



National Vaccine
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Search Results

From the 11/12/2021 release of VAERS data:

Found 2,620 cases where Vaccine is COVID19 and Symptom is Aborted pregnancy or Abortion or Abortion complete or Abortion early or Abortion incomplete or Abortion induced or Abortion late or Abortion missed or Abortion of ectopic pregnancy or Abortion spontaneous or Abortion spontaneous complete or Abortion spontaneous incomplete or Foetal cardiac arrest or Foetal death or Premature baby death or Premature delivery or Stillbirth

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Table

	 	
Manufacturers	Count	Percent
GLAXOSMITHKLINE BIOLOGICALS	1	0.04%
JANSSEN	100	3.82%
MODERNA	689	26.3%
PFIZER/BIONTECH	2,015	76.91%
SANOFI PASTEUR	1	0.04%
UNKNOWN MANUFACTURER	14	0.53%
TOTAL	† 2,820	† 107.63%

† Because some cases have multiple vaccinations and symptoms, a single case can account for multiple entries in this table. This is the reason why the Total Count is greater than 2620 (the number of cases found), and the Total Percentage is greater than 100.

Case Details (Sorted by Onset Date)

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VAERS ID: [1074149](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-03-05
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	- / 2	- / OT

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Exposure during pregnancy](#)

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? Yes

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No reported medical history.)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: 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.

VAERS ID: [1100545](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-03-15
Location: Ohio

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 2	- / -

Administered by: Unknown **Purchased by:** ?
Symptoms: [Abortion spontaneous](#)
SMQs: Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:
Diagnostic Lab Data:
CDC Split Type: USPFIZER INC2021243074

Write-up: 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.

VAERS ID: [1142921](#) (history) **Vaccinated:** 2021-01-15
Form: Version 2.0 **Onset:** 0000-00-00
Age: 38.0 **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-03-29
Location: Pennsylvania

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	- / 1	- / OT

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Exposure during pregnancy](#)

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? Yes

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: 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.

VAERS ID: [1157569](#) (history) **Vaccinated:** 2021-01-01
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-04-01
Location: Pennsylvania

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	- / 1	- / OT

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Pregnancy](#), [Product dose omission issue](#)

SMQs: Termination of pregnancy and risk of abortion (narrow), Normal pregnancy conditions and outcomes (narrow), Medication errors (broad)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? Yes

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (no adverse event reported)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Miscarriage; Pregnancy; well past the 42 day mark; A Spontaneous report was received from a Healthcare Professional concerning a female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and the patient subsequently found out that she was pregnant . Patient had a miscarriage and now wants to receive the second dose of her vaccine. Well past the 42 day mark Patient now wants to receive the second dose of the Moderna Covid-19 vaccine. The patients medical history was not provided.No concomitant medication information was provided. On an unknown date in JAN 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, The patient The patient subsequently found out that she was pregnant . Patient had a miscarriage and now wants to receive the second dose of her vaccine. Well past the 42 day mark Patient now wants to receive the second dose of the Moderna Covid-19 vaccine. Laboratory details was not provided.No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events Pregnancy and Miscarriage was resolved. The outcome of the event well past 42 days was unknown.; Reporter's Comments: This is a case of product exposure during pregnancy with spontaneous abortion for this female (age unknown). Patient missed her second dose. She will continue to be contacted for further monitoring of AEs post abortion. .

VAERS ID: [1309633](#) (history) **Vaccinated:** 0000-00-00

Form: Version 2.0 **Onset:** 0000-00-00

Age: **Submitted:** 0000-00-00

Sex: Female **Entered:** 2021-05-12

Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
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COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	- / -
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Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#)

SMQs:, Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021502339

Write-up: I had a very early miscarriage; This is a spontaneous report from a contactable consumer reporting for herself. This pregnant female patient of unspecified age received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unknown date, for COVID-19 immunization. Medical history and concomitant medications were not reported. On an unknown date after the first vaccine shot the patient had a very early miscarriage. The outcome was unknown. Information on the lot/batch number has been requested.

VAERS ID: [1320144](#) (history) **Vaccinated:** 0000-00-00

Form: Version 2.0 **Onset:** 0000-00-00

Age: **Submitted:** 0000-00-00

Sex: Female **Entered:** 2021-05-15

Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#)

SMQs:, Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:**Other Medications:****Current Illness:****Preexisting Conditions:****Allergies:****Diagnostic Lab Data:****CDC Split Type:** USPFIZER INC2021487534

Write-up: I know someone that just had a miscarriage from it (Covid Vaccine); This is a spontaneous report from a non-contactable consumer. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The reporter said: "I know someone that just had a miscarriage from it (Covid Vaccine)". The outcome of event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

VAERS ID: [1364029](#) [\(history\)](#) **Vaccinated:** 0000-00-00**Form:** Version 2.0 **Onset:** 0000-00-00**Age:** **Submitted:** 0000-00-00**Sex:** Female **Entered:** 2021-06-01**Location:** Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	UNKNOWN / UNK	- / OT

Administered by: Unknown **Purchased by:** ?**Symptoms:** [Abortion spontaneous](#), [Exposure during pregnancy](#)**SMQs:**, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** No**Permanent Disability?** No**Recovered?** Yes**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:****Allergies:****Diagnostic Lab Data:****CDC Split Type:** USMODERNATX, INC.MOD20211

Write-up: First trimester miscarriage; Received the Moderna COVID-19 Vaccine while pregnant; This spontaneous pregnancy case was reported by a consumer and describes the occurrence of ABORTION SPONTANEOUS (First trimester miscarriage) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. Unknown) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On an unknown date,

the patient experienced ABORTION SPONTANEOUS (First trimester miscarriage) (seriousness criterion medically significant) and EXPOSURE DURING PREGNANCY (Received the Moderna COVID-19 Vaccine while pregnant). The delivery occurred on an unknown date, which was reported as Spontaneous Abortion. At the time of the report, ABORTION SPONTANEOUS (First trimester miscarriage) outcome was unknown and EXPOSURE DURING PREGNANCY (Received the Moderna COVID-19 Vaccine while pregnant) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. No concomitant medications was reported. No treatment details were provided. Company Comment : This is a case of product exposure during pregnancy with associated AEs for this female. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: This is a case of product exposure during pregnancy with associated AEs for this female. 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.

VAERS ID: [1366573](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Unknown **Entered:** 2021-06-02
Location: New Jersey

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	LA / SYR

Administered by: Pharmacy **Purchased by:** ?

Symptoms: [Abortion](#), [Exposure during pregnancy](#), [Human chorionic gonadotropin decreased](#), [Ultrasound scan](#)

SMQs: Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Fertility disorders (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? Yes

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data: B hcg decrease, control sonogram 2nd report

CDC Split Type:

Write-up: I got the vaccine while I was pregnant (and I had to the agent in vaccination site before) About 2 to 3 weeks later ultrasound reported abortion

VAERS ID: [1380742](#) [\(history\)](#) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-06-08
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	UNKNOWN / 1	- / OT

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Exposure during pregnancy](#)

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? Yes

Died? No

Permanent Disability? No

Recovered? Yes

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20211

Write-up: Caused misscarrage; Vaccine exposure during pregnancy; Based on the current case data, this case has been classified as invalid. This spontaneous pregnancy case was reported by a consumer and describes the occurrence of ABORTION SPONTANEOUS (Caused misscarrage) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. Unknown) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On an unknown date, the patient experienced ABORTION SPONTANEOUS (Caused misscarrage) (seriousness criteria medically significant and congenital anomaly) and EXPOSURE DURING PREGNANCY (Vaccine exposure during pregnancy). At the time of the report, ABORTION SPONTANEOUS (Caused misscarrage) outcome was unknown and EXPOSURE DURING PREGNANCY (Vaccine exposure during pregnancy) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant or treatment medications were reported. 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. This is a case of product exposure during pregnancy with associated AE. Reporter did not allow further contact; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. This is a case of product exposure during pregnancy with associated AE .

VAERS ID: [1381144](#) ([history](#)) **Vaccinated:** 2021-04-08
Form: Version 2.0 **Onset:** 0000-00-00
Age: 35.0 **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-06-08
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EN6206 / UNK	- / -

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Pyrexia](#)

SMQs:, Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Termination of pregnancy and risk of abortion (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? Yes

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021586249

Write-up: High fever that resulted in loss of pregnancy; High fever; This is a spontaneous report from a non-contactable other healthcare professional (patient). A 35-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EN6206), via an unspecified route of administration on 08Apr2021 12:00 (at the age of 35-year-old) as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. No other medications the patient received within 2 weeks of vaccination. On an unspecified date, the patient experienced high fever that resulted in loss of pregnancy. Events caused doctor or other healthcare professional office/clinic visit. Patient received treatment for events. The mother reported she became pregnant while taking BNT162B2. The mother was 3 weeks pregnant at the onset of the event. The mother was due to deliver on 17Dec2021, and last menstrual period date was on 12Mar2021. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was recovered with sequel. No follow-up attempts are possible. 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 events Pregnancy loss and fever 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.

VAERS ID: [1390729](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-06-11
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	- / UNK	- / OT

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Exposure during pregnancy](#)

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? Yes

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: Spontaneous miscarriage; Spontaneous miscarriage; This spontaneous retrospective pregnancy case was reported by a consumer and describes the occurrence of ABORTION SPONTANEOUS (Spontaneous miscarriage) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On an unknown date, the patient experienced ABORTION SPONTANEOUS (Spontaneous miscarriage) (seriousness criterion medically significant) and EXPOSURE DURING PREGNANCY (Spontaneous miscarriage). The delivery occurred on an unknown date, which was reported as Spontaneous Abortion. For foetus 1, The outcome was reported as Spontaneous Abortion NOS. Spontaneous miscarriage. Gestation period not reported. At the time of the report, ABORTION SPONTANEOUS (Spontaneous miscarriage) and EXPOSURE DURING PREGNANCY (Spontaneous miscarriage) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant medications were not reported. Treatment information was not provided. Company Comment: This case concerns a female patient, unknown age, who experienced an event of drug exposure during pregnancy and also experienced an event of spontaneous abortion. Limited information regarding the events has been provided at this time and is insufficient for causality assessment. Further information has been requested.; Sender's Comments: This case concerns a female patient, unknown age, who experienced an event of

drug exposure during pregnancy and also experienced an event of spontaneous abortion. Limited information regarding the events has been provided at this time and is insufficient for causality assessment. Further information has been requested.

VAERS ID: [1398511](#) ([history](#)) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-06-15
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	- / 1	- / OT

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Exposure during pregnancy](#)

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: had a miscarriage; had vaccine during the first 10 weeks and had a miscarriage; This spontaneous retrospective pregnancy case was reported by a consumer and describes the occurrence of ABORTION SPONTANEOUS (had a miscarriage) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On an unknown date, the patient experienced ABORTION SPONTANEOUS (had a miscarriage) (seriousness criterion medically significant) and EXPOSURE DURING PREGNANCY (had vaccine during the first 10 weeks and had a miscarriage). The delivery occurred on an unknown date, which was reported as Spontaneous Abortion. For foetus 1, The outcome was reported as Spontaneous Abortion NOS. At the time of the report, ABORTION SPONTANEOUS (had a miscarriage) and EXPOSURE DURING PREGNANCY (had vaccine during the first 10 weeks and had a miscarriage) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medication and treatment drug was reported. It was reported that the baby died Company comment: This is a case of product exposure during pregnancy which resulted in Spontaneous Abortion, for this female with undocumented age. Very limited information has been provided at this time.; Sender's Comments: This is a case of product exposure during pregnancy which resulted in

Spontaneous Abortion, for this female with undocumented age. Very limited information has been provided at this time.

VAERS ID: [1419852](#) ([history](#)) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-06-23
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	- / 1	- / OT

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Exposure during pregnancy](#), [Product dose omission issue](#)

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Medication errors (broad)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? Yes

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: This spontaneous prospective pregnancy case was reported by a consumer and describes the occurrence of ABORTION SPONTANEOUS (lost the pregnancy) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On an unknown date, the patient experienced ABORTION SPONTANEOUS (lost the pregnancy) (seriousness criterion medically significant), EXPOSURE DURING PREGNANCY (Vaccine exposure during Pregnancy) and PRODUCT DOSE OMISSION ISSUE (Missed second dose). At the time of the report, ABORTION SPONTANEOUS (lost the pregnancy) outcome was unknown and EXPOSURE DURING PREGNANCY (Vaccine exposure during Pregnancy) and PRODUCT DOSE OMISSION ISSUE (Missed second dose) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Concomitant product use was not provided by the reporter. No treatment information was provided. Moderna Customer Care agent attempted a warm transfer but when retrieving the caller the caller was no longer on the line. But the agent informed that the caller received the first dose of the Moderna COVID-19 vaccine in March. At the time of vaccination the caller did not know they were pregnant and did not get second dose once they found out for safety reasons. The caller lost the pregnancy and now wants to know if they can get the second dose. This is a case of product exposure during

pregnancy with associated AEs for this female patient of unknown age. Patient declined further contact no further details is expected.; Sender's Comments: This is a case of product exposure during pregnancy with associated AEs for this female patient of unknown age. Patient declined further contact no further details is expected.

VAERS ID: [1429299](#) [\(history\)](#) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-06-26
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN	UNKNOWN / UNK	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Exposure during pregnancy](#)

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? Yes

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions: Comments: Patient was pregnant at the time of vaccination.

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210648176

Write-up: MISCARRIED WITHIN A WEEK OF HER J&J VACCINE; VACCINE EXPOSURE DURING PREGNANCY; This spontaneous pregnancy report received from a consumer via a company representative via social media concerned a 30 year old female. The patient's height, and weight were not reported. The patient was pregnant at the time of vaccination (gravida 1). The date of the patient's last menstrual period and expected delivery date was not reported. The patient's obstetrician (OB) told her that it was safe to get vaccinated. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, expiry: UNKNOWN) dose, start therapy date were not reported, 1 total administered for prophylactic vaccination (vaccine exposure during pregnancy). The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, within a week after vaccination, the patient had miscarriage. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from vaccine exposure during pregnancy, and the outcome of miscarried within a week of vaccination was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210648705.; Sender's Comments: V0: 20210648176 -Covid-19 vaccine ad26.cov2.s- Miscarriage within a week of her J&J vaccine. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the

event(s). V0: 20210648176 -Covid-19 vaccine ad26.cov2.s-Vaccine exposure during pregnancy. This event(s) is considered not related. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: SPECIAL SITUATIONS

VAERS ID: [1432856](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-06-29
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	UNKNOWN / 1	- / OT

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Exposure during pregnancy](#)

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: Miscarriage shortly after the 1st dose; Vaccine exposure during pregnancy; This spontaneous prospective pregnancy case was reported by a consumer and describes the occurrence of ABORTION SPONTANEOUS (Miscarriage shortly after the 1st dose) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. Unknown) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On an unknown date, the patient experienced ABORTION SPONTANEOUS (Miscarriage shortly after the 1st dose) (seriousness criterion medically significant) and EXPOSURE DURING PREGNANCY (Vaccine exposure during pregnancy). The delivery occurred on an unknown date. At the time of the report, ABORTION SPONTANEOUS (Miscarriage shortly after the 1st dose) and EXPOSURE DURING PREGNANCY (Vaccine exposure during pregnancy) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. No concomitant medication information was not given. No treatment information was given.; Sender's Comments: This is a case of exposure of product during pregnancy with the vaccine mRNA -1273 with reported AE of spontaneous abortion. There is very limited information regarding this events has been provided at this time. Further information has been

requested.

VAERS ID: [1484472](#) (history) **Vaccinated:** 2021-05-22
Form: Version 2.0 **Onset:** 0000-00-00
Age: 35.0 **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-07-19
Location: New York

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 2	RA / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Blood test](#), [Diarrhoea](#), [Exposure during pregnancy](#), [Muscle spasms](#), [Myalgia](#), [Pain in extremity](#), [Ultrasound abdomen](#), [Urine analysis](#), [Vaginal haemorrhage](#)

SMQs: Rhabdomyolysis/myopathy (broad), Haemorrhage terms (excl laboratory terms) (narrow), Pseudomembranous colitis (broad), Dystonia (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Eosinophilic pneumonia (broad), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Noninfectious diarrhoea (narrow), Tendinopathies and ligament disorders (broad)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? Yes

Hospitalized? No

Previous Vaccinations:

Other Medications: prenatal vitamin, calcium and vitamin D, probiotic

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data: ultrasound, blood work, urinalysis

CDC Split Type: vsafe

Write-up: After the second vaccine, I felt arm soreness, muscle aches, around the 30th I started cramping when i was out on a walk during the heat wave, I had some loose bowels, i went to ER on the 2nd I started bleeding. They did a bunch of blood work and an ultrasound, they said the baby was about 8 weeks along, It looks like the baby stopped developing around 6 weeks, My HCG levels started dropping, on my follow up I lost baby, I was bleeding and having discharge until about July 11.

VAERS ID: [1489818](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-07-21
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Maternal exposure during pregnancy](#)

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021856456

Write-up: had a miscarriage after being around someone that had the Pfizer vaccine:

Unspecified; had a miscarriage after being around someone that had the Pfizer vaccine:

Unspecified; This is a spontaneous report from a contactable consumer or other non hcp. This is a spontaneous report received from a contactable consumer. This consumer reported for a female (neighbour patient). A female patient of an unspecified age received bnt162b2

(BNT162B2, solution for injection, Lot number and expiration date was not reported), via an unspecified route of administration on an unspecified date as dose number unknown, single for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced had a miscarriage after being around someone that had the pfizer vaccine on an unspecified date. The mother reported she became pregnant while taking bnt162b2. Reporter is calling regarding the Pfizer Covid 19 vaccine. She has been doing some research and her neighbour and her mother had the Pfizer covid virus vaccine. Reporter gave them a ride to pick up their car, which is about 15 minutes from her house. Ever since she gave them a ride , she (caller) has been having really horrible and very massive headaches. She has never had so much pain over her head in her life. Reporter had done some research and unfortunately, she was supposed to stay away from them. They were in her car. She got their spiked proteins and now could have inflammation in her brain, which is causing neurological brain damage by being in a confined area with someone who got the Pfizer vaccine. Report 3 of 3 is for the female that had a miscarriage after being around someone who had the Pfizer vaccine. The outcome of the event was unknown. Information about batch/lot number has been requested Follow-up (14Jul2021): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up attempts completed. No further information is expected.

VAERS ID: [1500693](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-07-24
Location: New Jersey

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Unknown **Purchased by:** ?
Symptoms: [Abortion spontaneous](#)
SMQs: Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:

Diagnostic Lab Data:**CDC Split Type:** USPFIZER INC2021889783

Write-up: Miscarriage; This is a spontaneous report received from a contactable consumer or other non hcp. This consumer reported information for both mother and fetus/baby. A female patient of an unspecified age received bnt162b2 (PFIZER-COVID19 Vaccine, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date as dose number unknown, single for covid-19 immunization. The patient medical history and concomitant medications were not reported. On an unspecified date the patient experienced miscarriage at 6 weeks and reported that event took place after use of product. The mother was 6 Weeks pregnant at the onset of the event. The outcome of event was unknown. No follow-up attempts are possible, information about lot/batch number cannot be obtained.

VAERS ID: [1509217](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-07-28
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 2	- / -

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Exposure during pregnancy](#), [Myocarditis](#)

SMQs:, Cardiomyopathy (broad), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Immune-mediated/autoimmune disorders (broad)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021907736

Write-up: myocarditis; had three miscarriages following the pfizer vaccine; became pregnant while taking bnt162b2; This is a spontaneous report from a contactable consumer from a Pfizer sponsored Program. This consumer reported for a female patient (wife's friend). A pregnant female patient of an unspecified age received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, formulation: solution for injection batch/lot number was not reported, expiration date was not reported), via an unspecified route of administration on an unspecified date as DOSE 2, SINGLE for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient historical vaccine included first dose of BNT162B2 for COVID-19 immunization. It was reported that, reporter stated that his wife's friend had three miscarriages following the Pfizer vaccine, the first one in the first trimester they could not find baby's heart beat. 2nd one had miscarriage a couple weeks after and then she conceived again and was in the hospital with myocarditis, her doctor said it was due to genetics and she lost the third one also. Reporter reports his wife's female friend had her first miscarriage, after the second vaccine and also reports that 82% of people, that got the vaccine experienced miscarriage and spontaneous abortion. Reporter states, his wife's friend had a total of 3 miscarriages and clarifies, that the first miscarriage occurred after both doses of the Pfizer Covid vaccine, reporter also states that she was also diagnosed with myocarditis and has spent hundreds of dollars on her medical bills. Reporter stated that this woman's doctor, said it was not caused from the vaccine, that it was genetic, and he did not report this to the VAERS website. The mother reported she became pregnant while taking BNT162B2. The reporter assessed the events as non-serious. The outcome of the events was unknown. Information about lot/batch number has been requested.

VAERS ID: [1512628](#) (history) **Vaccinated:** 0000-00-00

Form: Version 2.0 **Onset:** 0000-00-00

Age: 31.0 **Submitted:** 0000-00-00

Sex: Female **Entered:** 2021-07-29

Location: California

Vaccination / Manufacturer	Lot / Dose	Site / Route
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COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 2	- / SYR
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Administered by: Private **Purchased by:** ?
Symptoms: [Abortion spontaneous](#)
SMQs:, Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? Yes
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations: Miscarriage at 6.5 weeks pregnant
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:
Diagnostic Lab Data:
CDC Split Type:
Write-up: Miscarriage at 6.5 weeks pregnant.

VAERS ID: [1512934](#) ([history](#)) **Vaccinated:** 1983-09-17
Form: Version 2.0 **Onset:** 0000-00-00
Age: 38.0 **Submitted:** 0000-00-00
Sex: Unknown **Entered:** 2021-07-29
Location: Ohio

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	- / -

Administered by: Pharmacy **Purchased by:** ?
Symptoms: [Abortion spontaneous](#), [Exposure during pregnancy](#), [Thrombosis](#)
SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (broad), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? Yes
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:

Preexisting Conditions:**Allergies:****Diagnostic Lab Data:****CDC Split Type:**

Write-up: Pt was approximately three months pregnant, and miscarried shortly after receiving vaccine, this was per mother. Case reports daughter had problems with pregnancy prior to receiving the COVID vaccine, and after examining following the miscarriage and noted finding huge blood clots.

VAERS ID: [1524852](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-08-04
Location: North Dakota

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	- / UNK	- / OT

Administered by: Unknown **Purchased by:** ?

Symptoms: [Maternal exposure during pregnancy](#), [Premature delivery](#), [Premature separation of placenta](#)

SMQs: Haemorrhage terms (excl laboratory terms) (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? Yes

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? Yes, ? days

Extended hospital stay? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: placenta separate after the vaccine (unconfirmed vaccine); baby was delivered at 32 weeks; pregnancy; This spontaneous retrospective pregnancy case was reported by an other health care professional and describes the occurrence of PREMATURE SEPARATION OF PLACENTA (placenta separate after the vaccine (unconfirmed vaccine)), PREMATURE DELIVERY (baby was delivered at 32 weeks) and MATERNAL EXPOSURE DURING PREGNANCY (pregnancy) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On an unknown date, the patient experienced PREMATURE SEPARATION OF PLACENTA (placenta separate after the vaccine (unconfirmed vaccine)) (seriousness criteria hospitalization and medically significant), PREMATURE DELIVERY (baby was delivered at 32 weeks) (seriousness criterion hospitalization) and MATERNAL EXPOSURE DURING

PREGNANCY (pregnancy) (seriousness criterion hospitalization). The delivery occurred on an unknown date, which was reported as Premature. For neonate 1, The outcome was reported as Pre-Term Birth NOS. At the time of the report, PREMATURE SEPARATION OF PLACENTA (placenta separate after the vaccine (unconfirmed vaccine)), PREMATURE DELIVERY (baby was delivered at 32 weeks) and MATERNAL EXPOSURE DURING PREGNANCY (pregnancy) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medication provided. No treatment information mentioned. This is a case of product exposure during pregnancy with associated AEs. Very limited information regarding this event/s has been provided at this time. Further information has been requested.; Sender"s Comments: This is a case of product exposure during pregnancy with associated AEs. Very limited information regarding this event/s has been provided at this time. Further information has been requested.

VAERS ID: [1646741](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-08-28
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Unknown **Purchased by:** ?
Symptoms: [Foetal death](#)
SMQs: Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? Yes
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? Yes
Hospitalized? Yes, ? days
Extended hospital stay? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:
Diagnostic Lab Data:

CDC Split Type: USPFIZER INC202101016416

Write-up: Patient lost baby 4 weeks prior to estimated date of birth. Emergency c section.; This is a spontaneous report from a non-contactable consumer. A female patient of an unspecified age received BNT162b2 (PFIZER BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Lot number- unknown) via an unspecified route of administration on an unspecified date as dose number unknown, single for COVID-19 immunization. Medical history and concomitant medications were not reported. Prior to vaccination, the patient was not diagnosed with COVID-19. Patient was pregnant at the time of vaccination was reported. Due date of pregnancy was 30Aug2021, gestation period of 12 weeks [unspecified]. The patient did not

receive any other vaccines within 4 weeks prior to the COVID vaccine. On an unspecified date, patient lost baby 4 weeks prior to estimated date of birth. Emergency c section. Adverse event resulted in Emergency room/department or urgent care, hospitalization, Congenital anomaly or birth defect. Since the vaccination, the patient had not been tested for COVID-19. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-202101016957 Mother case/Fetal case

VAERS ID: [1692222](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-09-11
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Unknown **Purchased by:** ?
Symptoms: [Abortion spontaneous](#)
SMQs: Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC202101127752

Write-up: lost her baby; This is a spontaneous report from a non-contactable consumer. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as dose number unknown, single for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The reported stated that the patient lost her baby. The mother reported she became pregnant while taking bnt162b2. It was reported that the doctors said that can't prove it was from the vaccine but they say they are pretty damn sure it was because of the vaccine. The outcome of event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

VAERS ID: [1711595](#) ([history](#)) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-09-18
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	UNKNOWN / UNK	- / -

Administered by: Unknown **Purchased by:** ?
Symptoms: [Abortion spontaneous](#)
SMQs: Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC202101144476

Write-up: had miscarriage after the vaccination; This is a spontaneous report from a Pfizer sponsored program via non-contactable consumer. This consumer reported similar events for two patients. This is the first of two reports. This is a maternal report. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: Unknown, Expiration date: Not reported), via an unspecified route of administration, on an unspecified date as dose number unknown, single for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was pregnant at the time of vaccination. The patient had a miscarriage after the vaccination on an unspecified date. The mother reported she became pregnant while taking BNT162B2. The pregnancy resulted in spontaneous abortion. The fetal outcome is intrauterine death. The outcome of the event was unknown at the time of report. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; **Sender's Comments:** Based on plausible dose- event relationship post-vaccination and the causal role of BNT162B2 vaccine cannot be excluded for the reported events. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate, Linked Report(s) : US-PFIZER INC-202101144532 Same reporter/event, diff patient

VAERS ID: [1711596](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-09-18
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Unknown **Purchased by:** ?
Symptoms: [Abortion spontaneous](#)
SMQs: Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC202101144532

Write-up: had miscarriage after the vaccination; This is a spontaneous report from a Pfizer sponsored program received from a non-contactable consumer. This consumer reported similar events for two patients. This is the second of two reports. This is a maternal report. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date as dose number unknown, single for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient was pregnant at the time of vaccination. The patient had miscarriage after the vaccination on an unspecified date. The mother reported she became pregnant while taking BNT162B2. The pregnancy resulted in spontaneous abortion. The fetal outcome is intrauterine death. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; **Sender's Comments:** Linked Report(s) : US-PFIZER INC-202101144476 Same reporter/ event, diff patient

VAERS ID: [1711671](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-09-18
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
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COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) /
PFIZER/BIONTECH

- / UNK

- / -

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Exposure during pregnancy](#)

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC202101148505

Write-up: got the vaccine lost her baby a week later; This is a spontaneous report from a contactable other healthcare professional via the Pfizer-sponsored Program. A pregnant female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number/expiry date unknown), via an unspecified route of administration on an unspecified date as dose number unknown, single for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter informed that a mother (patient) that she knows who got the vaccine lost her baby a week later. The reporter thinks that the patient's physician may have already reported this. The outcome of the event was unknown. The lot number for BNT162B2 was not provided and will be requested during follow-up.; Sender's Comments: Based on the information available and close temporal association, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported events . The case will be reassessed once new information is available The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

VAERS ID: [1711750](#) ([history](#))

Vaccinated: 0000-00-00

Form: Version 2.0

Onset: 0000-00-00

Age:

Submitted: 0000-00-00

Sex: Female

Entered: 2021-09-18

Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#)**SMQs:**, Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** No**Permanent Disability?** No**Recovered?** No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:****Allergies:****Diagnostic Lab Data:****CDC Split Type:** USPFIZER INC202101154129

Write-up: had miscarriage after vaccination; This is a spontaneous report from a non-contactable consumer via a Pfizer Sponsored Program. This consumer reported for two female patients. This is the first of two reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number and expiry date not reported), via an unspecified route of administration, on an unspecified date, as dose number unknown, single, for COVID-19 immunisation. The patient medical history was not reported. There were no concomitant medications. The patient had miscarriage after vaccination on an unspecified date. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-202101154145 different patient, same reporter/product/event

VAERS ID: [1711751](#) (history)**Vaccinated:** 0000-00-00**Form:** Version 2.0**Onset:** 0000-00-00**Age:****Submitted:** 0000-00-00**Sex:** Female**Entered:** 2021-09-18**Location:** Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Unknown **Purchased by:** ?**Symptoms:** [Abortion spontaneous](#)**SMQs:**, Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** No**Permanent Disability?** No**Recovered?** No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No

Previous Vaccinations:**Other Medications:****Current Illness:****Preexisting Conditions:****Allergies:****Diagnostic Lab Data:****CDC Split Type:** USPFIZER INC202101154145

Write-up: patient had miscarriage after vaccination; This is a spontaneous report from a non-contactable consumer via a Pfizer Sponsored Program. This consumer reported for two female patients. This is the second of two reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot number was not reported), via an unspecified route of administration on an unspecified date as dose number unknown, single for covid-19 immunisation. The patient medical history was not reported. There were no concomitant medications. The patient had miscarriage after vaccination on an unspecified date. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected; Sender's Comments: Linked Report(s) : US-PFIZER INC-202101154129 different patient, same reporter/product /event

VAERS ID: [1725535](#) (history) **Vaccinated:** 0000-00-00**Form:** Version 2.0 **Onset:** 0000-00-00**Age:** **Submitted:** 0000-00-00**Sex:** Female **Entered:** 2021-09-23**Location:** Michigan

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Unknown **Purchased by:** ?**Symptoms:** [Abortion spontaneous](#)**SMQs:**, Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** No**Permanent Disability?** No**Recovered?** No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:****Allergies:****Diagnostic Lab Data:****CDC Split Type:** USPFIZER INC202101198116

Write-up: miscarriage; This is a spontaneous report from a Pfizer-sponsored program reported by a contactable consumer (patient's mother). A female patient unspecified age received BNT162B2 (COMIRNATY, formulation: solution for injection) via an unspecified route of administration on an unspecified date as dose number unknown, single for COVID-19

immunisation. Patient medical history and concomitant medications were not reported. Reporter stated that both reporter and her husband received both doses of product. No side effects, "everything was good". Travelled to visit daughter, daughter experienced a miscarriage. Daughter did not receive product, or "anyone else". Her daughter is pregnant and had a miscarriage while the mom went to visit her daughter, after receiving the vaccine. She wants to know if the vaccine causes shedding. She has been hearing different stories about that. Follow-up attempts are completed. No further information is expected.

VAERS ID: [1730473](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-09-24
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Unknown **Purchased by:** ?
Symptoms: [Abortion spontaneous](#)
SMQs: Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC202101200080

Write-up: lost baby; This is a spontaneous report from a Pfizer-Sponsored Program via Regulatory Authority Support from a non-contactable consumer. The reporter reported three same cases. This is one the three cases. A pregnant female patient of an unspecified age received BNT162B2 (PFIZER BIONTECH COVID-19 VACCINE, lot/batch number unknown) via an unspecified route of administration as a single dose, on an unspecified date, for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had lost her baby after receiving the covid-19 vaccine. Outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; **Sender's Comments:** Linked Report(s) : US-PFIZER INC-202101200160 Same reporter/drug/event, different patients.;US-PFIZER INC-202101200159 Same reporter/drug/event, different patients.

VAERS ID: [1730474](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-09-24
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Unknown **Purchased by:** ?
Symptoms: [Abortion spontaneous](#)
SMQs: Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC202101200159

Write-up: lost baby; This is a spontaneous report from a Pfizer-Sponsored Program via Regulatory Authority with Support from a non-contactable consumer. The reporter reported three same cases. This is one the three cases. A pregnant female patient of an unspecified age received BNT162B2 (PFIZER BIONTECH COVID-19 VACCINE, lot/batch number unknown) via an unspecified route of administration as a single dose, on an unspecified date, for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had lost her baby after receiving the covid-19 vaccine. Outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; **Sender's Comments:** Linked Report(s) : US-PFIZER INC-202101200160 Same reporter/drug/event, different patients.;US-PFIZER INC-202101200080 Same reporter/drug/event, different patients.

VAERS ID: [1730475](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-09-24
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
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COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -
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Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#)

SMQs:, Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC202101200160

Write-up: lost baby after receiving the covid-19 vaccine.; This is a spontaneous report from a Pfizer-Sponsored Program via Regulatory Authority with Support from a non-contactable consumer. No patient identifiers were provided but the reporter has firsthand knowledge of the patient and was reporting on a specific patient. The reporter reported three same cases. This is one of the three cases. A female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, LOT/Batch number and expiration date unknown) via an unspecified route of administration on unspecified date at single dose, dose number unknown for COVID-19 immunization. Patient was pregnant at time of vaccination and event onset. Medical history and concomitant medications were not reported. Caller inquiring on if the vaccine was FDA approved. Started reading ISI and caller interrupted and asked about women that are pregnant. Caller stated that the patient had lost her baby after receiving the covid-19 vaccine. Outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-202101200159 Same reporter/drug /event, different patients.;US-PFIZER INC-202101200080 Same reporter/drug/event, different patients.

VAERS ID: [1730476](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: 20.0 **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-09-24
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abdominal pain](#), [Abortion spontaneous](#), [Haemorrhage](#), [Menstruation delayed](#), [Nausea](#), [Vomiting](#)

SMQs:, Acute pancreatitis (broad), Haemorrhage terms (excl laboratory terms) (narrow), Retroperitoneal fibrosis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Termination of pregnancy and risk of abortion (narrow), Fertility disorders (broad)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? Yes, ? days

Extended hospital stay? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC202101202715

Write-up: Hemorrhaging in the hospital; Suspected to be pregnant has a miscarriage; Her period has also become "messed up" that became longer and heavier with cramping and nausea and vomiting.; Her period has also become "messed up" that became longer and heavier with cramping and nausea and vomiting; Her period has also become "messed up" that became longer and heavier with cramping and nausea and vomiting; Her period has also become "messed up" that became longer and heavier with cramping and nausea and vomiting; This is a spontaneous report from a Pfizer Sponsored Program A contactable consumer reported for a female patient A female patient of age 3 decade received bnt162b2 (BNT162B2, Formulation: Solution for injection, Batch/Lot number: Not reported) Via an unspecified route of administration on an unspecified date as a dose number unknown, single for (at the age of 3 decade) COVID-19 immunization. Patient medical history and concomitant medication were not provided. After administration of the vaccine, on an unspecified date she was hemorrhaging in the hospital and suspected to be pregnant, has a miscarriage. Her period has also become "messed up" that became longer and heavier with cramping and nausea and vomiting. Outcome of the event was unknown. The lot number for the vaccine, [BNT162B2], was not provided and will be requested during follow up.

VAERS ID: [1739932](#) (history) **Vaccinated:** 0000-00-00

Form: Version 2.0 **Onset:** 0000-00-00

Age: **Submitted:** 0000-00-00

Sex: Female **Entered:** 2021-09-28

Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN	- / UNK	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Maternal exposure during pregnancy](#)

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No**Permanent Disability?** No**Recovered?** No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:****Allergies:****Diagnostic Lab Data:****CDC Split Type:** USJNJFOC20210924179**Write-up:** SPONTANEOUS ABORTION; MATERNAL EXPOSURE DURING PREGNANCY;

This spontaneous pregnancy report received from a consumer concerned multiple patients.

"This case reported 49 instances of miscarriages post vaccination." No past medical history or

concurrent conditions were reported. The patients received covid-19 vaccine ad26.cov2.s

(suspension for injection, route of admin, and batch number were not reported) dose, start

therapy date were not reported, 1 total administered for prophylactic vaccination. The patients

were pregnant at the time of vaccination (maternal exposure during pregnancy). The batch

number was not reported. The company was unable to perform follow up to request batch/lot

numbers. No concomitant medications were reported. The date of the patient's last menstrual

period and expected delivery date were not reported. On an unspecified date, the patients

experienced miscarriage (spontaneous abortion). The action taken with covid-19 vaccine

ad26.cov2.s was not applicable. The outcome of the spontaneous abortion and maternal

exposure during pregnancy was not reported. This report was serious (Other Medically

Important Condition).; Sender's Comments: V0-20210924179-Covid-19 Vaccine Ad26.CoV2.s-

Spontaneous Abortion. This event(s) is considered un-assessable. The event(s) has a

compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific

plausibility. There is no information on any other factors potentially associated with the event(s).

V0-20210924179-Covid-19 Vaccine Ad26.CoV2.s-Maternal Exposure during pregnancy. This

event(s) is considered not related. The event(s) has a compatible/suggestive temporal

relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more

likely to be associated with the event(s) than the drug. Specifically: SPECIAL SITUATIONS

VAERS ID: [1740111](#) (history)**Vaccinated:** 0000-00-00**Form:** Version 2.0**Onset:** 0000-00-00**Age:****Submitted:** 0000-00-00**Sex:** Female**Entered:** 2021-09-28**Location:** Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	- / 1	- / OT

Administered by: Unknown **Purchased by:** ?**Symptoms:** [Abortion spontaneous](#), [Illness](#), [Maternal exposure during pregnancy](#)**SMQs:**, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** No**Permanent Disability?** No

Recovered? Yes
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:
Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20213

Write-up: miscarriage when she became sick from the first vaccine; became sick from the first vaccine; Maternal exposure during pregnancy; This spontaneous prospective pregnancy case was reported by a consumer and describes the occurrence of ABORTION SPONTANEOUS (miscarriage when she became sick from the first vaccine) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On an unknown date, the patient experienced ABORTION SPONTANEOUS (miscarriage when she became sick from the first vaccine) (seriousness criterion medically significant), ILLNESS (became sick from the first vaccine) and MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy). At the time of the report, ABORTION SPONTANEOUS (miscarriage when she became sick from the first vaccine) and ILLNESS (became sick from the first vaccine) outcome was unknown and MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. No concomitant medications were reported. No treatment medications were reported. This case concerns of a female patient with no age and no relevant medical history reported who experienced the unexpected events of spontaneous abortion, illness and Maternal Exposure during pregnancy. The occurrence of these events are unknown as well as the time to onset from the vaccine administration with Moderna since the date of the first dose of the vaccine is also unknown. Other details of the pregnancy was also not reported like the LMP and EDD. The benefit-risk relationship of Spikevax is not affected by this report.; Sender's Comments: This case concerns of a female patient with no age and no relevant medical history reported who experienced the unexpected events of spontaneous abortion, illness and Maternal Exposure during pregnancy. The occurrence of these events are unknown as well as the time to onset from the vaccine administration with Moderna since the date of the first dose of the vaccine is also unknown. Other details of the pregnancy was also not reported like the LMP and EDD. The benefit-risk relationship of Spikevax is not affected by this report.

VAERS ID: [1751737](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-10-01
Location: New York

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN	UNKNOWN / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: [Exposure during pregnancy](#), [Stillbirth](#)

Write-up: STILLBIRTH; VACCINE EXPOSURE DURING PREGNANCY; This spontaneous pregnancy report received from a health care professional concerned multiple female (three mothers) patients with unspecified ethnic origin and race. No past medical history or concurrent conditions were reported. It was not reported whether the patient had been pregnant before. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, expiry date was unknown) dose was not reported, therapy start date were not reported, 1 total dose administered for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow up to request batch/lot numbers. No concomitant medications were reported. unspecified date, the patients experienced stillbirth, and vaccine exposure during pregnancy. Reporter stated that, the patients (three mothers) had stillbirths due to the vaccine (the pregnancy resulted in a stillbirth). The date of the patient's last menstrual period and expected delivery date were not reported. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the stillbirth and vaccine exposure during pregnancy was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210955784-COVID-19 VACCINE AD26.COV2.S- Still birth. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event. 20210955784-COVID-19 VACCINE AD26.COV2.S- Vaccine exposure during pregnancy. This event is considered not related. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event than the drug. Specifically: SPECIAL SITUATIONS

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EN6204 / 1	LA / IM

COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) /
PFIZER/BIONTECH

ER8729 / 2

LA / IM

Administered by: School **Purchased by:** ?**Symptoms:** [Abortion spontaneous](#), [Ultrasound scan abnormal](#)**SMQs:**, Malignancy related therapeutic and diagnostic procedures (narrow), Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** No**Permanent Disability?** No**Recovered?** Yes**Office Visit?** Yes**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:****Allergies:****Diagnostic Lab Data:** FIRST TRIMESTER MISCARRIAGE CONFIRMED POST VACCINE BY ULTRASOUND AND Beta HCG. Patient is recovering from physical and emotional trauma. Will continue to follow.**CDC Split Type:****Write-up:** Miscarriage, 05/20/2021**VAERS ID:** [1791289](#) (history)**Vaccinated:** 0000-00-00**Form:** Version 2.0**Onset:** 0000-00-00**Age:****Submitted:** 0000-00-00**Sex:** Female**Entered:** 2021-10-16**Location:** Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Unknown **Purchased by:** ?**Symptoms:** [Abortion spontaneous](#)**SMQs:**, Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** No**Permanent Disability?** No**Recovered?** No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:**

Preexisting Conditions:**Allergies:****Diagnostic Lab Data:****CDC Split Type:** USPFIZER INC202101343886

Write-up: miscarriages; This is a spontaneous report from a Pfizer Sponsored Program. A contactable consumer (patient's friend) reporting same event under the same suspect product for four patients. This is one of four reports. A female patient of unspecified age received bnt162b2 (Pfizer covid vaccine), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported, Caller unwilling to complete the report) as dose number unknown, single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient was pregnant. The patient blamed her miscarriage on the vaccine. The outcome of event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-202101375474 same report/drug/AE, different patients;US-PFIZER INC-202101375755 same report/drug/AE, different patients;US-PFIZER INC-202101375754 same report/drug/AE, different patients

VAERS ID: [1791323](#) ([history](#)) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-10-16
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#)

SMQs:, Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC202101375474

Write-up: miscarriages; This is a spontaneous report from a Pfizer Sponsored Program. A contactable consumer (patient's friend) reporting same event under the same suspect product for four patients. This is one of four reports. A female patient of unspecified age received bnt162b2 (Pfizer covid vaccine), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported, Caller unwilling to complete the report) as dose number unknown, single dose for COVID-19 immunization. Medical history and concomitant

medications were not reported. The patient was pregnant. The patient blamed her miscarriage on the vaccine. The outcome of event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-202101343886 same report/drug/AE, different patients

VAERS ID: [1791324](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-10-16
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Unknown **Purchased by:** ?
Symptoms: [Abortion spontaneous](#)
SMQs:, Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:
Diagnostic Lab Data:
CDC Split Type: USPFIZER INC202101375754

Write-up: miscarriages; This is a spontaneous report from a Pfizer Sponsored Program. A contactable consumer (patient's friend) reporting same event under the same suspect product for four patients. This is one of four reports. A female patient of unspecified age received bnt162b2 (Pfizer covid vaccine), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported, Caller unwilling to complete the report) as dose number unknown, single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient was pregnant. The patient blamed her miscarriage on the vaccine. The outcome of event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-202101343886 same report/drug/AE, different patients

VAERS ID: [1791325](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-10-16
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Unknown **Purchased by:** ?
Symptoms: [Abortion spontaneous](#)
SMQs: Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC202101375755

Write-up: miscarriages; This is a spontaneous report from a Pfizer Sponsored Program. A contactable consumer (patient's friend) reporting same event under the same suspect product for four patients. This is one of four reports. A female patient of unspecified age received bnt162b2 (Pfizer covid vaccine), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported, Caller unwilling to complete the report) as dose number unknown, single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient was pregnant. The patient blamed her miscarriage on the vaccine. The outcome of event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Linked Report(s) : US-PFIZER INC-202101343886 same report/drug/AE, different patients

VAERS ID: [1807540](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-10-22
Location: Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
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COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 3	- / -
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Administered by: Unknown**Purchased by:** ?**Symptoms:** [Foetal death](#)**SMQs:** Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** No**Permanent Disability?** No**Recovered?** No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:****Allergies:****Diagnostic Lab Data:****CDC Split Type:** USPFIZER INC202101334457

Write-up: patients has received both the regular and the booster Pfizer Covid vaccines but subsequently had a baby demise; This is a spontaneous report from a non-contactable nurse. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number and expiry date not reported), via an unspecified route of administration on an unspecified date, as dose 1, single, and then second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number and expiry date not reported), via an unspecified route of administration on an unspecified date, as dose 2, single, and then third dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number and expiry date not reported), via an unspecified route of administration on an unspecified date, as dose 3 (booster), single, all for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient received both the regular and the booster Pfizer covid vaccines but subsequently had a baby demise on an unspecified date. It was reported that the patient wants to donate the fetus to Pfizer for eventual studies. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported event of fetal demise due to temporal relationship. However, the reported event may possibly represent intercurrent medical condition in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. 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.

VAERS ID: [1810558](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-10-23
Location: Louisiana

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Infertility female](#)

SMQs:, Termination of pregnancy and risk of abortion (narrow), Fertility disorders (narrow), Sexual dysfunction (broad)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC202101352584

Write-up: two pregnant women lost their baby and can no longer have children.; two pregnant women lost their baby and can no longer have children.; This is a spontaneous report from a contactable consumer or other non HCP. This consumer reported similar events for 2 patients. This is the first of 2 reports. A female patient of an unspecified age received bnt162b2 (BNT162B2) unknown dose number, via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation . The patient medical history and concomitant medications were not reported. It was reported that two pregnant women lost their baby and can no longer have children. (medically significant) on an unspecified date with outcome of unknown. The lot number for the vaccine, [BNT162B2], was not provided and will be requested during follow up.; Sender's Comments: Linked Report(s) : 202101366241 Same reporter, drug and events, different patient

VAERS ID: [1810600](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-10-23
Location: Louisiana

Vaccination / Manufacturer	Lot / Dose	Site / Route
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COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -
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Administered by: Unknown**Purchased by:** ?**Symptoms:** [Abortion spontaneous](#), [Infertility female](#)**SMQs:**, Termination of pregnancy and risk of abortion (narrow), Fertility disorders (narrow), Sexual dysfunction (broad)**Life Threatening?** No**Birth Defect?** No**Died?** No**Permanent Disability?** No**Recovered?** No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:****Allergies:****Diagnostic Lab Data:****CDC Split Type:** USPFIZER INC202101366241

Write-up: two pregnant women lost their baby and can no longer have children.; two pregnant women lost their baby and can no longer have children.; This is a spontaneous report from a contactable consumer. This consumer reported similar events for 2 patients. This is the second of 2 reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose (dose number unknown) for COVID-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. On an unspecified date, the patient experienced miscarriage and she can no longer have children. The outcome of the events was unknown. The reporting consumer stated that "two pregnant women lost their baby and can no longer have children". The lot number for the vaccine BNT162B2 was not provided and will be requested during follow up.; Sender's Comments: Linked Report(s) : US-PFIZER INC-202101352584 Same reporter, drug and events, different patient

VAERS ID: [1842053](#) [\(history\)](#) **Vaccinated:** 0000-00-00**Form:** Version 2.0 **Onset:** 0000-00-00**Age:** **Submitted:** 0000-00-00**Sex:** Female **Entered:** 2021-11-04**Location:** Minnesota

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN	UNKNOWN / UNK	- / -

Administered by: Other **Purchased by:** ?**Symptoms:** [Abortion spontaneous](#), [Exposure during pregnancy](#)**SMQs:**, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** No

Permanent Disability? No**Recovered?** No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:****Allergies:****Diagnostic Lab Data:****CDC Split Type:** USJNJFOC20211103304

Write-up: SPONTANEOUS ABORTION; DRUG EXPOSURE DURING PREGNANCY; This spontaneous pregnancy report was received from literature: Spontaneous Abortion Following COVID-19 Vaccination During Pregnancy. JAMA. 2021 Sep 08; 326/161629-1631. This report concerned multiple patients. The objective of this study was case-control surveillance of COVID-19 vaccination during pregnancy and spontaneous abortion. The patients' height, and weight were not reported. No past medical histories and concurrent conditions were reported. It was not reported whether the patients had been pregnant before. The patients received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown and expiry: unknown) dose, start therapy date were not reported 1 total administered for prophylactic vaccination. The patients were pregnant at the time of vaccination (drug exposure during pregnancy). The batch numbers were not reported and have been requested. No concomitant medications were reported. On an unspecified date, the patients experienced drug exposure during pregnancy. The date of the patients' last menstrual period and expected delivery date were not reported. On an unspecified date, the pregnancy resulted in a spontaneous abortion. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the drug exposure during pregnancy and spontaneous abortion was not reported. The authors concluded that among women with spontaneous abortions, the odds of COVID-19 vaccine exposure were not increased in the prior 28 days compared with women with ongoing pregnancies. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20211103304 -covid-19 vaccine ad26.cov2.s- spontaneous abortions, This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). 20211103304 -COVID-19 VACCINE AD26.COV2.S- drug exposure during pregnancy. This event is considered not related. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event than the drug. Specifically: SPECIAL SITUATIONS.

VAERS ID: [1842452](#) ([history](#)) **Vaccinated:** 0000-00-00**Form:** Version 2.0 **Onset:** 0000-00-00**Age:** **Submitted:** 0000-00-00**Sex:** Female **Entered:** 2021-11-04**Location:** Unknown

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	- / UNK	- / OT

Administered by: Unknown **Purchased by:** ?**Symptoms:** [Abortion spontaneous](#), [Maternal exposure during pregnancy](#)**SMQs:** Pregnancy, labour and delivery complications and risk factors (excl abortions and

stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? Yes

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20213

Write-up: My daughter just had a miscarriage; Maternal exposure during pregnancy; Based on the current case data, this case has been classified as invalid. This spontaneous retrospective pregnancy case was reported by a consumer and describes the occurrence of ABORTION SPONTANEOUS (My daughter just had a miscarriage) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On an unknown date, the patient experienced ABORTION SPONTANEOUS (My daughter just had a miscarriage) (seriousness criterion medically significant) and MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy). The delivery occurred on an unknown date, which was reported as Spontaneous Abortion. For foetus 1, The outcome was reported as Spontaneous Abortion NOS. At the time of the report, ABORTION SPONTANEOUS (My daughter just had a miscarriage) outcome was unknown and MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. No concomitant medication is provided by reporter. No treatment was provided. Company Comment: This is a case of maternal exposure during pregnancy of this female patient, unknown age with no disclosed medical history, who experienced the serious, unexpected event of spontaneous abortion. The patient received the unspecified dose of vaccine at unknown weeks of gestation. Spontaneous abortion occurred on unknown date after the unspecified dose of Moderna vaccine. The benefit-risk relationship of Moderna vaccine is not affected by this report.; Sender's Comments: This is a case of maternal exposure during pregnancy of this female patient, unknown age with no disclosed medical history, who experienced the serious, unexpected event of spontaneous abortion. The patient received the unspecified dose of vaccine at unknown weeks of gestation. Spontaneous abortion occurred on unknown date after the unspecified dose of Moderna vaccine. The benefit-risk relationship of Moderna vaccine is not affected by this report.

VAERS ID: [1856780](#) ([history](#))

Vaccinated: 0000-00-00

Form: Version 2.0

Onset: 0000-00-00

Age:

Submitted: 0000-00-00

Sex: Female

Entered: 2021-11-10

Location: Unknown

Vaccination / Manufacturer	Lot /	Site /
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	Dose	Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Maternal exposure timing unspecified](#)

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC202101458306

Write-up: miscarried; Maternal Drug Exposure; This is a spontaneous report from a non-contactable consumer. A female patient (reporter's friend's daughter-in-law) of unspecified age received BNT162B2 (COMIRNATY), via an unspecified route of administration on an unspecified date at single dose, and via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced miscarried on an unspecified date. Patient got pregnant, received the Pfizer vaccine, miscarried; got pregnant again, got the Pfizer vaccine and miscarried again. Outcome of events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

VAERS ID: [1860344](#) (history) **Vaccinated:** 2021-10-06

Form: Version 2.0 **Onset:** 0000-00-00

Age: 34.0 **Submitted:** 0000-00-00

Sex: Female **Entered:** 2021-11-11

Location: South Carolina

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	FF8839 / 2	LA / -

Administered by: Pharmacy **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Pregnancy test](#), [Ultrasound scan](#)

SMQs:, Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No**Office Visit?** Yes**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:** Comments: List of non-encoded Patient Relevant History: Patient Other Relevant History 1: None**Allergies:**

Diagnostic Lab Data: Test Name: pregnancy test; Test Result: Positive ; Test Name: ultrasound; Result Unstructured Data: Test Result: measuring small (about 7 weeks); Comments: At an ultrasound at 8 weeks 4 days the baby was measuring small (about 7 weeks) and had a lower heart rate.; Test Name: ultrasound; Result Unstructured Data: Test Result: measured 7 weeks and 1 day with no heartbeat; Comments: At an ultrasound at 10 weeks the baby measured 7 weeks and 1 day with no heartbeat, resulting in a miscarriage.

CDC Split Type: USPFIZER INC202101463694

Write-up: 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 34-year-old female patient received second dose of bnt162b2 (BNT162B2), via an unspecified route of administration, administered in left arm on 06Oct2021 18:45 (Batch/Lot Number: FF8839) as dose 2, single for covid-19 immunisation. Patient received first dose of BNT162B2 on 24Aug2021 12:45 PM in left arm with lot number FC3183. No other vaccine in four weeks. None other medications in two weeks. None medical history. No Covid prior vaccination. Patient last menstrual date: 02Aug2021. Patient received a positive pregnancy test about two weeks after first vaccine at about 6 weeks pregnant. At an ultrasound at 8 weeks 4 days the baby was measuring small (about 7 weeks) and had a lower heart rate. At an ultrasound at 10 weeks the baby measured 7 weeks and 1 day with no heartbeat, resulting in a miscarriage. The event resulted in: healthcare professional office/clinic visit, Congenital anomaly or birth defect, and received treatment. NO covid tested post vaccination. The outcome of miscarriage was recovering as reported.; Sender's Comments: Linked Report(s) : US-PFIZER INC-202101551947 Same reporter/drug, different patient and event (fetus case).

VAERS ID: [1864318](#) ([history](#)) **Vaccinated:** 2021-04-08**Form:** Version 2.0 **Onset:** 0000-00-00**Age:** 29.0 **Submitted:** 0000-00-00**Sex:** Female **Entered:** 2021-11-12**Location:** South Carolina

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	ER8734 / 2	LA / -

Administered by: Pharmacy **Purchased by:** ?**Symptoms:** [Maternal exposure during pregnancy](#), [Premature delivery](#), [Urine analysis](#)**SMQs:**, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** No**Permanent Disability?** No

Recovered? No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:****Allergies:****Diagnostic Lab Data:** Test Date: 20210303; Test Name: Urine POC, IQC; Test Result: Positive
; Comments: Pregnancy**CDC Split Type:** USPFIZER INC2021416982

Write-up: I am pregnant for 8 weeks; Premature live birth; This is a spontaneous report from a contactable consumer (patient). This consumer or other non hcp reported information for both mother and fetus/baby. This is a mother report. A 29-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Batch/Lot Number: ER8734) via an unspecified route of administration, administered in Arm Left on 08Apr2021 at 16:00 (at the age of 29-year-old) as dose 2, single for COVID-19 immunisation. The patient medical history was not reported. There were no concomitant medications. Historical vaccine included bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Batch/Lot Number: EN6204) via an unspecified route of administration, administered in Arm Left on 11Mar2021 at 16:30 (at the age of 29-year-old) as dose 1, single for COVID-19 immunisation. It was reported that patient did not smoke and drink alcohol during pregnancy. It was reported that patient did not use illicit drugs during pregnancy. It was reported that patient had no previous Pregnancy. It was reported that patient had no problems before delivery, during delivery and after delivery. Gestational age at birth in weeks reported as 34 weeks. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. It was reported that the patient's husband did not smoke and drink alcohol during pregnancy. It was reported that the patient's husband did use illicit drugs during pregnancy. The patient reported she was pregnant for 8 weeks (maternal exposure during pregnancy) and she has not had any symptoms so far, she was feeling well. She sent this message making myself available for any follow-up or research that you want to do with pregnant women, she will be happy if she can help or contribute with something in some study. Thank you very much and congratulations on your work. On 01Nov2021 it was reported that premature live birth on unknown date in 2021. The mother reported she became pregnant while taking bnt162b2. The mother was 9 Weeks pregnant at the onset of the event. The mother was due to deliver on 06Nov2021. The patient underwent lab tests and procedures which included urine analysis: positive on 03Mar2021 Pregnancy. Outcome of the events was unknown. Information on the lot/batch number has been requested. Follow up (01Nov2021): This is a follow-up spontaneous report received from a contactable consumer. This consumer reported in response to EDP letter which included that: dose 1 and dose 2 information, patient age, height, weight and clinical course information.

VAERS ID: [1012113](#) (history)**Vaccinated:** 2020-12-29**Form:** Version 2.0**Onset:** 0000-00-00**Age:****Submitted:** 0000-00-00**Sex:** Female**Entered:** 2021-02-08**Location:** Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
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COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	UNKNOWN / UNK	- / OT
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Administered by: Other **Purchased by:** ?

Symptoms: [Abortion missed](#), [Maternal exposure during pregnancy](#)

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Asthma; Reflux oesophagitis

Allergies:

Diagnostic Lab Data:

CDC Split Type: DEPFIZER INC2021067329

Write-up: pregnancy; Missed abortion in the 7th week of pregnancy; This is a spontaneous report from a non-contactable physician downloaded from the Regulatory authority DE-PEI-PEI2021001194. A 35-year-old female patient received bnt162b2 (COMIRNATY, solution for injection, lot number and expiration date were unknown), unknown route of administration on 29Dec2020 at a single dose for COVID-19 immunisation. Medical history included asthma and reflux oesophagitis. The patient's concomitant medications were not reported. The patient experienced missed abortion in the 7th week of pregnancy on an unspecified date with outcome of unknown. It was mentioned that after vaccination the patient developed missed abortion. No follow-up attempts are possible, information on batch number cannot be obtained.

VAERS ID: [1053462](#) (history) **Vaccinated:** 2021-01-06
Form: Version 2.0 **Onset:** 0000-00-00
Age: 32.0 **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-02-25
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EL0141 / UNK	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Headache](#), [Human chorionic gonadotropin](#), [Maternal exposure during pregnancy](#), [Pain in extremity](#), [Pregnancy test](#), [SARS-CoV-2 test](#)

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Tendinopathies and ligament disorders (broad), COVID-19 (broad)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No**Recovered?** No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:** FOLIC ACID**Current Illness:****Preexisting Conditions:** Medical History/Concurrent Conditions: Folic acid supplementation**Allergies:****Diagnostic Lab Data:** Test Name: Blood hcg; Result Unstructured Data: Test Result:Blood hcg showed early miscarriage; Test Name: pregnancy test; Test Result: Positive ; Test Name: COVID-19; Result Unstructured Data: Test Result:No - Negative COVID-19 test**CDC Split Type:** GBPFIZER INC2021147303

Write-up: Maternal exposure during pregnancy; Early miscarriage; Headache; Painful arm; This is a spontaneous report from a consumer or other non hcp. This is a report received from the Regulatory Agency (RA). Regulatory authority report number GB-MHRA-WEBCOVID-202102100805410190. Safety Report Unique Identifier GB-MHRA-ADR 24731748. A 32-year-old female patient started to receive BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0141), via an unspecified route of administration, on 06Jan2021 at SINGLE DOSE for covid-19 immunisation. Medical history included folic acid supplementation. Concomitant medication included folic acid for Folic acid supplementation. The patient experienced maternal exposure during pregnancy, early miscarriage, headache and painful arm on an unspecified date. The events were assessed as medically significant by the reporter. The mother reported she became pregnant while taking bnt162b2. Patient was exposed to the medicine first-trimester (1-12 weeks). The patient underwent lab tests and procedures which included Blood hcg: blood hcg showed early miscarriage, pregnancy test: positive and COVID-19: no - negative covid-19 test on unspecified date. Outcome of the event early miscarriage was recovered with sequelae while outcome of the events painful arm and headache was recovered on an unspecified date. Outcome of the remaining event was unknown. No follow-up attempts are possible. No further information is expected.

VAERS ID: [1067790](#) (history) **Vaccinated:** 0000-00-00**Form:** Version 2.0 **Onset:** 0000-00-00**Age:** **Submitted:** 0000-00-00**Sex:** Female **Entered:** 2021-03-03**Location:** Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Other **Purchased by:** ?**Symptoms:** [Foetal death](#)**SMQs:** Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** Yes**Date died:** 0000-00-00**Permanent Disability?** No**Recovered?** No

Office Visit? No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:****Allergies:****Diagnostic Lab Data:****CDC Split Type:** ILPFIZER INC2021208688

Write-up: A woman in week 20 or 24 was vaccinated and the next day the fetus died; This is a spontaneous report from a contactable physician who reported similar events for two patients. This is the first of two reports. A pregnant female patient (in week 20 or 24 of pregnancy) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient was vaccinated and the next day the fetus died on an unspecified date. The reporter did not think there was a connection but due to the proximity to the vaccine she reported. Information about batch/lot number as been requested.; Sender's Comments: Based on the information provided by the reporter, it appears unlikely that subject product, BNT162B2 vaccine, contributed to the event of fetal death. There is very limited information provided in this report. This case will be reassessed upon receipt of follow-up information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : IL-PFIZER INC-2021209291 same reporter/vaccine/event different patient; Reported Cause(s) of Death: fetal death

VAERS ID: [1067791](#) (history) **Vaccinated:** 0000-00-00**Form:** Version 2.0 **Onset:** 0000-00-00**Age:** **Submitted:** 0000-00-00**Sex:** Female **Entered:** 2021-03-03**Location:** Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Other **Purchased by:** ?**Symptoms:** [Foetal death](#)**SMQs:** Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** Yes**Date died:** 0000-00-00**Permanent Disability?** No**Recovered?** No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No

Hospitalized? No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:****Allergies:****Diagnostic Lab Data:****CDC Split Type:** ILPFIZER INC2021209291

Write-up: A woman in week 40 of pregnancy was vaccinated and the next day the fetus died; This is a spontaneous report from a contactable physician who reported similar events for two patients. This is the second of two reports. A pregnant female patient (in week 40 of pregnancy) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient was vaccinated and the next day the fetus died on an unspecified date. The reporter did not think there was a connection but due to the proximity to the vaccine she reported. Information about batch/lot number has been requested.; Sender's Comments: Limited information precludes a medically meaningful assessment of the case. Based on the current available information and in agreement with reporter's assessment, the event is unlikely related to the suspected drug of BNT162B2. The case will be reassessed if additional information becomes available., Linked Report(s) : IL-PFIZER INC-2021208688 same reporter/vaccine /event different patient; Reported Cause(s) of Death: Fetal death

VAERS ID: [1089826](#) (history) **Vaccinated:** 0000-00-00**Form:** Version 2.0 **Onset:** 0000-00-00**Age:** **Submitted:** 0000-00-00**Sex:** Female **Entered:** 2021-03-11**Location:** Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	- / -

Administered by: Other **Purchased by:** ?**Symptoms:** [Abortion spontaneous](#)**SMQs:** Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** No**Permanent Disability?** No**Recovered?** No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:****Allergies:****Diagnostic Lab Data:****CDC Split Type:** CRPFIZER INC2021076087

Write-up: I lost the baby; The initial case was missing the following minimum criteria: there was no indication that patient experienced an adverse event BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE). Upon receipt of follow-up information on 27Feb2021, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable nurse (patient) received by Medical Information Team. This is the maternal report. A 28-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The applicant indicated that the first dose of Pfizer's COVID-19 vaccine was administered. After the application, she discovered that she was pregnant. She wanted to know what Pfizer recommendations have for her. The mother reported she became pregnant while taking bnt162b2. As of 27Feb2021, patient lost the baby and a few days ago they administered the second dose (as reported). The outcome of event was unknown.; Sender's Comments: Pfizer comment: Based on the information provided by the reporter, it appears unlikely that the suspect drug contributed to the reported event abortion spontaneous, that most likely was due to intercurrent conditions. This case will be reassessed when additional information becomes available. This impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

VAERS ID: [1090242](#) ([history](#)) **Vaccinated:** 2020-12-29
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-03-11
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Inappropriate schedule of product administration](#), [Pregnancy test](#), [Product supply issue](#)

SMQs: Termination of pregnancy and risk of abortion (narrow), Medication errors (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? Yes

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data: Test Date: 20210105; Test Name: pregnancy test; Test Result: Positive

CDC Split Type: DEPFIZER INC2021009218

Write-up: I suffered an early miscarriage; The next appointment at the vaccination center was in mid-Apr2021/ continue to be vaccinated after an elapsed vaccination interval of more than 42 days; The next appointment at the vaccination center was in mid-Apr2021/ continue to be vaccinated after an elapsed vaccination interval of more than 42 days; This is a spontaneous report based on information received by Pfizer from Biontech [manufacturer control number: 5308], license party for Comirnaty. A contactable physician (patient) reported that a female patient of unspecified age received the first dose of BNT162B2 (COMIRNATY, lot number and expiry date unknown) via an unspecified route of administration on 29Dec2020 at single dose for Covid-19 immunization. Medical history and concomitant medications were not reported. The patient said she was a doctor in a clinic and had received the first vaccination with vaccine Comirnaty on 29Dec2020. In the course of the procedure, it turned out that she was pregnant, which was why she canceled the second vaccination appointment at the clinic. She had taken a pregnancy test on 05Jan2021, which showed positive. Her second vaccination would be on 19Jan2021. She did not know she was pregnant before she received the vaccine. In the meantime, she suffered an early miscarriage in 2021 and inquired at the clinic about the possibility of a second vaccination. Unfortunately, from now on only with another vaccine (Astra Zeneca). The next appointment at the vaccination center was in mid-Apr2021. She was asking how she should continue to be vaccinated after an elapsed vaccination interval of more than 42 days. Again 2 times or is there any data on "mixing" different vaccines. Nature of Pregnancy was early pregnancy. The outcome of the event early miscarriage was recovered, of other events was unknown. Information on the lot/batch number has been requested. Follow-up (15Feb2021): New information received from the same contactable physician (patient) included: case upgraded to serious, reaction data (removed event she was pregnant, added event early miscarriage, The next appointment at the vaccination center was in mid-Apr2021/ continue to be vaccinated after an elapsed vaccination interval of more than 42 days, outcome and event details). Information on the lot/batch number has been requested.; Sender's Comments: Based on temporal association and known product profile of BNT162B2 (COMIRNATY, lot number and expiry date unknown), the contributory role of the product cannot be totally excluded. This case will be reassessed should 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.

VAERS ID: [1093067](#) ([history](#)) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-03-12
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	- / -

Administered by: Other **Purchased by:** ?
Symptoms: [Abortion spontaneous](#), [Histology](#)
SMQs: Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No

Recovered? No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:****Allergies:****Diagnostic Lab Data:** Test Name: histology; Result Unstructured Data: Test Result:unknown**CDC Split Type:** CZPFIZER INC2021078947

Write-up: Miscarriage of pregnancy; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received first dose of BNT162b2 (COMIRNATY; Lot Number not provided), via an unspecified route of administration, on an unspecified date as a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Two days after application of the first dose of vaccine she had found out that she was pregnant. The reporter stated that the pregnancy was not prospering. The fetus stopped developing in the week , when the vaccine was administered. Result from histology was pending. The outcome of the event was not reported. Information on the lot/batch number has been requested. Follow-up (01Mar2021): New information reported from a contactable consumer includes: updated event "Miscarriage of pregnancy". Information on the lot/batch number has been requested.

VAERS ID: [1161743](#) (history) **Vaccinated:** 0000-00-00**Form:** Version 2.0 **Onset:** 0000-00-00**Age:** **Submitted:** 0000-00-00**Sex:** Unknown **Entered:** 2021-04-02**Location:** Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EK4240 / 1	- / OT

Administered by: Other **Purchased by:** ?**Symptoms:** [Foetal death](#), [Foetal exposure during pregnancy](#)**SMQs:**, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** Yes**Date died:** 0000-00-00**Permanent Disability?** No**Recovered?** No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** Yes, ? days**Extended hospital stay?** No**Previous Vaccinations:****Other Medications:****Current Illness:**

Preexisting Conditions:**Allergies:****Diagnostic Lab Data:****CDC Split Type:** ILPFIZER INC2021347056

Write-up: IUFD; IUFD; This is a spontaneous report received from a contactable other healthcare professional (HCP). Regulatory report number is not provided. This other hcp reported information for both mother and fetus. This is the fetus report. Only this case is serious. A fetus patient of an unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Solution for injection, Lot Number: EK4240, expiry date not reported) dose 1, transplacental on an unspecified date at a single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient's mother is a 39-year old female who was at risk pregnancy because of twins. On an unspecified date, the patient experienced IUFD (intrauterine fetal death), which was reported as serious with criteria as hospitalization as the patient's mother was hospitalized on unknown dates with diagnosis as IUFD, and as medically significant. Event description was provided as IUFD of one of the fetuses (time range of events was reported as 11 days). The patient died on an unspecified date. The cause of death was IUFD. It was unknown if an autopsy was performed. No follow-up attempts possible. No further information expected.; Sender's Comments: Linked Report(s) : IL-PFIZER INC-2021349377 Maternal report; Reported Cause(s) of Death: IUFD; IUFD

VAERS ID: [1165285](#) (history) **Vaccinated:** 0000-00-00**Form:** Version 2.0 **Onset:** 0000-00-00**Age:** **Submitted:** 0000-00-00**Sex:** Female **Entered:** 2021-04-04**Location:** Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 2	- / -

Administered by: Other **Purchased by:** ?**Symptoms:** [Abortion spontaneous](#)**SMQs:**, Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** No**Permanent Disability?** No**Recovered?** No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:** Comments: List of non-encoded Patient Relevant History: Patient Other Relevant History 1: None**Allergies:****Diagnostic Lab Data:****CDC Split Type:** FIPFIZER INC2021310503**Write-up:** Miscarriage on week 8-9; This is a spontaneous report from a contactable nurse

(patient). A 30-year-old female patient received the first and second doses of BNT162B2 (COMIRNATY, Lot number and expiration date were not reported) as a single dose, with route of administration and therapy dates unspecified, for COVID-19 immunization. The patient had no relevant medical history and concomitant medications. The patient was pregnant at the time of vaccination. The patient had received the vaccine approximately on pregnancy weeks 2 and 5 (the patient did not know she was pregnant). The patient had a miscarriage on pregnancy week 8-9. This was diagnosed in ultrasound on pregnancy week 12. On ultrasounds performed in weeks 6 and 8, the fetus was normal and the heart rate was strong. It was not known what caused the miscarriage but the patient wanted to know if the relationship of the vaccine with miscarriages was investigated at some point. The patient had considered the reported event to be serious (medically significant). The patient had no other medications or illnesses, and was basically healthy. The mother reported she became pregnant while taking BNT162B2. The pregnancy resulted into spontaneous abortion. The fetal outcome was intrauterine death.; Sender's Comments: Based on a reported drug event chronological association, the company cannot completely rule out a reasonable possibility that BNT162B2 (COMIRNATY) caused the miscarriages (PT: Abortion spontaneous). 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.

VAERS ID: [1193958](#) (history) **Vaccinated:** 2021-02-17
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-04-11
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	- / -

Administered by: Other **Purchased by:** ?
Symptoms: [Glucose tolerance test](#), [Histology](#), [Laboratory test](#), [Prenatal screening test](#), [SARS-CoV-2 test](#), [Stillbirth](#), [Ultrasound antenatal screen](#), [X-ray](#)
SMQs:, Termination of pregnancy and risk of abortion (narrow), COVID-19 (broad)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? Yes, ? days
Extended hospital stay? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions: Medical History/Concurrent Conditions: Multigravida; Ovarian cyst; Slipped disc; Thalassemia minor; Varicose veins of lower extremities
Allergies:
Diagnostic Lab Data: Test Name: OGTT; Result Unstructured Data: Test Result:normal; Test

Name: histological check of the placenta; Result Unstructured Data: Test Result:unknown results; Test Name: genetic test; Result Unstructured Data: Test Result:unknown results; Test Name: Growth rate week 32; Result Unstructured Data: Test Result:normal; Test Name: integrated test; Result Unstructured Data: Test Result:normal; Test Name: PCR test for COVID 19; Result Unstructured Data: Test Result:negative; Test Name: Late (anatomy) ultrasound; Result Unstructured Data: Test Result:normal; Test Name: Nuchal translucency screening; Result Unstructured Data: Test Result:1:800; Test Name: ultrasound check; Result Unstructured Data: Test Result:fetus with no heartbeat and no movement; Test Name: x-ray; Result Unstructured Data: Test Result:unknown results

CDC Split Type: ILPFIZER INC2021353566

Write-up: In an ultrasound check it showed a fetus with no heartbeat and no movement/ IUFD; This is a spontaneous report received from a contactable other healthcare professional. This other healthcare professional reported information for both mother and fetus. This is the maternal report. A 40-year-old female patient received the first dose of BNT162B2 (COMIRNATY, Solution for injection, lot number and expiry date were not reported), via an unspecified route of administration, on 17Feb2021 at a single dose for COVID-19 immunization. Medical history included thalassemia minor, varicose veins in the legs, slipped disc, simple ovarian cyst removal, and 6th pregnancy. The patient was pregnant at the time of vaccination, at 34 weeks age of gestation. Concomitant medications were not reported. After she felt lessening of fetal movement in the course of the night and in the morning, she woke up and did not feel fetal movement. Negated water secretion, labor or bleeding. This refers to a woman aged 40, healthy except for Thalassemia minor, Varicose veins in the legs, status after a slipped disc and simple ovarian cyst removal. The patient was in week 34+1 of her 6th pregnancy (3 children). According to the report, the pregnancy was spontaneous. Nuchal translucency screening was normal. Integrated test 1:800. Did not have an amniocentesis. Late (anatomy) ultrasound normal, normal OGTT. Growth rate week 32 summarized as normal. The day before (on 17Feb2021) received the first injection of the vaccine for COVID 19 in a community setting. When she was given it there was no fetal heartbeat. In an ultrasound check it showed a fetus with no heartbeat and no movement. PCR test for COVID 19 when she was admitted was negative. The patient gave birth on 19Feb2021 in the evening and the fetus was without external birth defects except for syndactyly in fingers 4-5 in the right leg. Even with request and repeated explanation, the woman refused an autopsy but agreed to a genetic test, x-rays, medical photographs and histological check of the placenta in addition to a corona test from the placenta and from the fetus. Reason for hospitalization/diagnosis on hospitalization was IUFD (intrauterine fetal death). At the time of report, patient hospitalization status was "released". Outcome of the event was unknown. No follow-up attempts are possible, information about lot/batch number cannot be obtained.; 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 Stillbirth cannot be totally excluded. It is possible that there was no fetal heartbeat prior to administering the vaccine (When she was given it there was no fetal heartbeat.). 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) : IL-PFIZER INC-2021348948 Fetus case

VAERS ID: 1200410 <small>(history)</small>	Vaccinated: 2021-01-15
Form: Version 2.0	Onset: 0000-00-00
Age:	Submitted: 0000-00-00
Sex: Female	Entered: 2021-04-13
Location: Foreign	

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Blood test](#), [Investigation](#), [SARS-CoV-2 test](#), [Scan](#)

SMQs:, Termination of pregnancy and risk of abortion (narrow), COVID-19 (broad)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications: FOLIC ACID; LANSOPRAZOLE

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Gastritis; Miscarriage; Pregnancy

Allergies:

Diagnostic Lab Data: Test Name: blood work; Result Unstructured Data: Test Result:unknown results; Test Name: private; Result Unstructured Data: Test Result:unknown results; Comments: 2 x; Test Name: scans or investigations; Result Unstructured Data: Test Result:pregnancy of unknown location resulting in; Comments: miscarriage; Test Date: 20210325; Test Name: COVID-19 virus test; Test Result: Negative ; Comments: No - Negative COVID-19 test; Test Name: Internal scans; Result Unstructured Data: Test Result:unknown results; Comments: 1 x

CDC Split Type: GBPFIZER INC2021343726

Write-up: miscarriage; This is a spontaneous report from a contactable consumer (patient) received from the Regulatory Authority. The regulatory authority report number is GB-MHRA-WEBCOVID-202103290116140840, Safety Report Unique Identifier GB-MHRA-ADR 25042453. A 41-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 15Jan2021 (Lot number was not reported) as single dose for COVID-19 immunisation. Patient had not had symptoms associated with COVID-19. Patient was not enrolled in clinical trial. Medical history included miscarriage, pregnancy, gastritis. Concomitant medications included folic acid taken for folic acid supplementation; lansoprazole taken for gastritis from Sep2020 to 13Feb2021. The patient experienced the loss, miscarriage, foetal exposure during pregnancy on an unspecified date, pregnancy unexpected on 20Feb2021. It was also reported as unexpected pregnancy resulting in pregnancy of unknown location and miscarriage. The patient believed the vaccine enabled the pregnancy. The loss, given her age, was likely to be a natural occurrence. The patient believed she couldn't conceive after having her only child 24 years before 2021. The child and the patient was exposure to the medicine before pregnancy. The pregnancy occurred the following month 20Feb2021 resulting in loss. Details of scans or investigations was pregnancy of unknown location resulting in miscarriage. The investigations included internal scans 1 x, private 2 x NHS and blood work. Patient had not tested positive for COVID-19 since having the vaccine. The patient lab test included negative COVID-19 test on 25Mar2021. The case was reported as serious with seriousness criteria other medically important condition. The events outcome was unknown. No follow up attempts are possible, information about lot/batch number cannot be obtained.

VAERS ID: [1231491](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-04-20
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#)

SMQs:, Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: FRPFIZER INC2021088597

Write-up: spontaneous abortion; This is a spontaneous report from a contactable physician. A pregnant 31-year-old female patient received first dose of BNT162B2 (COMIRNATY, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The moment of vaccination with 1st dose the patient was 4 weeks of amenorrhea. Medical history and concomitant medications were not reported. On 06Apr2021, it was reported that the patient had quickly experienced spontaneous abortion on an unspecified date after receiving the 1st dose of BNT162B2. The reporting physician had no more information since she was not the physician who monitored the pregnancy. The outcome of the event was unknown. Information on the lot number has been requested. Amendment: This follow-up report is being submitted to amend previously reported information: The statement "the moment of vaccination with 1st dose the patient was 4 weeks of amenorrhea" was added on the narrative. The gestation period was populated as 4 weeks and the event "pregnant female patient received BNT162B2" was updated as "pregnant female patient received BNT162B2/ the patient was 4 weeks of amenorrhea" and recoded to maternal exposure during pregnancy, first trimester. Vaccine reporter details was reflected in the corresponding data field. Follow-up (06Apr2021): New information received from a contactable physician includes: reaction data (event was updated to spontaneous abortion). This case was upgraded to serious. Follow-up attempts are completed. No further information is expected.

VAERS ID: [1245720](#) ([history](#)) **Vaccinated:** 2021-01-28
Form: Version 2.0 **Onset:** 0000-00-00
Age: 36.0 **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-04-23
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EJ6797 / 2	LA / OT

Administered by: Other **Purchased by:** ?

Symptoms: [Chills](#), [Foetal death](#), [Gynaecological examination](#), [Headache](#), [Ultrasound foetal](#)

SMQs:, Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications: EXACYL

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Delivery (39th week pregnancy, daughter, 3190g, 49cm, severe persistent pulmonary hypertension of the newborn); Prothrombin mutation G20210A (heterozygote); Uterine operation; Von Willebrand's disease (type I)

Allergies:

Diagnostic Lab Data: Test Date: 20210407; Test Name: gynecological examination; Result Unstructured Data: Test Result: fetus without cardiac action; Test Date: 20210309; Test Name: foetal ultrasound; Result Unstructured Data: Test Result: gestational sac; Test Date: 20210317; Test Name: foetal ultrasound; Result Unstructured Data: Test Result: gestational sac, embryo; Comments: embryo relevant to 6th week of pregnancy with cardiac action

CDC Split Type: CZPFIZER INC2021254933

Write-up: the fetus is unfortunately without cardiac action, the pregnancy has to be terminated by revision; strong headache; chills; This is a spontaneous report from a contactable nurse (patient) received via a Pfizer Medical Information team. A 36-year-old female patient received second dose of BNT162B2 (COMIRNATY, lot number: EJ6797), intramuscularly administered in arm left, on 28Jan2021 at age, at single dose, for covid-19 immunisation. Medical history included prothrombin mutation 20210GA, heterozygote from Nov2019; Von Willebrand disease type I -diagnosed in Nov2019; submucous myoma resection twice Sep2019, Nov2019; delivery in Mar2012 (Number of previous pregnancies/other children: delivery Mar2012, induced due to Intrauterine growth retardation (IUGR), 39th week of pregnancy, daughter, 3190 g, 49 cm, post delivery adaptation ongoing hyposaturation, transferred to superior department, diagnosis severe persistent pulmonary hypertension of the newborn). Concomitant medication included tranexamic acid (EXACYL). Historical vaccines included inactivated influenza vaccine (VAXIGRIP TETRA, lot number U3H622V) on 13Nov2020 at age of 35 years old and the patient was not aware of any adverse events; and the first dose of BNT162B2 (COMIRNATY, lot number: EL1484), via intramuscular administered in arm left, on 07Jan2021 at years old, at single dose, for covid-19 immunization. First day of last menstrual period was 26Jan2021.

Estimated date of conception was 13Feb2021. Pregnancy discovered on 05Mar2021. Estimated delivery date was 06Nov2021. Gestational period at time of initial exposure was 1st trimester (also reported as 19th day of the cycle). After 2nd dose of BNT162B2 applied on 28Jan2021, the patient experienced strong headache approximately 3 days and chills. Laboratory tests included Ante-natal check-up/fetal ultrasound: gestational sac on 09Mar2021; and gestational sac, embryo relevant to 6th week of pregnancy with cardiac action on 17Mar2021. 11th-13th week, screening examinations. From 12th week observation in practice due to risk pregnancy, due to above mentioned diagnosis also observed in hematological center. The mother did not smoke, drink alcohol or use illicit drugs during this pregnancy. The pregnancy went well so far, waiting for the screening examinations. On 08Apr2021, it was reported that "on 07Apr2021, gynecological examination was performed, the fetus is unfortunately without cardiac action, the pregnancy has to be terminated by revision". The outcome of events was unknown. Follow-up (08Apr2021): New information received from the same contactable nurse (patient) includes: new event (fetus is unfortunately without cardiac action, the pregnancy has to be terminated by revision, this was upgraded to serious, medically significant). Follow-up attempts are completed. No further information is expected.; Sender's Comments: Based on known drug safety profile, there is reasonable possibility of causal association between the event foetal death and the suspect vaccine BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

VAERS ID: [1265529](#) ([history](#)) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-04-28
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	ER6166 / 2	- / -

Administered by: Other **Purchased by:** ?
Symptoms: [Foetal death](#)
SMQs: Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 0000-00-00
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? Yes, ? days
Extended hospital stay? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:

Allergies:**Diagnostic Lab Data:****CDC Split Type:** ILPFIZER INC2021446854

Write-up: IUFD; This is a spontaneous report received from a contactable other HCP. This other hcp reported information for both mother and fetus/baby. This is a maternal report. A 21-year-old female patient received second dose of bnt162b2 (BNT162B2), via an unspecified route of administration on an unspecified date (Batch/Lot Number: ER6166) as single dose for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient previously took first dose of bnt162b2 for covid-19 immunization. The patient experienced iufd (Foetal death in utero, death, hospitalization) on an unspecified date. The mother reported she became pregnant while taking bnt162b2. The mother was 3 Trimester pregnant at the onset of the event. The patient died on an unspecified date. It was not reported if an autopsy was performed. Time range was one week. The clinical course was reported as follows: A pregnant woman at week 39 went to the emergency room because her water broke, noted that she did not feel fetal movements from the night denying contractions or bleeding. The anatomical scans during pregnancy were normal. In the emergency room, a fetus was found without a pulse, a normal amount of amniotic fluid, an estimated weight of 2700 grams. Are interested in performing a genetic test. No follow-up attempts are possible. No further information 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 cannot be totally 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.; Reported Cause(s) of Death: IUFD

VAERS ID: [1276126](#) ([history](#)) **Vaccinated:** 2021-02-10
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-05-01
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EJ6795 / 2	- / -

Administered by: Other **Purchased by:** ?**Symptoms:** [Abortion spontaneous](#), [Maternal exposure during pregnancy](#), [SARS-CoV-2 test](#)**SMQs:**, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), COVID-19 (broad)**Life Threatening?** No**Birth Defect?** No**Died?** No**Permanent Disability?** No**Recovered?** No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:**

Other Medications:**Current Illness:**

Preexisting Conditions: Medical History/Concurrent Conditions: COVID-19; Disease risk factor; Maternal vaccine exposure (COVID-19 vaccine exposure during pregnancy week: 5)

Allergies:

Diagnostic Lab Data: Test Date: 20201208; Test Name: corona, bevestigd met test; Test Result: Positive

CDC Split Type: NLPFIZER INC2021420861

Write-up: Early miscarriage; Vaccination during pregnancy; This is a spontaneous report from a contactable consumer downloaded from the Regulatory Authority e-WEB, regulatory authority number NL-LRB-00502812. A 32-year-old female patient received the second dose of bnt162b2 (COMIRNATY; Lot Number: EJ6795), via an unspecified route of administration on 10Feb2021 at 0.3 mL, single for covid-19 immunisation. Medical history included covid-19 from 08Dec2020 to an unknown date, disease risk factor from an unknown date and unknown if ongoing, maternal exposure timing unspecified from an unknown date and unknown if ongoing; COVID-19 vaccine exposure during pregnancy week: 5. The patient's concomitant medications were not reported. The patient received first dose of COVID vaccine COMIRNATY on 19Jan2021 at 0.3ml for COVID-19 immunization and experienced painful arm. The patient experienced a miscarriage (other medically important condition), 5 days after administration. The miscarriage occurred at a pregnancy duration of about 9 weeks. This was the second Covid vaccination. The first vaccination took place at a pregnancy duration of about 5 weeks. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on 08Dec2020. The outcome of the event was unknown. Sender's comment: Since the nature of the reported reaction does imply seriousness according to one of the Regulatory Authority criteria, the reaction (miscarriage) was considered as serious by the Regulatory Authority. No follow-up attempts are possible. No further information is expected. Lot/Batch number already obtained.

VAERS ID: [1287509](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-05-04
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EL1406 / 1	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion missed](#), [Maternal exposure during pregnancy](#)

SMQs: Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? Yes, ? days

Extended hospital stay? No

Previous Vaccinations:**Other Medications:****Current Illness:**

Preexisting Conditions: Medical History/Concurrent Conditions: Miscarriage (Her sister had 3 miscarriages without a test for hypercoagulability)

Allergies:**Diagnostic Lab Data:**

CDC Split Type: ILPFIZER INC2021443481

Write-up: missed abortion; Exposure during pregnancy; This is a spontaneous report from a contactable healthcare professional received via the Regulatory Authority. A 28-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on an unspecified date (Lot Number: EL1406) as single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Family history included her sister had 3 miscarriages without a test for hypercoagulability. The patient was pregnant at the time of vaccination (exposure during pregnancy). It was reported that the patient was on week 22+6, and had missed abortion on an unspecified date, fetus suits week 21. Nuchal translucency and early systems inspection were not performed. The patient was admitted to the hospital due to the missed abortion. The outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.; **Sender's Comments:** The information available in this report of missed abortion is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

VAERS ID: [1326355](#) ([history](#)) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-05-18
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#)

SMQs:, Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? Yes

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:**Preexisting Conditions:****Allergies:****Diagnostic Lab Data:****CDC Split Type:** AUPFIZER INC2021509591

Write-up: Abortion spontaneous; This is a spontaneous report from a contactable other health professional via the Regulatory Authority. Regulatory authority report number is 544763. A female patient of an unspecified age received bnt162b2 (COMIRNATY), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for COVID-19 immunization. The patient medical history and concomitant medications were not reported. On an unspecified date, the patient experienced abortion spontaneous. The outcome of the event was recovered on an unspecified date. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

VAERS ID: [1348886](#) (history) **Vaccinated:** 2021-02-10
Form: Version 2.0 **Onset:** 0000-00-00
Age: 37.0 **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-05-26
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EJ6789 / 2	LA / OT

Administered by: Other **Purchased by:** ?**Symptoms:** [Abortion spontaneous](#)**SMQs:**, Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** No**Permanent Disability?** No**Recovered?** Yes**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:** Medical History/Concurrent Conditions: Spontaneous abortion (One previous spontaneous abortion)**Allergies:****Diagnostic Lab Data:****CDC Split Type:** NOPFIZER INC2021521598

Write-up: Spontaneous abortion; This is a spontaneous report from a contactable other healthcare professional, downloaded from the WEB, Regulatory Authority Report Number: NO-NOMAADVRE-FHI-2021-Un88aa, Safety Report Unique Identifier: NO-NOMAADVRE-E2B_00023000. This other healthcare professional reported information for both mother and fetus/baby. This is a maternal report. A 37-years-old female patient received bnt162b2 (COMIRNATY), dose 2 intramuscular, administered in the left arm on 10Feb2021 at 13:00 (Batch/Lot Number: EJ6789) as 2ND DOSE, SINGLE for COVID-19 immunization. Medical

history included one previous spontaneous abortion. The patient's concomitant medications were not reported. The patient previously received the first dose of bnt162b2 (COMIRNATY) (Batch/lot number: EJ 6789) in Jan2021 for COVID-19 immunization. The patient was 1 week pregnant at the time of the second dose of the vaccine. It was not known at the time of vaccination. The mother became pregnant while taking bnt162b2 and was 10 weeks pregnant at the onset of the event. The patient had a spontaneous abortion in 2021, in week 10. The event spontaneous abortion resolved in 2021 while the outcome of the rest of the events was unknown. Relatedness of drug to reaction/event was reported as Possible. Sender Comment: Since the vaccine is new, it will be subject to special monitoring to identify any new safety information as soon as possible. It is especially important that serious and/or unusual side effects be reported. Your message is therefore important to expand knowledge about adverse reactions that were not discovered in the studies, and it is an important contribution to international cooperation to maintain safe vaccination worldwide. No follow-up attempts are possible. No further information is expected.

VAERS ID: [1364345](#) ([history](#)) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-06-01
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#)

SMQs: Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: AUPFIZER INC2021562973

Write-up: Abortion spontaneous; This is a spontaneous report from a contactable other health professional. Regulatory authority report number is 550251). A 27-year-old female patient received bnt162b2 (COMIRNATY), via an unspecified route of administration on an unspecified date as UNKNOWN, SINGLE DOSE for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced abortion spontaneous on an unspecified date with outcome of unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

VAERS ID: [1380094](#) ([history](#)) **Vaccinated:** 2021-03-03
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-06-08
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	ER0866 / 2	- / -

Administered by: Other **Purchased by:** ?
Symptoms: [Abortion spontaneous](#), [Ultrasound scan](#)
SMQs:, Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? Yes
Office Visit? Yes
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: EUTHYROX
Current Illness:
Preexisting Conditions:
Allergies:

Diagnostic Lab Data: Test Date: 20210411; Test Name: Ultrasound; Result Unstructured Data: Test Result:the fetus inside me was seen without pulse

CDC Split Type: ILPFIZER INC2021583731

Write-up: abortion. During 12 week (11Apr2021) test showed that the fetus inside me was seen without pulse; This is a spontaneous report received from a non contactable consumer. A 36-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration on 03Mar2021 09:45 AM (Lot Number: ER0866) as single dose for covid-19 immunisation. The patient's medical history was not reported. Concomitant drug included levothyroxine sodium (EUTHYROX, patient received within 2 weeks of vaccination), route of administration, start and stop date, batch/lot number and dose were not reported for an unspecified indication. The patient previously received first dose of bnt162b2 (lot number: EL7834) on 09Feb2021 for COVID-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Allergies to medications, food, or other products reported as no. The patient experienced abortion on an unknown date. During 12 weeks (11Apr2021) ultrasound (US) test showed that the fetus inside the patient was seen without pulse. It seemed that he stopped developing about three weeks before. The patient underwent lab tests and procedures which included ultrasound scan: the fetus inside me was seen without pulse on 11Apr2021. Treatment for the event included misoprostol (CYTOTEC). AE resulted in visit in an office/ clinic of a physician or other medical care provider. The outcome of the event was recovered. No follow-up attempts are possible; No further information is expected.

VAERS ID: [1380385](#) ([history](#)) **Vaccinated:** 2021-04-29
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-06-08
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	UNKNOWN / 1	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion](#), [Pregnancy test](#), [Ultrasound scan](#), [Vaginal haemorrhage](#)

SMQs:, Haemorrhage terms (excl laboratory terms) (narrow), Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Abstains from alcohol; Non-smoker

Allergies:

Diagnostic Lab Data: Test Date: 20210428; Test Name: pregnancy test; Test Result: Negative ; Test Name: ultrasound; Result Unstructured Data: Test Result:abortion

CDC Split Type: MXPFIZER INC2021581363

Write-up: abortion; vaginal bleeding; This is a spontaneous report from a contactable physician reporting for mother. A 30-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 29Apr2021 (Batch/Lot Number: unknown) as single dose for COVID-19 immunisation. The patient was a healthy person with 30 years of age without diseases. The patient did not smoke, did not drink, did not take drugs and she had a 2-year-old child. The patient's concomitant medications were none. The patient experienced abortion on an unspecified date. The patient reported she became pregnant while taking bnt162b2 on 29Apr2021. The mother was due to deliver on 07Jan2022. The patient got the vaccine on 29Apr2021, last period was 02Apr2021 and she had a pregnancy test on 28Apr2021, it was still negative. The patient was pregnant. The patient had bleeding for 1 week and through ultrasound she had an abortion. On 21May2021, she was still with vaginal bleeding. The patient stated "if I had known about the risk, I would not receive the vaccine". The patient underwent lab tests and procedures which included pregnancy test: negative on 28Apr2021, ultrasound: abortion on an unspecified date. The outcome of abortion was unknown. The outcome of vaginal bleeding was not resolved. Information on lot/batch number has been requested.; Sender's Comments: Based on the temporal association, a causal relationship between the events and bnt162b2 cannot be completely excluded. The case will be reassessed when 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.

VAERS ID: [1390597](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-06-11
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#)

SMQs:, Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: QAPFIZER INC2021611429

Write-up: Miscarriage; This is a spontaneous report from a contactable consumer (patient) received via a Pfizer-sponsored program, Pfizer.com - General Company Information. A pregnant female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) via an unspecified route of administration on an unspecified date (Batch/Lot number: Unknown) as a single dose for COVID-19 immunisation. Medical history was not reported. Concomitant medications were not reported. The patient received the BNT162B2 vaccine when she was 1 month pregnant but she did not know she was pregnant. The fetus heartbeat stopped in 8 weeks. This was her first miscarriage. It was reported that the vaccination could be one of the reasons for the miscarriage. Information on the lot/batch number has been requested.

VAERS ID: [1392288](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-06-11
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Foetal death](#)

SMQs:, Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: BRPFIZER INC2021547005

Write-up: 50-day-old baby died/ fetal death; The initial case was missing the following minimum criteria: no adverse event. Upon receipt of follow-up information on 28May2021, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received BNT162B2 (COMIRNATY), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as 1st dose, single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient informed that after a week and three days (10 days) that she took the first dose of BNT162B2 vaccine, her 50-day-old baby died. She chose not to do curettage and wait for her body to notice fetal death. Obviously, she does not blame the vaccine beforehand because fetal death in the first trimester of pregnancy can have many reasons. However, knowing that research on the effects of the vaccine on embryos is still scarce, she would like to collaborate with this information so that pharmacists are aware and can, perhaps, prevent new cases, in the case of an adverse effect. Outcome of the event was unknown. The mother was pregnant at 1st trimester at the onset of the event. The fetal outcome is intrauterine death. Information on the lot/batch number has been requested.; **Sender's Comments:** Event fetal death represents an intercurrent medical condition and unrelated to BNT162B2 .

VAERS ID: [1393259](#) ([history](#)) **Vaccinated:** 0000-00-00

Form: Version 2.0 **Onset:** 0000-00-00

Age: **Submitted:** 0000-00-00

Sex: Female **Entered:** 2021-06-11

Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

COVID19: COVID19 (COVID19 (UNKNOWN)) / UNKNOWN MANUFACTURER	- / UNK	- / -
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Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Off label use](#), [Product use issue](#), [SARS-CoV-2 test](#)

SMQs:, Termination of pregnancy and risk of abortion (narrow), Medication errors (broad), COVID-19 (broad)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Pregnancy (healthy pregnancies in the past)

Allergies:

Diagnostic Lab Data: Test Name: COVID-19 virus test; Test Result: Negative ; Comments: No - Negative COVID-19 test

CDC Split Type: GBPFIZER INC2021617884

Write-up: miscarriage/ Miscarriage of pregnancy; Patient received BNT162B2 and COVID-19 VACCINE ASTRAZENECA; Patient received BNT162B2 and COVID-19 VACCINE ASTRAZENECA; This is a spontaneous report from a contactable consumer (patient). This report was received from the Regulatory Agency (UK-MHRA). The regulatory authority report number is GB-MHRA-WEBCOVID-202105261611038430-5A6DX, Safety Report Unique Identifier GB-MHRA-ADR 25365609. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Lot number was not reported) as UNKNOWN, SINGLE for COVID-19 immunisation; and COVID-19 vaccine astrazeneca (COVID-19 VACCINE ASTRAZENECA), via an unspecified route of administration on an unspecified date (Lot number was not reported) at unspecified dose for an unspecified indication. Medical history included healthy pregnancies in the past. It was unknown if patient was pregnant at time of vaccination. The patient had no concomitant medications. Patient has not had symptoms associated with COVID-19. Patient was not enrolled in clinical trial. The patient reported that after spending lots of time with vaccinated family members, she had a miscarriage/ miscarriage of pregnancy on unspecified date. The patient reported she had no physical health conditions that could have caused it. She have had healthy pregnancies in the past. This was the first ever miscarriage and the timing fit with when her family was vaccinated. The event was considered serious, medically significant. The patient underwent lab tests and procedures which included COVID-19 virus test: no - negative covid-19 test on an unspecified date. Patient has not tested positive for COVID-19 since having the vaccine. The outcome of the event was reported as not recovered. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

VAERS ID: [1393424](#) (history) **Vaccinated:** 2021-03-12
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-06-11
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 2	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#)

SMQs: Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? Yes

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications: FOLIC ACID

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Folic acid supplementation; Pregnancy (Patient no longer pregnant at the time of reporting.)

Allergies:

Diagnostic Lab Data:

CDC Split Type: GBPFIZER INC2021619892

Write-up: Miscarriage; This is a spontaneous report from a contactable other health professional. This is a report received from the Regulatory Authority). The Regulatory authority report number is (GB-MHRA-WEBCOVID-202105271507133230-8N5QL) and the Safety Report Unique Identifier is (GB-MHRA-ADR 25372875). A 35-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via unspecified route of administration on 12Mar2021 at single dose for COVID-19 immunization. Patient last menstrual period date was 02Mar2021. Perfectly fit and healthy. Patient had not had symptoms associated with COVID-19. Not had a COVID-19 test. Patient was not enrolled in clinical trial. Patient was not currently breastfeeding. Medical history included pregnancy, patient no longer pregnant at the time of reporting, folic acid supplementation. Concomitant medication included folic acid for folic acid supplementation. The patient patient was exposed to the medicine first-trimester (1-12 weeks). The patient experienced miscarriage on an unspecified date in 2021. Serious criteria was reported as congenital anomaly. The outcome of the event was resolving. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

VAERS ID: [1411322](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-06-18
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion](#), [Exposure during pregnancy](#), [Oropharyngeal pain](#), [Overdose](#)

SMQs:, Drug abuse and dependence (broad), Oropharyngeal conditions (excl neoplasms, infections and allergies) (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Medication errors (broad)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: BRPFIZER INC2021630175

Write-up: vaccine exposure during pregnancy; 2 days later I lost the baby; sore throat; 225 g in 0.45 mL suspension; This is a spontaneous report from a non-contactable consumer (patient) from Pfizer medical information team received through the chatbot. A female pregnant patient of an unspecified age received BNT162B2 (COMIRNATY, 225 g in 0.45 mL suspension for injection Batch/lot number and expiry date: not reported) via an unspecified route of administration UNKNOWN, SINGLE DOSE for COVID-19 IMMUNISATION. The patient medical history and concomitant medications were not reported. Five days after the vaccination, on an unspecified date, the patient experienced sore throat. Two days later, on an unspecified date, the patient lost the baby. The outcome of the events was unknown. No follow-up attempts are possible, information about batch number is not available. No further information is expected.

VAERS ID: [1415930](#) (history) **Vaccinated:** 0000-00-00

Form: Version 2.0 **Onset:** 0000-00-00

Age: **Submitted:** 0000-00-00

Sex: Female **Entered:** 2021-06-21

Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Haemorrhage](#), [SARS-CoV-2 test](#)

SMQs:, Haemorrhage terms (excl laboratory terms) (narrow), Termination of pregnancy and risk of abortion (narrow), COVID-19 (broad)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? Yes, ? days

Extended hospital stay? No

Previous Vaccinations:

Other Medications: FOLIC ACID

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Folic acid supplementation; Lactation decreased; Pregnancy (Patient no longer pregnant at the time of reporting.)

Allergies:

Diagnostic Lab Data: Test Name: COVID-19 virus test; Test Result: Negative ; Comments: No - Negative

CDC Split Type: GBPFIZER INC2021657565

Write-up: bleeding; Miscarriage; This is a spontaneous report from a contactable consumer received from the Regulatory Agency (RA). The regulatory authority report number is GB-MHRA-WEBCOVID-202106051808003500-BUOMA. Safety Report Unique Identifier is GB-MHRA-ADR 25426261. A 36-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration on an unspecified date (Lot number was not reported) at single dose for COVID-19 immunization. Medical history included lactation decreased, pregnancy (Patient no longer pregnant at the time of reporting), folic acid supplementation. Patient did not have symptoms associated with COVID-19, patient is not enrolled in clinical trial, patient is not currently breastfeeding. Concomitant medication included folic acid taken for vitamin supplementation, start and stop date were not reported. The patient experienced bleeding, maternal exposure during pregnancy and miscarriage on an unspecified date. The events were serious for hospitalization. Patient had not been tested positive for COVID-19 since having the vaccine. There was an adverse effect on any aspect of the pregnancy for the medicine and pregnancy adverse effect was miscarriage. Patient was exposed to the medicine first-trimester (1-12 weeks). The patient started bleeding and miscarried 2 weeks later. The patient lab test included COVID-19 virus test: no-negative on an unspecified date. The outcome of bleeding was resolving, the outcome of other miscarriage was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

VAERS ID: [1419048](#) ([history](#))

Vaccinated: 2021-05-15

Form: Version 2.0

Onset: 0000-00-00

Age:

Submitted: 0000-00-00

Sex: Female

Entered: 2021-06-23

Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	- / -

Administered by: Other

Purchased by: ?

Symptoms: [Abortion spontaneous](#)**SMQs:**, Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** No**Permanent Disability?** No**Recovered?** No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:** Comments: Patient has not had symptoms associated with COVID-19 Not had a COVID-19 test Patient is not enrolled in clinical trial**Allergies:****Diagnostic Lab Data:****CDC Split Type:** GBPFIZER INC2021671609

Write-up: Miscarriage; This is a spontaneous report from a contactable consumer or other non hcp received from the Regulatory Agency. The regulatory authority report number is GB-MHRA-WEBCOVID-202106072146044340-UFKMP. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 15May2021 as single dose for Covid-19 immunization. Relevant medical history and concomitant medications were not reported. The patient experienced miscarriage on an unspecified date with outcome of not recovered. No follow-up attempts are possible. No further information is expected.

VAERS ID: [1420879](#) (history) **Vaccinated:** 0000-00-00**Form:** Version 2.0 **Onset:** 0000-00-00**Age:** **Submitted:** 0000-00-00**Sex:** Female **Entered:** 2021-06-23**Location:** Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Other **Purchased by:** ?**Symptoms:** [Abortion spontaneous](#)**SMQs:**, Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** No**Permanent Disability?** No**Recovered?** No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:**

Current Illness:**Preexisting Conditions:****Allergies:****Diagnostic Lab Data:****CDC Split Type:** AUPFIZER INC2021678384

Write-up: Abortion spontaneous; This is a spontaneous report from a contactable healthcare professional via the regulatory authority. The regulatory authority report number is 561521. A 31-year-old female patient received bnt162b2 (COMIRNATY), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) at single dose for covid-19 immunisation. The patient was pregnant at the time of vaccination. The patient's medical history and concomitant medications were not reported. On an unknown date, the patient experienced abortion spontaneous. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

VAERS ID: [1427545](#) (history) **Vaccinated:** 2021-03-12**Form:** Version 2.0 **Onset:** 0000-00-00**Age:** 32.0 **Submitted:** 0000-00-00**Sex:** Female **Entered:** 2021-06-25**Location:** Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	LA / -

Administered by: Other **Purchased by:** ?**Symptoms:** [Abortion spontaneous](#)**SMQs:** Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** No**Permanent Disability?** No**Recovered?** No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:** WELLBUTRIN**Current Illness:****Preexisting Conditions:** Medical History/Concurrent Conditions: Infertility**Allergies:****Diagnostic Lab Data:****CDC Split Type:** CAPFIZER INC2021690747

Write-up: We miscarried not long after; This is a spontaneous report received via COVAES from a contactable nurse (patient). A 32-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 12Mar2021 11:00 (Batch/Lot number was not reported) as single dose for covid-19 immunisation at hospital when 32 years old. Medical history included infertility. Concomitant medication included bupropion hydrochloride (WELLBUTRIN) taken for an unspecified indication, start and stop date were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient received the covid vaccine and was advise not to get pregnant for the next 28 days. The patient suffered from

infertility and needed IVF to get pregnant so she didn't think much more of that but less than 3 weeks later (on 02Apr2021) to her surprise she got pregnant naturally. She miscarried not long after. Might not be related but decided to report it anyways. The patient did not have COVID-19 prior to vaccination and was not covid tested post vaccination. Information about lot/batch number has been requested.; Sender's Comments: There are not elements supporting a causative role of BNT162B2 vaccine for the reported miscarriage. The event is deemed to be an intercurrent occurrence. 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.

VAERS ID: [1428595](#) (history) **Vaccinated:** 2021-03-17
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-06-25
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EE8492 / 2	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Maternal exposure during pregnancy](#), [SARS-CoV-2 test](#)

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), COVID-19 (broad)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications: FOLIC ACID

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Hypothyroidism; Pregnancy (The patient had 2 previous normal pregnancies with no miscarriages); Pregnancy (Patient no longer pregnant at the time of reporting.)

Allergies:

Diagnostic Lab Data: Test Name: COVID-19 virus test; Test Result: Negative ; Comments: No - Negative COVID-19 test

CDC Split Type: GBPFIZER INC2021692452

Write-up: Miscarriage; Maternal exposure during pregnancy; This is a spontaneous report from a contactable consumer. This is a report received from the Regulatory Agency (RA). The regulatory authority report number is GB-MHRA-WEBCOVID-202106111926336710-K9ZIE, Safety Report Unique Identifier is GB-MHRA-ADR 25461365. A 37-year-old pregnant female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, formulation: solution for injection, Lot Number: EE8492), via an unspecified route of administration on 17Mar2021 as dose 2, single for COVID-19 immunisation. The patient's medical history included pregnancy

and Patient no longer pregnant at the time of reporting, hypothyroid. The patient had 2 previous normal pregnancies with no miscarriages. The patient did not had symptoms associated with COVID-19 and not enrolled in clinical trial. The patient was not currently breastfeeding. Historical vaccination included bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) as dose 1 on an unspecified date for COVID-19 immunization. Concomitant medications included 400 ug of folic acid (FOLIC ACID) taken for vitamin supplementation. The patient has not tested positive for COVID-19 since having the vaccine. The patient received vaccine at 2 weeks after conception and her pregnancy was anembryonic. On an unspecified date, the patient reported maternal exposure during pregnancy and had miscarriage at 10 weeks. The patient underwent lab tests and procedures which included COVID-19 virus test: negative. The outcome of the event maternal exposure during pregnancy was unknown. The outcome of the event miscarriage was recovering. No follow-up attempts are possible. No further information is expected.

VAERS ID: [1433054](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-06-29
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Foetal death](#)

SMQs: Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Pregnancy

Allergies:

Diagnostic Lab Data:

CDC Split Type: BEPFIZER INC2021699309

Write-up: Intra-uterine death; This is a spontaneous report from a contactable physician downloaded from the Regulatory Authority BE-FAMHP-DHH-N2021-95109. This is a maternal report. A female patient of an unspecified age received bnt162b2 (COMIRNATY), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as DOSE NUMBER UNKNOWN, SINGLE for covid-19 immunisation. Medical history included pregnancy. The patient's concomitant medications were not reported. The patient experienced unborn child died intra-uterine on an unspecified date. The mother reported she became pregnant while taking bnt162b2. The mother was 35 weeks pregnant at the onset of the event. The fetal outcome is intrauterine death. The outcome of the event was unknown.

VAERS ID: [1434835](#) (history) **Vaccinated:** 2021-05-24
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-06-29
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EW3143 / 1	- / -

Administered by: Other **Purchased by:** ?
Symptoms: [Abortion spontaneous](#), [SARS-CoV-2 test](#)
SMQs: Termination of pregnancy and risk of abortion (narrow), COVID-19 (broad)
Life Threatening? No
Birth Defect? Yes
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:

Diagnostic Lab Data: Test Name: COVID-19 virus test; Result Unstructured Data: Test Result: No - Negative COVID-19 test

CDC Split Type: GBPFIZER INC2021709835

Write-up: Miscarriage; This is a spontaneous report from a contactable consumer received from the Regulatory Agency. The regulatory authority report number is GB-MHRA-WEBCOVID-202106141239251170-VUZDK. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: Ew3143), via an unspecified route of administration on 24May2021 as DOSE 1, SINGLE for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Patient has not had symptoms associated with COVID-19. Patient is not enrolled in clinical trial. The patient experienced miscarriage on an unspecified date. The event caused congenital anomaly. The mother reported she became pregnant while taking bnt162b2. The pregnancy resulted in spontaneous abortion. The patient underwent lab tests and procedures which included COVID-19 virus test was no - negative COVID-19 test on an unspecified date. Patient has not tested positive for COVID-19 since having the vaccine. Outcome of the event was not recovered. No follow-up attempts are possible. No further information is expected.

VAERS ID: [1438982](#) (history) **Vaccinated:** 2021-03-06
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-07-01
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 2	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Stillbirth](#)

SMQs:, Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: ILPFIZER INC2021720247

Write-up: Had a stillbirth on Saturday 12Jun2021, this is the 33rd week of pregnancy; This is a spontaneous report from a contactable consumer or other non hcp via Pfizer colleague. This consumer or other non hcp reported information for both mother and fetus. This is a maternal report. A 35-years-old female patient received second dose of bnt162b2 (PFIZER BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Expiry Date: unknown, Batch/Lot number: unknown), via an unspecified route of administration on 06Mar2021 as single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. Previously, the patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection; Expiry Date: unknown, Lot number: unknown), via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunization. On 12Jun2021 Saturday, the patient had stillbirth and was in 33rd week of pregnancy. A genetic disease diagnosed by biochemical tests or DNA tests shown PTEN Hamartoma tumor syndrome, macrocephaly. The patient would like to respect her request for privacy and medical confidentiality. The patient was also not interested in receiving messages and telephone calls in near future. Info about lot/batch will be asked upon FU.; Sender's Comments: Linked Report(s) : IL-PFIZER INC-2021720556 mother/fetus case

VAERS ID: [1441731](#) ([history](#))

Vaccinated: 0000-00-00

Form: Version 2.0

Onset: 0000-00-00

Age:

Submitted: 0000-00-00

Sex: Female

Entered: 2021-07-01

Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Contusion](#), [Epistaxis](#), [Hallucination](#), [Migraine](#), [SARS-CoV-2 test](#)

SMQs: Haemorrhage terms (excl laboratory terms) (narrow), Anticholinergic syndrome (broad), Dementia (broad), Psychosis and psychotic disorders (narrow), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Accidents and injuries (narrow), Termination of pregnancy and risk of abortion (narrow), COVID-19 (broad)

Life Threatening? Yes

Birth Defect? Yes

Died? Yes

Date died: 2021-03-05

Permanent Disability? Yes

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data: Test Name: COVID-19 virus test; Test Result: Negative ; Comments: No - Negative COVID-19 test

CDC Split Type: GBPFIZER INC2021776658

Write-up: Miscarriage; Nosebleed; Bruise; Migraine; Hallucination; This is a spontaneous report from a contactable consumer received from the Regulatory Agency (RA). The regulatory authority report number is GB-MHRA-WEBCOVID-202106230919115640-1PBPG, Safety Report Unique Identifier GB-MHRA-ADR 25523828. A female patient of unspecified age received Unknown dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Lot number was not reported) as dose number unknown, single for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. Patient has not had symptoms associated with COVID-19. Patient is not enrolled in clinical trial. On an unspecified date, the patient experienced nosebleed, bruise, migraine and hallucination. The above mentioned events were reported as serious with seriousness criteria as Disabling/Incapacitating, life threatening, and Other medically important condition. On an unspecified date, the patient experienced miscarriage with seriousness criteria as Results in death, congenital anomaly/birth defect, Disabling/Incapacitating, life threatening, and Other medically important condition. The patient underwent lab tests and procedures which included COVID-19 virus test on an unspecified date: negative (No - Negative COVID-19 test). The outcome of event nosebleed was not recovered, for events Bruise and hallucination was recovering, for event migraine was recovered on an unspecified date, and for event miscarriage was fatal. The patient died on 05Mar2021. It was not reported if an autopsy was performed. Patient has not tested positive for COVID-19 since having the vaccine. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Reported Cause(s) of Death: Miscarriage

VAERS ID: [1442914](#) (history)

Vaccinated: 2021-05-21

Form: Version 2.0

Onset: 0000-00-00

Age: 28.0

Submitted: 0000-00-00

Sex: Female

Entered: 2021-07-02

Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	UNKNOWN / 1	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Biopsy](#), [Culture](#), [Foetal death](#), [Investigation](#), [Maternal exposure during pregnancy](#)

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? Yes

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? Yes, ? days

Extended hospital stay? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Miscarriage (Repeated miscarriage due to unknown cause (each time early miscarriage before 12 weeks))

Allergies:

Diagnostic Lab Data: Test Name: placental biopsy; Result Unstructured Data: Test

Result:unknown; Test Name: placental cultures; Result Unstructured Data: Test

Result:unknown; Test Name: TORCH screening; Result Unstructured Data: Test

Result:unknown; Comments: Torches screening in the mother (toxoplasmosis, cytomegalovirus , herpes, parvo B 19).

CDC Split Type: BEPFIZER INC2021730289

Write-up: intra-uterine foetal death; Maternal Exposure During Pregnancy, second trimester;

This is a spontaneous report from a contactable physician downloaded from the regulatory authority-WEB, regulatory authority number BE-FAMHP-DHH-N2021-94496. A 28-year-old female patient received bnt162b2 (COMIRNATY), dose 1 via an unspecified route of administration on 21May2021 (at the age of 28-years-old) as dose 1, single for COVID-19 immunisation. Medical history included repeated miscarriage due to unknown cause (each time early miscarriage before 12 weeks). The patient's concomitant medications were not reported. The patient was pregnant at time of vaccination: second trimester (also reported 14 weeks). The patient experienced intra-uterine foetal death. The patient underwent lab tests and procedures which included: placental biopsy, torches screening (toxoplasmosis, cytomegalovirus, herpes, parvo B 19) and placental cultures, all with unknown results. The patient had termination of pregnancy with birth of lifeless foetus and curettage given placental retention. The outcome of event was reported as resolved. Reporter's Comment: Treatment - Yes termination of pregnancy with birth of lifeless foetus - curettage given placental retention Evolution of the ADR - recovered. Situations - Other: possibly no causal relationship, but still needs to be reported. Examinations - placental biopsy/ placental cultures/ Torches screening in the mother (toxoplasmosis, cytomegalovirus , herpes, parvo B 19. ADR description - intra uterine foetal death the crown torso length of the foetus was 14 weeks which corresponds to the time of administration of the vaccine. Comirnaty Batch/lot number UNKNOWN. Dosage text: First dose administered the crown trunk length of the fetus was 14 weeks, which corresponds to the time of vaccine administration. No follow-up attempts are possible; information about lot/batch number cannot be obtained. ; Reporter's Comments: Situations -

Other: possibly no causal relationship, but still needs to be reported.

VAERS ID: [1449235](#) (history) **Vaccinated:** 2021-03-03
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-07-06
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EP9598 / 2	LA / OT

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion](#)

SMQs: Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? Yes

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: NOPFIZER INC2021730516

Write-up: ABORTION; This is a spontaneous report from a contactable other hcp downloaded from the European Medicines Agency (EMA) EudraVigilance-WEB, regulatory authority number NO-NOMAADVRE-FHI-2021-U2m959. A 35-years-old female patient received second dose of BNT162B2 (COMIRNATY, Formulation: Solution for Injection, Batch/Lot number: EP9598) via intramuscularly, administered in left arm on 03Mar2021 at 09:30 as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient received first dose of BNT162B2 (PFIZ-ER-BIONTECH COVID-19 VACCINE, Lot number: unknown) on 10Feb2021 for covid-19 immunisation. The patient took a pregnancy test that confirmed she was pregnant on 14Apr2021. Conception was 1-2 weeks earlier. Gestation period was 3-4 weeks. Two days later she had a miscarriage. The outcome of the event was resolved. No follow-up attempts possible. No further information expected. Lot/Batch number already obtained. ; Reporter's Comments: Reporter type: Ambulance worker No more information available

VAERS ID: [1449610](#) (history) **Vaccinated:** 2021-05-29
Form: Version 2.0 **Onset:** 0000-00-00
Age: 39.0 **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-07-06
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	- / 1	- / OT

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Dyspnoea](#), [Maternal exposure during pregnancy](#), [Rash](#), [Ultrasound scan vagina](#)

SMQs: Anaphylactic reaction (narrow), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Cardiomyopathy (broad), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), Hypersensitivity (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? Yes

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications: FOLIC ACID

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Miscarriage; Pregnancy (Patient no longer pregnant at the time of reporting.)

Allergies:

Diagnostic Lab Data: Test Date: 20210618; Test Name: Transvaginal US; Test Result: Inconclusive ; Result Unstructured Data: Gestational age: 5 weeks 5 days, gestational sac present ,sac size4x4x3mm Yolk sac absent, amniotic sac absent, embryo absent: subsequent miscarriage

CDC Split Type: GBMODERNATX, INC.MOD20212

Write-up: miscarriage; i'm certainly not putting fault on the vaccine; Maternal exposure during pregnancy; rash on my arm at site of injection; This regulatory authority case was reported by a consumer and describes the occurrence of ABORTION SPONTANEOUS (miscarriage) in a 39-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3002332) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Miscarriage and Pregnancy (Patient no longer pregnant at the time of reporting.). Concomitant products included FOLIC ACID for an unknown indication. On 29-May-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced ABORTION SPONTANEOUS (miscarriage) (seriousness criterion medically significant), DYSPNOEA (i'm certainly not putting fault on the vaccine), MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) and RASH (rash on my arm at site of injection). At the time of the report, ABORTION SPONTANEOUS (miscarriage), DYSPNOEA (i'm certainly not putting fault on the vaccine) and RASH (rash on my arm at site of injection) had resolved and MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-Jun-2021, Ultrasound scan vagina: unknown (Inconclusive) Gestational age: 5 weeks 5 days, gestational sac present ,sac size4x4x3mm Yolk sac absent, amniotic sac absent, embryo absent: subsequent miscarriage. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. treatment information was not reported Patient was exposed to the medicine first-trimester (1-12 weeks). Company Comment : This is a case of product exposure during pregnancy with

associated AEs Abortion spontaneous, Dyspnea and Rash for this 39-year-old female. No further information is expected.; Sender's Comments: This is a case of product exposure during pregnancy with associated AEs Abortion spontaneous, Dyspnea and Rash for this 39-year-old female. No further information is expected.

VAERS ID: [1456934](#) (history) **Vaccinated:** 2021-04-07
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-07-08
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: [Abortion spontaneous](#)
SMQs: Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:

Diagnostic Lab Data:

CDC Split Type: DEPFIZER INC2021793119

Write-up: wind egg; This is a spontaneous report from a non-contactable consumer reported for self. This 24-year-old female patient received bnt162b2 (COMIRNATY), via an unspecified route of administration on 07Apr2021 (Batch/Lot number was not reported) as dose number unknown, single for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced wind egg (abortion spontaneous) on an unspecified date. The mother reported she became pregnant while taking bnt162b2. Outcome of the event was unknown. No follow-up attempts are possible, information about lot/batch number cannot be obtained.

VAERS ID: [1458414](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-07-08
Location: Foreign

Vaccination / Manufacturer	Lot /	Site /
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	Dose	Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	ET2838 / 1	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion missed](#)

SMQs:, Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? Yes, ? days

Extended hospital stay? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Pregnancy (with no miscarriages in the past)

Allergies:

Diagnostic Lab Data:

CDC Split Type: ILPFIZER INC2021785936

Write-up: missed abortion; This is a spontaneous report received from a contactable other HCP via regulatory authority. A 33-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on an unspecified date (Lot Number: ET2838) as DOSE 1, SINGLE for covid-19 immunisation. Medical history included pregnancy with no miscarriages in the past. The patient's concomitant medications were not reported. She was hospitalized for observation after a missed abortion at 14 weeks of gestation, this was the second pregnancy with no previous abortions. The pregnancy resulted in spontaneous abortion. The fetal outcome is intrauterine death. The patient was discharged. The event outcome was unknown. No follow-up attempts are possible. No further information is expected.; **Sender's Comments:** Limited information can not support a complete medical assessment. Based on the information currently available, the event missed abortion most likely represented an intercurrent medical condition and was unrelated to Bnt162b2 vaccine. Case will be re-assessed upon the additional information provided. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

VAERS ID: [1459521](#) (history) **Vaccinated:** 0000-00-00

Form: Version 2.0 **Onset:** 0000-00-00

Age: **Submitted:** 0000-00-00

Sex: Female **Entered:** 2021-07-09

Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	- / 1	- / OT

Administered by: Unknown **Purchased by:** ?
Symptoms: [Abortion spontaneous](#)
SMQs:, Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:
Diagnostic Lab Data:
CDC Split Type: BEMODERNATX, INC.MOD20212

Write-up: On an unknown date, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On an unknown date, the patient experienced ABORTION SPONTANEOUS (Pregnancy stopped prematurely) (seriousness criterion medically significant). At the time of the report, ABORTION SPONTANEOUS (Pregnancy stopped prematurely) had not resolved. The action taken with mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown) was unknown. Concomitant medications were not reported. Treatment information in response to events was not provided. This is a case of Abortion spontaneous in a female patient of unknown age and unknown medical history. Dates of vaccine administration and event were not reported, therefore it is unclear if event occurred following vaccine exposure during pregnancy. No further information is expected.; **Sender's Comments:** This is a case of Abortion spontaneous in a female patient of unknown age and unknown medical history. Dates of vaccine administration and event were not reported, therefore it is unclear if event occurred following vaccine exposure during pregnancy. No further information is expected.

VAERS ID: [1462451](#) [\(history\)](#) **Vaccinated:** 2021-05-19
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-07-11
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	- / -

Administered by: Other **Purchased by:** ?
Symptoms: [Abortion spontaneous](#)
SMQs:, Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-05-19
Permanent Disability? Yes

Recovered? No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:****Allergies:****Diagnostic Lab Data:****CDC Split Type:** GBPFIZER INC2021784423**Write-up:** Miscarriage; This is a spontaneous report received from a contactable consumer.

This is a report received from the Regulatory Authority report. A female patient of an unspecified age received bnt162b2 (Pfizer BioNTech covid-19 vaccine, Solution for injection, batch/lot number was not reported), dose 1 via an unspecified route of administration on 19May2021 as dose 1, single for covid-19 immunization. The patient's medical history and concomitant medications were not reported. Patient has not had symptoms associated with covid-19, not had a covid-19 test. Patient was not enrolled in clinical trial. Patient has not tested positive for covid-19 since having the vaccine. On an unspecified date, patient experienced miscarriage (abortion spontaneous). The patient died on 19May2021. It was not reported if an autopsy was performed. Note: The week patient was given first vaccine, baby died and eventually miscarried following the discovery of this at 12 week scan. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Miscarriage

VAERS ID: [1462902](#) (history)**Vaccinated:** 2021-05-29**Form:** Version 2.0**Onset:** 0000-00-00**Age:****Submitted:** 0000-00-00**Sex:** Female**Entered:** 2021-07-11**Location:** Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	UNKNOWN / 1	- / -

Administered by: Other **Purchased by:** ?**Symptoms:** [Abortion spontaneous](#)**SMQs:** Termination of pregnancy and risk of abortion (narrow)**Life Threatening?** No**Birth Defect?** No**Died?** No**Permanent Disability?** No**Recovered?** No**Office Visit?** No**ER Visit?** No**ER or Doctor Visit?** No**Hospitalized?** No**Previous Vaccinations:****Other Medications:****Current Illness:****Preexisting Conditions:**

Allergies:**Diagnostic Lab Data:****CDC Split Type:** NLPFIZER INC2021770681

Write-up: Miscarriage; This is a spontaneous report from a contactable consumer or other non hcp downloaded from the regulatory authority-WEB NL-LRB-00584459. This consumer reported information for both mother and fetus/baby. This is the mother report. An adult female patient received the first dose of bnt162b2 (COMIRNATY), via an unspecified route of administration on 29May2021 (Batch/Lot Number: Unknown) as DOSE 1, SINGLE for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced miscarriage on an unspecified date. The event was assessed as medically significant by the reporter. The mother reported she became pregnant while taking bnt162b2. The mother was 8 Weeks pregnant at the onset of the event. The pregnancy resulted in spontaneous abortion. The fetal outcome is intrauterine death. Outcome of the event was not recovered. Case Summary and Reporter's Comments Text: Past drug therapy BioNTech/Pfizer vaccine (Comirnaty): no Miscarriage: Additional information ADR: Heart stopped within 14 days after vaccination confounding factors: COVID-19 vaccine exposure during pregnancy week: 6 weeks Previous COVID-19 infection: No No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reporter's Comments: Past drug therapy BioNTech/Pfizer vaccine (Comirnaty): no Miscarriage: Additional information ADR: Heart stopped within 14 days after vaccination confounding factors: COVID-19 vaccine exposure during pregnancy week: 6 weeks Previous COVID-19 infection: No; Sender's Comments: Linked Report(s) : NL-PFIZER INC-2021859656 fetus case

VAERS ID: [1472196](#) (history) **Vaccinated:** 2021-06-12
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-07-15
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	FA1027 / 1	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#)

SMQs:, Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? Yes

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications: FOLIC ACID

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Folic acid supplementation; Pregnancy (Patient no longer pregnant at the time of reporting.)

Allergies:

Diagnostic Lab Data:

CDC Split Type: GBPFIZER INC2021773019

Write-up: miscarriage/Early miscarriage; This is a spontaneous report from a contactable consumer received from the Regulatory Agency (RA). The regulatory authority report number is GB-MHRA-WEBCOVID-202106211354209200-TE0LJ, Safety Report Unique Identifier GB-MHRA-ADR 25511084. A 27-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: FA1027), via an unspecified route of administration on 12Jun2021 as dose 1, single for COVID-19 immunization. Medical history included pregnancy (patient no longer pregnant at the time of reporting) and folic acid supplementation, both from an unknown date and unknown if ongoing. Patient has not had symptoms associated with COVID-19 and not had a COVID-19 test. Patient is not enrolled in clinical trial. Patient is not currently breastfeeding. Concomitant medications included folic acid taken for vitamin supplementation, start and stop date were not reported. The patient experienced miscarriage/early miscarriage on an unspecified date. It was reported that the medicine had an adverse effect on any aspect of the pregnancy. It was also reported that the patient experienced miscarriage 24 hours after receiving first dose. Patient was exposed to the medicine first-trimester (1-12 weeks). The reporter assessed the event as non-serious. Patient has not tested positive for COVID-19 since having the vaccine. The outcome of the event was recovered on an unspecified date. No follow up attempts are possible. No further information is expected.

VAERS ID: [1472268](#) (history) **Vaccinated:** 2021-05-18
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-07-15
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EW4109 / 1	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#)

SMQs: Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: GBPFIZER INC2021774190

Write-up: Miscarriage of pregnancy; This is a spontaneous report from a contactable consumer received from the Regulatory Agency (RA). The regulatory authority report number is GB-MHRA-WEBCOVID-202106211940174840-TURSX, Safety Report Unique Identifier: GB-

MHRA-ADR 25514849. This consumer reported information for both mother and baby. This is the maternal report. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EW4109), via an unspecified route of administration on 18May2021 as dose 1, single for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Patient has not had symptoms associated with COVID-19 and not had a COVID-19 test. Patient is not enrolled in clinical trial. The patient experienced miscarriage of pregnancy on an unspecified date. The outcome of the event was not recovered. No follow-up attempts are possible. No further information is expected.

VAERS ID: [1472337](#) (history) **Vaccinated:** 0000-00-00
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-07-15
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	- / -

Administered by: Other **Purchased by:** ?
Symptoms: [Abortion spontaneous](#), [Menstrual disorder](#), [Vaccine bacteria shedding](#)
SMQs: Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? Yes

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Miscarriage

Allergies:

Diagnostic Lab Data:

CDC Split Type: GBPFIZER INC2021774072

Write-up: miscarriage; Prolonged bacterial vaccine shedding; my periods have been severely adversely affected; This is a spontaneous report from a contactable consumer or other non-healthcare professional received from the Regulatory Authority. The regulatory authority report number is GB-MHRA-WEBCOVID-202106220104092930-FKNWS, Safety Report GB-MHRA-ADR 25517116. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration on an unspecified date as dose 1, single for COVID-19 immunisation. Medical history included miscarriage. The patient's concomitant medications were not reported. Patient has not had symptoms associated with COVID-19 Not had a COVID-19 test Patient is not enrolled in clinical trial. No medical issues previous to the person getting this poison injected Patient. Reporter stated that, Not vaccinated. A member of household was, and her periods had been severely adversely affected. She had less bleeding during miscarriage. On an unspecified date, the patient experienced miscarriage, prolonged bacterial vaccine shedding

and her periods have been severely adversely affected. The patient's hospitalization was prolonged as a result of all events. Patient has not tested positive for COVID-19 since having the vaccine. The outcome of the event miscarriage was resolved and my periods have been severely adversely affected was unknown and other event was not resolved Case Narrative: Not vaccinated. A member of household is and my periods have been severely adversely affected. I had less bleeding during miscarriage. You need to stop vaccinating people with this poison! No follow-up attempts are possible. Information about lot/batch number cannot be obtained.

VAERS ID: [1473082](#) (history) **Vaccinated:** 2021-05-18
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-07-15
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [SARS-CoV-2 test](#)

SMQs:, Termination of pregnancy and risk of abortion (narrow), COVID-19 (broad)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? Yes

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data: Test Name: COVID-19 virus test; Test Result: Negative

CDC Split Type: GBPFIZER INC2021814341

Write-up: Miscarriage; This is a spontaneous report from a contactable consumer. This is a report received from the Regulatory Agency (RA). The regulatory authority report number is GB-MHRA-WEBCOVID-202106290915153710-98QTS, Safety Report Unique Identifier is GB-MHRA-ADR 25562135. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18May2021 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. Patient had not had symptoms associated with COVID-19, was not enrolled in clinical trial. The patient was pregnant at time of vaccination. The patient experienced miscarriage in 2021 with outcome of recovered. The patient underwent lab tests and procedures which included COVID-19 virus test was negative. Patient has not tested positive for COVID-19 since having the vaccine. The event was reported as serious and seriousness criteria was provided as other medically important condition. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

VAERS ID: [1475700](#) ([history](#)) **Vaccinated:** 2021-06-01
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-07-16
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	- / -

Administered by: Other **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Menstruation irregular](#), [Off label use](#), [Product use issue](#), [Vaginal haemorrhage](#)

SMQs: Haemorrhage terms (excl laboratory terms) (narrow), Termination of pregnancy and risk of abortion (narrow), Fertility disorders (broad), Medication errors (broad)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications: FOLIC ACID; SERTRALINE

Current Illness: Breast feeding

Preexisting Conditions: Medical History/Concurrent Conditions: Anxiety; Miscarriage; Pregnancy (Patient no longer pregnant at the time of reporting.)

Allergies:

Diagnostic Lab Data:

CDC Split Type: GBPFIZER INC2021809656

Write-up: irregular periods; light spotting occurred throughout early pregnancy; miscarriage/early miscarriage; ongoing breastfeeding, received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE); ongoing breastfeeding, received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE); This is a spontaneous report from a contactable consumer. This is a report received from the Regulatory Agency (RA). Regulatory authority report number [GB-MHRA-WEBCOVID-202106280819346800-ADNMT], Safety Report Unique Identifier [GB-MHRA-ADR 25553142]. A 32-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 01Jun2021 as dose 1, single for COVID-19 immunisation. Medical history included abortion spontaneous from an unknown date and unknown if ongoing, pregnancy from an unknown date and unknown if ongoing (Patient no longer pregnant at the time of reporting), ongoing breast feeding and anxiety from an unknown date and unknown if ongoing. Concomitant medications included folic acid (Manufacture Unknown) taken for an unspecified indication, start and stop date were not reported; sertraline (Manufacture Unknown) taken for anxiety state, start and stop date were not reported. On an unspecified date, the patient experienced irregular periods, light spotting occurred throughout early pregnancy, miscarriage/early miscarriage. The outcome of the event "miscarriage/early miscarriage" was recovering. The outcome of the events "irregular periods" and "light spotting occurred throughout early pregnancy" was recovered on an unspecified date. The clinical course was reported as follows: Vaccine given on 01Jun2021 around the time of conception. Light spotting occurred throughout early pregnancy, then a full miscarriage 3-4

weeks later. Possibly completely unrelated but the patient saw a lot of people reporting heavier or irregular periods after the vaccine so wondered if the vaccine and miscarriage could be connected. Patient has not tested positive for COVID-19 since having the vaccine. Additional information: Unsure if the medicine has an adverse effect on any aspect of the pregnancy. Patient did not take folic acid supplement during pregnancy. Patient was exposed to the medicine first-trimester (1-12 weeks). No follow-up attempts are possible; information about lot/batch number cannot be obtained.

VAERS ID: [1485544](#) (history) **Vaccinated:** 2021-06-08
Form: Version 2.0 **Onset:** 0000-00-00
Age: 35.0 **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-07-19
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	3002332 / 1	- / OT

Administered by: Unknown **Purchased by:** ?

Symptoms: [Abortion spontaneous](#), [Maternal exposure during pregnancy](#), [SARS-CoV-2 test](#)

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow), COVID-19 (broad)

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? Yes

Office Visit? No

ER Visit? No

ER or Doctor Visit? No

Hospitalized? No

Previous Vaccinations:

Other Medications: CYCLIZINE; FOLIC ACID

Current Illness: Motor neuron disease (carrier of I114T-MND gene)

Preexisting Conditions: Medical History/Concurrent Conditions: Pregnancy (Patient no longer pregnant at the time of reporting.)

Allergies:

Diagnostic Lab Data: Test Date: 2021; Test Name: COVID-19 virus test; Test Result: Negative
 ; Result Unstructured Data: Negative

CDC Split Type: GBMODERNATX, INC.MOD20212

Write-up: Miscarriage; Early miscarriage; Maternal exposure during pregnancy; This regulatory authority prospective pregnancy case was reported by a pharmacist and describes the occurrence of ABORTION SPONTANEOUS (Miscarriage) and ABORTION SPONTANEOUS (Early miscarriage) in a 35-year-old female patient (gravida 1) who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3002332) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Pregnancy (Patient no longer pregnant at the time of reporting.). Concurrent medical conditions included Motor neuron disease (carrier of I114T-MND gene). Concomitant products included FOLIC ACID for Folic acid supplementation, CYCLIZINE from 10-Jun-2021 to an unknown date for Nausea. On 08-Jun-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On an unknown date, the patient experienced ABORTION SPONTANEOUS (Miscarriage) (seriousness criterion medically significant), ABORTION SPONTANEOUS (Early miscarriage) (seriousness criterion medically significant) and MATERNAL EXPOSURE

DURING PREGNANCY (Maternal exposure during pregnancy). The delivery occurred on an unknown date. For neonate 1, The outcome was reported as Spontaneous Abortion NOS. Patient was exposed to the medicine first-trimester (1-12 weeks). At the time of the report, ABORTION SPONTANEOUS (Miscarriage) and ABORTION SPONTANEOUS (Early miscarriage) had resolved and MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, SARS-CoV-2 test: negative (Negative) Negative. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient experienced miscarriage which was noted at 12 week scan. Patient stated that heart beat of the fetus was stopped around 9 weeks and she took vaccine a week prior to this. Treatment information was not provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

VAERS ID: [1487904](#) ([history](#)) **Vaccinated:** 2021-04-22
Form: Version 2.0 **Onset:** 0000-00-00
Age: **Submitted:** 0000-00-00
Sex: Female **Entered:** 2021-07-20
Location: Foreign

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	UNKNOWN / 1	- / -

Administered by: Other **Purchased by:** ?
Symptoms: [Abortion spontaneous](#), [Menstrual disorder](#)
SMQs:, Termination of pregnancy and risk of abortion (narrow)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:
Diagnostic Lab Data:
CDC Split Type: DEPFIZER INC2021861766

Write-up: early miscarriage; Menstrual cycle disorder; This is a spontaneous case from a non-contactable consumer regarding herself. A 33-years-old female patient received bnt162b2 (COMIRNATY), dose 1 via an unspecified route of administration on 22Apr2021 (Batch/Lot Number: Unknown) as single dose, dose 2 via an unspecified route of administration on 04Jun2021 (Batch/Lot Number: Unknown) as single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient

experienced early miscarriage and menstrual cycle disorder on an unspecified date in 2021 with outcome of unknown. No follow-up attempts are possible, information about lot/batch number cannot be obtained.

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VAX=COVID19

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