

# COVID-19 Vaccines and Pregnancy: Conversation Guide for Clinicians

ACOG recommends that pregnant individuals have access to COVID-19 vaccines.

While limited, current safety data on the use of COVID-19 vaccines in pregnancy do not indicate any safety concerns.

In the interest of patient autonomy, ACOG recommends that pregnant individuals be free to make their own decision regarding COVID-19 vaccination. While pregnant individuals are encouraged to discuss vaccination considerations with their clinical care team when feasible, documentation of such a discussion should not be required prior to receiving a COVID-19 vaccine.

For more information on vaccinating pregnant women against COVID-19 see [ACOG's Practice Advisory](#).

**The following talking points are intended to help guide risk and benefit conversations with pregnant patients:**

## Risk of COVID-19 Infection During Pregnancy

- While the known absolute risk is low, pregnancy is associated with increased risk of maternal severe illness, ICU admission, mechanical ventilation and death
- There is a known increased risk of complications from COVID-19 in pregnant patients with underlying health conditions (e.g. diabetes, obesity, increasing age, and cardiovascular disease)
- There is increased risk for certain racial and ethnic populations

## Safety of COVID-19 Vaccines

- Pregnant women were not included in COVID-19 vaccine clinical trials, however observational data from vaccinated pregnant individuals is being collected by CDC and manufacturers and to date no safety signals have been identified
- Based on limited self-reported information, no specific safety signals have been observed in pregnant people enrolled in v-safe and the v-safe pregnancy registry; however longitudinal follow-up is needed
- Early data from CDC's v-safe pregnancy registry demonstrate that the side effects and adverse events observed among pregnant individuals in v-safe did not indicate any safety concerns
- Data from Developmental and Reproductive Toxicity (DART) animal-model studies for the Pfizer-BioNtech, Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines have not demonstrated any safety concerns in pregnancy
- 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
- Any of the currently authorized COVID-19 vaccines can be administered to pregnant or lactating people; ACIP does not state a product preference. However, pregnant, lactating, and post-partum people aged <50 years should be aware of the rare risk of thrombosis with thrombocytopenia syndrome (TTS) after receipt of the Janssen COVID-19 vaccine and that other FDA- authorized COVID-19 vaccines (i.e., mRNA vaccines) are available (see ACOG's Practice Advisory for more information regarding TTS related to the Janssen COVID-19 vaccine)
  - » Patients receiving the Janssen COVID-19 vaccine should be informed of symptoms of TTS, including severe headache, visual changes, abdominal pain, nausea and vomiting, back pain, shortness of breath, leg pain or swelling, petechiae, easy bruising, or bleeding. Patients who experience these symptoms should be counseled to seek immediate medical evaluation.
- None of the COVID-19 vaccines available for use under EUA cause infertility
- Injection site and systemic events (side effects) are common e.g. pain at the site of injection, fever, muscle pain, joint pain, headaches, fatigue, and other symptoms may be present after vaccination
  - » Acetaminophen is recommended for pregnant women who experience fever or if desired for other side effects
  - » These side effects are a normal part of the body's reaction to the vaccine and developing antibodies to protect against COVID-19 illness
- On-going safety monitoring planned through many government and non-government programs
  - » Encourage pregnant patients who get vaccinated to sign up for CDC's [v-safe](#) safety monitoring program
- **Other safety programs include:**
  - [Vaccine Adverse Event Reporting System \(VAERS\)](#)
  - [Vaccine Safety Datalink \(VSD\)](#)
  - Manufacturer-sponsored reporting systems
    - ♦ [Pfizer-BioNtech](#)
    - ♦ [Moderna](#)
    - ♦ [Janssen](#)

## □ Efficacy of COVID-19 Vaccines

- There is limited data available on the efficacy of COVID-19 vaccines in pregnancy, but so far, the vaccines appear to be equally effective in pregnant individuals and non-pregnant individuals
- All currently available COVID-19 vaccines have demonstrated high efficacy among their respective clinical trial endpoints
  - » Vaccine efficacy is based on the time and place where the trials were conducted and the circulating SARS-CoV-2 virus(es) and direct comparison of the results of these trails is inappropriate at this time
- Individuals can receive any product that is made available to them and can be confident in the vaccine's ability to provide a high level of protection from COVID-19 illness
- Two doses of mRNA vaccines (Pfizer-BioNtech & Moderna) are necessary to achieve protection
- One dose of adenovirus vector vaccine (Janssen) are necessary to achieve protection
- COVID-19 vaccines may prevent severe COVID-19 disease
- The duration of protection provided by vaccination is unknown

## □ Pregnant Patient's Individual Risk Based on Circumstances

- The efficacy of the vaccine
- The ability to limit exposures (eg. living space, transportation, work environment, availability of PPE)
- The risk and potential severity of maternal disease (see above), including the effects of disease on the fetus and newborn
- The safety of the vaccine for the pregnant patient and the fetus

## □ Safety and Efficacy for the Newborn

- There is currently no data available regarding protection of the newborn with maternal immunization
  - » IgG antibodies after maternal vaccination in the third trimester have been shown in observational studies. However, no data is available to demonstrate if this prevents COVID-19 disease in neonates
- There is currently no vaccine available for infants or young children

## □ Special Considerations for Communities of Color

- 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. 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
- All individuals should have the option of receiving any of the FDA-authorized COVID-19 vaccines available. If any individual chooses one type of COVID-19 vaccine over another for any reason, this decision should be supported.

## □ Continued Support

- 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:
  - » Wearing a mask
  - » Staying at least six feet away from others
  - » Avoiding crowds
  - » Washing hands with soap and water for 20 seconds or using hand sanitizer with at least 60% alcohol
  - » Following [CDC travel guidance](#)
  - » Following quarantine guidance after exposure to COVID-19
  - » Following any applicable workplace guidance

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### ADDITIONAL RESOURCES

- ACOG Patient FAQs: Coronavirus (COVID-19) and Women's Health Care: <https://www.acog.org/womens-health/faqs/coronavirus-covid-19-and-womens-health-care>
- ACOG Patient FAQs: Coronavirus (COVID-19), Pregnancy, and Breastfeeding: <https://www.acog.org/womens-health/faqs/coronavirus-covid-19-pregnancy-and-breastfeeding>
- CDC: Answering Patients' Questions: <https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html>
- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>