COVID-19 Vaccination Considerations for Obstetric–Gynecologic Care

Practice Advisory.

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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

ACOG recommends that all eligible persons, 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.

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, recently pregnant, and nonpregnant individuals.

- The U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the following vaccines:
    - Pfizer-BioNtech mRNA vaccine (BNT162b2): for use in individuals age 12 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.
    - Janssen Biotech, Inc. (Johnson & Johnson) Ad26.COV2.S vaccine: for use in individuals age 18 and older as a single dose regimen.
- After an explicit, evidence-based review of all available data, the Advisory Committee on Immunization Practices (ACIP) has 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 Janssen (Johnson & Johnson) COVID-19 vaccine in persons aged ≥ 18 years (CDC 2021).

- ACOG strongly recommends that all eligible persons 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.
- ACOG recommends that pregnant individuals be vaccinated against COVID-19.
- ACOG recommends that lactating individuals be vaccinated against COVID-19.
- While a conversation with a clinician may be helpful, it is not a requirement prior to vaccination, as this may cause unnecessary barriers to access.
- Similar to their non-pregnant 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 non-clinical community-based vaccination sites such as schools, community centers, and other mass vaccination locations.
- Pregnancy testing is not a requirement prior to receiving any EUA-approved COVID-19 vaccine.
- Claims linking COVID-19 vaccines to infertility are unfounded and have no scientific evidence supporting them. ACOG recommends vaccination for all eligible people who may consider future pregnancy.
- 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.
- Expected side effects should be explained as part of counseling patients, including that they are a normal part of the body's reaction to the vaccine and developing antibodies to protect against COVID-19 illness.
- 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 thrombosis with thrombocytopenia syndrome (TTS) after receipt of the Janssen COVID-19 vaccine and that other FDA-authorized COVID-19 vaccines are available (i.e., mRNA vaccines).
- Obstetrician-gynecologists are encouraged to assess and document patients' COVID-19 vaccination status.
- 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.

COVID-19 Vaccine Authorization Overview

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 Recommendations

The Advisory Committee on Immunization Practices (ACIP) develops recommendations on how to use vaccines to control disease in the United States. The Committee's recommendations are sent to CDC's Director for approval. Once the ACIP recommendations have been reviewed and approved by the CDC Director and the U.S. Department of Health and Human Services, they are published in CDC's Morbidity and Mortality Weekly Report (MMWR). The MMWR publication represents the final and official CDC recommendations for immunization of the U.S. population (ACIP). ACOG has representation on the ACIP, including on the ACIP COVID-19 working groups and safety monitoring group.

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 Janssen (Johnson & Johnson) COVID-19 vaccine in persons aged ≥ 18 years (CDC 2021).

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 12 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.
- **Janssen Biotech Inc. (Johnson & Johnson)** monovalent vaccine (Ad26.COV2.S): for use in individuals age 18 years and older as a single dose regimen.

See 'Thrombosis with Thrombocytopenia Syndrome' below for more information on the rare clotting events associated with the Janssen Biotech Inc. COVID-19 vaccine.

The EUA authority allows the FDA to strengthen the nation's public health protections against chemical, biological, radiological, and nuclear (CBRN) threats by facilitating the availability and use of medical countermeasures needed during public health emergencies.

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives (FDA 2017).

Data on the safety and effectiveness of the vaccine(s) continues to be collected during the EUA period (FDA 2017).

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 & 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 non-pregnant 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 (Janssen Biotech Inc.)

The Janssen (Johnson & Johnson) 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 severe acute respiratory syndrome coronavirus-2 (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 non-pregnant 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 breastmilk 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.

Adenovirus-vector vaccines

Based on the results from clinical trials in the U.S., the 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% effective 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 below). In the Pfizer-BioNtech study subgroup of persons age 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 Janssen Biotech Inc. COVID-19 vaccine were generally mild and transient, resolving in 1-2 days following vaccination among safety study participants. In the Janssen Biotech Inc. 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 1. Mild Side Effects Among All Study Participants*

	Injection Site Reactions	Fatigue	Chills	Muscle Pain	Joint Pain	Headaches
Moderna	91.6%	68.5%	43.4%	59.6%	44.8%	63%
Pfizer-BioNTech	84.10%	62.90%	31.90%	38.30%	23.60%	55.10%
Janssen Biotech Inc.	48.6%	38.2%	N/A	33.2%	N/A	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 non-pregnant individuals. For the Pfizer-BioNtech vaccine, through January 18, 2021, nearly 10 million doses were administered, and monitoring by the Vaccine Adverse Event Reporting System detected 50 cases (5.0 cases per million doses administered) of anaphylaxis following vaccination (ACIP Slides). For the Moderna vaccine, through January 18, 2021, over 7.5 million doses were administered, and monitoring by the Vaccine Adverse Event Reporting System detected 28 cases (2.8 cases per million doses administered) of anaphylaxis following vaccination (ACIP Slides).

Anaphylaxis was not reported among any of the clinical trial participants for the Janssen COVID-19 vaccine. Allergic reactions and anaphylaxis rates will be monitored for the Janssen COVID-19 vaccine and information will be updated as soon as it is available (FDA 2021).

If anaphylaxis is suspected in a pregnant individual after receiving a COVID-19 vaccination, anaphylaxis should be managed the same as non-pregnant 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 non-pregnant 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 (TTS)

Background

FDA has added a warning about the possibility of Thrombosis with Thrombocytopenia Syndrome (TTS) to the 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 VAERS following receipt of the 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 age 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 Janssen COVID-19 vaccine and that other FDA-authorized COVID-19 vaccines are available (i.e., mRNA vaccines). Patients who choose not to receive the 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 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 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 Janssen COVID-19 vaccine (CDC Clinical Considerations).

Diagnosis and Treatment

Patients receiving the Janssen COVID-19 vaccine should be informed of symptoms of TTS, including severe headache, visual changes, abdominal pain, nausea and vomiting,

back pain, shortness of breath, leg pain or swelling, petechiae, easy bruising, or bleeding. Patients who experience these symptoms should be counseled to seek immediate medical evaluation. Symptoms most commonly appear 6-14 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.

Guillain-Barré Syndrome

Multiple safety systems have reported a higher-than expected number of cases of Guillain-Barré syndrome following the use of the Janssen COVID-19 vaccine. However, investigations into this complex diagnosis are ongoing and additional information is needed to fully understand the potential relationship between Guillain-Barré syndrome and the Janssen COVID-19 vaccine. It appears the absolute risk of Guillain-Barré syndrome following vaccination remains very low; therefore, the benefits of prevention of severe COVID-19 illness through vaccination outweigh this very rare risk.

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.

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 post-natal 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 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 (i.e., 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 provide the first safety data to help inform the use of the vaccine in pregnancy until there are more data in this population.

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

V-safe and V-safe Pregnancy Registry Data

As of July 19, 2021, there have been over 136,500 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 July 19, 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 non-pregnant 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 2.

Further, 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. Data reported by CDC indicates that the proportion of spontaneous abortions reported after COVID-19 vaccination are consistent with the known background rate of this outcome. However, a risk estimate has not yet been established.

Table 2. V-safe pregnancy registry outcomes of interest in COVID-19 vaccinated pregnant individuals

Pregnancy Complications†	Background Rate	V-safe Pregnancy Registry Overall
Gestational diabetes	7-14%	10%
Preeclampsia or gestational hypertension	10-15%	15%
Eclampsia	0.27%	0%
Intrauterine growth restriction	3-7%	1%
Neonatal Outcomes*	**Background Rate**	**V-safe Pregnancy Registry Overall**
Preterm birth	8-15%	9.4%
Congenital anomalies	3%	2.2%
Small for gestational age	3.5%	3.2%
Neonatal death	0.38%	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: 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

COVID-19 vaccines are available to all people 12 and older. ACOG strongly recommends that all eligible persons 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, 12-17 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 2-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 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.

Obstetric Care Recommendations and Considerations

Pregnant Individuals

COVID-19 Infection Risk in Pregnancy

Available data suggest that symptomatic 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). 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 (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. Obstetrician–gynecologists and other obstetric care providers should routinely assess their pregnant patients' vaccination status. Based on this assessment they should recommend needed vaccines to their pregnant patients. There is no evidence of adverse maternal or fetal effects from vaccinating pregnant individuals with COVID-19 vaccine, and a growing body of data demonstrate the safety of such use. Therefore, individuals who are or will be pregnant should receive the COVID-19 vaccine. While pregnant individuals are encouraged to discuss vaccination considerations with their clinical care team when feasible, written permission or documentation of such a discussion should not be required prior to receiving a COVID-19 vaccine.

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 the use of vaccines approved under EUA for the prevention of COVID-19 by pregnant patients. 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 a conversation with a clinician may be helpful, it should not be required prior to vaccination as this may cause unnecessary barriers to access.

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 Janssen COVID-19 vaccine and that other FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines) are available.

Additional Vaccination Considerations for Pregnant Individuals

- Similar to their non-pregnant 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 non-clinical 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. There is no need to avoid initiation or discontinue breastfeeding in patients who receive a COVID-19 vaccine (ABM 2020).

Gynecologic Care Recommendations and Considerations

Individuals Contemplating Pregnancy

Vaccination is strongly recommended for non-pregnant 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 non-pregnant individuals, COVID-19 mRNA vaccines are not a cause of infertility. Adenovirus vector vaccines such as the 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). 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 has 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 placed a special call for research focused on this issue. 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.

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, with Black and Latinx populations generally vaccinated at lower rates than others, in part related to differential access (KFF, 2021).

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
- Be knowledgeable of the existing avenues for vaccine access in traditionally underserved communities
- Continue to support patients who decide not to be vaccinated, share resources, and encourage the continued use of prevention measures

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

- 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 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: Janssen COVID-19 Vaccine

As discussed above, the safety of the 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 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 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 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

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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

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. 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 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 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 post-partum people aged <50 years should be aware of the rare risk of TTS after receipt of the 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 July 19, 2021, there have been over 136,500 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 Emergency Use Authorization (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 the Vaccine Adverse Event Reporting System or 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 here: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

Additional Resources

- 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

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