COVID-19 Vaccine
Questions and Answers for Parents

August 8, 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.

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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.

CDC recommends COVID-19 primary series vaccines 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 doctor 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?

Which vaccine should my child get? Pfizer or Moderna?

Both the Moderna and Pfizer vaccines are safe and effective at helping to prevent COVID-19. Caregivers may choose which vaccine their child gets, but most health care providers will only have one type of vaccine available. Caregivers are encouraged to get whichever vaccine is available to their child.

Both vaccines are effective in reducing the rate of infection and create similar levels of immunity in kids. It is estimated that both vaccines decrease the rate of hospitalization, the rate of MIS-C, and the rate of ICU stays.

- Pfizer: Children 6 months through 4 years receive a three-dose primary series. (Two doses three to eight weeks apart and a third dose at least two

months later. If immunocompromised, dose one and two should be three weeks apart.) Each dose is one-tenth of the Pfizer dose adults receive.

- Moderna: Children 6 months through 5 years receive a two-dose primary series. (Two doses four to eight weeks apart. If immunocompromised, the doses should be four weeks apart.) Each dose is one quarter of the Moderna dose adults receive.
- Please reference the CDC's At-A-Glance COVID-19 Vaccination Schedules for more information.

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 all recommended COVID-19 vaccines, including any booster dose(s) when eligible.

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.

View the COVID-19 Vaccination Schedule or the COVID-19 Vaccination Schedule for Moderately or Severely Immunocompromised to learn about vaccine dose timing.

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. View CDC's [At-A-Glance COVID-19 Vaccination Schedules](#) to learn more.

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, 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 COVID-19 outbreak?

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)](#).

COVID-19 vaccine and other vaccines, like the flu vaccine, may be administered during the same visit.

Many infectious diseases are serious. At a time when our health care system may be overwhelmed, it is critical that we avoid outbreaks of vaccine preventable diseases, like flu, measles, pertussis (whooping cough), and mumps.

Please keep in mind that the COVID-19 vaccine may be administered without regard to timing of other vaccines. This means that your child may receive an age appropriate COVID-19 vaccine and other vaccines (like the flu vaccine) on the same day or at any time before or after another vaccine.

Many medical offices are taking extra steps to make sure that well visits can happen safely during the COVID-19 outbreak, including:
- Scheduling sick visits and well-child visits during different times of the day.
- Asking patients to remain outside until it's time for their appointment to reduce the number of people in waiting rooms.
- Offering sick visits and well-child visits in different locations.
- Screening for symptoms by phone before the appointment.
- Asking everyone to wear masks during their appointment.

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.
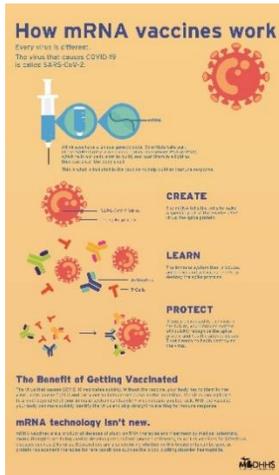
COVID-19 mRNA vaccines give instructions to our cells to make a harmless piece of what is called the "spike protein" which is the same protein found on the surface of the virus that causes COVID-19 disease. Next, our cells display this protein piece on its surface, similar to how the COVID-19 virus would. 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.
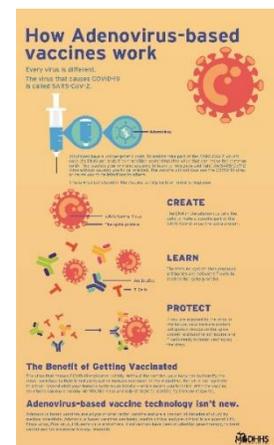
Protein subunit vaccines

[How Protein Subunit COVID-19 Vaccines work](#)
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.

[Novavax](#) is a protein subunit vaccine. Currently, there are no COVID-19 protein subunit vaccines available for anyone under 18 years of age.

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/MISCChildren](#) to learn more about this post-COVID-19 syndrome.

While children and teens may not be as likely to get severely ill from COVID-19, it can still happen. With this in mind, parents should consider the following:

Michigan data:

- In Michigan, more than 436,618 confirmed COVID-19 cases have been reported among youths ages 0 to 19 years as of July 26, 2022.
- Forty-seven COVID-19 deaths have been reported in youths ages 0 to 19 years as of July 26, 2022.
- In Michigan, 308 children have been identified as having Multisystem Inflammatory Syndrome in Children (MIS-C) as of July 26, 2022.

National data:

Over time, children 5-11 years are making up a greater proportion of total cases. As of August 3, 2022, more than 5.4 million children aged 5-11 years have been infected, representing 6.6% of all cases in the U.S. Children aged 12-17 years make up an additional 7.3%. Overall, there have been over 14.4 million COVID-19 cases in children aged 0-17 years in the U.S. ([CDC COVID Data Tracker](#))
More than 144,378 children ages 0-17 years have been hospitalized due to COVID-19 in the U.S (between 8/1/2020-8/1/2022). ([CDC COVID Data Tracker](#))

- 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](#))
- More than 1,733 children and teens up to 17 years of age in the U.S. have died from COVID-19 (as of August 3, 2022). ([CDC COVID Data Tracker](#))
- There have been 8,639 cases of MIS-C, (including 70 deaths) reported on or before June 27, 2022. ([CDC COVID Data Tracker)](#)
    - Fifty percent of children with MIS-C were between the ages of 5 and 13 years.
    - 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.

- To date, the majority (57%) of MIS-C patients have been of Hispanic/Latino or Non-Hispanic Black race/ethnicity. Hispanic/Latino and Non-Hispanic Black populations are also disproportionately affected by COVID-19 overall.

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.

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

- The risk of myocarditis from COVID-19 **infection** appears to be **greater** than the risk of myocarditis from COVID-19 **vaccination**.
- The cases of myocarditis that have occurred so far were more often in boys and young men and more often after the second dose. 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.
- To date, about 530 million doses of the COVID-19 vaccines have been given, and about 16.6 million of these have been in teens (12 through 17 years old).

- 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).
- 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 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?

Right now, we do not know how long antibodies last after infection. There is not enough information currently available to say if or for how long after infection someone is protected from COVID-19, which is also known as natural immunity. Early evidence suggests natural immunity from COVID-19 may not last very long, but more studies are needed to better understand this. Re-infections have been reported. Currently, it is recommended to receive the COVID-19 vaccine even if there is a previous history of COVID-19 infection. It's important to remember that the virus that causes COVID-19 is very new, and scientists are actively working to study it.

Data from clinical trials indicate that mRNA COVID-19 vaccines are safe in persons with evidence of a prior COVID-19 infection. 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 in the 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 the COVID-19 vaccine**, when available to them.
- **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).

It's important to teach children and teens how to practice social distancing, especially for those who are not eligible to be vaccinated. The key to slowing the spread of COVID-19 is to limit contact as much as possible.

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:
- Keep the outing short and always follow the 6 feet distancing rule.
- 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.

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) social distancing, 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](#).

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?

For vaccination of youth 6 months through 4 years (Pfizer) and 6 months through 5 years (Moderna):
Both vaccines are effective in reducing the rate of infection and create similar levels of immunity in kids. It is estimated that both vaccines decrease the rate of hospitalization, the rate of MIS-C, and the rate of ICU stays.

[Side effects](#) reported in the clinical trials for children ages 6 months to 4 years (Pfizer) and 6 months to 5 years (Moderna) were minimal and consistent with other age groups. Moderna recipients reported slightly higher rates of side effects than Pfizer recipients.

For vaccination of youth ages 5 through 11 years:
The vaccine's safety was studied in approximately 3,100 children ages 5 through 11 who received the vaccine and no serious side effects have been detected in the ongoing study.
  – The available safety data to support the EUA include more than 4,600 participants (3,100 vaccine, 1,538 placebo) ages 5 through 11 years enrolled in the ongoing study. In this trial, a total of 1,444 vaccine recipients were followed for safety for at least two months after the second dose.
Side effects were generally mild to moderate in severity and occurred within two days after vaccination, and most went away within one to two days.

For vaccination of youth ages 12 through 15 years:
There were a smaller number of participants in this trial than in trials for adults, but thousands of adolescents received the COVID-19 vaccines during clinical trials and tens of millions of adults in the United States have received COVID-19 vaccines under the most intense safety monitoring in U.S. history.

It is important to note that although the trial enrolled a relatively narrow range of ages (12-15 years and 16-25 years), there were 1,131 participants ages 12-15 years who received the Pfizer BioNTech vaccine and there were 1,867 participants ages 16-25 years that received the vaccine. The earlier published clinical trial supporting EUA for 16 years and above was larger (18,860 vaccine recipients) it was also across a much broader age range (16-89 years).

The good news is that through the trial it was noted that adolescents showed similar side effect patterns to adults and that those aged 12-15 years had immune responses that were higher as compared to those aged 16-25 years, and the vaccine efficacy estimate was 100% for symptomatic lab-confirmed COVID-19.

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 multipleCOVID-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.

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.

- o **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.
    - o 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.
    - o 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.
    - o 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.
    - o Vaccine recommendations may change if safety monitoring reveals new information on vaccine risks (like if scientists detect a new serious side effect).
    - o 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](#)

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.

On August 21, 2021, the U.S. Food and Drug Administration granted full approval for the first COVID-19 vaccine. The vaccine known as the Pfizer-BioNTech COVID-19 Vaccine and will now be marketed as Comirnaty (koe-mir'-na-tee), for the prevention of COVID-19 disease in individuals 16 years of age and older.

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.