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Safety monitoring of bivalent mRNA COVID-19 vaccine among pregnant persons in the vaccine adverse event reporting System – United States, September 1, 2022 – March 31, 2023

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Abstract

Background: Pregnant persons are at increased risk of severe COVID-19 illness. Bivalent mRNA COVID-19 vaccination is recommended for everyone, including pregnant persons. However, data are limited on the safety of bivalent mRNA COVID-19 vaccination during pregnancy.

Objective: To evaluate and summarize reports to the Vaccine Adverse Event Reporting System (VAERS), a national spontaneous reporting system, among pregnant persons who received bivalent mRNA COVID-19 vaccine.

Methods: VAERS U.S. reports of adverse events (AEs) in pregnant persons who received the bivalent mRNA COVID-19 vaccine from 9/1/2022–03/31/2023 were identified. Clinicians reviewed all reports and available medical records. AEs of these reports were compared with AEs reported to VAERS following monovalent mRNA COVID-19 booster vaccination in pregnancy.

Results: VAERS received 136 reports for pregnant persons who received bivalent mRNA COVID-19 vaccine; 87 (64 %) after BNT162b2 (Pfizer-BioNTech), and 48 (35 %) after mRNA-1273 (Moderna); 28 (20.6 %) reports were classified as serious. The most common

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Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

CRediT authorship contribution statement

Pedro L. Moro: Conceptualization, Formal analysis, Investigation, Methodology, Project administration, Supervision, Writing – original draft, Writing – review & editing. **Grace Carlock:** Formal analysis, Investigation, Methodology, Software, Supervision, Validation, Writing – review & editing. **Nimita Fifadara:** Investigation, Methodology, Writing – review & editing. **Tei Habenicht:** Investigation, Methodology, Writing – review & editing. **Bicheng Zhang:** Formal analysis, Investigation, Methodology, Validation, Writing – review & editing. **Penelope Strid:** Formal analysis, Investigation, Methodology, Writing – review & editing. **Paige Marquez:** Conceptualization, Formal analysis, Investigation, Methodology, Validation, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

pregnancy-specific outcomes reported included 12 (8.8 %) spontaneous abortions (<20 weeks gestation), 6 (4.4 %) episodes of preterm delivery, and 5 (3.7 %) reports of preeclampsia. One stillbirth (≥20 weeks gestation) was reported. No maternal or infant deaths were reported. There were 6 reports of AEs in infants, which included 3 reports of admissions to the neonatal intensive care unit: two infants with low birth weight, and one infant with a patent ductus arteriosus and patent foramen ovale. Non-pregnancy-specific adverse events were mostly COVID-19 infection and systemic reactions (e.g., headache, fatigue). Pregnancy-specific conditions were reported less frequently after bivalent mRNA COVID-19 vaccination compared to monovalent mRNA COVID-19 booster vaccination (3rd and 4th dose).

Conclusions: Based on this review of reports to VAERS, the safety profile of bivalent mRNA COVID-19 vaccination in pregnant persons was comparable to that observed for monovalent mRNA COVID-19 booster vaccination (3rd and 4th dose) in pregnant persons.

Keywords

Adverse events; Epidemiology; Coronavirus; COVID-19; mRNA COVID-19 vaccines; Bivalent mRNA COVID-19 vaccine; BA.4/BA.5 strains; SARS-CoV-2; Pregnancy; Surveillance; Vaccine safety

1. Introduction

Coronavirus disease 2019 (COVID-19) vaccines protect against serious illness, including hospitalization and death, from COVID-19 disease and its complications [1]. On August 31, 2022, the U.S. Food and Drug Administration (FDA) authorized bivalent formulations of BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) COVID-19 vaccines, which provide additional protection to known and studied variants [2,3]. These bivalent mRNA vaccines were authorized for use as a single dose ≥ 2 months after completion of primary series or monovalent booster vaccination; bivalent mRNA vaccine from Pfizer-BioNTech was authorized for persons ages ≥ 12 years, and from Moderna for adults ages ≥ 18 years [2,3]. On September 1, 2022, the Advisory Committee on Immunization Practices (ACIP) recommended that all people ages ≥ 12 years receive an age-appropriate bivalent mRNA COVID-19 vaccination [4]. These bivalent vaccines became the only mRNA COVID-19 vaccines authorized for use in the United States on April 18, 2023, when the authorizations for the monovalent mRNA COVID-19 vaccines ended [5]. Several clinical studies have shown that primary series and booster dose vaccination with monovalent mRNA COVID-19 vaccines are safe in pregnant persons [6]. However, data are limited on the safety of bivalent mRNA COVID-19 vaccination in pregnant persons. To assess the safety of bivalent mRNA COVID-19 vaccines administered to pregnant persons, reports of adverse events (AEs) submitted to the Vaccine Adverse Event Reporting System (VAERS) from September 1, 2022, through March 31, 2023 were reviewed.

2. Material and Methods

VAERS is a national passive vaccine safety surveillance system implemented in 1990 and co-administered by the Centers for Disease Control and Prevention (CDC) and the FDA. VAERS receives spontaneous reports of AEs from healthcare providers, vaccine recipients,

manufacturers, and other reporters following vaccination [7]. Vaccine manufacturers are required to report AEs that come to their attention, and healthcare providers who administer COVID-19 vaccines are required to report the following events to VAERS: vaccine administration errors, serious AEs,[8] regardless of causality, and cases of myocarditis, pericarditis, multisystem inflammatory syndrome in children and adults, and COVID-19 that results in hospitalization or death [9].

Signs and symptoms of AEs reported to VAERS are coded by trained personnel using the Medical Dictionary for Regulatory Activities (MedDRA), a clinically validated, internationally standardized medical terminology [10]. A VAERS report may be assigned one or more MedDRA preferred terms (PT). A PT is a distinct descriptor for a symptom, sign, disease, diagnosis, therapeutic indication, investigation, surgical or medical procedure [10]. Reports are further classified as serious (per U.S. Code of Federal Regulations) if one of the following is reported: death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, or a congenital anomaly[8]. VAERS routinely requests medical records for reports classified as serious [7].

2.1. Review of reports

VAERS reports were identified among pregnant persons who received bivalent mRNA COVID-19 vaccine (BNT162b2 or mRNA-1273) from September 1, 2022, through March 31, 2023, using a search strategy previously described [11]. Reports of pregnant persons who received a booster dose (dose 3 or 4) of monovalent mRNA COVID-19 vaccine during August 19, 2021, through January 8, 2023, were also identified to be used as a comparator. Clinicians manually reviewed all identified reports and accompanying medical records when available. Data on demographics and medical history were reviewed to assess the nature of the reported AE. AEs were classified as pregnancy-specific (e. g., spontaneous abortion, stillbirth), non-pregnancy-specific (e.g., a local or systemic reaction), or infant-specific (e.g., birth defect); a report could contain more than one type of these AEs. Data were collected and managed using Research Electronic Data Capture (REDCap), a secure web-based software platform of electronic data capture tools hosted at CDC [12,13].

Rates were estimated for stillbirth, preterm delivery and preeclampsia and then compared to background rates. To calculate rates, the vaccination coverage of bivalent mRNA COVID-19 vaccine among pregnant persons was applied to national vital statistics data on monthly live births and fetal deaths (i.e., stillbirths), and a modeled national estimate of pregnancies. Using data from the Vaccine Safety Datalink, COVID-19 vaccination coverage among pregnant persons who completed the primary series of COVID-19 vaccination before and during pregnancy was multiplied by vaccination coverage among pregnant persons who received bivalent mRNA COVID-19 vaccine before or during pregnancy, per week, from September 2022 through March 2023 [14]. The median of weekly vaccine coverage was determined for each month of the study period (Supplemental Table 1). The median monthly bivalent mRNA COVID-19 vaccine coverage among pregnant persons was applied to the 2022 national monthly provisional live birth counts for the corresponding month in the study period to determine live births that may have been exposed to bivalent mRNA COVID-19 vaccine during pregnancy [15]. Similarly, the median bivalent mRNA COVID-19 vaccine

coverage was multiplied by 2021 monthly fetal deaths (≥20 weeks by obstetric estimate) among U.S. residents ages 15–49 years, for the corresponding month in the study period (Supplemental Table 2) [16]. The stillbirth rate was determined by dividing the number of stillbirths reported in VAERS by the number of live births and fetal deaths that may have been exposed to bivalent mRNA COVID-19 vaccine during pregnancy, within the study period. The preterm delivery/preterm infant and preeclampsia rates were determined by dividing the number of reported occurrences by the number of live births that may have been exposed to bivalent mRNA COVID-19 vaccine during pregnancy. The most recent data on annual pregnancies within the United States estimated that 5,507,000 pregnancies occurred in 2019 [17]. The annual number of pregnancies was multiplied by 0.58, as the study period spanned 30 weeks, and by the overall median bivalent mRNA COVID-19 vaccine coverage rate for the study period (12.9 %).

2.2. Analysis

Frequencies of the most commonly reported MedDRA coding terms (PTs), demographic descriptors and selected pregnancy and infant outcomes were calculated using R software (version 4.2.1). The proportion of specific AEs after bivalent mRNA COVID-19 vaccine were compared to those after booster doses (3rd and 4th doses) of monovalent mRNA COVID-19 vaccines administered to pregnant persons described in reports to VAERS.

2.3. Ethics

VAERS is a vaccine safety system that performs routine public health surveillance and is therefore not subject to Institutional Review Board review and informed consent requirements. This study was reviewed by CDC and was conducted consistently with applicable federal law and CDC policy.§.

§See e.g., 45C.F.R. part 46, 21C.F.R. part 56; 42 U.S.C. §241(d); 5 U. S.C. §552a; 44 U.S.C. §3501 et seq.

3. Results

During September 1, 2022, through March 31, 2023, VAERS received 136 reports of pregnant persons involving bivalent mRNA COVID-19 vaccination: 87 (64 %) received BNT162b2, 48 (35 %) received mRNA-1273, and vaccine manufacturer was not known for one report. Of these 136 reports, 85 (62.5 %) reports described AEs, of which 28 (20.6 %) were classified as serious. Medical records were obtained for 28 (20.6 %) reports among serious and non-serious. Table 1 shows the characteristics of pregnancy reports in VAERS, which were similar for BNT162b2 and mRNA-1273. The trimester when bivalent mRNA COVID-19 vaccine was administered was known in 79 reports; most vaccinations were administered during the first (n = 26; 32.9 %) or third (n = 31; 39.2 %) trimester of pregnancy. Seasonal influenza vaccine was the most commonly co-administered vaccine, documented in 10 (7.4 %) reports. Another 43 (31.6 %) reports described vaccination administration errors without an associated AE; an additional 8 reports described exposure to the vaccine during pregnancy but neither a vaccine administration error nor an AE were reported.

The most frequent pregnancy-specific AEs reported after administration of bivalent mRNA COVID-19 vaccine (Table 2) were spontaneous abortion (n = 12, 8.8 %), placental abnormality (n = 8, 5.9 %), and preterm delivery (n = 6, 4.4 %). In six (50 %) spontaneous abortion reports, maternal age was 35 years or older. The percentages of spontaneous abortion and stillbirth reports after bivalent mRNA COVID-19 vaccination in pregnant persons were lower compared to after booster doses of monovalent mRNA COVID-19 vaccine. Additionally, a lower percentage of reports after bivalent vaccine involved pregnancy-specific AEs compared to reports after monovalent booster; 41 (30.1 %) of bivalent vaccine reports involved pregnancy-specific AEs, compared to 154 (36.1 %) of monovalent booster reports.

Among non-pregnancy-specific conditions (Table 3), COVID-19 infection was the most commonly reported AE (n = 18, 13.1 %), followed by fatigue (n = 11, 8.1 %). All other non-pregnancy specific AEs were each reported in less than 5 % of the reports, and consisted mostly of local or systemic reactions, such as chills, malaise, pain, injection site pain, peripheral swelling, and fever. Coughing and respiratory tract congestion were also among the most commonly reported AEs.

There were 45 reports of vaccine administration errors, two of which documented AEs (injection site pain/malaise and syncope), while the remaining 43 did not document any AEs. The most common vaccination errors were incorrect product formulation administered and product storage error, which comprised 16 (36 %) and 14 (31 %) of the vaccination error reports, respectively.

During the study period, approximately 228,834 live births occurred among persons who received a bivalent mRNA COVID-19 vaccination before or during pregnancy (Supplemental Table 2). The following were estimated based on reporting to VAERS: a stillbirth reporting rate of 0.4 per 100,000 live births and fetal deaths, a preterm delivery reporting rate of 2.6 per 100,000 live births, and a preeclampsia reporting rate of 2.2 per 100,000 live births. These reporting rates are contextualized with background rates in Table 4.

4. Discussion

During September 1, 2022, through March 31, 2023, approximately 230,113 persons received bivalent mRNA COVID-19 vaccine during or just preceding their pregnancy. VAERS received 136 reports involving pregnant persons who received bivalent vaccination. In the current analysis, AEs after bivalent mRNA COVID-19 vaccination were compared with those after booster doses of monovalent mRNA COVID-19 vaccination and did not detect any new, unexpected, or concerning safety issues with bivalent vaccination during pregnancy.

The most common pregnancy-specific condition reported after bivalent mRNA COVID-19 vaccination was spontaneous abortion (SAB), which accounted for nearly one-tenth of reports. This proportion is both lower than what was observed in this analysis for booster doses of monovalent mRNA COVID-19 vaccine, and noticeably lower than what was

reported after the primary series of COVID-19 vaccines, where SAB accounted for nearly one-fourth of all reports in pregnant persons in VAERS [18]. A recent case-control study at eight healthcare systems in the Vaccine Safety Datalink found that receipt of a booster dose of monovalent mRNA COVID-19 vaccine was not associated with SAB [19]. SAB is common during pregnancy, the rate of which increases with maternal age, to as high as 80 % at 45 years of age [20]. In the reports of SAB received by VAERS after bivalent mRNA COVID-19 vaccination, almost half had advanced maternal age (35 years or older). Other pregnancy-specific conditions, such as preterm delivery and stillbirth were reported with lower or similar frequency than after a booster dose of monovalent mRNA COVID-19 vaccine. Reporting rates for stillbirth, preterm delivery, and preeclampsia were observed to be well below background rates for these conditions [20–23]. Among non-pregnancy specific AEs, the most commonly reported condition was COVID-19 infection/disease; systemic symptoms (chills, headache) were also frequently reported. These observations are consistent with requirements to report COVID-19 infection, and with systemic reactions that have been very frequently observed after bivalent mRNA COVID-19 vaccination [24].

VAERS is a passive surveillance system; our observations cannot be compared directly to findings from randomized controlled trials or other observational studies and need to be interpreted with this understanding. VAERS is subject to reporting biases (overreporting or underreporting) and inconsistency in the quality and completeness of reports. Stimulated reporting can occur after publicity around a potential AE, and AEs occurring closer to vaccination or those AEs that are more clinically serious in nature may be reported more frequently. There are no data on the number of doses of bivalent mRNA COVID-19 vaccine given to pregnant persons. However, there are data on vaccination coverage of bivalent mRNA COVID-19 vaccine in pregnant persons. These data was used to estimate the number of pregnant persons who may have received this vaccine used as the denominator to calculate reporting rates. Importantly, VAERS data generally cannot determine whether a vaccine caused an adverse event [7].

This review of the safety of bivalent mRNA COVID-19 vaccination in pregnancy based on reporting to VAERS did not identify any new or unexpected AEs. The proportions of AEs after bivalent mRNA COVID-19 vaccination in pregnant persons were similar to or lower than the proportion of corresponding AEs following booster vaccination with monovalent mRNA COVID-19 vaccine in pregnant persons in VAERS. Similarly, reporting rates for some pregnancy-specific conditions were below background rates. Data show that mRNA COVID-19 vaccines during pregnancy are effective and may reduce the risk of severe illness and other adverse health effects from COVID-19 for pregnant persons. COVID-19 vaccination might also help prevent stillbirths and preterm delivery [25]. The CDC will continue to monitor the safety of COVID-19 vaccines in pregnant persons.

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Data availability

Data is publically available.

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Table 1

Characteristics of reports received following bivalent mRNA COVID-19 vaccination in pregnant persons, VAERS, United States, September 1, 2022, through March 31, 2023.

Characteristic	All bivalent vaccines	Bivalent BNT162b2 vaccine	Bivalent mRNA-1273 vaccine
Total reports (N)	136 *	87	48
Maternal age in years, median (IQR)	33 (30,36)	33 (29, 37)	34.5 (32, 36)
Maternal age ≥ 35 years' n (%)	53 (39.0 %)	29 (33.3 %)	24 (50.0 %)
Interval from vaccination to adverse event in days, median (IQR) †	*N = 82* 20 (1, 60)	*N = 48* 22.5 (3, 69)	*N = 33* 20 (0, 46)
Gestational age in weeks at time of vaccination, median (IQR) †	*N = 69* 16.4 (8.4, 30.4)	*N = 42* 16.4 (8, 31.9)	*N = 26* 18.6 (8.8, 28.5)
Reports of serious adverse events, n (%) §	28 (20.6 %)	21 (24.1 %)	7 (14.6 %)
Reports with hospitalizations, n (%)	20 (14.7 %)	15 (17.2 %)	5 (10.4 %)
Reports with no adverse event, n (%)	51 (37.5 %)	36 (41.4 %)	15 (31.3 %)
Type of reporter, n (%)			
Patient/Parent	56 (41.2 %)	32 (37.2 %)	24 (50.0 %)
Provider	51 (37.5 %)	40 (46.5 %)	11 (22.9 %)
Other	4 (2.9 %)	3 (3.5 %)	1 (2.1 %)
Manufacturer	25 (18.3 %)	11 (12.8 %)	14 (29.2 %)
Trimester of pregnancy at time of vaccination, n (%) †	*N = 79*	*N = 49*	*N = 29*
First (0–13 weeks)	26 (32.9 %)	17 (34.7 %)	8 (27.6 %)
Second (14–27 weeks)	22 (27.9 %)	13 (26.5 %)	9 (31.0 %)
Third (≥28 weeks)	31 (39.2 %)	19 (38.8 %)	12 (41.4 %)
Additional vaccines, n (%)			
Other vaccines administered	12 (8.8 %)	6 (6.9 %)	6 (12.5 %)
Influenza	9 (6.6 %)	4 (4.6 %)	5 (10.4 %)
Influenza + Varicella	1 (0.7 %)	1 (1.1 %)	–
TDAP ‡	2 (1.5 %)	1 (1.1 %)	1 (2.1 %)

VAERS: Vaccine Adverse Event Reporting System.

*Vaccine manufacturer unknown for one report.

†Time from vaccination to adverse event was unknown for 54 reports; gestational age was unknown for 67 reports; trimester of vaccination was unknown for 57 reports.

§A report is defined as serious when one of the following is reported: death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, a birth defect[9].

‡Tdap: Tetanus, diphtheria & acellular pertussis vaccine.

Table 2

Reported adverse events* in pregnant persons following bivalent mRNA COVID-19 vaccination, VAERS, September 1, 2022, through March 31, 2023.

Adverse events*	All bivalent vaccinesN = 136	Bivalent BNT162b2 vaccine N = 87	Bivalent mRNA-1273 vaccine N = 48	Monovalent booster (BNT162b2 and mRNA-1273) N = 427
Pregnancy-specific and delivery conditions†N, (%)				
Spontaneous abortion (<20 weeks gestation)	12 (8.8 %)	8 (9.2 %)	4 (8.3 %)	61 (14.3 %)
Stillbirth (>20 weeks gestation)	1 (0.7 %)	–	1 (2.1 %)	13 (3.0 %)
Placenta Abnormality§	8 (5.9 %)	7 (8.0 %)	1 (2.1 %)	5 (1.2 %)
Preterm delivery (< 37 weeks)	6 (4.4 %)	5 (5.7 %)	1 (2.1 %)	17 (4.0 %)
Pre-eclampsia	5 (3.7 %)	4 (4.6 %)	1 (2.1 %)	12 (2.8 %)
Postpartum Hemorrhage	5 (3.7 %)	4 (4.6 %)	1 (2.1 %)	6 (1.4 %)
Premature Labor	4 (2.9 %)	2 (2.3 %)	2 (4.2 %)	8 (1.9 %)
Gestational Diabetes	4 (2.9 %)	2 (2.3 %)	2 (4.2 %)	8 (1.9 %)
Abnormal Fetal Heartrate	3 (2.2 %)	2 (2.3 %)	1 (2.1 %)	9 (2.1 %)
Premature Rupture of Membranes	3 (2.2 %)	–	3 (6.3 %)	10 (2.3 %)
Fetal Movement Decreased	2 (1.5 %)	1 (1.1 %)	1 (2.1 %)	17 (4.0 %)
All Other Pregnancy-Specific and Delivery Conditions‡	6 (4.4 %)	6 (6.8 %)	–	57 (13.3 %)
Infant outcomes				
Infant admitted to NICU§§	3 (2.2 %)	3 (3.4 %)	–	11 (2.6 %)
Low Infant Birth Weight	2 (1.5 %)	2 (2.3 %)	–	4 (0.9 %)
Infant with patent ductus arterious/patent foramen ovale	1 (0.7 %)	1 (1.1 %)	–	–
No pregnancy-specific conditions or infant outcomes reported	95 (69.9 %)	59 (67.8 %)	35 (72.9 %)	273 (63.9 %)

VAERS: Vaccine Adverse Event Reporting System.

*Adverse events are not mutually exclusive; percentages of adverse events do not constitute reporting rates.

†Percentages for all conditions calculated using total pregnancy reports.

§Placenta Abnormalities reported following bivalent vaccines included placental abruption (n = 3), retained placenta (n = 2), placenta previa (n = 2), and premature separation of placenta (n = 1).

‡Other pregnancy complications following bivalent vaccines included one occurrence each of ectopic pregnancy, subchorionic hematoma, and oligohydramnios. Other delivery complications following bivalent vaccines included one report of maternal fever, cervical insufficiency and arrested dilation, as well as one report of post-operative leukocytosis.

§§NICU, Neonatal Intensive Care Unit.

Table 3

Most common non-pregnancy-specific adverse events after bivalent mRNA COVID-19 vaccination and after booster doses (3rd or 4th dose) of monovalent mRNA vaccine in pregnant persons, VAERS September 1, 2022, through March 31, 2023*.

Adverse events	All bivalent vaccinesN = 136	BNT162b2 vaccineN = 87	mRNA-1273 vaccineN = 48	Monovalent Booster (BNT162b2 and mRNA-1273) N = 427
COVID-19	18 (13.2 %)	10 (11.5 %)	7 (14.6 %)	73 (17.1 %)
Fatigue	11 (8.1 %)	5 (5.7 %)	6 (12.5 %)	52 (12.2 %)
Cough	6 (4.4 %)	4 (4.6 %)	2 (4.2 %)	29 (6.8 %)
Headache	6 (4.4 %)	3 (3.4 %)	3 (6.3 %)	54 (12.6 %)
Respiratory Tract Congestion	6 (4.4 %)	4 (4.6 %)	2 (4.2 %)	22 (5.2 %)
Nasal congestion / Rhinorrhea	6 (4.4 %)	2 (2.3 %)	4 (8.3 %)	15 (3.5 %)
Nausea / Vomiting	6 (4.4 %)	5 (5.7 %)	1 (2.1 %)	54 (12.6 %)
Chills	5 (3.7 %)	3 (3.4 %)	2 (4.2 %)	37 (8.7 %)
Malaise	5 (3.7 %)	1 (1.1 %)	4 (8.3 %)	14 (3.3 %)
Pain	5 (3.7 %)	4 (4.6 %)	1 (2.1 %)	42 (9.8 %)
Injection Site Pain	4 (2.9 %)	1 (1.1 %)	3 (6.3 %)	19 (4.4 %)
Peripheral Swelling	4 (2.9 %)	1 (1.1 %)	3 (6.3 %)	3 (0.7 %)
Fever	4 (2.9 %)	3 (3.4 %)	1 (2.1 %)	49 (11.5 %)

Percentages are based on the number of adverse events divided by the total respective number of pregnancy reports and are not rates.

VAERS: Vaccine Adverse Event Reporting System.

*MedDRA codes are not mutually exclusive meaning one report may have several MedDRA codes.

Table 4

Reporting rates for selected pregnancy outcomes in VAERS compared to background rates following bivalent mRNA COVID-19 vaccination.

Outcome	Number of events observed	Reporting Rate VAERS	Background Rate
Spontaneous Abortion (<20 weeks gestation)	12	Not calculated	17.9/1,000 [20]
Stillbirth (≥20 weeks gestation)	1	0.4 / 100,000 live births and fetal deaths	574/100,000 [21]
Preterm Delivery/Premature Infant (< 37 weeks)	6	2.6 / 100,000 live births	10.1 % [22]
Preeclampsia	5	2.2 / 100,000 live births	2–8 % [23]

VAERS: Vaccine Adverse Event Reporting System.