



Safety of COVID-19 Vaccines

Denver Health strongly encourages its patients and staff to receive the COVID-19 Vaccine as it becomes available. We recognize that many questions exist around the safety and efficacy of the new vaccines. The following Fact Sheet is intended to provide an overview on the safety measures and data associated with these vaccines.

SAFETY FACTS: THE PFIZER and MODERNA VACCINES

Denver Health has received the Pfizer and Moderna vaccines based on the Food and Drug Administration's Emergency Use Authorization (EUA) and the State's decision on distribution. An EUA allows unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions. The Pfizer COVID-19 Vaccine is administered as a 2-dose series, about 3 weeks apart, and the Moderna vaccine is 2 doses given about 4 weeks apart. FDA has authorized the emergency use of the Pfizer COVID-19 Vaccine in individuals 16 years of age and older.

Both the Pfizer and Moderna vaccines were administered to more than 70,000 people in phase 3 trials who have been closely monitored for any adverse events. They appear to be very safe. Few serious adverse events attributed to the vaccine occurred in the studies and the rate of these events was not different from the group that received the placebo shot. Experience with vaccination in the United Kingdom suggests that rarely people with severe allergies may have an allergic reaction that requires medication to treat the reaction. In addition, the safety of these vaccines will continue to be evaluated through several programs.

The Pfizer and Moderna vaccines do not contain whole virus so they cannot cause COVID-19. mRNA vaccine technology is relatively new, and no prior mRNA vaccines have advanced past early clinical trial phases. The mRNA in the vaccine is taken into some cells in your body which then make a protein that is on the surface of the virus. Your body makes an immune response to this protein. mRNA often makes people think of DNA and wonder if the vaccines interact with our genes: however, they do not. mRNA works in a completely different part of our cells.

Both vaccines provoke a strong immune response, which can cause people to feel unwell for a day or so after the vaccine. For some, this is described as feeling like they have a hangover, and it is more common after the second dose of vaccine.

In the Pfizer and Moderna studies, the most common side effects include soreness, redness, or swelling around the injection site, fatigue, body aches, or headache. These reactions can be treated with ibuprofen or Tylenol if needed.

Safety in pregnant women

While the Pfizer COVID-19 vaccine has been found safe and effective in a large trial of more than 43,000 people, the trial did not enroll pregnant women. Neither FDA nor CDC have stated that pregnant women should not get the vaccine. There are no specific reasons to believe that an mRNA vaccine would pose a risk to a pregnant woman or the fetus, but any certainty about safety in pregnancy will have to wait for future study. If you are pregnant or might be pregnant, you are encouraged to speak to your health care provider about questions. It is not necessary to have a pregnancy test before receiving your vaccine. Pregnant women should avoid use of medications such as ibuprofen (Advil, Motrin) or Naproxen for treatment of any symptoms after vaccination.

Safety in breastfeeding

Breastfeeding mothers were not enrolled in the Pfizer COVID-19 vaccine clinical trial, and therefore we do not have definitive data about the safety of the vaccine in this scenario or any impact on lactation. However, there is no specific reason to suspect that the vaccine or any of its active components would enter breast milk or be harmful to your baby. If you have questions or concerns, you are encouraged to speak to your doctor.

Safety in immunocompromised individuals

The vaccination has not been studied in patients with immune compromising conditions. While it is not expected to be harmful to individuals who are immunocompromised, it may not be as effective in this population. Such persons are encouraged to speak to their health care provider before receiving the COVID-19 vaccine.

Who should NOT get the vaccine

You should not get the Pfizer or Moderna COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine.
- had a severe allergic reaction to any ingredient of this vaccine.

Ingredient list

These vaccines have a simple formulation and contain few ingredients, including the mRNA, a lipid capsule that protects the mRNA until it reaches our cells, sodium and potassium salts and other buffers to balance the pH to match our bodies, and sugars to help the vaccine stay effective at room temperature. Links to the precise ingredients in the [Pfizer](#) and [Moderna](#) vaccines are available.

Understanding and Reporting Potential Side Effects

There is a special vaccine monitoring system for the COVID vaccines called V-SAFE to report any issues with the vaccine in real time. The CDC and FDA encourage the public to report possible adverse events to the [Vaccine Adverse Event Reporting System \(VAERS\)](#). This national system collects these data to look for adverse events that are unexpected, appear to happen more often than expected or have unusual patterns of occurrence. Learn about the [difference between a vaccine side effect and an adverse event](#). Reports to VAERS help the CDC monitor the safety of vaccines.

Known side effects

- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)

There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine. You will be asked to stay in the vaccine area for 15 minutes after vaccination to monitor for any immediate reaction. If a severe allergic reaction occurs after you leave – **Call 911 immediately**. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Health care providers will be required to report certain adverse events following vaccination to VAERS. Health care providers also have to adhere to any revised safety reporting requirements according to FDA's conditions of authorized use throughout the duration of any Emergency Use Authorization; these requirements would be posted on [FDA's website](#).

EFFICACY: THE PFIZER and MODERNA VACCINES

Initial results of studies of the Pfizer and Moderna vaccines show that the vaccine decreased the risk of developing COVID-19 by about 95%. Both vaccines have been through Phase III trials.

In the Pfizer study, out of over 43,000 participants, 162 participants who received placebo (a saline injection) got sick with COVID-19 and only 8 participants who received the vaccine got sick with COVID-19. Efficacy was consistent across age, gender, race and ethnicity demographics. The vaccine was equally effective across all gender and race/ethnicity groups. Approximately 42% of global participants and 30% of U.S. participants have racially and ethnically diverse backgrounds, and 41% of global and 45% of U.S. participants are 56-85 years of age. There were 10 severe cases of COVID-19 observed in the trial, with nine of the cases occurring in the placebo group and one in the vaccine group.

The Pfizer vaccine started to include children age 12-16 years in the last 2 months, so we may know more about this population soon, but the Emergency Use Authorization (EUA) will not allow for pediatric vaccines.

The Moderna study involving 30,000 participants in the US, included 196 cases of COVID-19, of which 30 cases were severe. Vaccine efficacy against COVID-19 was 94.1%; vaccine efficacy against severe COVID-19 was 100%. The study had more than 7,000 Americans over the age of 65 and included 5,000 persons with high-risk chronic conditions such as diabetes, severe obesity and cardiac disease. The study included more than 11,000 participants from communities of color, representing 37% of the study population, which is similar to the diversity of the U.S. at large.

Additional Information:

Additional trials and tracking

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html>

<https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>