COVID-19 Vaccines and Pregnancy: Conversation Guide for Clinicians

ACOG recommends that pregnant individuals be vaccinated against COVID-19.

Obstetrician-gynecologists and other obstetric care providers should routinely assess their pregnant patients' vaccination status. Based on this assessment they should recommend needed vaccines to their pregnant patients. There is no evidence of adverse maternal or fetal effects from vaccinating pregnant individuals with COVID-19 vaccine, and a growing body of data demonstrate the safety of such use. Therefore, individuals who are or will be pregnant should receive the COVID-19 vaccine.

While pregnant individuals are encouraged to discuss vaccination considerations with their clinical care team when feasible, written permission or 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 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

- There is no evidence of adverse maternal or fetal effects from vaccinating pregnant individuals with COVID-19 vaccine, and a growing body
 of data demonstrate the safety of such use. Based on self-reported information, no specific safety signals have been observed in pregnant
 people enrolled in v-safe and the v-safe pregnancy registry and no safety signals have been reported in VAERS or other safety monitoring
 systems
- 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 did not demonstrate any safety concerns in pregnancy
- 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
- Multiple safety systems have reported a higher-than expected number of cases of Guillain-Barré syndrome following the use of the Janssen COVID-19 vaccine; however, more investigation is needed. It appears the absolute risk of Guillain-Barré syndrome following vaccination remains very low; therefore, the benefits of prevention of severe COVID-19 illness through vaccination outweigh this very rare risk.
- 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 is 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
- 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) is necessary to achieve protection
- COVID-19 vaccines decrease the risk of severe COVID-19 disease
 - » If you get sick after being vaccinated, your chances of becoming severely ill are extremely low
- The majority of hospitalized patients are individuals who did not receive a COVID-19 vaccine
- The duration of protection provided by vaccination is unknown

Safety and Efficacy for the Newborn

- There is accumulating data demonstrating that antibodies are passed to the fetus when a pregnant person is vaccinated
 - » 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
- No vaccines are currently 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 care for 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

- For patients who do not receive the vaccine, the discussion should be documented in the patient's medical record. During subsequent office
 visits, obstetrician-gynecologists should address ongoing questions and concerns and offer vaccination again. Clinicians should reinforce
 the importance of other prevention measures such as
 - » hand washing,
 - » physical distancing, and
 - » wearing a mask

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

