Yale Medicine | Yale NewHaven Health

Counseling Pregnant and Lactating Healthcare Workers About COVID-19 Vaccination

S: COVID-19 vaccine is now available for healthcare workers across Connecticut and Rhode Island and throughout the Yale New Haven Health system.

B: Healthcare workers and long-term care facility residents and staff are prioritized to receive the COVID-19 vaccine, which has been shown in two randomized control studies to be safe and effective. These studies excluded pregnant people, so data are limited for this population. The Pfizer-BioNTech vaccine is currently recommended in persons aged ≥ 16 years for the prevention of COVID-19 under an Emergency Use Authorization (EUA). The EUA process for the Moderna vaccine is underway. The Center for Disease Control and Prevention (CDC) has provided interim clinical considerations regarding the vaccination of pregnant and lactating people. **Pregnancy is not a contraindication to the Pfiizer-BioNTech vaccine and is not expected to be one for the Moderna vaccine.**

The most up to date studies show that while the overall risk of COVID-19 to individuals is low, pregnant people with COVID-19 have an increased risk of severe illness, including illness that results in ICU admission, mechanical ventilation, or death. Additionally, there may be an increased risk of adverse pregnancy outcomes, such as preterm birth. Lowering these risks, safely, in pregnant people is an important goal. There are very limited available data on the safety of COVID-19 vaccines in pregnant or lactating people. Animal developmental and reproductive toxicity (DART) studies are ongoing and preliminary results are reassuring. Studies in pregnant people are planned. In addition, the manufacturers are following outcomes on people enrolled in the clinical trials who became pregnant and registries are being developed. mRNA vaccines are not live vaccines and there are many examples of other vaccines used safely in pregnancy (influenza, TDAP). The mRNA in the vaccine is degraded quickly by normal cellular processes and does not enter the nucleus of the cell and is unlikely to reach and cross the placenta. Based on current knowledge, experts believe that mRNA vaccines will not pose a risk for people who are pregnant.

The American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine recommend that people who are recommended to receive a COVID-19 vaccine should be offered the vaccine, regardless of pregnancy or lactation status. Further, people planning pregnancy can receive a COVID-19 vaccine and can complete the vaccine if they become pregnant during the scheduled course of administration. There is no scientific basis or evidence for a reduction in fertility from the vaccine.

A: A pregnant or lactating person may choose to become vaccinated for COVID-19. Physicians and midwives taking care of pregnant people should support these choices with the tools for shared decision-making. While basic answers to frequently asked questions are available here, more information and help may be required.

This guidance is based on the most recent information available is subject to change. Clinicians should continue to monitor advice from professional organizations and the CDC as well as updates to this document.

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R: The following considerations are important when a pregnant or lactating person is deciding to receive the COVID-19 vaccine and will help with decision making:

1. A shared decision-making conversation with a medical care provider may help with the decision-making process. Attached with this document is a shared decision-making tool (from UMass/BayState Health) to guide this discussion.

2. Risk assessment of exposure to and of becoming ill from COVID-19 infection, which would include:
    a. Personal history of COVID-19 infection
    b. Rate of COVID-19 infections in the community
    c. Personal risk of contracting COVID-19 due to workplace, household, or community exposures
    d. Personal risk factors for developing a more severe form of COVID-19:
        - Pregnancy
        - Obesity (BMI of 30 kg/m^2 or higher)
        - Smoking
        - Type 2 diabetes mellitus
        - Cancer
        - Chronic kidney disease
        - Chronic obstructive pulmonary disease (COPD)
        - Heart conditions
        - Organ transplant recipient
        - There are other conditions that may increase the risk of severe COVID-19 illness. (click link)

3. Additional considerations that are also important when deciding to get the COVID-19 vaccine include:
    a. Personal beliefs and preferences regarding vaccines
    b. Personal beliefs and preferences regarding COVID-19 illnesses and risk

4. Pregnant people who experience fever following vaccination may be counseled to take acetaminophen as persistent and high fever might increase the risk of some adverse pregnancy outcomes. Acetaminophen may be offered as an option for pregnant people experiencing other post-vaccination symptoms as well.

5. Pregnant people who receive the vaccine should sign up for the smartphone-based CDC V-safe program to track side effects to a centralized database.

6. The following links to the latest guidance from relevant professional organizations are found here:
    - Society for Maternal-Fetal Medicine statement on SARS-CoV-2 vaccination in pregnancy, response to the FDA EUA of the Pfizer-BioNTech vaccine, and statement on provider considerations for engaging in COVID-19 counseling with pregnant and lactating patients.
    - American College of Obstetricians and Gynecologists Practice Advisory on Vaccinating Pregnant and Lactating Patients Against COVID-19.

7. Pregnant people should be counseled that mask wearing, social distancing, and hand hygiene remain important tools for reducing the risk for COVID-19 infection.

I'm pregnant. Should I get the COVID vaccine?

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

However, trials testing the vaccine in pregnant and breastfeeding women have not been completed.

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

Your options:

Get the COVID vaccine as soon as it is available

Wait for more information about the vaccine in pregnancy

What are the benefits of getting the 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.[1]
- Preterm birth may be more common for pregnant women with severe COVID, but other obstetric complications such as stillbirth do not appear to be increased.[2]
- Pregnant women are more likely to die of COVID than non-pregnant women with COVID who are the same age.[3,4]

2. The COVID vaccine will prevent 95% of COVID infections.

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

3. The COVID vaccine cannot give you COVID.

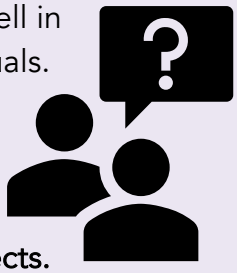
- The COVID vaccine has no live virus.[5]
- The COVID vaccine does NOT contain ingredients that are known to be harmful to pregnant women or to the fetus.
- Many vaccines are routinely given in pregnancy and are safe (for example: tetanus, diphtheria, and flu).

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

What are the risks of getting the COVID vaccine?

1. The COVID vaccine has not yet been tested in pregnant women.

- The vaccine was tested in over 20,000 people, and there were no serious side effects. However, it was not tested in pregnant women.
- We do not have data on whether the vaccine works as well in pregnancy as it did in the study of non-pregnant individuals.
- We do not have data on whether there are unique downsides in pregnancy, like different side effects or an increased risk of miscarriage or fetal abnormalities.



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

- Although there were no serious side effects reported, many people had some side effects. The side effects of the vaccine were:
  - injection site reactions like sore arm (84%)
  - fatigue (62%)
  - headache (55%)
  - muscle pain (38%)
  - chills (32%)
  - joint pain (24%)
  - fever (14%)
- About 1% of people will get a high fever (over 102°F). A persistent high fever during the first trimester of pregnancy might increase the risk of congenital defects or miscarriage. For those reasons, you may choose to delay your COVID vaccine until after the first trimester.
- The CDC recommends using Tylenol (acetaminophen) during pregnancy if you have a high fever.

What do the experts recommend?

COVID is very dangerous and can spread very easily. Because of this, ***"the Pfizer-COVID vaccine is recommended for persons 16 years of age and older in the U.S. population under the FDA's Emergency Use Authorization."*** (CDC)[6]

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** ***strongly recommends*** that pregnant individuals have access to COVID vaccines. They recommend that each person have a discussion with their healthcare professional about their own personal choice.[7]

The **American College of Obstetricians and Gynecologists** recommends that the COVID vaccine should ***not*** be withheld from pregnant individuals who meet criteria for vaccination.[8]

What else should I think about to help me decide?

1 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.

2 Think about your own personal risk.

Look at the columns below and think about *your* 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…

- ☐ 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 of COVID infections
- ☐ You are healthcare worker[9]

If you are at a higher risk of getting COVID, it probably makes sense to get the vaccine.

If you are not at higher risk for COVID 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 cases
- ☐ …you think the vaccine itself will make you very nervous (you are more worried about the unknown risks than about getting COVID)
- ☐ …you have had a severe allergic reaction to a vaccine

… it might make sense for you to wait for more information.

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.

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 the 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 the vaccine while pregnant.
4. 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.

Thoughts about this tool?

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

Feedback 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 for reporting symptoms after your vaccine. This will help researchers track side effects and learn more about how well the vaccine works.

More information about the COVID Vaccine

How does the COVID vaccine work?

- The Pfizer COVID 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.[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 and severe COVID. 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 in the placebo group, only 5 people got COVID in the vaccine group.**
- There were 9 cases of severe COVID in the placebo group and 1 case in the vaccine group.
- 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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7. SMFM statement on COVID vaccination in pregnancy: https://www.smfm.org/publications/339-society-for-maternal-fetal-medicine-smfm-statement-sars-cov-2-vaccination-in-pregnancy
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