Pediatrics and the COVID-19 Vaccine

The Food and Drug Administration (FDA) has granted expansion of the Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine for adolescents ages 12-15 years and the Advisory Committee on Immunization Practices (ACIP) has voted to recommend the use of the vaccine for this age group. The vaccine previously was authorized for persons aged 16 and older. Pfizer-BioNTech reported in March that their “vaccine was safe and 100% effective in this age group. Children ages 2-11 could potentially be eligible for a COVID-19 vaccine this fall.”

The American Academy of Pediatrics (AAP) has continued to advocate for pediatric vaccine trials in children and adolescents. By the end of April, children made up 22.4% of new COVID-19 cases, a percentage that has continued to increase, according to data from the AAP and Children’s Hospital Association. More than 3.78 million children have been infected with SARS-CoV-2 and at least 303 have died. The pandemic also has taken a toll on children’s mental and emotional health, social well-being and educational experience.

Professional organizations that have a statement in support of pediatric COVID-19 vaccination include:

- American Academy of Pediatrics
- Children’s Hospital Association
- American Academy of Family Physicians

Pediatric and family physician leaders across AMITA Health support the recommendations of these professional organizations and the Centers for Disease Control and Prevention (CDC) guidance that the COVID-19 vaccine is safe, effective and should be given to all who are eligible.

FAQs

Is the COVID-19 vaccine safe for my child?

- To date, Pfizer-BioNTech has started testing its COVID-19 vaccine in children younger than 12 and completed a study in 12-15-year-olds. The FDA has granted an extension for the 12-15-year-old age group for its EUA for vaccination indications that was approved in December 2020.
- Clinical trials showed the Pfizer-BioNTech vaccine was 100% effective and presented no serious safety concerns in adolescents (12-15 years of age), leading the FDA to grant the EUA.
- Pfizer and BioNTech conducted clinical trials in 2,260 adolescents with half randomized to receive the vaccine (2 doses, 3 weeks apart) and half to receive a placebo. Participants were followed for two months.
- Among 1,005 vaccine recipients, there were no cases of COVID-19, and 16 cases reported among 978 placebo recipients. An immunogenicity analysis in 190 participants also showed the immune response for 12-15-year-olds was just as favorable as the response for those ages 16-25 years.

Is there a difference in side effects for 12-15-year-olds?

The most common side effects in adolescents were pain at the injection site, tiredness, headache, chills, muscle pain, fever and joint pain, consistent with trials in older teens and adults. With the exception of pain at the injection site, more adolescents reported these side effects after the second dose than after the first dose. The Pfizer-BioNTech COVID-19 vaccine should not be given to anyone with a known history of a severe allergic reaction, including anaphylaxis, to any component of the vaccine. A full listing of the side effects is now available on the FDA website and a summary is found in the fact sheet that is provided to everyone who receives the vaccine.

What is the safety testing that has been done on COVID-19 vaccines? How do we know it is safe long-term?

The safety follow-up for COVID-19 vaccines is consistent with all other vaccine trials. As part of the original EUA request, Pfizer Inc. submitted a plan to continue monitoring the safety of the vaccine as it is used under EUA. This plan has been updated to include the newly authorized 12-15 year old population, and includes longer-term safety follow-up for participants enrolled in ongoing clinical trials, as well as other activities aimed at monitoring the safety of the Pfizer-BioNTech COVID-19 vaccine and ensuring that any safety concerns are identified and evaluated in a timely manner. The expectation for the adult phase 3 trials is 2 years of safety follow-up — longer than for most vaccines during development. It is impossible to know the very long-term safety profile of vaccines that have only been used in...
How quickly after immunization does the vaccine protect the recipient, and how long does immunity last?
For the mRNA vaccines developed by Pfizer-Biontech and Moderna, studies reported vaccine efficacy at 7 to 14 days after the second dose, which is likely how long it takes to get very high levels of neutralizing antibody. Studies to date have shown that both mRNA vaccines maintain high efficacy levels over a six-month period (e.g., 91% Pfizer-Biontech, 90% Moderna). More research will be conducted to monitor vaccine efficacy over time.

Can my child receive the COVID-19 vaccine at the same time as other routine vaccines?
The COVID-19 vaccine and other vaccines may now be administered without regard to timing. This includes simultaneous administration of the COVID-19 vaccine and other vaccines on the same day, as well as administration within 14 days. It is unknown whether reactogenicity—the property of a vaccine of being able to produce common, "expected" adverse reactions—is increased with coadministration, including other vaccines known to be more reactogenic, such as adjuvanted vaccines (i.e., DTaP, Hep A, Hep B, HIB, HPV, Tdap and pneumococcal).

If my child already had COVID-19, should they get the COVID-19 vaccine?
Yes, children of eligible age should get the COVID-19 vaccine regardless of whether they have had COVID-19 because experts do not yet know how long they are protected from getting sick again after recovering from the virus that causes COVID-19. Even if they have already recovered from COVID-19, it is possible — although rare — that they could be infected again. Learn more about why getting vaccinated is a safer way to build protection than getting infected.

Vaccination of children with known current SARS-CoV-2 infection should be deferred until the child has recovered from the acute illness (if the person had symptoms) and they have met criteria to discontinue isolation. This recommendation applies to children who experience SARS-CoV-2 infection before receiving any vaccine dose and those who experience SARS-CoV-2 infection after the first dose of an mRNA vaccine but before receipt of the second dose.

If my child was diagnosed with multisystem inflammatory syndrome in children (MIS-C) after having COVID-19, should they proceed with getting the vaccine?
Current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity. Thus, people with a history of multisystem inflammatory syndrome (MIS-C or MIS-A) should consider delaying vaccination until they have recovered from illness and for 90 days after the date of diagnosis of MIS-C or MIS-A, recognizing that the risk of reinfection and therefore, the benefit from vaccination, might increase with time following initial infection.

Are there concerns about fertility after receiving the COVID-19 vaccine?
There is currently no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems or problems trying to get pregnant. The CDC does not recommend routine pregnancy testing before COVID-19 vaccination. As with all vaccines, scientists continue to carefully study COVID-19 vaccines for side effects and will report findings as they become available.

Why is it important to vaccinate children when most who have been infected with COVID-19 have had mild symptoms?
Since March 2021, about 1.5 million adolescents ages 11-17 years have been diagnosed with COVID-19, according to the CDC data. Although most children have mild symptoms, we know they can infect adults in their families as well as others outside the home. Some of these adults may be at high risk of serious complications from COVID-19. From what we understand so far, it seems that older children are spreading the virus more easily than younger children; therefore, it makes sense to move towards immunizing the population of these children who may be contributing most to transmission. Furthermore, although infrequent, some children do get very sick from COVID-19, and prevention of serious illness in children is an important goal of vaccination.

Where can I go to get my child a COVID-19 vaccine?
We recommend that you contact your primary care physician or pediatrician’s office to determine the best location for your child to receive a COVID-19 vaccine.
Resources
American Academy of Family Physicians. COVID-19 Vaccine
Center for Disease Control and Prevention. Frequently Asked Questions about COVID-19 Vaccination