



Association of  
Immunization  
Managers



## Fertility, Pregnancy, and COVID-19 Vaccines

*August 4, 2021*

### Key Points for Public Health Practitioners

- Pregnant patients are at increased risk of becoming very ill from COVID-19 disease, being hospitalized in the ICU, needing a ventilator, having complications in their pregnancy, having a preterm baby, and possibly dying from COVID-19.
- There is no scientific evidence to support the rumor that COVID-19 vaccines affect the fertility of men or women or the ability of a person to become pregnant.
- There are three COVID-19 vaccines currently authorized by the FDA for use: Pfizer, Moderna, and Johnson and Johnson (J&J). These vaccines:
  - Do not replicate (or make copies of the COVID-19 virus) in our bodies.
  - Will not cause a pregnant person or their unborn baby to get COVID-19 disease.
  - Do not alter a person's DNA.
- The American College of Obstetricians and Gynecologists (ACOG) recommends that all pregnant individuals be vaccinated against COVID-19. The organization stands in support of vaccination during pregnancy based on the demonstrated safe use during pregnancy shown in tens of thousands of people.
- The current low vaccination rates and concerning increase in cases due to the delta variant make getting vaccinated during pregnancy even more important. ACOG says that, "Pregnant individuals who have decided to wait until after delivery to be vaccinated may be inadvertently exposing themselves to an increased risk of severe illness or death."
- The Pfizer, Moderna, and J&J COVID-19 vaccines were not tested in pregnant people during clinical trials. However, many pregnant people have been vaccinated among the millions of people who have received authorized vaccines. Based on reports as of June 2021, pregnant people who have been vaccinated

have similar side effects (headache, fever, sore arm) as non-pregnant people.

Reports from pregnant people:

- Have NOT shown any safety concerns in those who have received a COVID-19 vaccine during pregnancy.
  - There has NOT been an increase in miscarriage nor stillbirths, nor other pregnancy complications.
  - There has NOT been an increase in preterm births or birth defects among those vaccinated.
- Several national organizations—including ACOG, the Centers for Disease Control and Prevention (CDC), the American Academy of Family Physicians, and the American College of Nurse-Midwives—urge that COVID-19 vaccines be made available and accessible to pregnant individuals and that pregnant individuals should strongly consider taking the vaccine.
  - ACOG recommends COVID-19 vaccination for persons who are breastfeeding.

## COVID-19 Disease and Pregnancy

- Pregnant patients with COVID-19 are at increased risk of more severe illness compared with nonpregnant patients.
- Pregnant patients with COVID-19 are at increased risk of being hospitalized, being admitted to the intensive care unit (ICU), needing to be on a ventilator, and dying.
- Pregnant patients with comorbidities such as obesity and diabetes may be at an even higher risk of severe illness.
- The risk of preterm birth and pregnancy complications, such as preeclampsia, blood clots, and stillbirth, increases in pregnant patients who develop COVID-19 disease.

## How COVID-19 Vaccines Work

- The COVID-19 vaccines encourage the human body to create copies of the spike protein found on the coronavirus's surface. This “teaches” the body's immune system to fight the virus that has that specific spike protein on it, if you are exposed to the actual coronavirus in the future.
- None of the three authorized COVID-19 vaccines are live vaccines. They cannot replicate (make copies of themselves in your body).
- The mRNA 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.
- Adenovirus vector vaccines, such as the J&J vaccine, cannot replicate once they get into your body. The vector (which carries the instructions for “teaching” your

body to fight the virus) is cleared from your body after you are injected with the vaccine. Because it does not replicate in the cells, the vaccine cannot cause infection or alter your DNA.

## Pre-Pregnancy/Fertility and COVID-19 Vaccines

- There is no scientific evidence to support the claim that COVID-19 vaccines affect fertility and the ability to get pregnant. ACOG [recommends](#) vaccination for all those considering getting pregnant in the future.
- It is not necessary to delay becoming pregnant after completing both doses of the COVID-19 vaccine.

### Where did this rumor about infertility come from?

According to doctors at the Children's Hospital of Philadelphia's [Vaccine Education Center, CHOP](#):

*Confusion arose when a false report surfaced on social media, saying that the spike protein on this coronavirus was the same as another spike protein called syncitin-1 that is involved in the growth and attachment of the placenta during pregnancy. The false report said that getting the COVID-19 vaccine would cause a woman's body to fight this different spike protein and affect her fertility. The two spike proteins are completely different and distinct, and getting the COVID-19 vaccine will not affect the fertility of women who are seeking to become pregnant, including through in vitro fertilization methods. During the Pfizer vaccine tests, 23 women volunteers involved in the study became pregnant, and the only one who suffered a pregnancy loss had not received the actual vaccine, but a placebo.*

*Getting COVID-19, on the other hand, can have potentially serious impact on pregnancy and the mother's health.*

## Vaccine Effects on the Menstrual Cycle

- There have been stories of COVID-19 vaccines causing temporary changes in menstrual periods, such as heavier periods, early or late periods, and missed periods. According to ACOG, many factors can cause period changes, but vaccines have not previously been linked with period problems.
- ACOG plans to continue to monitor and evaluate available evidence on this issue. The National Institutes of Health has asked for further research in this area.
- There is no reason for individuals to schedule their vaccinations based on their menstrual cycles. Vaccines can be given to those currently menstruating.

## Recommendations for Use of COVID-19 Vaccines in Pregnant and Breastfeeding Patients

- The American College of Obstetricians and Gynecologists (ACOG) recommends that all pregnant individuals be vaccinated against COVID-19. The organization stands in support of vaccination during pregnancy based on the demonstrated safe use during pregnancy shown in tens of thousands of people.
- Pregnant individuals were not included in clinical trials of any of the vaccines currently available under emergency use authorization (EUA), but studies are underway. The organizations' recommendations in support of vaccination during pregnancy reflect evidence demonstrating the safe use of the COVID-19 vaccines during pregnancy from tens of thousands of reporting individuals over the last several months, as well as the current low vaccination rates and concerning increase in cases.
- While there are limited safety data available about COVID-19 vaccines and pregnancy, no data to date have suggested that the vaccines cannot be used in pregnant people.
- No safety signals were generated from Developmental and Reproductive Toxicity (DART) studies, nor from data from v-safe, the v-safe pregnancy registry, and other surveillance mechanisms among the thousands of pregnant women who have chosen to receive a COVID-19 vaccine.
- COVID-19 vaccines cannot cause infection in either the mother or the fetus.
- ACOG recommends that pregnant individuals be free to make their own decision regarding COVID-19 vaccination. While pregnant individuals are encouraged to discuss vaccination considerations with their clinical care team when feasible, written permission or documentation of such a discussion should not be required prior to receiving a COVID-19 vaccine.
- Individuals considering a COVID-19 vaccine should have access to available information about the safety and efficacy of the vaccine, including information about data that are not available. [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, but this conversation is not required.
- Clinicians should review the available data on risks and benefits of vaccination with pregnant patients, including the risks of not getting vaccinated.
- Side effects can occur in pregnant people after receiving COVID-19 vaccine similar to those expected in non-pregnant people (headache, fever, sore arm, etc.)
- Any of the currently authorized COVID-19 vaccines can be administered to pregnant or lactating people. The Advisory Committee on Immunization Practices (ACIP) does not state a product preference. However, pregnant, lactating, and postpartum people older than age 50 should be made aware of the rare risk of thrombosis with thrombocytopenia syndrome (TTS) after getting the J&J vaccine, and that other FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines) are available. ([CDC Clinical Considerations](#)).

- ACOG recommends vaccination of 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. Recent data (July 2021) have shown that more than 95% of those who are hospitalized and/or dying from COVID-19 are those who have remained unvaccinated. Pregnant individuals who have decided to wait until after delivery to be vaccinated may be inadvertently exposing themselves to an increased risk of severe illness or death. Those who have recently delivered and were not vaccinated during pregnancy are also strongly encouraged to get vaccinated as soon as possible.
- 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.
- If an individual receives a COVID-19 vaccine and becomes pregnant within 30 days of receipt of the vaccine, participation in CDC's v-safe program should be encouraged (see below for more information on CDC's v-safe program).
- Importantly, routine pregnancy testing is not recommended prior to receiving any EUA-approved COVID-19 vaccine.
- Vaccinating the pregnant individual may also protect the newborn after birth, through the passing of protective antibodies to the baby. This is still being studied.

ACOG recommends COVID-19 vaccines be offered to lactating (breastfeeding) individuals. 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. Concerns regarding the safety of vaccinating lactating individuals do not outweigh the potential benefits of receiving the vaccine. There is no need to avoid starting or to discontinue breastfeeding in patients who receive a COVID-19 vaccine ([ABM 2020](#)).

## Technical Information on COVID-19 Vaccines in Pregnancy

### Safety Data

#### Developmental and Reproductive Toxicity Data in Animals

- Data from Developmental and Reproductive Toxicity (DART) studies in animals were collected for the Pfizer-BioNtech, Moderna, and J&J COVID-19 vaccines. These studies do not show direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition (birth), or post-natal development.
- These DART studies provide the first safety data to help inform us about the use of the COVID-19 vaccines in pregnancy until there are more data in humans.

## COVID-19 Vaccine trials in Humans

- Pregnant individuals were not included in clinical trials of any of the three vaccines currently available under EUA, but studies are underway. However, few adults who became pregnant during the clinical trials and they are being followed to collect safety outcomes. Also, COVID-19 vaccine studies in pregnant people have begun or are planned.

## mRNA COVID-19 Vaccines (Pfizer-BioNtech & Moderna)

- The development and use of mRNA vaccines is relatively new. These vaccines use the body's own cells to generate the coronavirus spike protein, which, similar to all other vaccines, stimulates the body's immune cells to create antibodies (fighting cells) against COVID-19. The mRNA vaccines are not live virus vaccines, nor do they use an adjuvant (booster agent) to make the vaccine work better. Based on how these vaccines work and the safety and efficacy shown in clinical trials, it is expected that the safety and efficacy of the vaccine for pregnant individuals would be similar to that in non-pregnant individuals. That said, there are no safety data specific to mRNA vaccine use in pregnant or lactating individuals and the potential risks to a pregnant individual and the fetus are unknown.

## Adenovirus-vector Vaccines (Janssen Biotech Inc.)

- The Janssen (Johnson & Johnson) COVID-19 vaccine is a non-replicating viral vector vaccine. The vaccine cannot replicate once it gets into our bodies and it is quickly gotten rid of by our bodies after injection ([FDA 2021](#)). It is not a live virus vaccine. It was developed in a similar manner to vaccines made for HIV, and Ebola which were administered to pregnant individuals. Overall, these vaccines have an acceptable safety profile, without significant safety issues identified to date ([FDA 2021](#)). At this time, no evidence exists of risk to the fetus from vaccinating pregnant women with non-replicating vaccines in general.

## 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 health checker app ([CDC 2021](#)). People who receive the COVID-19 vaccine voluntarily enroll in this app. Based on the information from this app, no specific safety signals have been observed in pregnant people enrolled in v-safe; however long-term 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 indicate that the

reactogenicity (side effect) profile and adverse events (side effects) observed among pregnant individuals in v-safe did not indicate any safety concerns. Additionally, side effects were similar in pregnant and non-pregnant populations.

- Data for 827 completed pregnancies 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. As demonstrated below, no differences have been seen when comparing pregnant women participating in the v-safe pregnancy registry with the background rates of adverse pregnancy outcomes (meaning what would be expected in pregnant women who did not receive the vaccine).
- In over thousands of pregnancies, reports from v-safe pregnancy registry (Table 2) have NOT shown any safety concerns in those who have received COVID-19 vaccine during pregnancy.
  - There has NOT been an increase in miscarriage nor stillbirths, nor other pregnancy complications.
  - There has NOT been an increase in preterm births or birth defects in those vaccinated.

## Social Media Messages

*Talking points, like those above, are meant for just that – talking. They shouldn't be used verbatim in print, email or social media.*

*Talking points are most effective when you use your own language to share the basic information found in said content, sharing messages in a style of speech that is both expected and best understood by your audiences. For social media, that means keeping it short, conversational and not trying to tackle too much information at once. Stick to the most important details, and don't try to explain too much in a single post.*

*You wouldn't read Shakespeare to a fifth-grade class; instead, you would talk about the general themes of Shakespeare's stories and avoid the complicated language. We suggest a similar approach to using critical vaccine information on social media. For example:*

### **Twitter (limited to 280 characters with spaces):**

There is no research that shows #COVID19 vaccines affect women (or men's) fertility. Experts recommend women who want to become pregnant get vaccinated to stay as healthy as possible!

Getting vaccinated is the best way for moms-to-be to stay healthy. The available #COVID19 vaccines:

- Do not make copies of the virus that causes COVID-19 disease in our bodies.
- Do not give a pregnant person or their unborn baby COVID-19 disease.

- Do not change someone's DNA.

Breastfeeding? It's still safe for you to get any of the 3 available #COVID19 vaccines. Experts say you do not need to stop breastfeeding after being vaccinated, or delay vaccination.

Pregnant people who get COVID-19 disease are at higher risk of blood clots, stillbirth, and other issues. That's why it's so important to get vaccinated. It's safe and will help protect you and your unborn baby.

The rise of the Delta variant makes getting vaccinated during pregnancy more important than ever to protect moms-to-be. @ACOG recommends that all pregnant individuals be vaccinated against COVID-19.

### **Facebook:**

There is no research that shows COVID-19 vaccines affect women (or men's) fertility. Experts recommend women who want to become pregnant get vaccinated to stay as healthy as possible!

Getting vaccinated is the best way for moms-to-be to stay healthy. The available COVID-19 vaccines:

- Do not make copies of the virus that causes COVID-19 disease in our bodies.
- Do not give a pregnant person or their unborn baby COVID-19 disease.
- Do not change someone's DNA.

Breastfeeding? It's still safe for you to get any of the 3 available COVID-19 vaccines. Experts say you do not need to stop breastfeeding after being vaccinated, or delay vaccination.

Pregnant people who get COVID-19 disease are at higher risk of blood clots, stillbirth, and other issues. That's why it's so important to get vaccinated. It's safe and will help protect you and your unborn baby.

The rise of the Delta variant makes getting vaccinated during pregnancy more important than ever to protect moms-to-be. The organization that represents OB-GYNs—the American College of Obstetricians and Gynecologists—recommends that all pregnant individuals be vaccinated against COVID-19 as soon as possible.



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

<b>Pregnancy Outcomes*</b>	<b>Background Rate</b>	<b>V-safe Pregnancy Registry Overall</b>
Miscarriage (<20 weeks)	10-26%	15%
Stillbirth ( $\geq$ 20 weeks)	0.6%	.1%
<b>Pregnancy Complications†</b>	<b>Background Rate</b>	<b>V-safe Pregnancy Registry Overall</b>
Gestational diabetes	7-14%	10%
Preeclampsia or gestational hypertension	10-15%	15%
Eclampsia	0.27%	0%
Intrauterine growth restriction	3-7%	1%
<b>Neonatal Outcomes*</b>	<b>Background Rate</b>	<b>V-safe Pregnancy Registry Overall</b>
Preterm birth	8-15%	9.4%
Congenital anomalies	3%	2.2%

Pregnancy Outcomes*	Background Rate	V-safe Pregnancy Registry Overall
Pregnancy Outcomes*	Background Rate	V-safe Pregnancy Registry Overall
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](#)).

#### Additional Resources:

<https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/03/novel-coronavirus-2019>

<https://www.acog.org/womens-health/faqs/coronavirus-covid-19-pregnancy-and-breastfeeding>

<https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19>