

## Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

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## Methods

### *Study design*

V-safe and the v-safe pregnancy registry have been described previously.<sup>1-3</sup> Briefly, v-safe is a smartphone-based tool available for all people who have received a COVID-19 vaccination in the United States. Enrollment is voluntary, and participants complete web surveys which include questions about pregnancy status at the time of vaccination and since vaccination.<sup>2</sup> Persons who report that they were pregnant at the time of vaccination or since vaccination and are 18 years or older are contacted by telephone and invited to enroll in the v-safe pregnancy registry. Enrolled participants receive a telephone follow-up each trimester, during the postpartum period, and three months following live births.<sup>3</sup>

Given that the Janssen adenoviral vector COVID-19 vaccine is a different type of vaccine than mRNA COVID-19 vaccines, participants enrolled in the v-safe pregnancy registry who had received the Janssen vaccine (n=272) were not included in this analysis. At this time, there are limited data available on pregnancy outcomes in these participants because the Janssen vaccine was granted Emergency Use Authorization (EUA) several months after the mRNA COVID-19 vaccines.

This activity was reviewed by the Centers for Disease Control and Prevention (CDC) and was conducted consistent with applicable federal law and CDC policy; the activity met requirements of public health surveillance as defined in 45 CFR 46.102.<sup>4</sup>

### *Statistical Analysis*

Descriptive analyses were performed. Gestational age at vaccination was calculated using the self-reported date of vaccination, and either the self-reported estimated due date or date of the first day of the last menstrual period. When participants reported an SAB, the date of SAB was recorded based on clinical diagnosis when provided by the participant.

Life table methods were used to calculate the cumulative risk of SAB by gestational week.<sup>5</sup> Participants who received an mRNA COVID-19 vaccine preconception or before 6 weeks' of pregnancy were entered into the analysis at 6 weeks' gestation whereas participants who received their first eligible dose at or after 6 weeks' gestation entered the analysis in the week they received their first eligible dose.

Participants who did not have contact with the v-safe pregnancy registry at or after 20 weeks' gestation were censored at the time of last contact, and participants who reported other pregnancy outcomes (i.e., ectopic and molar pregnancies, induced abortions) were censored at the date of the outcome.

The cumulative probability of ongoing pregnancy for a given gestational week was calculated by taking the week-specific probability of ongoing pregnancy and the cumulative probability of ongoing pregnancy at the preceding week for each week up to the week of interest. The cumulative risk of SAB was calculated as one minus the cumulative probability of an ongoing pregnancy. Log normal confidence intervals were calculated for cumulative risk of SAB at each gestational week. The cumulative SAB risk was also age-standardized by maternal age.<sup>6</sup> Standard errors of the age-adjusted cumulative risk of SAB were estimated by dividing the age-adjusted rate by the square root of the number of SABs, and 95% confidence intervals were calculated.<sup>7</sup>

We conducted a sensitivity analysis to estimate the maximum possible risk of SAB in our cohort if all participants whom we were not able to contact in the second trimester (14-<28 weeks' gestation) experienced an SAB immediately after last contact. Statistical analyses were conducted using SAS software, version 9.4.

## Description of comparator populations

There are few high-quality epidemiologic studies of SAB risk from 6-<20 weeks, with virtually all estimates falling within the range of 11-22%.<sup>6, 8-10</sup> Given the lack of control group for this report, we used references from literature to evaluate whether the risk of SAB following COVID-19 vaccination preconception or during pregnancy was higher than what would be expected in the general population. Our registry had a higher percentage of White women than some other cohorts,<sup>8,9</sup> but registry participants had other characteristics predisposing them to higher risk of SAB, including older age<sup>6,8,9,10</sup> and a higher proportion with SAB in a previous pregnancy<sup>6,9,10</sup> (Table S1).

Both Goldhaber & Fireman, 1991 and Li et al., 2002 used a cohort from the Kaiser Permanente Medical Group in Northern California.<sup>8,9</sup> Goldhaber & Fireman, 1991 estimated a 13.0% cumulative risk



of SAB from 5-<20 weeks' gestation and a 11.1% cumulative risk of SAB from 6-<20 weeks' gestation.<sup>8</sup> We used the 11.1% cumulative risk estimate for comparison given that other studies as well as our report examined cumulative risk of SAB from 6-<20 weeks' gestation.<sup>8</sup> The study population in Goldhaber & Friedman was 65% White whereas it was more diverse in Li et al., 2002, with 38.4% White.<sup>8,9</sup> Average maternal age was 27 years and 31 years for participants in Goldhaber and Fireman, 1991 and Li et al., 2002, respectively.<sup>8,9</sup>

The study population for Magnus et al. 2019 consisted of all registered pregnancies between 2009-2013 from three national health registries in Norway (n=421,201).<sup>6</sup> A mean maternal age was not reported, but 20.9% were aged over 35 years.<sup>6</sup> Previous SAB was reported by 18.8% of study participants.<sup>6</sup> In this paper, SAB risk ranged from 9.8% (participants aged 25-29 years) to 53.6% (participants aged 45+ years), for an overall risk of 12.8%.<sup>6</sup>

The study population for Mukherjee et al., 2013 consisted of pregnant people in the Southeastern United States, of which 77% were White and 23% were Black, and 16.6% were aged over 35 years.<sup>10</sup> Mean maternal age was 29.8 years and 26.5 years for White and Black participants, respectively.<sup>10</sup> Previous SAB was reported by 22.3% of the study participants.<sup>10</sup> In Mukherjee et al., 2013, week-specific probability of SAB from 6-<20 weeks was stratified by White and Black race. Given that most of the participants for both the v-safe pregnancy registry and Mukherjee's study were White, we used their published figure to estimate the weekly cumulative risk and total cumulative risk of SAB from 6-<20 weeks among White women. Additionally, this gave us a more conservative estimate of the risk of SAB as this risk was slightly lower among White women compared to Black women. The total cumulative risk was 19.3%.<sup>10</sup> We used the estimated weekly cumulative risk among White women in our plot comparing the weekly cumulative risk of SAB in the v-safe pregnancy registry to published data.

Table S1: Population characteristics of comparator studies

	<b>Goldhaber and Fireman, 1991<sup>8</sup></b>	<b>Li et al., 2002<sup>9</sup></b>	<b>Magnus et al 2019<sup>6</sup></b>	<b>Mukherjee et al 2013<sup>10</sup></b>	<b>CDC v-safe</b>
<b>Study population</b>	Northern California	Northern California	Norway	Southeastern United States	United States
<b>Total # of pregnancies</b>	9,055	969	421,201	4,052	2,456
<b>Cumulative Risk of SAB 6-&lt;20 weeks' gestation</b>	11.1%	22%	12.8%	21.3%	14.1%
<b>Maternal age (years)</b>	27	31	--	White: 29.8 Black: 26.5	33.5
<b>Maternal age (% ≥ 35 years)</b>	--	24.9	20.9	16.6	33.3
<b>Race/ethnicity</b>					
<b>White</b>	65%	38.4%		77%	77%
<b>Black</b>		7.0%		23%	
<b>Hispanic</b>		21.0%			
<b>Asian</b>		27.3%			
<b>Obesity</b>	---	---	---	20.7%	17.8%
<b>Pre-existing diabetes</b>	---	2.2%	---	0.6%	1.1%
<b>Previous SAB</b>	---	20.4%	18.8%	22.3%	27.5%

## Supplementary Figure 1. Flow diagram of participants enrolled in the CDC v-safe pregnancy registry

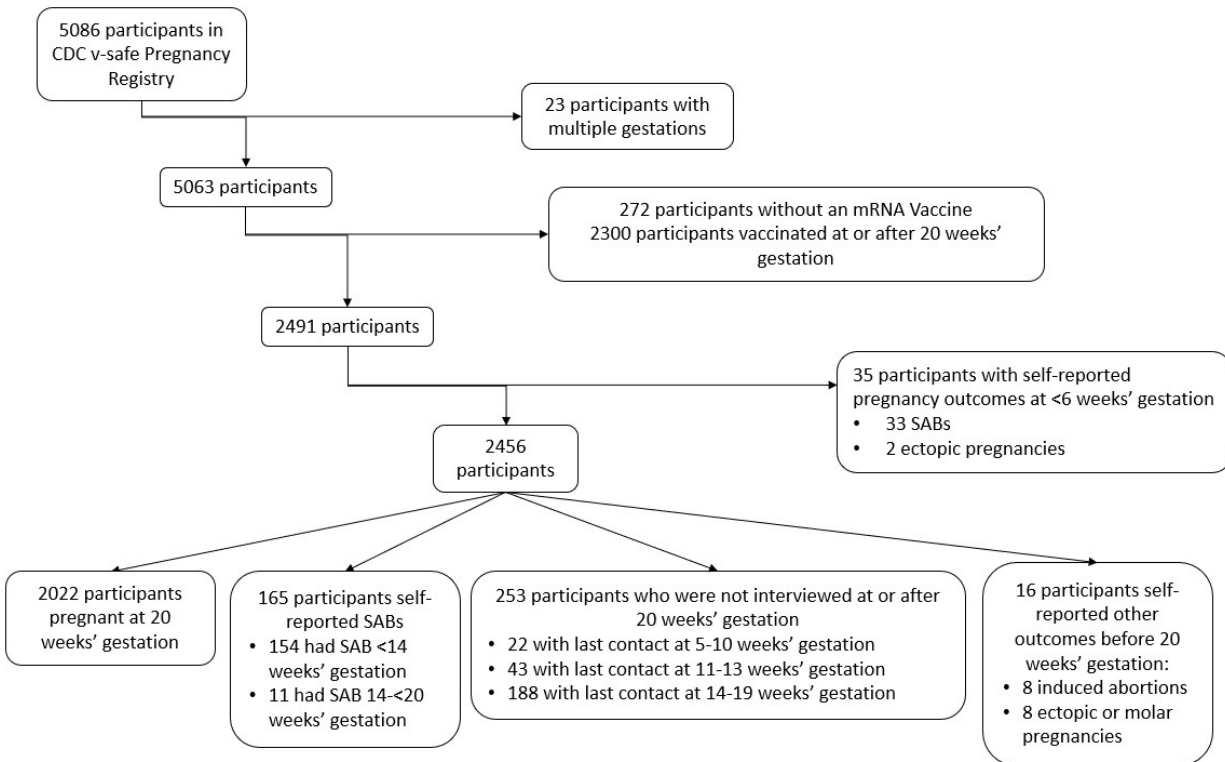


Table S2. Pregnancy Status at 20 Weeks' Gestation among Pregnant People Receiving mRNA COVID-19 Vaccines in the Preconception Period and through 20 Weeks' Gestation, CDC v-safe COVID-19 Vaccine Pregnancy Registry: December 14, 2020-July 19, 2021

<i>Characteristics</i>	<i>All</i>		<i>Self-reported SAB* 6-&lt;20 weeks' gestation</i>		<i>Ongoing pregnancies† at 20 weeks' gestation</i>		<i>Participants with ongoing pregnancy at contact prior to 20 weeks' gestation</i>		<i>Other pregnancy loss 6-&lt;20 weeks' gestation‡</i>	
	<i>n</i>	<i>%</i>	<i>n</i>	<i>%§</i>	<i>n</i>	<i>%§</i>	<i>n</i>	<i>%§</i>	<i>n</i>	<i>%§</i>
<b>Total</b>	<b>2456</b>		<b>165</b>		<b>2022</b>		<b>253</b>		<b>16</b>	
<b>Age at 1st eligible vaccine dose (years)</b>										
20-29	432	17.6	23	13.9	343	17.0	64	25.3	2	12.5
30-34	1205	49.1	71	43.0	1020	50.4	108	42.7	6	37.5
35-39	693	28.2	54	32.7	561	27.7	72	28.5	6	37.5
40+	126	5.1	17	10.3	98	4.8	9	3.6	2	12.5
<b>Race and Hispanic origin</b>										
Non-Hispanic White	1923	78.3	1113	68.5	1613	79.8	185	73.1	12	75.0
Hispanic	220	9.0	21	12.7	159	7.9	39	15.4	1	6.3
Non-Hispanic Asian	210	8.6	17	10.3	179	8.9	13	5.1	1	6.3
Non-Hispanic Multiple Races	48	2.0	7	4.2	34	1.7	6	2.4	1	6.3
Non-Hispanic Black	35	1.4	5	3.0	23	1.1	6	2.4	1	6.3
Non-Hispanic Native Hawaiian/Pacific Islander	8	0.3	0	0.0	6	0.3	2	0.8	0	0.0
Non-Hispanic American Indian/Alaskan Native	7	0.3	0	0.0	6	0.3	1	0.4	0	0.0
Missing	5	0.2	2	1.2	2	0.1	1	0.4	0	0.0
<b>Self-reported vaccine priority group</b>										
Non-healthcare essential worker	148	6.0	6	3.6	110	5.4	30	11.9	2	12.5

<i>Characteristics</i>	<i>All</i>		<i>Self-reported SAB* 6-&lt;20 weeks' gestation</i>		<i>Ongoing pregnancies† at 20 weeks' gestation</i>		<i>Participants with ongoing pregnancy at contact prior to 20 weeks' gestation</i>		<i>Other pregnancy loss 6-&lt;20 weeks' gestation‡</i>	
	<i>n</i>	<i>%</i>	<i>n</i>	<i>%§</i>	<i>n</i>	<i>%§</i>	<i>n</i>	<i>%§</i>	<i>n</i>	<i>%§</i>
Healthcare personnel <sup>  </sup>	2180	88.8	149	90.3	1822	90.1	196	77.5	13	81.3
<b>Vaccine type</b>										
Moderna	1162	47.3	85	51.5	944	46.7	126	49.8	7	43.8
Pfizer-BioNTech	1294	52.7	80	48.5	1078	53.3	127	50.2	9	56.3
<b>Number of vaccine doses reported</b>										
1	245	10.0	39	23.6	183	9.1	18	7.1	5	31.3
2	2211	90.0	126	76.4	1839	90.9	235	92.9	11	68.8
<b>Timing of Dose 1</b>										
Preconception <sup>¶</sup>	380	15.5	56	33.9	212	10.5	106	41.9	6	37.5
First trimester (>=2 and <14 weeks)	1230	50.1	107	64.8	971	48.0	142	56.1	10	62.5
Second trimester (>=14 and <20 weeks**)	846	34.4	2	1.2	839	41.5	5	2.0	0	0.0
<b>Timing of Dose 2 (n=2211)</b>										
Preconception <sup>¶</sup>	188	8.5	19	11.5	116	5.7	50	19.8	3	18.8
First trimester (>=2 and <14 weeks)	885	40.0	91	55.2	642	31.8	145	57.3	7	43.8
Second trimester (>=14 and <28 weeks)	1125	50.9	4	2.4	1081	53.5	40	15.8	0	0.0
After pregnancy outcome	13	0.6	12	7.3	0	0.0	0	0.0	1	6.3
<b>Comorbidities and past medical history</b>										
Obesity <sup>††</sup>	432	17.6	34	20.6	340	16.8	57	22.5	1	6.3
Pre-existing diabetes	27	1.1	2	1.2	23	1.1	2	0.8	0	0.0
Prior SAB	675	27.5	59	35.8	549	27.2	65	25.7	2	12.5
1 Prior SAB	452	67.0	33	20.0	373	18.4	44	17.4	2	12.5
2 or more Prior SABs	223	33.0	26	15.8	176	8.7	21	8.3	0	0.0

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Characteristics	All		Self-reported SAB* 6-<20 weeks' gestation		Ongoing pregnancies <sup>†</sup> at 20 weeks' gestation		Participants with ongoing pregnancy at contact prior to 20 weeks' gestation		Other pregnancy loss 6-<20 weeks' gestation <sup>‡</sup>	
	n	%	n	% <sup>§</sup>	n	% <sup>§</sup>	n	% <sup>§</sup>	n	% <sup>§</sup>
<i>*Spontaneous abortion</i>										
<i>†Includes 19 live births, 5 stillbirths, 2 induced abortions after 20 weeks' gestation, and 1996 pregnancies ongoing as of last interview</i>										
<i>‡Includes 8 induced abortions, 7 ectopic pregnancies, and 1 molar pregnancy</i>										
<i>§Column percentages provided for each variable according to pregnancy outcome/status; these should not be interpreted as risk estimates</i>										
<i>   Any person serving in a healthcare setting who has the potential for direct or indirect exposure to patients or infectious materials</i>										
<i>¶ Preconception defined as 4 weeks before last menstrual period up to 2 weeks after</i>										
<i>**Second trimester vaccination for dose 1 limited to receipt at less than 20 weeks' gestation per study criteria</i>										
<i>†† 12 cases missing information to calculate body mass index to determine whether participant affected by obesity (BMI at or greater than 30 kg/m<sup>2</sup>).</i>										

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Table S3. Cumulative risk of spontaneous abortion among CDC v-safe COVID-19 Vaccine Pregnancy Registry participants by age group, December 14, 2020-July 19, 2021

<i>Age group</i>	<i>Number at risk</i>	<i>Self-reported SAB*</i>	<i>Cumulative SAB risk (% , 95% CI)</i>
<b>20-29</b>	432	23	9.8 (5.9-13.4)
<b>30-34</b>	1205	71	13.0 (10.2-15.8)
<b>35-39</b>	693	54	16.7(12.6-20.6)
<b>40+</b>	126	17	28.8 (16.8-39.1)

\*SAB=spontaneous abortion

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