

The COVID-19 Vaccine

Answers to common questions about the COVID-19 vaccine. For more answers to commonly asked questions visit: <https://www.childrenscolorado.org/COVIDVaccineFAQ>

Is the COVID-19 vaccine safe?

Yes, the Pfizer/BioNtech, Moderna and Johnson & Johnson COVID-19 vaccines have gone through each step of the usual process required to understand the safety and effectiveness of a new vaccine. We will learn more about the safety of other COVID-19 vaccines as they go through the FDA's approval process.

Which COVID-19 vaccines have been approved?

At this time, the FDA has approved three vaccines: one from the drug companies Pfizer/BioNtech, one from Moderna, and one from Johnson & Johnson. The research for the Pfizer/BioNtech and Moderna vaccines shows that they are effective in preventing COVID-19 infection. This means they work very well at stopping people from getting sick with COVID-19.

The Johnson & Johnson vaccine showed slightly lower effectiveness in stopping people from getting infected; however, all three of these COVID-19 vaccines are very effective at preventing severe illness, hospitalization, or death from COVID-19.

Will my child be able to get the vaccine?

The Pfizer vaccine is now available for kids 5 and up. For kids under 5 years old, we still need the results from clinical trials before the vaccine can be approved. Kid's bodies are different, and they may react differently to this vaccine than adults do.

As of late 2021, the Moderna and Johnson & Johnson COVID-19 vaccines are only approved for people 18 years and older.

How does a vaccine work?

To understand how a vaccine works, it's helpful to know how viruses work. The virus enters the body, attaches to your cells and takes over the cell to make copies of itself. The immune system then makes antibodies that kill the virus off. But, while the immune system is learning how to fight the virus, the virus can still cause a lot of harm. A vaccine's job is to train the body to recognize a virus (or a bacteria) as soon as it comes along before it can cause any harm. Vaccination causes the immune system to make antibodies and to form a memory of what a virus looks like. If your body sees that virus later on, you already have antibodies and your immune system is prepared to stop the virus in its tracks.

What is mRNA?

Both Pfizer's and Moderna's vaccines use a technology called messenger RNA. Some types of traditional vaccines use parts of the virus that are dead or weakened to get the immune system ready

to fight the germs. mRNA, tells cells what to build inside themselves to protect themselves from the virus.

The advantage of mRNA vaccines is that they're faster to make. The main downside is that mRNA vaccines need to be stored at very cold temperatures, which makes it harder to get the vaccines to where they need to go and for storing them.

These are the first mRNA-based vaccines ever approved by the FDA, but the science behind them is based on many years of research on this type of vaccine.

How are vaccines tested for safety and to make sure they work?

Once scientists learn more about the virus and test potential vaccines in animals, they eventually start testing in humans. Those tests are called clinical trials, and they happen in three phases.

Phase one

The big question in phase one is, "Is it safe?" Phase one trials involve a small group of people. If the vaccine is shown to have harmful effects, the testing ends, and the research process starts over again.

Phase two

Phase two often involves a randomized control trial, where participants are split into two groups: one gets the vaccine being tested; another gets a placebo, or a medicine that doesn't have any effect. In this phase, researchers are building a better understanding of the vaccine's safety, as well as how and if it works.

Phase three

The final phase involves the largest group of people, often in the thousands or tens of thousands. This phase seeks to answer, "How effective is it, and how does it work best?" Researchers study how the vaccine works on people of different ages and medical histories, comparing different doses and how often the vaccine needs to be given to work.

How does a new vaccine get approved?

- If a treatment is shown through clinical trials to be safe and effective, the pharmaceutical company then submits all their data to the FDA.
- The FDA reviews the data and decides whether to approve the vaccine — meaning it decides whether the vaccine is safe and effective enough to be made available to the public.

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IN CARE OF KIDS

- The FDA also has an outside group of experts called the Vaccines and Related Biological Products Advisory Committee, or VRBPAC for short. This group has 15 experts who study vaccines and other related topic areas.
- All its members are fully vetted for potential conflicts of interests and not beholden to political interests. In general, without the VRBPAC approval, the FDA doesn't approve a new vaccine.
- After the FDA approves a vaccine, then the Advisory Committee on Immunization Practices (ACIP) reviews all of that same information about the vaccine and also considers the public health impact that this vaccine could have. The ACIP is a group of experts that includes medical and public health professional as well as public representatives.
- ACIP uses all of the available information about a vaccine and the disease it prevents to make a recommendation to the CDC about how the vaccine should be used by doctors and public health professionals. The CDC usually accepts this recommendation and makes their final vaccine guidance available for people and their doctors.

How were these vaccines created so quickly?

For the past 30-40 years, Scientists and researchers have been studying mRNA vaccines as a way to stop other types of infections and cancers. Scientists also used their knowledge and experience from creating other vaccines for coronavirus infections like MERS and SARSCOV1 to help jump start their research on creating a COVID-19 vaccine. This meant that scientists were ready when COVID-19 became a pandemic. Thousands of scientists from around the world were all working on the same problem at the same time, increasing the chance of successfully coming up with a safe and effective vaccine. A lot of money was invested to solve this problem quickly to help keep people and communities safe.

In the United States, The U.S Department of Health and Human Service made a special program called Operation Warp Speed to help drug companies quickly make a safe and effective COVID-19 vaccine. They gave money to six different drug companies to try to make a successful vaccine within a year and a half. Operation Warp Speed helps drug companies overcome the usual challenges of making a vaccine:

- Funding – vaccines cost a lot of money to develop. Operation Warp Speed helped drug companies start working on research and making the vaccines by paying companies up front. The U.S Government spent tens of billions of dollars with the hope of making at least one vaccine that works.
- Efficiency – It takes a lot of people and organizations to create a vaccine that works. Operation Warp Speed helped make this process go smoother.

Where can I find more up-to-date information about the vaccine?

Immunize Colorado:

<https://www.immunizecolorado.org/healthcare-professionals/covid-19/covid-19-vaccine-faq>

Vaccinate Your Family:

<https://vaccinateyourfamily.org/vaccines-diseases/covid19/>

Centers for Disease Control and Prevention (CDC):

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

Coronavirus Vaccine Tracker:

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

Children's Hospital Colorado COVID-19 Vaccine Updates:

<https://www.childrenscolorado.org/conditions-and-advice/parenting/parenting-articles/covid-vaccine-updates/>

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