

## Preliminary data show no safety concerns for pregnant women receiving COVID-19 vaccines

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**Editor's note:** For the latest news on COVID-19, visit <http://bit.ly/AAPNewsCOVID19>.

Health officials have not detected safety concerns among thousands of pregnant women who have received a COVID-19 vaccine or their babies.

While more study is needed on vaccination early in pregnancy, officials say the new preliminary data may help women decide whether to be vaccinated.

“**This study** adds to a growing evidence confirming that pregnant people develop a robust immune response to COVID-19 vaccination without so far seeing any adverse events to the mom or the fetus,” Centers for Disease Control and Prevention (CDC) Director Rochelle P. Walensky, M.D., M.P.H. said in an [interview with editors of the \*New England Journal of Medicine\* \(NEJM\)](#) where the study was published.

Pregnant women who contract SARS-CoV-2 are believed to be at higher risk for severe illness and adverse pregnancy outcomes. However, they were not included in vaccine trials and are instead encouraged to talk to their doctors about potential risks and benefits of vaccination.

Experts from the CDC compiled data from three safety monitoring systems on pregnant women who chose to receive one of the two available mRNA COVID-19 vaccines between Dec. 14, 2020, and Feb. 28, 2021.

Data from 35,692 pregnant women from the v-safe monitoring system found the most common side effects to be the same as non-pregnant women — injection-site pain, fatigue, headache and myalgia, [according to the NEJM study](#). Pregnant women only had slightly higher rates of injection-site pain.

The frequency of severe adverse events also was similar between the groups, with slightly higher rates of nausea and vomiting after the second vaccine dose among pregnant women.

In a second v-safe registry specifically for pregnant women, 827 women had completed a pregnancy. Roughly 14% experienced a pregnancy loss and 86% had a live birth. Due to the timing of the study, nearly all who had a live birth had received a vaccine in their third trimester.

Among the live births, about 9% were preterm, 3% had a baby that was small for his or her gestational age and 2% of the infants had a major congenital anomaly. The anomalies did not follow a specific pattern. No neonatal deaths were reported.

“I think the results are actually quite reassuring as the proportion of the pregnancy outcomes such as pregnancy loss and health effects to the newborn are really quite consistent with what we’d expect in the background rate of the population,” Dr. Walensky told *NEJM* editors.

A third monitoring system, the Vaccine Adverse Event Reporting System, received 221 reports of adverse events from pregnant women. Of those, 30% were specific to pregnancy including 46 spontaneous abortions.

Authors noted they will need more time to study whether women vaccinated shortly before pregnancy or early in pregnancy experience issues such as preterm birth or congenital anomalies.

“Meanwhile, the present data can help inform decision making about vaccination by pregnant persons and their health care providers,” they wrote.

In addition to protecting women from SARS-CoV-2 infection, recent research has indicated that pregnant women vaccinated in the third trimester may pass antibodies to their babies. The CDC recommends women considering vaccination consider their risk of exposure to SARS-CoV-2, the potential risks of illness for themselves and their babies, how well the vaccine works and the evidence so far about vaccine safety.

## Resources

- [CDC information on COVID-19 vaccines for people who are pregnant or breastfeeding](#)
- [CDC guidance for clinicians on each of the three authorized COVID-19 vaccines](#)
- [How to enroll as a COVID-19 vaccinator](#)
- [AAP interim guidance on COVID-19](#)