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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.
- 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)	
<20, (Pregnancy Loss)	85 (1.1%)	1822 (4.1%)	<0.001
20-36 weeks (Overall Preterm)	622 (7.8%)	4213 (9.6%)	<0.001
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%)	0.002
32-36 weeks (Moderate to Late Preterm)	512 (6.4%)	3291 (7.5%)	<0.001
37+ weeks (Term)	7240 (91.1%)	38012 (86.3%)	<0.001

*Likely includes incidences of Pregnancy Loss

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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^{1,2} and neither the Janssen nor the AstraZeneca vaccine trials included pregnant women.^{3,4}
- 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.⁵⁻⁷
- 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 (%)	
Race			<0.001
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%)	
Ethnicity			<0.001
Hispanic or Latino	12256	1051 (8.6%)	
Not Hispanic or Latino	29276	5463 (18.7%)	
Other/Missing/Declined	10462	1433 (13.7%)	
Marital Status			<0.001
Married	32098	6161 (19.2%)	
Single	13303	1177 (8.8%)	
Other/Missing/Declined	6593	609 (9.2%)	
Patient Region			<0.001
Northeast	17339	3321 (19.2%)	
Midwest	NR*	NR*	
South	24127	3662 (15.2%)	
West	10487	958 (9.1%)	
Maternal Age			<0.001
Under 35 years	39126	5342 (13.7%)	
35 years or older	12868	2605 (20.2%)	

*Cell size ≤10

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.

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References:

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