# Vaccine Confident Playbook



## Addressing concerns related to pregnancy, breastfeeding, and fertility

#### The Issue

Women who are pregnant, recently postpartum, or breastfeeding may be concerned that COVID-19 vaccines could harm the fetus or their newborn baby. Any person—including parents of adolescents—may be concerned about the possibility that COVID-19 vaccination could interfere with future fertility.

#### **Sound Bites**

- > COVID-19 vaccination is recommended for all people 12 years and older, including people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future.
- > Pregnant and recently pregnant people are at an increased risk for severe illness from COVID-19, compared with nonpregnant people.
- > Pregnant women with COVID-19 are at increased risk of preterm birth and might be at increased risk of other adverse pregnancy outcomes, compared with pregnant women without COVID-19.
- A growing body of evidence suggests that the benefits of receiving a COVID-19 vaccine outweigh any known or potential risks of vaccination during pregnancy.
- > The safety of COVID-19 vaccines in pregnancy continues to be closely monitored through systems such as the v-safe pregnancy registry.
- > Women who get the COVID-19 vaccine while pregnant or lactating may pass protective antibodies along to their baby.
- > There currently is no evidence that any vaccines, including COVID-19 vaccines, cause female or male fertility problems.

## **Questions for Exploring Patient Concerns**

- > What do you know about the risks of COVID-19 disease during pregnancy?
- > What is your biggest concern about getting a COVID-19 vaccine during pregnancy?
- > If you get COVID-19 disease while you are pregnant, you may become severely ill or possibly have pregnancy complications. The vaccines appear to be safe but have limited data. Which seems like the bigger risk? Why?
- > What would need to be true for you to feel comfortable getting a COVID-19 vaccine while you are pregnant [or breastfeeding]?
- What have you heard about the potential impact of a COVID-19 vaccine on fertility?



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### What We Know

Pregnant women and recently pregnant women with symptomatic COVID-19 infection are at increased risk of more severe illness compared with nonpregnant women.<sup>1-4</sup> This includes increased risk of admission to an intensive care unit, need for mechanical ventilation and ventilatory support, and death. The risk of severe illness may be even higher in pregnant patients with comorbidities such as obesity and diabetes.

Additionally, pregnant women with COVID-19 appear to be at increased risk of preterm birth and might be at increased risk of other adverse pregnancy outcomes (e.g., stillbirth, pregnancy loss).<sup>1-5</sup>

Both the Centers for Disease Control and Prevention (CDC) and the American College of Obstetricians and Gynecologists recommend that all eligible persons—including people who are pregnant, are breastfeeding, were recently pregnant, are trying to get pregnant now, or might become pregnant in the future—receive a COVID-19 vaccine. The Society for Maternal-Fetal Medicine also recommends that pregnant and lactating people be vaccinated against COVID-19.

Evidence about the safety of COVID-19 vaccines during pregnancy is limited because pregnant volunteers were excluded from preauthorization clinical trials. Postauthorization information is being collected from three U.S. vaccine safety monitoring systems: the CDC smartphone-based active-surveillance system ("v-safe"), the v-safe pregnancy registry (a subset of adult volunteers who received vaccination during pregnancy or in the periconception period), and the Vaccine Adverse Event Reporting System (VAERS). Early data from these systems have not indicated any obvious safety signals with respect to pregnancy or neonatal outcomes associated with COVID-19 vaccination in the third trimester of pregnancy.<sup>6</sup> A number of clinical trials designed to study the safety and efficacy of COVID-19 vaccines in pregnant women are underway or planned.

The preauthorization clinical trials also excluded women who were breastfeeding. As a result, no data could be collected regarding the safety of COVID-19 vaccines in lactating women, the effects of vaccination on the breastfed baby, or the effects on milk production or excretion. Neither mRNA vaccines nor viral vector vaccines are anticipated to pose a risk to lactating women or their breastfed babies.

A small prospective cohort study reported promising results about the possible protective abilities of COVID-19 vaccines.<sup>7</sup> The study included 131 reproductive-aged women who received an mRNA vaccine; 84 were pregnant and 31 were lactating. Vaccine-induced antibody titers in the pregnant and lactating women were equivalent to those in the 16 nonpregnant women and higher than those in sera from 37 pregnant women who had been infected with SARS-CoV-2 and included as a second comparison group. Vaccine-generated antibodies were present in all umbilical cord blood and breastmilk samples, suggesting that vaccination of pregnant and lactating women may confer robust neonatal immunity.

There currently is no evidence that any vaccines, including COVID-19 vaccines, cause female or male fertility problems.<sup>1,2</sup>

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#### References

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