



## Addressing Concerns Related to Pregnancy, Breastfeeding, and Fertility

*Note: While this section was written with COVID-19 vaccines in mind, many of the general principles apply to other vaccines as well. Individual vaccines may vary in their antigenic components or dosage forms, but the principles of human behavior and good communication skills transcend most differences between vaccines.*

### The Issue

Women who are pregnant, recently pregnant, 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

- > Pregnant and recently pregnant people with COVID-19 disease are at increased risk for severe illness and death compared with nonpregnant people. The same is true with influenza, RSV, and other preventable infections. See references for routine vaccination during pregnancy.<sup>1,2</sup>
- > Pregnant women with COVID-19 disease are at increased risk of preterm birth and stillbirth—and might be at increased risk of other adverse pregnancy outcomes—compared with pregnant women without COVID-19.
- > A growing body of evidence on the safety and effectiveness of COVID-19 vaccination indicates that the benefits of vaccination during pregnancy outweigh any known or potential risks.
- > COVID-19 vaccination is recommended for people who are pregnant, lactating, trying to get pregnant now, or who might become pregnant in the future.
- > Women who get the COVID-19 vaccine while pregnant or lactating pass protective antibodies to their baby.
- > The safety of COVID-19 vaccines in pregnancy continues to be closely monitored through systems such as the V-safe COVID-19 vaccine pregnancy registry.
- > No evidence exists that any vaccines, including COVID-19, cause female or male fertility problems.

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### 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. A growing body of evidence shows vaccination during or after pregnancy to be safe, but data still are limited. 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?

### What We Know

Pregnant and recently pregnant people are at higher risk for more severe COVID-19 illness compared with nonpregnant people.<sup>3,5</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 are at increased risk for preterm birth and stillbirths, and they might be at increased risk for other complications.

Based on the available evidence from systematic reviews, case-control studies, case series, and cohort studies, the Centers for Disease Control and Prevention (CDC) includes pregnancy (or recent pregnancy, for at least 42 days following the end of pregnancy) on the list of underlying medical conditions associated with high risk for severe COVID-19.<sup>5,6</sup> Both the CDC and the American College of Obstetricians and Gynecologists (ACOG) recommend COVID-19 vaccination (including staying up to date with vaccinations) for people who are pregnant, lactating, trying to get pregnant now, or might become pregnant in the future.<sup>3,5</sup>

Evidence about the safety of COVID-19 vaccines during pregnancy is limited because pregnant volunteers were excluded from preauthorization clinical trials.<sup>3</sup> Information has been collected via the Vaccine Adverse Event Reporting System (VAERS) from the beginning.<sup>7</sup> Data from these systems did not indicate any specific safety signals among pregnant persons who received mRNA COVID-19 vaccines.<sup>8</sup>

The clinical trials also did not include women who were lactating.<sup>5</sup> As a result, there are limited data 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 secretion.

In contrast, evidence of the benefits of COVID-19 vaccination during or after pregnancy and in lactating individuals is accumulating. Recent studies have shown that antibodies produced after COVID-19 vaccination are transferred to the newborn; vaccination during pregnancy also reduces the risk of COVID-19 hospitalization in infants younger than 6 months of age.<sup>3,5</sup> There are recent reports that the antibodies developed from mRNA COVID-19 vaccination both during and after pregnancy were present in breastmilk samples, suggesting a potential protective effect.<sup>3,5</sup>

There is no evidence that any vaccines, including COVID-19 vaccines, cause female or male fertility problems.<sup>3,5</sup>

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### *Recommendations from ACOG include:<sup>9</sup>*

- > ACOG strongly recommends that pregnant individuals be vaccinated against COVID-19. Given the potential for severe illness and death during pregnancy, COVID-19 vaccination series is a priority for this population.
- > Vaccination may occur in any trimester, and emphasis should be on vaccine receipt as soon as possible to maximize maternal and fetal health.
- > For patients who do not receive any COVID-19 vaccine, the discussion should be documented in the patient's medical record. During subsequent office visits, obstetrician–gynecologists should address ongoing questions and concerns and offer vaccination again.
- > COVID-19 vaccines may be administered simultaneously with other vaccines, including within 14 days of receipt of another vaccine. This includes vaccines routinely administered during pregnancy, such as influenza and Tdap (tetanus, diphtheria, and acellular pertussis vaccine).
- > Pregnant patients who get vaccinated should be encouraged to sign up for the CDC's V-safe safety monitoring program.

## References

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