

Counseling Pregnant and Lactating People About COVID-19 Vaccination

S: COVID-19 vaccine is available for pregnant persons and questions arise about the use and safety of the vaccine for this population.

B: The COVID-19 vaccines have been shown in multiple randomized control studies to be safe and effective. These studies excluded pregnant people, so data are limited for this population. The 2 dose Pfizer-BioNTech mRNA vaccine is currently recommended in persons aged ≥ 16 years for the prevention of COVID-19 under an Emergency Use Authorization (EUA). The 2 dose Moderna mRNA vaccine and 1 dose Johnson & Johnson (Janssen) adenovector vaccine are currently recommended under an EUA for individuals ≥ 18 years of age. The Center for Disease Control and Prevention (CDC) has provided [interim clinical considerations](#) regarding the vaccination of pregnant and lactating people. **Pregnancy is not a contraindication to the Pfizer-BioNTech, Moderna, or Janssen vaccines.**

The most up to date studies show that while the overall risk of COVID-19 to individuals is low, pregnant people with COVID-19 have an increased risk of severe illness, including illness that results in ICU admission, mechanical ventilation, or death. Additionally, there may be an increased risk of adverse pregnancy outcomes, such as preterm birth. Lowering these risks, safely, in pregnant people is an important goal. There are very limited available data on the safety of COVID-19 vaccines in pregnant or lactating people. Animal developmental and reproductive toxicity (DART) studies are ongoing and preliminary results are reassuring. Trials in pregnant people are planned. In addition, the CDC and the manufacturers are following outcomes on people enrolled in the clinical trials who became pregnant and registries are ongoing. 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. Most reports (73%) to the Vaccine Adverse Event Reporting System (VAERS) from pregnant people involved nonpregnancy-specific adverse events (local and systemic reactions). 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.

mRNA vaccines (Pfizer, Moderna) are not live vaccines and there are many examples

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of other vaccines used safely in pregnancy (influenza, TDAP). The mRNA in the vaccine is degraded quickly by normal cellular processes and does not enter the nucleus of the cell and is unlikely to reach and cross the placenta. Based on current knowledge, experts believe that mRNA vaccines will not pose a risk for people who are pregnant. The risk from adenovector vaccines (Janssen) 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 and do not replicate. These types of vaccines have been tested before in pregnancy (RSV, Zika) with no safety signals.

The American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine advise that people who are recommended to receive a COVID-19 vaccine should be offered the vaccine, regardless of pregnancy or lactation status. Further, people planning pregnancy can receive a COVID-19 vaccine and can complete the vaccine if they become pregnant during the scheduled course of administration. There is no scientific basis or evidence for a reduction in fertility or increase in miscarriage risk from the vaccine.

A: A pregnant or lactating person may choose to become vaccinated for COVID-19. Physicians and midwives taking care of pregnant people should support these choices with the tools for shared decision-making. While basic answers to frequently asked questions are available [here](#), more information and help may be required.

R: The following considerations are important when a pregnant or lactating person is deciding to receive the COVID-19 vaccine and will help with decision making:

1. A shared decision-making conversation with a medical care provider may help with the decision-making process. Attached with this document is a shared [decision-making tool](#) (from UMass/BayState Health) to guide this discussion.
2. Risk assessment of exposure to and of becoming ill from COVID-19 infection, which would include:
 - a. Personal history of COVID-19 infection
 - b. Rate of COVID-19 infections in the community
 - c. Personal risk of contracting COVID-19 due to workplace, household, or community exposures
 - d. Personal risk factors for developing a more severe form of COVID-19:
 - Pregnancy
 - Obesity (BMI of 30 kg/m² or higher)
 - Smoking
 - Type 2 diabetes mellitus
 - Cancer
 - Chronic kidney disease
 - Chronic obstructive pulmonary disease (COPD)
 - Heart conditions
 - Organ transplant recipient
 - [There are other conditions that may increase the risk of severe COVID-19 illness. \(click link\)](#)

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3. Additional considerations that are also important when deciding to get the COVID-19 vaccine include:
 - a. Personal beliefs and preferences regarding vaccines
 - b. Personal beliefs and preferences regarding COVID-19 illnesses and risk
4. Pregnant people who experience fever following vaccination may be counseled to take acetaminophen as persistent and high fever might increase the risk of some adverse pregnancy outcomes. Acetaminophen may be offered as an option for pregnant people experiencing other post-vaccination symptoms as well.
5. Pregnant people who receive the vaccine should sign up for the smartphone-based [CDC V-safe program](#) to track side effects to a centralized database.
6. The following links to the latest guidance from relevant professional organizations are found here:
 - Society for Maternal-Fetal Medicine [statement on SARS-CoV-2 vaccination in pregnancy](#), [response to the FDA EUA of the Pfizer-BioNTech vaccine](#), and [statement on provider considerations for engaging in COVID-19 counseling with pregnant and lactating patients](#).
 - American College of Obstetricians and Gynecologists [Practice Advisory on Vaccinating Pregnant and Lactating Patients Against COVID-19](#).
7. Pregnant people should be counseled that mask wearing, social distancing, and hand hygiene remain important tools for reducing the risk for COVID-19 infection.

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