

## COVID Vaccine VAERS Reports for Spontaneous Abortion / Fetal Death / Premature Labor - April 10, 2021

Notes	Vaccine Type	Vaccine Manufacturer	VAERS ID	Age	Onset Interval	Adverse Event Description
	COVID19 VACCINE	JANSSEN	1099034-1	30-39 years	0 days	30 weeks pregnant at time of receiving vaccine. Estimated due date May 20, 2021. Had dull headache immediately following vaccine. At 4pm I had chills and then started having contractions every 5 minutes. I called my OBGYN who recommended that I drink fluids and lay on my side to decrease the presumed Braxton Hicks contractions. This did not decrease the contractions. I came to the hospital where I was admitted to labor and delivery with contractions 2-4 minutes apart and a 99.6 degree temperature. I was given an oral medication to stop the contractions, a 2 part series of injections to speed up lung development of my unborn child, and IV fluids were administered.
	COVID19 VACCINE	JANSSEN	1117494-1	30-39 years	0 days	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.

COVID19 VACCINE	MODERNA	1004202-1	Unknown	0 days	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
COVID19 VACCINE	MODERNA	1038034-1	Unknown	0 days	Pregnancy loss; Vaginal bleeding; Vaccine exposure during pregnancy; A spontaneous report was received from a nurse practitioner who was 31-year-old, female, patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced vaccine exposure during pregnancy, pregnancy loss (abortion spontaneous), and vaginal bleeding (vaginal hemorrhage). The patient's medical history was not provided. Concomitant medications reported as taken since conception included magnesium, prenatal vitamins, vitamin B and vitamin C. On 10 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 011LZ0A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. On 10 Jan 2021, the pregnant patient was exposed to the mRNA-1273 vaccine. On 02 Feb 2021, the patient developed vaginal bleeding, so she went to her obstetrician and had an ultrasound exam. The patient reported that there was no heartbeat at fifteen weeks and five days. No treatment information was provided. The patient's prior positive pregnancy test, last menstrual period, conception and due dates were not provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the event, pregnancy loss and vaccine exposure during pregnancy, was considered resolved. The outcome of the event, vaginal bleeding, was unknown.; Reporter's Comments: This case concerns a 31 year old, female subject, who experienced a spontaneous abortion and drug exposure before pregnancy. Very limited information has been provided at this time. Further information has been requested
COVID19 VACCINE	MODERNA	1058751-1	40-49 years	0 days	The evening of my vaccination, I began to feel feverish, weak and achy. During the night I woke with heavy bleeding and found out the following morning I had miscarried my otherwise healthy pregnancy.

COVID19 VACCINE	MODERNA	1065910-1	30-39 years	0 days	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.
COVID19 VACCINE	MODERNA	1086871-1	Unknown	0 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	0924247-1	30-39 years	0 days	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 and 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.

COVID19 VACCINE	PFIZER\BIONTECH	0925639-1	30-39 years	0 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	0950562-1	30-39 years	0 days	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
COVID19 VACCINE	PFIZER\BIONTECH	0953086-1	30-39 years	0 days	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: EJ1685) 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.

COVID19 VACCINE	PFIZER\BIONTECH	0965558-1	18-29 years	0 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	1006011-1	18-29 years	0 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	1010528-1	30-39 years	0 days	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.

COVID19 VACCINE	PFIZER\BIONTECH	1057557-1	30-39 years	0 days	<p>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.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1065919-1	18-29 years	0 days	<p>miscarried; patient was pregnant at the time of the vaccine; patient was pregnant at the time of the vaccine; This is a spontaneous report from a contactable healthcare professional reporting for herself. A 29-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number and expiry date not reported) via an unspecified route of administration at right arm, at the age of 29-year-old, on 30Jan2021 02:00 AM, single dose for COVID-19 immunization. Relevant medical history and concomitant medications were reported as none. The patient had no known allergies. The patient did not receive any other vaccine in four weeks or any other medications in two weeks. The patient was pregnant at the time of the vaccine 30Jan2021 and miscarried on 01Feb2021. LMP was provided as 01Jan2021, gestation period was reported as 4 weeks and due date was provided as 08Oct2021. The patient did not have covid prior vaccination and was not tested for covid post vaccination. The patient did not receive any treatment in response to the event miscarried. Outcome of the event miscarried was not recovered. Information on the lot/batch number has been requested.; Sender's Comments: Based on the compatible temporal association, a possible contributory role of suspect vaccine BNT162B2 in triggering the miscarriage in this 29-year-old pregnant patient cannot be excluded. Additional information regarding relevant medical history, underlying conditions, 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.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1075313-1	30-39 years	0 days	miscarried at 12 weeks; received first dose of bnt162b2 on 18Dec2020, second dose on 11Feb2021; received first dose of bnt162b2 on 18Dec2020, second dose on 11Feb2021; This is a spontaneous report from a contactable nurse (Patient). A 38-year-old female patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number el3248) intramuscular in right arm on 11Feb2021 17:00 at single dose for covid-19 immunisation. No medical history. No COVID prior to vaccination. Other medications in two weeks include prenatal vitamins. Patient received first dose of bnt162b2 (lot number ek5730) on 18Dec2020 12:00 PM intramuscular in right arm. No other vaccine in four weeks. Patient's last menstrual date was 01Nov2020. Patient miscarried at 12 weeks after receiving the second dose of vaccine. Dilation and curettage performed. Outcome was recovered with sequel. Nasal Swab COVID tested negative post vaccination on 18Feb2021.; 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 'miscarried' 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.
COVID19 VACCINE	PFIZER\BIONTECH	1107257-1	30-39 years	0 days	Miscarriage; Pregnant at time of vaccination; Pregnant at time of vaccination; 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.
COVID19 VACCINE	PFIZER\BIONTECH	1113942-1	30-39 years	0 days	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
COVID19 VACCINE	MODERNA	0916065-1	30-39 years	1 day	EDD - 4/1/2021 - Contractions at 26 w 3 days sent to L&D to be monitored on 12/28/20. Covid-19 Sars Vaccine given 1st dose 12/27/20. Patient was diagnosed with Fetal Hydrops. Patient Hospitalized 12/28/20 - current MFM consulting in hospital & outpatient
COVID19 VACCINE	MODERNA	0917350-1	18-29 years	1 day	27Dec2020 - patient developed some swelling (went about 1 inch out from injection site) and discomfort at the injection site - had taken Advil and was using a cool compress. 29Dec2020 - patient had to leave work early since she was not feeling well - very fatigued and a little dizzy (able to eat/drink) - denied any COVID illness s/s (no cough, fever, loss of taste/smell, etc). She ended up going to the local ED - since she was still very fatigued and was feeling like she was going to pass out - blood work and U/S done - this is where she found out she had been pregnant but had lost the pregnancy (no heart beat). Per her report - all other blood work was unremarkable. No other medications given to her during this visit and was just told that she would be 'passing the products of conception within this next week'.
COVID19 VACCINE	MODERNA	0962952-1	18-29 years	1 day	Miscarriage

COVID19 VACCINE	MODERNA	0994135-1	30-39 years	1 day	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.
COVID19 VACCINE	MODERNA	1047536-1	30-39 years	1 day	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
COVID19 VACCINE	MODERNA	1066027-1	30-39 years	1 day	I was 34 weeks, 5 days pregnant at the time of vaccination (due date 3/26/2021). The next day at 10pm my water broke and I went into early labor. I had my baby on Friday in the early morning. Prior to this, I had no risks or warning signs of early labor (e.g. preeclampsia, gestational diabetes, etc) and was generally following a routine pregnancy path.
COVID19 VACCINE	PFIZER\BIONTECH	0906529-1	30-39 years	1 day	When I got the vaccination I was 32weeks pregnant and on Saturday I had spontaneous rupture of the amniotic fluids and went immediately to the hospital and was immediately given steroid, magnesium for the baby. And on Sunday around 3:45PM I got a second round of the steroids and was transferred for observation. On Monday, at 8:06am I went into early labor I delivered my baby at 33weeks gestation and she weighed 3lb 11oz. Expected Date of Delivery-2/8/2021. I was a high risk patient d/t Fibroids but have experienced no issues the entire pregnancy and my last ultrasound was 12/17 and baby was healthy with no complications at that time.
COVID19 VACCINE	PFIZER\BIONTECH	0968006-1	40-49 years	1 day	Miscarriage on 01/03/21 (due date 08/08/21) 2 previous pregnancies with live births (2006,2010)
COVID19 VACCINE	PFIZER\BIONTECH	1025363-1	40-49 years	1 day	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.
COVID19 VACCINE	MODERNA	0958501-1	30-39 years	2 days	Client was pregnant at time of vaccination. She had consulted with 2 OBGYNs that are following her concerning if she should receive the covid vaccine. They both stated yes. She received her 1st covid vaccination to her left deltoid between 12pm - 1300 on 1/14/21. She did not experience any complications or feel any side effects immediately after vaccination. She was monitored by nursing staff for over 30 min to be prudent. On 1/16/21 the Sat following vaccination she began experiencing cramping in her stomach and began to bleed vaginally. She consulted w her OBGYN and was monitored. She miscarried on 1/19/21.

COVID19 VACCINE	MODERNA	1045927-1	30-39 years	2 days	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.
COVID19 VACCINE	MODERNA	1102166-1	30-39 years	2 days	I received the first dose of the vaccine on 1/31/21. I was 33 weeks pregnant, with an estimated due date on 3/21/21. This was my first pregnancy and I had no complications up to that point. On 2/2/21 I began experiencing menstrual type cramps, which continued for a few days. On 2/5/21, my OBGYN suggested I be examined in Labor and Delivery, where it was determined I was in pre-term labor. Contractions were temporarily stopped, however my water broke on 2/7/21 and it was suggested that I be induced. I was induced on a later date at 34w1d pregnant and delivered my son, who weighed in at 4lbs. 15oz.
COVID19 VACCINE	PFIZER\BIONTECH	0918034-1	30-39 years	2 days	I was 28 weeks and 5 days pregnant when I received the first dose of the COVID19 vaccine. Two days later (12/25/2020 in the afternoon), I noticed decreased motion of the baby. The baby was found to not have a heartbeat in the early am on 12/26/2020 and I delivered a 2lb 7oz nonviable female fetus at 29 weeks gestation. I was 35 years old at the time of the fetal demise and the only pregnancy history for this pregnancy included a velamentous cord insertion that was being closely monitored by a high risk OB. My estimated due was March 12, 2021.
COVID19 VACCINE	PFIZER\BIONTECH	0932028-1	18-29 years	2 days	Miscarriage at 6 weeks pregnant
COVID19 VACCINE	PFIZER\BIONTECH	0932107-1	30-39 years	2 days	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)
COVID19 VACCINE	PFIZER\BIONTECH	0964070-1	30-39 years	2 days	Hi, I actually not sure if the cause of my problem was caused 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 covid19 vaccine. On January 19 I started seeing some spot of blood at first I thought it was nothing to worry 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 caused by the injection or not. Am just worried that this 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 covid19 vaccine.
COVID19 VACCINE	PFIZER\BIONTECH	1056747-1	30-39 years	2 days	Approximately 36 hours after second dose- patient went into late preterm labor of 36w6d. Infant was born weighing 6lbs 3.8oz on 2/21/21. Due date was 3/14/21.
COVID19 VACCINE	PFIZER\BIONTECH	0987914-1	30-39 years	3 days	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
COVID19 VACCINE	PFIZER\BIONTECH	1011050-1	30-39 years	3 days	Positive pregnancy test 1/10/21. EDD 9/18/21 based on LMP (12/12/21). Woke up extremely dizzy and could not get out of bed without almost falling over and very nauseated. Symptoms eventually subsided around 10:00 am. Did not have dizziness again. Had a confirmatory Ultrasound on 2/4/21 which measured 5weeks, 5 days and no yolk sac. Was supposed to be 7 weeks, 5 days. Determined that I miscarried.
COVID19 VACCINE	PFIZER\BIONTECH	1031823-1	30-39 years	3 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	1051502-1	30-39 years	3 days	Approx 6 weeks at time of second administration with a due date of sept 28th. Would have been 3 weeks pregnant at time of 1st injection. 3 days after second injection, I began to miscarry. This was confirmed by declining HCG levels. Ultrasound to follow in one week.

COVID19 VACCINE	PFIZER\BIONTECH	1070733-1	30-39 years	3 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	0936919-1	30-39 years	4 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	0955432-1	30-39 years	4 days	I had vaginal bleeding and receive a Ultra sound. Which I had a miscarriage. My estimated delivery was August 25,2021.
COVID19 VACCINE	PFIZER\BIONTECH	0977301-1	30-39 years	4 days	Patient with underlying MS and pregnancy. Patient reported that Fever, body aches, chills, fatigue after administration of 2nd dose. Presented to the Emergency Department / OB triage in labor 4 days later (1.24.21) Patient is a 34 y.o. female at 37w0d with Estimated Date of Delivery: 2/14/21 who presents today with spontaneous labor. HOSPITAL COURSE: Patient underwent an uncomplicated vaginal delivery and was discharged home in stable condition. ESTIMATED DUE DATE: Estimated Date of Delivery: 2/14/21 GESTATIONAL AGE AT DELIVERY: 37w0d. Patient weight = 2.63 KG
COVID19 VACCINE	PFIZER\BIONTECH	1006169-1	40-49 years	4 days	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.

COVID19 VACCINE	PFIZER\BIONTECH	1114382-1	Unknown	4 days	Baby stop growing 3 days later (7 weeks 3 days per sono); Baby stop growing 3 days later (7 weeks 3 days per sono); This is a spontaneous report from a contactable Other HCP. This Other HCP reported events for herself and fetus. This is a fetus report. A 40-year-old mother received bnt162b2 (BNT162B2), dose 2 administered in Arm Left on 20Feb2021 (Batch/Lot Number: EI9266) as SINGLE DOSE, dose 1 administered in Arm Left on 27Jan2021 (Batch/Lot Number: EI3248) as SINGLE DOSE for covid-19 immunisation. The mother medical history included allergies: Shellfish. No other vaccine in four weeks. No COVID prior vaccination. Concomitant medication included 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). The mother was pregnant. Last menstrual date: 04Jan2021. Due Date: 11Oct2021. The mother 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 AM. AE resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The patient died on 24Feb2021 08:00 AM. It was not reported if an autopsy was performed.; Sender's Comments: Based on provided information and temporal association the reported events causal relationship with the suspect drug cannot be excluded. However there is very limited information provided in this report. Additional information is needed to better assess the case, including complete medical history and diagnostics workup. 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.,Linked Report(s) : US-PFIZER INC-2021277400 Same reporter/drug, different patient /event (mother case); Reported Cause(s) of Death: Baby stop growing 3 days later (7 weeks 3 days per sono); Baby stop growing 3 days later (7 weeks 3 days per sono)
COVID19 VACCINE	MODERNA	0967274-1	18-29 years	5 days	I was pregnant and my baby died two days after I took it and I got really sick
COVID19 VACCINE	PFIZER\BIONTECH	0943837-1	30-39 years	5 days	Approximately 5 days after administration at 6 weeks pregnant, I began bleeding. The following day (6 days after administration) miscarriage was confirmed via ultrasound
COVID19 VACCINE	PFIZER\BIONTECH	0967274-1	18-29 years	5 days	I was pregnant and my baby died two days after I took it and I got really sick
COVID19 VACCINE	PFIZER\BIONTECH	0990450-1	30-39 years	5 days	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.

COVID19 VACCINE	PFIZER\BIONTECH	1106446-1	18-29 years	5 days	20 weeks and 3 days pregnant with a girl at time of COVID vaccine, due date July 14th 2021. Anatomy scan on 2/26/21 and everything was normal. Two prior pregnancies both healthy and carried full term in 2017 and 2019. Spontaneous preterm labor on March 6th, 2021. Resulted in baby being born and dying about an hour and a half later due to how early she was. Labs came back normal, no signs of infection, placenta pathology came back normal. Baby was healthy as of 2/26/21 and was born alive.
COVID19 VACCINE	MODERNA	0923743-1	30-39 years	6 days	I had a miscarriage on 01/01/2021 Estimated date of Delivery 09/7/ 2021
COVID19 VACCINE	PFIZER\BIONTECH	0917595-1	30-39 years	6 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	0926723-1	30-39 years	6 days	I suffered from a miscarriage. 12 weeks along. It had been a healthy pregnancy otherwise.
COVID19 VACCINE	PFIZER\BIONTECH	0958755-1	40-49 years	6 days	Pt was 18 weeks pregnant at the time of the vaccine. Second pregnancy. Pt is a physician. Pregnancy was entirely normal up to that time. On 1/18/2021, she began to have heavy vaginal bleeding probably due to a placental abruption and subsequently delivered at 18 weeks. Baby was stillborn. Ultrasound done 1/15/2021 normal. Lethal event for the fetus. The patient did well.
COVID19 VACCINE	MODERNA	0941086-1	30-39 years	8 days	Miscarriage
COVID19 VACCINE	MODERNA	1096757-1	30-39 years	8 days	Patient received her Covid 19 vaccines on 1/6/21 and 2/3/21. On 3/3/21 at her routine prenatal visit, she was diagnosed with an intrauterine fetal demise. Based on the fetal measurements, the demise happened at 17-18 weeks of gestation, which would be sometime between 2/6/21 and 2/13/21. Medically, I don't suspect that the demise is related to the vaccine, but for the sake of accurate tracking, I feel compelled to report the sequence of events.
COVID19 VACCINE	PFIZER\BIONTECH	0949729-1	18-29 years	9 days	Miscarriage. Expected due date in August 2021. No prior pregnancy history.
COVID19 VACCINE	PFIZER\BIONTECH	1028368-1	30-39 years	9 days	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.
COVID19 VACCINE	JANSSEN	1145902-1	40-49 years	10-14 days	spontaneous abortion at approximately 8 weeks gestation, 10 days after vaccine administration
COVID19 VACCINE	JANSSEN	1146214-1	18-29 years	10-14 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	0922289-1	30-39 years	10-14 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	0985993-1	30-39 years	10-14 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	0995949-1	30-39 years	10-14 days	Miscarriage reported
COVID19 VACCINE	PFIZER\BIONTECH	1010113-1	18-29 years	10-14 days	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

COVID19 VACCINE	PFIZER\BIONTECH	1015666-1	30-39 years	10-14 days	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 ELO142), 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.
COVID19 VACCINE	PFIZER\BIONTECH	1064123-1	40-49 years	10-14 days	Fetal demise sometime between 15-18 weeks based on ultrasound findings. EDC 7/30/2021
COVID19 VACCINE	PFIZER\BIONTECH	1098641-1	18-29 years	10-14 days	The patient began having vaginal bleeding and contractions on 3/11/21 at 24 weeks 6 days and presented to labor and delivery in preterm labor. We were able to delay delivery for about 24 hours but she did deliver at 25 weeks 0 days. Earlier in her pregnancy she had some vaginal spotting (last time was on 1/15/21 and her cervix was closed on sonogram). In her first trimester she had significant hyperemesis treated with medication and IV fluids but this resolved after the first trimester.
COVID19 VACCINE	PFIZER\BIONTECH	1054826-1	30-39 years	Over 120 days	Premature infant born at hospital after premature labor was found to have injured brain tissue (PVL) on cranial ultrasound after delivery. Timing of the injury coincides with maternal clinical illness after second Covid vaccine, about two weeks prior to delivery. The mother and father asked me whether the Covid vaccine could have contributed to the brain injury. I reassured them that the Covid vaccine is felt to be safe during pregnancy, but that I would report the concern.
COVID19 VACCINE	JANSSEN	1137248-1	30-39 years	15-30 days	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.
COVID19 VACCINE	MODERNA	0966887-1	30-39 years	15-30 days	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.)
COVID19 VACCINE	MODERNA	0970929-1	30-39 years	15-30 days	A miscarriage was determined on 1/18/2021. There is no history of miscarriages.
COVID19 VACCINE	MODERNA	1033412-1	30-39 years	15-30 days	20 weeks gestation at time of vaccine administration. Saw OB that morning (1/12/21), normal exam and fetal heart rate. Normal anatomy scan 1/8/21, normal genetic screening. Fetal demise noted at 24 week OB visit on 2/9/21, stillborn baby delivered 2/12/21.
COVID19 VACCINE	MODERNA	1033516-1	30-39 years	15-30 days	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, dots/ sac. I had an uneventful pregnancy up to that point, feeling well as I had with prior pregnancies.""

COVID19 VACCINE	MODERNA	1047157-1	18-29 years	15-30 days	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)
COVID19 VACCINE	MODERNA	1063163-1	30-39 years	15-30 days	Saw OB on Jan 4 and there was a strong heartbeat and no defects or problems noted in any bloodwork up to that point in the pregnancy. Received my second vaccine on Jan 19. On Feb 3 I went to my next ultrasound appointment and was told that the baby had no heartbeat. It was estimated that the baby had likely passed a couple weeks prior but I am not certain of the timeline in regards to receiving the second vaccine.
COVID19 VACCINE	PFIZER\BIONTECH	0928892-1	30-39 years	15-30 days	I was approximately six weeks pregnant at time of my first vaccine. At subsequent OB visit three weeks later I had miscarried. It may not be related to the vaccine at all, but given this is a new vaccine and not studied in pregnant women I thought it was best to report it.
COVID19 VACCINE	PFIZER\BIONTECH	0970490-1	30-39 years	15-30 days	Miscarriage
COVID19 VACCINE	PFIZER\BIONTECH	1007832-1	18-29 years	15-30 days	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
COVID19 VACCINE	PFIZER\BIONTECH	1023866-1	18-29 years	15-30 days	Miscarriage at 6 weeks 1 day. Vaginal bleeding and decline in HCG hormone. Pregnancy not viable.
COVID19 VACCINE	PFIZER\BIONTECH	1038491-1	18-29 years	15-30 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	1042347-1	Unknown	15-30 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	1044756-1	30-39 years	15-30 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	1048833-1	30-39 years	15-30 days	~ 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.
COVID19 VACCINE	PFIZER\BIONTECH	1059748-1	30-39 years	15-30 days	I went into preterm labor at 20 weeks, 3 days on and delivered a live pre-term baby boy who died shortly thereafter. He weighed 11 oz. My estimated delivery date was to be 06/25/2021. This was my second pregnancy, and I had not had my 20 week ultrasound yet. There is no known cause of why I experienced pre-term labor and an autopsy was not performed on my son. My first pregnancy was uneventful and I delivered at full-term.

COVID19 VACCINE	PFIZER\BIONTECH	1090217-1	30-39 years	15-30 days	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
COVID19 VACCINE	MODERNA	1096573-1	30-39 years	31-60 days	I went into labor during which I started bleeding and was rushed into have an emergency C-section. I had a placenta abruption. Both mom and baby are doing fine. Estimated due date was 03/01/2021. Birth weight was 6 lbs 14 oz
COVID19 VACCINE	PFIZER\BIONTECH	1028819-1	30-39 years	31-60 days	First trimester miscarriage after receiving both vaccine doses while pregnant. Granada 5, Para 3 at time of vaccine administration. Due date 9/17/2021
COVID19 VACCINE	PFIZER\BIONTECH	1050476-1	30-39 years	31-60 days	Fetal demise at gestational age 14 weeks. Exact age when patient received first dose of COVID-19 vaccine. Patient had suffered from hyperemesis prior to vaccine, but had improved prior to vaccine. No other complications in pregnancy estimated date of delivery was July 14, 2021
COVID19 VACCINE	PFIZER\BIONTECH	1074788-1	18-29 years	31-60 days	At 8 weeks pregnancy (2 weeks after first shot) started bleeding and had a subchorionic hematoma. By 10 week subchorionic hematoma resolved. Received second shot and of Feb. 1 week later, at 12 weeks pregnancy, fetus had no heart beat! It measured normal size (as expected) and limited normal first trimester anatomy by ultrasound. But NO heart beat. Something insulted this placenta to lead to fetal demise.
COVID19 VACCINE	MODERNA	1053973-1	30-39 years	61-120 days	Wife did not know she was pregnant at the time, had the vaccine and miscarried the child at 12 weeks. OBGYN stated baby had miscarried 2-3 weeks earlier. D&C procedure performed 2/23 to remove remains of fetus.
COVID19 VACCINE	PFIZER\BIONTECH	1071787-1	30-39 years	61-120 days	Miscarriage after 2nd dose given
COVID19 VACCINE	MODERNA	1074149-1	Unknown	Unknown	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.

COVID19 VACCINE	MODERNA	1087526-1	30-39 years	Unknown	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 learned 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.
COVID19 VACCINE	MODERNA	1106171-1	Unknown	Unknown	no fetal heartbeat; pregnant and received vaccine; A spontaneous report was received from a 37-year old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) while pregnant, and there was not fetal heartbeat. The patient's medical history was not provided. Products known to have been used by the patient, within two weeks prior to the event, included prenatal vitamins. The consumer received the second of the two planned doses of mRNA-1273 on 26-JAN-2021 (Batch# 041L20A) intramuscularly for prophylaxis of COVID-19 infection. On 02-MAR-2021, the patient stated her fetus had no heartbeat. No treatment information was 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 outcome of the events was considered recovered.; Reporter's Comments: This is a case of product exposure during pregnancy for this 37 year old woman with associated event of absent fetal heartbeat. The patient will continue to be contacted for follow-up.
COVID19 VACCINE	PFIZER\BIONTECH	1035009-1	18-29 years	Unknown	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.

COVID19 VACCINE	PFIZER\BIONTECH	1051018-1	18-29 years	Unknown	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.
COVID19 VACCINE	PFIZER\BIONTECH	1100545-1	Unknown	Unknown	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.

Dataset: The Vaccine Adverse Event Reporting System (VAERS)

Query Parameters:

State / Territory: The United States/Territories/Unknown

Symptoms: ABORTION SPONTANEOUS; FOETAL DEATH; PREMATURE LABOUR; THREATENED LABOUR

Vaccine Products: COVID19 VACCINE (COVID19)

VAERS ID: All

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

Show Totals: False

Show Zero Values: Disabled

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

Query Date: Apr 22, 2021 5:21:16 PM

Suggested Citation: Accessed at <http://wonder.cdc.gov/vaers.html> on Apr 22, 2021 5:21:16 PM

Messages:

1. The full results are too long to be displayed, only non-zero rows are available.
2. VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
3. **These results are for 97 total events.**
4. When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.
5. Click on a VAERS ID to see a report containing detailed information for the event.

Footnotes:

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

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Caveats:

1. 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.

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3. Some items may have more than 1 occurrence in any single event report, such as Symptoms, Vaccine Products, Manufacturers, and Event Categories. If data are grouped by any of these items, then the number in the Events Reported column may exceed the total number of unique events. If percentages are shown, then the associated percentage of total unique event reports will exceed 100% in such cases. For example, the number of Symptoms mentioned is likely to exceed the number of events reported, because many reports include more than 1 Symptom. When more than 1 Symptom occurs in a single report, then the percentage of Symptoms to unique events is more than 100%. More information: <http://wonder.cdc.gov/wonder/help/vaers.html#Suppress>.

4. Data contains VAERS reports processed as of 4/10/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. More information: <http://wonder.cdc.gov/wonder/help/vaers.html#Reporting>.

5. For more information on how many persons have been vaccinated in the US for COVID19 to date, see <https://covid.cdc.gov/covid-data-tracker/#vaccinations/>