BABY DEATHS

after vaccination for COVID 19

Reported on VAERS May 1st 2021

1007832	02/06/2021	I developed swelling and hives over 75% of my body and was given a shot of Epi shot because my throat closed. I developed a weakened immune system from the vaccine. I am 8 week pregnant and developed a Blighted Ovum and I am currently going through a miscarriage to date. Rather not release any info regarding the pregnancy
959645	01/20/2021	I started having cramps Friday night and Saturday morning I started bleeding, by Saturday evening I was passing clots and tissue. ER doctor and nurses did tests and found I was having a miscarriage.
1215397	04/15/2021	4/1/2021 patient received JNJ Vaccine 4/12/2021 Miscarriage was confirmed on Ultrasound done by and also Right Pelvic vein thrombosis seen. 4/13/2021 Patient placed on Anticoagulation.
1235494	04/21/2021	pain in arm; Miscarried; No fetal heartbeat.; Menstrual bleeding; Pregnant; General sick and tired feeling; Did not want to get out of bed; Pretty tired; Headache; This spontaneous prospective pregnancy case was reported by a consumer and describes the occurrence of ABORTION SPONTANEOUS (Miscarried) in a 25-year-old female patient (gravida 1, para 1) who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Anxiety on 01-Jan-2010. Concomitant products included FLUOXETINE for Anxiety, PRENATAL VITAMINS [ASCORBIC ACID;BETACAROTENE;CALCIUM SULFATE;COLECALCIFEROL;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL ACETATE;RIBOFLAVIN;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;ZINC OXIDE] for Pregnancy, MISOPROSTOL (CYTOTEC) for an unknown indication. On 12-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. The patient's last menstrual period was on an unknown date and the estimated date of delivery was 15-Nov-2021. On 12-Mar-2021, the patient experienced EXPOSURE DURING PREGNANCY (Pregnant). 12-Mar-2021, the patient experienced MALAISE (General sick and tired feeling), FEELING ABNORMAL (Did not want to get out of bed), FATIGUE (Pretty tired) and HEADACHE (Headache). On 22-Mar-2021, the patient experienced VAGINAL HAEMORRHAGE (Menstrual bleeding). On 01-Apr-2021, the patient experienced FOETAL GROWTH ABNORMALITY (Baby had not grown). On 09-Apr-2021, the patient experienced ABORTION SPONTANEOUS (Miscarried) (seriousness criterion medically significant), FOETAL HEART RATE ABNORMAL (No fetal heartbeat.) and HEREDITARY DISORDER (Genetic issue). On 12-Mar-2021, EXPOSURE DURING PREGNANCY (Pregnant) had resolved. On 09-Apr-2021, ABORTION SPONTANEOUS (Miscarried), FOETAL GROWTH ABNORMALITY (Baby had not grown) and FOETAL HEART RATE ABNORMAL (No fetal heartbeat.) had resolved. At the time of the report, VAGINAL HAEMORRHAGE (Menstrual bleeding), MALAISE (General sick and tired feeling), FEELING ABNORMAL (Did not want to get out of bed), HEREDITARY DISORDER (Genetic issue), FATIGUE (Pretty tired) and HEADACHE (Headache) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Mar-2021, Ultrasound foetal abnormal: abnormal (abnormal) Had some bleeding and found out it was subchorionic hemorrhage. Bleeding is in another part of the uterus where is baby is not. On 01-Apr-2021, Ultrasound scan: abnormal (abnormal) Saw baby heartbeat but was informed baby had not grown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment information provided mentioned ultrasound and cytotec. Action taken with mRNA-1273 in response to the event was not applicable as patient took both doses of the vaccine. Patient reported that she does not blame Moderna, as her OB feels the miscarriage was related to a "genetic issue. This case was linked to MOD-2021-060699 (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 13-Apr-2021: Patient updated AE and mentions fetal complications resulting in miscarriage. Events and outcome of case thus updated with new information.; Sender's Comments: Based on the current available information and the temporal association between the product use and the start date of the events a causal relationship cannot be excluded.

975126	01/26/2021	G2P0, 5w5d; The patient is calling with vaginal bleeding in pregnancy. Calling with c/o dizziness with headache; Has a history of migraines; States she has subclinical hypothyroidism. Has tried Tylenol 500 mg for headache that worked for a little while; She denies vomiting, but does have nausea; Will try to increase water and protein intake; Will let us know if she gets worse/vision changes and will check in with PCP as they wanted to do a VV if dizziness got worse. Bleeding continued into following day. Documented as likely / threatened miscarriage.
932028	01/09/2021	Miscarriage at 6 weeks pregnant
967169	01/22/2021	Miscarriage? around 7 weeks pregnant at the time of vaccine, estimated delivery date was 8/19/2021
1006011	02/05/2021	Miscarriage; The mother reported she became pregnant while taking bnt162b2; The mother reported she became pregnant while taking bnt162b2; This is a spontaneous report from a contactable consumer reported for herself. A 27-year-old female patient (Pregnant) received first dose of bnt162b2 (lot number: EL3248), via an unspecified route of administration in left arm on 16Jan2021 16:30 at single dose for covid-19 immunization. Medical history included asthma, covid-19 from an unknown date and unknown if ongoing. The patient's concomitant drug included prenatal vitamins. The patient experienced miscarriage on 21Jan2021 with outcome of recovering. The event was reported as non-serious. The adverse event result in emergency room/department or urgent care. No treatment received for the adverse event. The mother reported she became pregnant while taking bnt162b2. The mother was 8 weeks pregnant at the onset of the event. The mother was due to deliver on 19Aug2021. Last menstrual date: 22Nov2020. Facility where the most recent COVID-19 vaccine was administered: Hospital. The patient was not received any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient hadn't been tested for COVID-19. Not known allergies to medications, food, or other products.
1220313	04/16/2021	Spontaneous Abortion. Miscarriage started on it's own at home. Bleeding lasted 14 days, then turned to excessive hemorrhaging and ended up getting an emergency D&C. Was 10 weeks pregnant at time of miscarriage. EDD was 10/23/2021.
1010113	02/07/2021	Miscarriage - first vaccine at 10 weeks and 3 days with prior proof of heartbeat/movement, second vaccine at 13 weeks and 3 days; learned of miscarriage at 14 weeks 3 days with measurements of 12 weeks 3 days on U/S
1023866	02/11/2021	Miscarriage at 6 weeks 1 day. Vaginal bleeding and decline in HCG hormone. Pregnancy not viable.

1035009	02/17/2021	embryonic demise/loss of pregnancy; patient was pregnant at the time of vaccination of the second dose; patient was pregnant at the time of vaccination of the second dose; This is a spontaneous report from a contactable healthcare professional. A 28-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EL1284), intramuscular in the left arm on 12Jan2021 at 08:00 at a single dose, received in the Doctor's office/urgent care for covid-19 immunisation. Medical history included anxiety and allergies: gets hives from anything cold (fluid, food, air) that touches her. Concomitant medication included venlafaxine for anxiety. The patient was pregnant at the time of vaccination of the second dose, last menstrual date was 23Nov2020, delivery date was 30Aug2021, gestation period was 7 weeks. The patient experienced embryonic demise/loss of pregnancy in Jan2021, patient was hospitalized for 1 day and treatment was received for the event. The patient underwent lab tests and procedures which included didn't see a fetal heartbeat at 6 week on u/s, and 7 weeks still no heartbeat on u/s, HCG didn't go down until second u/s, so fetal demise occurred between 6 -7 weeks, D&C performed and no genetic abnormalities were found in fetal tissue. Doctor and patient, who is a nurse, do not think the fetal demise is related to the vaccine, but wanted to document the loss for data in case they would start to see a trend. The patient does not intend to pursue further investigation into the vaccine as a cause. After the first dose (received on 21Dec2020 at 08:00, the patient had a sore arm and then two days later found out she was pregnant. The doctor discussed with patient and pharmacist whether to get second dose. Patient is a nurse and decided to get second dose. No major symptoms were reported after second dose until the miscarriage. The patient recovered from the event with lasting effects/sequel.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.
1038491	02/18/2021	Patient was newly pregnant, received 2nd dose of covid vaccine. Patient then began bleeding on 2/13/21. On 2/15/21 confirmed with OBGYN that HCG levels were low and that she was having a miscarriage. Patient has a healthy 2 year old living child. No past history of miscarriages, no family history of miscarriage.
1047157	02/22/2021	Miscarriage at 8 weeks of pregnancy, 2/14/21. Tissue passed naturally without medical intervention. Hormone levels dropped without concern. The week prior to miscarriage sharp sporadic headaches (migraine-like but only lasting a few minutes at a time and coming frequently) started, and have continued daily through today (2/22/21)
1146214	03/30/2021	Was 5 weeks pregnant at time of vaccine with strong HCG levels, approximately 2 weeks after vaccination patient suffered a miscarriage. Vaginal bleeding, cramping and passed large clots including a sac like tissue.
1210176	04/14/2021	Patient had miscarriage with 5 month stillborn baby
949729	01/15/2021	Miscarriage. Expected due date in August 2021. No prior pregnancy history.
962952	01/21/2021	Miscarriage

965558	01/22/2021	Miscarriage; pregnant patient received the vaccine; pregnant patient received the vaccine; This is a spontaneous report from a contactable nurse (patient). This pregnant 29-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number EK5730), intramuscular at single dose in the left arm on 20Dec2020 for COVID-19 immunisation. Medical history included none. Concomitant medication included venlafaxine. The patient experienced miscarriage (medically significant) on 09Jan2021 with outcome of recovering. Treatment unknown. The event required a visit to the emergency room. The patient was pregnant while taking BNT162B2. The patient was 4 weeks pregnant at the onset of the event. Patient last menstrual period date was 27Nov2020. The pregnancy due to deliver was on 03Sep2021. The vaccine was administered at Workplace Clinic. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. She received the second dose of BNT162B2 (Lot number EL0142), intramuscular in the left arm on 13Jan2021.; Sender's Comments: Based on the temporal relationship, the association between the event miscarriage with BNT162b2 can not be complete 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.
1051018	02/24/2021	After the vaccine the patient miscarried the baby; This is a spontaneous report from Pfizer-sponsored program via a contactable pharmacist. A 29-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; batch/lot number and expiration date unknown), 0.3 ml via an unspecified route of administration on 15Jan2021 at 10:00-11:30am as a single dose for COVID-19 immunization, administered in the right arm. Patient has no past medical history. Concomitant medication includes One-a-day vitamin, Ongoing. No prior Vaccinations within 4 weeks prior. First Day of Last menstrual period: 6-13 Dec2020. Patient reports one previous pregnancy: full term live birth via vaginal birth with epidural at 40 weeks and 1 day. The father used marijuana, at an unspecified frequency. Patient was unaware that she was pregnant, guesses she was about 3 weeks when she got the first shot of the vaccine. Ten days after the vaccine, the patient miscarried the baby. The clinical outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Miscarriage of pregnancy cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
1195464	04/11/2021	Patient was about 15 weeks pregnant and this was her first pregnancy. Her anticipated due date was Oct 1st 2021. On April 9th 2021 during a scheduled doctor visit at 3pm both baby and mother were in good health. On the same evening after the appointment she went for vaccination at Pharmacy and received the J&J vaccine. After receiving the vaccine in about 15 mins she felt like urinating and noticed blood in the urine and felt vaginal dilation. Within the next 15 to 20 mins she started experiencing mild labor pains and contractions. In the next 30 mins she started bleeding and was immediately taken to the ER. In the ER it was confirmed that she was having a miscarriage and the fetus was delivered. She also had to undergo emergency surgery to remove any remaining placenta in the uterus.

947096	01/15/2021	15 weeks pregnant, due date 7/4/21. Fourth pregnancies one two year old, two miscarriage's. My left arm became super tender, I woke up with significant joint pain in my right knee. I almost couldn't walk, it was chronic pain when I tried to walk. It lasted about 24 hours and went away. I did inform my OB.
956263	01/19/2021	I received the vaccination on 1/14 and started to get an itching sensation that night - nothing noticeably or concern and was able to go to sleep. The next morning I was very itchy and red and started to break out in hives that started to get worse and spread through my body. I took Benadryl throughout the day and at night to help my sleep. On Saturday morning my eyes were swollen and red, I had severe hives all over my body and had to go to the ER for some type of relief. This was immediately after I woke up, the right side of my body was extremely hot and I went to the restroom and looked in the mirror and didn't recognize myself. At the ER, they put me on Prednisone - to take 2 tablets for 3 days, Famotidine - taking 1 tab, 2 times a day for 5 days, and Benadryl, 1 tab, 3X a day until the symptoms subside - It is currently 1/19 and my skin will start to heat up, primarily in my hands and start to itch, but no more hives or anything severe. I am currently pregnant with my first child, due date 7/7/2021. I have had no previous pregnancies, miscarriages, or abortions.
986501	01/29/2021	7:00 pm that night, my arm started to hurt very intensely and then the next day when I woke up and it hurt - felt like it broke my arm. It hurt really bad - couldn't left it or move it. I took Tylenol once or twice that day with six hours in between. I was a little bit drowsy and headache and a little bit nauseous. So I slept that day. I felt like my arm got hit by truck. 10th - I felt better that day. By Monday, the 11th, I was totally fine. Pregnancy: I'm due May 29, 2021; I have had a miscarriage before so it's my second pregnancy. So far everything has been normal.
1070733	03/03/2021	miscarriage; This is a spontaneous report from a contactable nurse (patient). A 30-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), 2nd dose on 08Jan2021 in right arm and 1st dose on 15Dec2020 in left arm, both via intramuscular at single dose for COVID-19 immunisation. The patient medical history was not reported. The patient previously took amoxicillin and experienced allergy. Concomitant medication included prenatal vitamins. The patient experienced miscarriage on 11Jan2021 with outcome of recovered. The event resulted in doctor or other healthcare professional office/clinic visit. The mother reported she became pregnant while taking bnt162b2. The mother was 11 weeks pregnant at the onset of the event. The mother was due to deliver on 07Aug2021. Date of LMP was 26Oct2020. Therapeutic measures were taken as a result of miscarriage included misoprostol (CYTOTEC). Information of lot/batch number has been requested.; Sender's Comments: The limited information provided precludes a full clinical assessment of the case. Considering the product-event temporal relationship, a causal association between the reported 'miscarriage' and the administration of bnt162b2 cannot be completely excluded. Case will be reassessed once with additional 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.
1124657	03/22/2021	Received 2nd dose of covid vaccine at 11 weeks, 6 days. Had follow up normal ultrasound at 12 weeks, 2 days. Missed miscarriage noted at 15 weeks, 1 day. Last measurement of baby noted to be 12 weeks, 6 days. Closely monitored during first trimester with no abnormalities noted. Normal ultrasound at 12 weeks, several days after baby stopped growing with fetal demise at some point there after

1135569	03/25/2021	Early miscarriage; This is a spontaneous report from a contactable other health care professional (Patient). A 30-year-old female patient (pregnant, last menstrual date 19Jan2021, Delivery date: 26Oct2021, Gestational period 4 weeks) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL9269), via an unspecified route of administration on right arm on 19Feb2021 at 15:15 at the age of 30 years old at a single dose for COVID-19 immunisation at hospital. The patient's medical history included rheumatoid arthritis. There were no known allergies. Concomitant medications included prenatal vitamin. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient received other medications within 2 weeks of vaccination. The patient experienced early miscarriage on 01Mar2021. No treatment was received in response to the adverse event. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, patient was not tested for COVID-19. The patient was recovering from the event. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Pending the limited information on clinical course, the company does not attribute the event early miscarriage to BNT162B2. The detailed document of pregnancy, relevant risk factors, status of rheumatoid arthritis are missing for a medically meaningful assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.
917595	01/02/2021	I was about 6 weeks pregnant when I received the vaccine on 12/26/20. I had a miscarriage on 1/1/21. I have a pregnancy history of one prior healthy full term pregnancy in 2019.
953086	01/18/2021	I had a very early miscarriage at five weeks; I had a very early miscarriage at five weeks; I had a very early miscarriage at five weeks; This is a spontaneous report from a contactable Physician (patient). A 31-year-old female patient received BNT162B2 first dose of (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EJI685) intramuscular at arm right on 19Dec2020 06:30 at single dose for covid-19 immunization. Facility type vaccine was hospital. Medical history was none. The patient had no known allergies or other medical history. There were no concomitant medications. No other vaccine in four weeks and no other medications in two weeks. The patient experienced a very early miscarriage at five weeks on 01Jan2021. The event result in doctor or other healthcare professional office/clinic visit. No treatment received. The outcome of the event miscarriage was recovered in Jan2021. No covid prior vaccination and no covid tested post vaccination.; Sender's Comments: All pregnancies have a risk of birth defect, loss, or other adverse outcomes. The data on BNT162B2 administered to pregnant women is insufficient to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.
960019	01/20/2021	miscarriage, estimated 5 weeks
964070	01/22/2021	Hi, I actually not sure if the couse of my problem was couse by the Vaccine given to me on January 17 2021. At the time of the injection given to me I was pregnant don't know how long because I just had found out about it. I took the injection because I wanted to be safe for the health of my baby and my family..am just curious about the side effect of this covi19 vaccine. On January 19 I started seen some spot of blood at first I thought it was nothing to worried about but then around 8am I that day I saw that I was bleeding more and more not a crazy bleeding but I ended up at the emergency room on January 19 around 3:45pm. To find out that I was having a miscarriage..so now I don't know if this was couse by the injection or not. Am just worried that these is a side effect of this injection and nobody knows about it. Please reply me back I want to know more I already have both covi19 vaccine.

966887	01/22/2021	Miscarried at 7.5 weeks between vaccination #1 and #2. I do not believe the vaccine was a cause, however, it was recommended to report just in case. This was a second pregnancy, first miscarriage. EDD was 9-1-2021. First pregnancy was uncomplicated. Pregnancy tests were negative prior to receiving the first vaccine and then turned positive on 12-29-2020 (5 days after getting first vaccine.)
1047536	02/22/2021	Received vaccine on 02/02, 4 weeks pregnant on 02/03 02/03-02/05: Severe lethargy, tiredness, pain at injection sites, fever all lasting 48 hours. Symptoms subsided after taking tylenol on 02/05. I'm not attributing this to the vaccine, but on 02/12, my hcg started to plateau and decline, no egg yolk or fetal pole was seen at 6 weeks (2/17). Sac was measuring at 5 weeks. I eventually had a miscarriage on 2/21
1048833	02/23/2021	~ 5 weeks pregnant at the time of 2nd vaccination. Miscarriage ~2 weeks later. Transvaginal ultrasound shows gestational age only 5 weeks when should have been 7. HCG level reflects only 4-5 weeks when should have been 7.
1057557	02/26/2021	Miscarriage 8 days after receiving 2nd vaccine at 6 weeks pregnant; receiving 2nd vaccine at 6 weeks pregnant; receiving 2nd vaccine at 6 weeks pregnant; This is a spontaneous report from a contactable other healthcare professional (patient). A 31-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot/batch number not reported, via an unspecified route of administration in the left arm on 28Jan2021 08:30 at a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) in the left arm on 07Jan2021 at 09:00 AM for COVID-19 immunization. Patient was pregnant. Patient has no other vaccines in four weeks and no other medications in two weeks. Patient has no COVID prior vaccination and no known allergies. On 05Feb2021 at 06:00 PM, patient experienced miscarriage 8 days after receiving 2nd vaccine at 6 weeks pregnant. No treatment received for the event miscarriage. The event resulted in doctor's office/clinic visit. The patient was not tested for COVID post vaccination. The outcome of the event miscarriage was recovering. Information on the lot/ batch number has been requested.; Sender's Comments: Based on the compatible temporal association, a possible contributory role of the vaccination with BNT162B2 in triggering the onset of miscarriage in this patient at 6 weeks pregnant cannot be excluded. Additional information regarding relevant medical history, concomitant medications and detailed clinical course around the event onset will aid in comprehensive assessment of the case. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.

1104214	03/16/2021	I was 9 weeks and 2 days pregnant with my first pregnancy (no history of miscarriages) when I received my first dose of the Moderna vaccine on 1/9/2021. I had a routine appointment with my OB-GYN the day prior, 1/8/2021, during which they completed a routine ultrasound. At that time, the ultra sound was completely normal with a healthy fetus and heart rate, and my due date was estimated to be 8/13/2021. Also at that time, I was advised by my OB-GYN to get the COVID vaccine, when offered to me, given my higher risk of contracting COVID due to my job as a healthcare worker with direct patient contact, and my higher risk for more severe illness if I contracted COVID due to pregnancy. I received the vaccine the next day with no immediate adverse reactions/events aside from some considerable arm soreness at the site of the vaccine and fatigue. Then 2 weeks and 6 days later I had another routine appointment with my OB-GYN (1/29/2021) at which point in time I was 12 weeks and 1 day pregnant. During this visit they conducted a second routine ultrasound. From this ultra sound they identified multiple abnormalities including an increased nuchal translucency of 3.5 mm, absent nasal bone, and presence of fluid around the fetus?s abdomen. These abnormalities were concerning for a chromosomal/genetic abnormality. Given these concerns I had labs drawn for maternal carrier screening (the Panorama and the Horizon 274), and I was referred to maternal fetal medicine for further imaging and testing. The results of the lab work took approximately 2 weeks to receive, but they came back normal without increased risk identified for any of the chromosomal/genetic conditions tested. I was seen by a high risk doctor and a genetic counselor within the maternal fetal medicine department on 2/2/2021. At this appointment I had a third ultrasound completed which confirmed the presence of an increased nuchal translucency now 4.3mm, and also found the presence of a cystic hygroma. These findings were again consistent with concerns for a chromosomal, genetic or other anatomical/structural condition and as such I had a chorionic villus sampling done that same day to assess the DNA of the fetus. These results also came back all normal without concern for any of the chromosomal or genetic conditions tested. I then had a follow up appointment and ultrasound with the maternal fetal medicine department on 2/19/2021, at which point I was 15 weeks and 1 day pregnant. This early anatomical scan revealed even more concerning findings with the fetus?s humerus measuring in the 1st percentile for gestational age and the fetus?s femur measuring in the 3rd percentile for gestational age. Per consultation with our genetic counselor this was indicative or some severe condition; however, it was not clear exactly what condition. Given the severity of the findings it was recommended to terminate the pregnancy. As such I had to undergo a dilation and evacuation procedure on 2/24/2021. We are currently still awaiting results of further genetic testing (exome testing), the results of which can take 2-3 months from the time of sending out the labs (sent out around 2/24/2021).
1128192	03/24/2021	Pregnant with second child at first and second dose of the covid vaccine. Due date was 10/15/2011. I experienced a miscarriage at 9 weeks pregnant on 3/17/2021.
1137248	03/26/2021	I had a miscarriage on 3/23/2021 at 6.4 weeks pregnant. I received the vaccine when I was about 4 weeks pregnant. My estimated due date was Nov. 13, 2021. I went to the doctor to get blood drawn to test progesterone and HGC levels. That evening, I miscarried. We are doing testing to see what may have caused the miscarriage but I have not had a miscarriage in the past. On Sept 9, 2020 I experienced a chromosomal stillbirth of a baby boy. His death was due to triploidy which is a fatal chromosomal abnormality.

1143480	03/29/2021	Miscarriage; spotting; This is a spontaneous report from a contactable nurse (patient). A 31-year-old female patient received her second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3249), intramuscular at right deltoid on 04Feb2021 at single dose for COVID-19 immunization. Medical history was reported as none. She has no known allergies and has no COVID prior to vaccination. Concomitant medications included folic acid, iron (PRENATAL) and fluoxetine. The patient has no other vaccine in four weeks. The patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Ek9231) at the age of 31-years-old, intramuscular at right arm on 14Jan2021 at 12:30 at single dose for COVID-19 immunization. The vaccine was administered in a hospital. The patient was pregnant, her last menstrual period was on 19Dec2020. Her expected due date is on 25Sep2021 and gestational period was 7 weeks (also reported as 3). The patient experienced miscarriage and spotting on 09Feb2021 which resulted in doctor or other healthcare professional office/clinic visit. She was not tested for COVID post vaccination. The outcome of the events was recovering.; 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 miscarriage and vaginal hemorrhage due to temporal relationship. However, the reported events may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
922443	01/06/2021	Vaccine administered on 12/29, severe burning while injecting and for 5-10 seconds after injecting. 12/30 noticed lesion on upper arm in area of injection- erythematous, warm, pruritic, raised area, about 4x4cm. No change until 1/5. 1/5: 7.5x4cm lesion, increased pruritus, warm, erythematic, and 3-5 pin-head sized vesicles with clear exudate formed on the medial side of lesion. Pregnancy history- 4 pregnancies in past 12 months with no live births. 2 miscarriages and 1 ectopic. LMP 12/12/20, patient was pregnant at time of injection but unaware.
923743	01/06/2021	I had a miscarriage on 01/01/2021 Estimated date of Delivery 09/7/ 2021
936919	01/12/2021	G3 P1 mother, estimated gestational age of baby = 4 weeks. On day 4 post-vaccine (1/11/21) started with heavy bleeding and labs confirmed miscarriage.
943837	01/14/2021	Approximately 5 days after administration at 6 weeks pregnant, I began bleeding. The following day (6 days after administration) miscarriage was confirmed via ultrasound
970490	01/25/2021	Miscarriage
985511	01/29/2021	1/4 - RECEIVED MODERNA VACCINE, PREGNANCY TEST CAME OUT NEGATIVE. 1/8 - PREGNANCY TEST CAME OUT POSITIVE 1/18 - HAD MISCARRIAGE, SAW TISSUE, NEGATIVE PREGNANCY HOME TEST, NEGATIVE HCT

1010528	02/08/2021	unfortunately she had a miscarriage about 5-6 days before her second dose; positive pregnancy test a few days after the first dose.; positive pregnancy test a few days after the first dose.; This is a spontaneous report from a contactable consumer. A 32-year-old female patient (3 weeks pregnant at time of vaccination) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231), via an unspecified route of administration on left arm on 31Dec2020 at single dose for covid-19 immunisation. The patient medical history was not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included iron and minerals nos, vitamins nos (PRENATAL VITAMINS). The patient had a negative pregnancy test in 2020 before getting the first vaccine dose, but then had a positive pregnancy test in Jan2021 a few days after the first dose, but unfortunately she had a miscarriage in Jan2021, about 5-6 days before her second dose. She has an appointment scheduled with OBGYN for the miscarriage. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the miscarriage was recovering.; Sender's Comments: Based on the temporal relationship, the association between the event miscarriage with BNT162b2 can not be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
1028368	02/13/2021	Miscarriage in first trimester. First dose received 12/22/2020 Conception date 01/03/2021 Second dose 01/27/2021 Miscarriage started 02/03/2021 First pregnancy. No other medical problems or pregnancy risks.
1033516	02/16/2021	At the time of administration of the first does of Moderna vaccine, I was 6 weeks pregnant. I had confirmed pregnancy with home positive test and missed period. I had an estimated due date of 9/24/2021. This was my 4th pregnancy. I have had two uncomplicated pregnancies to term. In September 2020 experienced a chemical pregnancy with early pregnancy loss at 5 weeks. The first 24 hours after 1st dose of vaccine I experienced extreme arm soreness in the arm that was vaccinated, causing headache and unable to sleep. After 24 hours I felt "normal". 2 weeks and 3 days following the first dose of Moderna, I had a miscarriage. On the night of 2/15/21 I lost the pregnancy with vaginal bleeding, bright red blood, passing tissue, clots/ sac. I had an uneventful pregnancy up to that point, feeling well as I had with prior pregnancies.
1044756	02/21/2021	I received my first dose of the COVID19 Pfizer vaccine on 12/30/20. At this point I was 4 weeks pregnant. I received my second vaccine dose for the series on 1/22/21. At this point I was 7 weeks pregnant. On 2/18/21 I was diagnosed with a miscarriage due to no fetal heartbeat on ultrasound. I now have to undergo a D&C in the operating room.
1045927	02/22/2021	positive at home pregnancy test 2/4/21 (same date as vaccine given). However, light bleeding/spotting started that night/next day but thought still normal. Heavier bleeding started 2/6/21 (Saturday) and continued through the weekend. Made appointment at hospital lab for Monday 2/8 to check HcG levels in blood. See below for details, but Dr. suggested repeat blood work on 2/10 as Hcg levels showed positive pregnancy, but very low. 2/10 Hcg levels slightly lower, which confirmed early miscarriage occurring.
1141203	03/28/2021	Moderna COVID?19 Vaccine EUA Received 1st vaccine Dec 29, 2020, received 2nd vaccine while unknowingly pregnant on January 27, 2021. Had chills, fatigue, body aches night of 2nd vaccination. Found out pregnant Feb 7, 2021 at 4 weeks pregnant. Had blighted ovum/anembryonic pregnancy with miscarriage March 12, 2021.
955432	01/19/2021	I had vaginal bleeding and receive a Ultra sound. Which I had a miscarriage. My estimated delivery was August 25,2021.
987914	01/30/2021	Received COVID vaccine on Friday afternoon, 1/22, developed some slight abdominal cramping 1/24 and 1/25, had severe abdominal and back pain resulting in miscarriage evening of 1/25. Estimated date of delivery: August 27, 2020 Also had known subchorionic hematoma, diagnosed on 1/19 via ultrasound at physician's (OBGYN) office

990450	02/01/2021	Miscarriage after 2nd vaccine.; Miscarriage after 2nd vaccine.; Miscarriage after 2nd vaccine.; Miscarriage after 2nd vaccine.; This is a spontaneous report from a contactable nurse reported for herself. This 33-year-old female patient received the 2nd dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Es1686), via intramuscular at left arm on 11Jan2021 08:00 am at single dose for COVID-19 immunisation. Medical history was unknown. Concomitant medications were none. The patient previously received the 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Ej1685) intramuscular at left arm on 21Dec2020 10:15 AM for COVID-19 immunisation. The patient had no known allergies. The patient had no other vaccine in four weeks, no other medications in two weeks. The patient was pregnant. Last menstrual date was 14Dec2020. Delivery due date was 16Sep2021. Gestation period was 3 weeks. The patient experienced miscarriage on 16Jan2021 after 2nd vaccine. AE resulted in congenital anomaly or birth defect. The patient had no COVID prior vaccination. The patient had COVID tested/nasal swab post vaccination with negative results on 11Jan2021 and 13Jan2021. Outcome of the events was unknown.; Sender's Comments: Based on the available information, a causal relationship between event miscarriage after the second COVID-19 vaccination and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
1087526	03/10/2021	I received my second vaccination in the morning on 02-04-21. I visited my OBGYN that afternoon learned that I was approximately seven weeks pregnant, and that my baby was healthy with a heartbeat, I returned to the OBGYN four weeks later for my routine visit and leaned that the fetus had died around week 8, which was approximately one week after receiving the vaccine. I had no other issues or complications that would have contributed to my miscarriage.
1159039	04/02/2021	Miscarriage 6 days after vaccination
1163402	04/03/2021	Miscarriage - due date was 10/16/2021
922289	01/06/2021	I suffered a miscarriage on 12/31/2020. I was at 5 weeks gestation. This was my first pregnancy. I had uterine bleeding and abdominal cramps on 12/31/2020 and underwent evaluation by my Obstetrician and was diagnosed with a miscarriage after ultrasound.

925639	01/07/2021	Miscarriage; patient was pregnant while taking BNT162B2; patient was pregnant while taking BNT162B2; This is a spontaneous report from a contactable Other Health Professional. A 34-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0140), intramuscularly on 22Dec2020 06:00 AM at single dose at Arm Right at Hospital for COVID. Medical history included ongoing sleep apnoea. There were no concomitant medications. There were no allergies to medications, food, or other products. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient did not receive any other medications the patient received within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient experienced miscarriage on 29Dec2020 13:00. The patient was pregnant while taking BNT162B2. The patient was 4 Weeks pregnant at the onset of the event. Patient last menstrual period date was 24Nov2020. The Pregnancy due to deliver was on 07Sep2021. The pregnancy resulted in spontaneous abortion. Since the vaccination, the patient has been tested for COVID-19 on an unknown date with unknown results. Nasal Swab on 28Dec2020 was Negative. There was no treatment received for the adverse event. The outcome of event was recovering.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to agency, Ethics Committees, and Investigators, as appropriate.
970929	01/25/2021	A miscarriage was determined on 1/18/2021. There is no history of miscarriages.
985993	01/29/2021	Previously G1P1, delivered normal healthy baby July 20, 2020. Second pregnancy conception 12/15/2020. First vaccine dose 12/22/2020. Vaginal bleeding started 1/2/2021 and tapered down 1/4/2021. Light bleeding continued 1/4/2021 - 1/18/2021. Second vaccine dose administered 1/12/2021. Bleeding increased from light/none to medium flow on 1/19/2021 - 1/22/2021. Home urine pregnancy tests positive x 2 on 1/22/2021. HCG 56 mIU/mL and progesterone 0.5 ng/mL on 1/22/2021. HCG 17 mIU/mL and progesterone <0.5 ng/mL on 1/25/2021. Bleeding decreased to light flow 1/22-1/25 and gone 1/26/2021. Dr. diagnosed as early pregnancy loss/miscarriage.
1031823	02/15/2021	The patient, who is my wife, went into preterm labor and delivered at 30 weeks and 3 days. Date of delivery was 2/9/21. EDD was 4/17/21. My wife is a G3P2. She had a very early miscarriage in 2016. She delivered a healthy child at 37 weeks and 3 days in 2018. During this current pregnancy, all prenatal visits, tests, and scans were unremarkable. Based on a gross examination of the placenta and a review of all clinical data by the patient's OBGYN, there was no obvious stimulus for the preterm labor. Fortunately, the baby is doing ok in the NICU at hospital.

1065910	03/02/2021	Miscarriage; Received vaccine when pregnant; A spontaneous report was received from a 34-year old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) when pregnant and experienced a miscarriage. The patient's medical history included three prior pregnancies, with two live births and one miscarriage. Products known to have been used by the patient, within two weeks prior to the event, included prenatal vitamins and doxylamine succinate/pyridoxine hydrochloride. The patient received their first of two planned doses of mRNA-1273 (Batch number: 011J20A) on 30 Dec 2020. On 27 Jan 2021, the patient received their second of two planned doses of mRNA-1273 (Batch number: 028L20A) intramuscularly for prophylaxis of COVID-19 infection. At 7 weeks gestation, the fetus had a normal heart beat. She reported that she had no complications with the pregnancy. On 08 Feb 2021, the patient had a miscarriage. Treatment information was not provided. The patient received both scheduled doses of mRNA-1273; therefore, action taken with the drug in response to the event is not applicable. The events received vaccine when pregnant and miscarriage were considered recovered.; Reporter's Comments: This report concerns a 34-year-old, P2G4 who experienced miscarriage 1 month 9 days post administration of first dose and 12 days after the last dose of mRNA-1273 vaccine. There is not enough information such as the last menstrual period, estimated date of conception and delivery and gestational age at the time of miscarriage. In addition, the patient's detailed medical history including any trauma and reason for previous miscarriage is lacking. Vaccine exposure during pregnancy is assessed as not applicable.
1071787	03/04/2021	Miscarriage after 2nd dose given
1107257	03/17/2021	Miscarriage; Pregnant at time of vacciation; Pregnant at time of vacciation; This is a spontaneous report from a non-contactable consumer. A 34-year-old female patient (16 weeks pregnant at time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 29Jan2021 (at the age of 34-years-old) as a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient experienced miscarriage at a routine OBGYN visit on 19Feb2021. The patient was hospitalized for the miscarriage on an unknown date for 2 days. The clinical outcome of the event miscarriage was unknown. The patient had not had COVID prior to the vaccination and has not tested positive post vaccination. Information about lot/batch has been requested.
1113942	03/19/2021	miscarriage; pregnant patient received BNT162B2; pregnant patient received BNT162B2; This is a spontaneous report from a non-contactable consumer. This consumer (patient) that a 34-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: en6201) at the age of 34-years, via an unspecified route of administration on 20Feb2021 at single dose for COVID-19 immunisation. Medical history was not reported. Patient was pregnant at time of vaccination, last menstrual date was 21Jan2021. No other vaccine in four weeks, no COVID-19 prior vaccination. Concomitant medication included ustekinumab (STELARA). The patient experienced miscarriage on an unspecified date (on 03Feb2021, as reported). The pregnant patient received BNT162B2 on 20Feb2021. No COVID-19 tested post vaccination. Outcome of the event was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021238716 Same product and AE , different patient
950091	01/16/2021	I was 5 weeks pregnant when I got my first dose of the Pfizer covid-19 vaccine. I miscarried 4 days later. I do not know if the vaccine contributed to my miscarriage but wanted to contribute to the existing data. I had no other side effects or symptoms other than soreness at the injection site. There were no complications with the miscarriage.
1107944	03/17/2021	After Dose1 I was 10 weeks pregnant went to doctor for sonogram. I went to doctor heart rate 160 doctor stated everything was fine I could start telling everyone I wa pregnant. On 2/5 I started having a miscarriage the fetus was 12 weeks. My blood work was good no abnormalities from the enzymes.(estimated of delivery 8/17/2021)

1205095	04/13/2021	6hrs after the vaccine I started having chills, body aches, light headed, & headache. Also at the same time I started spotting which I found out it was the symptoms of a miscarriage. On 04/11/2021 I continued with the same symptoms then later on that night i started feeling dizzy the bleeding continued. Around 2am on 4/12/2021 I was bleeding a lot & at 7am I went to the ER and they confirmed I had a miscarriage. I was 11 weeks pregnant. My estimated delivery date was 10/28/2021. On my previous appointments they said everything was going good with my pregnancy the only complication was hyperthyroidism which I had been taking medication for.
950562	01/16/2021	9 days after vaccine, I had a miscarriage. I was 5 weeks pregnant at that time. I had confirmation lab test 2 weeks prior of pregnancy and had labs with bhcg lower at time of bleeding to confirm miscarriage
1130755	03/24/2021	On 02-26-2021 I had a miscarriage, I found out my fetus had died during a pre-natal doctor's appointment. My fetus had expired before I received the first dose Pfizer vaccine. I believe it was coincidental and the Pfizer vaccine did not cause the miscarriage. After my miscarriage I was under heavy medication.
1179680	04/08/2021	Note: Very difficult to read product name and/ Manufacture Lot number secondary poor handwriting so there may be an error there. Healthy pregnancy this far. Was fourth pregnancy for patient with no history of prior miscarriage. No bleeding etc. prior to event or following event. Fetus was found to have no heart beat at well visit on 4/1. Ultrasound records reported fetus stopped growing appropriately at time of first vaccination. Estimated Due Date was 10/4.
926723	01/07/2021	I suffered from a miscarriage. 12 weeks along. It had been a healthy pregnancy otherwise.
932107	01/10/2021	Pfizer-BioNTech COVID-19 Vaccine EUA Miscarriage - (date of vaccination 1/6/21, miscarriage symptoms (cramping) started 1/8/21, confirmed 1/10/21; estimated date of delivery 8/30/21)
941086	01/13/2021	Miscarriage
947745	01/15/2021	When this individual received her Moderna Covid-19 vaccine (Dose #1) on 12-29-2020 she did not know her pregnancy status. She did not think she was pregnant. On Thursday 1-7-2021 around 4 AM she started experiencing severe abdominal pain. She did not go to work that day but did go in on Friday 1-8-2021. On Saturday 1-9-2021 she woke up with significant vaginal bleeding. On Monday 1-11-2021 she went to the OB/GYN and there she had a positive pregnancy test. The diagnosis of miscarriage was made at that time. A couple of days later, a repeat pregnancy test resulted in a negative reading.
953737	01/18/2021	3 weeks pregnant at time of first dose on 12/21/2020. Due date would have been 09/09/2021. Miscarriage on 01/14/2021 at 6 weeks.
1086358	03/09/2021	Janssen COVID-19 Vaccine EUA High fever started 9 hours after vaccination, continued until 24 hours after vaccination. Nausea and dizziness started 9 hours after vaccination, continued until 12 hours after vaccination. 5 weeks pregnant- spotting started 25 hours after vaccination. No proven correlation between potential miscarriage and Vaccine. Generalized, spotty red rash, slightly raised, no itch, on the front torso, from top of legs, groin area, up to shoulders, on front torso only (not on arms or back) 33 hrs after vaccination.
924247	01/06/2021	I was 5.5 weeks pregnant when I revived the Pfizer Covid Vaccine. Everything was seemingly going fine with my pregnancy until about 4 hours after receiving the vaccine when I went to the bathroom nd wiped and saw pink discharge on the toilet paper. I then began to have mild low abdominal cramping. The abdominal cramping and vaginal bleeding steadily increased in severity over the next 24 hours until I eventually had an obvious miscarriage the evening of 12/31/2020. I cant help but think the vaccine in some way caused my body to reject the pregnancy. Along with the miscarriage, I also had extreme tiredness with GI upset 12/31/20 - 1/02/2021.

994135	02/02/2021	I am 38 years old with no history of medical problems. I do NOT have a history of miscarriages and have one healthy child who is 22 months old. On 1/13/21, I took a home pregnancy test which came back positive. At that time, I had a missed period but also had several common pregnancy symptoms such as bloating, acne, fatigue and tender breast. later that week, I called OB/Gyn and spoke to an RN to schedule my 8/9 week ultrasound and to inquiry about the vaccine during pregnancy since I had no clue whether it was recommended/safe or not. the RN, very confident and without any disclaimer, stated that hospital is recommending all of their pregnant patients to receive the vaccine. Obviously, I decided to trust this medical professional who was so confident in her response. My normal pregnancy symptoms continued. On 1/19/21, I was 5 weeks pregnant and received my first dosage of the vaccine. felt fine other than a sore left arm. on 1/20/21, I woke up with a lot of abdominal cramping and pain. It was new to me but assumed it was normal. My cramping and pain continued until 1/21/21. On 1/21/21, I woke up without the cramping and pain. But, I also noticed that my breast were no longer tender and my skin had completely cleared up. I became concerned but prayed everything was fine since my home pregnancy test was still positive. On 1/22/21, by cramps continued once again but more mild. My pregnancy symptoms seemed as if they were no longer present but remained hopeful. On 1/23/21, I woke up with light spotting that only lasted through the morning. Soon after, I started having extreme abdominal pains. I prayed everything was fine. The pain continued and became worse. That night, the pain was so bad that I just went to bed. Right before going to bed, I noticed I had started spotting again. A little heavier than in the morning. I made sure to lay on my left side, hoping it was normal in pregnancy. On 1/24/21, I woke up with heavy bleeding and clotting. I went to the doctor and got an ultrasound and blood test. I was told by the doctor at Hospital that I had a miscarriage.
1022165	02/11/2021	PATIENT HAD A MISSED ABORTION, FOUND OUT 6DAYS AFTER VACCINATION. HAD HISTORY OF PREVIOUS MISCARRIAGES. WAS ON PROGESTERONE PESSARIES AND ASPIRIN. FETAL HEART BEAT MISSING ON ROUTINE REVIEW. GESTATION 10WEEKS+4DAYS. REQUIRED MEDICAL TERMINATION OF PREGNANCY.
1142921	03/29/2021	Pregnant patient miscarried; got pregnant in between the first and second dose; A spontaneous report was received from a pharmacist ,concerning a 38-year-old, female patient , who received Moderna's COVID-19 vaccine(mRNA-1273) and experienced getting pregnant in between the first and second doses (Exposure during pregnancy) and miscarried/abortion spontaneous. The patient's medical history was not reported. Concomitant medications were not reported. On 15 Jan 2021, patient received the first of two planned doses of mRNA-1273 (Lot/batch: unknown) vaccine intramuscularly for prophylaxis of COVID-19 infection. Between an unknown date and 17 Mar 2021, the patient become pregnant and experienced a miscarriage. On March 17 2021, the patient received the second of two planned doses of mRNA-1273 (Lot/batch: unknown) vaccine for prophylaxis of COVID-19 infection. The event, miscarriage, was medically significant. Laboratory details were not reported. Treatment information was not reported. Action taken with mRNA-1273 in response to the events was not applicable. At the time of report , the outcome of events; got pregnant in between first and second dose and pregnant patient miscarried were, were not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
973744	01/26/2021	Left arm became slightly itchy and a little red at injection site approximately 7 days after injection. At 10 days, larger portion of left arm at injection site is red and slightly swollen and hot. I am currently 10 weeks 3 days pregnant with an estimated due date of 08/22/21. I have one living child (2 years old) and three miscarriages since then to date.
995949	02/02/2021	Miscarriage reported

1015666	02/09/2021	patient was pregnant while taking BNT162B2; patient was pregnant while taking BNT162B2; Miscarriage 11 days post vaccine; This is a spontaneous report from a contactable Nurse. A 39-year-old female nurse reported that she received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number EL0142), into the left arm on 28Dec2020 at 07:30 AM at single dose for COVID-19 immunization. Medical history included asthma and eosinophilic esophagitis and allergies to Keflex ASA. Concomitant drugs were none. At the time of vaccination the patient was pregnant, her last menstrual date was on 20Nov2020, gestational period 6. The patient reported that on 08Jan2021 at 12:00 PM she had miscarriage 11 days post vaccine. The patient was seen at Doctor or other healthcare professional office/clinic visit. At the time of reporting the patient was recovering.; Sender's Comments: Based on temporal association, a possible contributory role of BNT162B2 cannot be completely excluded for reported miscarriage. However, information is limited, and miscarriage is multifactorial event. In the general population, the estimated background risk of miscarriage in clinically recognized pregnancies is 15% to 20%. 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.
1028819	02/14/2021	First trimester miscarriage after receiving both vaccine doses while pregnant. Granada 5, Para 3 at time of vaccine administration. Due date 9/17/2021
1090217	03/11/2021	Miscarriage; This is a Spontaneous report from a contactable consumer (patient). This consumer reported information for both mother and fetus. This is the maternal report. A 39-year-old female consumer reported that a 39-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot number: EL9269), via an unspecified route of administration at left arm on 04Feb2021 14:00 at a single dose for COVID-19 immunization. Medical history included allergies: Penicillin. No other vaccine in four weeks. Concomitant medications included (in two weeks) Prenatal vitamin, colecalciferol (VITAMIN D), folic acid (FOLATE) and sertraline hydrochloride (ZOLOFT 25mg). The patient's last menstrual date was 14Dec2020 and the delivery date was on 17Sep2021 (Gestational period: 8, as reported). An OB exam on 03Feb2021 showed healthy baby at 7w5d- heartbeat detected 152bpm; no abnormalities identified via ultrasound, Labs and hormone levels all within normal ranges. No issues detected. Mother received 1st dose of vaccine 04Feb2021. Per ultrasound on 20Feb2021, fetus stopped growing on 09Feb2021 (8w4d); no heartbeat detected. Miscarriage occurred 22Feb2021. AE resulted in Emergency room/department or urgent care, congenital anomaly (as reported). No treatment was administered. No COVID prior vaccination. Patient not COVID tested post vaccination. The outcome of the event was not recovered.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021225027 fetus case
1117494	03/19/2021	I started experiencing flu-like symptoms at around 5 PM on 3/14/21. I was feverish and had chills, muscle aches, and a headache. I had very strong chills for a few hours and then I noticed that my resting heart rate was around 128 bpm at around 1:30 AM on 3/15/21. I was running a 100.6 fever at that time. My fever subsided in the morning and the headache persisted throughout the day, and I was very tired as I did not get much sleep the night before. I did not work that day (Monday, 3/15). At the time I was about 7 weeks pregnant. I noticed some very light spotting later in the day on 3/15, and then I continued spotting on 3/16. I consulted a midwife at the facility at 4 PM on 3/16/21 and took a blood test to measure my hCG hormone levels. The following day, 3/17, I received the results that I had a normal level of hCG hormone and normal hemoglobin levels. As the day continued, the spotting turned into bleeding, and eventually the bleeding became heavy starting around 4 PM. I received an ultrasound on 3/18/21 at 8 AM and later spoke with a midwife from facility at 11 AM that day, confirming that there was no viable pregnancy detected via ultrasound. I had lost quite a bit of blood at that point. I am, as of 8:35 PM on Friday, March 19th, still bleeding and experiencing the impact of miscarriage.

1153120	03/31/2021	Bleeding right after the first shot; Pregnant; A spontaneous report was received from consumer, concerning herself, a 39-year-old, pregnant female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced a bleeding right after the 1st shot, pregnant. The patient's medical history include 3 miscarriages on Dec 2013 , Feb 2013, Apr 2013 (all not more 2months). Products known to have been used by the patient, included Progesterone 300mg indicated for after 3miscarriages, Tylenol, Folic acid 1mg . On 18JAN 2021, prior to onset of events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 041L20A) intramuscularly for prophylaxis of COVID-19 infection. On 22 FEB 2021, prior to onset of events, the patient received their second of two planned doses of mRNA-1273 (Lot number: 022M20A) intramuscularly for prophylaxis of COVID-19 infection. On 18 Jan 2021, the pregnant patient was exposed to the mRNA-1273 vaccine. She experienced bleeding right after the 1ST shot. She would like to be enrolled into the pregnancy registry. On 15JAN2021, the patient received a positive pregnancy test. Her last menstrual period was on 07 DEC 2020 and conception date was unknown. The patient's estimated due date is 12SEP2021. No treatment information was provided. Relevant laboratory test on 22 Feb 2021 last Ultrasound were done and the Result were normal. Action taken with mRNA-1273 in response to events were not provided. The outcome of the event bleeding right after the 1st shot was unknown and pregnant is ongoing.; Reporter's Comments: This is a case of product exposure on a 39-year-old pregnant of unknown gestation (LMP 07 DEC 2020) and experienced PV bleed right after the first shot. Very limited information regarding this event has been provided at this time. Patient will continue to be contacted for further monitoring of AEs during the pregnancy.
1209945	04/14/2021	The minute after the vaccination I had fainted, vision went, low blood pressure, after laying down became better. Rested almost an hour in order to be able to walk. next day, I had severe headache, with nausea, and a day later I had bleeding. Bleeding became severe, I had miscarriage. I was 7 weeks pregnant.
1025363	02/12/2021	About 12 hours after the vaccine I developed headache, fever 100.5, nausea and vomiting, and red rash across my chest up to my neck and under both breasts. All symptoms but the rash improved the following day. I went to have my 8 week pregnancy US 6 days after this second vaccine dose and there was no fetal heart rate. The baby measured 8.7mm and there should be a heart rate when the baby measures >7mm. I had all of my pregnancy symptoms up through the day of the vaccine and then they disappeared the day my vaccine symptoms improved. I do not have a history of miscarriage.

1151400	03/31/2021	I was 7 weeks pregnant at time of 2nd vaccine. Baby stop growing 3 days later (7 weeks 3 days per sono); I was 7 weeks pregnant at time of 2nd vaccine. Baby stop growing 3 days later (7 weeks 3 days per sono; I was 7 weeks pregnant at time of 2nd vaccine. Baby stop growing 3 days later (7 weeks 3 days per sono; I was 7 weeks pregnant at time of 2nd vaccine. Baby stop growing 3 days later (7 weeks 3 days per sono; This is a spontaneous report from a contactable Other HCP reported for herself and fetus. This is mother case. A 40-year-old pregnant female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot number: El9266), via an unspecified route of administration on Left arm on 20Feb2021 08:00 at single dose for covid-19 immunisation administered at Hospital. Medical history includes Shellfish Allergy. Historical vaccine includes first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot number: El3248), via an unspecified route of administration on Left arm on 27Jan2021 09:30 at single dose for covid-19 immunisation. Concomitant medications in two weeks include ascorbic acid, calcium pantothenate, cyanocobalamin, ergocalciferol, nicotinamide, pyridoxine hydrochloride, retinol palmitate, riboflavin, thiamine mononitrate (PRENATAL VITAMINS). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient reported, she was 7 weeks pregnant at time of 2nd vaccine. Baby stop growing 3 days later (7 weeks 3 days per sono) on 24Feb2021 08:00 on visit of Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The patient received Dilation and curettage (D&C) treatment for the events. Last menstrual date was 04Jan2021. Delivery date is Oct2021. Gestational period was 7 weeks. Prior to vaccination, was the patient was not diagnosed with COVID-19. The patient had COVID tested/nasal swab post vaccination with results pending on12Mar2021. The outcome of event Miscarriage was resolving and for the other events it was unknown. Follow-up attempts are completed. No further information is expected.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Induced abortion cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021278790 Same reporter/drug, different patient /event (Fetus case)
968006	01/23/2021	Miscarriage on 01/03/21 (due date 08/08/21) 2 previous pregnancies with live births (2006,2010)
981097	01/28/2021	A large area around my injection site was red, swollen, warm to touch, firm and itchy covering 3/4 of my upper arm into my underarm and lymph nodes. I received my first vaccine on 12/23/20 several days after injection the site became very itchy, red and swollen but in a much smaller area and persisted for several days leaving a small area of skin hyper pigmented for ~2 weeks. However I did not think it was considered an "Adverse" event and would have not reported it if the second dose was to a similar scale. Also, when I received first vaccine I did not know I was pregnant at the time. When I went to the doctor on 1/23/21 I was told I was 7.5 weeks pregnant, but there was no heart beat and I had miscarried. Being that I am over the age of 40 and a high risk for pregnancy and miscarriage I am unsure if my miscarriage is directly related to the vaccine but I felt it should add it to the report. My first vaccine was administered on 12/23/20 @ 5:30pm at Hospital

1124086	03/22/2021	Miscarriage; Heart stopped on pregnancy; This is a spontaneous report from a contactable consumer (patient). A 42-year-old female patient received her second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration in the left arm on 26Feb2021 06:00 PM at a single dose for COVID-19 immunisation. The patient's medical history was not reported. The patient had no known allergies. The patient was 8 weeks pregnant at the onset of the event. Last menstrual date was on 01Jan2021. There were no concomitant medications in two weeks and no other vaccine in four weeks. The patient previously received her first dose of BNT162B2 on an unspecified date at 06:00 PM in the left arm for COVID-19 immunisation. The patient had not been diagnosed with COVID prior to vaccination. The patient experienced miscarriage and heart stopped on pregnancy on 02Mar2021 03:00 PM. Treatment was unknown. Event resulted in doctor or other healthcare professional office/clinic visit. The patient was due to deliver on an unknown date. The patient underwent Covid PCR test post vaccination on 04Mar2021, pending results. Outcome of the events was unknown. Information on lot/ batch has been requested.
1006169	02/05/2021	I was approximately 4 weeks pregnant at the time that I received dose #1 (12/23/20)- I was unaware of the pregnancy. I was diagnosed with COVID on 12/28/20, but was first symptomatic on 12/24. I attributed my s/s initially to the vaccine. I was eventually tested on 12/28/20, as my symptoms worsened and I was positive for COVID. On 1/14/21 I received my second dose, my COVID s/s had been resolved since 1/4/21. On the evening of 1/18/21 I started experiencing mild abdominal pain. This progressed, on the evening 1/20 the pain was no longer tolerable. I went to the ER where I hemorrhaged and needed emergency surgery and a blood transfusion for a miscarriage. The surgery ultimately took place in the early morning hours of 1/22/21, followed by the blood transfusion.
1209601	04/14/2021	miscarriage a week after receiving Janssen vaccine
1068274	03/03/2021	face and jawline went absolutely numb; Headache; Swelling arm; This is a spontaneous report from a contactable consumer reported for herself. A 67-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), on 16Feb2021 10:15 (at the age of 67-year-old) from lot # EN6200 at single dose for COVID-19 immunization via intramuscular route at the left arm. The caller stated she had a half an hour of sitting afterwards and then they let her go. Concomitant medications included loratadine (CLARITIN) for sinusitis and insulin for Type 2 diabetes mellitus. Relevant medical history included type 2 diabetic (Diagnosed about 17 years ago), allergic to some food, allergic to sulfa, she had a number of allergies and she had an anaphylactic reactions in the past, asthma diagnosed around the age of 40, sinuses, high blood pressure after a D&C, she had a miscarriage, uterine dilation and curettage, one headache before this in her entire life. The patient had received Flu vaccine on unknown date. The patient, on 16Feb2021 had headache that lasted for 5 minutes. It was right after the first shot of the Pfizer COVID-19 vaccine, her face went numb and she couldn't breathe through her nose. She was only able to breathe through her mouth. Her jaw got really numb. It happened when she was driving home from the vaccination center and she had to pull over because she might go into an accident. She wasn't sure if she was having a stroke or not but she was scared since her sister had histories of multiple strokes. She wanted to know Pfizer's recommendations for the second dose considering her adverse events. He had a really short headache tonight, He stated "it hit me out of the blue right in my temporal; I got on the floor it was so bad. 5 minutes after I left my face went totally numb" She stated she also had the second headache she had ever had in her entire life. She also mentioned she had some swelling in her arm but she didn't think that was unusual. She clarified as she was driving home after receiving her shot, her entire face went numb and her jawline went numb. It scared her so bad. She thought she was having a stroke or something. She confirmed she recovered completely from this, the numbness cleared up in 10 minutes. The Outcome of the event swelling arm was unknown while the outcome of the other events was recovered on 16Feb2021.

1004202	02/05/2021	Presumed miscarriage; human chorionic gonadotropin decreased; Vaccine exposure during pregnancy; A spontaneous report was received from a consumer who was also a 31-years-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) who experienced vaccine exposure during pregnancy, human chorionic gonadotropin decreased and presumed miscarriage. The patient's medical history was not provided. The patient's prior history of pregnancies were two miscarriages (2013 and 2015) and two full term births (2017 and 2019) were reported. The patient's last menstrual period was 25 Nov 2021. The estimated due date was 1 Sep 2021. Concomitant medications included sertraline hydrochloride and vitamins. On 27 Dec 2020, the patient found out she was pregnant, but she already had some bleeding. On 28 Dec 2020, the patient received their first of two planned doses of mRNA-1273 (Lot number: 026L20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. On undisclosed date, after receiving the vaccine her human chorionic gonadotropin (hCG) levels went down to 0. Her health care professional presumed it was a miscarriage. Treatment for the event was not reported. On 19th Jan 2021, her hCG levels started to climb back up again. Action taken with the second dose of mRNA-1273 in response to the event was not reported. The outcome of the event, presumed miscarriage, and human chorionic gonadotropin decreased was unknown. The outcome of the event, vaccine exposure during pregnancy, was resolved on 28 Dec 2020.; Reporter's Comments: This spontaneous report concerns a 31-years-old, G5P2 female patient who experienced vaccine exposure during pregnancy and presumed miscarriage. The patient's last menstrual period was 25-Nov-2020 with estimated date of delivery as 01-Sep-2021. One day after the patient discovered she was pregnant; she received the first dose of mRNA-1273 vaccine (lot # 026L20A expiration date unknown). The event of presumed miscarriage (human chorionic gonadotropin (hCG) levels went down to 0) was diagnosed on an unknown date after vaccine administration. The HCG level began to climb up again 22 days after the vaccine administration. Based on the information provided which includes, the patient's obstetric history, vaginal bleeding the day prior to mRNA-1273 vaccination and without definitive confirmation of pregnancy loss, there is not enough evidence to assess that that there was a miscarriage and is also unlikely to be associated with mRNA-1273 administration. The event of vaccine exposure during pregnancy is considered not applicable
1042347	02/19/2021	Miscarriage; This is a spontaneous report from a contactable consumer(patient). This is a maternal report. A female patient of an unspecified age (Age: 29; Unit: Unknown) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were unknown), via an unspecified route of administration on 15Jan2021 at a single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient stated that her first dose of the Pfizer vaccine was on 15Jan2021 and reported that she had a miscarriage on Thursday 04Feb2021. It was reported that the patient missed her scheduled second dose of the Pfizer COVID-19 vaccine due to a miscarriage. The event was assessed as serious (medically significant). The outcome of the event was unknown. Information on the lot/batch number has been requested.

1070770 03/03/2021 Maternal exposure during pregnancy; Fetus stopped growing on 09Feb21 (8w4d); no heartbeat detected; This is a spontaneous report from a contactable consumer (parent). This consumer reported information for both mother and fetus. This is a fetus report. A patient of unspecified age and gender (fetus) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9269), transplacental on 04Feb2021 at 14:00 at single dose for COVID-19 immunisation. The patient medical history was not reported. Concomitant medication included ergocalciferol (VIT D), folic acid (FOLATE), ascorbic acid/betacarotene/calcium sulfate/colecalciferol/cyanocobalamin/ferrous fumarate/folic acid/ nicotinamide/pyridoxine hydrochloride/retinol acetate/riboflavin/thiamine mononitrate/tocopheryl acetate/zinc oxide (PRENATAL VITAMINS) and sertraline hydrochloride (ZOLOFT) at 25 mg, all transplacental. It was reported that OB exam on 03Feb21 showed healthy baby at 7weeks 5days heartbeat detected 152 bpm; no abnormalities identified via ultrasound; labs and hormone levels all within normal ranges. No issues detected. Mother received 1st dose of vaccine on 04Feb2021. Per ultrasound on 20Feb2021, fetus stopped growing on 09Feb2021 (8 weeks 4 days); no heartbeat detected. Miscarriage occurred on 22Feb2021. The fetus died on 22Feb2021. It was not reported if an autopsy was performed.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021204433 same drug and reporter, different patient and event; Reported Cause(s) of Death: Fetus stopped growing on 09Feb21 (8w4d); no heartbeat detected; Mother received 1st dose of vaccine 04Feb21. Per ultrasound on 20Feb21, fetus stopped growing on 09Feb21 (8w4d); no heartbeat detected. Miscarriage occurred 22Feb21.

1074149 03/05/2021 Miscarried at 6 weeks; Vaccine exposure during pregnancy; A spontaneous report was received from a healthcare professional concerning a 32 year old female patients who received Moderna's Covid 19 vaccine(mRNA1273) and experienced vaccine exposure during pregnancy and miscarried at 6 weeks. The patient's medical history was not provided. Concomitant product use was not provided. The patient received second of two planned dose of mRNA-1273 for prophylaxis of Covid 19 infection approximately 2.5 weeks before the miscarriage. The patient experienced vaccine exposure during pregnancy and miscarried at 6 weeks, approximately 2.5 after receiving her second dose of Moderna vaccine. The patient received both scheduled doses of mRNA-1273 prior to the events ; therefore, action taken with the drug in response to the events is not applicable. The outcome of the event, miscarriage spontaneous was considered as unknown. The outcome for the event of Vaccine exposure during pregnancy was recovered/resolved.; Reporter's Comments: This case concerns a 32 year old, female subject, who experienced a spontaneous abortion and drug exposure during pregnancy. The patient experienced vaccine exposure during pregnancy and miscarried at 6 weeks, approximately 2.5 after receiving her second dose of mRNA-1273. Very limited information has been provided at this time. Further information has been requested.

1086871	03/10/2021	Miscarriage; Vaccine exposure during pregnancy; A spontaneous report was received from a consumer who was also a 41-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) resulting in the event miscarriage/ abortion spontaneous and vaccine exposure during pregnancy. The patient's medical history included environmental allergies and an allergy to an unknown beauty product, kidney stone, endometriosis, anxiety, and paroxysmal supraventricular tachycardia. Products known to have been used by the patient, within two weeks prior to the event, included pre-natal vitamins and escitalopram oxalate. The patient received their first of two planned doses of mRNA-1273 (Batch number: 042L20A) intramuscularly on 14 Jan 2021. On 12 Feb 2021, the patient received their second of two planned doses of mRNA-1273 (Batch number: 012M20A) intramuscularly for prophylaxis of COVID-19 infection. On 21 Jan 2020, the patient had a positive pregnancy test. The first day of the patient's last menstrual period was on 24 Dec 2020. The estimated date of conception was not provided. The due date was estimated as 30 Sep 2021. On 22 Feb 2021, the patient had a miscarriage. There was no fetal heartbeat on the ultrasound. On 24 Feb 2021, the patient underwent a procedure to complete the miscarriage. The patient received both scheduled doses of mRNA-1273; therefore, action taken with the drug in response to the event is not applicable. The outcome of the events was considered recovered.; Reporter's Comments: This is a case of product exposure during pregnancy with an Adverse event of Spontaneous abortion for this 41-year-old female. Very limited information regarding this event has been provided at this time. Further information has been requested.
1100545	03/15/2021	miscarriage after receiving both doses of COVID19 vaccine; This is a spontaneous report received from Pfizer sponsored program from a contactable consumer reported for self. A female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number unknown) via unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient is pregnant at the time of vaccination. The patient's medical history and concomitant medications were not reported. The patient previously received the first dose of BNT162B2 on an unspecified date for COVID-19 immunisation. The patient had a miscarriage after receiving both doses of COVID-19 vaccines. The patient received no treatment. The outcome of event was unknown. Information about lot/batch number has been requested.
1109887	03/18/2021	patient received COVID-19 vaccine on 18Dec2020 and had a positive pregnancy test on 28Dec2020; patient received COVID-19 vaccine on 18Dec2020 and had a positive pregnancy test on 28Dec2020; patient received COVID-19 vaccine on 18Dec2020 and had a positive pregnancy test on 28Dec2020; fetal cystic hygroma; This is a spontaneous report from contactable consumers (one of them is patient herself) communicated to a Pfizer sales representative. A 32-year-old pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection), via an unspecified route of administration, first dose on 18Dec2020 (first dose given pre/peri conception), second dose on an unspecified date in 2021 (second dose given around 4 weeks gestation); both at single dose for COVID-19 immunization. This is my daughter and grandchild. The patient's medical history and concomitant medications were not reported. The patient received COVID-19 vaccine on 18Dec2020 and had a positive pregnancy test on 28Dec2020. The conception date was reported as 01Dec2020. The patient underwent lab test and procedures which included urine pregnancy test: Positive on 28Dec2020. Upon follow-up on 03Mar2021, it was reported that, miscarriage at 13 weeks gestation due to fetal cystic hygroma on 04Mar2021 05:30. The outcome of the event was unknown. No follow up attempts are possible; information about lot/batch number cannot be obtained. Follow-up (03Mar2021): New information received from a contactable consumer communicated to a Pfizer sales representative includes: New reporter (consumer), gestational period (13 weeks), suspect drug details (second dosage regimen), new event (fetal cystic hygroma) added. No follow-up attempts are needed. No further information is expected.

1245139 04/23/2021 FEVER; MUSCLE/BODY ACHE; DIZZINESS; BALANCE DISORDER; STIFF NECK; TIREDNESS; HEADACHE; NAUSEA; This spontaneous report received from a patient concerned a 69 year old female. The patient's height, and weight were not reported. The patient's past medical history included miscarriage, and tetanus shot allergy, and concurrent conditions included ehler danlos type iv vascular, anemia, aneurysm, cavernoma, double jointed, hemorrhage, gluten intolerance, grain intolerance, seasonal allergies, and heavy menstrual flow. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808609, and expiry: UNKNOWN) dose was not reported, administered on 06-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On APR-2021, the subject experienced muscle/body ache. On APR-2021, the subject experienced dizziness. On APR-2021, the subject experienced balance disorder. On APR-2021, the subject experienced stiff neck. On APR-2021, the subject experienced tiredness. On APR-2021, the subject experienced headache. On APR-2021, the subject experienced nausea. Laboratory data included: Blood test (NR: not provided) Low sodium and dehydration, and X-ray of nasal sinuses abnormal (NR: not provided) No abnormality found. On 07-APR-2021, the subject experienced fever. Laboratory data included: Body temperature (NR: not provided) 102.7 F. Treatment medications (dates unspecified) included: paracetamol. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from headache, and the outcome of tiredness, muscle/body ache, dizziness, balance disorder, nausea, stiff neck and fever was not reported. This report was non-serious.