



COVID-19 Vaccine Questions and Answers for Parents

October 25, 2022

COVID-19 vaccines are available for everyone ages 6 months and older, as recommended by the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP). COVID-19 vaccination provides parents with the opportunity to protect their children. Having a COVID-19 vaccine available for children will help reduce the chance of outbreaks in schools, daycares, and camps and in turn, further protect our communities.

Parents may have questions about vaccine safety and wonder if vaccination is the right choice for their child. While caution is understandable, it's important that all eligible individuals be vaccinated against COVID-19.

Table of Contents

Is there a COVID-19 vaccine for children?.....	2
Does my child need a COVID-19 vaccine booster?	2
When will COVID-19 vaccines have full FDA approval?	3
Which vaccine should my child get for a primary series? Pfizer, Moderna or Novavax?	3
Is the vaccine safe for all babies – or are there special considerations for babies born prematurely?	3
Do infants of mothers who were vaccinated or had COVID-19 still need to be vaccinated?.....	4
How do I know if my child is up to date on COVID-19 vaccine?	4
My child has a pre-existing condition/health problem. Should they get the COVID-19 vaccine? ...	4
Are the symptoms of COVID-19 infection different in children than in adults?	5
Can children and teens get the vaccine without parent permission?	5
Can my child receive routine vaccinations during the pandemic?	6
If kids have more mild illness, why is a vaccine necessary?.....	8
Is it safe for my child to get the COVID-19 vaccine given the stories about myocarditis?.....	9
Is it safe for my child to get a COVID-19 vaccine if they want to have a baby one day?.....	10
If I have recovered from COVID-19, am I immune to it?.....	10
How can I best protect my child from COVID-19?.....	11
Should children wear masks?.....	12
What studies were done to assure the vaccine is safe for children?	13
How were they able to develop the COVID-19 vaccine faster than vaccines from the past?	13
What are the different phases of clinical trials for vaccines?	15

Is there a COVID-19 vaccine for children?

Yes. Currently, the Pfizer and Moderna vaccines are available for children ages 6 months through 17 years. Novavax is also available for adolescents 12 through 17 years of age.

CDC recommends a COVID-19 vaccine primary series for everyone ages 6 months and older, and COVID-19 boosters for everyone ages 5 years and older, if eligible.

- COVID-19 vaccine schedules vary based on age, product, and immune status. Caregivers should consult with their child's health care provider to determine how many total COVID-19 vaccine doses are recommended.
- View CDC's [At-A-Glance COVID-19 Vaccination Schedules](#).

COVID-19 vaccine provides the opportunity to further protect your child from COVID-19 and help get life back to normal.

COVID-19 vaccines have gone through clinical trials and scientific review just like any other vaccine — including those your child has likely already received — with the same high level of quality and safety standards.

Vaccination gets our kids back to the programs, activities, and social interactions they need for academic, social, emotional, and physical development.

Source:

[Children's Hospital of Philadelphia: Should My Child Get the COVID-19 Vaccine?](#)

Does my child need a COVID-19 vaccine booster?

Most people are recommended to receive a booster dose of vaccine. Everyone 5 years of age and older are eligible for a dose of the omicron bivalent booster (Pfizer) if it has been at least two months since their last dose of COVID-19 vaccine.

- The omicron bivalent booster is an mRNA vaccine that targets the most recent and more contagious omicron variants (BA.4 and BA.5).
- Monovalent vaccines are no longer authorized for booster use*.

*With the exception of Novavax [which is authorized as a booster for 18 years and older in limited situations](#).

When will COVID-19 vaccines have full FDA approval?

On July 8, 2022, the U.S. Food and Drug Administration (FDA) granted full approval of Pfizer-BioNTech's COVID-19 vaccine, marketed as COMIRNATY, for adolescents 12 through 15 years of age. The Pfizer-BioNTech COVID-19 Vaccine has been, and will continue to be, authorized for emergency use in this age group since May 2021. COMIRNATY (COVID-19 Vaccine, mRNA) has been approved for use in individuals 16 years of age and older since August 2021.

Moderna (Spikevax) COVID-19 vaccine received full U.S. Food and Drug Administration (FDA) approval on January 31, 2022, for individuals ages 18 years and older. Once vaccines are approved by the FDA, companies can market the vaccines under brand names. Spikevax is the brand name for the Moderna COVID-19 vaccine.

Which vaccine should my child get for a primary series? Pfizer, Moderna or Novavax?

All three vaccines, Pfizer, Moderna, and Novavax are safe and effective at preventing severe illness and death from COVID-19. Caregivers may choose which vaccine their child gets, but health care providers may only have one type of vaccine available. Caregivers are encouraged to get whichever vaccine is available and medically appropriate for their child.

Is the vaccine safe for all babies – or are there special considerations for babies born prematurely?

In accordance with [general best practices](#), preterm infants (infants born before 37 weeks' gestation), regardless of birth weight, should receive COVID-19 vaccination at their chronological age and according to the [same schedule](#) and guidance as for full-term infants and children. Caregivers should talk to their health care provider about health situations specific to their child.

Do infants of mothers who were vaccinated or had COVID-19 still need to be vaccinated?

Yes. Infants of mothers who were vaccinated and/or had COVID-19 or SARS-CoV-2 infection before or during pregnancy should be vaccinated according to the [recommended schedule](#).

How do I know if my child is up to date on COVID-19 vaccine?

Up to date means a person has received a COVID-19 vaccine primary series, including any booster dose(s) recommended by the CDC.

To find out if your child is up to date on COVID-19 vaccine, check their immunization record, talk to their doctor, or use the [COVID-19 Up to Date Tool](#).

My child has a pre-existing condition/health problem. Should they get the COVID-19 vaccine?

Yes. Children and teens with pre-existing conditions like diabetes or heart conditions, those with Inflammatory Bowel Disease (e.g., Crohn's disease or ulcerative colitis) or other autoimmune diseases, or those who are taking medications that compromise their immune system, may be at higher risk of complications from COVID-19 infection – so it is especially important that they are vaccinated against COVID-19.

The COVID-19 vaccines that have been authorized or approved for use cannot cause COVID-19, even in those with weak immune systems. If you have questions about your child's health or the risks and benefits of receiving a COVID-19 vaccine, talk to your child's doctor.

We know that people with moderately or severely compromised immune systems are more vulnerable to COVID-19 and may not build the same level of immunity to COVID-19 vaccines compared to those who are not immunocompromised. COVID-19 vaccine schedules vary based on age, product, and immune status. Caregivers should consult with their child's health care provider to determine how many total COVID-19 vaccine doses are recommended.

Sources:

[Children's Hospital of Philadelphia: Should My Child Get the COVID-19 Vaccine?](#)

Are the symptoms of COVID-19 infection different in children than in adults?

The symptoms of COVID-19 appear to be similar in children and adults. Children with confirmed COVID-19 generally have mild, cold-like symptoms, such as fever, sore throat, runny nose, and cough. Vomiting and diarrhea have also been reported.

Health officials are advising parents to watch for symptoms related to a rare but serious inflammatory condition seen in children and linked to the COVID-19 virus, called Multisystem Inflammatory Syndrome in Children (MIS-C). If you notice any of the following symptoms, call your child's pediatrician:

- A fever lasting more than 24 hours.
- Abdominal pain, diarrhea, or vomiting.
- Rash or changes in skin color.
- Trouble breathing (call 911 if this symptom is present).
- Your child seems confused or overly sleepy.

Vaccination is the best protection against COVID-19 **and** MIS-C. [Recent studies](#) have shown that children ages 12 through 17 who have received two doses of the Pfizer vaccine were less likely to have severe outcomes from MIS-C.

Babies under the age of one and children with certain underlying conditions may be more likely to have severe illness from COVID-19. Studies are ongoing regarding how the disease impacts everyone, including children.

Be sure to let your child's pediatrician know if your child has tested positive for COVID-19 or has been exposed to the virus. Your pediatrician will let you know if your child can be seen in the office or if you need to go to the emergency department.

Sources:

[CDC: COVID-19 Frequently Asked Questions](#)

[CDC: For Parents – MIS-C associated with COVID-19](#)

[CDC: MIS-C and COVID-19](#)

[AAP: MIS-C and COVID-19](#)

Can children and teens get the vaccine without parent permission?

Minors, 6 months through 17 years of age, need parental consent to be vaccinated.

Can my child receive routine vaccinations during the pandemic?

Yes. Routine well-child visits and vaccine visits are essential, even during the COVID-19 pandemic. It's important that your family continue to receive their immunizations, including flu vaccines, on time and according to the [schedule recommended by the U.S. Centers for Disease Control and Prevention \(CDC\)](#). Many infectious diseases are serious. It is critical that we avoid outbreaks of vaccine preventable diseases, like flu, measles, pertussis (whooping cough), and mumps.

Prepare for the visit by calling your child's health care provider to ask when your child's vaccinations are due and what procedures are in place at the office.

Sources:

[CDC: Routine vaccinations during COVID-19](#)

[CDC: Keep Children Healthy during the COVID-19 Pandemic](#)

Can the COVID-19 vaccine be administered at the same time as other vaccines?

COVID-19 vaccines may be administered at the same time as other vaccines, including the flu vaccine – there is no waiting period. Your child's doctor may recommend getting multiple vaccines in one appointment. Be sure to have a discussion with your child's doctor to discuss what vaccines your child may need.

What is the difference between mRNA (Pfizer, Moderna) vaccines, adenovirus (Johnson & Johnson) vaccines and protein subunit (Novavax) vaccine?

Many vaccines put a weakened or inactivated germ into our bodies to trigger an immune response, but some of the current COVID-19 vaccines work a little different. Instead, they teach our cells how to make a protein—or even just a piece of a protein—that triggers an immune response inside our bodies. That immune response, which produces antibodies, is what protects us from getting infected or seriously ill if the real virus enters our bodies.

mRNA vaccines

Pfizer and Moderna are mRNA vaccines. mRNA stands for messenger ribonucleic acid.



[View How mRNA vaccines work online.](#)

COVID-19 mRNA vaccines give instructions to our cells to make a harmless piece of what is called the “spike protein” which is the same protein found on the surface of the virus that causes COVID-19 disease. Next, our cells display this protein piece on its surface, similar to how the COVID-19 virus would. Our immune systems recognize that the protein doesn’t belong there and begins building an immune response and making antibodies, like what happens in an actual COVID-19 infection. After the protein piece is made, our cells break down the ‘instructions’ from the vaccine. At the end of the process, our bodies have learned how to protect against any future COVID-19 infection.

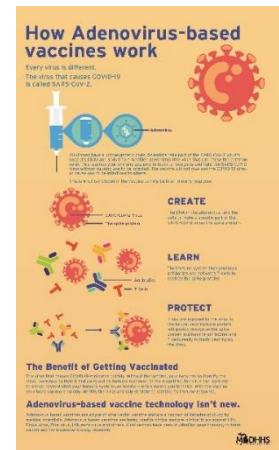
The benefit of mRNA vaccines, like all vaccines, is that those who are vaccinated gain protection without ever having to risk the serious consequences of getting sick with COVID-19.

Adenovirus vaccines

Johnson & Johnson is an adenovirus vaccine. Currently, there are no adenovirus vaccines available for anyone under 18 years of age.

[View how Adenovirus-based vaccines work online.](#)

In an Adenovirus-based vaccine, scientists take part of the SARS-CoV-2 virus’s code (its DNA) and add it to a modified adenovirus (a virus that can cause the common cold). This teaches your immune systems to learn to recognize and fight the SARS-CoV-2 virus without causing you to be infected. The vaccine will not give you the COVID-19 virus or cause you to be infectious to others.



Protein subunit vaccines

[Novavax](#) is a protein subunit vaccine. Novavax is available as a primary dose for individuals 12 years and older.

[View how Protein Subunit COVID-19 Vaccines work online](#)

Protein subunit COVID-19 vaccines contain pieces (proteins) of the virus that cause COVID-19; these proteins are called the “spike protein.” Protein subunit COVID-19 vaccines also contain another ingredient called an adjuvant that helps the immune system respond to that virus in the future. Once the immune system knows how to respond to the spike protein, the immune system will be able to respond quickly to

the actual virus spike protein and protect against COVID-19. Protein subunit vaccines have been around for many years and are the type used for pertussis (whooping cough), hepatitis B, the flu vaccine, and more.

Sources:

[University of Michigan: The Top 5 COVID-19 Vaccine Candidates Explained](#)

[CDC: Understanding mRNA COVID-19 Vaccines](#)

[CDC: Understanding Protein Subunit COVID-19 Vaccines](#)

[Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines](#)

[CDC: Different COVID19 Vaccines](#)

If kids have more mild illness, why is a vaccine necessary?

Though most children with COVID-19 have mild or no symptoms, some children can get severely ill and require hospitalization, and there is no way to tell in advance if your child will get a severe or mild case. Also, this age group can transmit the infection to more vulnerable family and community members, such as those who are unable to get the vaccine.

There have also been rare, tragic cases of children dying from COVID-19 and its effects, including Multisystem Inflammatory Syndrome in Children, or MIS-C. Visit Michigan.gov/MISCCchildren to learn more about this post-COVID-19 syndrome.

MIS-C can occur weeks after COVID-19 infection, even if the child or family did not know the child had COVID-19. Most children who become ill with MIS-C will need to be hospitalized and some will need to be treated in the pediatric intensive care unit. Symptoms of MIS-C include abdominal pain, vomiting, diarrhea, neck pain, rash, bloodshot eyes and exhaustion/fatigue.

[Find current case data for MIS-C in Michigan.](#)

[Find current case data for MIS-C in the United States.](#)

Things to consider:

- Over time, children 5-11 years are making up a greater proportion of total cases.
- Conditions such as obesity, asthma, and developmental delay, as well as other pre-existing conditions, increase the chance for hospitalization.
- Racial and ethnic minority groups have disproportionately higher hospitalization rates among every age group, including children aged younger than 18 years.
 - As of Feb. 19, 2022, for children ages 0-17 years, the rate of hospitalization is 150.6 for Non-Hispanic Black, 145.0 for Hispanic or

Latino, and 63.0 for Non-Hispanic White. ([Disparities in COVID-19-Associated Hospitalizations | CDC](#))

- CDC reports that 1,747 children and teens up to 17 years of age in the U.S. have died from COVID-19 (as of October 5, 2022). ([CDC COVID Data Tracker](#))

Getting adolescents vaccinated means they're safer to return to social activities and can provide parents and caregivers peace of mind knowing their family is protected. Further, vaccinating children is key to raising the level of immunity in the population and limiting the spread of COVID in our communities.

Source:

[Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines](#)

Is it safe for my child to get the COVID-19 vaccine given the stories about myocarditis?

Cases of myocarditis, or inflammation of the heart, have been reported after receipt of the COVID-19 mRNA vaccine. Myocarditis following vaccination is short-lived and tends to resolve on its own, whereas myocarditis following an infection tends to be [more severe](#). [The risk of myocarditis from COVID-19 infection appears to be greater than the risk of myocarditis from COVID-19 vaccination](#). Available data suggest that the [incidence of myocarditis following mRNA vaccines is about 1 per 50,000 vaccine recipients](#). Of interest, myocarditis also occurs more commonly after either acute COVID-19 or as part of the Multisystem Inflammatory Syndrome in Children (MIS-C).

This condition is continuing to be investigated. Here is what we know to date:

- The cases of myocarditis that have occurred so far were more often in boys and young men and more often after the second dose of COVID-19 vaccine. Symptoms occurred within several days after receipt of the dose. Recently immunized teens and young adults who experience chest pain or shortness of breath should be seen by a health care provider and report their recent vaccination.
- Myocarditis is somewhat common, particularly as a result of viral infections. In fact, cases tend to occur more often in the spring due to viruses that circulate at this time of year (specifically, coxsackie B viruses). Typically, about 100-200 cases occur per million people per year.

- Watch for symptoms that may include chest pain, pressure, heart palpitations, difficulty breathing after exercise or lying down, or excessive sweating. One or more of these symptoms may also be accompanied by tiredness, stomach pain, dizziness, fainting, unexplained swelling, or coughing. If a recently vaccinated teen develops these symptoms or you are unsure, contact the child's doctor or seek more immediate medical assistance if needed.

The CDC will continue to monitor the situation related to myocarditis, but for now, there is not a reason to stop vaccinating kids. The American Heart Association has also released a [statement](#) encouraging continued vaccination.

Source:

[Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines](#)

Is it safe for my child to get a COVID-19 vaccine if they want to have a baby one day?

Yes. According to the experts at the [American College of Obstetricians and Gynecologists \(ACOG\)](#), if you are planning or trying to get pregnant, you can get a COVID-19 vaccine. There is no evidence, during clinical trials or in the millions of doses already given, suggesting that fertility problems are a side effect of any of the COVID-19 vaccines available for use in the U.S. Like all vaccines approved/authorized for use in the U.S., the COVID-19 vaccines are being studied carefully now and continue to be monitored for side effects and safety for many years. Further, you do not need to delay getting pregnant after you get a COVID-19 vaccine.

If you find out you are pregnant after you have the first dose of a COVID-19 vaccine, you should still get the second dose and/or booster doses. Contact your doctor if you have any questions or concerns.

If I have recovered from COVID-19, am I immune to it?

Reinfection with the virus that causes [COVID-19](#) means a person was infected, recovered, and then later became infected again. After recovering from COVID-19, most individuals will have [some protection from repeat infections](#). However, reinfections do occur after COVID-19. We are still learning more about these reinfections.

It is recommended to receive the COVID-19 vaccine even if there is a previous history of COVID-19 infection. You may consider delaying your vaccine by three months from when your symptoms started or, if you had no symptoms, three months from when you received a positive test result. Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic COVID-19 infection, this includes people with prolonged post-COVID-19 symptoms. Viral testing to assess for COVID-19 infection or serologic testing to assess for prior infection solely for the purposes of vaccine decision-making is not recommended.

Vaccination of persons with known current COVID-19 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and [criteria](#) have been met for them to discontinue isolation. This recommendation applies to persons who develop COVID-19 infection before receiving any vaccine doses as well as those who develop infection after the first dose but before receipt of the second dose. While there is no recommended minimum interval between infection and vaccination, [current evidence](#) suggests the risk of COVID-19 reinfection is low three months after infection but may increase with time due to waning immunity.

Sources:

[CDC: Interim Clinical Considerations for Use of COVID-19 Vaccines](#)

[CDC: Frequently Asked Questions about COVID-19 Vaccination](#)

[Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines](#)

How can I best protect my child from COVID-19?

- **Get them vaccinated with an age appropriate COVID-19 vaccine.**
- **Teach children** about COVID-19 health and safety measures to help stop the spread.
- **Avoid people who are sick** (coughing and sneezing).
- **Stay home when sick**, except to get testing or medical care.
- **Cover coughs and sneezes** with a tissue and throw the tissue in the trash.
- **Wash hands often** with soap and water for at least 20 seconds, especially after blowing your nose, coughing, or sneezing; going to the bathroom; and before eating or preparing food.
 - If soap and water are not readily available, use an alcohol-based hand sanitizer with at least 60% alcohol. Always wash hands with soap and water if visibly dirty.

Clean and disinfect high-touch surfaces frequently in common areas (like tables, hard-backed chairs, doorknobs, light switches, remotes, handles, desks, toilets, and sinks).

For infants, the best way is to limit exposure and avoid unnecessary public contact. Infants as young as 6 months old can begin their COVID-19 vaccine series. Vaccination is the best protection against COVID-19.

To keep your baby healthy, when going out:

- Cover the infant carrier (not your baby) with a light blanket. This will help protect your baby, but still gives them the ability to breathe comfortably. Do not leave the blanket on the carrier in the car or at any time when your baby and carrier are not in your direct view. Check on your baby often.
- Do not put a mask on your baby, or any child under the age of two.
- Never leave children alone in the car. The temperature in your car can become deadly in a short time.
- Wash hands (and any children's hands) as soon as you return home.
- Try to surround your baby with caregivers that have been fully vaccinated.

You can find additional information from the CDC about preventing COVID-19 here:

- [CDC: How to Protect Yourself & Others](#)
- [CDC: Preventing COVID-19 Spread in Communities](#)
- [CDC: How Coronavirus Spreads](#)
- [CDC: Children and Coronavirus Disease 2019 \(COVID-19\)](#)

Source:

[CDC: COVID-19 Frequently Asked Questions](#)

Should children wear masks?

Masks should NOT be put on babies or children younger than two years of age because of the danger of suffocation. Children ages 2 years and older can wear masks or respirators to protect themselves and others from COVID-19.

Wearing masks is a public health measure people can take to reduce the spread of COVID-19 in addition to (not instead of) frequent hand washing, and other everyday preventive actions. If your child is wearing a mask, make sure to choose a well-fitting and comfortable mask or respirator that your child can wear

properly. A poorly fitting or uncomfortable mask or respirator might be worn incorrectly or removed often, and that would reduce its intended benefits.

[Masks protect both the wearer and others.](#) Masks are a simple barrier to help prevent your respiratory droplets from reaching others. Studies show that masks reduce the spray of droplets when worn over the nose and mouth. A mask also offers you some protection too and how well it protects you from breathing the virus in depends on the fabric used and how the mask is made.

More specifics on masks from the Michigan Department of Health and Human Services can be found at [Michigan.gov/MaskUp](https://www.michigan.gov/MaskUp).

Sources:

[MDHHS: Face Coverings Frequently Asked Questions](#)

[CDC: Use and Care of Masks](#)

What studies were done to assure the vaccine is safe for children?

Before authorizing or approving [COVID-19 vaccines](#), scientists conducted clinical trials with thousands of children and teens to establish their safety and effectiveness.

Through continued [safety monitoring](#), COVID-19 vaccination has been found to be safe for children and teens. Visit the CDC's vaccine safety website for information on the most recent studies about vaccine safety.

[COVID-19 Vaccine Safety in Children and Teens](#)

- [Children ages 5 through 11 years](#)
- [Children ages 12 through 17 years](#)

How were they able to develop the COVID-19 vaccine faster than vaccines from the past?

Thanks to unprecedented, worldwide collaboration from scientists, health and government officials, and manufacturers, the medical community was able to focus on the development and production of a safe and effective COVID-19 vaccine.

Through the strong collaborations COVID-19 vaccine research grew and expanded to where there are now multiple COVID-19 vaccines available in the U.S.

Video: “COVID-19 Vaccines: How Do We Know They Are Safe?”

Watch the video: [“COVID-19 Vaccines, How Do We Know They Are Safe?”](#)

The first two COVID-19 vaccines that were authorized for emergency use (Pfizer-BioNTech and Moderna) were built using a technology called mRNA, rather than using a weakened or dead virus as traditional vaccines do. Traditional vaccine production involves growing viruses in living cells and purifying the virus. There are challenges associated with this process that takes time. The mRNA vaccine has an advantage in that large amounts of the mRNA can be synthesized very rapidly.

While COVID-19 vaccines have been developed more quickly than other vaccines, speed did not affect safety. In addition to the advantage for mRNA vaccine production, the timeline was shortened without sacrificing quality by:

- Overlapping phase I and phase II clinical trials. Phase I studies include a small number of people and an evaluation on whether the vaccine causes an immune response and is safe. Scientists could look at data from a group of people as phase II was progressing to make these evaluations.
- While completing large phase III trials, manufacturers began producing the vaccine, so that if it was shown to be safe and effective, they would have large numbers of doses ready. This is not normally done because if the vaccine does not work, the manufacturer will have spent a significant amount of money to produce something that needs to be thrown away.
- While waiting for a vaccine to be ready, many other aspects of vaccine delivery were prepared (e.g., developing plans for how to distribute the first, limited quantities available, ensuring adequate supplies for distributing and administering vaccine.)

Past research on vaccines has identified potential successful approaches which has reduced the development time for a COVID-19 vaccine. These mRNA vaccines are a product of decades of study on RNA therapies and treatment by medical scientists. Beyond vaccines, cancer research has used mRNA to trigger the immune system to target specific cancer cells. mRNA technology has been used successfully for cancer immunotherapy by harnessing the body's immune system to identify and kill cancer cells in the same way the immune system identifies and targets infection from viruses or diseases.

Learn more about [how COVID-19 vaccines were developed and approved](#).

Sources:

[CDC: Understanding mRNA COVID-19 Vaccines](#)

[Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines](#)

[The Promise of mRNA Vaccines](#)

What are the different phases of clinical trials for vaccines?

The goal of the vaccine-approval process is to end up with a vaccine that is effective (the vaccine works in preventing the illness) and safe (there are no serious side effects or other problems). In the United States, this process has produced safe and effective vaccines for the flu, polio, measles, mumps, pertussis, and more. Over time, this process has saved millions of people from getting sick and dying.

The stages of development generally follow this timeline:

- **Exploratory stage:** This is the start of lab research to find something that can treat or prevent a disease. Vaccine development typically begins not at a pharmaceutical company, but in a research laboratory in a university, medical center, or biotech company. Scientists in these laboratories are most often funded by grants from the government or private foundations.
- **Pre-clinical stage:** Scientists use lab tests and testing in animals, such as mice or monkeys, to learn whether a vaccine might work. Many potential vaccines do not make it past this point. If the tests are successful, and the U.S. Food and Drug Administration (FDA) signs off, it's on to clinical testing.
- **Clinical development:** This is a three-phase process of testing in humans.
 - **Phase I** usually involves fewer than 100 people and seeks to answer two main questions: does the vaccine generate the expected immune response (does it work in creating antibodies to protect someone from the disease) and is the vaccine safe (does the vaccine show any serious side effects)?
 - **Phase II** involves several hundred people, comparing those who did and did not receive vaccine. During this phase, scientists try to determine the proper dose of vaccine to be given, and they continue to study the vaccine's safety. They also determine how to manufacture the vaccine — making sure the process and packaging creates a consistent vaccine, so that each batch produces similar results.
 - **Phase III** involves tens of thousands of study participants who are similar to the population that will receive the vaccine, again comparing

those who did and did not receive vaccine. During these studies, as with the previous phases, no one working with the patients, testing the samples collected from patients, or calculating the results, knows which participants received the vaccine and which did not (this is called a “double-blind” study). Researchers are also studying how long the vaccine can be used before it expires, taking into consideration how it will be transported and stored.

- **Regulatory review and approval:** Scientists with the FDA and CDC closely review the data from the clinical trials before a vaccine can be licensed and approved.
 - Additionally, the Advisory Committee on Immunization Practices (ACIP) – a group of independent medical and public health experts who review data on new and existing vaccines and diseases – will make recommendations for approval and use within specific age groups.
- **Manufacturing:** The vaccine goes into production. The FDA inspects the factory and approves drug labels.
- **Quality control:** Scientists and government agencies use databases such as the [Vaccine Adverse Event Reporting System \(VAERS\)](#) and the [Vaccine Safety Datalink Project](#) to monitor vaccine safety.
 - VAERS collects and analyzes reports of adverse events that happen after vaccination. Anyone can submit a report, including parents, patients, and health care professionals. That report is then evaluated by medical experts and examined for trends to identify any vaccine safety issues.
 - The Vaccine Safety Datalink Project, a network of health care organizations across the U.S., analyzes health care information from over 24 million people, which scientists use to actively monitor safety.
 - Vaccine recommendations may change if safety monitoring reveals new information on vaccine risks (like if scientists detect a new serious side effect).
 - The COVID-19 vaccines use standard safety programs, which are already in place, and the new quality control program known as [V-Safe](#). This new program is a vaccination health checker which uses smartphone technology to monitor and receive reports about adverse side effects.

Sources:

[CDC: Ensuring the Safety of COVID-19 Vaccines in the United States](#)

[CDC: Ensuring COVID-19 Vaccines Work](#)

[Children's Hospital of Philadelphia: Questions and Answers about COVID-19 Vaccines](#)
[CDC: V-safe After Vaccination Health Checker](#)