l'm pregnant. Should I get the COVID-19 vaccine?

For most people, getting the COVID-19 vaccine as soon as possible is the safest choice.

However, trials testing the vaccine in pregnant and

lactating people have not been completed.

The information below will help you make an informed choice about whether to get the COVID-19 vaccine while you are pregnant, lactating, or trying to get pregnant.

Your options:



Get the COVID-19 vaccine as soon as it is available



Wait for more information about the vaccine in pregnancy

What are the <u>benefits</u> of getting the COVID-19 Vaccine?

1. COVID-19 is dangerous. It is *more* dangerous for pregnant people.

 COVID-19 patients who are pregnant are 5 times more likely to end up in the intensive care unit (ICU) or on a ventilator than COVID-19 patients who are not pregnant.¹



- Pregnant women are more likely to die of COVID-19 than non-pregnant women with COVID-19 who are the same age.^{2,3}
- Preterm birth may be more common for pregnant people with severe COVID-19, but other pregnancy complications, such as stillbirth, do not appear to be increased.⁴

2. The COVID-19 vaccine may reduce your risk of COVID-19 infection by 95%.

- As COVID-19 infections go up in our communities, your risk of getting COVID-19 goes up too.
- Getting the vaccine may prevent you from getting COVID-19 and may help keep you from giving COVID-19 to people around you.

- The COVID-19 vaccine does NOT contain ingredients that are known to
- be harmful to pregnant people or to the fetus.

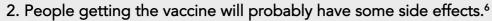
3. The COVID-19 vaccine <u>cannot</u> give you COVID-19.
The COVID-19 vaccine has no live virus.⁵

• Many vaccines are routinely given in pregnancy and are safe (for example: tetanus, diphtheria, and flu).

More details about how the vaccine works can be found on page 5.

What are the <u>risks</u> of getting the COVID-19 vaccine?

- 1. The COVID-19 vaccine has not yet been tested in pregnant people.
 - The vaccine was tested in over 20,000 people and there were no serious side effects. However, pregnant and lactating people were excluded.
 - We do not have data on whether the vaccine works as well in pregnancy as it did in the study of non-pregnant people or if the side effects may be different.
 - We do not have data on whether mRNA crosses the placenta or if there may be any fetal or neonatal impacts.



- Although there were no serious side effects reported, many people had some side effects. The side effects of the vaccine were:
 - pain at the injection site like arm soreness (84%)
 - fatigue (63%)
 - headache (55%)

- muscle pain (38%)
- chills (32%)
- joint pain (24%)
- mild fever (up to 15%)
- About 1% of people will get a high fever (over 102°F). A <u>persistent high</u> fever during the first trimester of pregnancy might lead to complications.
- The CDC recommends using Tylenol (acetaminophen) during pregnancy if you have a high fever.

What do the experts recommend?

COVID-19 is very dangerous and can spread very easily. Because of this the *"Pfizer-COVID-19 vaccine is recommended for persons 16 years of age and older in the U.S. population under the FDA's Emergency Use Authorization."* (CDC)⁷

The FDA acknowledges the lack of clinical data on the vaccine in pregnant people but indicated pregnant people can make their own decisions on vaccination.



The **Society for Maternal-Fetal Medicine** <u>strongly recommends</u> that pregnant individuals have access to COVID-19 vaccines. They recommend that each person have a discussion with their healthcare professional about their own personal choice.⁸

The American College of Obstetricians and Gynecologists recommends that the COVID-19 vaccine should <u>not</u> be withheld from pregnant individuals who meet criteria for vaccination.⁹

What else should I think about to help me decide?

Make sure you understand as much as you can about COVID-19 and about the vaccine. Ask a trusted source, like your midwife or doctor. Page 5 has more information about the vaccine.

2

Think about your own personal risk.

Look at the columns below and think about <u>your</u> risk of getting COVID-19 (left). Think about your safety - are you able to stay safe (right)?

The risks of getting sick from COVID-19 are higher if...

You have contact with people outside your household who do not wear masks You are 35 years old or older You are overweight You have other medical problems such as diabetes, high blood pressure, or heart disease You are a smoker You are a racial or ethnic minority, or your community has a high rate

or your community has a high rate of COVID-19 infections You are a work in a health care

setting⁹

If you are at a higher risk of getting COVID-19, it probably makes sense to get the vaccine. If you are not at higher risk for COVID-19 and...

You are always able to wear a mask You and the people you live with can socially distance from others for your whole pregnancy Your community does NOT have high or increasing COVID-19 cases You think the vaccine itself will make you very nervous (you are more worried about the unknown risks than about getting COVID-19) You have had a severe allergic reaction to a vaccine

... it might make sense for you to wait for more information prior to receiving the vaccine.

What about breastfeeding?

The Society for Maternal-Fetal Medicine reports that there is no reason to believe that the vaccine affects the safety of breastmilk.⁷ When we have an infection or get a vaccine, our bodies make antibodies to fight the infection. Antibodies formed from vaccines given during pregnancy do pass into the breastmilk and then to the baby to help prevent infections. Since the vaccine does not contain the virus, there is no risk of breastmilk containing the virus. Both the Society for Maternal-Fetal Medicine⁸ and American College of Obstetrics and Gynecologists⁹ recommend lactating individuals be offered the vaccine similar to non-lactating individuals as theoretical concerns do not outweigh potential benefits. There is no need to avoid initiation or discontinue breastfeeding in patients receiving the COVID-19 vaccine.

Summary

1. COVID-19 seems to cause more harm in pregnant people than in people of the same age who are not pregnant.

2. The risks of getting the COVID-19 vaccine during pregnancy are thought to be small but are not totally known.

3. You should consider your own personal risk of getting COVID-19. If your personal risk is high, or there are many cases of COVID-19 in your community, it probably makes sense for you to get the vaccine while pregnant.

4. Talking to your doctor or midwife may help you make this decision, but it is not necessary to receive the vaccine and whether to get the vaccine during pregnancy is your choice.

What do pregnant doctors think?

We know COVID can be terrible in pregnancy, and we know the vaccine doesn't contain live virus. As someone who is approaching my third trimester and working on the front lines of this disease, for me the choice is clear, I intend to be first in line as soon as they will let me have one. (Pregnant Emergency Department Doctor)

I am a little nervous about getting something that hasn't been tested in pregnant patients. Early pregnancy is a nerve-wracking time, even without the unknown of a new vaccine. So, I went over the risks and benefits of getting or not getting it as a front-line worker - with myself, my partner, and my doctors. We ended up deciding I should get the vaccine. (Pregnant Emergency Department Doctor)

I am still breastfeeding my baby, and I think the risk of exposing my infant and other children and partner to COVID is far greater than any theoretical risk this novel vaccine may have. I've decided to get vaccinated whenever it becomes available. (Breastfeeding OB/GYN Doctor)

Do you have more questions? Call your doctor or midwife to talk about your own personal decision.

Feedback about your experience with the vaccine

If you decide to get the vaccine, you may get a "V-safe information sheet" with instructions about the V-safe website and app for reporting symptoms after your vaccine (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html). This will help researchers track side effects and learn more about how well the vaccine works.

More information about the COVID-19 Vaccine

How does the COVID-19 vaccine work?

- The Pfizer COVID-19 vaccine is an mRNA vaccine (messenger RNA).
- mRNA is not new our bodies are full of it. mRNA vaccines been studied for the past two decades.
- mRNA vaccines mimic how viruses work. The mRNA is like a recipe card that goes into your body and makes one recipe for a brief time. The recipe is for a small part of the virus (the spike protein).
- When this spike protein is released from cells, the body recognizes it as foreign and the immune system responds. This immune response causes the side effect symptoms (like aches and fever) but leads to improved immunity.
- mRNA breaks down quickly, so it only lasts a brief time.
- This is also how the other viruses like a cold virus work viruses use our body and cells to make their proteins. Then our immune system attacks those proteins to keep us healthy.
- There is no live virus in this vaccine and there is no way for the vaccine to give people COVID-19.⁵

What did the research show?

We know that the Pfizer vaccine trial of over 40,000 people has shown that the vaccine lowers a person's chance of getting COVID-19 and severe COVID-19. In this study, 20,000 people got the vaccine and 20,000 people got a placebo (like a sugar pill).

- After one dose, the vaccine appears to be 50% effective. After 2 doses, the vaccine is 95% effective.
- In other words, for every 100 people who got COVID-19 in the placebo group, only 5 people got COVID-19 in the vaccine group.
- There were 9 cases of severe COVID-19 in the placebo group and only 1 case in the vaccine group.
- There were no serious safety concerns.
- There were 23 reported pregnancies in the trial (12 in the vaccine arm and 11 in the placebo arm). Vaccination occurred within 30 days of a last menstrual period (LMP) or in unknown relation to LMP. There was one miscarriage and one instance of retained products of conception – both in the placebo group. There were no other reported adverse outcomes.

Intended Use: This decision aid is intended for use by pregnant and lactating people (and people planning on becoming pregnant) who are considering getting the COVID-19 vaccine, as well as their healthcare providers, and their friends and family. It was created by the *Shared Decision-Making: COVID Vaccination in Pregnancy* working group at the University of Massachusetts Medical School – Baystate and adapted by the Maternal Fetal Medicine Group at the University of Minnesota.



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- DeBolt CA, et al. Pregnant women with severe or critical COVID-19 have increased composite morbidity compared to non-pregnant matched controls. Am J Obstet 2020 Nov doi: <u>10.1016/j.ajog.2020.11.022</u>
- DiMascio D, WAPM working group on COVID-19. Maternal and Perinatal Outcomes of Pregnancy Women with SARS-coV-2 infection. Ultrasound Obstet Gynecol. 2020 Sept. doi: 10.1002/uog.23107.
- 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. MMWR Morb Mortal Wkly Rep. 2020;69(44):1641–7.
- 4. Adhikari EH, et al. Pregnancy outcomes among women with and without severe acute respiratory syndrome coronavirus 2 infection. JAMA Network Open 2020 Nov 3(11):e2029256
- 5. Abbasi J. COVID-19 and mRNA Vaccines—First Large Test for a New Approach. JAMA. 2020;324(12):1125–1127. doi:10.1001/jama.2020.16866
- 6. Centers for Disease Control and Prevention. Local reactions, systemic reactions, adverse events, and serious adverse events: Pfizer-BioNTech COVID-19 Vaccine. Available at:

<u>https://www.cdc.gov/vaccines/covid-19/info-by-manufacturer/pfizer/reactogenicity.html</u>. Retrieved December 13, 2020

- 7. <u>https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-pfizer-biontech-etr.html</u> (Accessed Dec14, 2020)
- 8. SMFM statement on COVID vaccination in pregnancy: <u>https://www.smfm.org/publications/339-society-for-maternal-fetal-medicine-smfm-statement-sars-cov-2-vaccination-in-pregnancy</u>
- Vaccinating pregnant and lactating patients against COVID-19. American College of Obstetricians and Gynecologists. Practice Advisory. December 13 2020. <u>https://www.acog.org/en/clinical/clinical-guidance/practice-</u> <u>advisory/articles/2020/12/vaccinating-Pregnant-and-Lactating-Patients-Against-COVID-19</u>
- 10. Mutambudzi M, Niedwiedz C, Macdonald EB, *et al.* Occupation and risk of severe COVID-19: prospective cohort study of 120 075 UK Biobank participants. *Occupational and Environmental Medicine* Published Online First: 09 December 2020. doi: 10.1136/oemed-2020-106731