

# I'm pregnant. Should I get a COVID\* vaccine?

\*The information here is about the *Pfizer* and *Moderna* COVID-19 vaccines. These are also called "mRNA" vaccines.

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

However, these vaccines have not been tested in pregnant and breastfeeding women yet.

The information below will help you make an informed choice about whether to get an mRNA COVID vaccine while you are pregnant or trying to get pregnant.

## Your options:



Get a COVID vaccine as soon as it is available



Wait for more information about the vaccines in pregnancy

# What are the benefits of getting an mRNA COVID Vaccine?

- 1. COVID is dangerous. It is *more* dangerous for pregnant women.
  - COVID patients who are pregnant are 5 times more likely to end up in the intensive care unit (ICU) or on a ventilator than
     COVID patients who are not pregnant.<sup>1</sup>
  - Preterm birth may be more common for pregnant women with severe COVID.<sup>2</sup>
  - Pregnant women are more likely to die of COVID than non-pregnant women with COVID who are the same age.<sup>3,4</sup>
- 2. The mRNA COVID vaccines prevent about 95% of COVID infections.
  - As COVID infections go up in our communities, your risk of getting COVID goes up too.
  - Getting a vaccine will prevent you from getting COVID and may help keep you from giving COVID to people around you, like your family.

#### 3. The mRNA COVID vaccines cannot give you COVID.

- These vaccines have no live virus.<sup>5</sup>
- These vaccines do NOT contain ingredients that are known to be harmful to pregnant women or to the fetus.
- Many vaccines are routinely given in pregnancy and are safe (for example: tetanus, diphtheria, and flu).

More details about how these vaccines work can be found on page 5.

# What are the <u>risks</u> of getting an mRNA COVID vaccine?

### 1. These COVID vaccines have not yet been tested in pregnant people.

- These vaccines were tested in over 40,000 people, and there were no serious side effects related to the vaccine.
- We do not know if the vaccines work as well in pregnant people as they did in non-pregnant people.
- We do not know whether there are unique downsides in pregnancy, like different side effects or an increased risk of miscarriage or fetal abnormalities.
- The Moderna vaccine was tested in female rats to look at its effects on pregnancy. No significant negative effects were found on female fertility or fetal development.
- Some women became pregnant during the vaccine studies. Eighteen of these women were in the vaccine group, and two months later none had miscarried. There were seventeen women in the placebo group who became pregnant, and two months later two of them had had miscarriages. (In general, 10-20% of pregnancies end in miscarriage).
- Because these studies are still ongoing, we don't know how the rest of the pregnancy went for these women.

#### 2. People getting the vaccine will probably have some side effects.

- Many people had symptoms caused by their immune system's normal response to the vaccine. The most common side effects were:
  - injection site reactions like sore arm (~84%)
  - fatigue (~62%)
  - headache (~55%)

- muscle pain (~38%)
- chills (~32%)
- joint pain (~24%)
- fever (~14%)
- Of 100 people who get the vaccine, 1 will get a high fever (over 102°F). A
  persistent high fever during the first trimester might increase the risk of
  fetal abnormalities or miscarriage. The CDC recommends using Tylenol
  (acetaminophen) during pregnancy if you have a high fever. Another
  option is to delay your COVID vaccine until after the first trimester.

# What do the experts recommend?

Because COVID is dangerous and easily spread, the CDC says that the mRNA vaccines for COVID-19 are recommended for adults.<sup>7</sup>

However, because there are no studies of pregnant women yet, there are no clear recommendations for pregnant women. This is standard for a new drug and is not due to any particular concern with this vaccine.

The Society for Maternal-Fetal Medicine <u>strongly recommends</u> that pregnant individuals have access to COVID vaccines. They recommend that each person talk to their doctor or midwife about their own personal choice.<sup>8</sup>

The American College of Obstetricians and Gynecologists recommends that the COVID vaccine should <u>not</u> be withheld from pregnant individuals.<sup>9</sup>

# What else should I think about to help me decide?

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

Think about your own personal risk.

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

The risks of getting sick from COVID are higher if	If you are not at higher risk for COVID and
<ul> <li>You have contact with people outside your home</li> <li>You are 35 years old or older</li> <li>You are overweight</li> <li>You have other medical problems like diabetes, high blood pressure, or heart disease</li> <li>You are a smoker</li> <li>You are a racial or ethnic minority, or your community has a high rate of COVID infections</li> <li>You are a healthcare worker¹0</li> </ul>	<ul> <li>You are always able to wear a mask</li> <li>You and the people you live with can socially distance from others for your whole pregnancy</li> <li>Your community does NOT have high or increasing COVID cases</li> <li>You think the vaccine itself will make you very nervous (you are more worried about the unknown risks than about getting COVID)</li> <li>You have had a severe allergic reaction to a vaccine</li> </ul>
If you are at a higher risk of getting	it might make sense for you to wait
COVID, it probably makes sense to get	for more information.
the vaccine.	

# What about breastfeeding?

The Society for Maternal-Fetal Medicine and the Academy of Breastfeeding Medicine report that there is no reason to believe that the vaccine affects the safety of breastmilk.<sup>8,11</sup> The vaccine does not contain the virus, so there is no risk of infecting your baby. Because mRNA is fragile, it is very unlikely that any part of the vaccine gets into breastmilk.

When we have an infection or get a vaccine, our bodies make antibodies to fight the infection. Antibodies can pass into the breastmilk and then to the baby - and may help prevent infections.

# Summary

- 1. COVID seems to cause more harm in pregnant women than in women of the same age who are not pregnant.
- 2. The risks of getting an mRNA COVID vaccine during pregnancy are thought to be small but are not totally known.
- 3. You should consider your own personal risk of getting COVID. If your personal risk is high, or there are many cases of COVID in your community, it probably makes sense for you to get a vaccine while pregnant.
- 4. Whether to get a COVID 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. I'm approaching my third trimester and I work on the front lines of this disease, so 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'm 34 weeks and I'm going to try to get vaccinated after delivery, but during pregnancy I'm holding out. Pregnant women were excluded from the studies and, in the meantime, I don't see COVID patients at work so I feel like my exposure will be low during this second wave. (Pregnant physician)

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.

# Thoughts about this tool?

Was this decision aid helpful? Please take a moment to give us feedback about this decision aid at <a href="https://is.gd/COVIDVac">https://is.gd/COVIDVac</a> or by scanning the QR code below. We need your help!



# Tell the CDC about your experience with the vaccine

If you decide to get the vaccine, you will get a "V-safe information sheet" with instructions about the V-safe website and app. Consider registering so we can better counsel women in the future.

## More information about mRNA COVID Vaccines

#### How do mRNA COVID vaccines work?

- The Pfizer and Moderna COVID vaccines are mRNA vaccines (messenger RNA).
- mRNA is not new our bodies are full of it. mRNA vaccines have 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 way for the vaccine to give people COVID.<sup>5</sup>

#### What did the research show?

The Pfizer and Moderna mRNA vaccine trials each had over 30,000 people (including those who got placebo) and showed that the vaccine lowers a person's chance of getting COVID and severe COVID. In each study, over 15,000 people got the vaccine and over 15,000 people got a saline injection (placebo).

- After one dose, the vaccine appears to be 50% effective. After 2 doses, both vaccines are about 95% effective.
- In other words, for every 100 people who got COVID in the placebo group, only 5 people got COVID in the mRNA vaccine groups.
- Severe cases of COVID were also reduced in both mRNA vaccine groups.
- There were no serious safety concerns.

Intended Use: This decision aid is intended for use by pregnant women (and women 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. This group consists of experts in the fields of OB/GYN, Maternal-Fetal Medicine, Shared Decision-Making and risk communication, Emergency Medicine, and current COVID-19 research. Questions should be directed to Dr. Elizabeth Schoenfeld, Elizabeth.Schoenfeld@bhs.org. Feedback regarding the utility of this decision aid can be directed through the survey (see link on page 5).



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- 1. 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: 10.1016/j.ajoq.2020.11.022
- 2. 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
- 3. 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.
- Centers for Disease Control and Prevention. 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. November 2020:1-7.
- 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. https://www.fda.gov/media/144245/download
- 7. https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-pfizer-biontech-etr.html (Accessed Dec14, 2020)
- 8. SMFM statement on COVID vaccination in pregnancy: <a href="https://www.smfm.org/publications/339-society-for-maternal-fetal-medicine-smfm-statement-sars-cov-2-vaccination-in-pregnancy">https://www.smfm.org/publications/339-society-for-maternal-fetal-medicine-smfm-statement-sars-cov-2-vaccination-in-pregnancy</a>
- 9. <a href="https://www.acog.org/en/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-Pregnant-and-Lactating-Patients-Against-COVID-19">https://www.acog.org/en/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-Pregnant-and-Lactating-Patients-Against-COVID-19</a> (Accessed December 14, 2020)
- 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
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