

Considerations for COVID-19 Vaccination During Pregnancy and Lactation

Are individuals who are pregnant at increased risk of COVID-19 or its complications?

According to CDC, the [American Congress of Obstetrics and Gynecology](#) (ACOG), and the [Society for Maternal Fetal Medicine](#) (SMFM), individuals who contract COVID-19 while pregnant are at increased risk of severe illness such as ICU admission, mechanical ventilation, and death. We know that upwards of half of pregnant individuals also fall into another high-priority category, including frontline workers and/or those with underlying conditions. COVID-19 infection may increase risk of adverse outcomes, such as preterm birth, cesarean section, and neonatal ICU admission depending on the severity of prematurity. More concerning is that long-term effects of COVID-19 infection during pregnancy for the fetus and mother are unknown.

Is the COVID-19 vaccine safe?

All vaccines go through extremely rigorous testing both before and after they are offered to the public. Phase 3 trials, the final stage of testing, include tens of thousands of volunteers, half of which receive a vaccine. However, most of these studies, including the Pfizer-BioNTech and Moderna COVID-19 vaccine studies, do not include pregnant or lactating individuals, so we do not know for sure about the safety of the vaccine during pregnancy or lactation.

In the Pfizer-BioNTech vaccine study, for example, there was no difference in the occurrence of serious adverse events between those who received the vaccine and those who received the placebo. Because the vaccine was authorized for emergency use (EUA), we do not yet know about the long-term safety of the vaccine. FDA, CDC, and the manufacturer are continuing to monitor safety, including in a few study participants who became pregnant shortly after receiving the vaccine.

There are reassuring but extremely limited data from individuals who became pregnant after receiving the vaccine or placebo in the trials. As of November 14, 2020, 23 pregnancies were reported. Twelve patients received the vaccine, and 11 received the placebo. Of this group, there was 1 miscarriage in the placebo group. No other adverse outcomes were reported.

Is there any benefit to the baby if the mother receives the COVID-19 vaccine?

Yes. The vaccine will very likely prevent the mother from getting sick from COVID-19. Infection could put both the mother and the fetus at serious risk, so prevention is a benefit to the baby. Even if the mother does not have a severe form of the virus, we do not yet know the effects of the virus on pregnancies and fetuses as the pregnancy progresses after a COVID-19 infection.

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Furthermore, inactivated vaccines are safe and important to be given in pregnancy to protect pregnant individuals and their fetuses from known risks of infectious diseases (i.e., influenza, pertussis). In known vaccine data for influenza and pertussis, there is passive immunity (transfer of antibodies) from the mother to the fetus, which protects the neonate until vaccinations can be given according to standard vaccination guidelines. Therefore, ACOG recommends both influenza and Tdap vaccination during pregnancy. This same process may also occur with COVID-19 vaccination in the mother. There are no current data evaluating this process that relate to COVID-19 vaccination.

Is there a risk of harm to the baby if the mother receives the COVID-19 vaccine?

The Pfizer-BioNTech and Moderna COVID-19 vaccines are mRNA vaccines, which means they are inactivated and not live. We do not know for sure whether this vaccine will cause harm to a fetus, but it appears unlikely. Because the vaccine is not live, we do not believe it will cause harm to infants who are receiving breastmilk. According to CDC, COVID-19 infection may cause preterm birth. Pregnant women should speak with their health care provider to help them make a decision that is right for them.

What should individuals who are pregnant or lactating consider when deciding to receive COVID-19 vaccine?

Individuals who are pregnant or lactating should consider their risk of COVID-19 infection. They may be at higher risk for COVID-19 infection if the level of transmission in their community is high and should consider whether their occupation or other activities put them at a higher risk for infection. They should consider their personal health risk factors, if present, like obesity, hypertension, or diabetes, that may put them at even further increased risk for severe illness with COVID-19 infections.

What does ACOG and SMFM recommend regarding the COVID-19 vaccine?

These professional societies state that COVID-19 vaccination should not be withheld from pregnant individuals who meet criteria based on CDC ACIP-recommended prioritization groups.

What are the common adverse events from the vaccine?

The most common adverse event following immunization with mRNA COVID-19 vaccines are local injection site pain, fatigue, headache, chills, muscle and joint pain, and fever. Adverse events most often occurred within the first 3 days following vaccination, and usually resolved within 1 day of onset.

Note: If fever occurs following vaccination, individuals who are pregnant *should* take acetaminophen to treat the fever and notify their OB or MFM physician.

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What if patients who are pregnant or lactating experience an adverse effect after vaccination?

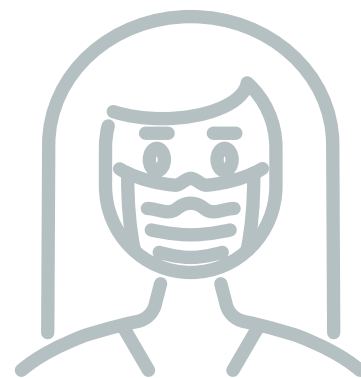
A new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines called V-safe has been launched. V-safe uses text messaging and web surveys from CDC to check in with vaccine recipients following COVID-19 vaccination. V-safe also provides second vaccine dose reminders if needed, and telephone follow-up to anyone who reports medically significant (important) adverse events. All persons who receive a COVID-19 vaccine are encouraged to **download V-safe to their smartphone or other electronic device**. Further, they should report any suspected adverse effect to their health care provider, in addition to reporting it through V-safe.

Should lactating individuals receive the vaccine?

COVID-19 vaccines should be offered to lactating individuals—similar to nonlactating individuals—when they meet criteria for receipt of the vaccines, based on prioritization groups outlined by the CDC ACIP. There are no data on the safety of COVID-19 vaccines in lactating individuals because the manufacturers chose to exclude these patients from the trials. While studies are currently under way to evaluate safety, the risks associated with vaccination with inactivated vaccines in lactation are extremely low. These risks must be weighed against the level of COVID-19 community transmission, occupational risk of contracting COVID-19, and their individual risk factors, as well as the importance of continued lactation for both maternal and infant benefits, even if they choose to receive a COVID-19 vaccine.

What should women remember when deciding to receive the COVID-19 vaccine?

As data emerge, information may change, and counseling and clinical recommendations may shift. We are committed to providing the most up-to-date information related to COVID-19 vaccination during pregnancy and lactation.



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