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**TO:** Health Care Providers, Health Care Facilities, and Local Health Departments

**FROM:** New York State Department of Health

# Guidance: COVID-19 Vaccination for People who are Pregnant, Lactating, or Planning to Become Pregnant

- No one should be denied access to a COVID-19 vaccine simply because they are pregnant or lactating.
- Pregnant and lactating people **should be encouraged** to consult with healthcare providers before deciding whether or not to get a COVID-19 vaccine.
- Pregnant and lactating people are not required to consult with a healthcare provider prior to being vaccinated and do not need to provide proof of permission from a healthcare provider to get vaccinated.
- Pregnant and lactating people may receive any of the three COVID-19 vaccines currently authorized by the U.S. Food and Drug Administration (FDA) for emergency use.
- Pregnant people are more likely to get severely ill with COVID-19 compared with non-pregnant people. Severe illness includes illness that requires hospitalization, intensive care, or a ventilator or special equipment to breathe, or illness that results in death. Additionally, pregnant people with COVID-19 might be at increased risk of adverse pregnancy outcomes, such as preterm birth, compared with pregnant women without COVID-19. Getting a COVID-19 vaccine during pregnancy can help protect you from severe illness from COVID-19.

## **Vaccinations for Pregnant People:**

- Based on current knowledge, experts believe that COVID-19 vaccines are not likely to pose a risk for people who are pregnant or trying to get pregnant.
  - Vaccine safety monitoring systems operated by the CDC have begun to collect data on vaccine safety in pregnant people. <u>Early data</u> from these systems are preliminary and did not identify any safety concerns for pregnant people who were vaccinated or for their babies. The CDC will continue to follow up with people vaccinated at any time during their pregnancy to better understand the effect of the vaccine on pregnancy and babies.
  - More studies are planned, and vaccine manufacturers are monitoring people in the clinical trials who become pregnant.
  - Among the limited data about the safety of COVID-19 vaccines for people who
    are pregnant, are studies in animals receiving a Moderna, Pfizer-BioNTech or
    Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccine before or
    during pregnancy which found no safety concerns.
- Based on ongoing monitoring and follow up with pregnant people who have received the COVID-19 vaccine, there has been no increase in rates of miscarriage or adverse pregnancy effects in pregnant people who received the COVID-19 vaccine. Studies

- on the impact of COVID-19 vaccination and pregnancy outcomes are continuing and findings will be updated as more information becomes available.
- If pregnant people have questions about getting vaccinated, a discussion with a healthcare provider might help them make an informed decision. If someone is pregnant or thinking about becoming pregnant, healthcare providers should discuss the risk to the pregnant person of getting COVID-19 and their increased risk of severe illness if they become ill. A vaccine may protect pregnant people from severe illness, which can help both the pregnant person and their fetus.
- A healthcare provider may want to discuss the following considerations with pregnant patients when deciding whether or not to be vaccinated:
  - o The level of virus activity/positivity rate within their community.
  - Likelihood of COVID-19 exposure within their community, especially based on their occupation.
  - Risk of COVID-19 to pregnant people and potential risks to pregnancy/fetus.
- Discussion about vaccination with pregnant people can present an important opportunity to discuss the importance of overall prevention measures (i.e. hand washing, physical distancing, mask wearing) as well as vaccinations.
- More information on the impact and considerations for pregnant people and COVID-19 vaccination can be found here:
  - MotherToBaby: supported by the CDC, MotherToBaby experts are available to answer questions chat. The free and confidential services is available Monday – Friday, 8 a.m. to 5 p.m. (local time).
    - To reach MotherToBaby: Call 1-866-626-6847 or chat live or send an email to MotherToBaby: https://mothertobaby.org/
  - https://www.acog.org/clinical/clinical-guidance/practiceadvisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-againstcovid-19
  - <a href="https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnant-people.html">https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnant-people.html</a>
- Pregnant people who receive a COVID-19 vaccine can help increase our understanding of the impact of the vaccine and pregnancy by participating in the v-safe pregnancy registry:

V-Safe is CDC's smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after vaccination. A <u>v-safe</u> <u>pregnancy registry</u> has been established to gather information on the health of pregnant people who have received a COVID-19 vaccine. If people enrolled in v-safe report that they were pregnant at the time of vaccination or after vaccination, the registry staff might contact them to learn more. Participation is voluntary and participants may opt out at any time. <a href="https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html">https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html</a>

### **Vaccinations for Lactating People:**

COVID-19 vaccines should be offered to lactating individuals similar to non-lactating individuals. Clinical trials for COVID-19 vaccines which are currently authorized did not include people who were breastfeeding.

- There is currently no data on the safety of COVID-19 vaccines in lactating people or the effects of the vaccine on the breastfed infant or milk production/excretion.
- If a lactating person is part of a group who is recommended (e.g. healthcare personnel) to receive the COVID-19 vaccine, they may choose to be vaccinated with any of the three COVID-19 vaccines currently authorized by the U.S. Food and Drug Administration (FDA) for emergency use.

# Vaccinations for People Who Would Like to Have a Baby:

If a patient is currently trying to get pregnant, or wants to get pregnant sometime in the future, they can receive any of the COVID-19 vaccines currently authorized for emergency use.

- There is no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems.
- CDC does not recommend routine pregnancy testing before COVID-19 vaccination.
- If a patient receives the COVID-19 vaccine, they do not need to avoid pregnancy after being vaccinated.
- Scientists are continuing to study COVID-19 vaccines for any side effects and will continue to report findings as they become available.

## **Frequently Asked Questions:**

- Q. Is it true that some of the COVID-19 vaccines can impact a person's fertility?
- A: There is no evidence that any of the COVID-19 vaccines impact fertility. If someone is trying to get pregnant now or wants to become pregnant in the future, they may receive a COVID-19 vaccine. There is currently no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems.
- Q: Are pregnant people required to consult a doctor before getting a COVID-19 vaccine?
- A: Pregnant people are encouraged to talk with their health care provider before getting vaccinated to discuss any concerns and the risk of COVID-19 infection for pregnant people. However, pregnant people are not required to talk to a health care provider if they do not wish to, and pregnant people are not required to provide a doctor's note in order to get vaccinated.
- Q: Do pregnant people have to provide written proof of physician approval to get a COVID-19 vaccine?
- A: No. Pregnant people do not need to provide a doctor's note or any other documentation in order to get the COVID-19 vaccine. Staff at the vaccination site will inform the pregnant person they may consult with a healthcare provider if they wish, but they should not delay vaccination if the pregnant person requests vaccination and is otherwise eligible.
- Q: Are the various COVID-19 vaccines safe for pregnant people?

- A: There are currently three different COVID-19 vaccines authorized for emergency use under an FDA EUA. Current data on the impact of these vaccines on pregnant people is limited; however, experts believe the vaccines are unlikely to pose a specific risk to people who are pregnant. Studies in animals receiving a Moderna, Pfizer-BioNTech, or Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccine before or during pregnancy found no safety concerns. Based on ongoing monitoring and follow up with pregnant people who have received the COVID-19 vaccine, there has been no increase in rates of miscarriage or adverse pregnancy effects in pregnant people who received the COVID-19 vaccine. Studies on the impact of COVID-19 vaccination and pregnancy outcomes are continuing and findings will be updated as more information becomes available.
- Q: Is one COVID-19 vaccine better for pregnant people than another?
- A: There is no data to show that outcomes or safety for pregnant people vary depending on which COVID-19 vaccine they receive.
- Q: Have any of the approved COVID-19 vaccines been tested on pregnant people?
- A: None of the COVID-19 vaccines currently authorized for Emergency Use were tested on pregnant people. However, the CDC & FDA have safety monitoring systems in place to gather information about vaccination during pregnancy and will continue to closely monitor the situation. Most of the pregnancies that are currently being tracked are ongoing so the CDC will continue to follow pregnancies long-term to fully understand the effects on pregnancy and infants.

### **Additional Resources:**

- ACOG: Vaccinating Pregnant & Lactating Individuals Against COVID-19
- CDC: COVID-19 Vaccinations for Pregnant & Breastfeeding People
- CDC: COVID-19 & Pregnant People
- NYS DOH COVID-19 Website
- NYS Local Health Department Directory
- Centers for Disease Control and Prevention (CDC) COVID-19 Website
- Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report:
  Characteristics of Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2
  Infection by Pregnancy Status United States, January 22-June 7, 2020.
- World Health Organization (WHO) COVID-19 Website
- New England Journal of Medicine, "Preliminary Findings of mRNA COVID-19 Vaccine Safety in Pregnant Persons"