The Vaccine Adverse Event Reporting System (VAERS) Results

Data current as of 05/06/2022

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS	JANSSEN	18-29 years	1271678-1	Hepatitis / Encephalopathy (seizures, ADEM, MISC/A) PRESENTING PROBLEM: Fever and chills [R50.9] Hepatitis [K75.9] Febrile illness, acute [R50.9] Acute nonintractable headache, unspecified headache type [R51.9] Seizure (HCC) [R56.9] MIS-C associated with COVID-19 (HCC) [M35.81] Active Issues Requiring Follow-up MIS-C/A - 2/2 COVID-19 infection vs idiosyncratic reaction to J&J vaccine -prednisone taper over 16 days as above -ID will be arranging follow up serial labs (CBC with diff, CMP, Ferritin level, CRP, LDH) -Bactrim prophylaxis while on steroids -Acyclovir 400 mg BID for prophylaxis (hx of recurrent HSV infection of eyelid) - duration to be clarified by ID at follow up - ASA 81 mg daily -TTE w/ normal coronaries. She will need cardiac MRI, to be arranged by adult congenital cardiology Generalized tonic-clonic seizures - witnessed and captured on EEG 4/9. No further events. Continue Keppra 1500 mg BID. outaptient f/u with neurology Abnormal MRI brain - diffuse T2 white matter hyperintensities - non-specific. She will need follow up MRI brain w/ and w/o contrast in 1 month and follow up with neurology clinic ADHD - given insomnia, Senthuri was recommended to avoid vyvanse for now. She will discuss with her outpatient prescriber Anxiety and depression - zoloft increased to 125 mg daily Insomnia - 2/2 trauma from critical illness. Improved with trazodone HS. Elevated EBV PCR - ID will continue to monitor. Nausea/vomiting - resolved. Likey 2/2 gastritis in setting of steroid use. PPI BID x 4 weeks DISCHARGE DISPOSITION: Home without services
HEPATITIS	JANSSEN	30-39 years	1168907-1	DRUG ADMINISTRATION ERROR; POSSIBLE EXTRA DOSE ADMINISTERED; This spontaneous report received from a patient concerned a 37 year old female. The patient's concurrent conditions included inflamed nerves, non-alcoholic, and non-smoker, and other pre-existing medical conditions included patient had no known allergies and no history of drug abuse. The patient was previously treated with gabapentin for inflamed nerves. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805018, and expiry: 25/MAY/2021) dose was not reported, administered on 10-MAR-2021 05:15 for prophylactic vaccination. No concomitant medications were reported. On MAR-2021, Laboratory data included: HIV infection (NR: not provided) not reported, and Hepatitis (NR: not provided) not reported. On 10-MAR-2021, the subject experienced drug administration error. On 10-MAR-2021, the subject experienced possible extra dose administered. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the drug administration error and possible extra dose administered was not reported. This report was non-serious. This report was associated with product quality complaint: 90000173646.; Sender's Comments: V1: Follow up information received in the current version has no impact on previous assessment. Medical assessment comment not required as per standard procedure as the case assessed as non-serious.
HEPATITIS	JANSSEN	30-39 years	1227297-1	MARCH 9: BODY ACHES AND HEADACHE, SLEEPLESSNESS. CONTINUED OFF AND ON OVER FOLLOWING DAYS. MARCH 18: BLOOD PRESSURE AND PULSE WERE TOO HIGH TO DONATE PLASMA MARCH 21: DIDN'T FEEL NORMAL, GASTROINTESTINAL ISSUES, FATIGUE, SLEEPLESSNESS, ABDOMINAL PAIN, RAPID WEIGHT LOSS, LOSS OF APPETITE MARCH 26: URINE STARTED DARKENING TO ORANGE COLOR DESPITE STAYING HYDRATED, FEVER, MALAISE. APRIL 1: WENT TO DONATE PLASMA AT BIOTEST PLASMA CENTER AND NOTICED BLOOD PLASMA WAS AN ODD COLOR. APRIL 4: EMERGENCY ROOM PRESENTED WITH ABDOMINAL PAIN, JAUNDICE, WHITE/LIGHT COLORED STOOL. BLOODWORK, ULTRASOUNDS, CT'S WERE DONE AND SHOWED INFLAMMATION IN LIVER/GALLBLADDER/GI TRACT. HIGH BILIRUBIN. APRIL 5: COLONOSCOPY PERFORMED. DIAGNOSIS: ULCERATIVE COLITIS. ERCP PERFORMED WITH LIVER BIOPSIES. DIAGNOSIS: COMMON BILE DUCT BLOCKAGE WITH CHOLECYSTITIS AND HEPATITIS. STENT WAS PLACED. POSSIBLE PRIMARY SCLEROSING CHOLANGITIS- DEPENDING ON BIOPSY RESULTS. APRIL 6: CHOLECYSTECTOMY, MORE LIVER BIOPSIES TAKEN. APRIL 7: LIVER BIOPSY RESULTS/DIAGNOSES: OVERLAP SYNDROME OF AUTOIMMUNE HEPATITIS & PRIMARY SCLEROSING CHOLANGITIS. PLACED ON PREDNISONE. AWAITING APPROVAL FOR REMICADE INFUSIONS WITH POSSIBLE NEED FOR LIVER TRANSPLANT IN THE FUTURE AS PSC PROGRESSES. AS OF APRIL 18: JAUNDICE STILL PRESENT, BILIRUBIN NOT DECREASING. BEING REFERRED TO MEDICAL CENTER FOR FURTHER OBSERVATION AND TREATMENT.
HEPATITIS	JANSSEN	40-49 years	1722453-1	Fever, nausea and swelling at injection site, went to ER 5/28- received 10 days of doxycycline and Keflex. Have had crippling pain issues since, extreme tiredness, nausea, headaches and left quadrant pain and lymph node swelling-
HEPATITIS	JANSSEN	40-49 years	2005953-1	Change in menstral cycle, weight gain, inflammation, intermittant heart racing, hypothyroidism, liver and gall bladder deficiency/ inflammation

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HEPATITIS	JANSSEN	40-49 years	2231284-1	I went to the recreation park for my first vaccination course. Within 5 minutes of getting the vaccine I started to feel bad. I started seeing cloudy, my pressure went down, I started with a lot of pain in my head. I felt that the body did not respond to me. The paramedics came and checked me out. They kept me under observation for a while until my heartbeat normalized and then I was able to go home. When I got home I started feeling dizzy and cold at night I had a fever. The next day I am short of breath and have a lot of pressure on my head. On the 3rd day the symptoms worsened and I went to see a doctor who gave me some medicine. Within a week I didn't feel any better so I went back to the doctor. It was when he did a blood test that my liver was inflamed and my lungs were inflamed and they gave me medicine. It almost took me 2 months to recover. Then I got attacks of depression and anxiety. I went to see a doctor but I didn't take the medicine myself, I got better. Today I still have sequela but I'm better.
HEPATITIS	JANSSEN	50-59 years	1897668-1	Tasted metal immediately upon injection, left arm numb within minutes. Later same night, severe headache, arms/legs asleep, disoriented (considered ER options), cold sweat with no fever, tremors, racing heartbeat, swollen tongue without airway obstruction (hard to swallow or speak properly), vertigo with room spinning even when lying still, could hear/feel heartbeat in ears and ringing in ears, sense of smell increased to the point of nausea, zero thirst or appetite, light sensitivity. Next week all of these remained but large bruises appeared for no reason as well. 7 weeks later (as of today) still have severe headaches most days or at least a regular headache and arms/legs still bruised, trembling and numb.
HEPATITIS	JANSSEN	60-64 years	2141995-1	SUSPECTED CLINICAL VACCINATION FAILURE; SUSPECTED COVID-19 INFECTION; LIVER INFLAMMATION; SEVERE LOSS OF APPETITE; WEIGHT LOSS OF AROUND 18 LBS; MODERATE NAUSEA; This spontaneous report received from a patient and concerned a 64 year old male of unspecified ethnicity. The patient's weight was 86.18 kilograms, and height was 183 centimeters. The patient's concurrent conditions included: cancer and immunocompromised. The patient received covid-19 vaccine ad26.cov2.s (dose number in series 1) (suspension for injection, route of admin not reported, batch number: 1805022 expiry: 25-MAY-2021) dose was not reported, 1 total administered on 06-MAR-2021 at left arm for prophylactic vaccination. The patient additionally received non-company suspect vaccine BNT 162 (dose number in series 2) (batch number: FH8027 expiry: unknown, form of admin, route of admin, and were not reported) dose was not reported, administered on 18-NOV-2021 at left arm for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, the patient developed covid virus (suspected clinical vaccination failure, suspected covid-19 infection) (dose number in series 1) with associated symptoms. On 10-JAN-2022, the patient was treated with Paxlovid tablet (2 different tablets) for covid virus to minimize result of covid and his associated symptoms with the medication. Around 25-JAN-2022, the patient experienced severe loss of appetite, weight loss of around 18 lbs, and moderate nausea (dose number in series 2). On an unspecified date, the patient experienced slightly jaundiced. On 08-FEB-2022, the patient experienced liver inflammation (dose number in series 2). The loss of appetite had improved slightly at a very slow rate. He did have an oncology appointment and they did blood work. He was called 3 days ago with results and they said he did have liver inflammation. He had no problem with the vaccines. Moderate nausea improved significantly, but the rate of improvement was very slow. He first noticed being slightly jaundiced 2 weeks ago. He did not have an exact date. His oncologist had scheduled for more labs in a week and a half. He also reported that associated with lack of appetite was weight loss of around 18 lbs., which had then stabilized. The action taken with covid-19 vaccine ad26.cov2.s, and bnt 162 was not applicable. The patient recovered from suspected covid-19 infection, was recovering from severe loss of appetite, moderate nausea, and weight loss of around 18 lbs, and the outcome of suspected clinical vaccination failure and liver inflammation was not reported. This report was serious (Other Medically Important Condition). This report was associated with a product quality complaint: 90000218644.; Sender's Comments: V0: 20220242568-covid-19 vaccine ad26.cov2.s- liver inflammation. 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). Therefore, this event(s) is considered unassessable. 20220242568- covid-19 vaccine ad26.cov2.s-Suspected Clinical Vaccination failure. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: SPECIAL SITUATIONS. Therefore, this event(s) is considered not related.

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HEPATITIS	JANSSEN	Unknown	1325834-1	"LOW PLATELET COUNT; INFLAMED LIVER; BLOOD CLOTS; HEADACHES; This spontaneous report received from a patient, via social media, via a company representative concerned a 33 year old male. The patient's weight, height, and medical history were not reported. The patient received COVID-19 VACCINE AD26.COV2.S (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, two weeks after vaccination, the patient experienced headaches, low platelet count, inflamed liver, and blood clots. It was stated the patient had an inflamed liver because of all the blood clots found; the patient is now on blood thinners for a minimum of 6 months. Laboratory data (dates unspecified) included: Low platelets (NR: not provided) 26K. The action taken with COVID-19 VACCINE AD26.COV2.S was not applicable. The outcome of the headaches, inflamed liver, blood clots and low platelet count was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This spontaneous report received from a patient, via social media, via a company representative concerned a 33-year-old man who experienced blood clots and low platelet (26,000) count two weeks after vaccine. Medical history, concomitant medications, and other details were not reported. It was stated the patient had an ""inflamed liver because of all the blood clots found""; the patient is now on blood thinners for a minimum of 6 months. Information is limited in this case, and the occurrence of blood clots and low platelet count could represent background incidence of such events in the general population. However, a relationship with Janssen Covid-19 vaccine cannot be ruled out and thus the relationship is considered indeterminate (Brighton Collaboration Criteria level 5)."
HEPATITIS	JANSSEN	Unknown	2065232-1	COVID PNEUMONIA; HEPATITIS FROM DRUGS; HALLUCINATIONS; REGULAR PNEUMONIA; PROBLEMS WITH KIDNEYS; INFECTIONS (NOT SURE IF UPPER RESPIRATORY TRACT OR URINARY TRACT); COULD BARELY WALK 1/2 A MILE WITHOUT GETTING OUT OF BREATH; WEIGHT LOSS (17 LB DURING HOSPITAL STAY OF 20 DAYS); This spontaneous report received from a patient concerned a 75 year old male. The patient's height, and weight were not reported. The patient's past medical history included: ex-smoker (was smoker for 67 years, but now not a smoker anymore), and toxic agent exposure, and concurrent conditions included: ischemic heart disease (toxic agent), emphysema (held in check 14 years, as shown by pulmonary function tests, remained the same), and COPD (Chronic obstructive pulmonary disease)- was considered 100% disabled but now okay. The patient was previously treated with covid-19 vaccine ad26.cov2.s (dose number in series 1) (suspension for injection, route of admin not reported, batch number: 1805020, and expiry: unknown) dose was not reported, 1 total was administered to left arm on 30-MAR-2021 for prophylactic vaccination. On 01-DEC-2021, patient was not feeling well, so he went to emergency room and tested positive for covid (confirmed covid-19 infection and confirmed clinical vaccination failure) following administration of covid-19 vaccine ad26.cov2.s (dose number in series 1), The patient received covid-19 vaccine ad26.cov2.s (dose number in series 2) (suspension for injection, route of admin not reported, batch number: 211D21A and expiry: unknown) dose was not reported, 1 total was administered on 30-NOV-2021 for prophylactic vaccination. No concomitant medications were reported. On 01-DEC-2021, the patient was not feeling well. He went to the emergency room and was tested positive for Covid and was then sent to home. On 05-DEC-2021, patient went to the hospital due to 102.9 F (body temperature), and on the same day he got hospitalized. Patient stated that during the first 6-7 days, he didn't believe he was going to go home. Patient stated, it was a terrifying experience, On an unspecified date, in DEC-2021, (during hospital stay) patient developed COVID pneumonia, hepatitis from drugs, problems with kidneys, infections (not sure if upper respiratory tract or urinary tract), hallucinations (saw colors but not people, went from black to greys and himself in the, then to colors but no people and happy), and picked up regular pneumonia. Patient was treated with antibiotics (had a reaction to both first and second ones), and also got shots in the abdomen every day to not cause clots. During hospitalization, patient did not need ventilator but was put on on 10L oxygen therapy. Patient was bedridden during hospital stay, so he lost 17 Ib and muscle mass (stated weight was 181 Ib on discharge day). On an unspecified date, patient had X-ray, which showed one lung was all white and the other one 3/4. On 25-DEC-2021, patient was sent home but he could barely walk 1/2 a mile without getting out of breath. Patient stated, doctors said he would take 9 weeks to 3 months to recover. Patient was happy because only a few weeks after discharge from hospital he could walk now, if he pushes it, he would get out of breath. Patient did breathing exercises and took vitamins and everything to got better. Patient stated, each day it got better. He attributes this to vaccine, stated it might have impacted his chances of survival. Patient was hospitalized for 20 days (dose number in series 2). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from could barely walk 1/2 a mile without getting out of breath, and the outcome of covid pneumonia, problems with kidneys, hepatitis from drugs, weight loss (17 Ib during hospital stay of 20 days), infections (not sure if upper respiratory tract or urinary tract), hallucinations and regular pneumonia was not reported (dose number in series 2). This report was serious (Hospitalization Caused / Prolonged). This report was associated with product quality complaint: 90000211650. This case, involving the same patient is linked to 20220140794.; Sender's Comments: V0: 20220123831-covid-19 vaccine ad26.cov2.s- covid pneumonia, problems with kidneys, hepatitis from drugs, weight loss (17 Ib during hospital stay of 20 days), infections (not sure if upper respiratory tract or urinary tract), hallucinations and regular pneumonia, could barely walk 1/2 a mile without getting out of breath. 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).

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HEPATITIS	MODERNA	18-29 years	1028607-1	Fever 24 hours, then recurred approximately 5 days later., prompted ED eval, then two days later prompted IM admission with hepatitis, fever, leukopenia.
HEPATITIS	MODERNA	18-29 years	1135945-1	Tightness on chest would come and go for 3 days Tightness on rear of neck would come and go for 2 days Inflammed Liver for a week
HEPATITIS	MODERNA	18-29 years	1374367-1	Jaundice, elevated liver enzymes. Etiology unclear after extensive work up. Not clearly related to Moderna vaccine.
HEPATITIS	MODERNA	30-39 years	1459945-1	On 5/31 patient developed acute abdominal pain and n/v. Evaluated 6/2 in hospital with fevers and dark urine, found to have elevated LFTs including bilis. Ultimately rehospitalized 6/6-6/13 for FUO, jaundice, transaminitis, fatigue. Also had conjunctivitis. No heart/lung issues. Had eosinophilia to 1000s. Ultimately required liver biopsy which showed hepatic congestion as if had cholangitis (but did not) and eosinophils. Ultimately discharged when LFTs and CBC stabilized.
HEPATITIS	MODERNA	30-39 years	1909481-1	"11/16/2021: Received Moderna booster shot around 10am. Started to feel nauseated around 5pm. By 10pm, was throwing up violently multiple times, stomach cramps, fever, chills, diarrhea, body aches 11/17/2021: Stayed home from work with nausea, diarrhea and body aches and fatigue. Epigastic pain (about 4 inches above belly button was severe). 11/18/2021: Went to work but epigastric pain continued, nausea, fatigue, head aches 11/19/2021: Nausea and epigastic pain continued Sun 11/21/2021: Went to ER d/t epigastric pain. Had CXR, EKG, labs and CT scan abd. Labs: D-dimer elevated to 651. CT found ""mild heterogeneity of the liver with possible periportal edema. Gallbladder wall is edematous with distention. No stones. C T impression: Abnormal liver with possible hepatitis. Gallbladder wall edema likely related to underlying liver disease. (Patient has no hx of liver issues). 11/22/2021: Went to see PCP Doc in Clinic and she ordered fasting labs and ultrasound for next day. 11/23/2021: Fasting ultrasound showed: Diffusely heterogeneous liver. Liver 17.5 cm in length (which is enlarged). Liver notes to be heterogeneous with changes suggesting underlying hepatitis. Normal gallbladder. 11/24/2021: 7 tubes of blood drawn. Labs showed Hgb dropped by 2 points to 11. Shortness of breath started and continued. 11/29/2021: Went to ER due to shortness of breath and lightheaded. CXR, EKG and labs were done. No new findings. Awaiting final send off lab results."
HEPATITIS	MODERNA	40-49 years	1057831-1	Patient developed sob. Admitted on 2/16/21 with cardiogenic shock, acute renal failure and liver inflammation. Diagnosed with multisystem inflammatory disorder from COVID-19. Thought to be related to diagnosis on 1/25/21 but given recent receipt of vaccine reporting in case there are trends.
HEPATITIS	MODERNA	40-49 years	1374407-1	"Severe hepatitis second Moderna vaccine 2/11/21 and felt feverish that night and the next several days. He took ibuprofen for a few days. His had subjective fevers after that that worsened in early March. His temperature was normal during these times. His urine got dark. His saw his PCP and labs showed increased LFTs. He was admitted. Liver biopsy 3/15/2021: Portal and lobular hepatitis with cholestatic features, negative for steatosis or fibrosis. Subsequent hepatology diagnosis was ""All his symptoms started after COVID vaccine #2 but unable to identify any other DILI source.""""
HEPATITIS	MODERNA	40-49 years	1684762-1	fever and hepatitis. hospitalized
HEPATITIS	MODERNA	40-49 years	1919275-1	I took the first shot and my psoriasis started to act up and inflamed. I was very ill and I also went to see the doctor and he was concerned that my liver was inflamed.
HEPATITIS	MODERNA	40-49 years	2072086-1	felt fatigue, body ache and arm sore 0n 1/8/22. then 1/9/22 am, I passed out in the bathroom. on 1/14/22 started mild urticarial which got worse every day, where my whole body was itching then huge hives develops. then I started having sore throat, bodyaches, chills and dry coughs. Pcr covid test negative on the onset of respiratory symptoms and 4 days later, repeated again, negative. Dr. is treating the symptoms with 6 day prednisone course, itching is slightly better, cough is worse, stared having wheezing, now taking albuterol as needed.
HEPATITIS	MODERNA	50-59 years	0972712-1	Patient had first dose of Moderna vaccine at another facility on 1/10/2021. Around 1/18/2021 she felt poorly, more fatigue and noted her urine was dark. By 1/22/2021 she opted to present to the ER where she was noted to have severe hepatitis (ALT 1600) but oddly a normal bilirubin. Her INR, CBC and vitals were normal. She was sent home from the ER and I saw her today 1/25/2021 in consultation for the liver enzyme issues. It is not clear that this is related to the vaccine. She may have hepatitis A or this could have been a medication/supplement induced hepatitis but due to the timing I felt it should be reported.
HEPATITIS	MODERNA	50-59 years	1033091-1	approximately 2.5 wks after vaccination, development of severe increasing back pain and chest pain and shortness of breath Dx acute moderately severe pericarditis with pericardial effusion, pneumonitis with bilateral small pleural effusions, hepatitis with elevated alk phos and LFT, bone marrow reaction with elevated WBC, new anemia and elevated platelets, markedly elevated d dimer and CRP with normal troponin and negative imaging for PE.
HEPATITIS	MODERNA	50-59 years	1158094-1	On the night of the getting first dose of Moderna on 3/31/21 patient started to have headache along with severe sharp continuous pain on right middle quadrant pain range 8/10. Patient visited PCP and was told her liver seems as swollen. She's still having the pain when she called the pharmacy around 7pm 4/1/01 it was worse when she lays down.
HEPATITIS	MODERNA	50-59 years	1233718-1	Pt received 1st dose Moderna about 3:30pm on 4/7/21, by midnight pt began experiencing nausea, vomiting and fever. Symptoms worsened each day following and began showing signs of jaundice on 4/10. Pt went to ER on 4/11 and was admitted to the hospital for elevated liver tests (inflamed liver) and dehydration. Pt remained in hospital until 4/16, and will follow up with PCP on 4/30 for blood work.

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HEPATITIS	MODERNA	50-59 years	1544994-1	On January 27th, 2021 , two minutes after the inject my heart rate and blood pressure increased and my face turned blood shot red and then I started to have a abdominal pain and tightness and nausea. They rushed me upstairs to the ER and gave me fluids and did a EKG and lab work. Lab work came back normal and they released me three hours later. A couple months had past and you developed a hives all over my body May 3, 2021. I contacted my Doctor and came in on the same day. My doctor thought it was a covid break through cases so they gave me a covid test and it came back negative. The Doctor prescribed me 5 days of prednisone and they also did blood work and the results came back that I had an elevated thyroid problem and something called ANA Titer and they came back positive with an autoimmune. On June 6, 2021, I had a liver biopsy, it was done to rule out autoimmune liver condition. After that I was referred to the Hospital on July 7, 2021, for results of biopsy which indicated liver inflammation with no autoimmune process. I went to the allergist on July 27, 2021, They tested for vaccine ingredients and I tested positive for polysorbate 80 allergy. I have to get blood work every 3 months for to check my liver for the next two years.
HEPATITIS	MODERNA	50-59 years	1707537-1	They also said I had some inflammation of the liver.; I had a huge amount of swelling underneath & above both my eyelids.; right back pain that went into the right shoulder blade.; I had vomiting; I had nausea; The pain radiated around my side to my back.; I started feeling a dull pain on my right side, above rib cage.; This spontaneous case was reported by a consumer and describes the occurrence of HEPATITIS (They also said I had some inflammation of the liver.), SWELLING OF EYELID (I had a huge amount of swelling underneath & above both my eyelids.), BACK PAIN (The pain radiated around my side to my back.), PAIN (I started feeling a dull pain on my right side, above rib cage.), ARTHRALGIA (right back pain that went into the right shoulder blade.), VOMITING (I had vomiting) and NAUSEA (I had nausea) in a 53-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 020F21A) for COVID-19 vaccination. The patient's past medical history included Gilbert's syndrome (blood disorder) and Kidney stones. On 02-Sep-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 02-Sep-2021, the patient experienced BACK PAIN (The pain radiated around my side to my back.) (seriousness criterion medically significant) and PAIN (I started feeling a dull pain on my right side, above rib cage.) (seriousness criterion medically significant). On 03-Sep-2021, the patient experienced HEPATITIS (They also said I had some inflammation of the liver.) (seriousness criterion medically significant), SWELLING OF EYELID (I had a huge amount of swelling underneath & above both my eyelids.) (seriousness criterion medically significant), ARTHRALGIA (right back pain that went into the right shoulder blade.) (seriousness criterion medically significant), VOMITING (I had vomiting) (seriousness criterion medically significant) and NAUSEA (I had nausea) (seriousness criterion medically significant). At the time of the report, HEPATITIS (They also said I had some inflammation of the liver.), SWELLING OF EYELID (I had a huge amount of swelling underneath & above both my eyelids.), BACK PAIN (The pain radiated around my side to my back.), PAIN (I started feeling a dull pain on my right side, above rib cage.), ARTHRALGIA (right back pain that went into the right shoulder blade.), VOMITING (I had vomiting) and NAUSEA (I had nausea) outcome was unknown. mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was withdrawn on an unknown date. Concomitant medication information not provided. Treatment information not provided. Patient was not been to work in a year, due to car wreck. patient was to advised not to take another dose of the vaccine. Company Comment: The report concerns a 53 year old female patient with medical history of gilbert's syndrome and kidney stones who experienced serious unexpected events of radiating back pain, dull aching pain, swelling of the eyelid, arthralgia, hepatitis, vomiting and nausea after vaccination with first dose of mRNA-1273 on the same day. It was reported that the patient was advised not to take the second dose of the vaccine. The medical history of gilbert's syndrome remains a confounder for the reported events. The benefit-risk relationship of mRNA-1273 is not affected by this report.; Sender's Comments: The report concerns a 53 year old female patient with medical history of gilbert's syndrome and kidney stones who experienced serious unexpected events of radiating back pain, dull aching pain, swelling of the eyelid, arthralgia, hepatitis, vomiting and nausea after vaccination with first dose of mRNA-1273 on the same day. It was reported that the patient was advised not to take the second dose of the vaccine. The medical history of gilbert's syndrome remains a confounder for the reported events. The benefit-risk relationship of mRNA-1273 is not affected by this report.
HEPATITIS	MODERNA	50-59 years	2093118-1	Jaundice beginning early Dec 2021, confirmed acute liver injury on labs on 12/14. Admitted to hospital Jan 2022 for acute liver failure, listed for transplant. Also recently received macrobid.
HEPATITIS	MODERNA	60-64 years	1041211-1	"Patient is meeting diagnostic criteria for multisystem inflammatory syndrome post-vaccination. He received his 1st Moderna COVID vaccination on 12/31/2020 (037K20A) and his second COVID vaccination on 2/5/21 (029L20A). He began developing high grade fevers on 1/22/21 and was admitted to our facility on 2/8/21 due to ""fever of unknown etiology"" associated with hepatitis and coagulopathy on laboratory studies. He underwent an extensive evaluation which failed to reveal any other infectious, rheumatologic, or hematologic explanation for his clinical syndrome. He was ultimately discharged to outpatient care with ongoing supportive care for his fevers. His liver associated enzymes were improving at discharge."
HEPATITIS	MODERNA	60-64 years	2038226-1	I began to run a low grade fever with headache and nausea. Over the next week I lost my appetite, began losing weight, had dark urine, and had difficulty sleeping. On 12/16 I had a CBC and my platelets were low and my white count was high. On 12/20 a metabolic panel revealed very high liver enzymes. I was told to go to the ER. I was diagnosed with an autoimmune reaction that caused hepatitis. On 12/18 I developed tonsillitis.

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS	MODERNA	65-79 years	1041894-1	"Patient and wife called in to report patient experiencing 7/10 constant stomach pain, uncontrollable shaking, and numbness and tingling bilateral feet. Patient reports receiving his first covid vaccine dose 2-17-21 and experiencing symptoms, today Patient states, ""I can't feel the bottoms of my feet"" and ""it feels like I'm going to throw up"". Patient denies difficulty breathing. Patient was able to check pulse will on phone with triage nurse with pulse 93 and blood pressure 147/107. Patient requesting to have triage nurse call 911-EMS; HPI The patient is a 69 year old male who states that he had the 1st dose of COVID vaccine yesterday morning. The patient states that approximately 24 hours later, he developed stomach cramping. He has nausea. He denies any diarrhea. He has not vomited. Patient denies any cough or shortness of breath. He complains of generalized weakness. The patient also has chronic back pain. Patient is noted to have a low-grade fever here, however, he does not report any fever. CHIEF COMPLAINT: WEAKNESS (per ems, pt got covid vaccine 24 hours ago, feeling weak and dizzy since 1500, tachycardia); Assessment/Plan DIAGNOSIS at time of disposition: 1. Hepatitis; The patient presents with a low-grade temperature, which isn't unexpected given that he received his COVID-19 vaccine yesterday. However, the patient complains of abdominal pain. Lab work does show elevated bilirubin, alk-phos, AST and ALT. The patient has no previous history of this. I did obtain both CT and ultrasound imaging of the gallbladder, which shows no pathology. Subsequently, the patient was reassessed. He is ambulated. He is steady on his feet. He does not desaturate. He has no subjective complaints while walking. I discussed the patient's lab abnormalities with him. The patient prefers to go home and follow up for lab retesting on Monday. Patient was given strict return instructions. He will return should he develop any new or worsening symptoms. He is going to have his labs redrawn on Monday and follow shortly with his primary care provider. Given the normal imaging studies, I do think that these findings are likely related to a reaction to his vaccination. This was discussed at length with the patient. Patient is discharged home in stable condition."
HEPATITIS	MODERNA	65-79 years	1083391-1	71yo M received first Moderna COVID vaccine 5d ago. 24hrs following pt started having fatigue, vertigo, body and joint aches, intermittent runny nose, PND, throat irritation and gravely voice, decreased smell, loss of taste, chills, and fever to 104.2. Chronic dry cough which pt is unsure if has recently been worse. No ear or sinus pressure/pain. no respiratory concerns at present. +nausea, no vomiting, no diarrhea/loose stools, + decrease in activity, +decrease in appetite. Also yellow/rust colored urine x4d getting darker esp today w/ decreased urinary frequency. No burning or urgency. No urine blood clots. No BM for 4d w/ decreased appetite but did have BM today which was normal w/o blood, black, or tarry stool. Pt had heart stent placed 1mth ago and started on plavix along w/ his daily ASA and atorvastatin increased from 10 to 40mg. No CP or SOB. Pt found to have elevated LFTs, alk phos, and bili w/ hepatitis reaction.
HEPATITIS	MODERNA	65-79 years	1112291-1	Suspected that pt developed aggressive immune activation after Vaccination that resulted in hepatitis flare and breakthrough viremia despite having completion viral suppression for years on Entecavir. I saw pt on 3/17/21. She reported symptoms of fever, and dizziness after the shot which confirms immune response from Moderna.
HEPATITIS	MODERNA	65-79 years	1126329-1	pt states that she woke up next day w/ severe epigastric pain, nausea, vomiting, loss of appetite, dark urine, pale stools. pt was very sick from 3/5 to 3/13. She had an appt w/ PCP on 3/19/21 for her annual exam. Labs showed her liver enzymes were elevated. Her labs were all high on this date but normal one year ago. Dr. told her the vaccine caused her to have vaccine induced hepatitis. Pt to FU w/ PCP on 4/22/21.
HEPATITIS	MODERNA	65-79 years	1157594-1	Vaccine Induced Hepatitis; liver enzymes were elevated; terrible flank pain; very cranky since the shot; nauseous; fatigue; vomiting; severe epigastric pain; urine had blood in it; sicker than a dog; A spontaneous report was received from nurse, concerning herself, a 72-year-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced fatigue, sickness, epigastric pain, covid arm, rusty urine, vomiting, nauseous and vaccine induced hepatitis. The patient medical history was reported as unknown. concomitant drugs were not provided. On 4 Mar 2021, the patient received their first two of two planned doses of mRNA-1273 (Lot number: 027A21A) intramuscularly in the arm of prophylaxis of COVID-19 infection. On 4 Mar 2021, Patient experienced fatigue, sickness, epigastric pain, rusty urine, blood I urine, vomiting, nauseous. On 19 Mar 2021 for her annual exam and her liver enzymes were elevated, doctor states that it was vaccine induced hepatitis. Action taken with mRNA-1273 in response to the events was not reported. The outcome of all events were unknown.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
				My father had his liver transplant in October 2020 with an absolutely perfect outcome. He never had any lab abnormalities indicating rejection, and he took meticulous care of taking his medications, having labs drawn, and touching base with the transplant clinic weekly. He returned to work about 2.5 months post transplant. He received his first Moderna vaccine as reported on 3/9/2021 without any side effects. He received his second Moderna COVID-19 vaccine on 4/6/2021 Given at same location as first Moderna COVID-19 vaccine, Lot number 016B21A on 04/06/2021, RA, IM. On 5/3/2021, we had a series of text messages about him driving me to a test and nothing was out of order. On 5/4/2021, he nearly crashed, was severely confused and never recovered from this. An extremely thorough workup was done (I can obtain these records), his liver function was completely normal, and nobody was able to truly determine a cause for his altered mental status. He did have 3 very elevated thyroid antibodies, and he was given IV steroids for presumed Hashimoto's Encephalopathy. Our impression as a family (and I am a (Privacy)) was that he was about 60-75% better on the steroids. The neurology team did not agree and the IV steroids were stopped with no oral taper. As he decompensated over the next 4 days, they realized that he was benefitting from steroids and started a long oral taper. It was somewhat helpful, but really the benefit was questionable. Prior to the May incident, he had had 1 separate episode of confusion while on a trip in (Privacy). He also had 2 episodes of bowel incontinence the same day. This episode occurred 8 days after his 2nd Moderna vaccine (Given at same location as first Moderna COVID-19 vaccine, Lot number 016B21A on 04/06/2021, RA, IM). The episode was short enough that he was able to drive the 9 hours home from the trip. As the month and a half long hospitalization ended on 6/18/2021, he had to be moved to assisted living as he was unable to live alone at that point. After that, things waxed and waned. His transplant medication had been changed from tacrolimus to sirolimus due to concern that tac could be contributing to altered mental status. He was doing fine on this and did not have any liver abnormalities. The lab draw times were inconsistent in assisted living, and I took him once to have accurate labs drawn at a (Privacy) facility. Ultimately, he was switched to cyclosporine as this could be better monitored given the circumstances. He was admitted for fluid overload of unknown cause in October 2021. Liver studies normal. He did have elevated creatinine so there was a balance of cyclosporine dose and the judicious use of lasix. In early December 2021, he suddenly became jaundiced, distended abdomen, difficulty breathing and weeping edema in bilateral LE. His bilirubin was over 12. He was admitted to (Privacy) where it was determined that he was in severe chronic rejection for which we knew of no cause. He had 3 liver biopsies. He had minimal acute rejection and severe chronic rejection with ductopenia and essentially no biliary tracts left. He failed treatment with IV steroids, IV thymoglobulin, and pheresis combined with IVIG. While on steroids, he developed a lucid period that lasted for about 2.5 weeks (well beyond steroid discontinuation) with minimal confusion. This was witnessed by physicians, NPs, PAs, nursing, and family. His baseline confusion returned around the time he started pheresis treatments. He did have some notable reduction in inflammation of the liver with normalization of AST and ALT but unfortunately bilirubin did not decrease. He was treated with pheresis in the event that he had antibody mediated rejection although his biopsy did not indicate that. It was determined that he truly did have chronic rejection. During the hospitalization, I was able to speak with a cognitive neurologist at (Privacy) who reviewed his case, including imaging, and went through my dad's story with me. We discussed that his MRI had not changed from 05/2021 to 10/2021, and as I learned about the chronic rejection, I began to wonder if the working diagnosis of vascular dementia was a red herring. He did have white matter changes on an MRI as early as 2005, which we do not have possession of. It is unknown for how long his brain might have looked like this. His cognitive function did worsen between the 2 most recent MRIs but that the MRI was unchanged was suspect. The cognitive neurologist felt that if he had some vascular dementia, it would only be stage 2 which would only be associated with mild cognitive impairment. She felt that the sudden onset and wide swings in his cognitive status were most likely reflective of underlying pathology. She further felt this way as dementia wouldn't fluctuate in this manner. She felt that his periods of lucidity were likely his true cognitive baseline. She felt that if the liver could be improved, there was a good chance that he would just have mild cognitive impairment. Unfortunately, once he finished pheresis and it failed to reduce bilirubin due to ductopenia, the only option would've been a second transplant, which he did not qualify for because of his cognitive status. He then developed renal failure without explanation or with the possibility of several different factors. It was not hepatorenal syndrome, which would be the most expected form of renal failure in a liver transplant patient. He had acute tubular necrosis. The only option was dialysis, but based on type of injury, it was unlikely to help and he also would not be able to have a kidney transplant for the same reasons as his liver. We declined dialysis and he died shortly after of uremia d/t renal failure. The overall feeling with the destruction of his liver consistent with chronic rejection was that this process had to have begun quite a few months prior. At a top transplant center with highly skilled professionals, they had never seen rejection not cause lab abnormalities to alert of its presence. In terms of what might be different about him than patients in the past, we can only point to the fact that he received his first Moderna vaccine roughly around the time the chronic rejection began and his sudden altered mental status that began in early May was likely a symptom and not a cause. We wonder about the vaccine as potential cause or trigger as it was not tested in transplant patients and it very well could have triggered some form of immune activation. Of course, we do not know for certain. We had an autopsy done but the results are not back yet. My rheumatologist at (Privacy) has also been involved with all things COVID and felt this could be a plausible explanation. We are all hoping that we might find some answer or cause so that we can help patients like him in the future who have severe cognitive changes without cause and normal liver function after transplant. We really want to look into this deeply.
HEPATITIS	**MODERNA**	**65-79 years**	2099727-1	

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
				transplant. We really want to look into this deeply.
HEPATITIS	MODERNA	65-79 years	2182240-1	Vaccination dates in 2021: 02/05 - started feeling weak, fatigued, muscle wasting; liver issues - clinical NASH/cirrhosis? 03/01; 03/05; 04/01; 08/35.
HEPATITIS	MODERNA	80+ years	1255807-1	On 1/6/21, 91 yo M amb to ER with c/c of allergic reaction to COVID x 1 day. Pt receive COVID vaccine Moderna Jan 3, 2021. Pt c/o fever, n/v, lower back pain, SOB, dark colored urine. Jaundice noted to bilat sclera and generalized skin. Patient hospitalized and discharged on 1/17/21. Admitting diagnosis was pneumonia, hepatitis, acute repiratory failure with hypoxia and acture renal failure. Patient was treated for sepsis due to acute cholangitis and completed 10 day course of IV zosyn
HEPATITIS	MODERNA	80+ years	1374272-1	but his liver had inflammation; jaundiced; dark urine; He did not receive second injection of the moderna vaccine; This spontaneous case was reported by a consumer and describes the occurrence of HEPATITIS (but his liver had inflammation) in an 83-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 028A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 27-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Mar-2021, the patient experienced PRODUCT DOSE OMISSION ISSUE (He did not receive second injection of the moderna vaccine). On 30-Mar-2021, the patient experienced CHROMATURIA (dark urine). On 01-Apr-2021, the patient experienced JAUNDICE (jaundiced). On an unknown date, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced HEPATITIS (but his liver had inflammation) (seriousness criterion medically significant). The patient was treated with PREDNISONE ongoing since an unknown date for Liver inflammation, at an unspecified dose and frequency. On 27-Mar-2021, PRODUCT DOSE OMISSION ISSUE (He did not receive second injection of the moderna vaccine) had resolved. At the time of the report, HEPATITIS (but his liver had inflammation), CHROMATURIA (dark urine) and JAUNDICE (jaundiced) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 06-Apr-2021, Biopsy liver: (abnormal) cancer free but liver had inflammation.. On 06-Apr-2021, Blood bilirubin: 36 (High) 36. On an unknown date, Blood bilirubin: 26 (Inconclusive) 26. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. On 30-Mar-2021, patient stated that his urine was getting dark and two days later, he started looking jaundiced. Patient saw the doctor on 06-Apr-2021. He was started on 20mg per day of prednisone. Company comment: Very limited information regarding this event has been provided at this time. Further information has been requested. This is also a case of a 83 year old male who missed dose as a result of experienced illness.; Sender's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested. This is also a case of a 83 year old male who missed dose as a result of experienced illness.
HEPATITIS	MODERNA	Unknown	1691985-1	"got blind; Hepatitis; heart inflammation; Eye problem; Kidney problem; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of BLINDNESS (got blind), HEPATITIS (Hepatitis) and CARDITIS (heart inflammation) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced BLINDNESS (got blind) (seriousness criterion medically significant), HEPATITIS (Hepatitis) (seriousness criterion medically significant), CARDITIS (heart inflammation) (seriousness criterion medically significant), EYE DISORDER (Eye problem) and RENAL DISORDER (Kidney problem). At the time of the report, BLINDNESS (got blind), HEPATITIS (Hepatitis), CARDITIS (heart inflammation), EYE DISORDER (Eye problem) and RENAL DISORDER (Kidney problem) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Concomitant medications were not reported. Treatment medications were not reported. Patient reported ""225 people got blind after vaccination. There are also other reports on hepatitis, eye problem, kidney problem, and heart inflammation. People are dying"". Very limited information regarding these events has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested."

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS	MODERNA	Unknown	1747849-1	Hepatitis; sick for a long time; Second dose administered 6 months later; This spontaneous case was reported by a pharmacist and describes the occurrence of HEPATITIS (Hepatitis) and ILLNESS (sick for a long time) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 28-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. In 2021, the patient experienced HEPATITIS (Hepatitis) (seriousness criteria hospitalization and medically significant) and ILLNESS (sick for a long time) (seriousness criterion hospitalization). On 11-Aug-2021, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Second dose administered 6 months later). The patient was hospitalized on sometime in 2021 due to HEPATITIS and ILLNESS. At the time of the report, HEPATITIS (Hepatitis) and ILLNESS (sick for a long time) outcome was unknown and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Second dose administered 6 months later) had resolved. mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) dosing remained unchanged. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications provided. No treatment medications provided. Could not get the second dose. She received the second dose on11AUG2021 and was told due to the time difference between the first dose and the second dose, it was too long, and she would need to get another dose of the vaccine. This case concerns a 67-year-old, female patient with no previous relevant medical history, who experienced the unexpected events of hepatitis, and illness. The events occurred on unknown days after the first dose of mRNA-1273 (Moderna COVID-19 Vaccine). The rechallenge was not applicable since only information about the first dose was disclosed. The benefit-risk relationship of mRNA-1273 (Moderna COVID-19 Vaccine) is not affected by this report.; Sender's Comments: This case concerns a 67-year-old, female patient with no previous relevant medical history, who experienced the unexpected events of hepatitis, and illness. The events occurred on unknown days after the first dose of mRNA-1273 (Moderna COVID-19 Vaccine). The rechallenge was not applicable since only information about the first dose was disclosed. The benefit-risk relationship of mRNA-1273 (Moderna COVID-19 Vaccine) is not affected by this report.
HEPATITIS	MODERNA	Unknown	1984035-1	Severe non-cholestatic hepatitis; She never developed hepatic dysfunction; This spontaneous case was reported by a physician and describes the occurrence of HEPATITIS (Severe non-cholestatic hepatitis) and HEPATIC FUNCTION ABNORMAL (She never developed hepatic dysfunction) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced HEPATITIS (Severe non-cholestatic hepatitis) (seriousness criterion medically significant) and HEPATIC FUNCTION ABNORMAL (She never developed hepatic dysfunction) (seriousness criterion medically significant). At the time of the report, HEPATITIS (Severe non-cholestatic hepatitis) and HEPATIC FUNCTION ABNORMAL (She never developed hepatic dysfunction) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Hepatic enzyme: improving (High) liver enzymes are improving and she never developed hepatic dysfunction.. On an unknown date, Laboratory test: normal (normal) Lab tests has otherwise been normal with no clear cause.. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered HEPATITIS (Severe non-cholestatic hepatitis) to be related. No further causality assessment was provided for HEPATIC FUNCTION ABNORMAL (She never developed hepatic dysfunction). I have a patient who developed severe non-cholestatic hepatitis, diagnosed about 2 weeks after dose one of her Moderna Vaccine. Lab testing has otherwise been normal with no clear cause. She was on a large volume of supplements and herbs. I believe that was the culprit or possibly an undiagnosed transient viral infection. However the patient is slightly overdue to dose #2 and is worried. Her liver enzymes are improving and she never developed hepatic dysfunction. I could find no data in the literature about case reports of vaccine induced hepatitis. I have asked her to delay dose #2 for another week. Please let me know if you have any guidance for me. She was on a large volume of supplements and herbs. However, the patient was slightly overdue to dose 2 and was worried. She never developed hepatic dysfunction. Doctor had asked her to delay dose 2 for another week. No concomitant medications were reported. No treatment information was provided. Company comment This case concerns a female patient of an unknown age, with medical history of consumer of large volume of supplements and herbs, who experienced the unexpected serious events of HEPATITIS and HEPATIC FUNCTION ABNORMAL. The events occurred approximately 2 weeks after the administration of the first dose of mRNA-1273 vaccine. Patient¦s medical history of consumer of large volume of supplements and herbs, remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.; Sender's Comments: This case concerns a female patient of an unknown age, with medical history of consumer of large volume of supplements and herbs, who experienced the unexpected serious events of HEPATITIS and HEPATIC FUNCTION ABNORMAL. The events occurred approximately 2 weeks after the administration of the first dose of mRNA-1273 vaccine. Patient¦s medical history of consumer of large volume of supplements and herbs, remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS	PFIZER\BIONTECH	6-17 years	1317129-1	HI, couple days after my son (17 years old) got the 2nd shot he was heaving a pressure in his chest and left arm so we rushed him to the hospital. When we got to the hospital with his level of 26 (normal 1) and blood test show also lever inflammation they hospitalized him right away. He was there 3 days and just got released. now he need to be under care with medication and visit to a heart cardiology doctor every few days for tests. he cannot do any activity (per to the doctor including computer games that can raise his heart rate)
HEPATITIS	PFIZER\BIONTECH	6-17 years	1322387-1	17-year old M with history of recurrent ear infections requiring PE tube placement who was in his usual state of health until 5/5 when he noticed a new itchy hive-like rash. He was short of breath 5/6, and developed fevers that night along with vomiting. He was seen 5/6 with negative COVID19 PCR and documented fever to 104. Fevers continued, and he was admitted the evening of 5/10 with concern for myocarditis. See below for hospital course. Additional information for Item 18: ...Screening labs were notable for mild lymphopenia, hyperbilirubinemia, hepatitis, and elevated inflammatory markers. Given prior COVID infection, rash, and systemic inflammation, additional studies including troponin, D-dimer, BNP, and EKG were obtained. EKG was reassuringly normal, however the D-dimer (2.48), troponin (1.27), and BNP (469) were elevated. Other work-up included chest x-ray which was unremarkable, and right upper quadrant ultrasound with incidental cavernous hemangioma of the liver. He was started on milrinone (5/11-5/12) after initial TTE was concerning for severely diminished LV function. Follow-up TTE 12 hours later was normal (on milrinone), and remained so after milrinone was discontinued 5/12. Follow-up TTE after discontinuation remained normal. Cardiac MRI was completed 5/14, although read remains pending. He received IVIG on 5/11, and was started on methylpred 50 mg IV BID, Anakinra 100 mg SQ BID 5/14, and transitioned to prednisone 30 mg PO BID with clinical improvement, down-trending troponin and systemic inflammatory labs. Subsequent CBCs have been notable for rising leukocytosis (5/16 WBC 56.3) and thrombocytosis (5/16 plts 690) and 4+ spherocytes (with no known personal or prior history of spherocytosis). He will likely be discharged 5/17. Infectious evaluation was unrevealing including cultures and viral studies. COVID spike and nucleocapsid antibodies were sent, but remain pending. Pt. initial COVID-19 infection was diagnosed October 2020, with positive saliva PCR testing. He was symptomatic for 3-5 days. He received his second dose of the Pfizer COVID19 vaccine 4/27 in his left arm; denies any significant reactions (arm swelling, injection site redness, lymphadenopathy, myalgias, fatigue, or fever). He has had passing contact with school classmates who have recently been diagnosed with COVID19.
HEPATITIS	PFIZER\BIONTECH	6-17 years	1443111-1	Fever, vomiting, rash, hepatitis with direct hyperbilirubinemia, acute kidney injury (resolving) Amoxicillin for strep throat, IVIG for possible Kawasaki disease,
HEPATITIS	PFIZER\BIONTECH	6-17 years	1641693-1	Hives, nausea, rash 1 day after vaccine. Mild transaminitis and rechecked 8/12/21 and increasing LFTs as below. hepatitis. Seen at ED and LFTs increasing so transferred to Hospital and admitted. LFTs improved and patient able to be discharged home. COVID antibodies IgG were checked given recent COVID + infection on July 1, 2021 and IgG was positive.
HEPATITIS	PFIZER\BIONTECH	6-17 years	1674923-1	Patient presented to ER from PCP on 09/03/2021 with complaints of left lower neck mass that started on 09/01/2021. Parents reported patient received first dose of Pfizer Covid Vaccination on 08/25/2021. Patient had CBC, BMP, Hepatic, TSH, mononucleosis screen, strep group A, and Covid-19 test. Patient given 0.9% NS 500ml, Decadron IV and Ativan IV. Mono test negative, Strep negative, Covid negative. CT soft tissue neck W contrast completed with impression of palpable lesion appears represent a large thyroid cyst.
HEPATITIS	PFIZER\BIONTECH	6-17 years	1766451-1	Patient received Covid 19 vaccinations on 6/23/2021 and on 7/14/2021 without immediate complications. He developed fevers on 8/23 and was diagnosed with multifocal pneumonia, severe anemia, and hepatitis with elevated AST/ALT and INR on 8/30. Subsequent work-op including imaging with PET-CT , bone marrow biopsy, and liver biopsy revealed severe autoimmune hepatitis based on massive lymphoplasmocytic hepatic infiltration by histology, elevated serum IgG and ANA. He was treated with prednisone and rituximab. His condition is currently improving, The degree of liver infiltration with lymphocytes and severity of hepatosplenomegaly is atypical what I usually see in new diagnosis of autoimmune hepatitis.
HEPATITIS	PFIZER\BIONTECH	18-29 years	1111673-1	I had chills, body aches; headaches; I felt feverish but I don' t know if I had a fever. Body aches were really intense - I didn't sleep the whole night. I had swelling a little on my arm - at injection site. My arm was sore. In general, my body was really sore and I couldn't get up from bed for 24 hours. I still had a bit of a headache and chills after the 24 hours so I stayed home from work 48 hours. I have been seen by a doctor -after the second vaccine, I had a flare up with my rash on my face (had been experiencing a rash on face prior to vaccine but this was a flare). My face flare up was that I broke out in a rash after finishing doxycycline. Didn't put me on another antibiotic because they wanted to wait and see with the rash - and the tests. Flare up - I couldn't eat; painful to wear a mask to work; couldn't sleep on my face. I was put on doxycycline again - on March 10th or 11th again because I couldn't handle the pain anymore. And it is getting refilled for another round. I have had to take a leave a absence from work the last two weeks.
HEPATITIS	PFIZER\BIONTECH	18-29 years	1632208-1	Severe hypothyroidism TSH of 69.8, recurrence of Epstein barr, severe multi system inflammation including kidney, liver, heart and thyroid as well as hands as evidenced by extreme labwork changes. Previously within that year all labwork was completely normal. No menstrual cycle for 4 months Extreme cold sensitivity Hair loss Jaundice scalera Extreme fatigue Joint pain Muscle pain and weakness ?Brain fog? Symptoms persisted 4 months plus and still have not completely resolved even with medication

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS	PFIZER\BIONTECH	18-29 years	1700216-1	Patient has experienced papular, pruritic rash on arms, knees, neck, face repeatedly since second dose of pfizer covid vaccine. Will intermittently experience symptoms of anaphylaxis which resolves with antihistamines and does not require epi.
HEPATITIS	PFIZER\BIONTECH	18-29 years	2206644-1	AFTER I GOT THE VACCINE, On august 04 i started having a pain on my right foot, it was a deep pain that don?t let me walk for about 3 weeks, i went to the foot doctor and they just got a bursitis after i got a MRI. i got steroid on pill and local injection for the pain on my superior side of the foot, but i was able to walk after 4 weeks but the pain started coming up on my leg and my back. i started PT on September 18 for about 6 weeks, the pain didn?t go away, i was not able to drive, but to more but don?t walk for 1 minute. I went to the Neurologists doctor, she did an EMG Test, they found my nerve inflamed, and a possibility of a back problem, started taking gabapentin for a month, didn?t work, then got a MRI and found a budged disc on my L4, L5. continued taking medication, then started seeing a Pain management, who put a steroid injection on November 20. GOT WORST the 1st 2 weeks, then I feel better. but on December 22 I got covid again, and 2 week after covid I got the same pain on my left foot and leg, was not able to walk for 2 days, took pregabalin that my doctor prescribe in case of any pain, and got better after 3 days, after that I have been not able to walk for more than 30 minute at the gym, I cannot dance for more than 5 minutes, and I cant driver more than 25 minute either, if I do something like this for more than that time , I started having pain on my nerves. I also had a stomach ultrasound and pelvis, they found inflation con my liver and found cysts on the ovaries that on 2020 when I got a pelvis ultrasound didn?t have. I also have more pain n my period every month and my immune system is weak I didn?t have any of those problem with my nerve or back before or inflammations, all of this came after vaccine since I got covid on 2020 and didn?t have any of this.
HEPATITIS	PFIZER\BIONTECH	30-39 years	1272531-1	Liver pain and inflammation, Stomach Cramps, chills since two hours after vaccination.
HEPATITIS	PFIZER\BIONTECH	30-39 years	1390908-1	Liver pain and inflammation; Liver pain; Stomach Cramps; chills; This is a spontaneous report from a contactable consumer, the patient. A 33-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot ER8736, second dose) solution for injection intramuscular in the right arm on 28Apr2021 at 15:00 (at the age of 33-years-old) as a single dose for COVID-19 vaccination. There was no medical history. There were no concomitant medications. There was no past drug history. Historical vaccine included BNT162B2 (first dose, lot ER8729) for COVID-19 vaccination on 07Apr2021 with no adverse effect reported. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. On 28Apr2021 at 18:00, the patient experienced liver pain and inflammation, stomach cramps, chills. There was no treatment for the events. The outcome of the events liver pain and inflammation, stomach cramps, chills was not recovered. The patient was not tested for COVID post vaccination.

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS	PFIZER\BIONTECH	30-39 years	1482928-1	"This patient was hospitalized on 03Jun2021 with jaundice and hepatitis.; This is a spontaneous report from a Pfizer sponsored program. A female patient of an unspecified age received BNT162B2 (Pfizer-BioNTech Covid-19 Vaccine, Formulation:Solution for injection,Batch/Lot number was not reported), via an unspecified route of administration on 07May2021 as DOSE 2, SINGLE for covid-19 immunization. The patient past Medical history included depression, anxiety and insomnia from 2017 and ongoing. The patient has been taking medication for this condition since at least 2017. Concomitant medication included Lurasidone Hydrochloride (LATUDA) taken for depression, anxiety from 2017, Trazodone taken for sleep disorder from 2017 and ongoing; vilazodone hydrochloride (VIIBRYD) taken for an unspecified indication from 2017 and ongoing. The patient experienced jaundice and hepatitis and was hospitalized on 03Jun2021 and his liver biopsy was done and reviewed by another physician who determined the patient's symptoms were related to a drug reaction. Caller is asking if Pfizer has any information on this adverse event being possibly related to the Pfizer BioNTech Covid-19 vaccine. Caller asking that his request be escalated to the drug experts. Response: section 18.1. LAB-1457-9.0. Revised: 19May2021. ""Participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, were included as were participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV). Informed caller that my colleagues and I were unable to find any further information regarding this adverse event in relation to the Pfizer BioNTech Covid-19 vaccine. Offered to escalate to second line. Caller states that the patient was hospitalized with jaundice and hepatitis. States the patient had a liver biopsy, which was sent to (address withheld) for a second opinion. Their findings showed a drug reaction. When probed about causality the caller stated that the only other possibility for the drug reaction that the liver biopsy showed is the amoxicillin. He states that however, that medication was stopped 2 months prior to onset of symptoms. He states there is a closer time frame between the vaccine and her symptoms. He feels that it is more likely that this was caused by a reaction to the vaccine than a reaction related to the amoxicillin. Caller states that this is all a bit confusing that she has hepatitis without the associated antibodies. States he would like more information on the Covid Vaccine and Hepatitis and other autoimmune issues. The patient lab tests included Liver biopsy: Result: Abnormal and liver function test: abnormal: on Jun2021. The patient was discharged from the hospital on 23Jun2021. The event outcome was Unknown for Liver biopsy and Not recovered for rest of the events. Communication: The caller was provided with company phone number of #, option 3, and hours of operation, prior to attempted warm transfer. Caller provided with report reference: #. Information on lot/batch number has been requested; Sender's Comments: The event of Hepatitis is assessed as possibly related to the suspect product BNT162B2 based on strong temporal association, but consider also possible contributory effects from concomitant medications of Trazadone which is known to cause Hepatitis in rare instances. 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."
HEPATITIS	PFIZER\BIONTECH	30-39 years	1500909-1	On 7/2/2021, the patient presented to clinic in the system with complaints of jaundice. Symptoms had been present for several days prior to this. She was found to have acute liver failure (AST 933, ALT 816, Bilirubin 12.8, Albumin 3.0) and was hospitalized at hospital. She had a liver biopsy on 7/6 which was consistent with severe acute hepatitis with hepatocyte loss (see more below). She was treated with steroids and discharged home. She was readmitted to Hospital on 7/21 after a syncopal event and with continued worsening liver failure. She was transferred to the medical center on 7/23 for evaluation by transplant hepatology.
HEPATITIS	PFIZER\BIONTECH	30-39 years	2095876-1	Received vaccine 1/27, developed fevers that night. She continued to have fever, also had chills, headache, body aches. Developed abdominal distension. Presented to ED on 1/31/2022. Found to have fever, tachycardia, tachypnea, leukocytosis, elevated lactate and abnormal LFTs. She was admitted to the ICU, started on antibiotics for presumed sepsis. Initial suspicion of cholecystitis, went for cholecystectomy and no cholecystitis but liver was inflamed, had biopsy. Subsequently, developed acute hypoxic respiratory failure with CT showing new pulmonary infiltrates. Bronchoscopy done and suggestive of diffuse alveolar hemorrhage, bronch studies pending but so far infectious work up negative. She also developed elevated troponin with normal echo. She developed anemia, required transfusion. She is currently intubated and remains in the ICU with ongoing fevers.
HEPATITIS	PFIZER\BIONTECH	30-39 years	2245899-1	I got a very bad cold at the end of February and I treated the cold over the counter for two weeks. I went to the Doctor on 03/01/22 and was diagnosed with a sinus infection and was prescribed amoxicillin for 10 days which I took. The following day the amoxicillin started giving me stomach issues and I went to a different doctor on 03/15/22 and was told to take over the counter medications and probiotics. Between 03/15/22 and 03/20/22 the stomach pain became worse. I went to the ER twice and was diagnosed with C-diff. I was then prescribed antibiotics for 7 days and I finished that antibiotic and have been finished for a month and I'm still having gastrointestinal issues and fatigue. I went to the ER and had both labs and CT.

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS	PFIZER\BIONTECH	40-49 years	1110045-1	Second Pfizer COVID vaccine given 2/12/2021. Developed symptoms one day after 2nd Pfizer vaccination with headache, body aches, chills, followed by abdominal pain, vomiting and diarrhea over the next 3 days, then became confused per wife so he came to ED for evaluation on 3/16/2021 and evaluated by me. Also had black stools and vomiting blood. Diagnoses: Septic shock, Gastrointestinal Bleeding with severe blood loss, Hepatitis with Hepatic Encephalopathy, Liver cirrhosis. Admitted to hospital 2/16/2021-discharged 2/21/2021. Since symptoms developed day after vaccination, I am compelled to report.
HEPATITIS	PFIZER\BIONTECH	40-49 years	1201709-1	I started having left abdominal pain under my ribs (spleen and liver) on the afternoon of Friday, April 2 that lasted though Sunday, April 11. I went to the ER at 1am on Sunday, April 4 because the pain would not improve and kept me awake. I was admitted to the hospital for two days with a host of CT scans, blood work, Xray and ultrasounds for a diagnosis of splenic infarction and inflammation of the liver which I have never had before. No other clots were found, just evidence of spleenic infarction and inflammation of the spleen. Labor shows evidence of the diagnosis and I have now been put on low dose aspirin 81 for blood clot concerns and preventative by the advise of Hemotologist.
HEPATITIS	PFIZER\BIONTECH	40-49 years	1268287-1	Swelling of the left arm 3 days after vaccine. Blood work done on 3rd day at an urgent care. Blood work showed Rhabdo (elevated CK levels) and inflammation in the liver. Hospitalized for 2 nights with an IV drip. Numbers slowly decreased.
HEPATITIS	PFIZER\BIONTECH	40-49 years	1768364-1	Hepatitis, jaundice over 2 weeks
HEPATITIS	PFIZER\BIONTECH	50-59 years	1658590-1	"Developed Hepatitis (NOT A,B,C). Found on 7/24/21 by chemistry blood test. Only symptom was ""dark urine"". Resolved (chemically) 1 month later"
HEPATITIS	PFIZER\BIONTECH	50-59 years	1900013-1	Radiating heat from chest to stomach. Extreme swelling of feet and legs. Skin broken open and peeling. Feet go from hot to cold. Blood work done 3 times at physicians office and once at the ER. Recommended Podiatrist. She recommended to see a Nuerologist. Referral was done and was scheduled for December 2. Now we are told she doesn't have an appointment there. A different referral was given to another Nuerologist but she can't be seen until December 14. Meanwhile no Dr at the ER nor at her primary care office will give any reason why she is having continued problems. They did say the blood work showed Liver inflamation but basically gave no reason why. ER said low in Potassium. Extremely painful to walk. She was given hormone therapy and muscle relaxor. Also Gabapatenin. Nothing given to help with pain.
HEPATITIS	PFIZER\BIONTECH	50-59 years	1902280-1	After getting my blood results from my physical exam Doctor notified me of a mild liver inflammation. I don't drink, I exercise regularly, and I eat a healthy diet, and being healthy my whole entire life until I got the Covid vaccine>
HEPATITIS	PFIZER\BIONTECH	50-59 years	2085110-1	I had a reaction 4-5 mins after vaccine. I experienced blurred vision, headache and felt light headed. I stayed 1/2 hour after and then went home thought symptoms would go away. Then two days later had heart palpitations, high anxiety. I told my spouse need to go to the hospital. My symptoms continued having stabbing chest pains, high anxiety (described as shaking), aching pain. I have followed up with Cardiologist, Phycologist. I'm having liver and gallbladder pain, depression nothing ever have no symptoms before. My left breast under my armpit seen my Urologist had couple mammograms. Due to loss of appetite for 3-4 months lost 55 pounds and missed work for 3-4 months. This has been hard for me to do my daily functions had to get short term disability.
HEPATITIS	PFIZER\BIONTECH	50-59 years	2202636-1	Immediately after receiving my third dose of the Pfizer Covid vaccine I began to have pain in my right side under my ribs. The sensation was pressure under my ribs over the next few weeks. I made an appointment during the holidays to see my primary care provider and was able to make an appointment in January. However the pressure became worse and spread to my entire mid abdomen and was shooting in nature. I went to the ER and was diagnosed with hepatitis with no changes in my labs. I followed up with my physician and he diagnosed me with NASH and I continue to have daily pain even after losing 20 pounds. My labs continue to remain unchanged. My doctor suggested that I report my NASH diagnosis to the government so that they can track the incidence of hepatitis occuring after the third booster shots.

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS	**PFIZER\BIONTECH**	**60-64 years**	1133488-1	minimal chronic portal inflammation (lymphs, rare eos, some neutrophils, no plasma cells seen); extensive cholestasis; symptoms of mild decrease appetite; some fatigue; This is a spontaneous report from a contactable Physician. A 61-Year-Old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) on 19Jan2021 at single dose via an unspecified route of administration for COVID-19 immunization. Relevant medical history included hemiparesis, hypertension, hyperlipidemia, recurrent UTI. Concomitant medications included AMLODIPINE BESILATE, calcium carbonate, colecalciferol (CALCIUM + VITAMIN D [CALCIUM CARBONATE;COLECALCIFEROL]) for UTI, cefalexin KEFLEX [CEFALEXIN] and nitrofurantoin for UTI. The patient received first dose of BNT162B2 on 29Dec2020. On 02Feb2021 the patient experienced minimal chronic portal inflammation, symptoms of mild decrease appetite, some fatigue and extensive cholestasis. Serologic workup was notable only for ASMA 1:160, including extensive viral and immune workup Liver performed on 24Feb2021: extensive cholestasis, normal reticulin and trichrome stains, minimal chronic portal inflammation; no lobular or interface activity. The patient underwent Sars Cov2 test on 22Feb2021 which resulted negative. At the time of the reporting the patient was recovering from the events.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events of Hepatitis, cholestasis and other events due to temporal relationship . Additional information is needed to better assess the case, including complete medical history, diagnostics including liver function tests/hepatic enzymes prior to subject drug therapy and during subject drug therapy, abdominal ultrasound, CT/MRI of abdomen, viral hepatitis serology, serum bilirubin, serum alkaline phosphatase, counteractive treatment measures and concomitant medications. There is limited information provided in this report. This case will be reassessed upon receipt of follow-up information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
HEPATITIS	**PFIZER\BIONTECH**	**60-64 years**	1574270-1	Pt. states that after receiving the 1st dose of Phizer 06/18/2021, started experiencing symptoms 08/21/2021 of HBP, Liver inflammation, severe headaches, and heart palpations. Still continuing, Primary visits (estimated) every 2 weeks.
HEPATITIS	**PFIZER\BIONTECH**	**60-64 years**	1628628-1	On 07/18/2021 abdominal pain and nausea. I went to the ER at midnight on 07/18/2021. As a result of the test: suspicious spot on the kidney, very inflamed gallbladder, suspicious mass on the liver, suspicious mass in the sigmoid colon. I was admitted to the hospital for further test. My white count was elevated. I was admitted to the hospital for 4 days for pain control, IV control and anti nausea medications, IV fluids and antibiotics. On day 3 or 4, I ended up having many more tests, I had another cat scan, 2 ultrasounds, an MRI, a colonoscopy. Every day everything got better and cleared up, and they found out it was not cancerous. They found a spot on my kidney that was the size of a pea, they will continue to observe. The doctors were looking at my liver and colon, and the kidney, and they said everything originally looked suspicious because everything was so inflamed that it caused it to look like it did on the cat scan. They diagnosed me with diverticulitis. I had 3 different types of antibiotics on IV. My liver enzymes were skyrocketed and they took me off the Zosyn. They took me off my simvastatin. They are monitoring my liver enzymes.

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS	PFIZER\BIONTECH	60-64 years	1648625-1	"I had flare up; my pinky is swollen; lot of discomfort in my wrist, in my hand; I had flare up; my pinky is swollen; lot of discomfort in my wrist, in my hand; Pain in my fingers and in my wrist; Pain in my fingers and in my wrist; It is really hard to be typing specially with my pinky; It is very stiff and swollen; Joint pain; Low white blood cells/White blood cells was I don't know it is like 3.5 may be, it was 2 something went up to 3; Low platelets; This a spontaneous report from a contactable consumer (patient). A 63-years-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/Lot Number: EM9809), dose 1 via an unspecified route of administration on 12Feb2021 as (At the age of 63-years) single dose for COVID-19 immunisation. Medical history included ventricular extrasystoles from an unknown date and unknown if ongoing. Concomitant medication included sultopride (TOPRAL [SULTOPRIDE]); simvastatin (ZOCOR); escitalopram oxalate (LEXAPRO); tolterodine l-tartrate (DETROL); vitamin d nos; omeprazole, and calcium all wares taken for an unspecified indication, start and stop date were not reported. It was reported that on 12Feb patient received his first vaccination it was a Pfizer Vaccination Priors to that she had bloodwork done with his general practitioner which has a result came back that she had low white blood cells and low platelets. So, she had referred to a hematologist. Now she got his COVID shot prior to going to hematologist and after she had his Covid shot the vaccination part, she had flare up and she had on his fingers are very, well one his pinky was swollen. So truly get stuck she guess not sure, but she means lot of discomfort in his wrist, in my hand. Right now, she had pain in his hand with his wrist. she takes Tylenol and Tylenol help with the pain. This is going on for a while. It was reported that reporter question is she haven't seen his, hematologist on Wednesday and she scheduled for his second shot on Friday. So, the flare up she don't know if this is because of the shot or because of she was having white blood cells. She only had one shot on 12Feb. she scheduled for my second shot on 05Mar, Friday. Reporter asking question is the flare up she don't, know if other people have experienced that she was with flare ups, having pain in his fingers and in his wrist. So, she doesn't know if it is due to the Covid vaccination or what she was dealing with. She had test is still she don't have rheumatoid arthritis. She doesn't have lupus and other. Should she not take second vaccination. It was reported that Treatment: Consumer stated, ""Just Tylenol that's it. She has a heating pad on right now. she used like bandage or icing hot some type of ointment to help with these."" It was reported that she was teacher, and it is really, teaching from home and it is really hard to be typing specially with his pinky you know it is not easy to typing it right now. It is very stiff and swollen. It was reported that she had his shot on 12Feb so 17Feb she had blood work done. she don't know the name but she can tell you for what they are looking for. They were looking for rheumatoid arthritis, they were looking for lupus, they were looking for hepatitis, they were looking for HIV and they also did to know blood levels. Lab Results: Consumer stated, ""Yeah they all are negative. Well Hepatitis is negative, HIV is negative, and Rheumatoid arthritis is negative. Result for the White blood cells was she don't know it is like 3.5 may be, it was 2 something went up to 3 she doesn't know. Also, the platelets where I don't know."" Upon Follow-up The caller said that she received the 1st dose on 12Feb2021. She's experiencing joint pain and swollen pinky finger on the left hand. Blood work (WBC and Platelet count) has been done 5 days after the 1st dose. The patient underwent lab tests and procedures which included hepatitis: negative, hiv test: negative, platelet count: low, platelet count: unknown result, rheumatoid arthritis: negative all ware performed on 17Feb2021, white blood cell count: low, and white blood cell count: 3.5 may be, it was 2 something went up to 3 was performed on 17Feb2021. The outcome of events joint pain, low white blood cells/white blood cells was i don't know it is like 3.5 may be, it was 2 something went up to 3, and low platelets was unknown, and outcome of all other events was not recovered. No follow-up attempts are possible. No further information is expected."

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS	PFIZER\BIONTECH	60-64 years	2141995-1	SUSPECTED CLINICAL VACCINATION FAILURE; SUSPECTED COVID-19 INFECTION; LIVER INFLAMMATION; SEVERE LOSS OF APPETITE; WEIGHT LOSS OF AROUND 18 LBS; MODERATE NAUSEA; This spontaneous report received from a patient and concerned a 64 year old male of unspecified ethnicity. The patient's weight was 86.18 kilograms, and height was 183 centimeters. The patient's concurrent conditions included: cancer and immunocompromised. The patient received covid-19 vaccine ad26.cov2.s (dose number in series 1) (suspension for injection, route of admin not reported, batch number: 1805022 expiry: 25-MAY-2021) dose was not reported, 1 total administered on 06-MAR-2021 at left arm for prophylactic vaccination. The patient additionally received non-company suspect vaccine BNT 162 (dose number in series 2) (batch number: FH8027 expiry: unknown, form of admin, route of admin, and were not reported) dose was not reported, administered on 18-NOV-2021 at left arm for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, the patient developed covid virus (suspected clinical vaccination failure, suspected covid-19 infection) (dose number in series 1) with associated symptoms. On 10-JAN-2022, the patient was treated with Paxlovid tablet (2 different tablets) for covid virus to minimize result of covid and his associated symptoms with the medication. Around 25-JAN-2022, the patient experienced severe loss of appetite, weight loss of around 18 lbs, and moderate nausea (dose number in series 2). On an unspecified date, the patient experienced slightly jaundiced. On 08-FEB-2022, the patient experienced liver inflammation (dose number in series 2). The loss of appetite had improved slightly at a very slow rate. He did have an oncology appointment and they did blood work. He was called 3 days ago with results and they said he did have liver inflammation. He had no problem with the vaccines. Moderate nausea improved significantly, but the rate of improvement was very slow. He first noticed being slightly jaundiced 2 weeks ago. He did not have an exact date. His oncologist had scheduled for more labs in a week and a half. He also reported that associated with lack of appetite was weight loss of around 18 lbs., which had then stabilized. The action taken with covid-19 vaccine ad26.cov2.s, and bnt 162 was not applicable. The patient recovered from suspected covid-19 infection, was recovering from severe loss of appetite, moderate nausea, and weight loss of around 18 lbs, and the outcome of suspected clinical vaccination failure and liver inflammation was not reported. This report was serious (Other Medically Important Condition). This report was associated with a product quality complaint: 90000218644.; Sender's Comments: V0: 20220242568-covid-19 vaccine ad26.cov2.s- liver inflammation. 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). Therefore, this event(s) is considered unassessable. 20220242568- covid-19 vaccine ad26.cov2.s-Suspected Clinical Vaccination failure. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: SPECIAL SITUATIONS. Therefore, this event(s) is considered not related.
HEPATITIS	PFIZER\BIONTECH	65-79 years	1010793-1	husband is breaking out in cold chills, and his bones are still sore.; inflamed liver; arm is still sore; Nauseated; has no energy; sick; no appetite; he is sweating; he is tired.; husband is breaking out in cold chills, and his bones are still sore.; This is a spontaneous report from a contactable consumer. This consumer reported for a 72-year-old male patient (husband) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EL3247), via an unspecified route of administration on 19Jan2021 08:00 at single dose on left arm for COVID-19 prevention. The medical history and concomitant medications were not reported. The patient got the shot on 19Jan2021. Since Jan2021, his arm was still sore, but he had been nauseated since then. He has no energy. He has had it almost four days. He was fine until he got it and his arm is sore and he is nauseated. He is usually on the go. The patient also has an inflamed liver. He has been sick since. The patient has no appetite, he is sweating, his bones are hurting, and he is tired. The consumer took her husband to his doctor, and they tested him for COVID, and it came back negative, but the consumer does not think the PA did the test right. The consumer doesn't know what to do with him, because he is still tired, and has no appetite. The patient is breaking out in cold chills, and his bones are still sore. When the patient got the vaccine, he was walking and talking, and by 11 AM that day, he was in bed. The patient had some labs done, and was being told that his liver is big, so the consumer did not know if the vaccine went to his liver. The outcome of the events was unknown.

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS	PFIZER\BIONTECH	65-79 years	1254062-1	liver inflamed and enlarged; liver inflamed and enlarged; Night sweats; Liver enzymes elevated; dizziness; weakness; fever highest 101.9; headache; nausea; body aches; chills; Abdominal tenderness; This is a spontaneous report from a non-contactable consumer (patient). A 67-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 03Feb2021 at 12:30 (at the age of 67 years) at a single dose in the left arm for COVID-19 immunization. Medical history included cystic fibrosis. Concomitant medications included elexacaftor, ivacaftor, tezacaftor (TRIKAFTA); bupropion hydrochloride (WELLBUTRIN); piroxicam (PAXIL [PIROXICAM]); omeprazole (PROTONIX [OMEPRAZOLE]); montelukast sodium (SINGULAIR); albuterol [salbutamol] (ALBUTEROL [SALBUTAMOL]); pancreatin (CREON); betaine hydrochloride, bromelains, cellulase, pancreatin, papain (DIGESTIVE ENZYMES). On 04Feb2021 at 13:00, the patient experienced headache, nausea, body aches, and chills. On 05Feb2021, the patient had a fever highest 101.9. On 06Feb2021, patient experienced dizziness, and weakness. On 08Feb2021, night sweats and liver enzymes elevated were noted, the patient kept getting worse. On 11Feb2021, the patient had liver inflamed and enlarged. It was also reported that abdominal tenderness was noted on an unspecified date in Feb2021. The events resulted in doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. The patient was also referred to a GI specialist. No treatment was given. The patient underwent lab tests and procedures which included body temperature: 101.9 on 05Feb2021; flu (influenza virus test) and nasal swab: both negative on 08Feb2021; blood work: unknown results and liver enzymes test: elevated both on 10Feb2021; chest x-ray: unknown results, CT scan: liver inflamed and enlarged, and liver enzymes test: unknown results on 11Feb2021; and nasal swab: negative on 18Feb2021. The outcome of the events was not recovered. Information about lot/batch number has been requested.
HEPATITIS	PFIZER\BIONTECH	65-79 years	1293724-1	Confusion, Myalgia, Fever, Diarrhea, Nausea Vomiting, ElevatedLiverEnzymes, Jaundice, ElevatedBunSCr, , Continues to feel weak and following up with PCP. Reports had no health issues prior to her second vaccine dose. She reports had fever, joint pain and nausea with first dose. Patient reports receiving her first COVID vaccine 12-23-20 and developed nausea, joint pain and fever. She had her second dose on 01-11-21 and noted nausea,vomiting, weakness, become jaundiced and fevers that required hospitalization and developed autoimmune problems. She reports hepatitis and kidney problems and PCP following.

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
				Hospitalized (9.25.21 - present; now in ICU intubated); COVID-19 positive (9.16.21); Fully Vaccinated HPI from admission: HISTORY OF PRESENT ILLNESS: Patient is a 66 y.o. male who presents today with SOB. He has a known history of coronary artery disease, hypertension, hyperlipidemia, atrial fibrillation on Xarelto. He is fully vaccinated against COVID-19. He presents the emergency department complaining of shortness breath that started 12 days ago. He eventually got tested + for COVID-19 09/16/2021. He has been monitoring his oxygen level at home when it was noted that he has been dropping below 80s. He then proceeded to be evaluated emergency department. He has been having generalized weakness and fatigue with mild cough. He denies chest pain nor hemoptysis. He has had intermittent fevers. He reports diarrhea, no abdominal pain. He states he initially lost his sense of taste and smell but slowly regaining it back. On admission his blood pressure is 153/79 heart rate 89 respiratory rate 25 94% NRB Chest x-ray showing bibasilar airspace opacities likely due to pneumonia. ASSESSMENT / PLAN: Acute respiratory failure COVID 19 pneumonia Received Pfizer COVID 19 vaccine 5/2021 Symptom onset 9/14/21 Positive test 09/16/2021 Chest x-ray showing bilateral airspace opacities Decadron 6 mg daily Out of the window for remdesivir Monitor CRP D-dimer Check procalcitonin Elevated procalcitonin at 0.27 Blood culture and sputum cultures Rocephin and azithromycin x5 days Progress note from 10.6.21: (intubated in ICU; declining status) ASSESSMENT / PLAN: 66 y.o. vaccinated patient with morbid obesity (BMI 34), aflutter on Xarelto, CAD (STEMI 12/4/2008 s/p D1 DES), HTN, hyperlipidemia, GERD presented with COVID-19 pneumonia on 9/25. AKI improving. Mild hepatitis. Symptom onset 9/14, positive test 9/16. Prior to this had newly identified well differentiated neuroendocrine tumors in his duodenum and was planning to undergo surgical resection 10/14/21. Otherwise does not appear to be immunosuppressed. Transferred to ICU 10/1 with progressive hypoxia as cc2; supported w/ HHFNC and prn NRBM. Assessment and Plan Acute respiratory failure with hypoxia Assessment & Plan Due to COVID-19 Pneumonia 9/26: On 100% HFNC and NRB 10/2: Intubated FIO2 (%): 60 % Type of Mechanical Vent: Avea Mechanical Rate: 34 breaths/min Set/Target Tidal Volume: 510 PEEP (cm H2O): 14 cm H2O Plan: - Lung protective ventilation - adjust Vt/Peep for pplat < 30 and driving pressure < 15 as able - daily assessment for prone position 16/8 for p/f < 150 (until p/f > 150 on Peep 10 or less and fio2 60% or less) Serial ABG - collect sputum culture - continue steroids * Pneumonia due to COVID-19 virus Overview Vaccinated: Pfizer 4/5/21, 5/3/21 Symptom onset 9/14 Positive test 9/16 Admission 9/25 Intubated 10/2 Treatment: Remdesivir: out of window Tocilizumab: none due to shortage Steroids: Dexamethasone 9/25 - 9/26 Methylprednisolone 60 mg iv q 12 9/26 - Assessment & Plan Patient has confirmedSARS-CoV-2/COVID-19 infection Vaccinated Isolation: Severe respiratory isolation Risk stratification (High if 1 from each or >1 clinical criteria): History - Age >/= 60 years old, History of cardiovascular disease, Diabetes (A1C >/= 7.6), BMI >/= 30 Labs: - Daily labs qAM: CMP, CBC with diff, - Every other day: CRP, ferritin, Fibrinogen, LDH, D-dimer, triglycerides. Therapy: - Dexamethasone 6mg daily transitioned to methylprednisolone - Unable to provide remdesivir or tocilizumab Respiratory failure and hemodynamics: Lung protective ventilation with 4-6 ml/kg and appropriate PEEP escalation. Initiate neuromuscular blockade and proning as appropriate. Concern for arrhythmia/hemodynamic worsening. Consider EKG and bedside cardiac US, evaluate for need for TTE. Pneumomediastinum Assessment & Plan - extensive, related to COVID-19, ARDS Plan: - okay to continue to monitor as there is no evidence of pneumothorax - monitor for changes in peak and plateau airway pressures. Shock Assessment & Plan - unclear etiology: Cardiogenic versus hemorrhagic versus adrenal insufficiency. - echocardiogram with no valvular dysfunction and normal LVEF. - troponins unremarkable Plan: - resolved at this time - continue antibiotics - stress dose steroids not continued
HEPATITIS	**PFIZER\BIONTECH**	**65-79 years**	1765265-1	

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS	**PFIZER\BIONTECH**	**65-79 years**	1790814-1	"they said he has myocarditis; his lungs seem to hurt; now he sometimes gets dizzy and he has to watch how he stands up; his heart rate was up/Heart rate would go from 180 to 50-60; Chest pain; tightness below his breast bone on both sides like a gorilla giving a bear hug; it was harder to breathe; States his sugar was 99.; This is a spontaneous report from a contactable consumer or other non hcp. A 65-years-old male patient received bnt162b2 (BNT162B2, Pfizer Biontech Covid-19 vaccine, Batch/Lot Number: EW0168), dose 1 via an unspecified route of administration, administered in Arm Right on 12May2021 at 14:00 as DOSE 1, SINGLE for covid-19 immunisation. Medical history included blood pressure abnormal from an unknown date and unknown if ongoing Since age 40 His blood pressure has been under control since he was 40 years old , tobacco user from an unknown date and unknown if ongoing Since age 15 he is a smoker and has smoked all his life since he was 15 years old but he exercises a whole lot , accident from an unknown date and unknown if ongoing he has an ab coaster that he did 1000 a day prior to this and an exercise bike that he does 1000 calories in 1 hour 45 minutes and then it was like he was hit by a train and he couldn't do anything and gets light headed , dizziness from an unknown date and unknown if ongoing. he has an ab coaster that he did 1000 a day prior to this and an exercise bike that he does 1000 calories in 1 hour 45 minutes and then it was like he was hit by a train and he couldn't do anything and gets light headed , gastrooesophageal reflux disease from an unknown date and unknown if ongoing. He was taking Colchicine 0.6mg 1 tablet by mouth twice a day for 14 days and something not related to any of that for his stomach because he kept getting acid reflux and something to pee better as he gets older , urinary incontinence from an unknown date and unknown if ongoing He was taking Colchicine 0.6mg 1 tablet by mouth twice a day for 14 days and something not related to any of that for his stomach because he kept getting acid reflux and something to pee better as he gets older. There were no concomitant medications. The patient previously took baby aspirin, metoprolol, losartan ""agp"", colchicine. The patient experienced myocarditis, harder to breathe his lungs seem to hurt, gets dizzy, sugar was 99 on an unspecified date and On 21 May2021 patient experienced chest pain, tightness below his breast bone on both sides, his heart rate was up/heart rate would go from 180 to 50-60. The patient was hospitalized for myocarditis, chest pain, tightness below his breast bone, harder to breathe, lungs seem to hurt from 23May2021 to 26May2021. The patient underwent lab tests and procedures which included acquired immunodeficiency syndrome: unknown results, blood choles-terol: unknown results, blood cholesterol: unknown results, blood glucose abnormal: 99, body mass index: 26.4, body temperature normal: 36.5 degrees celcius, cardiac monitoring: unknown results, hepatitis: unknown results, respiration abnormal: 16, sars-cov-2 test: didn''t have it, weight: 84.7 kg, weight: 84.7 kg , x-ray: unknown results on unknown date and , blood pressure measurement: 122/81 on 26May2021. Patient received treatment for myocarditis, chest pain, tightness below his breast bone on both sides while for other event treatment not received. The outcome of all events were unknown"
HEPATITIS	**PFIZER\BIONTECH**	**65-79 years**	1988648-1	2 weeks after receiving the first booster (3rd vaccine) patient started to experience fatigue, and was over tired. 3 weeks later the patient has hepatitis with transaminitis and cyanotic finger tips.
HEPATITIS	**PFIZER\BIONTECH**	**80+ years**	1656556-1	*** SEVERE NEUROLOGICAL IMPACT*** *** MASSIVE BRAIN INFLAMMATION*** *** DEATH *** 3/07/2021: Intractable stabbing pain in head at ears every 3-4 seconds. Pain level 10. 3/10/2021: Intractable stabbing pain in head at ears every 3-4 seconds. Pain level 10. ER visit Urgent Care ER Treatment: morphine IV ER Tests: CT brain w/o IV contrast; CTA carotid; Basic Metabolic Panel; CBC w platelet count Diagnosis: Neck muscle spasm Rx: tramadol (not helpful after morphine wore off) 3/12/2021: Intractable stabbing pain in head at ears every 3-4 seconds continues. Pain level 10. ER visit Urgent Care: ER Treatment: morphine pills - twice; Tylenol; Colace; Lidocaine ER Tests: XR 2 views; Basic Metabolic Panel; CBC w platelet count; Lactic acid, venous Diagnosis: Left ear pain; pneumonia due to infectious organism, unspecified laterality, unspecified part of lung Rx: amoxicillin-clavulanate; neomycin-polymyxin-hydrocortisone (did not fill these prescriptions) 3/14/2021: Intractable stabbing pain in head at ears every 3-4 seconds continues. Pain level 10. ER visit Hospital: admitted to hospital; treatment for 14 days; Discharge diagnosis: ACUTE METABOLIC ENCEPHALOPATHY and HEPATITIS 3/28/2021: Transferred to Hospice. 3/31/2021: Transferred to Home Hospice. 4/10/2021: Death occurred Death Certificate: PRESUMED MENINGITIS
HEPATITIS	**PFIZER\BIONTECH**	**Unknown**	1022069-1	he could barely eat breakfast, nausea, sleepy, sweating, lethargic, and after seeing his HCP his blood work says he has liver inflammation; He is unable to walk now without a walker; This is a spontaneous report from a non-contactable consumer (patient's wife). A 72 years old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Jan2021 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. Patient received vaccine on 19Jan2021. After he got home, he could barely eat breakfast, nausea, sleepy, sweating, lethargic on 19Jan2021 and after seeing his HCP his blood work says he had liver inflammation. He was unable to walk now without a walker in Jan2021. Outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS	PFIZER\BIONTECH	Unknown	1278995-1	infection in his liver; there was a spike in the blood work; This is a spontaneous report received from a contactable nurse and a consumer. A 57-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date as single dose for covid-19 immunisation; axitinib (INLYTA, Film-coated tablet, expiration date: 31Jul2023) orally from Feb2021 to an unspecified date at 5 mg cycle (two times a day on days 1-21 of every 21 day) for advanced renal cell carcinoma. Medical history included high blood pressure. No known drug allergies. Concomitant medications were not reported. The patient went to his chemo doctor and he's having an infection in his liver so right now they want him to stop it for now until he has an appointment. There was a spike in the blood work, but he did have his COVID shot. So, there's a possibility it's from that. Action taken in response to the events for axitinib was unknown. Outcome of the events was unknown. No follow-up attempts are needed. Information about lot/batch number cannot be obtained.; Sender's Comments: The patient had underlying advanced renal cell carcinoma, and was recently on treatment with axitinib (INLYTA). Based on information available, the reported liver infection with blood test abnormal were possibly due to co-suspect INLYTA, and unlikely causally related to the vaccine 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.
HEPATITIS	PFIZER\BIONTECH	Unknown	1425992-1	he developed a fever and fever lasted for 10 days/2 days after receiving the second dose, he developed a low grade fever; This is a spontaneous report from contactable consumer (Patient). A 78-years-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/Lot Number: EL9262), via an unspecified route of administration on 02Feb2021 as single dose for COVID-19 immunization. The patient previously received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/Lot Number: EH9899) via an unspecified route of administration on 12Jan2021 as 1st single dose for COVID-19 immunization. Medical history included hypertension. The patient's concomitant medications were not reported. On 22Jan2021, ten days later of first dose, he developed a fever and fever lasted for 10 days and on 03Feb2021, a day later receiving the second dose, he developed a low grade fever. Patient tested for COVID 5 times, did full bloodwork, chest x-ray, steph and flu test all tests were negative. On 01Feb2021, patient tested for hepatitis, urine analysis, CBC (full blood count) result was negative for all. The patient received treatment for the event was took Tylenol and Advil. The outcome of the event was not recovered. Follow-up attempts are completed. No further information is expected.

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS	PFIZER\BIONTECH	Unknown	1500651-1	"Kidneys and liver had an infection post vaccine.; Kidneys and liver had an infection post vaccine.; Exhaustion/drained; could not breathe; Had phlegm post second vaccine/ phlegm in her left lung; Blood clots in right lung/ almost died from those blood clots; Pneumonia; This is a spontaneous report received from a non-contactable consumer (patient's sister). A 35-year-old female patient received the 2nd dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on Apr2021 as single dose for Covid-19 immunization. Medical history was unknown. Concomitant medications were none. The patient previously received the 1st dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) on Apr2021 for Covid-19 immunization, experiencing pneumonia, blood clots in right lung, had blood clots on her right and left kidneys. The patient was hospitalized with pneumonia on Apr2021 after both doses of product. Blood clots in right lung. Stated no disclaimer. The patient asked if blood clots or pneumonia were reported adverse events. The patient experienced left lung blood clots, had phlegm post second vaccine. Kidneys and liver had an infection post vaccine. The patient was hospitalized for two weeks. ""She was healthy and vivacious and seemed very drained"". People were exhausted who took it for months before. The reporter asked what caused the exhaustion, if she had an allergic reaction, what chemical would cause those things. She almost died from taking this. The reporter said how come there was not a disclaimer, if it was a clinical trial for people to be experiments. The patient thought she was doing good and then was sent away to the hospital. The reporter talked to someone from CDC, she gave a vague description. Stated if acid, fats, salt and sugar. The reporter called FDA to get down to it, five basic ingredients, if Aluminum Salt was an ingredient. The patient was healthy for a while, then had blood clots in her right lung and phlegm in her left lung. She ""almost died"" from the blood clots in Apr2021. Right after she got the shot her sister immediately felt sick. She had pneumonia. She looked all over the internet for the Pfizer ingredients. She was asking what was in the vaccine. Her symptoms right after the shot were not fully developed, then it started getting worse and worse and worse and she thought it would dissipate. Stated something about really horrible side effects where she would wither away and it got worse and worse. Treatment: She was hospitalized for two weeks and then discharged to go home, they put her on oxygen because she could not breathe, she did not want to be on a respirator since she did not want this to be a prolonged thing. The patient was hospitalized from Apr2021 to 2021. The patient recovered from phlegm in her lung, her blood clots have to be monitored and had to check up to make sure they were gone. In regards to the pneumonia, reported she was still very weak. Her mother got an infection from a respirator with the tubes being in for long and the reporter did not want the patient to get an infection from a respirator. She got her second dose in the appropriate amount of time after the first dose, stated maybe it was two weeks, she did not know, whatever was the right amount of time after the first dose was when she got the second dose. The patient was young, healthy, and vivacious. Her health declined and she was still struggling. When she talked to her sister it sounded like she was barely breathing. She asked how come there was no disclaimer about this vaccine. She only heard about mild symptoms and the vaccine was forced on everyone to get it, she was not denying the pandemic. When this happened to the patient, she questioned what was in the vaccine. Reported a lot of people that had taken it were extremely exhausted even months after taking it. Outcome of the event had phlegm post second vaccine/ phlegm in her left lung was recovered, of the other events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained."

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS	**PFIZER\BIONTECH**	**Unknown**	1647184-1	"Inflammation of the liver; Elevated liver enzymes; nausea; trembling; vomiting; dizziness; weakness; elevated LFTs; electrolytes were off; muscles are wasting a little; This is a spontaneous report from a contactable Nurse. A male patient (friend) of an unspecified age (60 or 62-years-old, not specified) received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for Injection, Batch/Lot number and Expiry Date: Unknown) via an unspecified route of administration on an unspecified date as dose number unknown, single for COVID-19 immunization (5 or 6 months ago). Medical history and concomitant medications were not reported. Reporter reported that, the patient has ""been to the ER twice in the last month"" citing dates of 25Jul2021 and 05Aug2021. Reporter also stated that 'patient posted on 09May2021 that something was not right'. Reporter reported ""patient was fine, and now months after the vaccine, on an unspecified date patient got these symptoms which include nausea, trembling, vomiting, dizziness, weakness, elevated Liver Function Tests (LFTs) or Elevated liver enzymes and electrolytes were off"". At patient's second visit ""did a CT scan that showed atrophy in one leg, meaning the muscles were wasting a little but patient was walking fine"". Then LFTs were elevated a little which reporter blamed on the spike protein causing irritation, and said patient's electrolytes were off possibly due to the vomiting. Reporter stated LFTs could just be due to inflammation of the liver, but the patient did not drink any alcohol, and they did not look for Hepatitis B or Hepatitis C. At first ER visit, ""they said it was some diabetic something which it was not, patient did not take insulin, patient was not a diabetic"". At the second ER visit, ""they asked if patient had been in another state around the time of 11Sep then they said 'we think it was that syndrome' and were just labeling patient 'post-11Sep syndrome'. Reporter wanted to know if long-term post-vaccination complaints, liver enzymes would be elevated within a month after the vaccination and why patient had events and 'after seeing his legs' (not clear). The patient underwent lab tests and procedures which included computerised tomogram: showed atrophy in one leg, investigation: elevated liver enzymes, liver function test: elevated LFTs. The outcome of the events was unknown. As per report it was reported that, ""Reporter repeatedly told that, she was lying and listed the following reports from the internet: I know the spike protein, I know that's why people are having heart attacks because it irritates the lining of the heart and then it swells and there you go you have an issue. These young boys are sickened for life. Their hearts will never be well again. They're killing the military, too... and disabling them with your vaccine. There have been 500,000 deaths from this vaccine. Thousands have suffered. Post-menopausal women are bleeding again. VAERS has the reports of death on the website, then erases them."" Information about lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of BNT162B2 vaccine cannot be excluded for the reported events of ""Hepatitis"" due to temporal relationship and current known drug safety profile. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse 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"
HEPATITIS	**PFIZER\BIONTECH**	**Unknown**	1718309-1	had an US and CT, which showed a mildly enlarged/inflamed liver; had an US and CT, which showed a mildly enlarged/inflamed liver; discomfort; This is a spontaneous report from a contactable consumer (parent). A 17-years-old male patient received BNT162B2 (COMIRNATY, solution for injection), dose 2 via an unspecified route of administration on 04Apr2021 (Batch/Lot number was not reported) as DOSE 2, SINGLE for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient previously received BNT162B2 (COMIRNATY, solution for injection), dose 1, SINGLE on 14Mar2021 for covid-19 immunisation. On an unknown date in 2021, patient experienced discomfort, so had an ultrasound and CT, which showed a mildly enlarged/inflamed liver. Reporter said maybe there was a link. At the time of this report, the outcome of events was unknown. The lot number for BNT162b2 was not provided and will be requested during follow up.
HEPATITIS	**PFIZER\BIONTECH**	**Unknown**	1942346-1	Extreme tired and fever within 15 mins, fever on and off for 4 weeks and exhaustion. By week 5 fever woukd not go away. Got covid test, negative, still constant fever after 7 days but didnt feel like a had a cold or anything. Called 811 and they suggested i go to emergency at hosp in case i have an infection. Hosp confirmed i had fevee, gave me another covid test which was negative. Did urinalysis to see if i had unrinary infection, i did not. Sent home and if fever persists see family dr. After three more days i still had fever so made dr appt. The day i saw dr, my fever was starting to go away (constant fever lasted two weeks). Dr sent me for bloodwork. Bloidwork showed a had liver inflammation. A week after this lymohnodes on neck swelled. Went for more in depth bloodtest for various virus's, and auto immune tests, those were negative. Ct scan for my organs looked normal, ultrasound of lower organs looked normal. Finally after 5 mos i started to feel like i did before vaccine and bloodwork showed liver bloodwork normalling.

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS	PFIZER\BIONTECH	Unknown	2018540-1	"hepatocellular pattern of liver injury; Portal and lobular with interface hepatitis; new diagnosis of solitary hepatocellular carcinoma; This is a literature report. A 68 year-old male patient received bnt162b2 (BNT162B2) (Batch/Lot number: unknown) as dose number unknown, single for covid-19 immunisation. Relevant medical history included: ""autoimmune hepatitis"" (ongoing), notes: in treated remission (no medication changes or abnormal labs for a minimum of 6 months); ""Compensated cirrhosis"" (unspecified if ongoing). The patient's concomitant medications were not reported. The following information was reported: LIVER INJURY (medically significant), outcome ""recovering"", described as ""hepatocellular pattern of liver injury""; HEPATITIS (medically significant), outcome ""recovering"", described as ""Portal and lobular with interface hepatitis""; HEPATOCELLULAR CARCINOMA (medically significant), outcome ""recovering"", described as ""new diagnosis of solitary hepatocellular carcinoma"". The patient had pre-existing autoimmune hepatitis and displayed interface activity, demonstrated a significant plasma cell component. Timing of pattern presentation of injury was 19 days in relation to first dose of vaccine. The patient underwent the following laboratory tests and procedures: alanine aminotransferase: 245 IU/l; biopsy: inflammation severity: moderate, notes: Portal and lobular with interface hepatitis; mixed with plasma cells, notes: Cellular pattern of inflammation; normal bile ducts; blood alkaline phosphatase: 55 IU/l; blood bilirubin: 0.9 mg/dl; imaging procedure: new diagnosis of solitary hepatocellular carcinoma; international normalised ratio: 1.1; fibrous connective tissue: cirrhosis. Therapeutic measures Oral prednisone were taken as a result of liver injury, hepatitis, hepatocellular carcinoma. The author acknowledged that this series of patients with hepatic injury following mRNA-based COVID-19 vaccination contains retrospective and observational data without adjudication. Thus, this report is not structured to evaluate potential causality. Drug induced liver injury is not readily implicated in this patient series, although it cannot be wholly excluded. The author also considered unlikely direct hepatotoxicity from SARS-CoV-2 mRNA vaccines, noting the strong safety profile for delivery of lipid nanoparticle mRNA vaccines to human tissues. Rather, vaccine-induced immune-mediated hepatitis is a known phenomenon, and other autoimmune events (e.g., AIH, ITP) have been reported following COVID-19 vaccination. It is plausible that a similar mechanism is occurring here, whereby the host immune response directed against the COVID-19 spike protein triggers an aberrant, autoimmune-like hepatic condition in predisposed individuals. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: As per available information in the case provided, the causal association between the event liver injury, hepatitis, and hepatocellular carcinoma and the suspect drug BNT162B2 cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s) : 202101834329 Same article/drug/event and different patient."
HEPATITIS	PFIZER\BIONTECH	Unknown	2237758-1	"liver inflammation post vaccine; I had liver enzyme elevation post vaccine; This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from medical information team, Program ID: (005570). The reporter is the patient. A patient (no qualifiers provided) received BNT162b2 (COMIRNATY), as dose 1, single (Batch/Lot number: unknown) and as dose 2, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: HEPATITIS (medically significant), outcome ""unknown"", described as ""liver inflammation post vaccine""; HEPATIC ENZYME ABNORMAL (non-serious), outcome ""unknown"", described as ""I had liver enzyme elevation post vaccine"". The patient underwent the following laboratory tests and procedures: Hepatic enzyme abnormal: Eleveted, notes: had liver enzyme elevation; SARS-CoV-2 test: false negatives, notes: I was given a test known for false negatives. Additional information: The patient had initial 2 dose Pfizer vaccines. The had liver enzyme elevation and inflammation post vaccine. Is this a side effect and should get the booster. The patient believe have been infected twice. The patient was given a test known for false negatives and was sent home from hospital and became bedridden home alone for 6 months. The patient continue to had very poor sense of smell/taste. The patent live in name withheld now a hotbed if New variant cases. The information on the batch/lot number for BNT162b2 has been requested and will be submitted if and when received."
HEPATITIS A	JANSSEN	60-64 years	2228630-1	I have a previous diagnosis of COVID 01/19/2021 which I experienced long hauler symptoms with long recover time. Next day went to Hospital - Research Medical Center. to received the antibody infusion and 01/20/2021. August 2021, I had flu, body aches and fatigue, no appetite and taste and I was declining in health unable to stand and study and cognition function was deciding and was not eating and decided it was time to go the the hospital. Overnight stay for a specialist diagnosis of Hep A and thought thought a liver transplant was needed and they also discovered issue with liver. New hospital, the diagnosis the heart palpitation and advised of the order to get image of the heart, see how COVID impacted the heart. To monitor it. Clinical Depress with 05/2021 Rheubutrian, Lexapro and was removed.

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS A	MODERNA	65-79 years	2048165-1	This relates only to Moderna booster received on 12/16/21. beginning on 12/19 /21 I began to have severe diarrhea, pain and inflammation in all my joints, and low grade fever chills and sweats and profound fatigue. These symptoms occurred after the initial reaction to the booster immediately followingnits receipt on 12/16/2021. those symptoms resolved within 36 hours. The symptoms I experienced have lasted for a month. A gastroenterologist saw me for the diarrhea and said that he had seen other patients with similar protracted side effects from the booster. He prescribed Questran which has helped. The joint symptoms are lasting but are improving , likewise the fatigue. However I still feel worse than I did before. My Covid PCR test done at the time of my visit to Dr. is negative.
HEPATITIS A	PFIZER\BIONTECH	18-29 years	1106364-1	Within minutes of 2nd dose of vaccine, pt started urinating dark brown urine. This turned bloody / dark red in color. Over the next several days she had migraines, fever, nausea, diarrhea. She had a very heavy period that was not normal for her. She was treated twice for presumed UTI (once with macrobid and then with cefuroxime) in the days after the vaccine though cultures ended up negative. She was referred to me, a hematologist, when she was noted to have a dropping hemoglobin and platelet count. She appears to have a Coombs-negative hemolytic anemia and possibly ITP. She is feeling a little better but her labs remain abnormal. Please note this was reported on Pfizer website as well but I have not been contacted. Guidance would be sincerely appreciated. My cell phone was provided.
HEPATITIS A	PFIZER\BIONTECH	18-29 years	1392773-1	Please see housestaff note for full details. In brief, 20-year-old neurologically normal man with history of asthma now presenting with new onset fever, headache and then status epilepticus. On 5/25 the patient received his second dose of COVID vaccine and then started to have intermittent fevers up to 102.5. This was associated with malaise, nausea, fever, headache, myalgias. He came to ED on 5/30 and had IVF, analgesics and a cardiac workup that was unremarkable and was discharged with diagnosis of possible pericarditis/myocarditis. He then had ongoing worsening headaches and increasing fevers and was unable to get out of his bed, and so his wife called 911 and he came to ED on 6/3. There he had vomiting and transaminitis and was diagnosed with gastroenteritis treated with flagyl. Headaches progressed and were associated with dizziness; he had HCT read as unremarkable but then while awaiting MRI had convulsion. He was returned to his room and had two more and thus was intubated, placed on propofol/versed, Keppra, dilantin, and broad-spectrum antibiotics and acyclovir before transfer to UCSF. on 6/5/2021 found to have reduced urine output, and serum creatinine found to be 1.72 and climbed >7 in days later normalized spontaneously with fluid support to 4.26 with continued improvement. LFTs were also found to be elevated. Was acutely encephalopathic. Seizures resolved on Keppra treatment though had acute agitation for several days. Slowly returning to neurologic baseline. with AKI and LFTs slowly normalizing.
HEPATITIS A VIRUS TEST POSITIVE	MODERNA	60-64 years	1402149-1	So I got my first vaccine on 12/20/2020 and got labs on 1/16/2021 which was part of a routine visit and they found those to be elevated so they said to repeat the labs and on the 30th I repeated my labs not thinking that the vaccine on the 21st would impact that but the results were even more elevated. On Feb 1st I had a phone visit with my PCP to review my results and then started seeing a gastroenterologist, I had a scope done. I went back to them on the 22nd of March for a follow up of elevated liver enzymes and EKG was on March 4th as well. On March 26th I went to my PCP for an enlarged corroded gland, they said it was an inflammatory response which was on my right side which is where I received my vaccine as well. On April 23rd they repeated labs, went back to gastroenterology on April 30th. In February I was also admitted for observation because of chest pain, that was on the 15th. They did a lexiscan and found the four areas of concern in my right lung. Then I had a CT scan on 2/19/2021 to follow up with that. Repeat CAT scan to follow up with nodules on 6/3/2021. So I am currently repeating labs and going back to the gastroenterology on the 29th of this month (June). I also have an appnt on July 17th to follow up with my Cardio.
HEPATITIS A VIRUS TEST POSITIVE	PFIZER\BIONTECH	Unknown	1249903-1	positive result for Hepatitis A, Food Poisoning, and Mononucleosis; positive result for Hepatitis A, Food Poisoning, and Mononucleosis; positive result for Hepatitis A, Food Poisoning, and Mononucleosis; This is a spontaneous case report received from a contactable consumer(patient) via Pfizer-sponsored program. A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: unknown), via an unspecified route of administration on 09Feb2021 as a single dose for COVID-19 immunisation. Medical history included kidney transplant. The patient's concomitant medications were not reported. On unspecified date, the patient experienced hepatitis A virus test positive, food poisoning . He questioned if it was wrong of him to get vaccinated and get bloodwork done on the next day and if the vaccine may have caused this. The patient underwent lab tests and procedures which included blood test with unknown result, hepatitis A virus test positive. The clinical outcome of the events was unknown. Information on the lot/batch number has been requested. Follow-up attempts are completed. No further information is expected.

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS B	JANSSEN	65-79 years	1758808-1	Patient didn?t feel well the day after his COVID vaccine. He was extremely tired and he had body aches. This continued until his 1st visit to the hospital on July 1st. He was jaundice and weak. They diagnosed cirrhosis, high blood pressure and low blood platelets. He stayed in the hospital for 3-4 days and was released. 4-5 days later we went to the hospital again with the same symptoms. This time they told him he had hepatitis B along with the other things already diagnosed, again he was released from the hospital after a few days. 5-6 days later he had a doctors appointment, she told him he needed to go back to the hospital. This stay was for 16 days. He needed platelets and was then diagnosed with an aggressive form of lymphoma, received treatment and was released on July 30. That evening he started with a cough and felt progressively worse. August 3rd he was scheduled for more blood platelets, arrived to the hospital and was again admitted. They then diagnosed him with an ecoli infection which was to much for his weakened state and he passed away on August 10
HEPATITIS B	MODERNA	18-29 years	1270924-1	one of our Ambulance staff inadvertently used the same syringe to vaccinate eight people ? he did change the needles in between each patient.
HEPATITIS B	MODERNA	30-39 years	1270900-1	one of our Bi-County Ambulance staff inadvertently used the same syringe to vaccinate eight people ? he did change the needles in between each patient.
HEPATITIS B	MODERNA	40-49 years	2059217-1	tested positive for Hepatitis B after blood donation. I have been donating blood for over 20 years and have never been rejected for anything in the blood. I tested positive after the third vaccine.
HEPATITIS B	MODERNA	60-64 years	1438562-1	polyarthralgias developed suddenly, shortly after administration of second dose of COVID-19 vaccine. Prior to, had no history of RA or any other autoimmune diseases. Swelling, arthritis on hands and feet, worsened stiffness in mornings that last 20 minutes and has persisted since 5/15/21. Pertinent physical exam findings: Tender Joints: Right- 1st cmc 2nd & 3rd mcp 3rd and 4th pip in right Carpi ulnaris tendon pain on right Subtalar joint Left: 2nd and 4th pip Subtalar joint (L worse than R) esp on inversion. Pes anserinus pain Swollen: Right: 2nd and 3rd MCP Left: 3rd and 4th PIP Subtalar swelling and tenderness. Synovitis Worse on left than right MTP squeeze negative on left and right foot Treatments: currently on Ibuprofen 400mg bid prn for pain
HEPATITIS B	MODERNA	60-64 years	1984050-1	tested Negative for Hepatitis B in April 2021 & July 2021; had a temperature of 99.4F.; This spontaneous case was reported by a nurse and describes the occurrence of THERAPEUTIC RESPONSE UNEXPECTED (tested Negative for Hepatitis B in April 2021 & July 2021) and PYREXIA (had a temperature of 99.4F.) in a 61-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 032L20A and 026L20A) for COVID-19 vaccination. The patient's past medical history included Hepatitis B (Patient get tested every 6 months.) in 1980. On 05-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 02-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 03-Feb-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced PYREXIA (had a temperature of 99.4F.). In April 2021, the patient experienced THERAPEUTIC RESPONSE UNEXPECTED (tested Negative for Hepatitis B in April 2021 & July 2021). At the time of the report, THERAPEUTIC RESPONSE UNEXPECTED (tested Negative for Hepatitis B in April 2021 & July 2021) and PYREXIA (had a temperature of 99.4F.) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In November 2020, Hepatitis B: positive (Positive) Positive. On 03-Feb-2021, Body temperature: 99.4 (High) 99.4. In April 2021, Hepatitis B: negative (Negative) Negative. In July 2021, Hepatitis B: negative (Negative) Negative. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not provided. Treatment information was not provided. This case was linked to MOD-2021-425676 (Patient Link).

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS B	**MODERNA**	**65-79 years**	1245471-1	cyst on kidney; cyst on pancreas; Hepatitis B; Jaundice; Cyst on liver; started getting ill; 2nd dose not administered within vaccine schedule window; MRI Abnormal; Ultrasound abnormal; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of RENAL CYST (cyst on kidney), PANCREATIC CYST (cyst on pancreas), HEPATITIS B (Hepatitis B), JAUNDICE (Jaundice) and CYST (Cyst on liver) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 013L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Stomach discomfort (Starting back in August 2020 she didn't feel good, had stomach issues off and on.) since August 2020. Concomitant products included LISINOPRIL for an unknown indication. On 22-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Feb-2021, the patient experienced RENAL CYST (cyst on kidney) (seriousness criterion hospitalization), PANCREATIC CYST (cyst on pancreas) (seriousness criterion hospitalization), HEPATITIS B (Hepatitis B) (seriousness criterion hospitalization), JAUNDICE (Jaundice) (seriousness criterion hospitalization), CYST (Cyst on liver) (seriousness criterion hospitalization), MAGNETIC RESONANCE IMAGING ABNORMAL (MRI Abnormal) and ULTRASOUND SCAN ABNORMAL (Ultrasound abnormal). On an unknown date, the patient experienced ILLNESS (started getting ill) and INCOMPLETE COURSE OF VACCINATION (2nd dose not administered within vaccine schedule window). The patient was hospitalized from 05-Feb-2021 to 08-Feb-2021 due to CYST, HEPATITIS B, JAUNDICE, PANCREATIC CYST and RENAL CYST. On 05-Feb-2021, MAGNETIC RESONANCE IMAGING ABNORMAL (MRI Abnormal) and ULTRASOUND SCAN ABNORMAL (Ultrasound abnormal) outcome was unknown. At the time of the report, RENAL CYST (cyst on kidney), PANCREATIC CYST (cyst on pancreas), HEPATITIS B (Hepatitis B), JAUNDICE (Jaundice), CYST (Cyst on liver) and ILLNESS (started getting ill) outcome was unknown and INCOMPLETE COURSE OF VACCINATION (2nd dose not administered within vaccine schedule window) had resolved. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Feb-2021, Hepatitis B: positive Positive. On 05-Feb-2021, Magnetic resonance imaging: abnormal (abnormal) Identified a cyst on her pancreas, cyst on her kidney and cyst on her liver.. On 05-Feb-2021, Ultrasound scan: abnormal (abnormal) Identified a cyst on her pancreas, cyst on her kidney and cyst on her liver.. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown.
				"was injected ""twice on right arm; Sluggish; Wrong technique in device usage process; low grade fever between 99F-101F; Pink and puffy at the site of the injection; Pink and puffy at the site of the injection; This spontaneous case was reported by a consumer and describes the occurrence of ACCIDENTAL OVERDOSE (was injected ""twice on right arm), SLUGGISHNESS (Sluggish), WRONG TECHNIQUE IN DEVICE USAGE PROCESS (Wrong technique in device usage process), PYREXIA (low grade fever between 99F-101F) and VACCINATION SITE ERYTHEMA (Pink and puffy at the site of the injection) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 002B21A and 014M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Open heart surgery (In isolation since) in December 2019. Previously administered products included for an unreported indication: HEPATITIS B VACCINE. Concomitant products included ACETYLSALICYLIC ACID (ASPIRIN (E.C.)), ROSUVASTATIN CALCIUM (CRESTOR), METOPROLOL, CALCIUM FRUCTOBORATE, CHONDROITIN SULFATE SODIUM, GLUCOSAMINE HYDROCHLORIDE, HYALURONIC ACID (MOVE FREE JOINT HEALTH), MINERALS NOS, VITAMINS NOS (CENTRUM A TO ZINC) and NAPROXEN SODIUM (ALEVE) for an unknown indication. On 26-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 26-Mar-2021, the patient experienced ACCIDENTAL OVERDOSE (was injected ""twice on right arm), SLUGGISHNESS (Sluggish), WRONG TECHNIQUE IN DEVICE USAGE PROCESS (Wrong technique in device usage process), PYREXIA (low grade fever between 99F-101F), VACCINATION SITE ERYTHEMA (Pink and puffy at the site of the injection) and VACCINATION SITE SWELLING (Pink and puffy at the site of the injection). On 26-Mar-2021, ACCIDENTAL OVERDOSE (was injected ""twice on right arm) had resolved. On 28-Mar-2021, PYREXIA (low grade fever between 99F-101F) had resolved. At the time of the report, SLUGGISHNESS (Sluggish) was resolving and VACCINATION SITE ERYTHEMA (Pink and puffy at the site of the injection) and VACCINATION SITE SWELLING (Pink and puffy at the site of the injection) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Mar-2021, Body temperature: between 99-101 f (abnormal) Between 99-101 F. In 2021, HIV antibody: pending Pending. In 2021, Hepatitis B: pending Pending. In 2021, Hepatitis C: pending Pending. Additional information: Patient stated that nurse injected needle in his arm and then said, ""wrong needle,"" and again gave him another injection so he could get ""full"" vaccination. Patient felt medication going into his arm with both injections. Reporter not sure if 1st injection was from last patient, or if he was given 2 injections of Moderna vaccine at the same time. Low grade fever resolved after taking acetaminophen (TYLENOL) q4hrs x 2 days. Patient went to urgent care after consulting with HCP to get tested for HIV, Hepatitis B, and Hepatitis C (results pending). Patient has follow-up with HCP regarding this issue.; Sender's Comments: This report refers to a case of accidental overdose for mRNA-1273 (lot # unknown) with associated AE reported of sluggishness, fever, vaccination site erythema, and vaccination site swelling."
HEPATITIS B	**MODERNA**	**Unknown**	1600341-1	

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS B	PFIZER\BIONTECH	30-39 years	1416533-1	he tested positive for hepatitis B virus with little EAG; his erythrocytes were a little high,; Hepatocytes was high; hematocrit was high; lymphocytes were high; his glucose was high; This is a spontaneous report from a contactable consumer (patient) and from a Pfizer sponsored program. A contactable 39-year-old male consumer (patient) reported that received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number ER8735), into the left arm on 21Apr2021 at 9.00 (at the age of 39-years-old) at single dose for COVID-19 immunization. The patient had received the fist dose of vaccine on 31Mar2021 (Lot: EP7534) in the left arm at 09.00. Medical history included psoriasis diagnosed 25 years before reporting when he was 15 years old. Family history included his mom died of cancer, but she did a lot of drugs and stuff. Concomitant drugs were none. The patient reported that 2 weeks after 2nd dose of vaccine he had blood work done. He said the result came back a little weird on 10May2021. Erythrocyte were a little high, Hepatocytes were high, hematocrit was high, lymphocytes were high, and it says he tested positive for hepatitis B virus with little EAG. Caller states his glucose was high but he thinks that's just from what he was eating. The patient stated that the events required a physician office video visit. Caller stated his doctor was having him do another blood work test. Caller stated the doctor thought maybe it was the vaccine that did it. At the time of reporting the outcome of the events was unknown.
HEPATITIS B	PFIZER\BIONTECH	60-64 years	1341319-1	Petechial rash onset bilateral lower extremities 2 days after 2nd vaccine. Labs pending.
HEPATITIS B	PFIZER\BIONTECH	Unknown	1387788-1	pernio, temporally associated with the second dose of Pfizer mRNA SARS-CoV-2 vaccine.; This is a literature report from the The journal of dermatology, 2021, doi: 10.1111/bjd.20404 entitled Pernio after COVID-19 Vaccination. A 64-year-old male presented to the emergency department in January 2021 with violaceous skin discoloration for 10 days that started on the left hallux and gradually spread to all toes on the bilateral feet. The patient received the second dose of the Pfizer COVID-19 vaccine 3 days prior to onset of the left toe discoloration. He denied hot or cold exposure, numbness, tingling, or pain. He denied history of pernio or other similar lesions, Raynaud's phenomenon, oral ulcers, photosensitivity, vascular disease, cardiac disease, hypercoaguable state, cardiac procedure, or autoimmune diseases. He denied previous or current symptoms of COVID-19 or exposure to those with COVID symptoms or a positive test. The estimated local prevalence of the virus was 7.6%. The patient had three negative COVID-19 PCR tests in the two months prior to presentation, and negative testing at presentation. The patient denied any adverse reactions after the first dose of the vaccine. The patient had painless, dark erythematous to violaceous discoloration of the bilateral toes, with an intact bulla on the left hallux. Abnormalities on initial laboratory studies included elevated C-reactive protein (CRP). The differential diagnosis included idiopathic pernio, connective tissue disease, hypercoagulable state, vasculitis/vasculopathy, COVID-19 infection, or reaction to the vaccine. Laboratory workup including Hepatitis B, Hepatitis C, HIV, ANA, ANCA, antiphospholipid antibodies, complements C3/C4/CH50, rheumatoid factor, and serum and urine protein electrophoresis was initiated to rule out other etiologies in the differential diagnosis. The key differentiating feature between COVID-19-associated pernio and idiopathic pernio is the lack of association with cold exposure. Idiopathic pernio was unlikely as the local weather was relatively mild; daily temperatures averaged 9 degree-20 degree C in the weeks before and after the lesions appeared. The patient was in stable condition and was discharged with clobetasol 0.05% ointment for the affected toes with plan to follow up in the outpatient dermatology clinic in two weeks. At follow up 15 days after initial presentation (28 days after vaccination), the clinical appearance of the toe discoloration was unchanged. The patient's symptoms were now exacerbated by cold temperatures and improved with rewarming and leg elevation. Laboratory workup was unrevealing. A punch biopsy of the left great toe was obtained, which revealed pathology consistent with pernio and immunohistochemistry (IHC) staining for SARS-CoV-2 of the tissue was negative. COVID infection remained a possibility. However, negative testing and lack of symptoms or contact with infected individuals argued against this. Thus, the final diagnosis was pernio, temporally associated with the second dose of Pfizer mRNA SARS-CoV-2 vaccine. The patient was counseled to use clobetasol as needed and avoiding cold exposure. This presentation suggests possible attribution of the pernio-like lesions to an immune response triggered by the COVID-19 mRNA vaccine, potentially similar to the immune response after Sars-CoV-2 itself, which also triggers pernio.; Sender's Comments: Based on the available public information and temporal association, the causal association cannot be excluded for the event Pernio, temporally associated with the second dose of Pfizer mRNA SARS-CoV-2 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS B	PFIZER\BIONTECH	Unknown	1954266-1	"Hepatitis B; This is a spontaneous report received from a non-contactable reporter(s) (Consumer or other non HCP) for a Pfizer sponsored program. The reporter is the patient. A male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (Batch/Lot number: unknown) as dose number unknown, single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: HEPATITIS B (medically significant), outcome ""unknown"", described as ""Hepatitis B"". Caller wants to have information about the Paxlovid. He mentioned that he had Hepatitis B. Paxlovid is not an active product. He is inquiring for Paxlovid indication of use for those people who had a history of Hepatitis B. He added that he already got the Covid-19 vaccine but he did not mention the brand of the vaccine. He also requested to be anonymous. No information gathered. Provided PMI contact number and hours of operation. Call got disconnected while connecting the call to PMI. Unable to gather the first and second dose date. No transfer was made. Submitted Manual AE form since the caller mentioned that he had Hepatitis B but it was not mentioned if this happened before or after receiving the Covid-19 vaccine. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected."
HEPATITIS B	PFIZER\BIONTECH	Unknown	2262945-1	"diagnosis of dermatomyositis, occurring in association with the COVID-19 vaccine; This is a literature report. A 77-year-old female patient received BNT162b2 (BNT162B2), as dose 1, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: DERMATOMYOSITIS (medically significant), 5 days after the suspect product(s) administration, outcome ""recovered"", described as ""diagnosis of dermatomyositis, occurring in association with the COVID-19 vaccine"". The patient underwent the following laboratory tests and procedures: Alanine aminotransferase (0-55): 154 IU/l, notes: elevated; Antibody test: remarkably elevated; Antinuclear antibody: No antibodies detected; Antinuclear antibody negative: No antibodies detected, notes: Jo-1; Aspartate aminotransferase (5-34): 256 IU/l, notes: elevated; Biopsy: revealed features of interface dermatitis with, notes: superficial perivascular mononuclear inflammation and dermal edema; revealed overexpression of major, notes: histocompatibility complex class I, inflammatory cells, necrotic fibers, and atrophic fibers organized in a perimysial pattern, suggesting an immune-mediated myopathy of a dermatomyositis type; Blood creatine phosphokinase (29-168): 2804 IU/l, notes: first day of presentation; 4476 IU/l, notes: 3 days; 1135 IU/l, notes: decreased significantly; Normalized, notes: 12 weeks after initial presentation; Computerised tomogram abdomen: No internal malignancy; Computerised tomogram pelvis: No internal malignancy; Computerised tomogram thorax: No internal malignancy; Enzyme level test: Normalized, notes: liver enzymes normalized twelve weeks after initial presentation; Flow cytometry: lymphoma disorder unremarkable; Hepatitis B: negative; Hepatitis C: negative; Additional cutaneous findings: included multiple vesicles and erythematous, notes: papules on the right upper extremity and reticulated, erythematous patches on both of her thigh; remarkably elevated; unknown results; showed basal vacuolar alteration with foci of, notes: necrotic keratinocytes; Mi2-a: No antibodies detected, notes: Mi2-alpha; No antibodies were detected, notes: Mi2-beta; No antibodies were detected, notes: PL-12; No antibodies were detected, notes: PL-7; physical examination: violaceous, poikilodermatous scaly plaques were, notes: observed on the anterior aspect of the neck and chest; Tuberculosis: negative. Therapeutic measures were taken as a result of dermatomyositis. She had received an initial dose of the COVID-19 vaccine 5 days before the onset of the symptoms. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Based on the available reported information, the causal association between the event dermatomyositis and the suspect drug BNT162B2 cannot be excluded."
HEPATITIS C	MODERNA	18-29 years	1270924-1	one of our Ambulance staff inadvertently used the same syringe to vaccinate eight people ? he did change the needles in between each patient.
HEPATITIS C	MODERNA	40-49 years	0967734-1	Elevated heart rate, blood pressure remained high at minimum of 165/110 chest tighten.. tingling/swelling in left hand and feet.. became weak speech slurred felt moments of wanting to pass out.
HEPATITIS C	MODERNA	40-49 years	1346681-1	Enlarged liver, autoimmune Hepatitis
HEPATITIS C	MODERNA	60-64 years	0938216-1	abd pain; dx with hep C and Covid positive12/14/2020
HEPATITIS C	MODERNA	60-64 years	1438562-1	polyarthralgias developed suddenly, shortly after administration of second dose of COVID-19 vaccine. Prior to, had no history of RA or any other autoimmune diseases. Swelling, arthritis on hands and feet, worsened stiffness in mornings that last 20 minutes and has persisted since 5/15/21. Pertinent physical exam findings: Tender Joints: Right- 1st cmc 2nd & 3rd mcp 3rd and 4th pip in right Carpi ulnaris tendon pain on right Subtalar joint Left: 2nd and 4th pip Subtalar joint (L worse than R) esp on inversion. Pes anserinus pain Swollen: Right: 2nd and 3rd MCP Left: 3rd and 4th PIP Subtalar swelling and tenderness. Synovitis Worse on left than right MTP squeeze negative on left and right foot Treatments: currently on Ibuprofen 400mg bid prn for pain
HEPATITIS C	MODERNA	60-64 years	1694187-1	small nerve neuropathy numbness and tingling in both toes and fingers. 24/7. Constant tingling and numbness. keeps me up at night. No treatment is available. This started 5 weeks after the 2nd vaccine and has been constant for the past 5 months. This started in my toes then spread to my fingers.
HEPATITIS C	MODERNA	60-64 years	1955797-1	With first dose, patient got sick. With second dose, patient did not get sick. In Nov. 2021, patient was diagnosed with Hepatitis C. Patient is of the belief that Hepatitis C is result of vaccination.

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS C	MODERNA	65-79 years	1599762-1	Little tired; This spontaneous case was reported by a consumer and describes the occurrence of FATIGUE (Little tired) in a 74-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 01SM20A or 015M20A) for COVID-19 vaccination. No Medical History information was reported. On 14-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 11-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 11-Feb-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced FATIGUE (Little tired). On 11-Feb-2021, FATIGUE (Little tired) had resolved. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 16-Mar-2021, Hepatitis C: false positive (abnormal) False positive result. Patient reported that before donating blood, he received a false positive Hepatitis C result. Concomitant medication was not provided Treatment information was not provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) was not applicable This case was linked to US-MODERNATX, INC.-MOD-2021-059819 (E2B Linked Report). Most recent FOLLOW-UP information incorporated above includes: On 26-May-2021: Follow up document was received on 26-MAY-2021. Reporter's address was added. Patient's first dose date, second dose batch no. were included. It contains significant information.; Sender's Comments: US-MODERNATX, INC.-MOD-2021-059819:Wife case
HEPATITIS C	MODERNA	Unknown	1600341-1	"was injected ""twice on right arm; Sluggish; Wrong technique in device usage process; low grade fever between 99F-101F; Pink and puffy at the site of the injection; Pink and puffy at the site of the injection; This spontaneous case was reported by a consumer and describes the occurrence of ACCIDENTAL OVERDOSE (was injected ""twice on right arm), SLUGGISHNESS (Sluggish), WRONG TECHNIQUE IN DEVICE USAGE PROCESS (Wrong technique in device usage process), PYREXIA (low grade fever between 99F-101F) and VACCINATION SITE ERYTHEMA (Pink and puffy at the site of the injection) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 002B21A and 014M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Open heart surgery (In isolation since) in December 2019. Previously administered products included for an unreported indication: HEPATITIS B VACCINE. Concomitant products included ACETYLSALICYLIC ACID (ASPIRIN (E.C.)), ROSUVASTATIN CALCIUM (CRESTOR), METOPROLOL, CALCIUM FRUCTOBORATE, CHONDROITIN SULFATE SODIUM, GLUCOSAMINE HYDROCHLORIDE, HYALURONIC ACID (MOVE FREE JOINT HEALTH), MINERALS NOS, VITAMINS NOS (CENTRUM A TO ZINC) and NAPROXEN SODIUM (ALEVE) for an unknown indication. On 26-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 26-Mar-2021, the patient experienced ACCIDENTAL OVERDOSE (was injected ""twice on right arm), SLUGGISHNESS (Sluggish), WRONG TECHNIQUE IN DEVICE USAGE PROCESS (Wrong technique in device usage process), PYREXIA (low grade fever between 99F-101F), VACCINATION SITE ERYTHEMA (Pink and puffy at the site of the injection) and VACCINATION SITE SWELLING (Pink and puffy at the site of the injection). On 26-Mar-2021, ACCIDENTAL OVERDOSE (was injected ""twice on right arm) had resolved. On 28-Mar-2021, PYREXIA (low grade fever between 99F-101F) had resolved. At the time of the report, SLUGGISHNESS (Sluggish) was resolving and VACCINATION SITE ERYTHEMA (Pink and puffy at the site of the injection) and VACCINATION SITE SWELLING (Pink and puffy at the site of the injection) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Mar-2021, Body temperature: between 99-101 f (abnormal) Between 99-101 F. In 2021, HIV antibody: pending Pending. In 2021, Hepatitis B: pending Pending. In 2021, Hepatitis C: pending Pending. Additional information: Patient stated that nurse injected needle in his arm and then said, ""wrong needle,"" and again gave him another injection so he could get ""full"" vaccination. Patient felt medication going into his arm with both injections. Reporter not sure if 1st injection was from last patient, or if he was given 2 injections of Moderna vaccine at the same time. Low grade fever resolved after taking acetaminophen (TYLENOL) q4hrs x 2 days. Patient went to urgent care after consulting with HCP to get tested for HIV, Hepatitis B, and Hepatitis C (results pending). Patient has follow-up with HCP regarding this issue.; Sender's Comments: This report refers to a case of accidental overdose for mRNA-1273 (lot # unknown) with associated AE reported of sluggishness, fever, vaccination site erythema, and vaccination site swelling."
HEPATITIS C	PFIZER\BIONTECH	18-29 years	1156692-1	The next morning, pt had 2 unwitnessed syncopal episodes.

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS C	PFIZER\BIONTECH	30-39 years	1278684-1	Hepatitis c 0.9 positive; Herpes or shingles on groin; Extreme fatigue; Fever; This is a spontaneous report from a contactable consumer (patient). A 39-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration, administered in arm right on 24Mar2021 13:30 (Batch/Lot number was not reported) as single dose, for COVID-19 immunisation. Medical history included hypothyroidism from an unknown date. Concomitant medication included sertraline hydrochloride (ZOLOFT) taken for an unspecified indication, start and stop date were not reported. The patient has no known allergies. The patient was not pregnant at the time of vaccination. The patient experienced Hepatitis c 0.9 positive, Herpes or shingles on groin, extreme fatigue, and fever on 11Apr2021. The patient underwent lab tests and procedures which included nasal swab: negative (covid tested post vaccination) on 15Apr2021 and Hepatitis C 0.9 positive on 11Apr2021. Therapeutic measures were taken as a result of the events which included Valtrex, cough syrup, antibiotics as treatment. The patient received the second dose of BNT162B2, administered in arm right on 14Apr2021 08:00. The outcome of the events was not recovered. Information on the lot/batch number has been requested.
HEPATITIS C	PFIZER\BIONTECH	40-49 years	1329526-1	acute diarrhea and it had been 16 days and it had not stopped. She has been going 7 to 10 times a day; Being dehydrated from having so many bowel movements; slight fever of 99.7 every night/She was still at 99.6, 99.7 so for the first few days it was over a 100/99 was a fever for her; Little bit of headache; ears got kind of hot; This is a spontaneous report from a contactable consumer (patient). A 48-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) (at 48 years of age), via an unspecified route of administration, administered in arm left on 19Apr2021 (Batch/Lot Number: ER8737) as 2ND DOSE, SINGLE for COVID-19 immunisation. Medical history included ongoing herpes simplex that has been going for years. Concomitant medication included aciclovir (ACYLO [ACICLOVIR]) taken for herpes simplex from an unspecified start date and ongoing. Historical vaccine included BNT162B2 dose 1 (Batch/Lot Number: ER8732) on 29Mar2021 in the left arm for COVID-19 immunisation. The patient got her second Pfizer vaccine on April 19th as soon as she got her shot, her ears got kind of hot and then she has had acute diarrhea and it had been 16 days and it had not stopped. She has been going 7 to 10 times a day. She was still running a slight fever of 99.7 every night and her doctor was, they have been trying everything they can to stop the diarrhea. Just a little bit of headache but she does not know if the headaches are from being dehydrated from having so many bowel movements, so with the headaches, so they cannot stop it. Her doctors have her on three medications, one of them was an antibiotic, one of them was Imodium (later confirmed as loperamide) just a few things and the other one was a muscle contractor in the GI tract trying to stop her muscles from spasming and he tested her for every parasite, every bacterial, everything, did a CAT scan, everything was coming back negative. She confirmed that she got the symptoms the very next day, so 20Apr2021 was the day that she started all her symptoms. So, still current. She was still at 99.6, 99.7 so for the first few days it was over a 100, so it did go down after the first 2 days but then after that it just stayed at 99. She mentioned that her temp usually runs at 96, so 99 was a fever for her. She added that she went to the hospital 2 times. In 2 different times because she got IV fluid. The first one was on 23Apr2021, the second time she went was on 03May2021. She confirmed that she went to the hospital for treatment and no hospitalization was done. She added that she was treated then was released, she was given fluid through an IV and then they released her, because all the diarrhea was making her dehydrated because she was losing so much. She did not get admitted, she just went in and was treated and released. She was tested for bacterial, parasite, HIV, Hep C, gonorrhea, chlamydia, STD everything. Everything they tested her was coming back negative. They also did CAT scan, they have done everything, but cannot figure out why the diarrhea won't stop, they have put her on all those stuffs, and nothing was working. She asked what she should do to stop the diarrhea. Therapeutic measures were taken as a result of the events. For diarrhea she was given antibiotic Vancomycin 250 mg three times a day for 10 day from 29Apr2021 and was still using; loperamide 2 mg four times a day from 23Apr2021 and was still using; and the next one was just put her on because she had to go back to the hospital the other day was dicyclomine 20 mg, four times a day from 3May2021 and ongoing. She was also given with Benadryl through an IV at the hospital and they also gave her a medicine to stop that 'poison reaction' (not clarified further), and then they have her scheduled with a GI specialist too. There was another name of the medicine that they treated her at the hospital, they said she was having a reaction, so they gave her atropine and then they put Benadryl, they gave her that at the ER on 23Apr2021. Also, they give her a COVID test and that was negative too at the hospital on the 23Apr2021. The outcome of the events was not recovered. Information about Batch/Lot number available. Additional information has been requested.
HEPATITIS C	PFIZER\BIONTECH	40-49 years	1715065-1	Change in menstrual cycle (heavy and two week early), extreme fatigue (started the day after the shot and continued for 3 months before beginning to wane), weight gain (6 pounds in 3 weeks, a 4% gain in a person with stable weight for 3+ years), deep muscle pain in the front of legs (quads)
HEPATITIS C	PFIZER\BIONTECH	40-49 years	1944230-1	Hepatitis C Nausea, body aches, jaundice, liver pain, fatigue, brain fog, dizziness, lightheadedness

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS C	PFIZER\BIONTECH	50-59 years	1856769-1	It is suspected that the vaccine also reactivated a preexisting Hep C infection; In early september, I developed systemic lymphadenopathy and lymphedema; In early september, I developed systemic lymphadenopathy and lymphedema; chronic active Epstein-Barr viral infection incited by the second vaccine dose; fatigue; low RBC; low lymphocyte counts; This is a spontaneous report from a contactable pharmacist (patient). A 51-years-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in arm left on 28Apr2021 (Lot Number: EW0169) as dose 2, single at the age of 51-years-old for covid-19 immunization. Medical history included asthma. Known allergies: penicillin (PCN), sulfa. No covid prior vaccination. The patient received other medications in two weeks (unspecified). The patient previously took bnt162b2 (Lot Number: ER8729) in arm left on 07Apr2021 for covid-19 immunisation. No other vaccine in four weeks. The patient developed crushing fatigue following second vaccine dose. Blood tests yielded several abnormalities, including low RBC and lymphocyte counts. By early Aug2021, the blood tests normalized, and the fatigue mostly resolved. In early Sep2021, the patient developed systemic lymphadenopathy and lymphedema. These progressed rapidly, leading him to go to the ER on 16Sep2021. Subsequently, the patient saw multiple specialists and had a plethora of tests performed, including 3 biopsies, multiple CT scans, multiple ultrasounds, and innumerable blood tests. The final diagnosis from his hematologist at hospital was chronic active Epstein-Barr viral infection incited by the second vaccine dose. In addition, an antibody test for hepatitis C came back positive with a quantitative PCR test revealing a low viral load. A repeat viral load test was negative, suggesting the patient cleared the virus. It is suspected that the vaccine also reactivated a preexisting Hep C infection. Adverse events start date was reported as Apr2021. AE resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care. The patient received treatment for the events (also reported AE treatment included multiple testing procedures). No covid tested post vaccination. Outcome of the events was recovering.; Sender's Comments: The event of Hepatitis C Relapse, fatigue, red blood cell count decreased, lymphocyte count decreased, lymphadenopathy, lymphedema, Epstein-Barr virus infection, is assessed as possibly related to the suspect drug BNT162B2 based on strong temporal association, but consider also possible contributory effects from patient's medical history and/or concomitant medications. 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.
HEPATITIS C	PFIZER\BIONTECH	60-64 years	1294745-1	"Feeling terrible all over; aching all over; his urine started smelling bad; Hepatitis C; His chest was also hurting; Dizzy; his arm hurt just from the shot.; This is a spontaneous report from a contactable consumer (patient). A 60-year-old male patient (weight: 83.91 kg, height: 178 cm) received the second dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine, Lot. ER8734, Expiration date: 31Jul2021) at single dose, in the right upper arm, on 10Apr2021 at 14:00, for COVID-19 immunisation. The patient had not received any other vaccines within 4 weeks prior to the BNT162B2 vaccine. Relevant medical history included arachnoiditis adhesive chronic from an unspecified date, in 1999 and ongoing, ulcerative colitis from an unspecified date, in 1996 and ongoing, chronic sinusitis from an unspecified date, venous reflux disease from an unspecified date and ongoing and polyps from an unspecified date (7 surgeries performed from polyps. Last surgery was Mar2016). The patient preciously, on 20Mar2021, at 14:00, received the first dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine, Lot. EP7534, Expiration date: 31Jul2021) in the right deltoid, at single dose, on for COVID-19 immunisation. He was good after the first shot, he had no problems. Concomitant medications were unknown. On 10Apr2021, the patient experienced dizzy (""after the second dose they got home and that evening while getting up off the couch, he got really dizzy"") and his arm hurt just from the shot. On 13Apr2021, he developed chest pain (his chest was also hurting) and had hepatitis C (""he got blood work done and just got it back and was told he has hepatitis C""). On 20Apr2021, his urine started smelling bad. On an unspecified date, the patient also experienced generalised aching (""aching all over"") and was feeling terrible all over. Relevant laboratory test, performed on an unspecified date, showed the following value: alkaline phosphate high, blood cholesterol high, eosinophil count 5.4 %, hepatitis C positive, low density lipoprotein (LDL) high and infectious mononucleosis (Mono) 13.5. The patient recovered from vaccination site pain on 10Apr2021, recovered from dizzy on 14Apr2021 and recovered from chest pain on 20Apr2021. The patient did not recover from hepatitis C and urine abnormal. Clinical outcome of feeling bad and generalised aching was unknown at time of this report."
HEPATITIS C	PFIZER\BIONTECH	60-64 years	1341319-1	Petechial rash onset bilateral lower extremities 2 days after 2nd vaccine. Labs pending.
HEPATITIS C	PFIZER\BIONTECH	60-64 years	2258619-1	pt brought to ED with extreme weakness; obtunded; found to be positive for COVID; admitted; given Decadron, Remdesivir, ABX, O2 supplementation; AKI; found to have hepatocellular carcinoma and Hepatitis C; respiratory status worsened; transferred to ICU; Pt had a PEA arrest requiring cardiac resuscitation/intubation with mechanical ventilation; pt's condition worsened; developed pulmonary infarct hemothorax and empyema; thoracotomy and decortication; family made pt a DNR; condition deteriorated and pt passed away in the hospital

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS C	PFIZER\BIONTECH	Unknown	1387788-1	pernio, temporally associated with the second dose of Pfizer mRNA SARS-CoV-2 vaccine.; This is a literature report from the The journal of dermatology, 2021, doi: 10.1111/bjd.20404 entitled Pernio after COVID-19 Vaccination. A 64-year-old male presented to the emergency department in January 2021 with violaceous skin discoloration for 10 days that started on the left hallux and gradually spread to all toes on the bilateral feet. The patient received the second dose of the Pfizer COVID-19 vaccine 3 days prior to onset of the left toe discoloration. He denied hot or cold exposure, numbness, tingling, or pain. He denied history of pernio or other similar lesions, Raynaud's phenomenon, oral ulcers, photosensitivity, vascular disease, cardiac disease, hypercoaguable state, cardiac procedure, or autoimmune diseases. He denied previous or current symptoms of COVID-19 or exposure to those with COVID symptoms or a positive test. The estimated local prevalence of the virus was 7.6%. The patient had three negative COVID-19 PCR tests in the two months prior to presentation, and negative testing at presentation. The patient denied any adverse reactions after the first dose of the vaccine. The patient had painless, dark erythematous to violaceous discoloration of the bilateral toes, with an intact bulla on the left hallux. Abnormalities on initial laboratory studies included elevated C-reactive protein (CRP). The differential diagnosis included idiopathic pernio, connective tissue disease, hypercoagulable state, vasculitis/vasculopathy, COVID-19 infection, or reaction to the vaccine. Laboratory workup including Hepatitis B, Hepatitis C, HIV, ANA, ANCA, antiphospholipid antibodies, complements C3/C4/CH50, rheumatoid factor, and serum and urine protein electrophoresis was initiated to rule out other etiologies in the differential diagnosis. The key differentiating feature between COVID-19-associated pernio and idiopathic pernio is the lack of association with cold exposure. Idiopathic pernio was unlikely as the local weather was relatively mild; daily temperatures averaged 9 degree-20 degree C in the weeks before and after the lesions appeared. The patient was in stable condition and was discharged with clobetasol 0.05% ointment for the affected toes with plan to follow up in the outpatient dermatology clinic in two weeks. At follow up 15 days after initial presentation (28 days after vaccination), the clinical appearance of the toe discoloration was unchanged. The patient's symptoms were now exacerbated by cold temperatures and improved with rewarming and leg elevation. Laboratory workup was unrevealing. A punch biopsy of the left great toe was obtained, which revealed pathology consistent with pernio and immunohistochemistry (IHC) staining for SARS-CoV-2 of the tissue was negative. COVID infection remained a possibility. However, negative testing and lack of symptoms or contact with infected individuals argued against this. Thus, the final diagnosis was pernio, temporally associated with the second dose of Pfizer mRNA SARS-CoV-2 vaccine. The patient was counseled to use clobetasol as needed and avoiding cold exposure. This presentation suggests possible attribution of the pernio-like lesions to an immune response triggered by the COVID-19 mRNA vaccine, potentially similar to the immune response after Sars-CoV-2 itself, which also triggers pernio.; Sender's Comments: Based on the available public information and temporal association, the causal association cannot be excluded for the event Pernio, temporally associated with the second dose of Pfizer mRNA SARS-CoV-2 vaccine. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
				"Fulminantmyocarditis following coronavirus disease 2019 vaccination; This is a literature report. A 80 year-old female patient received bnt162b2 (BNT162B2), administration date 02Feb2021 (Batch/Lot number: unknown) as dose 1, single for covid-19 immunisation. Relevant medical history included: ""appendectomy"" (unspecified if ongoing); ""cholecystectomy"" (unspecified if ongoing); ""hysterectomy"" (unspecified if ongoing). The patient's concomitant medications were not reported. The following information was reported: MYOCARDITIS (hospitalization, medically significant), outcome ""unknown"", described as ""Fulminantmyocarditis following coronavirus disease 2019 vaccination"". The patient underwent the following laboratory tests and procedures: adenovirus test: (unspecified date) negative; alanine aminotransferase (8-45): (unspecified date) 167 IU/l; aspartate aminotransferase (2-40): (unspecified date) 323 IU/l; atrial pressure: (unspecified date) 45/32 mmHg; (unspecified date) 11 mmHg; biopsy: (unspecified date) revealed fulminant myocarditis, notes: with extensive myocyte damage out of proportion to the inflammatory infiltrates; blood albumin (3.2-4.6): (unspecified date) 4.1 g/dl; blood bilirubin (0.2-1.2): (unspecified date) 0.6 mg/dl; blood creatinine: (unspecified date) 2.05 mg/dl; blood creatinine (0.57-1.11): (unspecified date) 1.15 mg/dl; blood culture: (unspecified date) negative; blood lactic acid: (unspecified date) 5.8 mmol/L; blood pressure measurement: (unspecified date) 94/64 mmHg; blood sodium (135-145): (unspecified date) 133 mmol/L; brain natriuretic peptide (normal high range 265): (unspecified date) 1511 pg/mL; coronavirus test: (unspecified date) negative; coxsackie virus test: (unspecified date) negative; c-reactive protein (normal high range 8): (unspecified date) 37 mg/l; culture urine: (unspecified date) negative; cytomegalovirus test: (unspecified date) negative; electrocardiogram: (unspecified date) showed nonspecific st-segment and t wave abnormali, notes: and low voltage QRS complexes throughout; heart rate: (unspecified date) 98, notes: Beats per minute; hepatitis c: (unspecified date) negative; hiv test: (unspecified date) negative; human metapneumovirus test: (unspecified date) negative; influenza virus test: (unspecified date) negative; interleukin level: (unspecified date) 93.4 pg/mL; investigation: (unspecified date) negative; (unspecified date) 3.4, notes: Unit : lg/mL; (unspecified date) positive, notes: 1417 copies/mL; (unspecified date) negative; (unspecified date) negative; (unspecified date) negative; magnetic resonance imaging heart: (unspecified date) showed resolving myocarditis, notes: with normal biventricular function, persistent myocardial oedema, and significantly reduced burden of patchy mid-myocardial fibrosis in the LV; oxygen saturation: (unspecified date) 99 %; parvovirus b19 test: (unspecified date) negative; platelet count (140-440): (unspecified date) 158, notes: unit: thousand/mm3; polymerase chain reaction: (unspecified date) negative; procalcitonin (normal high range 0.5): (unspecified date) 0.16 ng/ml; pulmonary arterial wedge pressure: (unspecified date) 32 mmHg; red blood cell count (4-5.2): (unspecified date) 4.55, notes: Unit: million/mm3; respiratory syncytial virus test: (unspecified date) negative; sars-cov-2 test: (unspecified date) negative; (unspecified date) negative; sputum culture: (unspecified date) negative; stress echocardiogram: (2015) negative, notes: for ischaemia and showed normal left ventricular (LV) function; troponin i (normal high range 0.344): (unspecified date) 72.65 ng/ml; white blood cell count (4.5-11): (unspecified date) 5.2, notes: Unit: thousand/mm3. Therapeutic measures were taken as a result of myocarditis. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Based on the information available and close temporal association, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported events . The case will be reassessed once new information is available The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate."
HEPATITIS C	**PFIZER\BIONTECH**	**Unknown**	2161699-1	
HEPATITIS C	**PFIZER\BIONTECH**	**Unknown**	2225232-1	"This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) for a Pfizer sponsored program. The reporter is the patient. A patient (no qualifiers provided) received bnt162b2 (BNT162B2), administration date 20Nov2021 (Batch/Lot number: unknown) as dose 3 (booster), single, administration date 09Apr2021 (Batch/Lot number: unknown) as dose 2, single and administration date 17Mar2021 (Batch/Lot number: unknown) as dose 1, single for Covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: HEPATITIS C (medically significant), outcome ""unknown"", described as ""Hep C""; HEPATIC ENZYME INCREASED (non-serious) with onset 2021, outcome ""unknown"", described as ""No history of elevated liver levels enzymes etc. until after two vaccinations and the booster"". The patient underwent the following laboratory tests and procedures: hepatic enzyme: (2021) elevated. Therapeutic measures were taken as a result of hepatitis C. Clinical course: The patient asked Where can find copies of liver impact studies related to the Pfizer Vaccine. The patient do not fall into any of the categories related to risk for Hep C infection. Any guidance you can provide as to current clinical trials or studies would be appreciated. The lot number for bnt162b2 was not provided and will be requested during follow up."

Symptoms	Vaccine Manufacturer	Age	VAERS ID	Adverse Event Description
HEPATITIS C	PFIZER\BIONTECH	Unknown	2237626-1	"This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from medical information team for a Pfizer sponsored program. The reporter is the patient. A female patient received bnt162b2 (BNT162B2), administration date 20Nov2021 (Batch/Lot number: unknown) as dose 3 (booster), single, administration date 09Apr2021 (Batch/Lot number: unknown) as dose 2, single and administration date 17Mar2021 (Batch/Lot number: unknown) as dose 1, single for Covid-19 immunization. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: HEPATITIS C (medically significant), outcome ""unknown"", described as ""Now undergoing Hep C treatment"". Therapeutic measures were taken as a result of hepatitis C. Clinical information: No history of elevated liver levels enzymes etc. until after two vaccinations and the booster. Patient asked where he can find copies of liver impact studies related to the Pfizer Vaccine. The lot number for bnt162b2 was not provided and will be requested during follow up."
HEPATITIS C	PFIZER\BIONTECH	Unknown	2262945-1	"diagnosis of dermatomyositis, occurring in association with the COVID-19 vaccine; This is a literature report. A 77-year-old female patient received BNT162b2 (BNT162B2), as dose 1, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: DERMATOMYOSITIS (medically significant), 5 days after the suspect product(s) administration, outcome ""recovered"", described as ""diagnosis of dermatomyositis, occurring in association with the COVID-19 vaccine"". The patient underwent the following laboratory tests and procedures: Alanine aminotransferase (0-55): 154 IU/l, notes: elevated; Antibody test: remarkably elevated; Antinuclear antibody: No antibodies detected; Antinuclear antibody negative: No antibodies detected, notes: Jo-1; Aspartate aminotransferase (5-34): 256 IU/l, notes: elevated; Biopsy: revealed features of interface dermatitis with, notes: superficial perivascular mononuclear inflammation and dermal edema; revealed overexpression of major, notes: histocompatibility complex class I, inflammatory cells, necrotic fibers, and atrophic fibers organized in a perimysial pattern, suggesting an immune-mediated myopathy of a dermatomyositis type; Blood creatine phosphokinase (29-168): 2804 IU/l, notes: first day of presentation; 4476 IU/l, notes: 3 days; 1135 IU/l, notes: decreased significantly; Normalized, notes: 12 weeks after initial presentation; Computerised tomogram abdomen: No internal malignancy; Computerised tomogram pelvis: No internal malignancy; Computerised tomogram thorax: No internal malignancy; Enzyme level test: Normalized, notes: liver enzymes normalized twelve weeks after initial presentation; Flow cytometry: lymphoma disorder unremarkable; Hepatitis B: negative; Hepatitis C: negative; Additional cutaneous findings: included multiple vesicles and erythematous, notes: papules on the right upper extremity and reticulated, erythematous patches on both of her thigh; remarkably elevated; unknown results; showed basal vacuolar alteration with foci of, notes: necrotic keratinocytes; Mi2-a: No antibodies detected, notes: Mi2-alpha; No antibodies were detected, notes: Mi2-beta; No antibodies were detected, notes: PL-12; No antibodies were detected, notes: PL-7; physical examination: violaceous, poikilodermatous scaly plaques were, notes: observed on the anterior aspect of the neck and chest; Tuberculosis: negative. Therapeutic measures were taken as a result of dermatomyositis. She had received an initial dose of the COVID-19 vaccine 5 days before the onset of the symptoms. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Based on the available reported information, the causal association between the event dermatomyositis and the suspect drug BNT162B2 cannot be excluded."
HEPATITIS VIRAL	MODERNA	50-59 years	1463785-1	"Patient presents in fulminant liver failure. Per GI team documentation: ""We do not have an etiology for this acute liver injury. The differential diagnosis includes drug-induced liver injury, acute viral hepatitis, ischemic hepatitis, autoimmune hepatitis and indeterminate. Acetaminophen and salicylate levels are negative. Alcohol level is negative. Although patient does abuse alcohol on a daily basis, her presentation is not consistent with acute alcoholic hepatitis. Serologies have been sent to evaluate the differential diagnosis and other potential causes of acute liver injury. Liver imaging including Doppler ultrasound does not reveal any abnormality and there is no evidence of chronic liver disease."" We have found four case reports of hepatitis/autoimmune hepatitis related to mRNA vaccines. We have additionally had a case of fulminant liver failure in our community a few months back of which no other etiology was identified other then mRNA vaccine. Because of such, and with no other identifiable cause, we are concerned her acute sudden liver failure was vaccine induced."
HEPATITIS VIRAL	PFIZER\BIONTECH	60-64 years	1282520-1	62F with stage 2 mycoises fungoides, peripheral neuropathy, HTN, HLD, admitted from hepatology clinic on 3/25/21 for worsening liver injury and URI symptoms, found to be COVID positive. Liver biopsy with evidence of severe hepatitis with bridging necrosis. Course complicated by increase encephalopathy 3/31/21 concerning for acute liver failure, requiring stay in COVID ICU, transferred to hepatology service on 4/2/21. DDx remains viral hepatitis, autoimmune hepatitis, and drug-induced liver injury now on steroid therapy as of 3/31/21 and NAC. Pt. had worsening ALF and encephalopathy, transitioned to comfort care. Pt died early morning of 4/4/21

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

Notes:

Caveats: 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.

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.

Key considerations and limitations of VAERS data:

- 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.
- Reports may include incomplete, inaccurate, coincidental and unverified information.
- 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.
- VAERS data are limited to vaccine adverse event reports received between 1990 and the most recent date for which data are available.
- VAERS data do not represent all known safety information for a vaccine and should be interpreted in the context of other scientific information.

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. (/wonder/help/vaers.html#Suppress)

Data contains VAERS reports processed as of 05/06/2022. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. More information. (/wonder/help/vaers.html#Reporting)

About COVID19 vaccines:

- 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/ (https://covid.cdc.gov/covid-data-tracker/#vaccinations/).
- One report may state that the patient received more than one brand of COVID-19 vaccine on the same visit. This is a reporting error, but explains why the total number of reports may not equal the total number of COVID-19 vaccine doses.

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: May 19, 2022 8:48:13 PM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 05/06/2022, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on May 19, 2022 8:48:13 PM

Query Criteria:

State / Territory: The United States/Territories/Unknown
Symptoms: HEPATITIS; HEPATITIS A; HEPATITIS A ANTIBODY ABNORMAL; HEPATITIS A VIRUS; HEPATITIS A VIRUS TEST POSITIVE; HEPATITIS B; HEPATITIS B VIRUS; HEPATITIS C; HEPATITIS C POSITIVE; HEPATITIS INFECTIOUS; HEPATITIS VIRAL
Vaccine Products: COVID19 VACCINE (COVID19)
VAERS ID: All
Group By: Symptoms; Vaccine Manufacturer; Age; VAERS ID
Show Totals: False
Show Zero Values: Disabled