a stroke. Treatment information was not provided. Action taken with mrna-1273 in response to the events was unknown. The outcome of the event(s) where his right lip is dripping and thought that it might be a stroke was unknown.; Reporter's Comments: Limited information regarding these events has been provided at this time. Further information has been requested.
COVID19 VACCINE	MODERNA	1095943-1	65+ years	15-30 days	Extreme fatigue began on 3/3/21 (3 weeks post vaccine). Left sided facial drop and left sided weakness began on 3/6/21. 2 days later, symptoms were communicated to doctor and patient admitted to hospital, where CT scan and MRI confirmed right-sided stroke. No predisposing factors (no preceding HTN, non- smoker, normal carotid arteries, no congenital heart defects, not on OCP, no history of blood clots or abnormal dotting factors.)

COVID19 VACCINE	MODERNA	1127653-1	65+ years	15-30 days	Death by Hemorrhagic Stroke
COVID19 VACCINE	MODERNA	1136657-1	65+ years	15-30 days	NA 74 y/o several comorbidities. Stroke
COVID19 VACCINE	MODERNA	1154501-1	65+ years	15-30 days	Within days symptoms of likely CVA. Within one week diagnosis of shingles.
COVID19 VACCINE	PFIZER\BIONTECH	0952497-1	40-49 years	15-30 days	<p>Patient with PMH of depression and GERD who presented 1/8 with constipation, abdominal discomfort and worsening dyspnea. Symptoms began around 12/29. COVID vaccine 12/19. Previously quite active, marathon runner, gained some weight over last couple years but was still in good enough shape to complete 10K in New Orleans in early February. In late February, had a flu-like illness, as did one of his friends from church. 2020 was hard on him - weight gain, decreased activity, stress, overall deconditioning. No issues apart from sore arm after COVID vaccine 12/19 but then starting getting abdominal fullness/discomfort around 12/29, which steadily worsened, also develop worsening dyspnea on slight exertion. No known sick contacts.. Work-up notable for pericardial effusion, pleural effusions. Echo with severe diffuse LV hypokinesis, concern raised for myocarditis. COVID PCR negative, serology negative. RVP negative. . Concern raised that COVID vaccine may have played a role in myocarditis. He was found to have the following conditions Acute heart failure with reduced EF NYHA FC II, non-ischemic cardiomyopathy. Myocarditis appears subacute per MRI hypertension obesity small pericardial effusion- asymptomatic no pericarditis suspected obstructive sleep apnea. .Started on the following medications. Continue Carvedilol 12.5mg BID, Farxiga 5mg daily, Digoxin 0.125mg daily, Entresto 97-103mg BID, and Spironolactone 25mg daily. Per MD note. While it remains uncertain, team is doubtful COVID vaccine played a role in his cardiac issues. Given the MRI findings are not acute, more likely that the cardiac insult occurred weeks to months ago - potentially in the setting of the February 2020 illness. Perhaps his ""deconditioning"" in 2020 was related to worsening cardiac function. Nevertheless, will hold on 2nd COVID vaccine dose given absence of a clear explanation for his myocarditis. conversation with team will continue to determine if candidate for second covid vaccine. If consensus is that myocarditis pre-dated vaccine, might be able to proceed with dose 2 of vaccine.""</p>
COVID19 VACCINE	PFIZER\BIONTECH	1009424-1	50-59 years	15-30 days	2 weeks after my second shot, I had a CVA causing complete loss of sensation in my left arm. I am in good health and do not have multiple risk factors for CVA. While the scans showed evidence of a CVA, no underlying cause has yet to be determined.
COVID19 VACCINE	PFIZER\BIONTECH	1010161-1	65+ years	15-30 days	Transient Ischemic Attack
COVID19 VACCINE	PFIZER\BIONTECH	1024013-1	65+ years	15-30 days	Had a stroke, blood clot removed from brain
COVID19 VACCINE	PFIZER\BIONTECH	1033542-1	50-59 years	15-30 days	I experienced and embolic Stroke that is currently not determined a cause for at this time
COVID19 VACCINE	PFIZER\BIONTECH	1035546-1	65+ years	15-30 days	<p>Stroke; This is a spontaneous report from a contactable consumer. A 94-year-old female patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 16Jan2021, at single dose, for COVID-19 immunisation. Medical history included ongoing hypertension (took medication). Patient did not have COVID-19 prior to vaccination. Concomitant included unspecified medication for hypertension. The patient experienced stroke on 31Jan2021. The patient was brought to the emergency room and hospitalized due to the event on 31Jan2021. No therapeutic measures were taken as a result of the event. The patient underwent lab tests and procedures which included COVID-19 virus test: negative in Feb2021 (a week before report); investigation: brain bleed and discovered she had a stroke (on unknown date in 2021). The patient died on 03Feb2021 due to stroke and old age. An autopsy was not performed. Patient's family did not attribute her death to the vaccine at all. The information on the Lot/Batch number has been requested.; Reported Cause(s) of Death: stroke; Old age</p>

COVID19 VACCINE	PFIZER\BIONTECH	1039905-1	65+ years	15-30 days	a possible transient ischaemic attack; the patient began retaining water; This is a spontaneous report from a non-contactable consumer (patient). An 87-year-old male patient received the 1st dose of bnt162b2 (BNT162B2) at single dose on 19Jan2021 for Covid-19 immunisation. Medical history included mitral valve replacement, pacemaker. The patient had not experienced Covid-19 prior vaccination. Concomitant medication included blood thinner, atorvastatin calcium (STATIN), lisinopril (manufacturer unknown), warfarin (manufacturer unknown). No other vaccine received in four weeks. In 2021 a few days after 1st vaccination the patient began retaining water. On 04Feb2021 the patient was hospitalized for a possible transient ischemic attack. The patient was hospitalized for a possible transient ischaemic attack and began retaining water from 04Feb2021 to an unknown date. Therapeutic measures were taken as a result of events. The outcome of unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.
COVID19 VACCINE	PFIZER\BIONTECH	1039950-1	50-59 years	15-30 days	Bell's Palsy; Occipital Neuralgia; Stroke; Fever 101 degree; Myalgia; Headache/severe cephalgia; Blurred vision; dizziness; neuropathic pain; This is a spontaneous report from a contactable Physician (patient). A 59-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Lot number ER9831, Intramuscular in left arm on 11Jan2021 08:20 at single dose for COVID prevention. Medical history included Asthma Moderate persistent on 20Jun2020. Concomitant medication was not reported. The patient previously received first dose of BNT162B2 on 23Dec2020 and experienced Aches, Fever 102 degree, myalgia, and headache. The patient experienced 101 degree, myalgia, Headache after the second dose of BNT162B2. The patient experienced Bell's palsy and occipital neuralgia on 28Jan2021 10:00 which resulted in stroke woke up and will lead to time off work and further imaging of cervical spine and possible nerve blocks. She had blurred vision and dizziness in addition to severe cephalgia and neuropathic pain. Treated with Aleve, steroids, Acyclovir + neurontin. Duration unknown as still with symptoms. The events Bell's palsy and occipital neuralgia resulted in Emergency room visit. Lab data included CT head with illegible Head Contrast, CT Angiogram head and MRI Head on 27Jan2021 with Result: NI. The outcome of Bell's palsy was Resolved with Sequel. The outcome of the event Stroke was unknown. The outcome of Fever 101 degree, Myalgia was resolved. The outcome of other events was not resolved.; Sender's Comments: The causal relationship between BNT162B2 and the reported events cannot be completely excluded based on temporal association. The information currently 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 RAs, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2020512578 Same patient/reporter,drug, different dose
COVID19 VACCINE	PFIZER\BIONTECH	1049684-1	65+ years	15-30 days	DX: CVA History The patient is a 92 y.o. female with a past medical history notable for History of CVA, history of arthritis, history of COPD, history of DVT, history of reflux, history of hypertension, history of hyperthyroidism, recent GI bleed. The patient presents for evaluation of worsening weakness at skilled care facility. Patient had history of stroke. Patient was assessed there was found of have another stroke. Patient's other care and therapies were reviewed. Patient's blood thinners recently stopped within the last 3 months due to GI bleed requiring multiple transfusions. Patient has been slow to recover. Patient has struggled with intake and weight loss. Patient's past medical history, past surgical history, social history, family history, medications allergies were reviewed.

COVID19 VACCINE	PFIZER\BIONTECH	1069560-1	60-64 years	15-30 days	Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve. VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire
COVID19 VACCINE	PFIZER\BIONTECH	1070759-1	65+ years	15-30 days	Something like a mini stroke occur; some kind of injury to his neck; This is a spontaneous report from a contactable consumer from a Pfizer Sponsored program Covax US Support. A 68-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot number EL9263), via an unknown route of administration on 27Jan2021 (at the age of 68-years-old) as a single dose for Covid-19 immunization. Medical history included a heart patient prior to the vaccine for which he takes heart medications from an unknown date. The patient's concomitant medications were reported as a lot of medications and heart medications for which he has been taking for years (unspecified). The patient did not receive any other vaccines within four weeks prior to the vaccination. On 15Feb2021 at 16:00, the patient experienced something like a mini stroke; and he had some kind of injury to his neck from an unknown date. The patient was hospitalized due to heart problems describes as mini stroke on 15Feb2021. The patient underwent lots of test (unspecified) on an unknown date with unknown results. The clinical outcome of the event mini stroke and neck injury was unknown. The patient was still hospitalized.
COVID19 VACCINE	PFIZER\BIONTECH	1094126-1	40-49 years	15-30 days	About a week and a half after receiving the second Pfizer vaccine my husband had a stroke
COVID19 VACCINE	PFIZER\BIONTECH	1095360-1	65+ years	15-30 days	SHORTNESS OF BREATH Bradycardia Hypothermia Cardiomyopathy Elevated troponin Acute renal failure (ARF) Death
COVID19 VACCINE	PFIZER\BIONTECH	1104238-1	65+ years	15-30 days	Client was scheduled to get second dose of Pfizer Covid-19 on 02/19/21. Received call from family stating that client suffered a stroke on 02/18/21 and was admitted to hospital.

COVID19 VACCINE	PFIZER\BIONTECH	1106603-1	65+ years	15-30 days	100 year old patient in reasonable health (reading, socializing, doing Zoom calls, etc.) took second Pfizer vaccine on February 5, 2021. On the morning of February 22, 2021 the patient suffered a major hemorrhagic stroke. He suffered severe paralysis, could not speak, and suffered from severe pain. Within 24 hours he was moved to Hospice Care. A day later on February 24, 2021 he died.
COVID19 VACCINE	PFIZER\BIONTECH	1145005-1	65+ years	15-30 days	Patient presented to the ED on 3/4/2021 with left facial droop, left-sided weakness, and dysarthria that started upon awakening that morning. Patient found to have an ischemic stroke and ultimately admitted to hospice. Patient expired on 3/10/2021.
COVID19 VACCINE	MODERNA	1041485-1	50-59 years	31-60 days	Patient suffered from a stroke 4 days after the second vaccination
COVID19 VACCINE	MODERNA	1049547-1	65+ years	31-60 days	Woke up with severe dizziness, nausea/vomiting and increased while at work(denies palpitations). In ER 1/2/2021-CT of head(WNL), MRI (saw lesion and physician thought she had a stroke). Neurologist consult on 1/3 and felt it was not a stroke and unsure the reason of dizziness.. 1/3 no arm or leg weakness. Order to see a cardiologist d/t residual dizziness and advised against 2nd moderna covid 19 vaccine.
COVID19 VACCINE	PFIZER\BIONTECH	1028567-1	40-49 years	31-60 days	CVA/thrombotic event. R sided weakness and sensory deficit. No preexisting risk factors. Hypercoaguable work up negative. Managed conservatively. Improvement without resolution of symptoms to date.
COVID19 VACCINE	MODERNA	1105646-1	65+ years	61-120 days	2 days after vaccine developed severe abd pain and ischemic colitis requiring hospitalization.
COVID19 VACCINE	JANSSEN	1153081-1	Unknown	Unknown	STROKE; ALWAYS RINGING IN THE EARS; This spontaneous report received from a patient concerned an 87 year old female. The patient's weight was 153 pounds, and height was 67 inches. The patient's past medical history included strokes but the last one was a long time ago. The patient was not pregnant at the time of reporting. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unk) dose was not reported, administered on 08-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. The reporter state that, the patient was taking two vaccine shots and was halfway between the two vaccines (2 weeks) second one would be on 29-MAR-2021. On 09-Mar-2021, the patient experienced TIA symptoms (feeling fuzzy, batch of color lights in her left eye, very slurred speech, difficulty understanding and difficulty in communication) and stated she was having a stroke. Patient also informed that she already had this a lot of time before, and her doctor told her to lay down, take an aspirin. Treatment medications (dates unspecified) included: acetylsalicylic acid. On 2021, the subject experienced always ringing in the ears. The reporter stated that, the patient had severe hearing impairment as patient continuously complained that her ears were ""always ringing an patient was unable to answer all the questions as she stated that she had to go for some physical therapy exercise and could not continue the discussion. Treatment medications (dates unspecified) included: acetylsalicylic acid. The action taken with covid-19 vaccine ad26.cov2.s was not applicable The patient had not recovered from stroke, and the outcome of always ringing in the ears was not reported. This report was serious (Other Medically Important Condition). Additional information was received on 18-Mar-2021. The following information was updated and incorporated into the narrative: The patient's demographics details (age and age group),event (Always ringing in the ears), reporter address details and other reference number.; Sender's Comments: V1: The following information updates addition of event (always ringing in the ears), patient's demographics details (age and age group), reporter details and other reference number. This updated information does not alter prior causality assessment of reported event. 20210316871-Covid-19 vaccine ad26.cov2.s-Stroke. 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""



COVID19 VACCINE	JANSSEN	1153102-1	65+ years	Unknown	STROKE; This spontaneous report received from a patient concerned an 84 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included sulfonamide allergy, non alcoholic, and cigarette smoker (one pack per day). The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, expiry date: unknown) dose was not reported, administered on 03-MAR-2021,13:36 right arm for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 04-MAR-2021, Patient experienced a stroke. Patient was sent to the ER. The patient was treated per stroke treatment guidelines, The patient was hospitalized for two days. The patient returned to hospital a week later. Professionals at the hospital found reason for blood loss, but could not find reason for the stroke. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from stroke on 06-MAR-2021. The reporter causality assessment for stroke was not related. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0:20210340063-Covid-19 vaccine ad26.cov2.s Stroke. 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
COVID19 VACCINE	JANSSEN	1153892-1	Unknown	Unknown	BLIND; STROKE; 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) dose and therapy start 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 in MAR-2021 (reported as last week), the patient had a stroke and made her blind. There was no other information known about the patient or vaccine administration site. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the blind and stroke was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: 20210333599- Covid-19 vaccine ad26.cov2.s-Blind, Stroke. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
COVID19 VACCINE	JANSSEN	1157526-1	Unknown	Unknown	STROKE AS A RESULT OF RECEIVING THE J&J VACCINE; This spontaneous report received from a patient via a company representative concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received JNJ78436735 (Ad26.COVID.S) (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination at unknown site. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient experienced stroke as a result of receiving the j&j vaccine. The action taken with JNJ78436735 (Ad26.COVID.S) was not applicable. The outcome of stroke as a result of receiving the j&j vaccine was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210353970 - COVID-19 VACCINE AD26.COVID.S - Stroke. 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.
COVID19 VACCINE	MODERNA	0947873-1	40-49 years	Unknown	TIAStroke numbness of R face and RUE Narrative: I recommended transfer via 911 from clinic to nearest ER; she refused and signed out against medical advice. She plans to go to ER by private vehicle driven by a friend.
COVID19 VACCINE	MODERNA	0954121-1	50-59 years	Unknown	TIAStroke Employee complained of numbness at injection and stated she would like to wait about 5 minutes to see if it got better. Employee then stated it started to travel down right arm. Employee was offered treatment and was taken to be evaluated. Employee complained of numbness at injection and stated she would like to wait about 5 minutes to see if it got better. Employee then stated it started to travel down right arm. Employee was offered treatment and was taken to be evaluated.
COVID19 VACCINE	MODERNA	0971034-1	Unknown	Unknown	ON Jan 16 complained of lightheadedness then felt better after supper and nap. Next day ok On Jan 22 did not get up, had stroke, taken by ambulance to hospital and transferred to medical facility.

COVID19 VACCINE	MODERNA	0991434-1	65+ years	Unknown	The patient developed an acute right posterior frontal stroke with weakness, dysarthria and hemineglect at 1015pm on 1/26. He had received the Moderna vaccine second dose on 1/25. He received tPA and is now in the ICU for monitoring. Also found to have atrial fibrillation on EKG which seems to be a new finding.
COVID19 VACCINE	MODERNA	0997531-1	50-59 years	Unknown	Narrative: Patient is a 49 year old man with past medical history of hypertension and kidney stones who presented with a chief complaint of word finding difficulties and slurred speech. Patient was last seen normal at 1230 pm on 1/21/2021. He got his covid vaccine and shortly after he developed a headache that was on both sides of his head. Felt like 8/10 pain. He then had difficulty with speaking - he didn't know what word to say so he would make a noise. He was on the phone, and that person recommended that he come to the ED to get evaluated. In the ED, a stroke code was called. BP 169/97. NIHSS 0. A CT non con did not show any acute bleed or any signs of a stroke. After the stroke code was ended, the patient has a headache severity 1/10 and did not have any word finding difficulties. Patient was non focal by the time that the stroke code was ended. In the setting of hypertension, a blood pressure of 169/97 on admission and fluctuating symptoms, most concerning on the differential is a TIA. Given his risk factors and episodic presentation, he will need to be worked up for a stroke. The differential also includes post-vaccination reaction vs complex migraine.
COVID19 VACCINE	MODERNA	1001421-1	65+ years	Unknown	Ischemic attack; Severe high blood pressure; A spontaneous report was received from a consumer concerning a 77-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced severe high blood pressure (BP) and ischemic attack. The patient's medical history included diabetes. Products known to have been used by the patient, within two weeks prior to the event, included atorvastatin calcium, bupropion hydrochloride, gabapentin, ibuprofen, estradiol and metformin. On 08 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 027L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 12 Jan 2021, the patient was taken by ambulance to the hospital with severe high BP. During her hospital stay the patient's BP readings were 190s/109. The patient was diagnosed with ischemic attack. On 14 Jan 2021, the patient was discharged from the hospital. Her BP readings since then have been 179/85. On 19 Jan 2021, the patient's BP reading was 145/80. Treatment for the event included lisinopril. Action taken with the second dose of mRNA-1273 in response to the event was not reported. The outcome of the events, severe high BP and ischemic attack, was considered unknown.; Reporter's Comments: This case concerns a 77-year-old female patient with medical history of diabetes who experienced the serious unlisted events of Hypertension and Transient ischaemic attack that required hospitalization. The events occurred approximately four days after receiving their first of two planned doses of mRNA-1273 (Lot number: 027L20A), 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 and the events are considered possibly related to the vaccine. Of note, patient's elderly age and history of diabetes are considered risk factors for the occurrence of the events.
COVID19 VACCINE	MODERNA	1057709-1	Unknown	Unknown	stroke; A spontaneous report was received from a consumer concerning a male patient who experienced a stroke/cerebrovascular accident. The patient's medical history was not provided. Concomitant medications were not provided. On an unspecified date, the patient received one of two planned doses of mRNA-1273 intramuscularly for the prophylaxis of COVID-19 infection. On an unspecified date, the patient reported that he had a stroke. Treatment information was not provided. Action taken with mRNA-1273 was not reported. The outcome of the event, stroke, was not reported/unknown.; Reporter's Comments: Very limited information regarding this event has been provided at this time. No further information is expected

COVID19 VACCINE	MODERNA	1122713-1	65+ years	Unknown	Stroke; Diabetic Ketoacidosis; A spontaneous report was received from a consumer concerning a 77-years old, male patient who experienced the events cerebrovascular accident and diabetic ketoacidosis. The patient's medical history included hypertension. Concomitant product use was not provided by the reporter. On 06 Feb 2021, prior to the onset of the events, the patient received his first of two planned doses of mRNA-1273 (lot/batch: unknown) intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, the patient experienced stroke and diabetic ketoacidosis. which caused hospitalization. On 13 Feb 2021, the patient was admitted to the hospital. On 04 Mar 2021, the patient was discharged. Treatment details was not provided. Action taken with mRNA-1273 in response to the events was not unknown. The outcome of the events cerebrovascular accident and diabetic ketoacidosis was unknown.; Reporter's Comments: Very limited information regarding these events has been provided at this time. However, the patient's advance age, diabetes, Hypertension, may remain contributing factor for this event.Further information has been requested
COVID19 VACCINE	PFIZER\BIONTECH	0934951-1	30-39 years	Unknown	Acute demyelinating encephalomyelitis; Slurring his speech; Stroke; This is a spontaneous report from a contactable physician. A 35-year-old male patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in deltoid (unknown if right or left) on 17Dec2020 at 30 ug, single for 'Preventative'. Medical history included hypertension. There were no concomitant medications.(Physician) He is calling about the Pfizer Covid 19 vaccine. States what is going on with the patient may be associated as a side effect. The patient got the vaccine two to three weeks ago, he clarifies the patient received the vaccine on 17Dec2020 and the patient ended up acutely developing (states it is a presumptive diagnosis) Acute demyelinating encephalomyelitis, states it looks like a radiologic diagnosis. The patient is an employee at hospital. When querying seriousness states it is medically significant but could be disabling but he thinks the patient will recover. Reporter seriousness for acute demyelinating encephalomyelitis: Medically significant, Hospitalization. Patient was hospitalized on Sunday and he is still admitted at this time. Dates when patient was in hospital for acute demyelinating encephalomyelitis was from 03Jan2021 to ongoing. Caller thinks the patient was flown to (Place) yesterday. The patient's mother asked the caller if the caller thought the acute demyelinating encephalomyelitis was from the vaccine and the caller responded that he did not think it was from the vaccine. He confirms the patient is still admitted in the hospital and the patient's attending neurologist is doctor. The caller heard about the patient from doctor. When querying covid vaccine dose, the caller states the standard dose is 30 mcg. This was clarified and documented as provided. The patient has not received his second dose yet. He asks if the patient should receive the second dose. He asks a general question if a pregnant patient can be given the Pfizer covid vaccine. He heard the patient had a stroke then the CFO tried to talk to him and the patient was slurring his speech. Caller spoke to the patient's mother this morning and caller told the mother that he would try to find out what is going on with the patient. He asked that the patient get an HIV test even though he does not think the patient is at risk. Vaccination facility type was Hospital. Vaccine administered at military facility was No. None additional vaccines administered on same date of the PFIZER suspect. AE acute demyelinating encephalomyelitis require a visit to Emergency Room, not visit to physician office. Prior Vaccinations (within 4 weeks) was none. He has heard of acute demyelinating encephalomyelitis being associated with vaccines in the past and states that it is rare and usually in kids. States he saw patients that may have had acute demyelinating encephalomyelitis back in the 80s and 90s. Therapeutic measures were taken as a result of acute demyelinating encephalomyelitis (Patient will get steroids tonight pending the review of the x-ray). The outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: The reported stroke with speech slurred, and the presumptive diagnosis of acute demyelinating encephalomyelitis (looks like a radiologic diagnosis by the reporting physician), was most likely an intercurrent disease, and unlikely causally related to the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE). 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

COVID19 VACCINE	PFIZER\BIONTECH	0971548-1	40-49 years	Unknown	TIA/mini stroke; This is a spontaneous report from non-contactable consumer via Pfizer Sales Representative. A 5-decade-old male patient received 1st dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. Medical history included insulin dependent diabetic in mid 40s. The patient's concomitant medications were not reported. The patient experienced TIA (transient ischaemic attack)/mini stroke on same day he received COVID vaccine. Outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.
COVID19 VACCINE	PFIZER\BIONTECH	0993529-1	Unknown	Unknown	stroke; This is a spontaneous report from a contactable physician via a sales representative. A patient of unspecified age and gender received bnt162b2 (BNT162B2), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The physician reported an employee of (institute name) suffered a stroke within a week of taking the Pfizer Covid Vaccine on an unknown date. Dr. (Name) told the physician that he didn't think it was related. The event outcome was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Very limited information is currently available. As the reported stroke occurred within a week of taking the Covid Vaccine, BNT162B2, the Company cannot completely exclude the possible causality between the reported event and the administration of the suspect. 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.
COVID19 VACCINE	PFIZER\BIONTECH	1000185-1	Unknown	Unknown	Had a stroke; This is a spontaneous report from a contactable consumer via Pfizer-sponsored programs. A male patient (reporter's husband) of an unspecified age received first single dose of BNT162B2 (Solution for injection, batch/lot number and exp date not reported), via an unspecified route of administration on an unspecified date for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got the first dose of Covid vaccine on an unspecified date (Friday) at 12:35 PM, and had a stroke on Saturday morning at 10:30AM and was confined at the hospital (date/s unspecified) at the time of reporting. Reporter asked if there was any correlation or any fact sheets available with the vaccine and the stroke that happened to the patient. The outcome of the event was unknown. Information about lot number and expiry date for the suspect product will be requested in follow-up attempts.
COVID19 VACCINE	PFIZER\BIONTECH	1035528-1	Unknown	Unknown	stroke; couldn't speak; feeling tired; diarrhea; This is a spontaneous report from a Pfizer-sponsored program. A non-contactable consumer (patient) reported that a female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date not reported), 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. The patient had a stroke (medically significant) after the first shot and couldn't speak, was feeling tired as well and diarrhea. She wanted to know if she could still take the second shot. Patient does not want to give any information. The outcome of the events was unknown. No follow-up attempts are possible. Information about lot/batch number could not be requested.
COVID19 VACCINE	PFIZER\BIONTECH	1035531-1	Unknown	Unknown	mild stroke; This is a spontaneous report from a contactable consumer (patient) received via a Pfizer-sponsored program. A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose as vaccine. Medical history and concomitant medications were not reported. On an unspecified date, the patient had a mild stroke after the 1st vaccine and she's asking if she could go early to facility for the second dose. The outcome of the event was unknown. Information about lot/batch number has been requested.

COVID19 VACCINE	PFIZER\BIONTECH	1045624-1	Unknown	Unknown	Patient passed hit her head; Stroke; This is a spontaneous report from a non-contactable consumer (patient) via Pfizer sales representative. A 68-year-old female patient received single dose of BNT162B2(Solution for injection, lot number and exp date not reported), via an unspecified route of administration on an unspecified date at SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was not pregnant at the time of vaccination and was not pregnant at the time of reporting. The patient did not have COVID prior vaccination. On an unspecified date, the patient passed hit her head and had emergency surgery; and stroke. The adverse events resulted in: Hospitalization (date/s unspecified). The patient was not covid tested post vaccination. The outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.
COVID19 VACCINE	PFIZER\BIONTECH	1053724-1	65+ years	Unknown	Within a few days after receiving the vaccination I noticed a significant blurring of vision in my left eye. Consulted my ophthalmologist, who diagnosed a central retinal vein occlusion, confirmed with an OCT., and referred me to a retina specialist. Primary care physician started me on Xarelto and referred me to a hematologist. I do not have any history of blood clots.
COVID19 VACCINE	PFIZER\BIONTECH	1062237-1	65+ years	Unknown	she had symptoms of a stroke; This is a spontaneous report from a contactable consumer (patient) via a Pfizer-sponsored program. An 81-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (lot number and expiration date not provided) first dose, 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. Initially, it was reported that the patient experienced symptoms of Bell's palsy before getting the second dose. It was further reported that the patient stated it was not true that she experienced Bell's palsy. She mentioned she had symptoms of a stroke on an unspecified date. She wanted to confirm that her appointment for next 20Feb2021 has not been cancelled. Consumer refused to continue with the survey. The outcome of the event was unknown. No follow-up attempts are possible; information about batch/lot number cannot be obtained. No further information is expected.
COVID19 VACCINE	PFIZER\BIONTECH	1065136-1	Unknown	Unknown	strokes; This is a spontaneous report from a contactable physician. This physician reported similar events for two patients. This is 1st of 2 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection, unknown lot number and expiration), via an unspecified route of administration on unspecified date at a single dose for COVID-19 immunization in a hospital. The patient's medical history reported as none. Concomitant medications were not reported. The physician reported that there were two patients who came in with strokes with no underlying condition/health risks, but they had been recently vaccinated with the COVID vaccine on unspecified date. The event resulted in physician office visit. Outcome of the event was unknown. The event was assessed as serious (hospitalization). No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on the implied time association, the possible contribution of suspect vaccine BNT162B2 to the event stroke cannot be excluded. The patient's age and detailed clinical course 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.,Linked Report(s) : US-PFIZER INC-2021163468 same reporter, product, event; different patient

COVID19 VACCINE	PFIZER\BIONTECH	1065137-1	Unknown	Unknown	<p>strokes; This is a spontaneous report from a contactable physician. This physician reported similar events for two patients. This is 2nd of 2 reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection, unknown lot number and expiration), via an unspecified route of administration on unspecified date at a single dose for COVID-19 immunization in a hospital. The patient's medical history was reported as none. Concomitant medications were not reported. The physician reported that there were two patients who came in with strokes with no underlying condition/health risks, but they had been recently vaccinated with the COVID vaccine on unspecified date. The outcome of the event was unknown. The event resulted in physician office visit. The event was assessed as serious (hospitalization). No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: The information is limited and does not allow a full medical assessment. Considering temporal relationship, a possible contribution role of vaccination with BNT162B2 to the onset of stroke, cannot be fully excluded. 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.,Linked Report(s) : US-PFIZER INC-2021163467 same reporter, product, event; different patient</p>
COVID19 VACCINE	PFIZER\BIONTECH	1065433-1	Unknown	Unknown	<p>stroke; blood clot in the heart; Hospitalization with racing and irregular heart beat; Hospitalization with racing and irregular heart beat; loss of motor function; This is a spontaneous report from a non-contactable consumer. A 46-year-old male patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) (brand=Pfizer) on an unspecified date at a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. If other vaccine in four weeks was unknown. Other medications in two weeks was unknown. If covid prior vaccination was unknown. If covid tested post vaccination was unknown. Known allergies was unknown. Historical vaccine included the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) (brand=Pfizer) on an unspecified date for COVID-19 immunization. Patient experienced hospitalization with racing and irregular heartbeat, blood clot in the heart, stroke, loss of motor function on an unspecified date. Treatment included intubation. The outcome of the events was unknown. Events resulted in hospitalization, life threatening illness (immediate risk of death from the event). No follow-up attempts are possible; information about lot/batch number cannot be obtained.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1068282-1	Unknown	Unknown	<p>she could have had a mild stroke; Headache; stroke type symptoms of confusion, difficulty talking and right side of face felt funny; stroke type symptoms of confusion, difficulty talking and right side of face felt funny; stroke type symptoms of confusion, difficulty talking and right side of face felt funny; This is a spontaneous report from a contactable consumer from a Pfizer-sponsored program. A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got a headache after covax last week Wednesday. On Thursday (unknown date), she had stroke type symptoms of confusion, difficulty talking and right side of face felt funny. The patient was taken to the emergency room on Friday and they said she could have had a mild stroke even though her tests were all negative. The outcome of the events was unknown. Information on the lot/batch number has been requested.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1070760-1	65+ years	Unknown	Lost part of my vision and it only lasted for three to four minutes; mini stroke/ TIA; This is a spontaneous report from a contactable consumer (patient). A 79-year-old female patient received bnt162b2(Pfizer-BioNTech COVID-19 Vaccine, Lot number: EL9284, Expiration date: 31May2021), via an unspecified route of administration at the left arm on 11Feb2021 14:00 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 11Feb2021 7pm, patient went to get something to open the can of soup but when she went into the pantry, she lost part of her vision and it only lasted for three to four minutes. The patient's daughter who is a neurologist thought it was the mini stroke or TIA (Feb2021). The doctor was setting up the sonogram for her arteries and her neck and also for her heart and said she might have to rely on a pacemaker. The outcome of the events was unknown.
COVID19 VACCINE	PFIZER\BIONTECH	1070761-1	Unknown	Unknown	A very ""mild"" stroke/heart attack; A very ""mild"" stroke/heart attack; This is a spontaneous report from a contactable consumer. A male elderly patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number not reported at the time of the report), via an unspecified route of administration from an unspecified date at SINGLE DOSE for Covid-19 immunization. The patient medical history and concomitant medications were not reported. It was reported that: ""I'm working on a story involving an elderly man whose family says he suffered a very ""mild"" stroke/heart attack about 4 days after getting the first dose of the Pfizer vaccine. The family says it took doctors a couple of days to confirm. They also said none of the doctors could say definitively that the vaccine had anything to do with what happened. The family says they still called the company to report it and have since received follow-up contact. While they were worried about him getting the second dose, they decided to proceed with that. He got the dose last week and the family says he's been fine. I wanted to reach out and see if you had a statement you'd like to provide. Also -Are strokes/heart attacks side effects of the Pfizer vaccine? If someone suffered a stroke or heart attack after getting the first shot and they believe it's related to the vaccine, should they get the second dose? "" The outcome of the events was unknown. Information on the lot/batch number has been requested.""
COVID19 VACCINE	PFIZER\BIONTECH	1100431-1	Unknown	Unknown	stroke; eye also felt funny found she blew a blood vessel; After the 2nd shot on the 29th she had the taste of rubber bands in her mouth; her face started to go numb.; Her Blood pressure was 150; she felt like she was hit by a truck; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer (patient) reported that a female patient of an unspecified age received second 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 included migraines and they cause numbness in her face sometimes. The patient's concomitant medications were not reported. After the 1st shot of BNT162B2 she had a metal taste in her mouth. After the 2nd shot on the 29nd she had the taste of rubber bands in her mouth. After waiting 10 mins her face started to go numb. Her Blood pressure was 150. HCP thought it was a stroke but she just went home. She had a history of migraines and they cause numbness in her face sometimes. She took migraine medications and it didn't help. Next day face numbness went away but she felt like she was hit by a truck. Her eye also felt funny found she blew a blood vessel. The outcome of events was unknown. Information on the lot/batch number has been requested.

COVID19 VACCINE	PFIZER\BIONTECH	1106291-1	65+ years	Unknown	small ischemic stroke; elevated white blood count; fever; body aches; chills; headache; This is a spontaneous report from a contactable consumer (patient). A 68-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot number EL9269, expiration date May2021), via an unknown route of administration on 15Feb2021 (at the age of 68-years-old) as a single dose in the left arm for COVID-19 Prevention/ immunization. The patient's medical history included a dental procedure on 18Feb2021 for a cracked tooth from an unknown date. The patient received procaine hydrochloride (NOVOCAIN) on 18Feb2021 for the dental procedure. On 18Feb2021 the patient experienced fever, body aches, chills, and a headache; and on an unknown date in Feb2021 the patient experienced a small ischemic stroke. The patient was hospitalized for the ischemic stroke on 19Feb2021. The patient underwent lab tests and procedures which included a Magnetic resonance imaging (MRI) of the brain on 20Feb2021 which showed a small ischemic stroke and white blood cell count which was elevated (in the low 20s) on 19Feb2021 and on 20Feb2021, white blood cell count was normal. Therapeutic measures were taken as a result of the ischemic stroke which included Plavix. The clinical outcome of the ischemic stroke was unknown; fever, body aches and chills were recovered on 19Feb2021; white blood cell count increased recovered on 20Feb2021; headache was not recovered. The patient was hospitalized for three days. The patient mentioned that he was not associating the stroke with the vaccine but rather associates it with the added stress on his body.
COVID19 VACCINE	PFIZER\BIONTECH	1121623-1	65+ years	Unknown	Stroke; Nasal swab COVID test post vaccination/positive; This is a spontaneous report from a non-contactable consumer (patient). A 69-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot number: EN6205, expiry date unknown), via an unspecified route of administration on 11Mar2021 at a single dose for COVID-19 immunization. Medical history included COVID-19 prior to vaccination on an unknown date. The patient's concomitant medications were not reported. The patient experienced stroke on 14Mar2021, two days (as reported) after having the vaccine. The event required an emergency room/department or urgent care visit and hospitalization for 2 days on unspecified dates in Mar2021. The patient received treatment for the event stroke and unspecified tests and monitoring was done. The event was also considered as a life threatening illness (immediate risk of death from the event) and has caused disability or permanent damage. The patient had a nasal swab COVID test post vaccination on an unspecified date in Mar2021 with a result of positive. The patient recovered from the event stroke with lasting effects while the outcome of the event nasal swab covid test post vaccination/positive was unknown. No follow-up attempts are possible. No further information is expected.

Dataset: The Vaccine Adverse Event Reporting System (VAERS)

Query Parameters:

State / Territory: The United States/Territories/Unknown

Symptoms: BASAL GANGLIA STROKE; BRAIN STEM STROKE; CARDIOMYOPATHY; CEREBELLAR STROKE; CEREBRAL SMALL VESSEL ISCHAEMIC DISEASE; CEREBROVASCULAR ACCIDENT; COLITIS ISCHAEMIC; CONGESTIVE CARDIOMYOPATHY; EMBOLIC STROKE; HAEMORRHAGIC STROKE; HAEMORRHAGIC TRANSFORMATION STROKE; HEAT STROKE; HYPOXIC-ISCHAEMIC ENCEPHALOPATHY; ISCHAEMIC CARDIOMYOPATHY; ISCHAEMIC CEREBRAL INFARCTION; ISCHAEMIC CONTRACTURE OF THE LEFT VENTRICLE; ISCHAEMIC LIMB PAIN; ISCHAEMIC SKIN ULCER; ISCHAEMIC STROKE; LACUNAR STROKE; MYOCARDIAL ISCHAEMIA; NECROSIS ISCHAEMIC; NIH STROKE SCALE; NIH STROKE SCALE ABNORMAL; NIH STROKE SCALE SCORE INCREASED; OCULAR ISCHAEMIC SYNDROME; OPTIC ISCHAEMIC NEUROPATHY; POST PROCEDURAL STROKE; PSEUDOSTROKE; RETINAL VEIN OCCLUSION; SPINAL STROKE; THROMBOTIC STROKE; TRANSIENT ISCHAEMIC ATTACK; VERTEBROBASILAR STROKE; WHITE MATTER LESION

Vaccine Products: COVID19 VACCINE (COVID19)

VAERS ID: All

Group By: Vaccine Type; Vaccine Manufacturer; VAERS ID; Age; Onset Interval

Show Totals: False

Show Zero Values: Disabled

Help: See <http://wonder.cdc.gov/wonder/help/vaers.html> for more information.

Query Date: Apr 20, 2021 11:04:41 AM

Suggested Citation: Accessed at <http://wonder.cdc.gov/vaers.html> on Apr 20, 2021 11:04:41 AM



Messages:

1. The full results are too long to be displayed, only non-zero rows are available.
2. VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- 3. These results are for 517 total events.**
4. When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.
5. Click on a VAERS ID to see a report containing detailed information for the event.

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Footnotes:

1. Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

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Caveats:

1. <p> VAERS accepts reports of adverse events and reactions that occur following vaccination. Healthcare providers, vaccine manufacturers, and the public can submit reports to VAERS. While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. This creates specific limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind. </p> <p> The strengths of VAERS are that it is national in scope and can quickly provide an early warning of a safety problem with a vaccine. As part of CDC and FDA's multi-system approach to post-licensure vaccine safety monitoring, VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also known as "safety signals." If a safety signal is found in VAERS, further studies can be done in safety systems such as the CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) project. These systems do not have the same limitations as VAERS, and can better assess health risks and possible connections between adverse events and a vaccine. </p> <p> Key considerations and limitations of VAERS data: <ul><li> Vaccine providers are encouraged to report any clinically significant health problem following vaccination to VAERS, whether or not they believe the vaccine was the cause. </li><li> Reports may include incomplete, inaccurate, coincidental and unverified information. </li><li> The number of reports alone cannot be interpreted or used to reach conclusions about the existence, severity, frequency, or rates of problems associated with vaccines. </li><li> VAERS data are limited to vaccine adverse event reports received between 1990 and the most recent date for which data are available. </li><li> VAERS data do not represent all known safety information for a vaccine and should be interpreted in the context of other scientific information. </li></ul> </p>

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3. Some items may have more than 1 occurrence in any single event report, such as Symptoms, Vaccine Products, Manufacturers, and Event Categories. If data are grouped by any of these items, then the number in the Events Reported column may exceed the total number of unique events. If percentages are shown, then the associated percentage of total unique event reports will exceed 100% in such cases. For example, the number of Symptoms mentioned is likely to exceed the number of events reported, because many reports include more than 1 Symptom. When more than 1 Symptom occurs in a single report, then the percentage of Symptoms to unique events is more than 100%. More information: <http://wonder.cdc.gov/wonder/help/vaers.html#Suppress>.
4. Data contains VAERS reports processed as of 4/10/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. More information: <http://wonder.cdc.gov/wonder/help/vaers.html#Reporting>.
5. For more information on how many persons have been vaccinated in the US for COVID19 to date, see <https://covid.cdc.gov/covid-data-tracker/#vaccinations/>