



COVID-19 VACCINES AND PREGNANCY

Sarah Carroll, MPH
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American College of Obstetricians and Gynecologists, 409 12th Street SW, PO Box 96920, Washington, DC 20090-6920



Conflicts of Interest

None

Background

COVID-19 Infection Risk in Pregnancy

- Available data suggest that symptomatic pregnant women with COVID-19 are at increased risk of more severe illness compared with nonpregnant peers.
- 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, when compared with symptomatic non-pregnant women.
- Given the growing evidence, CDC has included pregnancy as a factor that leads to increased risk for severe COVID-19 illness.

COVID-19 Vaccine Allocation and Authorization

It is important to note that COVID-19 vaccine development and regulatory approval is a rapidly changing process, and information and recommendations will evolve as more data are collected about these vaccines and their use in specific populations.

Advisory Committee on Immunization Practices: Vaccine Priority Phases

ACIP has made the following recommendations for prioritization of COVID-19 vaccine allocation:

- Phase 1a: Health care workers and long-term care facility residents
- Phase 1b: Persons aged ≥ 75 years and frontline essential workers
- Phase 1c: Persons aged 65-75 years, persons aged 16-64 years with high-risk medical conditions (**including pregnancy**), and other essential workers

Within national guidelines, state and local jurisdictions should have flexibility to administer vaccine based on local epidemiology and demand.

Advisory Committee on Immunization Practices (ACIP) Recommendations

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for use of:

- Pfizer-BioNTech COVID-19 vaccine in persons aged ≥ 16 years
- Moderna-1273 COVID-19 vaccine in persons aged ≥ 18 years

Advisory Committee on Immunization Practices

Clinical Considerations

Information for pregnant and lactating individuals has been posted on CDC's website under Clinical Considerations.

- A pregnant individual who is part of a group (e.g., healthcare personnel) recommended to receive a COVID-19 vaccine may choose to be vaccinated. A discussion with their healthcare professional can help the patient make an informed decision.
- Lactating individuals who are part of a group (e.g., healthcare personnel) recommended to receive a COVID-19 vaccine may choose to be vaccinated.

U.S. FDA Emergency Use Authorization and Approval

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the following vaccines:

- Pfizer-BioNtech mRNA vaccine (BNT162b2): for use in individuals age 16 years and older as a 2-dose regimen given 3 weeks (21 days) apart.
- Moderna mRNA-1273 vaccine: for use in individuals age 18 and older as a 2-dose regimen given 1 month (28 days) apart.

Pfizer-BioNtech and Moderna Vaccines Cont'd

- According to the EUA Fact Sheet for Health Care Professionals, available data on COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.
- The EUA Fact Sheet for Recipients and Caregivers for both Pfizer-BioNtech and Moderna vaccines states:

“If you are pregnant or breastfeeding, discuss your options with your healthcare provider”.

Safety of COVID-19 mRNA Vaccines

Despite ACOG's persistent advocacy for the inclusion of pregnant individuals in COVID-19 vaccine trials, none of the COVID-19 vaccines approved under EUA have been tested in pregnant individuals. However, studies in pregnant women 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.

Safety of COVID-19 Vaccines: DART data

DART studies provide the first safety data to help inform the use of the vaccine in pregnancy until there are more data in this population.

- Data from Developmental and Reproductive Toxicity (DART) studies for the Pfizer-BioNtech COVID-19 vaccine have been reported in Europe. According to the report presented to the European Medicines Agency, animal studies using the Pfizer/BioNtech COVID-19 vaccine do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition or post-natal development.
- A combined developmental and perinatal/postnatal reproductive toxicity (DART) study of Moderna's mRNA-1273 in rats was submitted to FDA on December 4, 2020. FDA review of this study concluded that mRNA1273 given prior to mating and during gestation periods at dose of 100 µg did not have any adverse effects on female reproduction, fetal/embryonal development, or postnatal developmental except for skeletal variations which are common and typically resolve postnatally without intervention.

ACOG Recommendations

Pregnant Individuals

- **ACOG recommends that** COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on ACIP-recommended priority groups.
- **ACOG recommends that** in the interest of patient autonomy, pregnant individuals should 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.

Additional Considerations for Pregnant Individuals

- Similar to their non-pregnant peers, vaccination of pregnant individuals with a COVID-19 mRNA vaccine may occur in any setting authorized to administer these vaccines. This includes any clinical setting and non-clinical community-based vaccination sites such as schools, community centers, and other mass vaccination locations.
- Pregnant women who experience fever following vaccination should be counseled to take acetaminophen.
- 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.

Additional Considerations for Pregnant Individuals Cont.

- Individuals should complete their 2-dose series with the same vaccine product.
- 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.

Lactating Individuals

- **ACOG recommends** COVID-19 vaccines be offered to lactating individuals similar to non-lactating individuals when they meet criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP.
- 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.

Individuals Contemplating Pregnancy

- **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.
- 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. It is not necessary to delay pregnancy after completing both doses of the COVID-19 vaccine.
- If an individual becomes pregnant after the first dose of the COVID-19 vaccine series, the second dose should be administered as indicated.
- Pregnancy testing should not be a requirement prior to receiving any COVID-19 vaccine.

ACOG Response to WHO Recommendations

World Health Organization Recommendations

- WHO recommendations for both the Pfizer and Moderna vaccines initially explicitly stated that these vaccines should not be given to pregnant women unless they are high-risk of exposure, such as health care workers.
- These recommendations do not align with CDC nor ACOG and other obstetric medical societies.

ACOG Response to WHO Recommendations

Recognizing that the WHO recommendations would create confusion among clinicians and the public, ACOG and SMFM worked quickly to put out a statement affirming its recommendations that **COVID-19 vaccines should be available to all pregnant individuals who are eligible and choose to be vaccinated.**

- This statement yielded the highest engagement of any ACOG social media post to date.



Clinical | Jan 27, 2021

ACOG and SMFM Joint Statement on WHO Recommendations Regarding COVID-19 Vaccines and Pregnant Individuals

Washington, DC – The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) are aware of the World Health Organization's (WHO) recommendation to withhold COVID-19 vaccines from pregnant individuals unless they are at high risk of exposure. ACOG and SMFM continue to stress that both COVID-19 vaccines currently authorized by the U.S. Food and Drug Administration should not be withheld from pregnant individuals who choose to receive the vaccine. ACOG's and SMFM's current guidance on the COVID-19 vaccine in pregnant patients remains in place.

Despite efforts by ACOG and SMFM to advocate for their inclusion, clinical trials that informed the emergency use authorization (EUA) of the vaccines did not include pregnant individuals. However, preliminary developmental and reproductive toxicity (DART) studies for both the Pfizer-BioNTech and Moderna vaccines are encouraging, with no safety signals reported. DART animal studies provide the first safety data to help inform the use of these vaccines in pregnancy until there are more data in this specific population. These studies do not indicate any adverse effects on female reproduction or fetal/embryonal development. ACOG and SMFM strongly urge manufacturers and federal agencies to collect and report data regarding the use of these vaccines in pregnancy.

WHO Revised Recommendations

- Shortly after the ACOG statement and strong engagement and support from members, WHO revised their recommendation to be slightly more permissive:

“those pregnant women at high risk of exposure to SARS-CoV-2 (e.g. health workers) or who have comorbidities which add to their risk of severe disease, may be vaccinated in consultation with their health care provider.”

ACOG RESOURCES

ACOG Practice Advisory

Comprehensive clinical guidance for ACOG members regarding COVID-19 Vaccination for Pregnant and Lactating Individuals.



Vaccinating Pregnant and Lactating Patients Against COVID-19

Practice Advisory | December 2020

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Last updated January 27, 2021

This Practice Advisory was developed by the American College of Obstetricians and Gynecologists' Immunization, Infectious Disease, and Public Health Preparedness Expert Work Group in collaboration with Laura E. Riley, MD; Richard Beigi, MD; Denise J. Jamieson, MD, MPH; Brenna L. Hughes, MD, MSc; Geeta Swamy, MD; Linda O'Neal Eckert, MD; Mark Turrentine, MD; and Sarah Carroll, MPH.

Summary of Key Information and Recommendations

COVID-19 vaccine development and regulatory approval are rapidly progressing. Thus, information and recommendations will evolve as more data are collected about these vaccines and their use in specific populations. This Practice Advisory is intended to be an overview of currently available COVID-19 vaccines and guidance for their use in pregnant and lactating patients.

Conversation Guide for Clinicians

Highlights the main conversation points for clinicians from ACOG's Practice Advisory to help discuss COVID-19 vaccines with pregnant individuals.

➤ Intended to help guide risk/benefit conversations

COVID-19 Vaccines and Pregnancy: Conversation Guide for Clinicians

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 and Moderna COVID-19 vaccines.

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
- 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 certain racial and ethnic populations

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.









Vaccinating Pregnant Individuals: Eight Key Recommendations for COVID-19 Vaccination Sites

- Brand new resource from ACOG intended for all variations of COVID-19 vaccination sites
- Provides key recommendations from ACOG regarding COVID-19 vaccines and pregnancy
- Not intended to be a guide for risk/benefit conversations



ACOG **Vaccinating Pregnant Individuals:** Eight Key Recommendations for COVID-19 Vaccination Sites

The American College of Obstetricians and Gynecologists (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. Further, pregnant individuals should not be denied COVID-19 vaccine(s) because of their pregnancy-status alone. COVID-19 vaccination sites should consider the recommendations below regarding vaccinating pregnant individuals.

	1 COVID-19 vaccines should be available and administered to pregnant individuals who choose to be vaccinated.
	2 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.
	3 Pregnancy testing should not be a requirement prior to receiving any EUA-approved COVID-19 vaccine.
	4 Similar to their non-pregnant peers, pregnant individuals can receive a COVID-19 mRNA vaccine in any setting authorized to administer these vaccines. This includes any clinical setting and non-clinical community-based vaccination sites such as schools, community centers, and other mass vaccination locations.
	5 Precautions should be discussed with any individual who reports a history of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate).
	6 If anaphylaxis is suspected in a pregnant individual after receiving a COVID-19 vaccination, anaphylaxis should be managed the same as in non-pregnant individuals (CDC).
	7 Pregnant individuals who experience fever following vaccination should be counseled to take acetaminophen. Acetaminophen has been proven to be safe for use in pregnancy and does not appear to impact antibody response to COVID-19 vaccines.
	8 Pregnant individuals who receive a COVID-19 vaccine should be educated about and encouraged to participate in CDC's V-SAFE program (see below for more information on CDC's V-SAFE program).

For more information, please visit ACOG's [Practice Advisory on Vaccinating Pregnant and Lactating Patients Against COVID-19 and CDC's Clinical Considerations](#).

Statement on Access to COVID-19 Vaccines for Pregnant Individuals

In response to reports of pregnant individuals being denied COVID-19 vaccines simply because of their pregnancy status, ACOG leveraged the *Maternal Immunization Task Force* to publish a joint statement with 17 partner organizations, further advocating for pregnant individuals to be free to make their own decision regarding their health, in conjunction with their clinical care team when appropriate.



Maternal Immunization Task Force and Partners Urge That COVID-19 Vaccine be Available to Pregnant Individuals

All pregnant individuals who choose to receive the COVID-19 vaccine must be allowed to do so in alignment with their state and local vaccination allocation plan. This includes the estimated 330,000 health care workers who are pregnant and should be allowed to receive the vaccine as part of the first phase of vaccine distribution plans. Reports of pregnant individuals being refused vaccination are concerning.

Pregnant individuals who otherwise meet the criteria for COVID-19 vaccines should not be denied the opportunity to be vaccinated, should they choose to do so. Although a conversation with a clinician may be helpful for patients to aid in their decision-making, it should not be required prior to vaccination.

As the COVID-19 vaccine rollout continues, use must reflect the vaccines' federal regulatory authorization as well as information and recommendations from the Centers for Disease Control and Prevention, the U.S. Food and Drug Administration, and expert healthcare organizations.

Currently, available data demonstrate that pregnant individuals are at increased risk of more severe illness and death due to COVID-19 than their non-pregnant counterparts¹. Providing pregnant individuals with the opportunity to be vaccinated can be critical to allowing them to protect themselves, particularly if their occupation puts them at increased risk of contracting the virus or they have underlying and comorbid conditions.

When pregnant individuals are excluded from the opportunity to decide whether to be vaccinated, it not only violates their bodily autonomy, it also puts them at risk of severe outcomes and death related to COVID-19 illness. Excluding this critical population at increased risk of severe illness and death related to COVID-19 is unethical.

In the interest of allowing pregnant individuals who would otherwise be considered a priority population for vaccines to make their own decisions regarding their health, our groups strongly recommend pregnant individuals should be free to make their own decision in conjunction with their clinical care team. All pregnant individuals must be supported in their decision about COVID-19 vaccination, whether they choose to receive the vaccine, or they opt to decline.

For more information, please visit ACOG's Practice Advisory on [Vaccinating Pregnant and Lactating Patients Against COVID-19](#) and the CDC's [Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States](#).

¹ Zambrano LD, Ellington S, Strid R, et al. Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status – United States, January 22–October 3, 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1641–1647. DOI: <https://doi.org/10.15585/mmwr.mm6944a1>

Patient Education Resources

COVID-19 resources on ACOG's Patient Education Portal include:

➤ Expert columns

➤ Frequently Asked Questions

The screenshot shows a web browser displaying the ACOG Patient Education Portal page titled "Coronavirus (COVID-19), Pregnancy, and Breastfeeding: A Message for Patients". The page includes a "FAQs" button, a "Share" button with social media icons, and a "Print" button. The content is reviewed by Lisa Holler, MD, MPH, FACOG, and was last updated on December 22, 2020. It features links for "Simplified Chinese" and "Arabic" versions. The main text states that ACOG is following the situation closely and provides information for pregnant and breastfeeding women. A disclaimer notes that the page is for informational reference only and not for specific medical advice. A link to acog.org/covid19 is provided for the latest updates. The page also includes a "Pamphlets" button for clinicians to subscribe to digital pamphlets and a "Questions about COVID-19, pregnancy, and breastfeeding?" section. The browser's address bar shows the URL <https://www.acog.org/coronavirus-covid-19-pregnancy-and-breastfeeding>. The Windows taskbar at the bottom shows the time as 9:11 PM on 2/2/2021.

Coding for COVID-19 Immunizations

Brand new practice management resource outlining coding specifics for COVID-19 vaccines

The screenshot shows a webpage from ACOG's Practice Management section. The page title is "Coding for COVID-19 Immunizations" dated February 3, 2021. The article text states that ACOG representatives to the AMA CPT Editorial Panel are working with vaccine developers to create codes for COVID-19 vaccines. It lists three vaccine types with their respective CPT codes:

- Pfizer-BioNTech COVID-19 Vaccine (NCD 10/NCD 11: 59267-1000-1; 59267-1000-01) CPT 91300**
Vaccine Administration
 - 1st Dose: 0001A
 - 2nd Dose: 0002A
- Moderna COVID-19 Vaccine (NCD 10/NCD 11: 80777-273-10; 80777-0273-10) CPT 91301**
Vaccine Administration
 - 1st Dose: 0011A
 - 2nd Dose: 0012A
- AstraZeneca COVID-19 Vaccine (NCD 10/NCD 11: 0310-1222-10; 00310-1222-10) CPT 91302**
Vaccine Administration

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Linda O'Neal Eckert, MD
Mark Turrentine, MD
Richard Beigi, MD
Yasser El-Sayed, MD

ACOG Staff

Dr. Christopher M. Zahn (VP, Practice)
Deanna Atkins (Web)
Farnese Motto (Clinical)
Jamila Vernon (Communications)
Janna Crabb (Web)
Jennifer Hicks (Patient Education)
Kate Connors (Communications)
Lamiya Ahmed (Clinical)
Madhu Rajaraman (Web)
Margaret Villalonga (Clinical)
Mary Schilling (Legal)
Megan McReynolds (Clinical)
Molly Hoffman (Communications)
Nancy O'Reilly (Clinical)
Olivia Bobrowsky (Patient Education)
Sarah Wright (Clinical)

Questions?