

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

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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 Developmental and Reproductive Toxicity (DART) studies for the Pfizer-BioNTech COVID-19 vaccine.

In the interest of allowing pregnant individuals who would otherwise be considered a priority population for a vaccines 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.

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

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**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
- Known Increased risk of complications from COVID-19 in pregnant patients with underlying health conditions (e.g. diabetes, obesity, increasing age, and cardiovascular disease)
- Increased risk for racial and ethnic minority communities

## Safety of COVID-19 Vaccines

- Vaccines currently available under EUA have not been tested in pregnant women. Therefore, there are no safety data specific to use in pregnancy.
  - » Developmental and Reproductive Toxicology (DART) animal data is forthcoming, though a verbal report of the data did not indicate any safety signals and clinical studies in pregnant individuals are planned
- 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.
- 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 each vaccination, particularly after the second dose of vaccine.
  - » 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
- 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 of cells and do not alter human DNA in vaccine recipients. As a result, mRNA vaccines cannot cause any genetic changes.

- 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](#)

#### □ **Efficacy of COVID-19 Vaccines**

- No data available in pregnancy, but likely to be similar efficacy to non-pregnant adults
- Depending on the vaccine, up to 95% efficacy in preventing symptomatic COVID-19 disease in the first few weeks after vaccination has been reported in non-pregnant patients
- Two doses of vaccine are necessary to achieve protection
- May prevent severe COVID-19 disease
- Duration of protection is unknown

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

- the level of disease activity in the community
- 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**

- No data available regarding protection of the newborn with maternal immunization
- No vaccines are currently available for infants or young children

#### □ **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>
- CDC: Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine: <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html>