

How will experts evaluate the COVID-19 vaccines in real-world conditions?

Experts are working on many types of real-world studies to determine vaccine effectiveness, and each uses a different method:

- **Case-control studies** will include cases (people who have the virus that causes COVID-19) and controls (people who do not have the virus that causes COVID-19). People who agree to participate in a case-control study will provide information on whether they received a COVID-19 vaccine or not. Experts will look to see if the cases were less likely to have received the vaccine than controls, which would show that the vaccine is working.
- **A test-negative design study** will enroll people who are seeking medical care for symptoms that could be due to COVID-19. In this special type of case-control study, experts will compare the COVID-19 vaccination status of those who test positive (meaning they have COVID-19) to those who test negative (meaning they do not have COVID-19).
- **Cohort studies** will follow people who have and haven't had a COVID-19 vaccine for several months to see if getting vaccinated protects them from getting the disease. This can be done in real time (prospectively) or by looking back in time (retrospectively) using data that were already collected, such as information in participants' medical records.
- **Screening method assessments** look at vaccination status among a group of cases (for example, cases detected through ongoing COVID-19 surveillance) and compares those cases with vaccination coverage among the overall population where those cases come from (for example people from the same state). By comparing coverage between these two groups, researchers can get an early estimate of whether a vaccine is working as expected.
- **Ecologic analysis assessments** look at groups of people – such as those in different geographic locations or at different times – to find out how many were vaccinated and how many were diagnosed with COVID-19. These analyses may be hard to interpret because the number of COVID-19 illnesses has changed rapidly over time and in different places.

CDC will use several methods because they can all contribute different information about how the vaccine is working.

What if I am pregnant or breastfeeding?

Currently, there are limited data available on the safety of COVID-19 vaccines for people who are pregnant. While studies have not yet been done, based on how mRNA vaccines work, experts believe they are unlikely to pose a risk for people who are pregnant. [mRNA vaccines](#) do not contain the live virus that causes COVID-19 and therefore cannot give someone COVID-19. Additionally, mRNA vaccines do not interact with genetic material DNA because the mRNA does not enter the nucleus of the cell. Cells break apart the mRNA quickly. However, the potential risks of mRNA vaccines to the pregnant person and her fetus are unknown because these vaccines have not been studied in pregnant women.

Pregnant people are at increased risk for severe illness from COVID-19

Observational data demonstrate that, while the chances for these severe health effects are infrequent, pregnant people [with COVID-19 have an increased risk of severe illness](#), including illness that results in ICU admission, mechanical ventilation, and death. Additionally, pregnant people with COVID-19 might be at increased risk of adverse pregnancy outcomes, such as preterm births.

Key considerations pregnant patients can discuss with their healthcare provider include:

- The likelihood of exposure to SARS-CoV-2, the virus that causes COVID-19
- Risks of COVID-19 to them and potential risks to their fetuses
- What is known about the vaccine: how well it works to develop protection in the body, known side effects of the vaccine, and lack of data during pregnancy

COVID-19 vaccination considerations for people who are breastfeeding

There are no data on the safety of COVID-19 vaccines in lactating women or on the effects of mRNA vaccines on the breastfed infant or on milk production/excretion. mRNA vaccines are not thought to be a risk to the breastfeeding infant. People who are breastfeeding and are part of a group recommended to receive a COVID-19 vaccine, such as healthcare personnel, may choose to be vaccinated. If they have questions around getting vaccinated while breastfeeding, a discussion with a healthcare provider might help them make an informed decision.

(January 2021)