Society for Maternal•Fetal Medicine
High-risk pregnancy experts

SMFM: Provider Considerations for Engaging in COVID-19 Vaccine Counseling With Pregnant and Lactating Patients
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SMFM strongly recommends that pregnant and lactating people have access to the COVID-19 vaccines and that they engage in a discussion about potential benefits and unknown risks with their healthcare providers regarding receipt of the vaccine. At this time, due to limited vaccine supply, the Centers for Disease Control and Prevention's (CDC) recommended priority group for vaccination are healthcare personnel and long-term care facility residents. As vaccine availability increases, vaccination recommendations will expand to include more groups, with the ultimate goal of access to all populations as the vaccine supply increases.

Pregnant Persons

What should be considered when counseling a pregnant person regarding COVID-19 vaccination?

Vaccination is available during pregnancy. Counseling should balance available data on vaccine safety with the lack of data related to fetal risk, risk of the pregnant person for SAR-CoV-2 infection acquisition, and their individual risk for severe disease. The level of COVID-19 community transmission and personal risk of contracting COVID-19 should be considered in counseling for vaccination.

Maternal and obstetrical risk of disease

Recent data indicate that pregnancy is an independent risk factor for COVID-19 disease severity, with an increased risk of ICU admission, mechanical ventilation, extracorporeal membrane oxygenation (ECMO), and death among pregnant patients with symptomatic COVID-19 infection compared with symptomatic nonpregnant patients. Although the absolute risk of severe morbidity and mortality remains low, reports have demonstrated a 3-fold increased risk for ICU admission, a 2.4 -fold increased risk for needing ECMO, and a 1.7-fold increased risk of death from COVID-19. Women with comorbidities (body mass index higher than 35 kg/m^2, diabetes, and heart disorders) and older-aged women appear to have a particularly elevated risk of adverse maternal outcomes. Other conditions that the CDC has identified as increasing the risk for severe illness from SAR-CoV-2 infection include cancer, chronic kidney disease, chronic obstructive pulmonary disease, heart conditions, immunocompromised state from organ transplant, sickle cell disease, and smoking. People of color, specifically Latina and Black patients, also continue to be disproportionately affected by severe maternal morbidity and

mortality and appear to have a disproportionately higher prevalence of COVID-19 infection and death. These disparities, which are caused by social determinants of health that act as barriers to health and well-being, have become more apparent and exaggerated during this crisis.

Recent data also indicate that there may be an increased rate of preterm birth and stillbirth among pregnant symptomatic and asymptomatic patients with SARS-CoV-2 infection.

Vaccine mechanism and administration

Pregnant and lactating people have been excluded in the recent vaccine trials; therefore, there are no data on the safety of the COVID-19 vaccines in pregnant people. Further studies are ongoing, and safety data will become available in the coming months.

The mRNA vaccines contain mRNA, a genetic material that encodes the SARS-COV-2 spike S protein, the predominant immunomodulatory target associated with adverse effects. They are not live vaccines, and preclinical data suggest rapid degradation (approximately 10-20 days) by normal cellular processes. There is no risk for insertional mutagenesis, as the mRNA does not enter the cell's nucleus. In other words, there is no risk of genetic modification to people receiving the vaccine.

The currently available vaccines are a 2-dose series administered intramuscularly 3 (for the Pfizer-BioNTech COVID-19 vaccine) to 4 (for the Moderna vaccine) weeks apart. For the Pfizer-BioNTech COVID-19 vaccine, administration of the second vaccine dose within a 4-day grace period (eg, on day 17 to 21) is considered valid; if more than 21 days have elapsed since the first dose, the second dose should be administered at the earliest opportunity (but no doses need to be repeated). The vaccines are not interchangeable, and persons should complete both doses to obtain full vaccine benefit. Both doses are necessary for protection. The efficacy of a single dose has not been systematically evaluated.

Vaccination should be offered regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. Viral or serologic testing for acute or prior infection, respectively, is not recommended for the purpose of vaccine decision-making.

A pregnancy test prior to vaccination is not recommended, nor are there data to guide timing of conception following vaccination. If a person decides to receive the vaccine, there are no trimester-specific vaccine considerations at this time.

Vaccination should not be given if the recipient is acutely ill.

Efficacy of vaccine

The currently available vaccines are given in two doses to achieve a high level of efficacy. Data indicate that the efficacy after the second dose of the Pfizer-BioNTech COVID-19 vaccine is 95.0% (95% CI, 90.3%–97.6%) and the Moderna COVID-19 vaccine is 94.1% (95% CI, 89.3%–96.8%). Patients should be counseled on the importance of completing the 2-dose series in order to optimize protection. It takes 1-2 weeks following the second dose to be considered fully vaccinated. Current information is limited about how well the vaccine works in the general population; how much it may reduce disease, severity, or transmission; and how long protection lasts. For this reason, the CDC recommends that vaccinated persons continue to follow all current guidance to protect themselves and others, including wearing a mask, handwashing, and social distancing as well as following quarantine guidance after exposure to someone with COVID-19.

Fetal risk

Counseling should also include the theoretical risk of harm to the fetus. The risk from mRNA vaccines is thought to be low due to the expected degradation of mRNA in the circulation. The Advisory Committee on Immunization Practices (ACIP) reports that preclinical studies have been reassuring. Individual decision-making needs to balance these theoretical risks with the risks associated with delayed vaccination and the possibility of maternal SARS-CoV-2 infection.

What are the expected side effects, and are they harmful?

Postvaccination signs and symptoms are typically mild to moderate in severity and occur within the first 3 days of vaccination (the day of vaccination and the following two days, with most occurring the day after vaccination) and resolve within 1 to 2 days. More frequent and severe signs and symptoms follow the second dose.

During the Pfizer-BioNTech COVID-19 vaccine trials, fever occurred in a small group after the first dose (3.7%) and second dose (15.8%). Therefore, pregnant patients who experience fever following vaccination should be counseled to take acetaminophen.

Who should not receive the vaccine?

The current package insert for the Pfizer-BioNTech COVID-19 vaccine states that severe allergic reaction (eg, anaphylaxis) to any component of the vaccine is a contraindication to vaccination. Therefore, a patient with a history of a severe allergic reaction to any vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous) should not receive the Pfizer-BioNTech COVID-19 vaccine at this time. Vaccine providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions.

The vaccine may be administered to persons with underlying medical conditions who have no contraindications to vaccination. Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19. These individuals may still receive COVID-19 vaccine unless otherwise contraindicated.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Moderna COVID-19 Vaccine.

Lactating Persons

What should be considered when counseling lactating persons regarding COVID-19 vaccination?

Vaccination is recommended for lactating persons. Counseling should balance the lack of data on vaccine safety and a person's individual risk for infection and severe disease. The theoretical risks regarding the safety of vaccinating lactating people do not outweigh the potential benefits of the vaccine.

CDC Resources

Healthcare workers:

https://www.cdc.gov/coronavirus/2019-ncov/hcp/vaccination.html

Safety monitoring:

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

CDC vaccine guidance:

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html#groups-considered

CDC V-safe:

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html