

ICRM COVID-19 Vaccination INFORMATION

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. The following information is intended to be an overview of currently available COVID-19 vaccines and guidance for their use in pregnant and lactating patients.

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 generated from DART studies for the Pfizer-BioNtech vaccine. Therefore, in the interest of allowing pregnant individuals who would otherwise be considered a priority population for a vaccine approved for use under EUA, 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 in to account the individual patient's values and perceived risk of various outcomes and should respect and support autonomous decision-making (ACOG 2013).

Pregnant women who experience fever following vaccination should be counseled to take acetaminophen, as fever has been associated with adverse pregnancy outcomes. Acetaminophen has been proven to be safe for use in pregnancy and does not appear to impact antibody response to COVID-19 vaccines.

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.

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.

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 the CDC's website www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html for more information on CDC's V-SAFE program).

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

Side Effects of COVID-19 vaccine

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 experienced mild side effects similar to influenza-like illness symptoms following vaccination such as injection site reactions (84.1%), fatigue (62.9%), chills (31.9%), muscle pain (38.3%), joint pain (23.6%), and headaches (55.1%). In the 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). Most of these symptoms resolved by day 3 after vaccination. 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. Due to the expected side effects listed above patients would ideally not receive a COVID-19 vaccination within 3 days of an embryo transfer or egg retrieval.

Finally, it is important to remember that pregnant patients were not included as part of the FDA safety and efficacy trials for the vaccines, so we cannot guarantee these vaccines are 100% safe during pregnancy. Ultimately, because pregnant patients are felt to be at increased risk for more severe COVID symptoms, it is thought the benefits of vaccination outweigh the theoretical risks.

Additionally, 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.

For more information you can view the full ACOG and ASRM practice guidelines following the links:

<https://www.acog.org/en/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-Pregnant-and-Lactating-Patients-Against-COVID-19>

<http://asrm.informz.net/z/cjUucD9taT05NzY2NjA4JnA9MSZ1PTEwNzczNzkwOTcmbGk9ODI5NDE0Mzg/index.html>