ACOG | Clinical
The American College of Obstetricians and Gynecologists

COVID-19 Vaccination Considerations for Obstetric–Gynecologic Care

Practice Advisory

December 2020

By reading this page you agree to ACOG's Terms and Conditions. Read terms

Last updated November 3, 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 Updates

This Practice Advisory provides overview of currently available COVID-19 vaccines and guidance for their use in pregnant, recently pregnant, and nonpregnant individuals. It has been updated to include the following:

- Recommendations on the use of a booster dose in pregnant and nonpregnant individuals for Moderna and Johnson & Johnson's Janssen (J&J/Janssen) vaccines.

Key Recommendations

- The American College of Obstetricians and Gynecologists (ACOG) recommends that all eligible persons greater than age 12 years, **including pregnant and lactating individuals**, receive a COVID-19 vaccine or vaccine series.
- 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.

- Obstetrician–gynecologists and other women's health care practitioners should lead by example by being vaccinated and encouraging eligible patients to be vaccinated as well.
- COVID-19 vaccines may be administered simultaneously with other vaccines. This includes vaccines routinely administered during pregnancy, such as influenza and Tdap.
- Moderately to severely immunocompromised people should receive a third dose of the Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines at least 28 days after the completion of the initial mRNA COVID-19 vaccine series. Currently, there is insufficient data to determine whether immunocompromised people who received J&J/Janssen COVID-19 vaccine also have an improved antibody response following an additional dose of the same vaccine.
- ACOG recommends that pregnant and recently pregnant people up to 6 weeks postpartum, including pregnant and recently pregnant health care workers, receive a booster dose of COVID-19 vaccine following the completion of their initial COVID-19 vaccine or vaccine series.
- People aged 18–64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting and who received an mRNA COVID-19 vaccine for their initial series may receive a booster shot of COVID-19 vaccine at least 6 months after their initial series, based on their individual benefits and risks. Therefore, health care workers who received an mRNA COVID-19 vaccine for their initial series may receive a booster dose of COVID-19 vaccine at least 6 months after their initial series.
- All individuals aged 18 years and older, including pregnant and recently pregnant people, who received the J&J/Janssen vaccine as their initial COVID-19 vaccine should receive a single booster dose at least 2 months after their initial vaccine.
- Individuals qualifying for a COVID-19 booster may receive any vaccine product available to them; they do not have to receive the same product as their initial vaccine or vaccine series.

COVID-19 Vaccine Authorization Overview

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. This Practice Advisory provides overview of currently available COVID-19 vaccines and guidance for their use in pregnant, recently pregnant, and nonpregnant individuals aged 12 years and older. For guidance and recommendations for the use of these vaccines in individuals aged 11 years or younger, please visit the American Academy of Pediatrics.

Advisory Committee on Immunization Practices Recommendations

After an explicit, evidence-based review of all available data, the Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥12 years for the prevention of COVID-19 (CDC 2021), the use of the Moderna-1273 COVID-19 vaccine in persons aged ≥18 years (CDC 2020), and the use of the J&J/Janssen COVID-19 vaccine in persons aged ≥18 years (CDC 2021).

U.S. FDA Emergency Use Authorization and Approval

Table 1. Overview of FDA Emergency Use Authorization and Approval of COVID-19 Vaccines in the United States

Vaccine Product	**Pfizer- BioNTech**
EUA Status	EUA for use in individuals aged 12–15 years
Licensure Status	Licensed for use in individuals aged 16 years and older
No. Doses	2
Interval Between Doses	3 weeks (21 days)
Third Dose*	Included in EUA for moderately to severely immunocompromised individuals
Booster Dose**	Included in EUA for specific populations
Vaccine Product	**Moderna**
EUA Status	EUA for use in individuals aged 18 years and older
Licensure Status	N/A

No. Doses	2
Interval Between Doses	4 weeks (28 days)
Third Dose*	Included in EUA for moderately to severely immunocompromised individuals
Booster Dose**	Included in EUA for specific populations; administered as a half-dose (.25 mL)

Vaccine Product	**J&J/Janssen**
EUA Status	EUA for use in individuals aged 18 years and older
Licensure Status	N/A
No. Doses	1
Interval Between Doses	N/A
Third Dose*	N/A
Booster Dose**	Included in EUA for all individuals who initially received J&J/Janssen

*The FDA amended the emergency use authorization (EUA) for the Pfizer-BioNTech and Moderna COVID-19 vaccines to allow for a third dose for moderately to severely immunocompromised people at least 28 days after the completion of the initial mRNA COVID-19 vaccine series. Currently, there are insufficient data to determine whether immunocompromised people who received the J&J/Janssen COVID-19 vaccine also have an improved antibody response following an additional dose of the same vaccine.

**FDA amended the EUA for the Pfizer-BioNTech and Moderna COVID-19 vaccines to allow for use of a single booster dose, to be administered at least 6 months after completion of the primary series in:

- individuals aged 65 years and older;

- individuals aged 18–64 years at high risk of severe COVID-19; and

- individuals aged 18–64 years whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19, including severe COVID-19.

FDA amended the EUA for the J&J/Janssen COVID-19 vaccine to allow for a booster dose for all individuals aged 18 years and older who received J&J/Janssen as their initial COVID-19 vaccine. The booster dose should be administered at least 2 months following the initial vaccine.

Individuals qualifying for booster doses may receive any vaccine product available to them; they do not have to receive the same product as their initial vaccine or vaccine series.

See below for ACOG's recommendations related to booster doses.

COVID-19 Vaccine Information

At the time of this publication, three vaccines developed for the prevention of COVID-19 have received EUA from the FDA. However, COVID-19 vaccines are rapidly emerging and additional EUAs are likely to materialize. ACOG will strive to update this guidance as quickly as possible while maintaining accurate, evidence-based information.

mRNA COVID-19 Vaccines (Pfizer-BioNtech and Moderna)

The development and use of mRNA vaccines is relatively new. These vaccines consist of messenger RNA (mRNA) encapsulated by a lipid nanoparticle (LNP) for delivery into the host cells. These vaccines utilize the body's own cells to generate the coronavirus spike protein (the relevant antigens), which, similar to all other vaccines, stimulates immune cells to create antibodies against COVID-19. 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 and do not alter human DNA in vaccine recipients. As a result, mRNA vaccines cannot cause any genetic changes (CDC, Zhang 2019, Schlake 2012). 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 nonpregnant individuals. Further, a growing body of observational data so far have not identified any safety concerns for COVID-19 vaccination during pregnancy.

Adenovirus-Vector Vaccines (J&J/Janssen Biotech Inc.)

The Janssen (J&J/Janssen) COVID-19 vaccine (Ad26.COV2.S) is based on the AdVac® technology platform and is a monovalent vaccine composed of a recombinant, replication-incompetent human adenovirus type 26 (Ad26) vector, constructed to encode a stabilized form of the SARS-CoV-2 Spike (S) protein. The Ad26 vector cannot replicate following administration to humans, and available data demonstrate that it is cleared from tissues following injection (FDA 2021).

Ad26.COV2.S is not a live virus vaccine, it does not contain preservatives, and it does not replicate in the cells. Based on data from ongoing and completed clinical trials of Ad26-vectored vaccines including COVID-19, HIV, and Ebola administered to pregnant individuals, overall, the Ad26-based vaccines have an acceptable safety and reactogenicity profile. In addition, the review of the available pregnancy data is not suggestive of a pregnancy-related safety concern (FDA 2021).

Efficacy of Available COVID-19 Vaccines

All currently available COVID-19 vaccines have demonstrated high efficacy among their respective clinical trial endpoints. Additionally, a growing body of evidence suggests that fully vaccinated people are less likely to have asymptomatic infection or transmit SARS-CoV-2 to others.

mRNA vaccines

Based on results from clinical trials, the Pfizer-BioNTech COVID-19 vaccine was 95% effective at preventing laboratory-confirmed COVID-19 illness in people who received two doses who had no evidence of previous infection (CDC).

Based on results from clinical trials, the Moderna vaccine was 94.1% effective at preventing laboratory-confirmed COVID-19 illness in people who received two doses who had no evidence of being previously infected (CDC).

A prospective cohort study from two academic centers found that vaccinated pregnant and lactating women produced comparable immune responses to nonpregnant controls, and generated higher antibody titers than those observed following SARS-CoV-2 infection in pregnancy. Further, vaccine-generated antibodies were present in umbilical cord blood and breast milk after maternal vaccination (Gray 2021, Prabhu 2021, Juncker 2021).

Each of these vaccines appeared to have high efficacy in clinical trials among people of diverse age, sex, race, and ethnicity categories and among persons with underlying medical conditions. Further, during the

race, and ethnicity categories and among persons with underlying medical conditions. Further, during the rollout of COVID-19 vaccines, data continue to demonstrate high vaccine efficacy in preventing hospitalization and death (ACIP Slides).

Adenovirus-Vector vaccines

Based on the results from clinical trials in the U.S., the J&J/Janssen COVID-19 vaccine has been shown to be 66.9% effective at preventing moderate/severe COVID-19 illness and 76.7% effective at preventing severe/critical COVID-19 illness after a single dose. This vaccine also demonstrated 93.1% effectiveness at preventing hospitalizations 14 days following vaccination (Janssen 2021).

Safety of Available COVID-19 Vaccines

Side Effects

Expected side effects should be explained during counseling, including that they are a normal part of the body's reaction to the vaccine and developing antibodies to protect against COVID-19 illness.

Most study participants for both the Pfizer-BioNTech and Moderna vaccines experienced mild side effects similar to influenza-like illness symptoms following vaccination (see Table 2 below). In the Pfizer-BioNTech study subgroup of persons aged 18–55 years, fever greater than 38 °C occurred in 3.7% after the first dose and 15.8% after the second dose (FDA 2020). In the Moderna vaccine trials, fever greater than 38°C was reported in 0.8% of vaccine recipients after the first dose, and 15.6% of vaccine recipients after the second dose (FDA 2020). Most of these symptoms resolved by day 3 after vaccination for both vaccines.

As is typical with adenovirus vaccines, side effects for the J&J/Janssen COVID-19 vaccine were generally mild and transient, resolving in 1–2 days following vaccination among safety study participants. In the J&J/Janssen safety study group, 9.0% of individuals receiving a COVID-19 vaccine experienced fever greater than 38°C following vaccination. Fever had a median duration of 1 day (FDA 2021).

Patients should be counseled about more severe side effects and when to seek medical care. For more information and details on side effects, see Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events: Pfizer-BioNTech COVID-19 Vaccine from the CDC.

Table 2. Mild Side Effects Among All Study Participants*

	Moderna
Injection Site Reactions	91.6%
Fatigue	68.5%
Chills	43.4%

Chills	45.4%
Muscle Pain	59.6%
Joint Pain	44.8%
Headaches	63%

	Pfizer-BioNTech
Injection Site Reactions	84.10%
Fatigue	62.90%
Chills	31.90%
Muscle Pain	38.30%
Joint Pain	23.60%
Headaches	55.10%

	J&J/Janssen
Injection Site Reactions	48.6%
Fatigue	38.2%
Chills	N/A
Muscle Pain	33.2%
Joint Pain	N/A
Headaches	38.9%

**Fever was the least common side effect reported; see text above for data on frequency of fever*

Allergic Reactions Including Anaphylaxis

Allergic reactions including anaphylaxis have been reported to be rare following COVID-19 vaccination in nonpregnant individuals. Anaphylaxis has been observed in 5 cases per million doses administered for the Pfizer-BioNTech vaccine, 4.9 cases per million doses administered of the Moderna vaccine, and 7.6 cases per million doses administered for the J&J/Janssen vaccine (ACIP August 2021).

If anaphylaxis is suspected in a pregnant individual after receiving a COVID-19 vaccination, anaphylaxis should be managed the same as in nonpregnant individuals (eg, rapidly assess airway, breathing, circulation, and mental activity; call for emergency medical services; place the patient in a supine position, and administration of epinephrine) (CDC). Similar to nonpregnant individuals, anaphylaxis may recur after the individual begins to recover, and monitoring in a medical facility for at least several hours is advised, even after complete resolution of symptoms and signs.

For more information on the management of anaphylaxis after COVID-19 vaccination, see CDC's website.

Thrombosis with Thrombocytopenia Syndrome

Thrombosis with Thrombocytopenia Syndrome

Background

FDA has added a warning about the possibility of thrombosis with thrombocytopenia syndrome (TTS) to the J&J/Janssen COVID-19 vaccine EUA and fact sheets regarding this syndrome. The EUA fact sheet should be provided to all vaccine recipients and their caregivers before vaccination with any authorized COVID-19 vaccine.

Considerations for Women of Reproductive Age and Pregnant Individuals

Most cases of TTS reported to the Vaccine Adverse Event Reporting System (VAERS) following receipt of the J&J/Janssen COVID-19 vaccine to date have occurred in women of reproductive age. None of these individuals were pregnant. While TTS is a clinically serious condition, it is critical to emphasize the rarity of this syndrome, which has occurred in approximately 8.9 out of every million doses of Janssen COVID-19 vaccine administered to females aged 18-49 years (Shimabukuro, 2021).

Given the low incidence of TTS following vaccination and the high risk of serious illness from COVID-19 infection, women under age 50, including pregnant individuals, can receive any FDA-authorized COVID-19 vaccine available to them. However, they should be aware of the rare risk of TTS after receipt of the J&J/Janssen COVID-19 vaccine and that other FDA-authorized COVID-19 vaccines are available (ie, mRNA vaccines). Patients who choose not to receive the J&J/Janssen COVID-19 vaccine should be strongly encouraged to receive one of the other COVID-19 vaccines available under EUA.

Although the overall general risk of thrombosis is increased during pregnancy and the postpartum period, and with certain hormonal contraceptives, experts believe that these factors do not make people more susceptible to TTS after receipt of the J&J/Janssen COVID-19 vaccine. Given these differing mechanisms, there is no recommendation to discontinue or change hormonal contraceptive methods in women who have received or plan to receive the J&J/Janssen COVID-19 vaccine. Additionally, people who take aspirin or anticoagulants as part of their routine medications, including during pregnancy, do not need to stop or alter the dose of these medications prior to receipt of the J&J/Janssen COVID-19 vaccine (CDC Clinical Considerations).

Diagnosis and Treatment

Patients receiving the J&J/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. Symptoms most commonly appear 6–14

should be counseled to seek immediate medical evaluation. Symptoms most commonly appear 0–14 days following vaccination (ASH).

The American Society for Hematology (ASH) has issued guidance related to diagnosing and managing TTS. Of critical importance, TTS should not be treated with the same drugs used to treat other blood clots. Specifically, heparin should not be used to treat TTS. See the ASH guidance for more details on diagnosis and treatment protocols for TTS.

Myocarditis and Pericarditis

Since April 2021, cases of myocarditis (1 per 100,000) and pericarditis (1.8 per 100,000) have been reported in the United States after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna), particularly in adolescents and young adults (Diaz 2021). There has not been a similar reporting pattern observed after receipt of the J&J/Janssen COVID-19 vaccine. Reported cases have occurred predominantly in male adolescents and young adults aged 16 years and older. Onset was typically within several days after mRNA COVID-19 vaccination, and cases have occurred more often after the second dose than the first dose. Surveillance of these cases following mRNA COVID-19 vaccination are ongoing.

Clinicians should consider the diagnoses of myocarditis and pericarditis in adolescents or young adults with acute chest pain, shortness of breath, or palpitations. In this population, coronary events are less likely to be a source of these symptoms. In most cases, patients who presented for medical care have responded well to medications and rest and had prompt improvement of symptoms. Clinicians should report all cases of myocarditis and pericarditis post COVID-19 vaccination to VAERS.

For more information, see CDC and the American Heart Association.

Guillain-Barré Syndrome

Multiple safety systems have reported a higher-than expected number of cases of Guillain-Barré syndrome following the use of the J&J/Janssen COVID-19 vaccine. However, investigations into this complex diagnosis are ongoing and additional information is needed to fully understand the potential relationship between Guillain-Barré syndrome and the J&J/Janssen COVID-19 vaccine. It appears the absolute risk of Guillain-Barré syndrome following vaccination remains very low (estimated crude reporting rate of 1 per 100,000 doses); therefore, the benefits of prevention of severe COVID-19 illness through vaccination outweigh this very rare risk (Woo 2021).

Available Safety Information Related to the Use of COVID-19 Vaccines in Pregnancy

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 have begun and post-market surveillance is underway.

studies in pregnant women have begun and post-market surveillance is underway.

Developmental and Reproductive Toxicity Data

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 postnatal development (EMA).

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 (FDA).

In a reproductive developmental toxicity study, female rabbits were administered 1 mL of the J&J/Janssen COVID-19 vaccine (a single human dose is 0.5 mL) by intramuscular injection 7 days prior to mating and on gestation days 6 and 20 (ie, one vaccination during early and late gestation, respectively). No vaccine-related adverse effects on female fertility, embryo-fetal or postnatal development up to postnatal day 28 were observed (FDA 2021). Further, based on data from ongoing and completed clinical trials of Ad26-vectored vaccines including COVID-19, HIV, and Ebola administered to pregnant individuals, overall, the Ad26-based vaccines have an acceptable safety and reactogenicity profile, without significant safety issues identified to date. In addition, the review of the available pregnancy data is not suggestive of a pregnancy-related safety concern (FDA 2021).

These DART studies provided the first safety data to help inform the use of the vaccine in pregnancy.

Among participants of Phase II/III COVID-19 vaccine clinical studies in nonpregnant adults, a few inadvertent pregnancies that have occurred are being followed to collect safety outcomes.

Post-Administration Pregnancy Surveillance Data

As of October 25, 2021, there have been nearly 170,000 pregnancies reported in CDC's v-safe post-vaccination health checker (CDC 2021). Based on limited self-reported information, no specific safety signals have been observed in pregnant people enrolled in v-safe; however longitudinal follow-up is needed.

CDC is currently enrolling pregnant individuals in a v-safe pregnancy registry, and as of October 25, 2021, 5,100 pregnant individuals were enrolled. Data collected through February 28 from the v-safe pregnancy registry did not indicate any safety concerns based on the reactogenicity profile and adverse events observed among pregnant individuals. Additionally, side effects were similar in pregnant and nonpregnant populations. Specific neonatal outcomes data published in The New England Journal of Medicine, along with pregnancy complication data from 275 completed pregnancies presented at the March 1, 2021 ACIP meeting are included in Table 3.

No differences have been seen when comparing pregnant individuals participating in the v-safe pregnancy registry with the background rates of adverse pregnancy outcomes. It appears that the spontaneous abortion rate following COVID-19 vaccination during pregnancy is consistent with the background rate; however the ideal denominator has not appeared in published literature (Shimabukuro 2021). Data reported by CDC indicate that the proportion of spontaneous abortions reported after COVID-19 vaccination is consistent with the known background rate of this outcome. However, a risk estimate has not yet been established (Shimabukuro 2021, Zauche 2021).

In addition to data reported from the v-safe pregnancy registry, a case-control study using data from the Vaccine Safety Datalink found that among women with spontaneous abortions, the odds of COVID-19 vaccine exposure were not increased in the prior 28 days compared with women with ongoing pregnancies (Kharbanda 2021).

Table 3. V-safe Pregnancy Registry Outcomes of Interest in COVID-19-Vaccinated Pregnant Individuals

Pregnancy Complications	**Gestational diabetes**
Background Rate	7-14%
V-safe Pregnancy Registry Overall	10%
Pregnancy Complications	**Preeclampsia or gestational hypertension**
Background Rate	10-15%
V-safe Pregnancy Registry Overall	15%

Pregnancy Complications	**Eclampsia**
Background Rate	0.27%
V-safe Pregnancy Registry Overall	0%

Pregnancy Complications	**Intrauterine growth restriction**
Background Rate	3-7%
V-safe Pregnancy Registry Overall	1%

Neonatal Outcomes	**Preterm birth**
Background Rate	8-15%
V-safe Pregnancy Registry Overall	9.4%

Neonatal Outcomes	**Congenital anomalies**
Background Rate	3%
V-safe Pregnancy Registry Overall	2.2%

Neonatal Outcomes	**Small for gestational age**
Background Rate	3.5%
V-safe Pregnancy Registry Overall	3.2%

Neonatal Outcomes	**Neonatal death**
Background Rate	0.38%
V-safe Pregnancy Registry Overall	0%

**Shimabukuro TT, Kim SY, Myers TR, Moro PL, Oduyebo T, Panagiotakopoulos L, et al. Preliminary findings of mRNA Covid-19 vaccine safety in pregnant persons. CDC v-safe COVID-19 Pregnancy Registry Team [published online April 21, 2021]. N Engl J Med. DOI: 10.1056/NEJMoa2104983. Available at: https://www.nejm.org/doi/10.1056/NEJMoa2104983.*

†Shimabukuro T. COVID-19 vaccine safety update. Advisory Committee on Immunization Practices (ACIP), Atlanta, GA;

Shimabukuro T. COVID-19 vaccine safety update. Advisory Committee on Immunization Practices (ACIP). Atlanta, GA: Centers for Disease Control and Prevention; 2021. Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf. Retrieved March 1, 2021.

Evidence will continue to be gathered through these systems and will provide clinicians with critically needed data to inform future recommendations related to COVID-19 vaccination during pregnancy (ACIP slides).

General Recommendations and Considerations

ACOG recommends that all eligible persons greater than age 12 years, including pregnant and lactating individuals, receive a COVID-19 vaccine or vaccine series. Obstetrician–gynecologists and other women's health care practitioners should lead by example by being vaccinated and encouraging eligible patients to be vaccinated as well.

- There is currently no preference for the use of one COVID-19 vaccine over another. However, 12- to 17-year-olds are only eligible to receive the Pfizer-BioNTech vaccine at this time.
- Individuals who receive either the Pfizer-BioNTech or Moderna COVID-19 vaccine should complete their two-dose series with the same vaccine product.
- COVID-19 vaccines may be administered simultaneously with other vaccines, including within 14 days of receipt of another vaccine. This includes vaccines routinely administered during pregnancy, such as influenza and Tdap.
- 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 COVID-19 vaccines or polysorbate) (CDC). Locations administering COVID-19 vaccines should adhere to CDC guidance for use of COVID-19 vaccines, including screening recipients for contraindications and precautions, having the necessary supplies available to manage anaphylaxis, implementing the recommended postvaccination observation periods, and immediately treating suspected cases of anaphylaxis with intramuscular injection of epinephrine (CDC).
- Individuals, including those who are pregnant and/or breastfeeding, with a history of SARS-CoV-2 infection should receive a COVID-19 vaccine.
- 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).
- Obstetrician–gynecologists are encouraged to assess and document patients' COVID-19 vaccination status in the medical record.

- Moderately to severely immunocompromised individuals (ie, people who have undergone solid organ transplantation or have been diagnosed with conditions that are considered to have an equivalent level of immunocompromise) should receive an additional dose (ie, a third dose) of an mRNA COVID-19 vaccine after an initial two-dose primary mRNA COVID-19 vaccine series. The additional dose should be administered at least 28 days after the completion of the initial mRNA COVID-19 vaccine series.
- People aged 65 years and older and residents in long-term care settings who received an mRNA COVID-19 vaccine for their initial series should receive a booster shot of COVID-19 vaccine at least 6 months after their initial series.
- People aged 50–64 years with underlying medical conditions who received an mRNA COVID-19 vaccine for their initial series should receive a booster shot of COVID-19 vaccine at least 6 months after their initial series.
- People aged 18–49 years with underlying medical conditions who received an mRNA COVID-19 vaccine for their initial series may receive a booster shot of COVID-19 vaccine at least 6 months after their initial series, based on their individual benefits and risks (see recommendations for boosters during pregnancy in Obstetric Care Recommendations and Considerations).
- People aged 18–64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting and who received an mRNA COVID-19 vaccine for their initial series may receive a booster shot of COVID-19 vaccine at least 6 months after their initial series, based on their individual benefits and risks. Therefore, health care workers who received an mRNA COVID-19 vaccine for their initial series may receive a booster dose of COVID-19 vaccine at least 6 months after their initial series.
- All individuals aged 18 years and older including pregnant and recently pregnant people who received the J&J/Janssen vaccine as their initial COVID-19 vaccine should receive a single booster dose of COVID-19 vaccine at least 2 months after their initial vaccine.
- Individuals qualifying for a COVID-19 booster may receive any COVID-19 vaccine product available to them; they do not have to receive the same product as their initial vaccine or vaccine series.

Obstetric Care Recommendations and Considerations

Pregnant Individuals

COVID-19 Infection Risk in Pregnancy

COVID-19 Infection Risk in Pregnancy

Pregnant and recently pregnant patients with COVID-19 are at increased risk of more severe illness compared with nonpregnant peers (Ellington MMWR 2020, Collin 2020, Delahoy MMWR 2020, Khan 2021). Available 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 nonpregnant women (Zambrano MMWR 2020, Khan 2021). Pregnant and recently pregnant patients with comorbidities such as obesity and diabetes may be at an even higher risk of severe illness consistent with the general population with similar comorbidities (Ellington MMWR 2020, Panagiotakopoulos MMWR 2020, Knight 2020, Zambrano MMWR 2020, Allotey 2020, Metz 2021, Galang 2021).

COVID-19 Vaccination

ACOG recommends that pregnant individuals be vaccinated against COVID-19. As of October 16, 2021, only about one third of pregnant individuals have been vaccinated against COVID-19 (CDC COVID Data Tracker). Given the potential for severe illness and death during pregnancy, the importance of completion of the initial COVID-19 vaccination series should be emphasized for this population. Obstetrician–gynecologists and other obstetric care providers should routinely assess their pregnant patients' vaccination status. On the basis of 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 (Ciapponi 2021, Wainstock 2021, Kachikis 2021, Magnus 2021). Therefore, individuals who are or will be pregnant should receive the COVID-19 vaccine. Vaccination may occur in any trimester and emphasis should be on vaccine receipt as soon as possible to maximize maternal and fetal health.

COVID-19 Booster During Pregnancy

Due to the potential for severe illness and death from SARS-CoV-2 infection during pregnancy, in addition to waning immunity (ACIP slides), ACOG recommends that pregnant and recently pregnant people up to 6 weeks postpartum, including pregnant and recently pregnant health care workers, receive a booster dose of COVID-19 vaccine following the completion of their initial COVID-19 vaccine or vaccine series. Specifically:

- Pregnant and recently pregnant people who **received J&J/Janssen** vaccine should receive a COVID-19 booster at least 2 months following their initial vaccine.

- Pregnant and recently pregnant people who **received an mRNA** vaccine should receive a booster at least 6 months following their initial vaccine series.

- Pregnant and recently pregnant people can receive any COVID-19 vaccine available to them for their booster dose; it does not have to be the same product as their initial vaccine or vaccine series.
- These recommendations also apply to pregnant and recently pregnant (eg, up to 6 weeks postpartum) individuals who completed their initial COVID-19 vaccine or vaccine series prior to pregnancy.

As stated above, efforts should be focused on increasing the initial series of COVID-19 vaccination among pregnant people.

COVID-19 Vaccine Counseling

Individuals should have access to available information about the safety and efficacy of the vaccine. A conversation between the patient and their clinical team may assist with decisions regarding COVID-19 vaccination during pregnancy. Important considerations include the potential efficacy of the vaccine, the potential risk and severity of maternal disease, including the effects of disease on the fetus and newborn, and the safety of the vaccine for the pregnant patient and the fetus. 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.

When recommending the COVID-19 vaccine, clinicians should review the available data on risks and benefits of vaccination with pregnant patients, including the risks of not getting vaccinated in the context of the individual patient's current health status and risk of exposure, including the possibility for exposure at work or home and the possibility for exposing high-risk household members. Conversations about risk should take into account the individual patient's values and perceived risk of various outcomes and should respect and support autonomous decision-making (ACOG 2013).

Any of the currently authorized COVID-19 vaccines can be administered to pregnant, recently pregnant, or lactating people; ACIP does not state a product preference. However, pregnant, lactating, and recently pregnant people aged <50 years should be aware of the rare risk of TTS after receipt of the J&J/Janssen COVID-19 vaccine and that other FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines) are available.

Additional Vaccination Considerations for Pregnant Individuals

Additional Vaccination Considerations for Pregnant Individuals

- Similar to their nonpregnant peers, vaccination of pregnant individuals with a COVID-19 vaccine may occur in any setting authorized to administer these vaccines. This includes any clinical setting and nonclinical community-based vaccination sites such as schools, community centers, and other mass vaccination locations.
- 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.
- 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.
- 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.

Lactating Individuals

ACOG recommends that lactating individuals be vaccinated against COVID-19. While lactating individuals were not included in most clinical trials, COVID-19 vaccines should not be withheld from lactating individuals who otherwise meet criteria for vaccination. Theoretical concerns regarding the safety of vaccinating lactating individuals do not outweigh the potential benefits of receiving the vaccine, and a growing body of evidence demonstrates that COVID-19 vaccination is safe during lactation (Bertrand 2021, Kachikis 2021). There is no need to avoid initiation or discontinue breastfeeding in patients who receive a COVID-19 vaccine (ABM 2020).

Information for pregnant and lactating patients can be found on ACOG's patient website: Coronavirus (COVID-19), Pregnancy, and Breastfeeding: A Message for Patients.

Gynecologic Care Recommendations and Considerations

Individuals Contemplating Pregnancy

Vaccination is strongly recommended for nonpregnant individuals. Based on the benefit–risk assessment, COVID-19 vaccination continues to be recommended for all persons aged ≥12 years under

the FDA's EUA. Further, ACOG recommends vaccination for individuals who are actively trying to become pregnant or are contemplating pregnancy. Additionally, it is not necessary to delay pregnancy after completing both doses of the COVID-19 vaccine.

Claims linking COVID-19 vaccines to infertility are unfounded and have no scientific evidence supporting them. Given the mechanism of action and the safety profile of the mRNA vaccines in nonpregnant individuals, COVID-19 mRNA vaccines are not a cause of infertility. Adenovirus vector vaccines such as the J&J/Janssen COVID-19 vaccine cannot replicate following administration, and available data demonstrate that it is cleared from tissues following injection. Because it does not replicate in the cells, the vaccine cannot cause infection or alter the DNA of a vaccine recipient and is also not a cause of infertility (Evans, 2021, Morris 2021). Additionally, a growing body of data demonstrate that seropositivity to the SARS-CoV-2 spike protein, whether from vaccination or infection, does not prevent embryo implantation or interfere with early pregnancy development (Morris 2021). Therefore, ACOG recommends vaccination for all eligible people who may consider future pregnancy.

If an individual becomes pregnant after the first dose of a COVID-19 vaccine requiring two doses (Pfizer-BioNTech or Moderna), the second dose should be administered as indicated.

Finally, routine pregnancy testing is not recommended and should not be required prior to receiving any EUA-approved COVID-19 vaccine.

Routine Mammography

Reports of some patients developing temporary contralateral or ipsilateral lymphadenopathy after a COVID-19 vaccination have raised concerns about the possible effect on interpretation of mammogram screening results. A Radiology Expert Scientific Panel has issued a recommendation that mammograms should be conducted prior to COVID-19 vaccination or postponed, if possible, for 4–6 weeks following the second vaccine dose to avoid uncertainty in interpretation of mammogram results.

Screening mammograms are an essential part of preventive care, so postponing screening should only be considered when it does not unduly delay care. If a mammogram is performed fewer than 4–6 weeks after COVID-19 vaccination, patients should inform the mammogram technologist or radiologist when the vaccine was administered, which vaccine was received, and in which arm to aid in interpretation of screening results.

Reports of Post-Vaccination Menstrual Disturbances

There have been anecdotal reports of temporary changes in menstruation patterns (eg, heavier menses,

early or late onset, and dysmenorrhea) in individuals who have recently been vaccinated for COVID-19. While environmental stresses can temporarily impact menses, vaccines have not been previously associated with menstrual disturbances.

ACOG will continue to monitor and evaluate available evidence on this issue. The National Institutes of Health has funded institutions to explore potential links between COVID-19 vaccination and menstrual changes (NIH 2021). Also, an open survey to gather qualitative data on post-vaccination menstrual patterns has been initiated.

Additionally, there is no reason for individuals to schedule their vaccinations based on their menstrual cycles; vaccines can be given to those currently menstruating.

Information for patients can be found on ACOG's patient website: Coronavirus (COVID-19) and Women's Health Care: A Message for Patients.

Health Equity Considerations and Communities of Color

Communities of color have been disproportionately affected by the COVID-19 pandemic. Individuals in communities of color are more likely to have severe illness and even die from COVID-19, likely due to a range of social and structural factors including disparities in socioeconomic status, access to care, rates of chronic conditions, occupational exposures, systemic racism, and historic and continued inequities in the health care system. 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. With time, greater proportions of Black Americans have expressed desire for vaccination such that the majority surveyed affirm their intent for vaccination (Pew Research Center, 2021). Despite intent to obtain vaccination, inequities in vaccine distribution persist. Recent data suggest that, while disparities in access have narrowed over recent months, Black and Latinx populations generally remain vaccinated at lower rates than others, in part related to differential access (Kaiser Family Foundation 2021). With the spread of the more transmissible Delta variant, which most profoundly affects unvaccinated people, equitable vaccine access remains essential.

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 while also addressing misinformation about the vaccine.
- Be knowledgeable of the existing avenues for vaccine access in traditionally underserved

communities.

- 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.

If the patient is amenable to further discussion:

- Inform about the testing process, existing safety data, and continued monitoring of safety and efficacy data on COVID-19 vaccines; there have not been shortcuts with the testing of this vaccine.
- Discuss the increased incidence of infection and severe illness from COVID-19 in communities of color.
- Connect patients to trust-building resources developed by people who may have shared experiences and identities (see below for resource examples).
- Note that individuals from communities of color were included in clinical trials (9.8% of Pfizer-BioNTech overall Phase II/III participants were Black and 26.2% were Hispanic/Latinx; 9.7% of Moderna overall Phase II/III participants were Black and 20% were Hispanic/Latinx; 13% of J&J/Janssen overall Phase II/III participants were Black and 14.7% were Hispanic/Latinx), and the vaccine was equally effective among different demographics, including race and ethnicity

Health Equity Considerations: J&J/Janssen COVID-19 Vaccine

As discussed above, the safety of the J&J/Janssen COVID-19 vaccine has been closely investigated. Along with a discussion of the risk profile, there has been discussion in public health, social, and political spaces about whether young women should avoid the J&J/Janssen vaccine or preferentially choose an mRNA vaccine based on the concerns for TTS. Ultimately, public health officials decided to reaffirm that, in general, there is no preference for one COVID-19 vaccine over another. Limiting vaccine use to specific populations could potentially reduce the number of TTS cases but could also impact vaccine access. The J&J/Janssen COVID-19 vaccine is an effective and safe intervention against COVID-19 that offers flexibility in distribution and implementation. The required refrigerator temperature storage is widely available; this has the potential to impact availability in areas and distribution sites that would otherwise be unable to meet the storage requirements of other vaccine options. Additionally, the impact the one-dose protocol on vaccine uptake and series completion should be accounted for when considering marginalized populations that may face barriers to obtaining a second dose such as those with unstable housing, underresourced geographic areas, or carceral facilities.

Balancing the risk of TTS in women aged 18–49 who receive the J&J/Janssen COVID-19 vaccine with the need for equitable distribution of all effective COVID-19 vaccines requires nuanced evaluations of individual risk profiles. Risk–benefit conversations should include consideration of an individual's likelihood of developing severe disease from COVID-19, barriers they may face to completing a one- or two-dose vaccine series, availability of different vaccine options, as well as an individual's risk tolerance and vaccine acceptance. These discussions are critical to individualized care and ensuring that generalized recommendations do not negatively impact overall vaccine distribution inequities.

All eligible 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.

Additional Health Equity Resources

- American College of Obstetricians and Gynecology. Addressing health equity during the COVID-19 pandemic. Position Statement. Washington, DC: ACOG; 2020. Available at: https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2020/addressing-health-equity-during-the-covid-19-pandemic. Retrieved December 11, 2020.
- American Medical Association. Prioritizing Equity video series: COVID-19 Vaccine & Equitable Distribution. Available at https://www.ama-assn.org/delivering-care/health-equity/prioritizing-equity-video-series-covid-19-vaccine-equitable. Retrieved March 16, 2021.
- Centers for Disease Control and Prevention. Rapid Community Assessment Guide. Available at: https://www.cdc.gov/vaccines/covid-19/vaccinate-with-confidence/rca-guide/index.html. Retrieved March 16, 2021.
- Centers for Disease Control and Prevention. Ensuring Equity in COVID-19 Vaccine Distribution. Available at: https://www.cdc.gov/vaccines/covid-19/planning/health-center-program.html. Retrieved March 16, 2021.
- Centers for Disease Control and Prevention. Health Equity Considerations and Racial and Ethnic Minority Groups. Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html. Retrieved December 13, 2020
- Chandler R, Guillaume D, Parker AG, Mack A, Hamilton J, Dorsey J, et al. The impact of COVID-19

among Black women: evaluating perspectives and sources of information [published online November 5, 2020]. Ethn Health. DOI: 10.1080/13557858.2020.1841120. Available at:

https://www.tandfonline.com/doi/full/10.1080/13557858.2020.1841120. Retrieved December 11, 2020.

- COVID-19 Vaccine Education and Equity Project. Available at: https://covidvaccineproject.org/. Retrieved March 16, 2021.
- Health Resources and Services Administration. Ensuring Equity in COVID-19 Vaccine Distribution. Available at https://www.hrsa.gov/coronavirus/health-center-program. Retrieved March 16, 2021.
- Joint statement on ensuring racial equity in the development and distribution of a COVID-19 vaccine. Health Leads blog. October 26, 2020. Available at: https://healthleadsusa.org/communications-center/blog/joint-statement-on-covid19-vaccine-equity/ . Retrieved December 11, 2020.
- Kaiser Family Foundation. Greater than COVID. Available at: https://www.greaterthancovid.org/. Retrieved March 16, 2021.
- Kaiser Family Foundation. KFF COVID-19 Vaccine Monitor. Available at: https://www.kff.org/coronavirus-covid-19/dashboard/kff-covid-19-vaccine-monitor-dashboard/. Retrieved July 28, 2021.
- Schoch-Spana M, Brunson E, Hosangadi D, Long R, Ravi S, Taylor M, Trotochaud M, Veenema TG on behalf of the Working Group on Equity in COVID-19 Vaccination. Equity in Vaccination: A Plan to Work with Communities of Color Toward COVID-19 Recovery and Beyond. Baltimore, MD: Johns Hopkins Center for Health Security; 2021. https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2021/20210209-CommuniVax-national-report.pdf
- The Colorado Health Foundation. Heartwired: COVID-19 Vaccine Messaging Guide. Available at: https://coloradohealth.org/reports/heartwired-covid-19-vaccine-messaging-guide. Retrieved September 30, 2021.

Vaccine Confidence

Vaccine hesitancy, particularly around COVID-19 vaccines, exists among all populations. When communicating with patients, it is extremely important to underscore the general safety of vaccines and emphasize the fact that no steps were skipped in the development and evaluation of COVID-19 vaccines. This can be done by briefly highlighting the safety requirements of vaccines, and ongoing safety monitoring even after vaccines are made available.

monitoring even after vaccines are made available.

The following are some messages to consider using when discussing COVID-19 vaccines with patients:

- Vaccines are one of the greatest public health achievements of the 20th century. Before the widespread use of vaccines, people routinely died from infectious diseases, several of which have since been eradicated thanks to robust immunization programs.
- All available COVID-19 vaccines are highly effective. Community members may interpret efficacy data to imply that the J&J/Janssen COVID-19 vaccine is inferior to other available vaccines. Individuals should 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.
- Community members may interpret the recent findings related to TTS and the J&J/Janssen COVID-19 vaccine to mean that the vaccine is not safe. However, as described above, these are exceedingly rare events and individuals can receive any of the currently authorized COVID-19 vaccines. Pregnant, lactating, and postpartum people aged <50 years should be aware of the rare risk of TTS after receipt of the J&J/Janssen COVID-19 vaccine and that other FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines) are available.
- Several vaccines have safely been given to pregnant and lactating individuals for decades.
- To date, safety data on COVID-19 vaccines administered during pregnancy do not reveal any safety concerns.
- The rigor of COVID-19 vaccine clinical trials with regards to monitoring safety and efficacy meet the same high standards and requirements as with a typical vaccine approval process.
- While there has been a worldwide attempt to develop COVID-19 vaccines rapidly, this does not mean that any safety standards have been relaxed. In fact, there are additional safety monitoring systems to track and monitor these vaccines, including real-time assessment.
- Side effects such as influenza-like illness can be expected with these vaccines; however, this is a normal reaction as the body develops antibodies to protect itself against COVID-19. COVID-19 vaccines cannot cause COVID-19 infection. It is important not to be dissuaded by these side effects, because in order to get the maximum protection against COVID-19, patients need two doses of the vaccine.
- Safety monitoring continues well beyond the EUA administration.
    - COVID-19 Vaccine Monitoring Systems for Pregnant People
    - CDC V-Safe COVID-19 Vaccine Pregnancy Registry: A registry to collect additional health information from v-safe participants who report being pregnant at the time of vaccination or

a positive pregnancy test after vaccination. This information helps CDC monitor the safety of COVID-19 vaccines in people who are pregnant. V-safe is a new smartphone-based, after-

vaccination health checker for people who receive COVID-19 vaccines. V-safe uses text messaging and web surveys from CDC to check in with vaccine recipients following COVID-19 vaccination. V-safe also provides second vaccine dose reminders if needed, and telephone follow-up for anyone who reports a symptom or health condition for which they seek medical attention.

- CDC's V-Safe: A new active surveillance smartphone-based after-vaccination health checker for people who receive COVID-19 vaccines. V-safe will use text messaging and web surveys from CDC to check in with vaccine recipients for health problems following COVID-19 vaccination. Information on pregnancy status at the time of vaccination and at subsequent follow-up time points will also be collected. The system will provide telephone follow-up to anyone who reports medically significant (important) adverse events or exposure to COVID-19 vaccines during pregnancy or periconception period. As of October 25, 2021, there have been nearly 170,000 pregnancies reported in CDC's v-safe after-vaccination health checker.
- Vaccine Adverse Event Reporting System (VAERS): A national early warning system to detect possible safety problems in U.S.-licensed vaccines. VAERS is co-managed by the CDC and the FDA. Healthcare professionals are encouraged to report any clinically significant adverse events following vaccination to VAERS, even if they are not sure if vaccination caused the event. In addition, we are anticipating that the following adverse events will be required to be reported to VAERS for COVID-19 vaccines administered under an EUA:
    - Vaccine administration errors (whether associated with an adverse event or not)
    - Serious adverse events (irrespective of attribution to vaccination) (such as death, life-threatening adverse event, inpatient hospitalization)
    - Multisystem inflammatory syndrome (MIS) in children (if vaccine is authorized in children) or adults
    - Cases of COVID-19 that result in hospitalization or death
- CDC's National Healthcare Safety Network (NHSN): An acute-care and long-term care facility monitoring system with reporting to VAERS
- Vaccines and Medications in Pregnancy Surveillance System (VAMPSS): A national surveillance system designed to monitor the use and safety of vaccines and asthma medications during pregnancy

- FDA is working with large insurer/payer databases on a system of administrative and claims-based data for surveillance and research

- Additional safety monitoring information can be found at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html.

Additional Resources

- ACOG COVID-19 Patient Education Materials. https://www.acog.org/womens-health/covid-19
- CDC Vaccination Considerations for People who are Pregnant or Breastfeeding. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html
- Baystate Health & University of Massachusetts Medical School COVID-19 Vaccine Decision Tool. https://foamcast.org/covidvacpregnancy/?fbclid=IwAR35gMR8Tdx-qEC2CBGAfNYiTMeRhw7W-x0eGjABEh8eqODTujv49bkuzwE
- Frequently Asked Questions about COVID-19 Vaccination. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html
- CDC's Talking to Recipients about COVID-19 Vaccines. https://www.cdc.gov/vaccines/covid-19/hcp/index.html
- CDC's Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites. https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

---

References

1. Academy of Breastfeeding Medicine. Considerations for COVID-19 vaccination in lactation. ABM Statement. Available at: https://abm.memberclicks.net/abm-statement-considerations-for-covid-19-vaccination-in-lactation. Retrieved December 21, 2020.

2. Advisory Committee on Immunization Practices. ACIP recommendations. Available at: https://www.cdc.gov/vaccines/acip/recommendations.html. Retrieved December 11, 2020.

3. Advisory Committee on Immunization Practices. Thrombosis with thrombocytopenia syndrome (TTS) following Janssen COVID-19 vaccine. Atlanta, GA: ACIP; 2021. Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-04-23/03-COVID-Shimabukuro-508.pdf. Retrieved April 27, 2021.

4. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine — United States, December 21, 2020–January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021.

5. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020. MMWR Morb Mortal Wkly Rep 2021;70:46–51.

6. Allotey J, Stallings E, Bonet M, Yap M, Chatterjee S, Kew T, et al. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis. BMJ 2020;370:m3320. Available at: http://www.bmj.com/content/370/bmj.m3320.abstract. Retrieved June 4, 2021.

7. American Society of Hematology. Thrombosis with thrombocytopenia syndrome (also termed vaccine-induced thrombotic thrombocytopenia). Available at: https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia. Retrieved April 27, 2021.

8. Bertrand K, Honerkamp-Smith G, Chambers CD. Maternal and child outcomes reported by breastfeeding women following messenger RNA COVID-19 vaccination. Breastfeed Med 2021;16:697–701. doi: 10.1089/bfm.2021.0169.

9. Centers for Disease Control and Prevention. COVID-19 (coronavirus disease): people with certain medical conditions. Available at: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html. Retrieved December 11, 2020.

10. Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19): people with certain medical conditions. Available at: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html. Retrieved December 7, 2020.

11. Centers for Disease Control and Prevention. Local reactions, systemic reactions, adverse events, and serious adverse events: Pfizer-BioNTech COVID-19 Vaccine. Available at: https://www.cdc.gov/vaccines/covid-19/info-by-manufacturer/pfizer/reactogenicity.html. Retrieved December 13, 2020

12. Centers for Disease Control and Prevention. Understanding mRNA COVID-19 Vaccines. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html. Retrieved December 13, 2020

13. Centers for Disease Control and Prevention. Health equity considerations and racial and ethnic minority groups. Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html. Retrieved December 13, 2020

14. Centers for Disease Control and Prevention. ACIP COVID-19 Vaccines Work Group. Phased allocation of COVID-19 vaccines. Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-20/02-COVID-Dooling.pdf. Retrieved December 21, 2020.

15. Ciapponi A, Bardach A, Mazzoni A, Alconada T, Anderson SA, Argento FJ, et al. Safety of components and platforms of COVID-19 vaccines considered for use in pregnancy: a rapid review. Vaccine 2021;39:5891–908. doi: 10.1016/j.vaccine.2021.08.034.

16. Collin J, Byström E, Carnahan A, Ahrne M. Public Health Agency of Sweden's Brief Report: pregnant and postpartum women with severe acute respiratory syndrome coronavirus 2 infection in intensive care in Sweden. Acta Obstet Gynecol Scand 2020;99:819-22. Available at: https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/aogs.13901. Retrieved December 11, 2020.

17. Delahoy MJ, Whitaker M, O'Halloran A, Chai SJ, Kirley PD, Alden N, et al. Characteristics and maternal and birth outcomes of hospitalized pregnant women with laboratory-confirmed COVID-19 - COVID-NET, 13 states, March 1-August 22, 2020. COVID-NET Surveillance Team. MMWR Morb Mortal Wkly Rep 2020;69:1347-54. Available at: https://www.cdc.gov/mmwr/volumes/69/wr/mm6938e1.htm. Retrieved December 11

at: https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e1.htm. Retrieved December 11, 2020.

18. Diaz GA, Parsons GT, Gering SK, et al. Myocarditis and pericarditis after vaccination for COVID-19. JAMA 2021;326(12):1210–1212.

19. Dooling K, Marin M, Wallace M, et al. The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID-19 Vaccine — United States, December 2020. MMWR Morb Mortal Wkly Rep 2021;69:1657-1660. DOI: http://dx.doi.org/10.15585/mmwr.mm695152e2

20. Ellington S, Strid P, Tong VT, Woodworth K, Galang RR, Zambrano LD, et al. Characteristics of women of reproductive age with laboratory-confirmed SARS-CoV-2 infection by pregnancy status - United States, January 22-June 7, 2020. MMWR Morb Mortal Wkly Rep 2020;69:769-75. Available at: https://www.cdc.gov/mmwr/volumes/69/wr/mm6925a1.htm. Retrieved December 11, 2020.

21. Ethical issues in pandemic influenza planning concerning pregnant women. Committee Opinion No. 563. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;121:1138-43. Available at: https://journals.lww.com/greenjournal/Fulltext/2013/05000/Committee_Opinion__No__563__Ethical_Issues_in.47.aspx. Retrieved December 11, 2020.

22. European Medicines Agency. COVID-19 vaccine Moderna. Annex I: summary of product characteristics. Amsterdam: EMA; 2021. Available at: https://ec.europa.eu/health/documents/community-register/2020/20201221150522/anx_150522_en.pdf. Retrieved January 27, 2021.

23. Evans MB, Alexander C, Barnard E, Ezzati MM, Hill MJ, Hoyos LR, et al. COVID-19 vaccine and infertility: baseless claims and unfounded social media panic. Washington, DC: American Society for Reproductive Medicine; 2021. Available at: https://www.fertstertdialog.com/posts/covid-19-vaccine-and-infertility-baseless-claims-and-unfounded-social-media-panic. Retrieved March 9, 2021.

24. Gray KJ, Bordt EA, Atyeo C, Deriso E, Akinwunmi B, Young N, et al. COVID-19 vaccine response in pregnant and lactating women: a cohort study [published online March 24, 2021]. Am J

in pregnant and lactating women: a cohort study [published online March 24, 2021]. Am J Obstet Gynecol. DOI: 10.1016/j.ajog.2021.03.023. Available at: https://www.ajog.org/article/S0002-9378(21)00187-3/fulltext. Retrieved April 27, 2021.

25. Hamel L, Lopes L, Muñana C, Artiga S, Brodie B. The undefeated survey on race and health. San Francisco, CA: Kaiser Family Foundation; 2020. Available at: https://www.kff.org/report-section/kff-the-undefeated-survey-on-race-and-health-main-findings/. Retrieved December 11, 2020.

26. Juncker HG, Mulleners SJ, van Gils MJ, et al. The Levels of SARS-CoV-2 Specific Antibodies in Human Milk Following Vaccination. Journal of Human Lactation. June 2021. Available at: https://journals.sagepub.com/doi/full/10.1177/08903344211027112. Retrieved July 28, 2021.

27. Kachikis A, Englund JA, Singleton M, Covelli I, Drake AL, Eckert LO. Short-term reactions among pregnant and lactating individuals in the first wave of the COVID-19 vaccine rollout. JAMA Netw Open 2021;4:e2121310. doi: 10.1001/jamanetworkopen.2021.21310.

28. Kharbanda EO, Haapala J, DeSilva M, Vazquez-Benitez G, Vesco KK, Naleway AL, et al. Spontaneous abortion following COVID-19 vaccination during pregnancy [published erratum appears in JAMA 2021 Sep 10]. JAMA 2021. doi: 10.1001/jama.2021.15494.

29. Knight M, Bunch K, Vousden N, Morris E, Simpson N, Gale C, et al. Characteristics and outcomes of pregnant women admitted to hospital with confirmed SARS-CoV-2 infection in UK: national population based cohort study. UK Obstetric Surveillance System SARS-CoV-2 Infection in Pregnancy Collaborative Group. BMJ 2020;369:m2107. Available at: https://www.bmj.com/content/369/bmj.m2107. Retrieved December 11, 2020.

30. Magnus MC, Gjessing HK, Eide HN, Wilcox AJ, Fell DB, Håberg SE. Covid-19 vaccination during pregnancy and first-trimester miscarriage [letter]. N Engl J Med 2021. doi: 10.1056/NEJMc2114466

31. ModernaTX. Fact sheet for healthcare providers administering vaccine (vaccination providers) emergency use authorization (EUA) of the Moderna COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). Cambridge, MA: ModernaTX; 2020. Available at: https://www.fda.gov/media/144637/download. Retrieved December 21, 2020.

32. ModernaTX. Fact sheet for recipients and caregivers emergency use authorization (EUA) of the Moderna COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19) in individuals

18 years of age and older. Cambridge, MA: ModernaTX; 2020. Available at: https://www.fda.gov/media/144638/download. Retrieved December 21, 2020.

33. Moore JT, Ricaldi JN, Rose CE, Fuld J, Parise M, Kang GJ, et al. Disparities in incidence of COVID-19 among underrepresented racial/ethnic groups in counties identified as hotspots during June 5-18, 2020 - 22 states, February-June 2020. COVID-19 State, Tribal, Local, and Territorial Response Team. MMWR Morb Mortal Wkly Rep 2020;69:1122-6. Available at: https://www.cdc.gov/mmwr/volumes/69/wr/mm6933e1.htm. Retrieved December 11, 2020.

34. Oliver S, Gargano J, Marin M, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine — United States, December 2020. MMWR Morb Mortal Wkly Rep. ePub: 20 December 2020. doi: http://dx.doi.org/10.15585/mmwr.mm695152e1.

35. Oliver SE, Gargano JW, Scobie H, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021. MMWR Morb Mortal Wkly Rep. ePub: 2 March 2021. doi: http://dx.doi.org/10.15585/mmwr.mm7009e4.

36. Panagiotakopoulos L, Myers TR, Gee J, Lipkind HS, Kharbanda EO, Ryan DS, et al. SARS-CoV-2 infection among hospitalized pregnant women: reasons for admission and pregnancy characteristics - eight U.S. health care centers, March 1-May 30, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1355-9. Available at: https://www.cdc.gov/mmwr/volumes/69/wr/mm6938e2.htm. Retrieved December 11, 2020.

37. Pfizer-BioNTech COVID-19 vaccine (BNT162, PF-07302048). Vaccines and Related Biological Products Advisory Committee briefing document. Available at: https://www.fda.gov/media/144246/download. Retrieved December 11, 2020.

38. Prabhu M, Murphy EA, Sukhu AC, Yee J, Singh S, Eng D, et al. Antibody response to coronavirus disease 2019 (COVID-19) messenger RNA vaccination in pregnant women and transplacental

disease 2019 (COVID-19) messenger RNA vaccination in pregnant women and transplacental passage into cord blood [published online April 28, 2021]. Obstet Gynecol. DOI: 10.1097/AOG.0000000000004438. Available at:

https://journals.lww.com/greenjournal/Fulltext/9900/Antibody_Response_to_Coronavirus_Disease_2019.184.aspx. Retrieved June 4, 2021.

39. Schlake T, Thess A, Fotin-Mleczek M, Kallen KJ. Developing mRNA-vaccine technologies. RNA Biol. 2012;9(11):1319-1330. doi:10.4161/rna.22269. U.S. Food and Drug Administration. December 11, 2020 communication to Pfizer Inc. Available at: https://www.fda.gov/media/144412/download. Retrieved December 13, 2020

40. Shimabukuro T. COVID-19 vaccine safety update. Advisory Committee on Immunization Practices (ACIP). Atlanta, GA: Centers for Disease Control and Prevention; 2021. Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf. Retrieved March 1, 2021.

41. Shimabukuro TT, Kim SY, Myers TR, Moro PL, Oduyebo T, Panagiotakopoulos L, et al. Preliminary findings of mRNA Covid-19 vaccine safety in pregnant persons. CDC v-safe COVID-19 Pregnancy Registry Team [published online April 21, 2021]. N Engl J Med. DOI: 10.1056/NEJMoa2104983. Available at: https://www.nejm.org/doi/10.1056/NEJMoa2104983. Retrieved April 27, 2021.

42. U.S. Food and Drug Administration. Fact sheet for healthcare providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Pfizer-Biontech COVID-19 vaccine to prevent Coronavirus Disease 2019 (COVID-19). Available at: https://www.fda.gov/media/144413/download. Retrieved December 13, 2020

43. U.S. Food and Drug Administration. Fact Sheet for Recipients and Caregivers. Emergency Use Authorization (EUA) of the Pfizer-Biontech COVID-19 vaccine to prevent Coronavirus Disease 2019 (COVID-19) in individuals 16 years of age and older. Available at: https://www.fda.gov/media/144414/download. Retrieved December 13, 2020

44. U.S. Food and Drug Administration. Emergency Use Authorization of medical products and related authorities. Monitoring and reporting of adverse events. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#monitoring. Retrieved December

use authorization medical products and related authorities#monitoring. Retrieved December 13, 2020

45. U.S. Food and Drug Administration. FDA briefing document: Moderna COVID-19 vaccine. Silver Spring, MD: FDA; 2020. Available at: https://www.fda.gov/media/144434/download. Retrieved December 18, 2020.

46. U.S. Food and Drug Administration. Moderna COVID-19 vaccine EUA. Letter of authorization. Silver Spring, MD: FDA; 2020. Available at: https://www.fda.gov/media/144636/download. Retrieved December 21, 2020.

47. U.S. Food and Drug Administration. Janssen COVID-19 vaccine EUA letter of authorization. Silver Spring, MD: FDA; 2021. Available at: https://www.fda.gov/media/146303/download. Retrieved March 1, 2021.

48. U.S. Food and Drug Administration. Fact sheet for healthcare providers administering vaccine (vaccination providers). Emergency use authorization (EUA) of the Janssen COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). Silver Spring, MD: FDA; 2021. Available at: https://www.fda.gov/media/146304/download. Retrieved March 1, 2021.

49. U.S. Food and Drug Administration. Fact sheet for recipients and caregivers. Emergency use authorization (EUA) of the Janssen COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19) in individuals 18 years of age and older. Silver Spring, MD: FDA; 2021. Available at: https://www.fda.gov/media/146305/download. Retrieved March 1, 2021.

50. U.S. Food and Drug Administration. COVID-19 vaccine Ad26.COV2.S VAC31518 (JNJ-78436735) sponsor briefing document. Vaccines and Related Biological Products Advisory Committee meeting. Silver Spring, MD: FDA; 2021. Available at: https://www.fda.gov/media/146219/download. Retrieved March 1, 2021.

51. Wainstock T, Yoles I, Sergienko R, Sheiner E. Prenatal maternal COVID-19 vaccination and pregnancy outcomes. Vaccine 2021;39:6037-40. doi: 10.1016/j.vaccine.2021.09.012.

52. Woo EJ, Mba-Jonas A, Dimova RB, Alimchandani M, Zinderman CE, Nair N. Association of Receipt of the Ad26.COV2.S COVID-19 Vaccine With Presumptive Guillain-Barré Syndrome, February-July 2021. JAMA 2021;326(16):1606-1613. Doi: 10.1001/jama.2021.16496

53. Zambrano LD, Ellington S, Strid P, Galang RR, Oduyebo T, Tong VT, 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. CDC COVID-19 Response Pregnancy and Infant Linked Outcomes Team. MMWR Morb Mortal Wkly Rep 2020;69:1641-7. Available at: https://www.cdc.gov/mmwr/volumes/69/wr/mm6944e3.htm. Retrieved December 11, 2020.

54. Zauche LH, Wallace B, Smoots AN, Olson CK, Oduyebo T, Kim SY, et al. Receipt of mRNA Covid-19 vaccines and risk of spontaneous abortion. CDC v-safe Covid-19 Pregnancy Registry Team. N Engl J Med 2021. doi: 10.1056/NEJMc2113891.

55. Zhang C, Maruggi G, Shan H and Li J (2019) Advances in mRNA Vaccines for Infectious Diseases. Front. Immunol. 10:594. doi: 10.3389/fimmu.2019.00594

A Practice Advisory is a brief, focused statement issued to communicate a change in ACOG guidance or information on an emergent clinical issue (eg, clinical study, scientific report, draft regulation). A Practice Advisory constitutes ACOG clinical guidance and is issued only on-line for Fellows but may also be used by patients and the media. Practice Advisories are reviewed periodically for reaffirmation, revision, withdrawal or incorporation into other ACOG guidelines.

This information is designed as an educational resource to aid clinicians in providing obstetric and gynecologic care, and use of this information is voluntary. This information should not be considered as inclusive of all proper treatments or methods of care or as a statement of the standard of care. It is not intended to substitute for the independent professional judgment of the treating clinician. Variations in practice may be warranted when, in the reasonable judgment of the treating clinician, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology. The American College of Obstetricians and Gynecologists reviews its publications regularly; however, its publications may not reflect the most recent evidence. Any updates to this document can be found on www.acog.org or by calling the ACOG Resource Center.

While ACOG makes every effort to present accurate and reliable information, this publication is provided "as is" without any warranty of accuracy, reliability, or otherwise, either express or implied. ACOG does not guarantee, warrant, or endorse the products or services of any firm, organization, or person. Neither ACOG nor its officers, directors, members, employees, or agents will be liable for any loss, damage, or claim with respect to any liabilities, including direct, special, indirect, or consequential damages, incurred in connection with this publication or reliance on the information presented.

Publications of the American College of Obstetrician and Gynecologists are protected by copyright and all rights are reserved. The College's publications may not be reproduced in any form or by any means without written permission from the copyright owner.

The American College of Obstetricians and Gynecologists (ACOG), is the nation's leading group of physicians providing health care for women. As a private, voluntary, nonprofit membership organization of more than 58,000 members, ACOG strongly advocates for quality health care for women, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing

women's health care. www.acog.org

Topics COVID-19 Coronavirus Vaccine-preventable diseases Immunization Lactation

American College of Obstetricians and Gynecologists
409 12th Street SW, Washington, DC 20024-2188

Copyright 2021. All rights reserved.
Privacy Statement | Terms and Conditions of Use