COVID-19 vaccine safety in pregnancy:
Updates from the v-safe COVID-19 vaccine pregnancy registry

Sep 22, 2021

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v-safe COVID-19 vaccine pregnancy registry
CDC COVID-19 Vaccine Task Force

For more information: www.cdc.gov/COVID19
Disclaimer

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V-safe pregnancy registry enrollment

Pregnancies reported to v-safe*

Individuals Reporting Pregnancy

Eligibility screening†

Consent for registry enrollment and follow-up

Eligible Individuals

*Pregnancy questions in v-safe assessments on first survey after each dose and on post-vaccination days 21 and 42 and months 3, 6, and 12

†Eligibility determined from verbal interviews and responses to 3-question web-based v-safe follow-up survey received prior to May 31, 2021. Eligible individuals received COVID-19 vaccination during pregnancy or periconceptional period (≤ 30 days before the first day of the last menstrual period before pregnancy)
V-safe pregnancy registry active follow-up

- Participants interviewed during each trimester, postpartum, and during early infancy
V-safe pregnancy registry participants, by vaccine manufacturer as of September 13, 2021, N=5096

- **Pfizer-BioNTech**: N=2584 (50.7%)
- **Moderna**: N=2236 (43.9%)
- **Janssen/J&J**: N=276 (5.4%)
Timing of first COVID-19 vaccination during periconception or pregnancy among v-safe pregnancy registry participants

Among 5093 participants*

N=277
(5.4%)

N=1428
(28.0%)

N=2119
(41.6%)

N=1269
(24.9%)

*Eligibility dates missing for 3 participants

Definitions:
Periconceptional: ≤30 days before the first day of the last menstrual period before pregnancy;
First trimester: 1st day of LMP to <14 weeks gestational age; Second trimester: 14-28 weeks; Third trimester: ≥28 weeks

Data as of September 13, 2021
Estimated month of delivery among enrolled participants, by timing of 1st COVID-19 vaccination received during periconception or pregnancy.
Estimated month of delivery among enrolled participants, by timing of 1st COVID-19 vaccination during periconception or pregnancy

Timing of 1st COVID-19 vaccination
- Periconception
- 1st Trimester
- 2nd Trimester
- 3rd Trimester

Postpartum and Infant follow-up window^ not yet reached

Estimated date of delivery

Expected Delivery Month

^Postpartum and infant follow-up interviews lag expected date of delivery by approximately 19 weeks
### V-safe pregnancy registry participant characteristics (N=5096 enrolled)

<table>
<thead>
<tr>
<th>Age</th>
<th>Enrolled %</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;20</td>
<td>0</td>
</tr>
<tr>
<td>20-24</td>
<td>1.1</td>
</tr>
<tr>
<td>25-34</td>
<td>65.3</td>
</tr>
<tr>
<td>35-44</td>
<td>33.3</td>
</tr>
<tr>
<td>&gt;45</td>
<td>0.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Race/Ethnicity*</th>
<th>Enrolled %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Hispanic Black</td>
<td>1.4</td>
</tr>
<tr>
<td>Non-Hispanic White</td>
<td>79.4</td>
</tr>
<tr>
<td>Non-Hispanic Asian</td>
<td>8.4</td>
</tr>
<tr>
<td>Non-Hispanic Other</td>
<td>2.3</td>
</tr>
<tr>
<td>Hispanic</td>
<td>8.1</td>
</tr>
</tbody>
</table>

*Race/Ethnicity, Missing/Declined N=20 (of the 5096) Data as of September 13, 2021
V-safe pregnancy registry participant occupation, as derived from vaccine priority group question

Data as of September 13, 2021
V-safe pregnancy registry analysis of early pregnancy loss
Receipt of mRNA COVID-19 vaccines and risk of spontaneous abortion (SAB)*

- **Objective**: Assess the cumulative risk of SAB after mRNA COVID-19 vaccination

- **Data source**: CDC’s v-safe pregnancy registry, COVID-19 vaccination data 2020–21

- **Methods**:
  - Included 2456 pregnant people enrolled in v-safe pregnancy registry
    - Received at least one dose of an mRNA COVID-19 vaccine before pregnancy or prior to 20 weeks of pregnancy
    - Did not have a pregnancy loss before 6 weeks of gestation
  - Lifetable methods to examine cumulative risk

No increased risk of spontaneous abortion (SAB) after COVID-19 vaccination during pregnancy

- Unadjusted cumulative risk of SAB after mRNA COVID-19 vaccination: 14.1%
- Age-standardized cumulative risk of SAB: 12.8% (95% CI: 10.8%–14.8%)
  - Similar to previously published baseline estimates of SAB (11%–22%)
- More evidence that mRNA COVID-19 vaccination during pregnancy is not associated with SAB

<table>
<thead>
<tr>
<th>Gestational Age</th>
<th>Participants at Risk</th>
<th>Participants Who Reported Spontaneous Abortion</th>
<th>Week-Specific Risk</th>
<th>Cumulative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 to &lt;7 weeks</td>
<td>904</td>
<td>15</td>
<td>1.7</td>
<td>1.7 (0.8–2.5)</td>
</tr>
<tr>
<td>7 to &lt;8 weeks</td>
<td>982</td>
<td>18</td>
<td>1.8</td>
<td>3.5 (2.3–4.6)</td>
</tr>
<tr>
<td>8 to &lt;9 weeks</td>
<td>1032</td>
<td>37</td>
<td>3.6</td>
<td>6.9 (5.4–8.5)</td>
</tr>
<tr>
<td>9 to &lt;10 weeks</td>
<td>1087</td>
<td>39</td>
<td>3.6</td>
<td>10.3 (8.4–12.0)</td>
</tr>
<tr>
<td>10 to &lt;11 weeks</td>
<td>1118</td>
<td>19</td>
<td>1.7</td>
<td>11.8 (9.9–13.7)</td>
</tr>
<tr>
<td>11 to &lt;12 weeks</td>
<td>1184</td>
<td>12</td>
<td>1.0</td>
<td>12.7 (10.7–14.6)</td>
</tr>
<tr>
<td>12 to &lt;13 weeks</td>
<td>1274</td>
<td>9</td>
<td>0.7</td>
<td>13.3 (11.3–15.2)</td>
</tr>
<tr>
<td>13 to &lt;14 weeks</td>
<td>1394</td>
<td>5</td>
<td>0.4</td>
<td>13.6 (11.6–15.6)</td>
</tr>
<tr>
<td>14 to &lt;15 weeks</td>
<td>1534</td>
<td>0</td>
<td>0</td>
<td>13.6 (11.6–15.6)</td>
</tr>
<tr>
<td>15 to &lt;16 weeks</td>
<td>1632</td>
<td>2</td>
<td>0.1</td>
<td>13.7 (11.7–15.7)</td>
</tr>
<tr>
<td>16 to &lt;17 weeks</td>
<td>1742</td>
<td>2</td>
<td>0.1</td>
<td>13.8 (11.8–15.8)</td>
</tr>
<tr>
<td>17 to &lt;18 weeks</td>
<td>1848</td>
<td>2</td>
<td>0.1</td>
<td>13.9 (11.9–15.9)</td>
</tr>
<tr>
<td>18 to &lt;19 weeks</td>
<td>1941</td>
<td>3</td>
<td>0.2</td>
<td>14.0 (12.0–16.0)</td>
</tr>
<tr>
<td>19 to &lt;20 weeks</td>
<td>2052</td>
<td>2</td>
<td>0.1</td>
<td>14.1 (12.1–16.1)</td>
</tr>
</tbody>
</table>

Cumulative risk of spontaneous abortion in the v-safe pregnancy registry and in two historical cohorts

V-safe pregnancy registry infant outcomes at birth
Estimated month of delivery, among enrolled participants, by timing of 1\textsuperscript{st} COVID-19 vaccination during periconception or pregnancy

Note: postpartum and infant follow-up interviews lag expected delivery date by approximately 19 weeks
V-safe pregnancy registry enrolled pregnancies included in maternal and infant outcomes cohort

5096 enrolled participants
- 2912 with EDD after May 15, 2021
- 7 withdrew
- 2177 estimated date of delivery (EDD) before May 15, 2021
- 501 pending follow-up
- 63 lost to follow-up

1613 pregnancies
- 1634* Live born infants
- 30% 2nd trimester vaccination
- 70% 3rd trimester vaccination

* Includes 42 infants from twin gestations

- Participants enrolled in first trimester: 1427
- Pregnancies and follow-up ongoing; therefore, data are incomplete
- Will be included in future reports

Data as of September 13, 2021
**Infant outcomes among v-safe pregnancy registry enrolled participants* with pregnancies ending in live birth (N=1634 infants)**

<table>
<thead>
<tr>
<th>Live born infants</th>
<th>All infants N=1634 (%)</th>
<th>Background rate %†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preterm a</td>
<td>99 (6.5)</td>
<td>8-15</td>
</tr>
<tr>
<td>Small for gestational age b</td>
<td>45 (2.8)</td>
<td>3.5</td>
</tr>
<tr>
<td>Admitted to NICU c</td>
<td>158 (9.7)</td>
<td>9.3</td>
</tr>
<tr>
<td>Neonatal or infant death d</td>
<td>0 (0)</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>

* Maternal and infant outcomes cohort defined as participants with completed follow-up and expected delivery dates prior to May 15, 2021, to account for the lag in ascertaining outcomes at infant 3-month follow-up.


a Preterm birth denominator is live births among mothers vaccinated before 37 weeks' gestation (n=1,514 infants)

b Birthweight below the 10th percentile for gestational age and sex using INTERGROWTH-21st Century growth standards


Preliminary birth defects data among live born infants of participants vaccinated in the 2nd or 3rd trimester

- Most birth defects arise in the first trimester; most pregnancies in the registry that were vaccinated in the first trimester are ongoing
- V-safe pregnancy registry participants report birth defects during the postpartum interview
  - Response to question “Was your baby diagnosed with a birth defect?”
- Reported birth defects were reviewed for inclusion and categorized by birth defect experts
- Birth defects were defined as a structural abnormality, chromosome anomaly, or genetic syndrome
Participant reports of birth defects among live born infants of participants vaccinated in the 2\textsuperscript{nd} or 3\textsuperscript{rd} trimester (N=1574)

<table>
<thead>
<tr>
<th>Birth Defect Categories</th>
<th>Specific defects N=52*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart and circulatory system</td>
<td>16</td>
</tr>
<tr>
<td>\textit{Septal defects}</td>
<td>11</td>
</tr>
<tr>
<td>Musculoskeletal system</td>
<td>8</td>
</tr>
<tr>
<td>\textit{Polydactyly and syndactyly}</td>
<td>4</td>
</tr>
<tr>
<td>Genitalia</td>
<td>7</td>
</tr>
<tr>
<td>\textit{Hypospadias}</td>
<td>5</td>
</tr>
<tr>
<td>Kidney and urinary system</td>
<td>5</td>
</tr>
<tr>
<td>Cleft lip +/- cleft palate</td>
<td>4</td>
</tr>
<tr>
<td>Chromosomal anomalies</td>
<td>4</td>
</tr>
<tr>
<td>\textit{Trisomy 21}</td>
<td>3</td>
</tr>
<tr>
<td>Nervous system</td>
<td>3</td>
</tr>
<tr>
<td>Respiratory system</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
</tr>
</tbody>
</table>

Among the 45 infants with birth defects:

- Types of reported birth defects are consistent with data from birth defects surveillance in the United States
- No unusual types or clusters of birth defects noted
- The v-safe pregnancy registry has demonstrated its capability in identifying birth defect outcomes and their distinct types

*Among 45 infants who had one or more major birth defect; 6 infants had >1 birth defect; 1 infant was from a twin gestation
v-safe pregnancy registry

Data as of September 6, 2021
Closing thoughts on COVID-19 vaccination and pregnancy
Closing thoughts

- Accumulating data on the safety of COVID-19 vaccination during pregnancy from the v-safe pregnancy registry adds to the growing body of evidence of the safety of COVID-19 vaccination during pregnancy
  - No evidence of any increase in spontaneous abortion rates
  - No evidence of any disproportionate infant outcomes
- CDC will continue to monitor the safety of COVID-19 vaccination during pregnancy
Acknowledgments

Thank you to the many people who continue to contribute to the vaccine safety monitoring work

- V-safe After Vaccination Health Checker Team
- V-safe COVID-19 Pregnancy Registry Team
- Vaccine Safety Datalink Team
- VAERS Team
- Participants in all of the above vaccine safety monitoring systems
- CDC COVID-19 Vaccine Task Force
Thank you!

For more information, contact CDC
1-800-CDC-INFO (232-4636)

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