

# COVID-19 Vaccination during Pregnancy: A Structured Electronic Medical Record Data Study

## Objective

To compare pregnancy loss rates, preterm birth rates, and gestational age at delivery in women vaccinated against COVID-19 during pregnancy vs. those unvaccinated against COVID-19.

## Conclusions

- This is one of the largest real-world studies to date in women who received the COVID-19 vaccination during pregnancy.
- Vaccination rates varied significantly across race/ethnicity.
- Vaccinated patients had lower preterm birth and pregnancy loss rates compared with unvaccinated patients.

Presenting author: Mr. Gregory Poorman

Email Mr. Poorman at [Greg.Poorman@Dorsata.com](mailto:Greg.Poorman@Dorsata.com) for more information

## References:

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Barbara Levy<sup>1</sup>, MD FACOG FACS; C. Daniel Mullins<sup>2</sup>, PhD; Seema Haider<sup>1</sup>, MSc; Amanda Elfman<sup>1</sup>; Gregory W. Poorman<sup>1</sup>, MPH; George Saade<sup>3</sup>, MD

1. Dorsata, Inc., Arlington, VA, USA
2. Department of Practice, Sciences, and Health Outcomes Research; University of Maryland School of Pharmacy, Baltimore, MD, USA
3. Maternal-Fetal Medicine, University of Texas Medical Branch, Galveston, TX, USA

## Background

- Clinical trials for both the Moderna and Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccines required a negative pregnancy test as an eligibility criterion and excluded all knowingly pregnant potential participants<sup>1,2</sup> and neither the Janssen nor the AstraZeneca vaccine trials included pregnant women.<sup>3,4</sup>
- Despite this, the Center for Disease Control and Prevention, the Society for Maternal-Fetal Medicine, and the American College of Obstetricians and Gynecologists recommend COVID-19 vaccination for all people 6 months or older, including pregnant and lactating individuals.<sup>5-7</sup>
- Real world clinical data on COVID-19 vaccination during pregnancy is needed.

## Statistical Analysis

- The primary outcome measure was gestational age (GA) at delivery.
- We analyzed the data using chi-square tests, with significance set at p<0.01.

## Results

- A total of 51,994 pregnant women were identified—7,947 (15.3%) in the vaccinated group and 44,047 (84.7%) in the unvaccinated group.

## Vaccination Rates

- Vaccination rates varied significantly across race, ethnicity, marital status, patient region, and maternal age (P<0.001; Table 1).
  - By race, vaccination rate was highest in Asian patients (19.3%) and lowest in Black patients (11.2%; p<0.001).
  - By ethnicity, vaccination rate was highest in non-Hispanic or Latino patients (18.7%) and lowest in Hispanic or Latino patients (8.6%; p<0.001).
  - By patient region, vaccination rate was highest in the Northeast (19.2%) and lowest in the West (9.1%).

## Methods

### Study Design

- Retrospective, observational electronic medical record (EMR) review to evaluate pregnancy loss rates, preterm birth rates, and gestational age at delivery in women vaccinated against COVID-19 during pregnancy vs. those unvaccinated.

### Inclusion Criteria

- Patients who delivered between February 11, 2021 and June 2, 2022.
- The vaccinated group included women who had at least one COVID-19 vaccination documented in their EMR between 30 days prior to pregnancy and delivery.
- The unvaccinated group included women who were eligible for a COVID-19 vaccine without a COVID-19 vaccination documented.

Table 1. Vaccination Rates by Demographics

| Demographic               | N     | Vaccinated, N (%) |                  |
|---------------------------|-------|-------------------|------------------|
| <b>Race</b>               |       |                   | <b>&lt;0.001</b> |
| White                     | 30396 | 5257 (17.3%)      |                  |
| Black or African American | 4217  | 473 (11.2%)       |                  |
| Asian                     | 2971  | 572 (19.3%)       |                  |
| Other/Missing/Declined    | 14410 | 1645 (11.4%)      |                  |
| <b>Ethnicity</b>          |       |                   | <b>&lt;0.001</b> |
| Hispanic or Latino        | 12256 | 1051 (8.6%)       |                  |
| Not Hispanic or Latino    | 29276 | 5463 (18.7%)      |                  |
| Other/Missing/Declined    | 10462 | 1433 (13.7%)      |                  |
| <b>Marital Status</b>     |       |                   | <b>&lt;0.001</b> |
| Married                   | 32098 | 6161 (19.2%)      |                  |
| Single                    | 13303 | 1177 (8.8%)       |                  |
| Other/Missing/Declined    | 6593  | 609 (9.2%)        |                  |
| <b>Patient Region</b>     |       |                   | <b>&lt;0.001</b> |
| Northeast                 | 17339 | 3321 (19.2%)      |                  |
| Midwest                   | NR*   | NR*               |                  |
| South                     | 24127 | 3662 (15.2%)      |                  |
| West                      | 10487 | 958 (9.1%)        |                  |
| <b>Maternal Age</b>       |       |                   | <b>&lt;0.001</b> |
| Under 35 years            | 39126 | 5342 (13.7%)      |                  |
| 35 years or older         | 12868 | 2605 (20.2%)      |                  |

\*Cell size ≤10

## Exclusion Criteria

- Patients with any dose of COVID-19 vaccination documented as administered before December 11, 2020.

## Data Source

- Dorsata’s point-of-care EMR workflows are designed for specific clinical indications in Women’s Health including prenatal care.
- For select research topics, patient data are collected from patients’ EMR as a collaborative effort among obstetrician-gynecologists (Ob-Gyns) using the Dorsata EMR application.
- Dorsata supports >700 Ob-Gyn providers managing more than 70,000 births across 20 states and a diverse patient demographic and payer mix.
- More information is available at [www.dorsata.com](http://www.dorsata.com).
- Institutional Review Board approval was granted by WCG IRB

## Gestational Age at Delivery in Vaccinated vs. Unvaccinated Group

- GA at delivery in Vaccinated and Unvaccinated groups are shown in Table 2 (N=51,994).
  - Vaccinated patients had significantly lower rates of pregnancy loss (GA<20 weeks; vaccinated: 1.1% vs. unvaccinated: 4.1%; P<0.001).
  - Vaccinated patients had significantly lower rate of preterm delivery (GA<37 weeks; vaccinated: 7.8% vs. unvaccinated: 9.6%; P<0.001).

Table 2. Gestational Age at Delivery in Vaccinated vs. Unvaccinated Cohorts

| GA at Delivery (weeks), N (%)          | Vaccinated (N=7947) | Unvaccinated (N=44047) |                  |
|--|---------------------|------------------------|------------------|
| <b>&lt;20, (Pregnancy Loss)</b>        | <b>85 (1.1%)</b>    | <b>1822 (4.1%)</b>     | <b>&lt;0.001</b> |
| <b>20-36 weeks (Overall Preterm)</b>   | <b>622 (7.8%)</b>   | <b>4213 (9.6%)</b>     | <b>&lt;0.001</b> |
| 20-24, (Extreme Preterm*)              | 43 (0.5%)           | 346 (0.8%)             | 0.012            |
| 25-27 weeks (Extreme Preterm)          | 22 (0.3%)           | 183 (0.4%)             | 0.043            |
| 28-31 weeks (Very Preterm)             | 45 (0.6%)           | 393 (0.9%)             | <b>0.002</b>     |
| 32-36 weeks (Moderate to Late Preterm) | 512 (6.4%)          | 3291 (7.5%)            | <b>&lt;0.001</b> |
| <b>37+ weeks (Term)</b>                | <b>7240 (91.1%)</b> | <b>38012 (86.3%)</b>   | <b>&lt;0.001</b> |

\*Likely includes incidences of Pregnancy Loss