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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 Guidance for People who are Pregnant, Lactating, or Planning to Become Pregnant

- Centers for Disease Control & Prevention (CDC), the American College of Obstetricians &
 Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) recommend that all
 pregnant individuals be vaccinated against COVID-19.
- This recommendation is based on analysis of safety data on 2,500 women receiving the COVID-19 vaccine. This analysis showed no increased risk of miscarriage for those who received at least one dose of the Pfizer or Moderna vaccine before 20 weeks of pregnancy.
- Vaccination of pregnant people against COVID-19 also serves to build antibodies which may protect their baby from COVID-19 infection.
- No one should be denied access to a COVID-19 vaccine simply because they are pregnant, planning to be pregnant, or lactating.
- People who are pregnant, planning to be pregnant, and/or lactating 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.
- People who are pregnant, planning to be pregnant, and/or lactating may receive any of the three COVID-19 vaccines currently authorized by the U.S. Food and Drug Administration (FDA) for emergency use.
- Data has shown that pregnant people are more likely to experience severe complications and
 even death when infected 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:

- The CDC and other medical associations including ACOG and SMFM strongly recommend that all pregnant people are fully vaccinated against COVID-19.
- Based on data analysis of several thousand pregnant individuals who have received at least one
 dose of a COVID-19 vaccine, data shows no increased risk of miscarriage among those who are
 immunized.
- Early data suggests that receiving an mRNA COVID-19 vaccine during pregnancy reduces the risk for COVID-19 infection.

- Vaccination of pregnant people against COVID-19 also serves to build antibodies which may protect their baby from COVID-19 infection.
- Vaccine safety monitoring systems operated by the CDC are continuing 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. Many pregnancies reported in these safety monitoring systems are ongoing and the CDC will continue to follow people vaccinated during all trimesters of pregnancy.
 - More studies are planned, and vaccine manufacturers are monitoring people in the clinical trials who become pregnant.
 - Additional research, looking into the effect of COVID-19 on pregnancy, birth, the
 postpartum period, as well as infants exposed to COVID-19 during pregnancy are
 ongoing. A list of those studies can be found online here.
- 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.
 - The CDC recently released U.S. data on the safety of receiving an mRNA COVID-19 vaccine during pregnancy. This report analyzed data from three safety monitoring systems in place to gather information about COVID-19 vaccination during pregnancy. This data did not find any safety concerns for pregnant people who were vaccinated, or their infants.
- 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:
 - 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 at:
 - 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-against-covid-19

- https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnant-people.html
- 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 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. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

Vaccinations for Lactating People:

COVID-19 vaccines should be offered to lactating individuals similar to non-lactating individuals.

- Recent reports have shown that breastfeeding people who have received mRNA COVID-19
 vaccines have antibodies in their breastmilk, which could help protect their babies. This means
 COVID-19 vaccination during pregnancy might help protect babies against COVID-19. More data
 are needed to determine how these antibodies, similar to those produced with other vaccines,
 may provide protection to the baby.
- COVID-19 vaccines do not cause infection, including in pregnant people or their babies
- A lactating person 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:

- COVID-19 vaccination is recommended for everyone 12 years of age and older, including people who are trying to get pregnant now or might become pregnant in the future, as well as their partners.
- Professional medical organizations serving people of reproductive age, including adolescents, emphasize that there is no evidence that COVID-19 vaccination causes a loss of fertility. These organizations also recommend COVID-19 vaccination for people who may consider getting pregnant in the future.
- Professional societies for male reproduction recommend that men who want to have babies in the future be offered COVID-19 vaccination.
- There is no evidence that vaccines, including COVID-19 vaccines, cause fertility problems in either males and/or females.
- There is currently no evidence that antibodies made following COVID-19 vaccination or that vaccine ingredients would cause any problems with becoming pregnant now or in the future.
- 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.
- In a recent in vitro fertilization (a type of fertility treatment) study, researchers compared pregnancy success rates among three groups of women:

- O Women with:
 - Antibodies from having been vaccinated against COVID-19
 - Antibodies from having a recent infection with the virus that causes COVID-19
 - No antibodies from either having a recent infection with the virus that causes
 COVID-19 or from having been vaccinated against COVID-19
- The study found no differences in pregnancy success rates among the three groups.
- Like with all vaccines, scientists are studying COVID-19 vaccines carefully for side effects and will report findings as they become available.
- Currently no evidence shows that any vaccines, including COVID-19 vaccines, cause male
 fertility problems. A recent small study of 45 healthy men who received an mRNA COVID-19
 vaccine (i.e., Pfizer-BioNTech or Moderna) looked at sperm characteristics, like quantity and
 movement, before and after vaccination.12 Researchers found no significant changes in these
 sperm characteristics after vaccination.

Frequently Asked Questions:

- Q: Is pregnancy a valid medical exemption from the requirement that certain individuals be vaccinated (e.g., healthcare workers)?
- A: No. Pregnancy alone is not a valid "health condition" upon which to base a medical exemption.
- 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: Centers for Disease Control & Prevention (CDC), the American College of Obstetricians & Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) recommend that all pregnant individuals be vaccinated against COVID-19. 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: Yes. 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.

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. Safety analysis of analysis of data on 2,500 women receiving the COVID-19 vaccine showed no increased risk of miscarriage for those who received at least one does of the Pfizer or Moderna vaccine before 20 weeks of pregnancy.

Additional Resources:

- ACOG and SMFM Recommend COVID-19 Vaccination for Pregnant Individuals
- ACOG: Vaccinating Pregnant & Lactating Individuals Against COVID-19
- CDC: COVID-19 Vaccinations for Pregnant & Breastfeeding People
- CDC: COVID-19 & Pregnant People
- CDC: "New CDC Data: COVID-19 Vaccination Safe for Pregnant People"
- NYS DOH COVID-19 Website
- NYS Local Health Department Directory
- CDC COVID-19 Website
- CDC 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"