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Risk of spontaneous abortion after mRNA COVID-19 vaccination received just prior to or during pregnancy: Complete data from CDC COVID-19 vaccine pregnancy registry

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Abstract

Data on spontaneous abortion after COVID-19 vaccination during pregnancy are limited. We used data from the Centers for Disease Control and Prevention's COVID-19 Vaccine Pregnancy Registry (C19VPR) to assess risk of spontaneous abortion (SAB) among women receiving ≥ 1 mRNA COVID-19 vaccine up to 30 days before last menstrual period or during pregnancy. We calculated risk of SAB from 6 to 20 weeks' gestation using a fetuses-at-risk approach ($n = 12,097$). Pregnancies entered the risk pool at gestational age at vaccination. Risk of SAB in C19VPR was compared with pre-pandemic estimates. Cox proportional hazard models were used to compare risk by vaccine manufacturer. Cumulative risk of SAB was 10.79% (95%CI 10.01, 11.56). Risk of SAB among Moderna recipients was similar to Pfizer-BioNTech (adjusted

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Sabrina A. Madni: Writing – review & editing, Writing – original draft, Visualization, Methodology, Formal analysis, Data curation, Conceptualization. **Christine K. Olson:** Writing – review & editing, Supervision, Conceptualization. **Lauren Head Zauche:** Writing – review & editing, Writing – original draft, Validation, Methodology, Data curation, Conceptualization. **Aliza Macheffsky:** Writing – review & editing, Data curation, Conceptualization. **Ansley V. Waters:** Writing – review & editing, Validation, Data curation.

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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.

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.

hazard ratio 0.92; 95%CI 0.79, 1.07). Risk estimates of SAB were below or within pre-pandemic estimates. Generalizability may be limited due to homogeneity of the C19VPR cohort.

Keywords

COVID-19; Pregnancy; Vaccination; Spontaneous abortion

1. Background

Pregnant women eligible for COVID-19 vaccination in the United States remain less likely to receive COVID-19 vaccines than other vaccines recommended during pregnancy [1]. A qualitative analysis of pregnant women's hesitation about COVID-19 vaccines reported hesitancy due to lack of research about safety in pregnancy [2]. Understanding risk for adverse pregnancy outcomes after COVID-19 vaccination can inform decisions and recommendations about vaccination in pregnancy. As part of comprehensive vaccine safety monitoring, the US Centers for Disease Control and Prevention (CDC) established the COVID-19 Vaccine Pregnancy Registry (C19VPR) in January 2021 to collect data on COVID-19 vaccination, pregnancy outcomes, and participant and infant health [3]. To provide early findings, a preliminary report assessed the risk of spontaneous abortion (SAB) (14.1%) [4]; however, only approximately 25% of the C19VPR cohort data were available at the time of the preliminary report. This analysis updates findings to include all C19VPR participants and adds to the literature by comparing risk of SAB across vaccine manufacturers.

2. Methods

2.1. Study design and cohort selection

The C19VPR identified potential participants through V-safe [5]. Women aged 18–54 reporting COVID-19 vaccination to V-safe between December 15, 2020, and June 21, 2021, were screened for C19VPR eligibility. Based on reported last menstrual period (LMP) and estimated due date (EDD), women who received COVID-19 vaccination up to 30 days before their last menstrual period preceding pregnancy or during pregnancy were eligible for enrollment. C19VPR collected pregnancy-related information directly from participants. Vaccination information was originally collected through V-safe and then confirmed through C19VPR. Participants could also report additional vaccination directly to C19VPR. Participant interviews varied based on when vaccination and pregnancy outcome were reported. Interviewer-administered phone surveys were scheduled for each trimester and twice in the postpartum period based on reported estimated due date. Some participants may have been interviewed only once. For example, if a woman reported vaccination at 8 weeks' gestation, experienced a loss at 12 weeks, and was first contacted at 14 weeks, she would only complete one interview. Detailed C19VPR methodology is published elsewhere [3]. Data collection occurred from January 2021 to September 2022. This activity was reviewed by the CDC, deemed not research, and was conducted consistent with applicable federal law and CDC.¹

2.2. Exclusion criteria

In total, 23,249 participants reported 23,265 eligible pregnancies (receipt of ≥ 1 COVID-19 vaccine up to 30 days prior to LMP or during pregnancy from December 2020 to June 21, 2021); 16 participants reported two registry-eligible pregnancies [3]. We excluded multiple gestation pregnancies ($n = 426$), pregnancies lost to follow-up < 6 weeks' gestation ($n = 3$), pregnancy outcomes reported as occurring < 6 weeks' gestation ($n = 154$), pregnancies of participants who received a Janssen vaccine ($n = 711$; excluded due to small number receiving this adenoviral-vector vaccine), and pregnancies with no COVID-19 vaccination prior to 20 weeks' gestation ($n = 9,874$). Loss to follow-up was defined as failure to provide information on pregnancy outcome. All outcomes after 6 weeks' gestation were included, even if they were not interviewed until what would have been 20 weeks' gestation. The final sample included 12,097 pregnancies.

2.3. Exposure

At the time of C19VPR enrollment, only monovalent index virus COVID-19 vaccines were available. For 96.7% of participants, the registry-eligible dose was also the first COVID-19 vaccine dose received, given the timing of C19VPR enrollment relative to vaccine availability [3]. Booster doses had not yet been authorized by the Food and Drug Administration (FDA) at the time of C19VPR enrollment.

2.4. Outcome

At each call, participants were asked if their pregnancy was still ongoing. Participants indicating that they were no longer pregnant could report (1) "miscarriage," (2) "stillbirth," (3) "induced abortion," (4) "live birth," or (5) "another outcome including ectopic or molar pregnancy." Participants also reported the date and gestational age of pregnancy outcome. Analytic gestational age at outcome was calculated from the pregnancy end date and LMP ($[\text{pregnancy end date}] - [\text{LMP}] / 7$) for the most accurate dating. If dates were not reported, we used participant-reported gestational age at pregnancy outcome.

To confirm participant-reported pregnancy outcome, we requested medical records for participants who reported SAB occurring ≥ 17 weeks' gestation, stillbirth, or neonatal death occurring within 1 day of delivery and consented to medical record release ($n = 71$). The majority (84.4%) of participants consented to medical record release; those who did not consent were not excluded from the analysis. Obstetric subject matter experts conducted review of available medical records; pregnancy outcomes were reclassified according to medical record documentation if necessary [3].

2.5. Statistical analysis

We calculated descriptive statistics for pregnancy characteristics overall and by vaccine manufacturer (i.e., Moderna or Pfizer-BioNTech). We used a fetuses-at-risk approach to estimate week-specific and cumulative risks of SAB overall and by manufacturer. Cumulative risk provides a more accurate estimate of risk compared with crude incidence,

¹See e.g., 45C.F.R. part 46.102(l)(2), 21C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq.

as it accounts for differing exposure timing through censoring; crude incidence may underestimate risk by ignoring time-at-risk variability. Left censoring was used to ensure fetuses did not enter the analysis until gestational week of COVID-19 vaccination prior to or during pregnancy. Including unexposed time in the analysis (i.e., not applying left censoring) would dilute the estimated risk by attributing person-time without any exposure-related event potential, leading to underestimation of risk. Right censoring was used to ensure that fetuses contributed to the analysis only until pregnancy outcome had occurred. Other pregnancy outcomes (i.e., induced abortion, ectopic or molar pregnancy) were censored at gestational age at pregnancy end [6]. Participants who did not report date or gestational age at outcome or were lost to follow-up were censored at gestational age of last contact. Sensitivity analyses include outcomes reported to have occurred prior to 6 weeks' gestation ($n = 154$) and exclusion of participants who received COVID-19 vaccines only prior to LMP ($n = 1012$). We compared cumulative risk of SAB in the C19VPR cohort to pre-pandemic estimates and the preliminary C19VPR report by graphing cumulative risk at each gestational week [4,7–9]. As most C19VPR participants were non-Hispanic White, we graphed an approximation of Mukherjee et al.'s (2013) estimates for White participants as a comparator (Supplement Table 1) [7]. To understand differences in estimates between the current analysis and preliminary C19VPR report estimates, we stratified the complete cohort by timing of enrollment in a post-hoc analysis (Supplement 2).

A higher proportion of Moderna participants were vaccinated prior to 6 weeks' gestation (Table 1); earlier inclusion in the risk pool can bias risk estimates because risk of SAB is higher early in pregnancy and then gradually declines. For manufacturer comparisons, we matched individual pregnancies in the Pfizer-BioNTech group to individual pregnancies in the Moderna group using 4-week intervals of gestational age at vaccination. Participants receiving doses 1 and 2 from different manufacturers were excluded from manufacturer-specific analyses ($n = 10$). We assessed for effect modification by vaccine manufacturer among the matched subset ($n = 10,052$) using Cox proportional regression to calculate hazard ratios adjusted for variables associated with SAB and vaccine manufacturer (i.e., race and ethnicity and gestational age at vaccination).

3. Results

Among 71 participant-reported pregnancy outcomes reviewed for consistency with medical records, four participant-reported SABs were reclassified as other pregnancy outcomes. No reported stillbirths or neonatal deaths were reclassified as SABs.

Most C19VPR participants were non-Hispanic White (79.1%), aged 30–34 years (48.0%), reported urban residency (93.0%), and received two doses of mRNA COVID-19 vaccine prior to pregnancy outcome (93.7%) (Table 1). The majority reported vaccine manufacturer as Pfizer-BioNTech (58.5%) (Table 1). Compared to participants receiving Pfizer-BioNTech vaccines, more participants receiving Moderna vaccines were Hispanic or non-Hispanic Black, reported rural residence, had BMI ≥ 30 , and were vaccinated prior to 4 weeks' gestation (Table 1). Compared to the most recent comparison group, C19VPR participants were older, had higher BMI, and had increased history of SAB (Supplement 1) [7].

Cumulative risk of SAB was 10.79% (95% CI 10.01, 11.56) (Table 2). The sensitivity analysis including SABs occurring <6 weeks' gestation resulted in a cumulative risk of 13.50% (95% CI 12.63, 14.37) (data not shown). The sensitivity analysis excluding participants who received all COVID-19 vaccines prior to LMP resulted in a cumulative risk of 9.69% (95% CI 8.74, 10.62) (data not shown). Vaccine manufacturer was not significantly associated with risk of SAB (adjusted HR 0.92; 95% CI 0.79, 1.07) in the subset matched on gestational age at first COVID-19 vaccine dose (data not shown).

Cumulative risk of SAB among the C19VPR cohort was lower than pre-pandemic estimates (11.7%–21.4%) and week-specific risk of SAB was lower for C19VPR participants at all gestational weeks (Fig. 1) [7–9]. We found a lower cumulative risk of SAB (10.8%) compared with the C19VPR preliminary report (14.1%) (Fig. 1) [4]. EFigure1 includes additional information on the comparison of risk based on timing of enrollment.

4. Discussion

Among pregnancies with mRNA COVID-19 vaccination prior to 20 weeks' gestation, cumulative risk of SAB was below pre-pandemic estimates. We found no association between vaccine manufacturer (i.e., Pfizer-BioNTech versus Moderna) and risk of SAB. Findings are based on the first monovalent (index) mRNA COVID-19 vaccine formulations for the original SARS-CoV-2 variant. Few studies have assessed risk of adverse pregnancy outcomes following receipt of COVID-19 vaccines formulated after index virus COVID-19 vaccines. Newer mRNA COVID-19 vaccines are formulated using similar processes [10], and data suggest similar safety profiles between formulations [11]. Post-authorization vaccine safety studies provide critical data in helping patients and providers compare the risks of COVID-19 vaccination and illness.

Few studies in the United States have assessed the risk of SAB after COVID-19 vaccination. An analysis of data from the Vaccine Safety Datalink found no increase in odds of having received COVID-19 vaccination in the 28 days prior to SAB compared to ongoing pregnancies [12]. International studies have found no association between pre-pregnancy COVID-19 vaccination and SAB but were limited in sample size ($n < 2000$) [13,14]. A 2022 metaanalysis that pooled cohorts to increase analytic power found no increased risk of SAB following COVID-19 vaccination [15].

Published estimates of SAB in the United States use data sourced primarily from health systems' birth cohorts, which often lack national representativeness and, critical to the evaluation of SAB risk, lack early pregnancy data and data on non-live births [16–18]. Current safety monitoring systems in the United States often identify participants based on exposure (e.g., vaccination) rather than pregnancy status, resulting in a lack of data on early pregnancy and an inability to construct a comparison group of unexposed pregnancies. Generally, observational cohorts assessing SAB are subject to left truncation bias, as an unknown proportion of pregnancies is not identified because of pregnancy losses prior to enrollment [19]. Enrolling participants at the start of pregnancy or when trying to become pregnant, rather than after exposure event during pregnancy (e.g., vaccination), would facilitate a more comprehensive understanding of pregnancy outcomes in the US.

Understanding risk of SAB is challenging, requiring vaccination and enrollment of participants early in pregnancy. Our analysis has several strengths. Data on timing of vaccination during pregnancy enabled us to calculate week-specific risk, with pregnancies entering the risk pool only after participants were vaccinated. Week-specific and cumulative risk using the fetuses-at-risk approach is a more precise measure than overall prevalence because denominator at each gestational week includes only pregnancies wherein vaccination and no other outcome has occurred. Although this analysis was based primarily on participant report, we conducted clinical review of medical records to reduce misclassification of late fetal loss and early infant death.

Our analysis has several limitations. First, differences in estimated cumulative risk of SAB in this report versus preliminary findings may suggest that potential participants who had an SAB were less likely to enroll if contacted several months after the SAB [4]. However, analysis of the complete cohort was sufficiently powered to detect an increase in cumulative risk of SAB, whereas the preliminary analysis was not. Second, due to the limited number of women who received only one COVID-19 vaccine dose prior to pregnancy outcome, we were unable to assess risk by number of doses in pregnancy. Third, the registry cohort is largely homogenous. As many C19VPR participants were older, White, living in urban areas, and had low-to-normal BMI, it is likely that the cohort had differential access to prenatal care when compared to the pre-pandemic comparators. Though we used an approximation of Mukherjee et al.'s (2013) estimates for White participants as a comparator, generalizability remains limited. Fourth, the C19VPR cohort may be subject to healthy vaccinee bias, wherein healthier people participate in vaccination programs. Further, people who experienced a spontaneous abortion may be less likely to participate to avoid talking about their experience, further biasing towards the null. However, therapeutic abortions may have been reported as miscarriages, biasing away from the null. Among 20 outcomes reported as SABs ≥ 17 weeks' gestation for which medical record review was conducted, 4 (20%) were reclassified as induced abortions whereas only 4 (7.7%) of 52 reviewed stillbirths were reclassified as SABs. Fifth, our cohort includes only vaccinated women, resulting in the need to use previously published data for comparison. Use of pre-pandemic estimates as comparators rather than a contemporaneous control group may bias results due to temporal trends in the rate of SAB. Sixth, use of self-reported data presents challenges, especially regarding gestational age at outcome, timing of exposure, and certainty of pregnancy outcome among participants who did not undergo medical record review.

Despite its limitations, this updated report adds to the literature by comparing risk of SAB across vaccine manufacturers. While comparisons to pre-pandemic rates should be interpreted with caution due to demographic homogeneity of the C19VPR cohort, caveated dissemination of findings is critical in an environment where women report a desire for additional safety data. Acknowledgement of limitations in comparing contemporary data to historical data can be used to inform future emergency response public health safety monitoring programs that aim to assess risk of early pregnancy outcomes. As of February 9, 2026 CDC website states that receiving COVID-19 vaccination is especially important for women who are pregnant, breastfeeding, trying to get pregnant, or might become pregnant in the future (<https://www.cdc.gov/covid/vaccines/stay-up-to-date.html>).

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Data availability

CDC COVID-19 Vaccine Pregnancy Registry Data were collected under an Assurance of Confidentiality. De-identified and aggregated data may be made available upon review of submitted proposals.

Appendix A.: Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.vaccine.2026.128340>.

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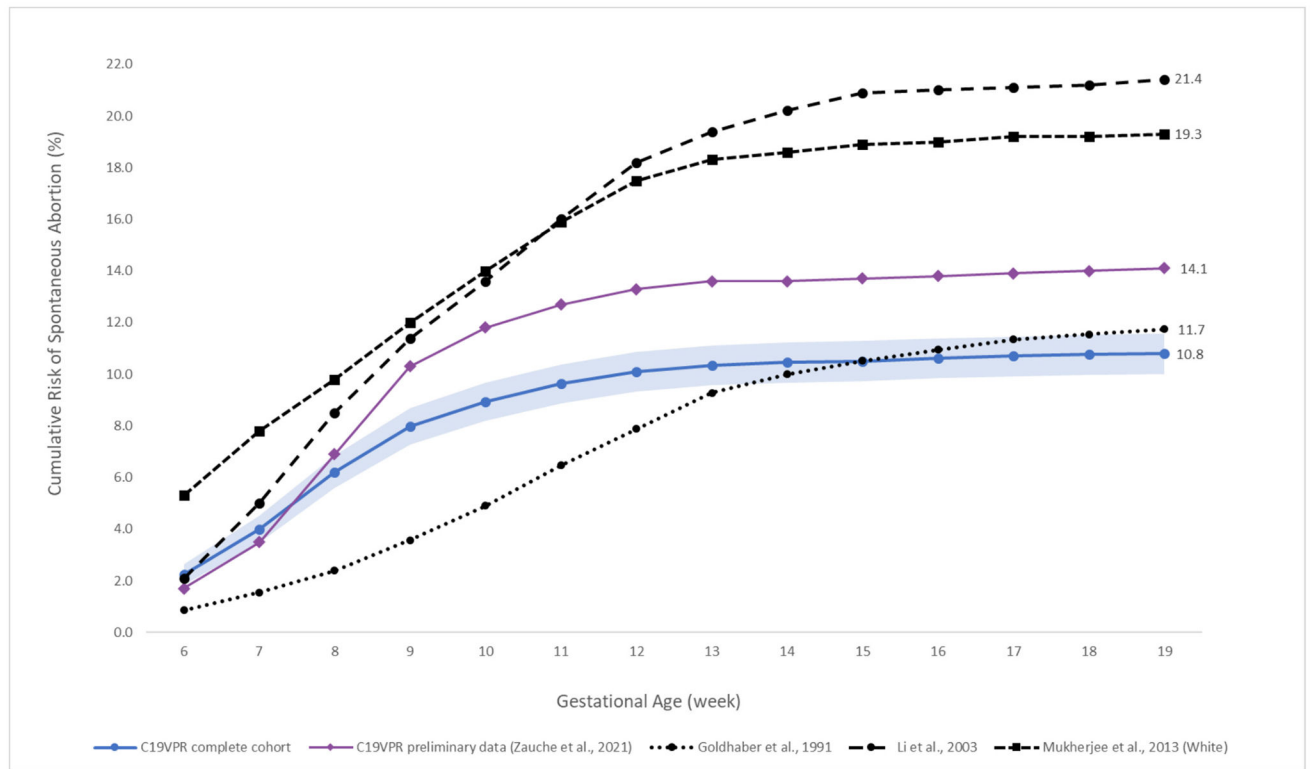


Fig. 1. Cumulative risk of spontaneous abortion among CDC COVID-19 Vaccine Pregnancy Registry (C19VPR) participants receiving an mRNA COVID-19 vaccine prior to 20 weeks' gestation compared to published pre-pandemic estimates, January 2021–September 2022^a.

Table 1

Spontaneous abortion (SAB) and participant-reported demographics by COVID-19 vaccine manufacturer among pregnancies with mRNA COVID-19 vaccination prior to 20 weeks' gestation, CDC COVID-19 Vaccine Pregnancy Registry, January 2021–September 2022 ($n = 12,097$).

	Overall		Pfizer-BioNTech		Moderna	
	(n = 12,097)		(n = 7071; 58.5%)		(n = 5026; 41.5%)	
	n	%	n	%	n	%
SAB ^a	666	5.5	345	4.9	321	6.4
Age at vaccination (years)						
18–24	193	1.6	100	1.4	93	1.9
25–29	1949	16.1	1111	15.7	838	16.7
30–34	5812	48.0	3449	48.8	2363	47.0
35–39	3544	29.3	2060	29.1	1484	29.5
40+	599	5.0	351	5.0	248	4.9
Number of doses prior to pregnancy end						
One	759	6.3	391	5.5	368	7.3
Two	11,338	93.7	6680	94.5	4658	92.7
Race and ethnicity						
Non-Hispanic Black	293	2.4	164	2.3	129	2.6
Non-Hispanic White	9568	79.1	5597	79.2	3971	79.0
Hispanic	1136	9.4	628	8.9	508	10.1
Non-Hispanic, Another race	1100	9.1	682	9.7	418	8.3
Reported previous SAB	3302	27.3	1934	27.4	1368	27.2
Parity						
0	5376	44.4	3179	45.0	2197	43.7
1	4582	37.9	2670	37.8	1912	38.0
2+	2139	17.7	1222	17.3	917	18.3
Pre-existing chronic hypertension	554	4.6	307	4.3	237	4.7
Pre-pregnancy BMI (kg/m²)						
< 18.5	207	1.7	117	1.7	90	1.8
18.5–24.9	6203	51.3	3731	52.8	2472	49.2
25.0–29.9	3127	25.9	1797	25.4	1330	26.5
≥ 30	2560	21.2	1426	20.2	1134	22.6
Urban resident	11,247	93.0	6718	95.0	4529	90.1
GA at first COVID-19 vaccine (weeks)						
>0.0	2132	17.6	1151	16.2	981	19.5
0 to 3.9	1843	15.2	1049	14.8	794	15.8
4.0 to 7.9	1522	12.6	895	12.7	627	12.5
8.0 to 11.9	1150	12.5	889	12.6	621	12.4
12.0 to 15.9	2634	21.8	1623	23.0	1011	20.1
> 16.0	2456	20.3	1464	20.1	992	19.7

Abbreviations: SAB = spontaneous abortion, BMI = body mass index, GA = gestational age.

^a Overall prevalence of spontaneous abortion is less precise than cumulative risk of spontaneous abortion based on the fetuses-at-risk approach.

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Table 2

Risk of spontaneous abortion among participants receiving an mRNA COVID-19 vaccine prior to 20 weeks' gestation in the CDC COVID-19 Vaccine Pregnancy Registry (n = 12,097)^a.

Gestational Week	Fetuses at Risk ^b	Spontaneous Abortion ^c	Week-Specific Risk	Cumulative Risk	
	<i>n</i>	<i>n</i>	%	%	95% <i>CI</i>
<6 weeks ^d	5174	–	–	–	–
6 to < 7 weeks	5174	116	2.24	2.24	(1.84, 2.64)
7 to < 8 weeks	5365	96	1.79	3.99	(3.47, 4.51)
8 to < 9 weeks	5565	129	2.32	6.22	(5.58, 6.85)
9 to < 10 weeks	5828	110	1.89	7.99	(7.28, 8.68)
10 to <11 weeks	6075	63	1.04	8.94	(8.21, 9.67)
11 to <12 weeks	6432	49	0.76	9.64	(8.88, 10.38)
12 to <13 weeks	6913	35	0.51	10.09	(9.33, 10.85)
13 to <14 weeks	7554	22	0.29	10.35	(9.58, 11.12)
14 to <15 weeks	8267	9	0.11	10.45	(9.68, 11.22)
15 to <16 weeks	8897	6	0.07	10.51	(9.74, 11.28)
16 to <17 weeks	9505	11	0.12	10.62	(9.84, 11.38)
17 to <18 weeks	10,092	9	0.09	10.70	(9.92, 11.46)
18 to <19 weeks	10,677	8	0.07	10.76	(9.99, 11.53)
19 to <20 weeks	11,253	3	0.03	10.79	(10.01, 11.56)

^aThe denominator for spontaneous abortion included participants who received their first COVID-19 vaccine dose prior to 20 weeks' gestation from January 2021–September 2022 (n = 12,097). Pregnancies enter as fetuses at risk during gestational week of vaccination.

^bFetuses at risk column represents to number of fetuses included in the denominator for that gestational week. 12,097 fetuses overall were included in the analysis. The number at each gestational week is both left censored to exclude fetuses not yet exposed to COVID-19 vaccination and right censored to exclude pregnancies that have already ended (i.e., fetuses at risk = total pregnancies – not yet vaccinated – pregnancy already ended).

^cSpontaneous abortion (SAB) was based primarily on participant report. For pregnancies ending at or after 17 weeks' gestation with consent to medical record release (n = 71), obstetric subject matter experts conducted review of available medical records. Pregnancy outcomes were reclassified according to medical record documentation if necessary.

^dFetuses at risk prior to 6 weeks' gestation (n = 5174) include those who were vaccinated prior to 6 weeks' gestation. Outcomes reported prior to 6 weeks' gestation not shown.