

Vaccine safety and the speed of vaccine development

How do we know if COVID-19 vaccines are safe?

COVID-19 vaccines were tested in large clinical trials to make sure they meet safety standards. Many people were recruited to participate in these trials to see how the vaccines offers protection to people of different ages, races, and ethnicities, as well as those with different medical conditions.

The Food and Drug Administration (FDA) carefully reviews all safety data from clinical trials and an authorizes emergency vaccine use only when the expected benefits outweigh potential risks. The CDC's Advisory Committee on Immunization Practices (ACIP) reviews all safety data before recommending any COVID-19 vaccine for use in the U.S. population. The FDA and CDC will continue to monitor the safety of COVID-19 vaccines, to make sure even very rare side effects are identified.

What is Operation Warp Speed and how were vaccines developed so quickly?

The federal government, through [Operation Warp Speed \(OWS\)](#), has been working since the start of the pandemic to make a COVID-19 vaccine available. This accelerated timeline has raised concerns for some that safety may be sacrificed in favor of speed. However, safety remains a top priority.

To accelerate vaccine development while maintaining standards for safety and efficacy, OWS has selected the most promising vaccine candidates and is providing coordinated government support. Rather than eliminating steps from traditional development timelines, steps have proceeded simultaneously, such as starting manufacturing of the vaccine at industrial scale well before the demonstration of vaccine efficacy and safety as happens normally. This increases the financial risk, but not the risk of the vaccines.

Vaccine side effects

Can COVID-19 vaccines cause you to get very sick?

Most people do not have serious problems after being vaccinated and the vaccines themselves will not give you COVID-19. Common side-effects of COVID-19 vaccines include pain or swelling on the arm where you got the shot, as well as fever, chills, tiredness and headache. These symptoms usually go away on their own within a week. These side effects are a sign that your immune system is doing exactly what it is supposed to do. It is working and building up protection to disease.

How do we know COVID-19 vaccines are safe, could they cause long-term problems?

COVID-19 vaccines are being tested in large clinical trials to assess their safety. However, it does take time, and more people getting vaccinated before we learn about very rare or long-term side effects. That is why safety monitoring will continue. CDC has an independent group of experts that reviews all the safety data as it comes in and provides regular safety updates. If a safety issue is detected, immediate action will take place to determine if the issue is related to the COVID-19 vaccine and determine the best course of action.

How do I report a problem or possible side effect to a COVID-19 vaccine?

The CDC and FDA encourage the public to report possible side effects (called 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. Reports to VAERS help the CDC monitor the safety of vaccines. Health care professionals will be required to report certain adverse events following vaccination to VAERS.

The CDC is also implementing a new smartphone-based tool called “v-safe” to check-in on people’s health after they receive a COVID-19 vaccine. When you receive your vaccine, you should also receive a v-safe information sheet telling you how to enroll in v-safe. If you enroll, you will receive regular text messages directing you to surveys where you can report any problems or adverse reactions you have after receiving a COVID-19 vaccine.

mRNA Vaccines

mRNA vaccines are being held to the same safety and efficacy standards as all other types of vaccines in the United States. The only COVID-19 vaccines the FDA will make available for use in the United States are those that meet these standards. While there are currently no licensed mRNA vaccines in the United States, researchers have been studying and working with them for decades. mRNA vaccines have been studied before for flu, Zika, rabies and cytomegalovirus (CMV). Beyond vaccines, cancer research has used mRNA to trigger the immune system to target specific cancer cells.

Can mRNA vaccines give someone COVID-19?

No, mRNA vaccines cannot give someone COVID-19. mRNA vaccines do not use the live viruses that causes COVID-19.

Will mRNA vaccines interact with my DNA in any way?

mRNA vaccines do not affect or interact with our DNA in any way. mRNA never enters the nucleus of the cell where our DNA is kept. The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions.

Viral vector vaccines

Viral vector vaccines are being held to the same safety and efficacy standards as all other types of vaccines in the United States. The only COVID-19 vaccines the FDA will make available for use in the United States are those that meet these standards.

How do viral vector vaccines work?

Adenoviral vector vaccines use a modified version of an adenovirus, a virus that can cause the common cold, to deliver important instructions to our cells. For COVID-19 viral vector vaccines, the harmless adenovirus will enter a cell in our body and then use the cell’s machinery to produce a harmless piece of the virus that causes COVID-19. This piece is known as a spike protein and it is only found on the surface of the virus that causes COVID-19. The cell displays the spike protein on its surface, and our immune system recognizes that it doesn’t belong there. This triggers our immune system to begin producing antibodies and activating other immune cells to fight off what it thinks is an infection. At the end of the process, our bodies have learned how to protect us against future infection with the virus that causes COVID-19. The Janssen/Johnson & Johnson and AstraZeneca Oxford COVID-19 vaccines are both viral vector vaccines.

Can viral vector vaccines give someone COVID-19?

No, viral vectors cannot cause infection with COVID-19 or with the virus used as the vaccine vector.

Will viral vector vaccines interact with my DNA in any way?

The genetic material delivered by the viral vector does not integrate into a person’s DNA.

Natural immunity rather than immunity from vaccines

Does getting sick with COVID-19 provide better protection than the vaccine gives?

Both COVID-19 and the vaccines are new. We do not know how long protection lasts for those who get infected or for those who are vaccinated. What we do know is that COVID-19 has caused very serious illness and death for a lot of people. If you get COVID-19, you also risk giving it to loved ones who may get very sick. Getting a COVID-19 vaccine is a safer choice. Keep in mind that the vaccines are not a perfect fix. We will still need to practice other precautions like wearing a mask, social distancing, handwashing until public health officials say otherwise.

If I have tested positive for COVID-19 and have recovered, do I need to be vaccinated?

Yes, even if you have already had COVID-19 you should be vaccinated. Experts do not yet know how long you are protected from getting sick again after recovering from COVID-19. Even if you have already recovered from COVID-19, it is possible—although rare—that you could be infected with the virus that causes COVID-19 again. If you were treated for COVID-19 with monoclonal antibodies or convalescent plasma, you should wait 90 days before getting a COVID-19 vaccine. Talk to your doctor if you are unsure what treatments you received or if you have more questions about getting a COVID-19 vaccine.

If I currently have COVID-19 can I be vaccinated?

People with COVID-19 should wait to be vaccinated until they have recovered from their illness and have met the [criteria](#) for discontinuing isolation.

Vaccine administration

When will I be able to receive a COVID-19 vaccine?

While the first COVID-19 vaccines were authorized in December of 2020, supplies have been limited. With the FDA's authorization of a third safe and effective COVID-19 vaccine, supplies will increase over time, and all adults should be able to get vaccinated later in 2021.

Which COVID-19 vaccine should I receive?

All three FDA authorized COVID-19 vaccines have been shown to prevent severe COVID-19 illness, hospitalizations and death. The different vaccines were studied at different times, in different countries, and under different conditions and thus comparing them is difficult. When it is your turn to get vaccinated, you should take the first vaccine available to you.

Can I be vaccinated against COVID-19 if I have an underlying medical condition?

Any currently authorized COVID-19 vaccine can be administered to persons with underlying medical conditions who have no contraindications to vaccination, including immunocompromised persons, people with autoimmune conditions, people with a history of Guillain-Barré syndrome, Bell's palsy, dermal filler use. Clinical trials demonstrate similar safety and efficacy profiles in persons with underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to persons without comorbidities.

Should you get the COVID-19 vaccine if you have allergies?

CDC recommends that people with a history of severe allergic reactions not related to vaccines or injectable medications—such as food, pet, venom, environmental or latex allergies—get vaccinated. If you have had an immediate allergic reaction, even if it was not severe, to a vaccine or injectable therapy for another disease, ask your doctor if you should get a COVID-19 vaccine.

Some people have experienced [severe allergic reactions](#)—also known as anaphylaxis—after getting a COVID-19 mRNA vaccine. If you have had a severe allergic reaction to any ingredient in an mRNA COVID-19 vaccine, including polyethylene glycol (PEG) or polysorbate, you should not get either of the currently available mRNA COVID-19 vaccines. If you had a severe allergic reaction after getting the first dose of an mRNA COVID-19 vaccine, [CDC recommends](#) that you not get the second dose.

If you have had an immediate allergic reaction (e.g., hives, swelling, wheezing), even if it was not severe, to any ingredient in an mRNA COVID-19 vaccine, CDC recommends that you not get either of the currently available mRNA COVID-19 vaccines. If you had an immediate allergic reaction after getting the first dose of an mRNA COVID-19 vaccine, you should not get the second dose.

Should you get the COVID-19 vaccine if you are pregnant or breastfeeding?

Available data suggest that pregnant patients with COVID-19 are at increased risk of more severe illness and death, compared with nonpregnant individuals. There are limited data available about the safety of COVID-19 vaccines for people who are pregnant. People who are pregnant and part of a [group recommended](#) to receive COVID-19 vaccine, may choose to be vaccinated. A conversation between pregnant patients and their clinicians, while not required, may help them decide whether to get vaccinated. Key considerations include: the current risk of exposure to SARS-CoV-2, the risk of COVID-19 to the patient and their fetus, and how well the vaccine works to protect against COVID-19 and any known side effects of the vaccine.

Similarly, data is lacking on the safety of COVID-19 vaccines in lactating women and 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 health care personnel, may choose to be vaccinated. For more information see the CDC's [vaccine considerations for people who are pregnant or breastfeeding](#) and the AMA's [Daily COVID Update](#) featuring experts from the American Academy of Pediatrics and the American College of Obstetricians and Gynecology.

Will COVID-19 vaccines be available for young children?

At first, COVID-19 vaccines may not be recommended for children, as only non-pregnant adults participate in clinical trials. As more studies are completed, COVID-19 vaccine may be available for children. How many doses of the vaccine are needed?

Both COVID-19 mRNA vaccines require two shots to get the most protection. The timing between your first and second shot depends on which vaccine you received.

- If you received the [Pfizer-BioNTech](#) vaccine, you should get your second shot three weeks (or 21 days) after your first.
- If you received the [Moderna](#) vaccine, you should get your second shot one month (or 28 days) after your first.

You should get your second shot as close to the recommended three-week or one-month interval as possible. However, your second dose may be given up to [six weeks \(42 days\) after the first dose, if necessary](#). You should not get the second dose earlier than the recommended interval.

The Janssen viral vector vaccine is a single dose vaccine.

Are the vaccine candidates interchangeable?

For the mRNA vaccines (Pfizer and Moderna), the same vaccine brand must be used for both shots. The safety and efficacy of a mixed series has not been studied. If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time.

If first dose of mRNA COVID-19 vaccine was received, but a patient is unable to complete series with same or different mRNA vaccine (e.g., contraindication), a single dose of Janssen COVID-19 vaccine may be administered at minimum interval of 28 days from mRNA dose. These patients would be considered to have received valid, single-dose Janssen vaccination, not mixed vaccination series (mRNA/viral vector).

How much will the vaccine cost?

Vaccine doses purchased with U.S. taxpayer dollars will be provided at no cost. However, vaccination providers will be able to charge an administration fee for giving the shot to someone. Vaccine providers can get this fee reimbursed by the patient's public or private insurance company or, for uninsured patients, by the Health Resources and Services Administration's Provider Relief Fund.

Herd Immunity

Once I have been vaccinated, can I stop wearing a mask and practicing social distancing?

According to the CDC, people are considered fully vaccinated for COVID-19 ≥ 2 weeks after they have received the second dose in a two-dose series (Pfizer-BioNTech or Moderna), or ≥ 2 weeks after they have received a single-dose vaccine (Johnson and Johnson/Janssen).

Fully vaccinated people, in non-health care settings, can:

- Visit with other fully vaccinated people indoors without wearing masks or physical distancing
- Visit with unvaccinated people from a single household who are at low risk for severe COVID-19 disease indoors without wearing masks or physical distancing
- Refrain from quarantine and testing following a known exposure if asymptomatic

For now, fully vaccinated people should continue to:

- Take precautions in public like wearing a well-fitted mask and physical distancing
- Wear masks, practice physical distancing, and adhere to other prevention measures when visiting with unvaccinated people who are at [increased risk for severe COVID-19](#) disease or who have an unvaccinated household member who is at increased risk for severe COVID-19 disease
- Wear masks, maintain physical distance, and practice other prevention measures when visiting with unvaccinated people from multiple households
- Avoid medium- and large-sized in-person gatherings
- Get tested if experiencing [COVID-19 symptoms](#)
- Follow guidance issued by individual employers

Follow CDC and health department travel requirements and recommendations. See the CDC's [Interim Public Health Recommendations](#) for Fully Vaccinated People for more information.

What percentage of the population needs to be vaccinated against COVID-19 for the population to have herd immunity?

Experts do not know what percentage of people would need to get vaccinated to achieve herd immunity to COVID-19. The percentage of people who need to have protection to achieve herd immunity varies by disease.