Pediatrician explains how COVID-19 vaccines for the youngest children are being tested

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For some parents of young children, the wait for COVID-19 vaccines has been long and agonizing.

Throughout 2021, vaccines against COVID-19 emerged as the most effective way to prevent severe forms of the disease. Vaccines are currently recommended for everyone five years and older in the United States but are not yet available for younger age groups. Though more rare in young children, severe disease leading to hospitalization and even death from COVID-19 can occur.

Recent U.S. rates of COVID-19-associated hospitalization in those under five have been the highest on record, as a result of the surge in cases from the highly transmissible omicron variant. Hospitalizations escalated to 14.8 per 100,000 people during January 2022, five times higher than during the delta variant surge in September 2021. Safe and effective vaccines for young children offer the prospect of protection as well as limitation to disruptions in child care and early childhood educational opportunities.

As a pediatrician specializing in infectious diseases, I have cared for many children with COVID-19 at our medical center. I have also had the opportunity to frequently spend time talking with parents about how to make the best choices to protect their young children from COVID-19.

Here's the latest on the clinical trials and formal review process for vaccines for this important group of patients.

COVID-19 vaccine timeline for the youngest children

On March 23, 2022, Moderna released interim results of its trial for young children, which included enrollment of 6,700 children in the six month to under six year age group. Moderna administered the vaccine as two doses in children, giving the kids in this age group one-fourth the adult dose.

The company reported robust antibody responses comparable to what

they saw in young adults between 18 and 25 years old. During the omicron surge, however, efficacy against infection was 44% in children six months to under two years and 38% in children between two and 6, the company said. On the same day, Moderna announced it is moving ahead with seeking emergency use authorization from the Food and Drug Administration for use of the vaccine.

Shortly before, during the height of the omicron surge, Pfizer-BioNTech, the company whose COVID-19 vaccine is the only one currently available for U.S. children and adolescents over five years, applied to the FDA to expand emergency use authorization of its COVID-19 vaccine for use in children under age 5. The kids in this part of their trial were given one-tenth the dose given to adults and teens.

Pfizer had previously announced that while two shots of this low dose of its vaccine generated antibody responses comparable to older groups in children ages six months to two years, adequate antibody responses did not develop in children ages two to five years. A three-dose series for all young children is now being tested. The FDA has deferred its review of Pfizer's emergency use authorization request until the third-dose data is available, which is expected in early April.

COVID-19 vaccines for young immune systems

COVID-19 vaccines have proved highly effective in the prevention of severe COVID-19 in adults and older children.

Prior to use, all vaccines go through rigorous testing in clinical trials, first in adults and then in children, recognizing that there may be biological differences in immune response for different age groups. Going down sequentially in age allows investigators and regulators to evaluate the optimal dose with the least number of side effects.

Both Moderna and Pfizer have tested their vaccines by age groups. The ongoing Pfizer trial for those under 12 years began in March 2021, following evaluation in adults and older teens and then 12- to 15-year-olds, for example. Children five to 11 next received one-third the dose given to adults and teens as two doses, which produced similarly high levels of protective antibody responses compared to 16-to-25-year-olds. Based on the robust immune response and safety established in this trial, the FDA expanded its emergency use authorization for children five to 11 in October 2021.

However, more recent work, including a study that is not yet peer-reviewed, suggests waning vaccine effectiveness during the omicron variant surge, with more pronounced decline over time in children ages five to 11. Reassuringly, protection against hospitalization remained strong, and boosters improved protection among eligible older teens. Pfizer and Moderna are planning to evaluate booster doses in children. Optimization of doses and intervals in all age groups may help maintain higher levels of protection in the face of the omicron variant.

How immune responses may differ in children by age

Vaccines work by teaching the immune system to make disease-fighting antibodies. Several factors determine how our bodies respond to vaccines, and one of these variables is age. Vaccine responses in particular may differ in the very young when immune systems may have less memory.

Testing by age groups helps to account for these differences in how the maturing immune system responds to different types of vaccines. It is common for childhood vaccines to be given in series to help train the young immune response to make better and stronger antibody responses with each subsequent dose.

Vaccine safety

Trials also evaluate vaccine reactions by age. Most COVID-19 vaccine side effects have been mild and short-lived, such as pain at the injection site. Pfizer and Moderna both report that their COVID-19 vaccines are similarly well-tolerated in the youngest age groups. Moderna reports the frequency of fever in keeping with other pediatric vaccines.

Even after trials are complete and vaccines are authorized or approved, safety monitoring continues. This allows even very rare side effects to be detected. One such example is that of myocarditis, or inflammation of the heart, which can occur in rare cases following COVID-19 vaccination. Reports indicate that these cases typically responded well to supportive care and resolved rapidly.

Few adverse events were reported among nearly 8 million vaccine doses given in those age five to 11, indicating even lower rates in this age group compared to in ages 12 and above. Outside of infancy, when babies may be born with congenital heart problems, myocarditis is generally uncommon in younger age groups, so it may prove to be rare following vaccination in young children.

Looking ahead

If the FDA grants emergency use authorization of a COVID-19 shot for children under five years of age following its upcoming review, it will clear the way for the vaccine to be distributed nationwide. The next step will be for the Centers for Disease Control and Prevention to endorse its use for the 18 million U.S. children in this age group—a decision that has usually come within days of FDA authorization for COVID-19 vaccines.

Young infants under the age of six months are not currently included in the vaccine clinical trials, but antibodies produced by mothers from vaccination in pregnancy can be passed on through the placenta to provide protection from COVID-19 during the first few months of life.

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