

FAQ - Vaccine info from American Academy of Pediatrics

Q: What side effects are noted to date with COVID-19 mRNA vaccines (Pfizer-BioNTech and Moderna)?

A: The side effects have been similar to other routine vaccines- sore arm, redness, fatigue, fever, chills, headache, myalgia, and arthralgia. The side effects are temporary and mostly mild or moderate. Side effects may be worse after the second dose in some individuals. Anaphylaxis has been observed following receipt of COVID-19 mRNA vaccines, but this has been rare. A full listing of the side effects is now available on the <u>FDA website</u> and a summary is found in the fact sheet that is provided to everyone who receives the vaccine. The potential for side effects that cause individuals to miss work should also be considered in planning.

Q: Do we need to worry about an increase in Multisystem Inflammatory Syndrome in Children (MIS-C) in kids receiving COVID-19 vaccine?

A: One of the reasons to perform vaccine trials in children is to make sure that they do not have any side effects that are pediatric-specific. Since there are also cases of MIS-A, in young adults, if MIS were to be a problem, we may see it in the larger adult trials. We have not, to date. There is no known biomarker to predict an immune response that leads to MIS-C. It is also possible that protection from COVID-19 by vaccination will also protect against its sequelae, including MIS-C.

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

A: The safety follow-up for COVID-19 vaccines is essentially the same that it is for all vaccine trials. 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 in humans for about 6 months. That said, no vaccines licensed have been found to have an unexpected long-term safety problem, which was found only years or decades after introduction.

Q: Will the vaccine be required for school entry?

A: When a vaccine is shown to be safe and effective in children, health authorities, including the CDC and the AAP, will make recommendations on when and how children should receive the vaccine. However, state governments decide which vaccines are required for school entry within their jurisdictions. Those decisions with respect to COVID-19 vaccine could vary by state and may also be influenced by whether the vaccine is FDA approved vs. administered under an EUA.

Q: Can COVID-19 vaccine be co-administered with other childhood or adolescent immunizations?

A: Administration of the COVID-19 vaccine with other childhood or adolescent immunizations has not yet been studied extensively. There are very few vaccines in which co-administration with other vaccines is problematic. However, given the lack of data, the CDC is currently recommending that COVID-19 vaccine be administered alone with a minimum interval of 14 days before or after administration with any other vaccines. In the case of COVID-19 vaccines that require two doses, this 14-day time period is for each administration, which means a "blackout" window of 28 days for the Janssen COVID-19 vaccine, 49 days for the Pfizer COVID-19 vaccine and 56 days for the Moderna COVID-19 vaccine.

Q: Do adolescents need special consent or assent to receive the COVID-19 vaccine?

A: Adolescents aged \geq 16 years do not need special consent to receive vaccine under an EUA. However, assent is required. Health care providers administering the vaccine should inform vaccine recipients the following: (1) FDA has authorized emergency use of the vaccine (2) known and potential risks and benefits related to emergency use (3) that they have the option to accept or refuse the product and (4) be informed of any available alternatives to the product and their known risks and benefits. Each recipient should receive a fact sheet that includes essential information about the vaccine. The fact sheets for health care professionals administering the vaccine as well as recipients were approved as part of the authorization and are available from the Pfizer and FDA websites:

Q: How quickly after immunization does the vaccine protect the recipient, and how long does immunity last?

A: 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 (eg. 91% Pfizer-BioNTech, 90% Moderna). More research will be conducted to monitor vaccine efficacy over time. For the Janssen viral vector vaccine, one dose is recommended, and immunity is shown 2 to 4 weeks after vaccination.

Q: What do we know about the new SARS-CoV-2 variants?

A: Multiple variants of SARS-CoV2 have been documented in the United States and globally during this pandemic. New variants have been identified in the United Kingdom (UK), South Africa, and Brazil, and some are reported to spread more rapidly than existing strains. Information about these variants is rapidly emerging. These variants seem to spread more easily and quickly than other variants, which may lead to more cases of COVID-19. Viruses often mutate, or develop small changes, as they reproduce and move through a population. Public health officials are monitoring this closely and continued surveillance is being conducted. Experts believe that the COVID-19 vaccine will provide protection against the new variants that have been reported to date.

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