

VIEWPOINT

Pediatric COVID-19 Vaccines

What Parents, Practitioners, and Policy Makers Need to Know

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The US Food and Drug Administration (FDA) granted Emergency Use Authorization for Pfizer-BioNTech's mRNA COVID-19 vaccine (BNT162b2) for children 5 to 11 years of age on October 29, 2021. The Centers for Disease Control and Prevention recommended use of the vaccine among children in this age group on November 2, 2021. Approximately 28 million children are now eligible for vaccination, with only those younger than 5 years remaining excluded from vaccine eligibility. The benefits of pediatric COVID-19 vaccines are clear. Vaccinations protect children, decrease spread to families and communities, and ensure educational continuity. What do parents, practitioners, and policy makers need to know about pediatric COVID-19 vaccines?

Safety and Effectiveness of Pediatric COVID-19 Vaccines

Clinical trials of BNT162b2 induced a robust immune response in children but had far fewer participants than in adult COVID-19 vaccine trials. The trial of the BNT162b2 vaccine was initially limited to 2268 children 5 to 11 years

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of age, 1518 of whom received 2 vaccine doses of 10 µg of mRNA (one-third the amount used in adult vaccines) spaced 3 weeks apart.¹ The other 750 children received a placebo vaccine. The study assessed safety, levels of neutralizing antibodies, and vaccine efficacy for at least 2 months after the second dose. At the FDA's request, an additional 1591 vaccinated children were followed up for 2.5 weeks after their second dose to expand surveillance for adverse events.

Pfizer-BioNTech reported an efficacy rate of 91% against symptomatic COVID-19 (a total of 19 COVID-19 cases, 16 cases among children in the placebo group [100.6 cases per 1000 person-years] and 3 cases among children who received the BNT162b2 vaccine [9.3 cases per 1000 person-years]).¹ The trial reported no cases of severe COVID-19, hospitalization, or death. Of the children who developed COVID-19, symptoms were milder in vaccine recipients, underscoring the vaccine protection conferred.

Adverse effects were similar to those reported among older children and adults in frequency and severity, including pain at the injection site (71%), fatigue (39.4%),

and headache (28%).¹ The study, however, was insufficiently large to assess risks of rare adverse events such as myocarditis and pericarditis that have been observed in young men 18 to 25 years of age after receiving mRNA vaccines. In these young men, cardiac risks were highest within the first week following the second mRNA dose, and most cases were clinically mild and resolved quickly. The cardiac risk in teenaged individuals varies but is estimated to be 180 cases per 1 million fully vaccinated males 12 to 15 years of age and 200 cases per 1 million for fully vaccinated males 16 to 17 years of age.¹

Given the lower risk of severe COVID-19 in young children, vaccine safety is paramount. The Centers for Disease Control and Prevention will monitor vaccine safety in children through multiple mechanisms, including the Vaccine Adverse Event Reporting System and the Vaccine Safety Datalink.

Where and When Can Children Get Vaccinated?

The rollout of vaccines for the 28 million children aged 5 to 11 years will differ from adolescent and adult vaccine campaigns. Instead of large vaccination sites, the Biden administration plans to focus vaccine delivery at pediatrician, family medicine physician, general practitioner, and nurse practitioner offices, as well as pharmacies and school health clinics.² Vaccines will be packaged in smaller vials that can be stored in refrigerators in clinicians' offices.

Benefits of Vaccinating Young Children

Severe illness has been uncommon among the more than 6 million children who have tested positive for SARS-CoV-2. Depending on the state, 0.1% to 2.0% and 0.00% to 0.03% of pediatric COVID-19 cases resulted in hospitalization and death, respectively.³ As of October 4, 2021, a total of 5217 cases of multisystem inflammatory syndrome in children (MIS-C) and 46 MIS-C deaths have been reported.⁴ The risk of severe illness and death is greater for children older than 10 years. Although the percentage of severe illness among pediatric cases is small, as infections increase, so too will the number of children who become seriously ill. At least 1.9 million children aged 5 to 11 years have been infected with SARS-CoV-2 and more than 8300 of them have been hospitalized, a third of whom needed intensive care.⁵ Nearly 100 children aged 5 to 11 years have died, making COVID-19 among the leading causes of death in this age group. Hospitalization rates among children aged 5 to 11 years are 3 times higher for Black, Hispanic, or Native American children than for White children, with rates of 45 to 50 per 100 000 children vs 15 per 100 000 children, respectively.⁵ Data from

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adolescents suggest that BNT162b2 vaccinations for children 5 to 11 years old will likely prevent most hospitalizations and deaths.⁶

Although pediatric studies did not examine whether vaccines reduce SARS-CoV-2 transmission, data from vaccinated adults suggest that vaccinated children will be likely to shed lower amounts of virus and be contagious for a shorter time. Thus, vaccinating children 5 to 11 years of age may lower transmission in families, schools, and communities.

Will COVID-19 Vaccines Keep Children and Schools Safe?

The effects of the pandemic on childhood education have been profound, with more than 2000 schools closed and 1 million students affected between August 2 and October 8, 2021.⁶ Remote learning has been associated with exacerbation of racial and socioeconomic disparities in educational achievement and increased rates of depression and anxiety.⁷ Vaccinating students could help ensure educational continuity along with other layers of protection, including higher community vaccination coverage, masking of students and staff, school ventilation, and testing unvaccinated students. These risk-mitigation measures should help reassure families who are concerned about their children contracting SARS-CoV-2 at school or in after-school activities, as well as transmitting the virus to siblings, parents, grandparents, or other family members. Pediatric vaccines may also reduce the time children spend in quarantine after exposure to a person with SARS-CoV-2 infection, which may help reduce disruptions to children's education.

COVID-19 Vaccine School Mandates

Currently, all states require a series of childhood vaccines as a condition of school entry, but only the Los Angeles Unified School District requires COVID-19 vaccination for students aged 12 years and older. California announced a COVID-19 mandate for children in kindergarten through 12th grade once the vaccine is authorized. Other school districts are likely to consider COVID-19 school mandates.

There are good reasons, however, to delay school mandates until the FDA fully licenses pediatric vaccines based on longer-term safety data. A Kaiser Family Foundation nationally representative survey of 219 parents found that only 59 parents (27%) reported they would vaccinate their 5- to 11-year-old child immediately, 72 (33%)

would "wait and see," and 66 (30%) would definitely not get their child vaccinated.⁸ Although children and adolescents 12 to 15 years of age have been eligible for vaccination since May 2021, less than half (47%) are fully vaccinated.⁴ Low uptake among adolescents may suggest similarly low coverage among younger children. Premature issuance of school mandates could create a backlash not only for COVID-19 vaccines, but also for other childhood vaccines such as measles, mumps, and rubella. Maintaining public and parental trust in childhood vaccinations is essential.

What Remains Unknown About Pediatric COVID-19 Vaccines?

Several questions remain unanswered about COVID-19 vaccines in children, including how long protection will last and whether young children will need booster doses, especially because of their lower risk of severe disease. Because the vaccine trials in children were not powered to fully assess the risk of rare events, such as myocarditis and pericarditis, there remains the possibility safety signals could emerge as the vaccines are administered to larger numbers of children. Clinical studies on the safety and efficacy of COVID-19 vaccines are ongoing for children 2 to 5 years of age and those 6 months to 2 years of age. Moderna is also likely to request authorization for its pediatric mRNA vaccine in the coming months.

Building Trust

COVID-19 vaccines are the most important intervention to contain SARS-CoV-2. The American Academy of Pediatrics and the American Academy of Family Physicians recommend vaccinating children aged 5 to 11 years.^{9,10} Yet, there are large divides in public trust, especially for pediatric COVID-19 vaccines. Public health officials must build trust, providing reassurance that pediatric COVID-19 vaccines will protect children and their classmates, families, and communities. This will require effective but nuanced vaccine education that encourages parents to voluntarily vaccinate their children. It is premature to mandate COVID-19 vaccines as a condition of school entry for children given the limited size of pediatric trials and the need for ongoing safety monitoring. Following longer-term safety surveillance and full FDA licensure, cities and states will likely include COVID-19 vaccines in their list of required childhood vaccines.

ARTICLE INFORMATION

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