

# Are pregnant and lactating women and their infants protected with the COVID-19 mRNA vaccines?

**Yes**, according to the results of a prospective cohort study that included 131 women, **COVID-19 mRNA vaccines produce an antibody response in pregnant and lactating women that is comparable to that in nonpregnant women** and superior to the antibody response to natural SARS-CoV-2 infection. Additionally, antibodies are present in both the umbilical cord blood and breast milk of vaccinated patients, supporting the transfer of immunity to the fetus and infant. Finally, there were no significant differences in vaccine adverse effects.

## **FAST TRACK**

*The primary objective was to evaluate the humoral immune response and adverse effects of mRNA vaccines in pregnant and lactating women compared with nonpregnant women and those who had natural COVID-19 infection during pregnancy*

Gray KJ, Bordt EA, Atyeo C, et al. COVID-19 vaccine response in pregnant and lactating women: a cohort study. *Am J Obstet Gynecol.* 2021;S0002-9378(21)00187-3. doi: 10.1016/j.ajog.2021.03.023

### **EXPERT COMMENTARY**

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**P**regnant women are among those at highest risk for severe disease and death from SARS-CoV-2 infection. However, exclusion of pregnant and lactating women from the initial COVID-19 vaccine trials has made counseling these patients challenging due to both the novelty of the vaccines themselves and the general

lack of data in this vulnerable population. Data for the efficacy and risks of vaccination are needed to inform shared decision making between clinician and patient.

### **Details of the study**

Gray and colleagues conducted a prospective cohort study of 84 pregnant, 31 lactating, and 16 nonpregnant women who received 1 of the 2 COVID-19 mRNA vaccines approved by the US Food and Drug Administration for emergency use authorization (BNT162b2 Pfizer/BioNTech or mRNA-1273 Moderna). The study's primary objective was to evaluate the humoral immune response (antibody quantification) and adverse effects of these vaccines in the pregnant and lactating women compared with both nonpregnant women and a cohort of 37 women who had natural COVID-19 infection during pregnancy.

Antibody quantification from blood and breastmilk was performed at 4 time points: V0, the first vaccine dose; V1, the second vaccine

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dose; V2, 2 to 6 weeks after the second vaccine dose; and at delivery. Umbilical cord blood also was collected from the subset of delivered patients (n = 13).

**Results.** The ultimately IgG-dominated antibody response to the vaccine in pregnant and lactating women was comparable to that in nonpregnant women, and all vaccine antibody responses were significantly higher than that in response to natural SARS-CoV-2 infection. IgG antibodies also were found in umbilical cord blood and breast milk, supporting the transfer of immunity to both the fetus and infant. There were no significant differences in adverse effects between pregnant and nonpregnant women.

### Study strengths and limitations

This study's main strength is that it demonstrated a similar increase in humoral immune response to the COVID-19 mRNA vaccines in a previously unstudied population of pregnant and lactating women, supporting the potential efficacy of the vaccines in this group at high risk for complications from SARS-CoV-2. Other data to support this include the increased vaccine antibody response compared with the antibody response after SARS-CoV-2 infection in pregnant women as well as the presence

### WHAT THIS EVIDENCE MEANS FOR PRACTICE

The study by Gray and colleagues provides some of the first data supporting the potential efficacy of the novel mRNA vaccines in pregnant and lactating women, as the antibody-mediated response is similar in this population to that in the nonpregnant population. Moreover, it provides reassurance that the antibodies are getting to the fetus and the infant via the umbilical cord blood and breast milk and that the adverse effect profile is similar. Clinicians can use these data to help their patients make more informed decisions about COVID-19 vaccination. Future studies still are needed for long-term data on immunity and safety for the fetus.

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of maternal-infant transfer of antibodies via cord blood and breast milk. All of these are important data to inform patients and practitioners who are trying to make shared, informed decisions about a novel vaccine during a global pandemic.

The main limitation of this study is a limited patient population of mostly White, non-Hispanic, health care workers with few comorbidities and only 13 delivered vaccinated patients within the study period. Long-term immunity, immune responses other than antibody titers, and potential fetal effects also were not explored in this study. ●

### FAST TRACK

*Future studies still are needed for long-term data on immunity and safety for the fetus*