COVID-19 in pregnant people and infants ages 0-5 months

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Centers for Disease Control and Prevention
COVID-19 in Pregnant People
COVID-19 in Pregnant People

Assessing risk of COVID-19 in pregnancy
1. Is pregnancy a risk factor for severe illness?

2. Is COVID-19 associated with increased risks for maternal complications and adverse pregnancy outcomes?

3. Are infants born to people with COVID-19 during pregnancy at risk for adverse outcomes?
# Living Systematic Review and Meta-Analysis: Assessing pregnancy as a risk factor for severe illness

<table>
<thead>
<tr>
<th>Outcomes</th>
<th># Studies</th>
<th># with event/# in group (%)</th>
<th>Odds ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Pregnant with covid-19</td>
<td>Non-pregnant with COVID-19</td>
</tr>
<tr>
<td>All cause mortality</td>
<td>11</td>
<td>242/122 222 (0.2)</td>
<td>5252/2 138 726 (0.2)</td>
</tr>
<tr>
<td>ICU admission</td>
<td>10</td>
<td>912/118 403 (0.8)</td>
<td>11 513/1 908 957 (0.6)</td>
</tr>
<tr>
<td>Invasive ventilation</td>
<td>8</td>
<td>310/116 458 (0.3)</td>
<td>3607/1 772 716 (0.2)</td>
</tr>
<tr>
<td>ECMO</td>
<td>5</td>
<td>19/30 694 (0.1)</td>
<td>122/432 623 (0.0)</td>
</tr>
<tr>
<td>ARDS</td>
<td>4</td>
<td>22/197 (11.2)</td>
<td>45/418 (10.8)</td>
</tr>
<tr>
<td>Major organ failure</td>
<td>4</td>
<td>5/197 (2.5)</td>
<td>28/418 (6.7)</td>
</tr>
</tbody>
</table>

ECMO: extracorporeal membrane oxygenation; ARDS: Acute respiratory distress syndrome


Total: 226,263 cases
738 ICU Admissions
329 Deaths
Living Systematic Review and Meta-Analysis: Assessing COVID-19 as a risk factor for adverse maternal and perinatal outcomes

<table>
<thead>
<tr>
<th>Outcomes</th>
<th># Studies</th>
<th># with event/# in group (%)</th>
<th>Odds ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Pregnant with COVID-19</td>
<td>Pregnant without COVID-19</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pregnant with COVID-19</td>
<td>Pregnant without COVID-19</td>
</tr>
<tr>
<td>Maternal outcomes:</td>
<td></td>
<td>47/11 362 (0.4)</td>
<td>37/411 126 (0.0)</td>
</tr>
<tr>
<td>All cause mortality</td>
<td>21</td>
<td>447/12 957 (3.4)</td>
<td>1962/459 359 (0.4)</td>
</tr>
<tr>
<td>ICU admission</td>
<td>21</td>
<td>1306/12 076 (10.8)</td>
<td>26 068/436 964 (6.0)</td>
</tr>
<tr>
<td>Preterm birth &lt;37 weeks</td>
<td>48</td>
<td>47/9338 (0.6)</td>
<td>1397/414 139 (0.3)</td>
</tr>
<tr>
<td>Perinatal outcomes:</td>
<td></td>
<td>16/3153 (0.5)</td>
<td>28/9 263 (0.3)</td>
</tr>
<tr>
<td>Stillbirth</td>
<td>25</td>
<td>687/4072 (16.9)</td>
<td>6968/193 124 (3.6)</td>
</tr>
<tr>
<td>Neonatal death</td>
<td>21</td>
<td>131/1073 (12.2)</td>
<td>246/3933 (6.3)</td>
</tr>
<tr>
<td>Admission to neonatal unit</td>
<td>29</td>
<td>1306/12 076 (10.8)</td>
<td>26 068/436 964 (6.0)</td>
</tr>
<tr>
<td>Fetal distress</td>
<td>6</td>
<td>447/12 957 (3.4)</td>
<td>1962/459 359 (0.4)</td>
</tr>
</tbody>
</table>

### SET-NET: Pregnancy and Infant Outcomes by Trimester of Infection, January 25, 2020–December 31, 2020

<table>
<thead>
<tr>
<th></th>
<th>First or second trimester infection</th>
<th>Third trimester infection</th>
<th>Adjusted prevalence ratio&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gestational age (N=27,430)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Term (≥37 weeks)</td>
<td>15,398 (88.2)</td>
<td>8,200 (82.2)</td>
<td></td>
</tr>
<tr>
<td>Preterm (&lt;37 weeks)</td>
<td>2,061 (11.8)</td>
<td>1,771 (17.8)</td>
<td>1.44 (1.35–1.54)</td>
</tr>
<tr>
<td><strong>NICU admission (N=32,319)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1,655 (10.2)</td>
<td>1,874 (11.6)</td>
<td>1.13 (1.06–1.21)</td>
</tr>
<tr>
<td>Term (≥37 weeks)</td>
<td>735 (4.5)</td>
<td>1,086 (6.7)</td>
<td>1.29 (1.16, 1.36)</td>
</tr>
<tr>
<td>Preterm (&lt;37 weeks)</td>
<td>920 (5.7)</td>
<td>788 (4.9)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>14,545 (89.8)</td>
<td>14,245 (88.4)</td>
<td></td>
</tr>
<tr>
<td><strong>Small-for-gestational age&lt;sup&gt;b&lt;/sup&gt; (N=34,522)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>827 (4.8)</td>
<td>1,017 (5.8)</td>
<td>1.16 (1.06–1.27)</td>
</tr>
<tr>
<td>No</td>
<td>16,274 (95.2)</td>
<td>16,404 (94.2)</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> Adjusted for maternal age, race and ethnicity, health insurance, and underlying conditions

<sup>b</sup><sup><i></i></sup><i>10<sup>th</sup></i> percentile for sex and gestational age per INTERGROWTH-21<sup>st</sup>

COVID-19 vaccination coverage among pregnant people
Percentage of pregnant people who have received a COVID-19 primary vaccine series and monovalent booster* from two data sources

<table>
<thead>
<tr>
<th>Percentage Completed Primary Series</th>
<th>Percentage Boosted*</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIS-ACM (September 2022)</td>
<td>77</td>
</tr>
<tr>
<td>VSD (October 2022)</td>
<td>72</td>
</tr>
<tr>
<td>From VSD:</td>
<td></td>
</tr>
<tr>
<td>❖ Overall, 43% of pregnant people have received primary series <strong>PLUS</strong> monovalent booster</td>
<td></td>
</tr>
<tr>
<td>❖ Overall, 57% of pregnant people unvaccinated or under-vaccinated</td>
<td></td>
</tr>
</tbody>
</table>

*Percentage boosted among those who received COVID-19 vaccine series


COVID-19 in infants ages 0-5 months
COVID-19-associated hospitalizations by age group, COVID-NET, March 1, 2020 – September 10, 2022

![Graph showing hospitalizations per 100,000 population by age group and delta strains from Pre-Delta to Omicron BA.5.

Cumulative influenza- and COVID-19-associated hospitalization rates per 100,000 among **infants 0-5 months**, FluSurv-NET and COVID-NET, 2017–2022

- **October 2020 to September 2021:** Cumulative COVID-19-associated hospitalization rates were similar to influenza-associated hospitalization rates during the 2017-18, 2018-19, and 2019-20 influenza seasons
- **October 2021 to April 2022:** Cumulative COVID-19-associated hospitalization rates were higher than influenza-associated hospitalization rates during those same pre-pandemic influenza seasons

COVID-19 epidemiology in infants ages 0-5 months

- Among infants 0-5 months of age with COVID-19-associated hospitalizations:¹
  - 84% of infants had COVID-19 symptoms (including 97% of those >1 month age)
  - 24% have an underlying health condition (prematurity was the most frequent)
  - 18% were admitted to the intensive care unit (ICU)

- Cumulative COVID-19-associated hospitalization rates by race and ethnicity are highest in infants ages 0-5 months who are non-Hispanic American Indian and Alaska Native, Hispanic, and non-Hispanic Black. ²

- According to death certificate data from January 1, 2020 through October 1, 2022:
  - 265 deaths involving COVID-19 have been reported among infants ages 0-5 months, accounting for 0.5% of all-cause deaths in this age group.³

For more details, please see extra slides.

Updates on COVID-19 vaccine safety in pregnancy:
  • Vaccine Safety Datalink
  • v-safe COVID-19 Vaccine Pregnancy Registry

Advisory Committee on Immunization Practices
October 19, 2022

Elyse O. Kharbanda, MD, MPH, HealthPartners Institute
Christine Olson MD, MPH, CDC

For more information: www.cdc.gov/COVID19
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 (CDC).
- Mention of a product or company name is for identification purposes only and does not constitute endorsement by CDC.
Overview

- Vaccine Safety Datalink
  - Present analyses of spontaneous abortion (case) and ongoing pregnancy (control) surveillance following COVID-19 booster vaccination
  - Provide summary of VSD studies of COVID-19 vaccine safety in pregnancy

- v-safe COVID-19 Vaccine Pregnancy Registry
  - Describe Pregnancy Registry participant cohort
  - Present preliminary data on pregnancy and infant outcomes
Vaccine Safety Datalink (VSD)

- Established in 1990
- Collaborative project between CDC and 9 integrated healthcare organizations, as of Sept 2022
- VSD expanding in 2022 to include additional sites
Objectives – case-control surveillance, 8 VSD sites

- **Primary:** To conduct “monthly” surveillance of spontaneous abortion (cases) and ongoing pregnancy (controls), in order to estimate the odds ratio for receiving a 3rd mRNA COVID-19 vaccine dose in the 28 days prior to the spontaneous abortion.

- **Secondary:** To evaluate odds ratios for receiving a 3rd mRNA COVID-19 vaccine in a 42-day window and for receiving any COVID-19 booster in a 28- or 42-day window.

Spontaneous abortion (SAB) defined as an intrauterine pregnancy ending in fetal demise before 20 weeks’ gestation.
Definition of a COVID-19 vaccine booster

- Booster dose defined as a COVID-19 vaccine dose administered at least 28 days after completion of the COVID-19 vaccine primary series*

- Primary analyses evaluated 3rd mRNA COVID-19 vaccine dose, after 2 prior mRNA COVID-19 vaccine doses

- Secondary analyses evaluated any COVID-19 vaccine booster dose
  - 2nd Janssen/J&J
  - mRNA vaccine after Janssen/J&J
  - 4th or subsequent mRNA vaccine dose

*Primary vaccine series: 2 mRNA COVID vaccine doses or 1 Janssen/J&J dose
mRNA COVID-19 vaccines are mRNA-1273, Moderna or BNT162b2, Pfizer-BioNTech
Spontaneous abortion (case) and 3rd COVID-19 mRNA vaccine (booster) in 28-day exposure window

Spontaneous abortions (SAB) and Ongoing pregnancies 6-19 weeks’ gestation; Stratified by gestational age groups (6-8, 9-13, 14-19 weeks), maternal age group, number of antenatal visits, race/ethnicity and VSD site
Spontaneous abortion (case) and 3rd COVID-19 mRNA vaccine (booster) in 28-day exposure window

Spontaneous abortions (SAB) and Ongoing pregnancies 6-19 weeks’ gestation; Stratified by gestational age groups (6-8, 9-13, 14-19 weeks), maternal age group, number of antenatal visits, race/ethnicity and VSD site
Spontaneous abortion (case) and ongoing pregnancy-period (control) surveillance and COVID-19 vaccine boosters in 28 (or 42) day exposure window

Spontaneous abortions (SAB) and Ongoing pregnancies 6-19 weeks’ gestation; Stratified by gestational age groups (6-8, 9-13, 14-19 weeks), maternal age group, number of antenatal visits, race/ethnicity and VSD site
Results: Receipt of 3rd COVID-19 mRNA COVID-19 vaccine dose in pregnancy
Nov 1, 2021 – June 12, 2022
112,718 unique pregnancies 6-19 weeks’ gestation

<table>
<thead>
<tr>
<th>Eight 28-day surveillance periods</th>
<th>Ongoing Pregnancies N (%)</th>
<th>Spontaneous abortions N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All included pregnancies</td>
<td>98,492</td>
<td>14,226</td>
</tr>
<tr>
<td>Vaccine type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>mRNA-1273, Moderna</td>
<td>4350 (4.4)</td>
<td>371 (2.6)</td>
</tr>
<tr>
<td>BNT162b2, Pfizer</td>
<td>6135 (6.2)</td>
<td>476 (3.3)</td>
</tr>
<tr>
<td>Total</td>
<td>10,485 (10.6)</td>
<td>847 (6.0)</td>
</tr>
</tbody>
</table>

Secondary analyses: 11,293 ongoing pregnancies and 904 pregnancies ending in spontaneous abortion received any COVID-19 vaccine booster in pregnancy
Adjusted Odds Ratios for 3rd mRNA COVID-19 vaccine in 28 days prior to SAB, overall and by vaccine type
Nov 1, 2021–Jun 12, 2022, 285,079 pregnancy-periods

<table>
<thead>
<tr>
<th>Primary analyses</th>
<th>*aOR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3rd mRNA COVID-19 vaccine in 28-day window</td>
<td>0.94 (0.86-1.03)</td>
</tr>
</tbody>
</table>

By vaccine type

<table>
<thead>
<tr>
<th>Vaccine Type</th>
<th>*aOR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRNA-1273, Moderna</td>
<td>0.93 (0.81–1.07)</td>
</tr>
<tr>
<td>BNT162b2, Pfizer-BioNTech</td>
<td>0.95 (0.84–1.07)</td>
</tr>
</tbody>
</table>

aOR = adjusted odds ratio; SAB= spontaneous abortion

*GEE models included covariates for gestational age group, surveillance period, VSD site, maternal age group, number of antenatal visits, and race/ethnicity and accounted for unique pregnancies that contributed data to ≥1 pregnancy-period
### Adjusted Odds Ratios for primary and secondary analyses

<table>
<thead>
<tr>
<th>Analyses</th>
<th>3rd mRNA COVID-19 vaccine in 28-day window</th>
<th>3rd mRNA COVID-19 vaccine in 42-day window</th>
<th>Any COVID-19 vaccine booster** in 28-day window</th>
<th>Any COVID-19 vaccine booster in 42-day window</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary analyses</td>
<td>0.94 (0.86-1.03)</td>
<td>0.97 (0.90-1.05)</td>
<td>0.94 (0.86-1.02)</td>
<td>0.96 (0.89-1.04)</td>
</tr>
<tr>
<td>Secondary analyses</td>
<td>0.94 (0.86-1.03)</td>
<td>0.97 (0.90-1.05)</td>
<td>0.94 (0.86-1.02)</td>
<td>0.96 (0.89-1.04)</td>
</tr>
</tbody>
</table>

**aOR (95% CI)**

- **Primary analyses**: Adjusted odds ratio for the 3rd mRNA COVID-19 vaccine in a 28-day window is 0.94 (0.86-1.03).
- **Secondary analyses**: Adjusted odds ratio for the 3rd mRNA COVID-19 vaccine in a 42-day window is 0.97 (0.90-1.05).
- Adjusted odds ratio for any COVID-19 vaccine booster in a 28-day window is 0.94 (0.86-1.02).
- Adjusted odds ratio for any COVID-19 vaccine booster in a 42-day window is 0.96 (0.89-1.04).

**Note:**
## Current VSD studies on COVID-19 vaccine safety in pregnancy

<table>
<thead>
<tr>
<th>Short title</th>
<th>Exposure</th>
<th>Outcome(s)</th>
<th>Status (as of 9/21/22)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spontaneous abortion case-control surveillance</td>
<td>Primary vaccine series</td>
<td>Spontaneous abortion – based on automated data</td>
<td>Published in JAMA 9/2021, Presented at ACIP 9/2021</td>
</tr>
<tr>
<td></td>
<td>Booster vaccination*</td>
<td></td>
<td>Topic of presentation today</td>
</tr>
<tr>
<td>Stillbirth and Spontaneous abortion case-control study</td>
<td>Primary vaccine series</td>
<td>Spontaneous abortion and stillbirth – based on chart review and expert adjudication</td>
<td>Chart reviews and expert adjudication of cases ongoing</td>
</tr>
<tr>
<td>Acute maternal outcomes (within 42 days of vaccination)</td>
<td>Primary vaccine series</td>
<td>Fever and other acute local and systemic reactions</td>
<td>Published in NEJM 7/2022</td>
</tr>
<tr>
<td></td>
<td>Booster vaccination*</td>
<td></td>
<td>Analyses ongoing</td>
</tr>
<tr>
<td>Pregnancy complications and birth outcomes</td>
<td>Primary vaccine series</td>
<td>Gestational diabetes, hypertensive disorders of pregnancy</td>
<td>Analyses ongoing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Small-for-gestational age, preterm birth</td>
<td>Published in MMWR 1/2022</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Birth defects, infant infections</td>
<td>Analyses ongoing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Growth and developmental outcomes</td>
<td>Planning analyses – awaiting infants to reach 2 years of age</td>
</tr>
</tbody>
</table>

*Monovalent booster vaccines; bivalent booster vaccines can be evaluated in the future*
Summary

• COVID-19 booster vaccination in early pregnancy was not associated with increased risk for spontaneous abortion

• The Vaccine Safety Datalink is continuing comprehensive surveillance of COVID-19 vaccine safety in pregnancy
  • No safety signals have been identified
  • Future studies will evaluate long-term outcomes and newer COVID-19 vaccines
Our team

This work was funded by CDC, contract: 200-2012-53526

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• Simon Hambidge
• Jim Donahue
• Tom Boyce
• Candace Fuller
v-safe COVID-19 Vaccine Pregnancy Registry enrollment & data collection

- **Active, smart-phone based monitoring system for COVID-19 vaccines**
- **Voluntary self-enrollment**
- **Started DEC 14, 2020**

**Individual Reporting Pregnancy**

- Reported a pregnancy into v-safe DEC 14, 2020 – JUN 20, 2021
- 18+ years of age
- Speak English or Spanish
- Pregnant at time of vaccination or vaccinated during periconceptional period

**Eligibility Screening**

- Eligibility determined from verbal interviews and responses to 3-question on 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)

**Eligible Individuals**

- Phone interviews conducted
  - Demographics, health over pregnancy
  - Pregnancy outcome
  - Birth hospitalization, postpartum
  - Infant health to 3 months of age
- Consent obtained for medical records

**Consent for registry enrollment and follow-up**

- Interviews completed
  - JAN 2021 – AUG 2022
- Medical record review ongoing

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*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 on 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)
Summary of eligibility & enrollment into the v-safe COVID-19 Pregnancy Registry

Over 65,000 participants reported a pregnancy into v-safe during the eligibility period* (Dec 2020-June 2021)

- Eligible: 36%
- Refused: 1%
- Not eligible: 3%
- Unreachable: 60%

Participation rate: 98%
Total enrolled: 22,953
Total pregnancies: 22,968
Mean age 33.9 yr
45% healthcare workers

*Excludes v-safe participants who in a subsequent survey reported they were not pregnant or did not provide permission to contact for pregnancy registry eligibility.
Abbreviations: J&J = Janssen/Johnson & Johnson; NH=non-Hispanic
Timing of first eligible COVID-19 vaccination among v-safe Pregnancy Registry participants*

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

*Total number of pregnancies excluding 35 participants who withdrew from the registry and 70 participants enrolled based on LMP, but later determined ineligible based on EDD.
### At-A-Glance: Self-reported interview data v-safe COVID-19 Pregnancy Registry

#### Pregnancy outcome among pregnancies with a known outcome* (n=21,703)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Pfizer BioNTech (N=12,751)</th>
<th>Moderna (N=8,365)</th>
<th>J&amp;J (N=587)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Live birth</td>
<td>12253</td>
<td>96.1</td>
<td>7916</td>
</tr>
<tr>
<td>Miscarriage (&lt;20 wk)</td>
<td>422</td>
<td>3.3</td>
<td>395</td>
</tr>
<tr>
<td>Stillbirth (≥20 wk)**</td>
<td>29</td>
<td>0.2</td>
<td>20</td>
</tr>
<tr>
<td>Induced Abortion</td>
<td>30</td>
<td>0.2</td>
<td>25</td>
</tr>
<tr>
<td>Other (e.g., ectopic)</td>
<td>17</td>
<td>0.1</td>
<td>10</td>
</tr>
</tbody>
</table>

*Analysis excludes 35 participants that withdrew and 70 deemed ineligible based on EDD. Pregnancy outcome unknown for 1160 pregnancies: 415 lost to follow up, and 745 may be captured during extended follow-up.

**Stillbirths adjudicated, and re-classified based on medical records where possible. 1 twin pregnancy with both a live and stillbirth is counted under both.

<table>
<thead>
<tr>
<th>Stillbirth Rate per 1,000 live births and still births</th>
<th>Pregnancy Registry</th>
<th>2017 NVSS Birth Data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.45</td>
<td>5.89 overall</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.89 NH-white</td>
</tr>
</tbody>
</table>

### Abbreviations:

J&J = Janssen/Johnson & Johnson; N=numerator; NH = non-Hispanic; NVSS = U.S. National Vital Statistics System, Birth Data
At-A-Glance: Self-reported interview data  
v-safe COVID-19 Pregnancy Registry

<table>
<thead>
<tr>
<th>Maternal conditions during pregnancy (n=22,863)*</th>
<th>Pfizer BioNTech</th>
<th>Moderna</th>
<th>J&amp;J</th>
<th>Published Incidence (%)†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertensive disorders of pregnancy**</td>
<td>1,704 12.8</td>
<td>1,083 12.2</td>
<td>77 11.1</td>
<td>8.5-13</td>
</tr>
<tr>
<td>Gestational diabetes</td>
<td>1,205 9.1</td>
<td>810 9.1</td>
<td>58 8.4</td>
<td>8-10</td>
</tr>
<tr>
<td>COVID-19 infection</td>
<td>464 3.5</td>
<td>311 3.5</td>
<td>33 4.8</td>
<td>--</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pregnancy complications among pregnancies resulting in live birth (n=20,726)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preterm birth</td>
</tr>
<tr>
<td>SGA (&lt;10th percentile)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Infant outcomes among live births (n=21,088)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infant death***</td>
</tr>
</tbody>
</table>

* Analyses excludes 35 participants that withdrew and 70 deemed ineligible based on EDD. Denominators for each vaccine type can be calculated by N/(%*0.01).
** Excludes preexisting hypertension.
***Infant deaths adjudicated with medical records where possible, 1 neonatal death re-classified as a stillbirth.
† The populations from which these rates are derived are not matched to the current study population for age, race and ethnicity, or other demographic and clinical factors. Abbreviations: J&J = Janssen/Johnson & Johnson; N=numerator.
No increased risk of spontaneous abortion (SAB) after COVID-19 vaccination during pregnancy.

v-safe COVID-19 Pregnancy Registry

- 2,456 participants with at least one eligible mRNA vaccination
- 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%)
No increased risk of major birth defects after COVID-19 vaccination during pregnancy

v-safe COVID-19 Pregnancy Registry

- 12,474 participants
  - Singleton pregnancies
  - Excluded those who reported COVID-19 during pregnancy

- Major birth defects reported for 429 (3.5%) fetuses or infants

Analysis inclusion criteria: registry participants with reported pregnancy outcome Dec 14, 2020, through Jan 31, 2022. Excluded participants who reported a miscarriage, ectopic or molar pregnancy, non-singleton pregnancy, or who reported having had COVID-19 during pregnancy.
SARS-CoV-2 infection after full vaccination not associated with increased risk of pregnancy-associated outcomes

v-safe COVID-19 Pregnancy Registry

<table>
<thead>
<tr>
<th></th>
<th>No SARS-CoV-2 infection reported (N=20,309) referent</th>
<th>SARS-CoV-2 infection after full vaccination* (N=325)</th>
<th>Prevalence ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stillbirth</td>
<td>51 (0.3%)</td>
<td>1 (0.3%)</td>
<td>1.22 (0.17, 8.90)</td>
</tr>
<tr>
<td>Preterm birth (&lt;37 weeks)</td>
<td>1,604 (7.9%)</td>
<td>30 (9.2%)</td>
<td>1.16 (0.83, 1.65)</td>
</tr>
<tr>
<td>Hypertensive disorder of pregnancy</td>
<td>2,817 (13.9%)</td>
<td>55 (16.9%)</td>
<td>1.22 (0.96, 1.56)</td>
</tr>
<tr>
<td>NICU admission</td>
<td>2,213 (10.9%)</td>
<td>37 (11.4%)</td>
<td>1.04 (0.77, 1.42)</td>
</tr>
<tr>
<td>Maternal ICU admission</td>
<td>102 (0.5%)</td>
<td>1 (0.3%)</td>
<td>0.61 (0.10, 4.38)</td>
</tr>
</tbody>
</table>

Analysis excluded pregnancies ending <20 weeks gestation, all induced abortions regardless of gestational age, SARS-CoV-2 infection prior to full vaccination.

* Fully vaccinated defined as 2 weeks after 1 dose of Janssen Covid-19 vaccine or 2 weeks after 2nd dose of Pfizer-BioNTech or Moderna Covid-19 vaccines

Preliminary data
Conclusions and next steps

- The v-safe COVID-19 Vaccine Pregnancy Registry adds to the growing body of evidence on the safety of COVID-19 vaccination during pregnancy
  - No evidence of increased risk for participant or infant outcomes
  - No evidence of any disproportionate outcomes by vaccine type or timing
- Early analyses will be replicated with the full registry cohort
- For select* participant and infant outcomes, participant-reported data are being confirmed with medical records to the extent possible
- CDC will continue to monitor the safety of COVID-19 vaccination during pregnancy with an extended follow-up through 15 months post-delivery

*e.g. possible birth defects/infant conditions, stillbirth, infant death, ICU admission, and hypertensive disorders of pregnancy. About 20% of participants have medical records requested.
Acknowledgements

- v-safe COVID-19 Vaccine Pregnancy Registry Participants
- v-safe COVID-19 Vaccine Pregnancy Registry staff and contributors
  - Andrea Sharma
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  - Victoria Okereke
  - Hayden Goodsir

  - Sarah Sheets
  - Jenna Chambless
  - Kendra Norris
  - Jennita Reefhuis
  - Jan Cragan
  - Cynthia Moore
  - Shana Godfred Cato
  - Sascha Ellington
  - Aliza Machefsky
  - David Shay
Thank you

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

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.
Effectiveness of maternal COVID-19 vaccination among pregnant people and infants

Katherine E. Fleming-Dutra, MD
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

cdc.gov/coronavirus
Current COVID-19 vaccine recommendations

- CDC recommends everyone stay up to date with COVID-19 vaccination, including all primary series doses and the most recent booster dose recommended for them by CDC.
  - People ages **5 years and older** are recommended to receive 1 updated (bivalent) mRNA booster dose.*

- Staying **up to date** with COVID-19 vaccinations is recommended for everyone, including people who are pregnant, trying to get pregnant now, or who might become pregnant in the future, and people who are breastfeeding.

- People who are moderately or severely immunocompromised have **different recommendations for COVID-19 vaccines**.

*Only bivalent Pfizer-BioNTech COVID-19 Vaccine is authorized for people age 5 years; both bivalent Moderna and Pfizer-BioNTech COVID-19 Vaccines are authorized for people ages 6 years and older.


## Composition of Monovalent (Original) and Bivalent (Updated) COVID-19 mRNA vaccines

### Monovalent (Original) mRNA COVID-19 vaccines

<table>
<thead>
<tr>
<th>Vaccine Type</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderna COVID-19 vaccine</td>
<td>50µg mRNA for spike protein from ‘ancestral’ (‘original’) SARS-CoV-2</td>
</tr>
<tr>
<td>Pfizer-BioNTech COVID-19 vaccine</td>
<td>30µg mRNA for spike protein from ‘ancestral’ (‘original’) SARS-CoV-2</td>
</tr>
</tbody>
</table>

### Bivalent (Updated) mRNA COVID-19 vaccines

<table>
<thead>
<tr>
<th>Vaccine Type</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderna COVID-19 vaccine</td>
<td>50µg mRNA for spike protein from ‘ancestral’ (‘original’) SARS-CoV-2</td>
</tr>
<tr>
<td>Pfizer-BioNTech COVID-19 vaccine</td>
<td>25µg mRNA for spike protein from ‘ancestral’ (‘original’) SARS-CoV-2</td>
</tr>
<tr>
<td></td>
<td>25µg mRNA for spike protein from Omicron (BA.4/BA.5) SARS-CoV-2</td>
</tr>
<tr>
<td></td>
<td>15µg mRNA for spike protein from Omicron (BA.4/BA.5) SARS-CoV-2</td>
</tr>
</tbody>
</table>
Monovalent mRNA vaccine effectiveness (VE) among pregnant people
VISION Multi-State Network of Electronic Health Records

- Test-negative design
- Assess *monovalent* mRNA VE against COVID-19-associated emergency department and urgent care visits and COVID-19-associated hospitalization
- Included encounters from June 2021 to June 2022
- *Delta* and *Omicron* variant periods were determined by time when each variant predominated in study site

VISION Network includes sites across 10 states; individuals sites denoted by dots on map.

VISION: **Monovalent** mRNA VE for emergency department and urgent care visits by number of doses and time since last dose receipt for pregnant people and non-pregnant women ages 18-45 years

<table>
<thead>
<tr>
<th>Vaccination status (days since last dose)</th>
<th>Delta VE (95% CI)</th>
<th>Omicron VE (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pregnant people—including those vaccinated either before or during pregnancy, by number of doses (days since last dose)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unvaccinated</td>
<td>Referent</td>
<td>Referent</td>
</tr>
<tr>
<td>2 doses (14-149 days)</td>
<td>87 (78 to 92)</td>
<td>39 (13 - 58)</td>
</tr>
<tr>
<td>2 doses (≥150 days)</td>
<td>78 (64 to 87)</td>
<td>11 (-16 - 32)</td>
</tr>
<tr>
<td>3 doses (7-119 days)</td>
<td>82 (53 to 93)</td>
<td>81 (68 - 89)</td>
</tr>
<tr>
<td>3 doses (≥120 days)</td>
<td>*</td>
<td>*</td>
</tr>
</tbody>
</table>

| **Non-pregnant women ages 18-45 years, by number of doses (days since last dose)** |                   |                     |
| Unvaccinated                             | Referent          | Referent            |
| 2 doses (14-149 days)                    | 88 (87 to 89)     | 36 (31 - 41)        |
| 2 doses (≥150 days)                      | 77 (75 to 79)     | 18 (14 - 22)        |
| 3 doses (7-119 days)                     | 90 (88 to 92)     | 69 (66 - 72)        |
| 3 doses (≥120 days)                      | 96 (73 to 99)     | 16 (7 - 25)         |

*Estimates with 95% confidence intervals (CI) widths >50 points are considered imprecise and not shown. Adjusted for age, geographic region, calendar time, local virus circulation, and propensity to be vaccinated based on propensity score models, which included estimated gestational age. COVID-like illness: included acute respiratory illness (e.g., COVID-19, respiratory failure, or pneumonia) or related signs or symptoms of acute respiratory, acute febrile or acute non-respiratory illness (cough, fever, dyspnea, vomiting, or diarrhea). Schrag et al. Estimation of COVID-19 mRNA Vaccine Effectiveness Against Medically Attended COVID-19 in Pregnancy During Periods of Delta and Omicron Variant Predominance in the United States JAMA Netw Open. 2022;5(9):e2233273. doi:10.1001/jamanetworkopen.2022.33273
**VISION: Monovalent mRNA VE for hospitalization by number of doses and time since last dose receipt for pregnant people and non-pregnant women ages 18-45 years**

<table>
<thead>
<tr>
<th>Vaccination status (days since last dose)</th>
<th>Delta VE (95% CI)</th>
<th>Omicron VE (95% CI)</th>
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<tbody>
<tr>
<td>Pregnant people—including those vaccinated either before or during pregnancy, by number of doses (days since last dose)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unvaccinated</td>
<td>Referent</td>
<td>Referent</td>
</tr>
<tr>
<td>2 doses (14-149 days)</td>
<td>99 (96 to 100)</td>
<td>*</td>
</tr>
<tr>
<td>2 doses (≥150 days)</td>
<td>98 (92 to 99)</td>
<td>*</td>
</tr>
</tbody>
</table>
| 3 doses (7-119 days) | 98 (80 to 100) | 94 (66 to 99) | *
| 3 doses (≥120 days) | * | * | |

<table>
<thead>
<tr>
<th>Non-pregnant women ages 18-45 years, by number of doses (days since last dose)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Unvaccinated</td>
<td>Referent</td>
<td>Referent</td>
</tr>
<tr>
<td>2 doses (14-149 days)</td>
<td>95 (93 to 97)</td>
<td>64 (44 to 77)</td>
</tr>
<tr>
<td>2 doses (≥150 days)</td>
<td>90 (87 to 93)</td>
<td>50 (35 to 61)</td>
</tr>
</tbody>
</table>
| 3 doses (7-119 days) | 99 (95 to 100) | 73 (60 to 82) | *
| 3 doses (≥120 days) | * | * | |

*Estimates with 95% confidence intervals (CI) widths >50 points are considered imprecise and not shown. Adjusted for age, geographic region, calendar time, local virus circulation, and propensity to be vaccinated based on propensity score models, which included estimated gestational age. COVID-like illness: included acute respiratory illness (e.g., COVID-19, respiratory failure, or pneumonia) or related signs or symptoms of acute respiratory, acute febrile or acute non-respiratory illness (cough, fever, dyspnea, vomiting, or diarrhea). COVID-like illness for hospitalization did not include signs and symptoms of acute non-respiratory illness. Schrag et al. Estimation of COVID-19 mRNA Vaccine Effectiveness Against Medically Attended COVID-19 in Pregnancy During Periods of Delta and Omicron Variant Predominance in the United States JAMA Netw Open. 2022;5(9):e2233273. doi:10.1001/jamanetworkopen.2022.33273
Summary: Maternal COVID-19 monovalent mRNA vaccine effectiveness (VE) among pregnant people

- VE for emergency department and urgent care visits and hospitalizations is similar among pregnant people and non-pregnant women ages 18-45 years.
  - VE was similar when stratified by doses given during pregnancy and doses given before or during pregnancy.
  - Time since last dose affects VE more than whether doses were given before or during pregnancy.

- VE is lower during Omicron predominance compared to Delta predominance in both pregnant and non-pregnant people, and this is likely due to a combination of factors, including mismatch between monovalent vaccine and predominant circulating variant.

Effectiveness of maternal monovalent mRNA vaccination in prevention of hospitalization among infants ages 0-5 months
Overcoming COVID-19: Effectiveness of maternal monovalent mRNA primary series in prevention of hospitalization among infants ages 0-5 months by variant period and timing of vaccination during pregnancy

- Maternal COVID-19 primary series vaccination protected infants ages 0-5 months from hospitalization for COVID-19
- Protection was lower during Omicron than Delta predominance

Summary

▪ COVID-19 can cause severe disease in pregnant people and infants.
▪ COVID-19 vaccination of pregnant people is safe for pregnant people and infants.
▪ Maternal monovalent mRNA COVID-19 vaccination protects pregnant people and infants ages 0-5 months from COVID-19, including from severe disease and hospitalization.
▪ Monovalent vaccine effectiveness was lower during Omicron predominance, when there was mismatch between the vaccine and predominant circulating variant.
▪ Everyone, including people who are pregnant, trying to become pregnant, may become pregnant, and who are breastfeeding, should stay up to date with COVID-19 vaccines and get the recommended updated (bivalent) booster, when eligible.
CDC’s guidance on staying up to date with COVID-19 vaccines and co-administration of vaccines applies to everyone, including pregnant people.

- COVID-19 vaccines may be administered without regard to timing of other vaccines.
  - This includes simultaneous administration of COVID-19 vaccine and other vaccines, such as influenza vaccine and Tdap (pertussis) vaccine, on the same day.
  - However, there are additional considerations if administering an orthopoxvirus vaccine, which can be found in the Clinical Guidance for COVID-19 Vaccination | CDC.

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- Division of Vital Statistics, National Center for Health Statistics
- Many more…
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.
Inclusion Criteria: Pregnant people with laboratory confirmed SARS-CoV-2 infection (PCR+) at any point during pregnancy


n=26,263
23%
n=37,363
33%
n=50,592
44%

COVID-19 weekly cases per 100,000 population among children ages 0–17 years by age group — United States
March 1, 2020 – September 18, 2022

Total number of COVID-19 cases

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1 year</td>
<td>747,894</td>
</tr>
<tr>
<td>1–4 years</td>
<td>2,299,590</td>
</tr>
<tr>
<td>5–11 years</td>
<td>5,719,747</td>
</tr>
<tr>
<td>12–17 years</td>
<td>6,291,719</td>
</tr>
</tbody>
</table>

Incident cases per 100,000 population

Case earliest date by end of week


Reporting may be incomplete for the most recent two weeks of data, denoted by the grey box.
Weekly percent of ED visits diagnosed with COVID-19 among children ages 0–17 years, National Syndromic Surveillance Program, May 3, 2020–September 24, 2022

Dashed line, on December 19, 2021, represents the first date when >50% of nationally sequenced SARS-CoV-2 specimens were Omicron variant. Data contains emergency department visits from NSSP ED data feeds consistently reporting data from 2020-2022. The data contains visits with an ICD-10 or SNOMED code for COVID-19.
Cumulative COVID-19-associated hospitalizations among infants ages 0-5 months by race and ethnicity, COVID-NET, March 2020 – September 2022


COVID-NET hospitalization data are preliminary and subject to change as more data become available.
Underlying conditions among infants ages 0-5 months with COVID-19-associated hospitalization, COVID-NET, March 20 – August 31, 2022

* Defined as one or more of the following: prematurity, congenital heart disease, neurologic disorder, abnormality of airway, chronic lung disease, immunocompromised condition, chronic metabolic disease, and chronic lung disease of prematurity/bronchopulmonary dysplasia.

Data are from a weighted sample of hospitalized infants and children with completed medical record abstractions. Sample sizes presented are unweighted with weighted percentages. COVID-NET hospitalization data are preliminary and subject to change as more data become available.

Source: COVID-NET data, October 11, 2022
Severity of COVID-19-associated hospitalizations among infants and children 0-4 years, COVID-NET, March 20 - August 31, 2022

BIPAP: bilevel positive pressure, CPAP: continuous positive pressure. Data are from a weighted sample of hospitalized infants and children with completed medical record abstractions. Data presented are weighted percentages.

COVID-NET hospitalization data are preliminary and subject to change as more data become available.

Length of stay among infants and children <5 years with COVID-19-associated hospitalizations, COVID-NET, March 20 - August 31, 2022

- Among infants and children age <5 years, hospital length of stay did not vary by age

<table>
<thead>
<tr>
<th>Age group</th>
<th>No.</th>
<th>Length of hospital stay, days, median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-5 months</td>
<td>472</td>
<td>1.5 (0.8, 2.6)</td>
</tr>
<tr>
<td>6-23 months</td>
<td>456</td>
<td>1.5 (0.6, 2.7)</td>
</tr>
<tr>
<td>2-4 years</td>
<td>315</td>
<td>1.6 (0.7, 2.8)</td>
</tr>
</tbody>
</table>

COVID-NET hospitalization data are preliminary and subject to change as more data become available.
Source: COVID-NET data, Accessed: October 11, 2022
Cumulative deaths involving COVID-19 in children by age based on death certificate data, National Center for Health Statistics, January 1, 2020–October 1, 2022

Among infants ages 0-5 months:
265 Deaths involving COVID-19
0.5% of all deaths in this age group

Source: https://data.cdc.gov/NCHS/Provisional-COVID-19-Death-Counts-by-Age-in-Years-/3apk-4u4f/data. Accessed 10/12/2022. The provisional counts for coronavirus disease (COVID-19) deaths are based on a current flow of mortality data in the National Vital Statistics System. National provisional counts include deaths occurring within the 50 states and the District of Columbia that have been received and coded as of the date specified. It is important to note that it can take several weeks for death records to be submitted to National Center for Health Statistics (NCHS), processed, coded, and tabulated. Therefore, the data shown on this page may be incomplete, and will likely not include all deaths that occurred during a given time period, especially for the more recent time periods. Death counts for earlier weeks are continually revised and may increase or decrease as new and updated death certificate data are received from the states by NCHS. COVID-19 death counts shown here may differ from other published sources, as data currently are lagged by an average of 1–2 weeks. https://www.cdc.gov/nchs/nvss/vsrr/covid19/tech_notes.htm
Additional slide footnotes

- **COVID-NET footnotes**: The Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network (COVID-NET) hospitalization data are preliminary and subject to change as more data become available. In particular, case counts and rates for recent hospital admissions are subject to lag. Lag for COVID-NET case identification and reporting might increase around holidays or during periods of increased hospital utilization. As data are received each week, prior case counts and rates are updated accordingly. COVID-NET conducts population-based surveillance for laboratory-confirmed COVID-19-associated hospitalizations in children (less than 18 years of age) and adults. COVID-NET covers nearly 100 counties in the 10 Emerging Infections Program (EIP) states (CA, CO, CT, GA, MD, MN, NM, NY, OR, TN) and four Influenza Hospitalization Surveillance Project (IHSP) states (IA [March 2020–May 2022], MI, OH, and UT). Incidence rates (per 100,000 population) are calculated using the National Center for Health Statistics' (NCHS) vintage 2020 bridged-race postcensal population estimates for the counties included in the surveillance catchment area. The rates provided are likely to be underestimated as COVID-19 hospitalizations might be missed due to test availability and provider or facility testing practices. The NCHS bridged-race data used for the denominator for race data provides population data for children ages 0–1 year. To calculate rates of hospitalization among children ages <6 months and 6 months to <12 months, the population for children ages 0–1 year is halved.

- **Cumulative influenza- and COVID-19-associated hospitalization rates per 100,000 children, FluSurv-NET and COVID-NET, 2017–2022**, FluSurv-NET = Influenza Hospitalization Surveillance Network; COVID-NET = COVID-19-Associated Hospitalization Surveillance Network. Each season, FluSurv-NET surveillance is conducted from around October 1 of one year to around April 30 of the subsequent year. The grayed-out area on each panel indicates weeks during which FluSurv-NET surveillance was not conducted but COVID-NET surveillance was conducted. FluSurv-NET rate lines were extended beyond week 18 for ease of comparison. For the 2021–22 influenza season, data were only included through the week ending April 9, 2022, the last week for which data were available at the time of submission. The COVID-NET surveillance period of October 2020–September 2021 begins at MMWR week 40 of year 2020 and ends at MMWR week 39 of year 2021. The COVID-NET surveillance period for October 2021–April 2022 includes MMWR week 40 of 2021 through MMWR week 14 of 2022 (the week ending April 9, 2022, the last week for which data were available at the time of submission). MMWR Week 53 for year 2020 is combined with MMWR Week 52 for consistency with other years.