

## Moderna, Pfizer vaccines shown safe and effective in pregnant & lactating women

March 26, 2021

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*Since pregnant and lactating women were excluded in the initial trials for coronavirus disease 2019 (COVID-19) vaccines, a team of researchers now has released study results that show the Moderna and Pfizer vaccines are indeed safe and effective for this population. It is the first data to substantiate the use of mRNA vaccines in pregnancy.*

Due to the omission of pregnant and lactating women in the initial trials, data were lacking for vaccine efficacy and infant humoral protection in this population, the research authors noted.

“Pregnant women were excluded due to the higher level of safety that is required to test vaccines in pregnant populations,” said Galit Alter, PhD, one of the study’s authors who is a professor of medicine at Harvard Medical School and group leader at the Ragon Institute of Massachusetts General Hospital, the Massachusetts Institute of Technology, and Harvard. “This was not a malicious exclusion, but one that developers have to follow to evaluate safety risks in different populations.”

The study, funded by the National Institutes of Health (NIH), was released on Thursday and is the first of its kind that collected data for a large cohort on maternal antibody generation in response to COVID-19 vaccination, the authors noted. It is scheduled to appear in the *American Journal of Obstetrics and Gynecology*. Researchers compared vaccine-generated immunity to immunity gained from natural infection with the virus. In fact, pregnant women who received either of the vaccines elicited comparable humoral immune responses when compared to non-pregnant controls, they said. Those who received either vaccine also generated higher antibody titers compared to those observed in those with actual COVID-19 infection in pregnancy. The antibodies were present in breastmilk and umbilical cord blood after vaccination.

“Given the enhanced risk of disease in pregnant women, Katie (Kathryn J. Gray, MD, PhD) and Andrea (Andrea G. Edlow, MD, MSc), felt that there is an unignorable urgency to begin to safely, carefully, and closely test vaccines in pregnant/lactating women that were eligible for the vaccine at the end of 2020 and beginning of 2021,” Alter said in an email response to questions. “This was a testament to the incredible partnership they stood up over the pandemic with their pregnant patients that felt safe and cared for. Coupled to the CDC V-safe program, they were able to do this study with the utmost rigor and safety and perform deep immunology that allowed them to build data to help inform the world on the performance of these new vaccines in pregnancy.” The [CDC V-safe program](#) allows vaccine recipients to report any side effects through an app.

For the study, 131 productive-age vaccine recipients (84 pregnant, 31 lactating, and 16 non-pregnant) were enrolled in a prospective cohort study at two academic medical centers, the authors said. Titers of SARS-CoV-2 Spike and RBD IgG, IgA and IgM were quantified in participant sera (N=131) and breastmilk (N=31) at baseline, second vaccine dose, 2-6 weeks post second vaccine, and at delivery by Luminex. Umbilical cord sera (N=10) titers were assessed at delivery. Titers were compared to those of pregnant women 4-12 weeks from natural infection (N=37) by ELISA. A pseudovirus neutralization assay was used to quantify neutralizing antibody titers for the subset of women who delivered during the study period. Post-vaccination symptoms were assessed via questionnaire. Kruskal-Wallis tests and a mixed effects model, with correction for multiple comparisons, were used to assess differences between groups.

The authors, discussing the clinical implications, said that when considering vaccination in pregnancy, evidence regarding maternal and fetal benefit, as well as potential maternal and fetal harm and effects on pregnancy outcomes should be weighed carefully. “While the absolute risk of severe COVID-19 is low in pregnant women, pregnancy is a risk factor for severe disease,” they wrote. “There are well-documented maternal, neonatal, and obstetric risks of SARS-CoV-2 infection during pregnancy. These data provide a compelling argument that COVID-19 mRNA vaccines induce similar humoral immunity in pregnant and lactating women as in the non-pregnant population. These data do not elucidate potential risks to the fetus.”

From Alter’s perspective, she hopes that pregnant and lactating women see that the vaccines are safe.

“There was no increased risk for side effects – nor were the side effects worse or more severe in this population,” she said. “Not only was it safe, but the vaccines also induce strong immune responses in the women, and more importantly these responses can be transferred to their babies that are totally immunologically naïve as they enter the world. So the news is fantastic and we hope women will feel reassured seeing the data. This is no longer just theory. This is actual data to substantiate the use of mRNA vaccines in pregnancy.”

### Reference

Gray KJ, Bordt EA, Atyeo C, Deriso E, et al. COVID-19 vaccine response in pregnant and lactating women: a cohort study, *American Journal of Obstetrics and Gynecology* (2021), doi: <https://doi.org/10.1016/j.ajog.2021.03.023>.