

COVID-19 Vaccines for Young Children Ages 6 Months – 4 Years

The American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), the Advisory Committee on Immunization Practices (ACIP), the Centers for Disease Control and Prevention (CDC) and the North Dakota Department of Health and Human Services (NDHHS) recommend all people ages 6 months and older stay up-to-date with COVID-19 vaccine. The information presented in this handout is compiled to help parents and guardians make an informed decision about COVID-19 vaccination for their children.

What COVID-19 vaccines are available for young children?

The Food and Drug Administration (FDA) has granted emergency use authorization (EUA) for COVID-19 vaccines for children ages 6 months through 4 years. Determining which vaccine your child is eligible to receive is dependent on history of vaccination and vaccine manufacturer. Parents or guardians should talk to their child's health care provider if they have questions regarding which vaccine their children are eligible to receive.

COVID-19 Illness & Complications in Young Children **Symptomatic Infection**

Children are less likely to develop symptoms if infected with COVID-19; however, there is still the chance that any child could develop symptoms and/or become severely ill due to COVID-19. Additionally, children with underlying health conditions are even more susceptible to experiencing mild to severe symptomatic infection.

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Hospitalization

While most children who contract COVID-19 will experience mild symptoms or no symptoms at all, some children can become severely ill from COVID-19 infection. These children may require hospitalization, intensive care, or a ventilator to help them breathe.

- [Nationally](#), about half of children hospitalized due to COVID-19 had no underlying medical conditions. Additionally, only 6% of children hospitalized were up-to-date with the COVID-19 vaccine.

Death

In rare cases, children who contract COVID-19 may die. Children with underlying health conditions such as asthma, diabetes, or obesity are at increased risk of death due to COVID-19.

- In the United States, over [900 children](#) from birth through 4 years have died.
- In [research](#) published in the Journal of the American Medical Association, it was found that for every 1,000,000 positive COVID-19 cases in this age group, 4 children died, marking COVID-19 the 7th leading cause of death for this group in the U.S. from 2020-2022.

Multisystem Inflammatory Syndrome (MIS-C)

COVID-19 infection has also been linked to a rare but serious health condition called multisystem inflammatory syndrome in children ([MIS-C](#)). Children who develop MIS-C experience inflammation in different body parts, including the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs. These children may face ongoing health issues due to heart or other organ damage as a result of COVID-19 infection.

- Since September 05, 2024, there have been over [9,700 cases of MIS-C](#) recorded in the United States with around 25% of those for children under the age of 5.
- MIS-C is more commonly reported among males (60%) and is disproportionately identified in Hispanic and Non-Hispanic Black children.

To learn more about the emergency warning signs and symptoms of MIS-C please visit the link [here](#). It is important that children seek medical attention as soon as possible if they begin to develop symptoms of MIS-C.

Post COVID-19 Conditions (“Long COVID”)

Young children may have trouble describing symptoms of acute COVID-19 infections and post-Covid, so information in this age group is particularly limited. Counts or rates of post-Covid

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conditions are not available and estimates are best observed nationally. A COVID-19 case in any age group is at risk of developing post-COVID symptoms, though children and adolescents observe the condition less often. Most frequent symptoms of long-Covid in children under the age of 5 include:

- Tiredness or fatigue
- Headache
- Trouble sleeping
- Trouble concentrating
- Muscle and joint pain
- Cough

These symptoms could affect your child's ability to attend school, daycare, or do their usual activities. If your child is experiencing long-term symptoms, consider speaking with their doctor to discuss their specific needs. One [study](#) showed that children ages 0-5 years with COVID-19 infection are more likely than those without COVID-19 infection to experience symptoms (e.g., fatigue, loss of taste, loss of smell) lasting more than four weeks after acute infection. There is [accumulating evidence](#) that COVID-19 vaccination reduces Post-COVID conditions among children and adults.

What children are at serious risk of COVID-19 illness?

Certain medical conditions might increase a child's risk of serious illness with COVID-19, including:

- Obesity
- Diabetes
- Asthma
- Congenital heart disease
- Genetic conditions
- Conditions affecting the nervous system or metabolism

Research also suggests disproportionately higher rates of COVID-19 in Hispanic and non-Hispanic Black children than in non-Hispanic white children ([Mayo Clinic](#)).

Questions About COVID-19 Vaccines for Young Children

How do COVID-19 vaccines work?

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COVID-19 vaccines work similarly to other vaccines. The vaccine stops the virus by helping the immune system make special proteins, called antibodies, to fight the virus. COVID-19 vaccines are not live virus vaccines and do not alter human DNA.

Are there side effects of COVID-19 vaccines?

Children may experience mild to moderate side effects after receiving a COVID-19 vaccine. Many children will not experience any vaccine side effects. However, during vaccine clinical trials for children of this age group the most common side effects reported after COVID-19 vaccination include pain at the injection site, irritability, drowsiness, and fatigue. Additionally, headache, diarrhea, muscle pain and joint aches were also reported but at lower frequencies. Side effects indicate that the immune system is working and building antibodies to fight the virus.

In rare cases, some young people may experience myocarditis/pericarditis (inflammation of the heart muscle) following a COVID-19 mRNA vaccination. These conditions occur most often in adolescent and young adult males and are typically mild to not life-threatening. Zero cases of myocarditis/pericarditis occurred during Pfizer's or Moderna's vaccine clinical trials among children ages 6 months – 5 years.

What is recommended for immunocompromised children ages 6 months – 4 years?

Children in this group who are [moderately to severely immunocompromised](#) are recommended to initially get anywhere from 1 to 3 doses with at least 1 of these doses being an updated COVID-19 vaccine. The number of doses received is dependent on the child's vaccination history.

There is the option for children to receive 1 additional dose COVID-19 vaccine from the same manufacturer at least 2 months since the previous dose. Additional doses beyond that may be administered, informed by clinical judgment of a healthcare provider and personal preference and circumstances.

Moderately or severely immunocompromised children can include those who have:

- Been receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection

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- Active treatment with high-dose corticosteroids or other drugs that may suppress your immune response

Parents or guardians should talk to their child's health care provider if they have further questions regarding their child's immunocompromising medical condition and whether getting additional doses are appropriate for them.

Can my child receive the COVID-19 vaccine at the same time as other vaccines?

Yes. COVID-19 and other vaccines can be administered at the same time. It is recommended that children receive [other important vaccines](#), including those that protect against the flu, whooping cough, tetanus, diphtheria, and measles. Certain vaccines are required for North Dakotans entering kindergarten. Schedule an appointment for your child TODAY to receive their COVID-19 and other routinely recommended vaccines. This is especially important if your child fell behind on immunizations during the pandemic.

Does my child need COVID-19 vaccination if they have already been infected with COVID-19?

Yes, CDC recommends that all individuals ages 6 months and older stay up to date on their COVID-19 vaccines even if they have previously tested positive for SARS-CoV-2 (the virus that causes COVID-19). This is because some children may not have mounted the [full protection](#) against COVID-19 following their previous infection. Meaning, they may not have enough antibodies needed to fight off this virus or other variants of the virus again in the future. Vaccines work to boost the immune system's response to future infections and protect your child from the risk of severe illness, hospitalization, and death due to COVID-19. Additionally, prior infection plus vaccination (hybrid immunity) has been shown to be the [best protection](#) in other age groups and is expected to be the best protection among young children as well.

Are the vaccines for young children effective?

Yes. The FDA required Moderna and Pfizer to prove immunobridging. This is a process that compares antibodies among this youngest age group to another age group (in this case, those ages 16-25 years) in which the efficacy of a vaccine is already established. Clinical trials found that antibody numbers were comparable to the older age group. In other words, the 2 doses of Moderna and 3 doses of Pfizer worked at building immunity against SARS-CoV-2 in young children.

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A [study](#) looking at the original Pfizer COVID-19 vaccine showed that it was 33% effective at preventing COVID-19 emergency department and urgent care visits during the Omicron wave.

About the COVID-19 Vaccine Clinical Trials for Children

Highlights from Pfizer's COVID-19 vaccine clinical trials for children ages 6 months through 4 years of age

- Pfizer's pediatric clinical trials included over 4,500 children. Of which, 1,678 children ages 6 months through 4 years were vaccinated during Pfizer's vaccine trial with a 3 dose primary series.
- The ratio of Pfizer vaccine to placebo vaccine among participants was 2:1.
- Levels of antibodies recorded after dose 3 exceeded those of adults.
- There were 10 symptomatic cases of COVID-19 identified among vaccinated participants within 7 days after the third dose.
- Three doses of the Pfizer-BioNTech COVID-19 vaccine was well-tolerated in this age group, and no new safety signals were identified.
- No hospitalizations due to COVID-19 or cases of MIS-C or myocarditis/pericarditis were reported by any trial participant.
- Some COVID-19 vaccinated children experienced reactions to either dose of the vaccine. Vaccine reactions were more commonly observed after dose 2 and were typically mild to moderate. Common side effects included pain at the injection site, irritability, drowsiness, and fatigue.

Highlights from Moderna's COVID-19 vaccine clinical trials for children ages 6 months through 5 years of age

- Approximately 11,700 children ages 6 months through 12 years were vaccinated during Moderna's pediatric vaccine trial. Including around 4,200 children ages 2 to under 6 years and around 2,500 children ages 6 months to under 2 years.
- Levels of antibodies recorded after dose 2 were the same or exceeded those in adults.
- No severe adverse events were determined to be related to vaccination in either group. No deaths, no myocarditis or pericarditis, and no multisystem inflammatory syndrome in children (MIS-C) were reported.
- Majority of adverse events were mild or moderate and were more frequently reported after dose two. The most commonly reported symptom was fever and was seen more often after dose two.
- All participants will be monitored for 12 months after their second injection to assess long-term protection and safety.

Please note, efficacy for these two vaccines cannot be directly compared due to the varying length of follow-up, the time period when these studies occurred, which variants were

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circulating at the time, and the different number of vaccine doses. Both of these vaccines have been shown to reduce the risk of severe illness and death due to COVID-19. They are also expected to decrease hospitalizations and intensive care unit (ICU) stays among this age group. Please speak with a trusted health care provider if you would like more information or help with deciding which COVID-19 vaccine (Pfizer or Moderna) is the best choice for your child.

Reasons to Vaccinate Young Children Against COVID-19

- While previous infection can lead to some immunity from COVID-19, vaccination after infection significantly enhances protection and further reduces risk of reinfection. [Scientific evidence](#) shows that 32% of children *failed* to make antibodies against SARS-CoV-2 after confirmed infection and had poor T-cell responses. Additionally, Omicron-induced immunity among unvaccinated people does not protect against other variants of concern that may circulate in the future. Fortunately, prior infection plus vaccination (hybrid immunity) has been shown to be the [best protection](#) in other age groups and could provide excellent protection in younger age groups as well.
- COVID-19 vaccines are safe, effective, and provide the single best way to protect children and prevent serious illness or even death due to COVID-19 disease.
- Most children have a grandparent or other person in their lives who are at higher risk of serious illness from COVID-19. Vaccinating all eligible children will help to prevent them from passing COVID-19 to loved ones and other vulnerable people in the community.
- Vaccinating children ages 6 months through 4 years can also help protect family members, including siblings who are immunocompromised and may not mount full protection through vaccination as well as siblings under the age of 6 months who are not yet eligible for vaccination.

Vaccine Safety Monitoring

COVID-19 vaccines are being administered under the most intensive vaccine safety monitoring effort in United States History. These web-based platforms give CDC scientists information about the safety of COVID-19 vaccines in real time. If any vaccine safety issues—also called adverse events—are reported, CDC scientists can quickly study them and determine if there is a safety concern with a particular vaccine. Here are some of the tools that CDC uses to keep close tabs on the safety of COVID-19 vaccines:

- [Vaccine Adverse Event Reporting System \(VAERS\)](#): VAERS is the national system that collects reports of adverse events that happen after vaccination.

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- [Vaccine Safety Datalink \(VSD\)](#): VSD utilizes data from nine different health systems in the U.S. and compares health and vaccine safety outcomes of those vaccinated to those who are not to determine if the outcome is caused by the vaccine.

For more information...

- [Pfizer Recipients and Caregivers Emergency Use Authorization Fact Sheet](#)
- [Moderna Recipients and Caregivers Emergency Use Authorization Fact Sheet](#)
- [COVID-19 in babies and children - Mayo Clinic](#)
- [Post-COVID Conditions | CDC](#)
- [FDA meeting for <5 COVID vaccine: Q&A - by Katelyn Jetelina \(Your Local Epidemiologist\)](#)

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