

## VDH Statement on COVID-19 Vaccine and Pregnancy

The American College of Obstetricians and Gynecologists (ACOG), Centers for Disease Control and Prevention (CDC), and the Virginia Department of Health (VDH) recommend that COVID-19 vaccines should not be withheld from pregnant, lactating, or individuals who intend to get pregnant and who meet criteria for vaccination based on Advisory Committee on Immunization Practices (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 developmental and reproductive toxicology (DART) studies for the Pfizer-BioNTech and Moderna COVID-19 vaccines.

Available data suggest that symptomatic pregnant patients with COVID-19 are at increased risk of more severe illness compared with their 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 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](#)). Additionally, pregnant patients with COVID-19 might be at increased risk of adverse pregnancy outcomes, such as preterm births ([Woodworth 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](#)). Furthermore, risk of ICU admission is higher for pregnant Asian and Native Hawaiian/Pacific Islander individuals ([Zambrano MMWR 2020](#)).

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 community transmission; the potential effectiveness 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.**

### *Vaccination Considerations*

- Expected side effects should be explained as part of counseling patients, including that side effects are a normal part of the body's reaction to the vaccine and development of antibodies to protect against COVID-19 illness.

- Pregnant women who experience fever following vaccination should be counseled to take acetaminophen. Acetaminophen has been proven 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 at the appropriate interval for the vaccine product used.
- 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 individuals who receive a COVID-19 vaccine should be educated about and encouraged to participate in CDC's V-SAFE program.
- Pregnant individuals with a history of allergies to any of the components of the vaccine should not be vaccinated; please adhere to the CDC recommendation for use.
- Pregnant individuals 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 wearing a mask, physical distancing, and hand washing.

### ***Contraindications***

- Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine is a contraindication to vaccination for the [Pfizer-BioNTech](#) and [Moderna](#) COVID-19 vaccines.

### **Lactating Individuals**

ACOG recommends COVID-19 vaccines be offered to lactating individuals similarly to non-lactating individuals if 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 them when they 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.

### *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 as well as the ongoing safety monitoring even after vaccines are made available. The following are some messages to consider when discussing COVID-19 vaccines with patients:

- Vaccines are one of the greatest public health achievements of the 20<sup>th</sup> 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, additional safety monitoring systems are in place to track and monitor these vaccines, including real-time assessment.
- Side effects such as pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever 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 Food and Drug Administration (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, it is anticipated 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; and
  - 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 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.
  - Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women who are vaccinated with the Moderna COVID-19 vaccine during pregnancy. Such women are encouraged to enroll in the registry by calling 1-866-MODERNA (1-866-663-3762).
  - The 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 at <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>.

### ***Additional Resources***

- <https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19>
- <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>
- <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html>