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. The Centers for Disease Control and Prevention's (CDC) recommended priority groups for vaccine distribution include pregnant people. As vaccine availability increases, vaccination recommendations will expand to include more groups, with the ultimate goal of access to all populations.

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, the pregnant person's risk for SAR-CoV-2 acquisition, and their individual risk for moderate or severe disease. The level of COVID-19 community transmission should also 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 that pregnancy is independently associated with 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. People with comorbidities (body mass index higher than 35 kg/m^2, diabetes, and heart disorders) and older-aged people also appear to have a particularly elevated risk of adverse maternal outcomes. In addition to pregnancy, other conditions that the CDC has identified as increasing the risk for severe illness from SARS-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 Hispanic or Latinx 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 patients with symptomatic SARS-CoV-2 infection.

Vaccine mechanism and administration

There are currently three COVID-19 vaccines authorized for use in the United States. Two are mRNA vaccines (Pfizer-BioNTech BNT162b2 and Moderna mRNA 1273 vaccines), and one is an adenoviral-vector vaccine (Janssen [a pharmaceutical company of Johnson & Johnson] Biotech Ad26.COV2.S). None of the currently authorized vaccines contain live virus.

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 to 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 Janssen Biotech one-dose vaccine uses an adenovirus to carry the gene for the coronavirus spike S protein, which is produced by the host cell and expressed on the cell membrane, where it is dectected by the host immune system to mimic components of the pathogen without causing disease. The same adenovirus vector platform has been used for other clinical vaccines in pregnant people, including Ebola, HIV, and RSV adenoviral vaccine studies, with no adverse pregnancy outcomes.

SMFM recommends following the CDC guidelines for vaccine administration. 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. Available data also do not indicate the need to delay attempting pregnancy 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

Two of the currently available vaccines are given in two doses to achieve a high level of efficacy. Data indicate that the efficacy is 95.0% (95% CI, 90.3%–97.6%) after the second dose of the Pfizer-BioNTech COVID-19 vaccine and 94.1% (95% CI, 89.3%–96.8%) after the second dose of the Moderna COVID-19 vaccine. Patients should be counseled about 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.

Data indicate that the one-dose vaccine (Janssen Biotech) is 72% (95% CI) effective at preventing moderate to severe disease, 85% effective in preventing severe disease, and 100% effective in preventing COVID-19–related hospitalization and death 28 days after vaccination.

Current information is limited about how well the vaccines work in the general population; how much they may reduce disease, severity, and 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 from infection, including wearing a mask, handwashing, and social distancing, and adhere to quarantine guidance after exposure to COVID-19.

Table 1. Approved Vaccines

	Age	Dose schedule	Efficacy	Technology
Pfizer-BioNTech	≥16 years	2 doses/ 21 days	95% after 2nd dose	mRNA
Moderna	≥18 years	2 doses/ 28 days	94.1% after 2nd dose	mRNA
Janssen Biotech	≥18 years	1 dose	72% moderate; 85% severe; 100% COVID-related hospitalization and death	Adenovector

Fetal considerations

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 risk from adenovector vaccines is also low; viral DNA carrying the gene encoding the coronavirus spike protein enters the host nucleus to be transcribed but is not integrated into the host's DNA. 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.

In a recent cohort study, maternal antibodies to SARS-CoV-2 were found to have crossed the placenta after infection during pregnancy, and cord blood antibody concentrations correlated with maternal antibody concentrations. These findings demonstrate the potential for maternal antibodies to transfer to the fetus and provide neonatal protection. They also suggest the need for further data to determine if SARS-CoV-2 antibodies are protective against newborn infection, the concentration needed to achieve protection, and whether vaccine-elicited antibodies are similar to naturally acquired antibodies.

What safety data are available about the vaccines and pregnancy?

Despite SMFM's advocacy efforts, pregnant and lactating people have been excluded in the recent vaccine trials; therefore, there are no clinical trial data on the safety of the COVID-19 vaccines in pregnant people. However, multiple trials are underway, and safety data will become available in the coming months. The CDC is also currently enrolling pregnant individuals in a pregnancy registry.

To date, over 30,000 pregnant people have self-reported within the CDC v-safe program, and the types and frequency of self-reported acute side effects do not appear to differ from those in the general population. Moreover, more than 1800 of these individuals have been followed longitudinally in a registry devoted specifically to pregnancy outcomes, such as miscarriage and stillbirth, pregnancy complications, maternal ICU admission, adverse birth complications, neonatal death, infant hospitalizations, and birth defects. These data do not indicate any concerning pregnancy outcomes, pregnancy complications, or neonatal outcomes compared with background data.Reports to the Vaccine Adverse Event Reporting System (VAERS) from pregnant people (73%) include both pregnancy/neonatal-specific and nonpregnancy-specific adverse events (local and systemic reactions). Miscarriage was the most frequently reported pregnancy-specific adverse event reported to VAERS; however, the numbers are within expected background rates. Data from both v-safe and VAERS have not shown any patterns to indicate safety problems with the Pfizer and Moderna COVID vaccines in pregnant people, and no unexpected pregnancy or infant outcomes have been reported. Safety monitoring in pregnant people is ongoing, and the Janssen Biotech vaccine will be included in future vaccine safety surveillance activities. For more information, see the slides from the March 1, 2021 ACIP meeting.

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. Pregnant

patients who experience fever following vaccination should be counseled to take acetaminophen.

Allergic reactions, including anaphylaxis, have been reported to be rare (4.7 per million for Pfizer-BioNTech and 2.5 per million for Moderna) following COVID-19 vaccination in nonpregnant individuals. Management of anaphylaxis in pregnant individuals is the same as in nonpregnant individuals. For more information on the management of anaphylaxis after COVID-19 vaccination, see the CDC website.

The vaccines 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 the vaccines unless otherwise contraindicated. For more information on vaccination in persons with underlying medical conditions, see the CDC website.

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