

# Pregnant Women Should Be Offered COVID-19 Vaccine, Experts Agree

*Sourced: Medscape's Coronavirus Resource Center 12/20/20 Ob/Gyn & Women's Health*

COVID-19 vaccines should not be withheld from people who are pregnant or lactating and want to be vaccinated, despite a lack of safety data in these populations, according to guidance from the Centers for Disease Control and Prevention (CDC), the American College of Obstetricians and Gynecologists (ACOG), and the Society for Maternal-Fetal Medicine.

Pregnant women who opt not to receive the vaccine should be supported in that decision as well, a practice advisory from ACOG recommends.

"Pregnant women who experience fever following vaccination should be counseled to take acetaminophen," the advisory notes.

In addition, women do not need to avoid pregnancy after receiving the Pfizer-BioNTech COVID-19 vaccine, according to the CDC's interim clinical considerations for its use. The US Food and Drug Administration issued an emergency use authorization (EUA) for the vaccine on December 11.

Although investigators excluded pregnant women from clinical trials, experts believe that mRNA vaccines, which are not live vaccines, "are unlikely to pose a risk for people who are pregnant" and "are not thought to be a risk to the breastfeeding infant," the CDC notes.

Meanwhile, women who are pregnant may be at greater risk of severe COVID-19, even though the absolute risk of severe illness is low. COVID-19 also may increase the risk of adverse pregnancy outcomes, such as preterm birth, although the data have been mixed with some studies finding an association and others not.

"If pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (eg, healthcare personnel), they may choose to be vaccinated," the CDC advises. "A conversation between the patient and their clinical team may assist with decisions regarding the use of vaccines approved under EUA for the prevention of COVID-19. While a conversation with a healthcare provider may be helpful, it is not required prior to vaccination."

## **Acknowledging Side Effects and Uncertainty**

ACOG's advisory reiterates that approach. The group notes that based on the mRNA vaccine's mechanism of action and its safety and efficacy in clinical trials, "it is expected that the safety and efficacy profile of the vaccine for pregnant individuals would be similar to that observed in nonpregnant individuals...That said, there are no safety data specific to mRNA vaccine use in pregnant or lactating individuals and the potential risks to a pregnant individual and the fetus are unknown."

In clinical trials, most participants experienced mild influenza-like symptoms following vaccination, including injection site reactions, fatigue, chills, muscle and joint pain, and headache. Among participants aged 18-55 years, fever greater than 38°C occurred in 3.7% of

participants after the first dose and in 15.8% after the second dose. Most symptoms resolved within a few days.

Women who are pregnant should treat fever with acetaminophen because "fever has been associated with adverse pregnancy outcomes," according to the ACOG guidance. "Acetaminophen has been proven to be safe for use in pregnancy and does not appear to impact antibody response to COVID-19 vaccines." Patients may treat other vaccine side effects, such as injection-site soreness with acetaminophen as well.

When counseling patients, clinicians should explain that side effects are a normal part of developing antibodies to protect against COVID-19. "Regardless of their decision," the group says, "these conversations provide an opportunity to remind patients about the importance of other prevention measures such as hand washing, physical distancing, and wearing a mask."

### **More Data Expected**

Data from developmental and reproductive toxicity studies in animals are expected soon, the CDC said. In addition, the manufacturer is following clinical trial participants who became pregnant during the study.

Women who are pregnant and their physicians should weigh factors such as the extent of COVID-19 transmission in the community, the patient's risk of contracting COVID-19, risks of COVID-19 to the patient and fetus, vaccine efficacy and side effects, and the lack of data about COVID-19 vaccination during pregnancy.

The Society for Maternal-Fetal Medicine recommends that pregnant and lactating women have access to COVID-19 vaccines in general and has advocated for the inclusion of women who are pregnant or lactating in vaccine trials. The society has suggested that health care professionals "counsel their patients that the theoretical risk of fetal harm from mRNA vaccines is very low." It published resources this week for physicians and patients focused on COVID-19 vaccination and pregnancy.

In a review published online December 10 in the *American Journal of Obstetrics & Gynecology* *MFM*, Amanda M. Craig, MD, of Duke University Health System in Durham, North Carolina, and coauthors note that there "is a theoretical risk for fetal harm from any untested medical intervention and this is no different for COVID-19 vaccines."

"Pregnant individuals should be given the opportunity, along with their obstetric provider, to weigh the potential risk of severe maternal disease against the unknown risk of fetal exposure, and make an autonomous decision about whether or not to accept a vaccine until pregnancy safety data are available," they write.