

Vaccinating Pregnant and Lactating Patients Against COVID-19

Practice Advisory 

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Summary of Key Information and Recommendations

COVID-19 vaccine development and regulatory approval are rapidly progressing. Thus, information and recommendations will evolve as more data are collected about these vaccines and their use in specific populations. This Practice Advisory is intended to be an overview of currently available COVID-19 vaccines and guidance for their use in pregnant and lactating patients.

- The U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the following vaccines:
 - Pfizer-BioNtech mRNA vaccine (BNT162b2): for use in individuals age 16 years and older as a 2-dose regimen given 3 weeks (21 days) apart.
 - Moderna mRNA-1273 vaccine: for use in individuals age 18 and older as a 2-dose regimen given 1 month (28 days) apart.
- After an explicit, evidence-based review of all available data, the Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for use of the Pfizer-

BioNTech COVID-19 vaccine in persons aged ≥ 16 years for the prevention of COVID-19 ([CDC 2020](#)) and the use of the Moderna-1273 COVID-19 vaccine in persons aged ≥ 18 years ([CDC 2020](#)).

- ACOG recommends that COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on ACIP-recommended priority groups.
- COVID-19 vaccines should be offered to lactating individuals similar to non-lactating individuals when they meet criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP.
- Individuals considering a COVID-19 vaccine should have access to available information about the safety and efficacy of the vaccine, including information about data that are not available. 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 by pregnant patients. Important considerations include:
 - the level of activity of the virus in the community
 - the potential efficacy of the vaccine
 - the risk and potential severity of maternal disease, including the effects of disease on the fetus and newborn
 - the safety of the vaccine for the pregnant patient and the fetus.
- While a conversation with a clinician may be helpful, it should not be required prior to vaccination, as this may cause unnecessary barriers to access.
- Vaccines currently available under EUA have not been tested in pregnant women. Therefore, there are no safety data specific to use in pregnancy. See details about the Food and Drug Administration's (FDA) EUA process below.
- Pregnancy testing should not be a requirement prior to receiving any EUA-approved COVID-19 vaccine.
- Pregnant patients who decline vaccination should be supported in their decision. Regardless of their decision to receive or not receive the vaccine, 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.
- Expected side effects should be explained as part of counseling patients, including that they are a normal part of the body's reaction to the vaccine and developing antibodies to protect against COVID-19 illness.
- The mRNA vaccines are not live virus vaccines, nor do they use an adjuvant to enhance vaccine efficacy. These vaccines do not enter the nucleus and do not alter human DNA in vaccine recipients. As a result, mRNA vaccines cannot cause any genetic changes.

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COVID-19 Infection Risk in Pregnancy

Available data suggest that symptomatic pregnant patients with COVID-19 are at increased risk of more severe illness compared with nonpregnant peers ([Ellington MMWR 2020](#), [Collin 2020](#), [Delahoy MMWR 2020](#), [Panagiotakopoulos MMWR 2020](#), [Zambrano MMWR 2020](#)). Although the absolute risk for severe COVID-19 is low, these data indicate an increased risk of ICU admission, need for mechanical ventilation and ventilatory support (ECMO), and death reported in pregnant women with symptomatic COVID-19 infection, when compared with symptomatic non-pregnant women ([Zambrano MMWR 2020](#)). Pregnant patients with comorbidities such as obesity and diabetes may be at an even higher risk of severe illness consistent with the general population with similar comorbidities ([Ellington MMWR 2020](#), [Panagiotakopoulos MMWR 2020](#), [Knight 2020](#), [Zambrano MMWR 2020](#)). Given the growing evidence, CDC has included pregnancy as a factor that leads to increased risk for severe COVID-19 illness ([CDC](#)). Similar to the general population, Black and Hispanic individuals who are pregnant have disproportionately higher rates of COVID-19 infection and death ([Ellington MMWR 2020](#), [Moore MMWR 2020](#), [Zambrano MMWR 2020](#)). Further, risk ([Zambrano MMWR 2020](#)) of ICU admission was higher for pregnant Asian and Native Hawaiian/Pacific Islander individuals. These disparities are due to a range of social and structural factors including disparities in socioeconomic status, access to care, rates of chronic conditions, occupational exposure, systemic racism, and historic and continued inequities in the health care system.

COVID-19 Vaccines in Development

It is important to note that COVID-19 vaccine development and regulatory approval is a rapidly changing process, and information and recommendations will evolve as more data are collected about these vaccines and their use in specific populations.

Advisory Committee on Immunization Practices Recommendations

The Advisory Committee on Immunization Practices (ACIP) develops recommendations on how to use vaccines to control disease in the United States. The Committee's recommendations are sent to CDC's Director for approval. Once the ACIP recommendations have been reviewed and approved by the CDC Director and the U.S. Department of Health and Human Services, they are published in CDC's Morbidity and Mortality Weekly Report (MMWR). The MMWR publication represents the final and official CDC recommendations for immunization of the U.S. population ([ACIP](#)).

ACOG has representation on the ACIP, including on the ACIP COVID-19 working groups. ACIP has made the following recommendations for prioritization of COVID-19 vaccine allocation:

Phase 1a: Health care workers and long-term care facility residents ([CDC 2020](#))

Phase 1b: Persons aged ≥ 75 years and frontline essential workers ([ACIP Slides 2020](#))

Phase 1c: Persons aged 65-75 years, persons aged 16-64 years with [high-risk*](#) medical conditions (including pregnancy), and other essential workers ([ACIP Slides 2020](#))

*[High-risk](#) medical conditions outlined by the CDC include:

- Pregnancy
- Cancer
- Chronic kidney disease
- COPD (chronic obstructive pulmonary disease)
- Heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
- Immunocompromised state (weakened immune system) from solid organ transplant
- Obesity (body mass index [BMI] of 30 kg/m² or higher but < 40 kg/m²)
- Severe Obesity (BMI ≥ 40 kg/m²)
- Sickle cell disease
- Smoking (current or history)
- Type 2 diabetes mellitus

As the availability of vaccine becomes more robust, ACIP will expand these recommendations to include additional priority populations. Within national guidelines, state and local jurisdictions should have flexibility to administer vaccine based on local epidemiology and demand ([ACIP Slides 2020](#)).

After an explicit, evidence-based review of all available data, the Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥ 16 years for the prevention of COVID-19 ([CDC 2020](#)) and the use of the Moderna-1273 COVID-19 vaccine in persons aged ≥ 18 years ([CDC 2020](#)). Information for pregnant and lactating individuals has been posted on CDC's website under [Clinical Considerations](#). Within these clinical considerations, CDC outlines that a pregnant individual who is part of a group (e.g., healthcare personnel) recommended to receive a COVID-19 vaccine may choose to be vaccinated. A discussion with their healthcare professional can help the patient make an informed decision. Further, CDC states that lactating individuals who are part of a group (e.g., healthcare personnel) recommended to receive a COVID-19 vaccine may choose to be vaccinated.

U.S. FDA Emergency Use Authorization and Approval

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the following vaccines:

- **Pfizer-BioNtech mRNA vaccine (BNT162b2)**: for use in individuals age 16 years and older as a 2-dose regimen given 3 weeks (21 days) apart
- **Moderna mRNA-1273 vaccine**: for use in individuals age 18 and older as a 2-dose regimen given 1 month (28 days) apart.

These vaccines have been shown to be about 95% effective at preventing COVID-19 illness after the second dose.

According to the EUA Fact Sheet for Health Care Professionals for both Pfizer-BioNtech and Moderna vaccines available data on COVID-19 vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. The EUA Fact Sheet for Recipients and Caregivers both Pfizer-BioNtech and Moderna vaccines states “If you are pregnant or breastfeeding, discuss your options with your healthcare provider”.

The EUA authority allows the FDA to strengthen the nation’s public health protections against chemical, biological, radiological, and nuclear (CBRN) threats by facilitating the availability and use of medical countermeasures needed during public health emergencies.

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives (FDA 2017).

Data on the safety and effectiveness of the vaccine(s) continues to be collected during the EUA period. (FDA 2017).

Vaccine Information and Recommendations

At the time of this publication, two vaccines developed for the prevention of COVID-19 have received EUA from the FDA. However, COVID-19 vaccines are rapidly emerging and additional EUAs are likely to materialize. ACOG will strive to update this guidance as quickly as possible while maintaining accurate, evidence-based information.

mRNA COVID-19 Vaccines

The development and use of mRNA vaccines is relatively new. These vaccines consist of messenger RNA (mRNA) encapsulated by a lipid nanoparticle (LNP) for delivery into the host cells. These vaccines utilize the body's own cells to generate the coronavirus spike protein (the relevant antigens), which, similar to all other vaccines, stimulates immune cells to create antibodies against COVID-19. The mRNA vaccines are not live virus vaccines, nor do they use an adjuvant to enhance vaccine efficacy. These vaccines do not enter the nucleus and do not alter human DNA in vaccine recipients. As a result, mRNA vaccines cannot cause any genetic changes ([CDC](#), [Zhang 2019](#), [Schlake 2012](#)). Based on the mechanism of action of these vaccines and the demonstrated safety and efficacy in Phase II and Phase III clinical trials, it is expected that the safety and efficacy profile of the vaccine for pregnant individuals would be similar to that observed in non-pregnant 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.

Side Effects

Expected side effects should be explained as part of counseling patients, including that they are a normal part of the body's reaction to the vaccine and developing antibodies to protect against COVID-19 illness. Most study participants for both the Pfizer-BioNTech and Moderna vaccines experienced mild side effects similar to influenza-like illness symptoms following vaccination (see table below). In the Pfizer-BioNTech study subgroup of persons age 18-55 years fever greater than 38°C occurred in 3.7% after the first dose and 15.8% after the second dose ([FDA 2020](#)). In the Moderna vaccine trials, fever greater than 38°C was reported in 0.8% of vaccine recipients after the first dose, and 15.6% of vaccine recipients after the second dose ([FDA 2020](#)). Most of these symptoms resolved by day 3 after vaccination for both vaccines. Patients should be counseled about more severe side effects and when to seek medical care. For more information and details on side effects, see [Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events: Pfizer-BioNTech COVID-19 Vaccine](#) from the CDC.

Table 1. Mild Side Effects Among All Study Participants*

Moderna

91.6%

68.5%

43.4%

59.6%

44.8%

63%

Pfizer-BioNTech

84.10%
62.90%
31.90%
38.30%
23.60%
55.10%

**Fever was the least common side effect reported; see text above for data on frequency of fever*

Available Safety Information Related to the use of COVID-19 Vaccines in Pregnancy

Despite ACOG's persistent advocacy for the inclusion of pregnant individuals in COVID-19 vaccine trials, none of the COVID-19 vaccines approved under EUA have been tested in pregnant individuals. However, studies in pregnant women are planned.

Data from Developmental and Reproductive Toxicity (DART) studies for the Pfizer-BioNtech COVID-19 vaccine are anticipated in mid-December, according to the manufacturer. From what has been communicated so far regarding these forthcoming data, there have not been any major safety signals identified.

A combined developmental and perinatal/postnatal reproductive toxicity (DART) study of Moderna's mRNA-1273 in rats was submitted to FDA on December 4, 2020. FDA review of this study concluded that mRNA1273 given prior to mating and during gestation periods at dose of 100 µg did not have any adverse effects on female reproduction, fetal/embryonal development, or postnatal developmental except for skeletal variations which are common and typically resolve postnatally without intervention (FDA).

These DART studies provide the first safety data to help inform the use of the vaccine in pregnancy until there are more data in this population.

Among participants of Phase II/III COVID-19 vaccine clinical studies in non-pregnant adults, a few inadvertent pregnancies that have occurred are being followed to collect safety outcomes.

ACOG Recommendations

Pregnant Individuals

ACOG recommends that COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on ACIP-recommended priority groups. While safety data on the use of COVID-19 vaccines in pregnancy are not currently available, there are also no data to indicate that the vaccines should be contraindicated, and no safety signals were generated from DART studies for the Pfizer-BioNtech and Moderna COVID-19 vaccines. Therefore, in the interest of allowing pregnant individuals who would otherwise be considered a priority population for vaccines approved

for use under EUA to make their own decisions regarding their health, ACOG recommends that pregnant individuals should be free to make their own decision in conjunction with their clinical care team.

Individuals considering a COVID-19 vaccine should have access to available information about the safety and efficacy of the vaccine, including information about data that are not available. 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 by pregnant patients. Important considerations include the level of activity of the pandemic in the community, the potential efficacy of the vaccine, the potential risk and severity of maternal disease, including the effects of disease on the fetus and newborn, and the safety of the vaccine for the pregnant patient and the fetus. While a conversation with a clinician may be helpful, it should not be required prior to vaccination as this may cause unnecessary barriers to access.

Clinicians should review the available data on risks and benefits of vaccination with pregnant patients, including the risks of not getting vaccinated in the context of the individual patient's current health status, and risk of exposure, including the possibility for exposure at work or home and the possibility for exposing high-risk household members. Conversations about risk should take into account the individual patient's values and perceived risk of various outcomes and should respect and support autonomous decision-making (ACOG 2013).

Vaccination Considerations

- Pregnant women who experience fever following vaccination should be counseled to take acetaminophen. Acetaminophen has been proven to be safe for use in pregnancy and does not appear to impact antibody response to COVID-19 vaccines.
- There is currently no preference for the use of one COVID-19 vaccine over another except for 16-17 year olds who are only eligible for the Pfizer-BioNtech vaccine.
- Individuals should complete their 2-dose series with the same vaccine product.
- COVID-19 vaccines should not be administered within 14 days of receipt of another vaccine. For pregnant individuals, vaccines including Tdap and influenza should be deferred for 14 days after the administration of COVID-19 vaccines.
- Anti-D immunoglobulin (i.e. Rhogam) should not be withheld from an individual who is planning or has recently received a COVID-19 vaccine as it will not interfere with the immune response to the vaccine.

Pregnant patients who decline vaccination should be supported in their decision. Regardless of their decision to receive or not receive the vaccine, 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.

Pregnant individuals who receive a COVID-19 vaccine should be educated about and encouraged to participate in CDC's V-SAFE program (see below for more information on CDC's V-SAFE program).

Lactating Individuals

ACOG recommends COVID-19 vaccines be offered to lactating individuals similar to non-lactating individuals when they meet criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP. While lactating individuals were not included in most clinical trials, COVID-19 vaccines should not be withheld from lactating individuals who otherwise meet criteria for vaccination.

Theoretical concerns regarding the safety of vaccinating lactating individuals do not outweigh the potential benefits of receiving the vaccine. There is no need to avoid initiation or discontinue breastfeeding in patients who receive a COVID-19 vaccine ([ABM 2020](#)).

Individuals Contemplating Pregnancy

Vaccination is strongly encouraged for non-pregnant individuals within the ACIP prioritization group(s). Further, ACOG recommends vaccination of individuals who are actively trying to become pregnant or are contemplating pregnancy and meet the criteria for vaccination based on ACIP prioritization recommendations. Additionally, it is not necessary to delay pregnancy after completing both doses of the COVID-19 vaccine.

Given the mechanism of action and the safety profile of the vaccine in non-pregnant individuals, COVID-19 mRNA vaccines are not thought to cause an increased risk of infertility.

If an individual becomes pregnant after the first dose of the COVID-19 vaccine series, the second dose should be administered as indicated. If an individual receives a COVID-19 vaccine and becomes pregnant within 30 days of receipt of the vaccine, participation in CDC's V-SAFE program should be encouraged (see below for more information on CDC's V-SAFE program).

Importantly, routine pregnancy testing is not recommended prior to receiving any EUA-approved COVID-19 vaccine.

Health Equity Considerations and Communities of Color

Communities of color have been disproportionately affected by the COVID-19 pandemic. Individuals in communities of color are more likely to have severe illness and even die from COVID-19 likely due to a range of social and structural factors including disparities in socioeconomic status, access to care, rates of chronic conditions, and occupational exposure, systemic racism, and historic and continued inequities in the health care system. Access to and confidence in COVID-19 vaccines is of critical importance for all communities, but willingness to consider vaccination varies by patient context, in part due to historic and continued injustices and systemic racism that has eroded trust in some communities of color. According to a recent Kaiser Family Foundation survey, only 50% of Black Americans compared with 65% of White Americans, would definitely or probably get vaccinated against COVID-19 even if the vaccine was free and determined safe by scientists, many citing distrust as a concern ([Hamel 2020](#)). When discussing COVID-19 vaccines with an individual who expresses concerns, it is critical to:

- Be aware of historical and current injustices perpetuated on communities of color
- Actively listen to and validate expressed fears and concerns
- Continue to support patients who decide not to be vaccinated, share resources, and encourage the continued use of prevention measures

If the patient is amenable to further discussion:

- Inform about the testing process, existing safety data and continued monitoring of safety and efficacy data on COVID-19 vaccines; there have not been shortcuts with the testing of this vaccine
- Discuss the increased incidence of infection and severe illness from COVID-19 in communities of color
- Note that individuals from communities of color were included in clinical trials (9.8% of Pfizer-BioNtech overall Phase II/III participants were Black and 26.2% were Hispanic/Latinx; 9.7% of Moderna overall Phase II/III participants were Black and 20% were Hispanic/Latinx) and the vaccine was equally effective among different demographics, including race and ethnicity.

Additional Health Equity Resources

- Centers for Disease Control and Prevention. Health Equity Considerations and Racial and Ethnic Minority Groups. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html>. Retrieved December 13, 2020

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Vaccine Confidence

Vaccine hesitancy, particularly around COVID-19 vaccines, exists among all populations. When communicating with patients it is extremely important to underscore the general safety of vaccines and emphasize the fact that no steps were skipped in the development and evaluation of COVID-19 vaccines. This can be done by briefly highlighting the safety requirements of vaccines, and ongoing safety monitoring even after vaccines are made available. The following are some messages to consider using when discussing COVID-19 vaccines with patients:

Vaccines are one of the greatest public health achievements of the 20th century. Before the widespread use of vaccines, people routinely died from infectious diseases, several of which have since been eradicated thanks to robust immunization programs.

- Several vaccines have safely been given to pregnant and lactating individuals for decades.
- The rigor of COVID-19 vaccine clinical trials with regards to monitoring safety and efficacy meet the same high standards and requirements as with a typical vaccine approval process.
- While there has been a worldwide attempt to develop COVID-19 vaccines rapidly, this does not mean that any safety standards have been relaxed. In fact, there are additional safety

monitoring systems to track and monitor these vaccines, including real-time assessment.

- Side effects such as influenza-like-illness can be expected with these vaccines, however this is a normal reaction as the body develops antibodies to protect itself against COVID-19. COVID-19 vaccines cannot cause COVID-19 infection. It is important not to be dissuaded by these side effects, because in order to get the maximum protection against COVID-19, patients need two doses of the vaccine.
- Safety monitoring continues well beyond the EUA administration.
 - CDC's V-SAFE: A new active surveillance smartphone-based after-vaccination health checker for people who receive COVID-19 vaccines. V-SAFE will use text messaging and web surveys from CDC to check in with vaccine recipients for health problems following COVID-19 vaccination. Information on pregnancy status at the time of vaccination and at subsequent follow up time points will also be collected. The system will provide telephone follow up to anyone who reports medically significant (important) adverse events or exposure to COVID-19 vaccines during pregnancy or periconception period.
 - Vaccine Adverse Event Reporting System (VAERS): A national early warning system to detect possible safety problems in U.S.-licensed vaccines. VAERS is co-managed by the CDC and the FDA. Healthcare professionals are encouraged to report any clinically significant adverse events following vaccination to VAERS, even if they are not sure if vaccination caused the event. In addition, we are anticipating that the following adverse events will be required to be reported to VAERS for COVID-19 vaccines administered under an Emergency Use Authorization (EUA):
 - Vaccine administration errors (whether associated with an adverse event or not)
 - Serious adverse events (irrespective of attribution to vaccination) (such as death, life-threatening adverse event, inpatient hospitalization)
 - Multisystem inflammatory syndrome (MIS) in children [if vaccine is authorized in children] or adults
 - Cases of COVID-19 that result in hospitalization or death
 - CDC's National Healthcare Safety Network (NHSN): An acute care and long-term care facility monitoring system with reporting to the Vaccine Adverse Event Reporting System or VAERS
 - Vaccines and Medications in Pregnancy Surveillance System (VAMPSS): A national surveillance system designed to monitor the use and safety of vaccines and asthma medications during pregnancy

medications during pregnancy

- FDA is working with large insurer/payer databases on a system of administrative and claims-based data for surveillance and research
- Additional safety monitoring information can be found here:
<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>

Additional Resources

- CDC Vaccination Considerations for People who are Pregnant or Breastfeeding <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html>
- Baystate Health & University of Massachusetts Medical School COVID-19 Vaccine Decision Tool <https://www.bmc.org/sites/default/files/documents/covid/COVIDVaccineSharedDecisionMakingInformationfor%20PregnantWoman.pdf>
- Frequently Asked Questions about COVID-19 Vaccination <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>
- CDC's Talking to Recipients about COVID-19 Vaccines <https://www.cdc.gov/vaccines/covid-19/hcp/index.html>
- CDC's Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html>

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