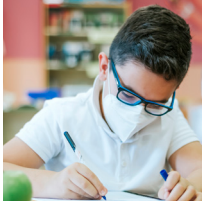
# **Questions** (and **Answers**) About Kids Under 12 and COVID-19 Vaccines



## How do I know the vaccines are safe and effective for my child?

COVID-19 vaccines have been made available for use in the U.S. only after evidence has shown that their benefits are greater than any risks that they may pose. And so far, clinical trials have shown that the vaccines offer great protection against COVID-19 and its long-term effects.

Although the first vaccine studies involved just adults, more recent studies have focused on children in different age groups. Now not only do we have very dependable evidence that the vaccines are highly effective for children ages 5-11, we also have specific guidance on what dose is right for them. More information will be coming for kids under age 5.

## Why were clinical trials just for children needed if the vaccine was shown to be safe in adults?

Children and adults respond to medicines and vaccines differently. That's because as children grow and change, so do their immune systems. Studies of how a vaccine works on kids help doctors know how best to treat them at different stages of their growth.

For example, the clinical trial testing the Pfizer-BioNTech COVID-19 vaccine in children ages 5-11 found that a smaller dose than the one for adults gave kids great protection from severe illness—and with few side effects.

## How are COVID-19 vaccine clinical trials for children different from those for adults?

- **Focus on dosage:** Because several safe and effective vaccines have already been approved for adults, every COVID-19 vaccine trial for children under age 12 has started with a search for the best dose. Researchers want to know how much vaccine a child needs to get the best protection—with the fewest side effects—based on their size and age.
- **Fewer volunteers:** Child-focused clinical trials for COVID-19 vaccines don't need as many volunteers as the larger adult trials did. Researchers can look at the immune responses and side effects experienced by children in the trial and compare that information with what we know about the responses and effects in vaccinated adults, adolescents, and teens.
- **Consent and assent:** Informed consent means that a research volunteer has clear information about the clinical trial's risks and benefits and can ask any questions about the trial before signing up. In a trial with children, informed consent comes from a child's parent or guardian. Researchers also have to explain the trial to any child who will participate. Kids age 7 and up give their own agreement, called assent. As with all clinical trials, volunteers can drop out of the trial at any time.

## What about reports of heart problems in older kids who received a COVID-19 vaccine?

Though still very rare, these reports came from cases in children age 12 and older, as well as young adults who received their second dose of an mRNA vaccine. The problems involved swelling in either the heart muscle (a condition called *myocarditis*) or the outer sac around the heart (a condition called *pericarditis*) after the second dose of an mRNA vaccine. The number

of myocarditis cases reported was small but higher than is typically expected for this age group. The good news is that most patients who had these heart issues and received care responded well to medicine and rest and felt better quickly.

Evidence from clinical trials and the experience of millions of people in the United States who have been vaccinated has been clear. It shows the benefit of COVID-19 vaccines—protection from becoming severely sick, needing to go the hospital, or dying—far outweighs the risk of serious side effects.

Also, the risk of developing myocarditis after the vaccine is much lower than the risk of getting myocarditis from COVID-19. Scientists say that that risk may be even lower for kids under age 12 who get the vaccine, because they will get a smaller dose than the dosage adolescents and teens receive.

**Find more shareable COVID-19 resources at [covid19community.nih.gov](covid19community.nih.gov).**