

# COVID-19 Vaccines: Safe and Effective in Children Aged 5 to 11 Years

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Coronavirus disease 2019 (COVID-19) vaccines have prevented an estimated 10.3 million hospitalizations and 1.1 million deaths in the United States alone through November 2021.<sup>1</sup> In late October and early November 2021, the Food and Drug Administration authorized and the Centers for Disease Control and Prevention (CDC) recommended the use of the Pfizer-BioNTech COVID-19 vaccine in children aged 5 to 11 years.<sup>2,3</sup> More than 4.4 million COVID-19 infections and 364 COVID-19 deaths have been reported among US children aged 5 to 11 years since the pandemic began.<sup>4</sup> During the recent Omicron surge, COVID-19-associated hospitalizations increased in this age group to a peak of 2.8 per 100 000 children.<sup>5</sup> Among children aged 5 to 11 years hospitalized with a positive COVID-19 test result during Omicron predominance, most (73%) had illness compatible with COVID-19 as the primary reason for admission and 32% had no known underlying conditions (CDC, unpublished data). In addition, 3460 children aged 5 to 11 years with multisystem inflammatory syndrome in children (MIS-C), a rare but serious post-COVID-19 hyperinflammatory condition, have been reported to the CDC.<sup>6</sup>

COVID-19 vaccines are being administered under the most intensive vaccine safety monitoring effort in United States history. In this issue of *Pediatrics*, Hause et al describe data from 3 US vaccine safety surveillance systems in the first 4 months after COVID-19 vaccine recommendations in

children aged 5 to 11 years.<sup>7</sup> Systemic reactions after vaccination were mostly mild to moderate and reported less frequently for children aged 5 to 11 years than older children. Myocarditis is a rare but serious adverse event that has been reported after mRNA COVID-19 vaccination, with the highest risk among adolescent boys and young adult men.<sup>8</sup> However, after 16 million doses were administered in children aged 5 to 11 years, the reporting rate of myocarditis among boys in this age group was 2.2 per 1 million doses administered, similar to the background rate of myocarditis in the population (0.2 to 2.2 per 1 million persons in a risk window through 7 days).<sup>9</sup>

In a preauthorization Phase 3 clinical trial, the efficacy of the 2-dose Pfizer-BioNTech COVID-19 vaccine series against symptomatic laboratory-confirmed COVID-19 among children aged 5 to 11 years was 90.9% (95% confidence interval: 68.3% to 98.3%), with cases accruing when Delta was the predominant variant.<sup>3</sup> Shortly after the vaccine was authorized for this age group, the Omicron variant emerged, leading to a substantial surge in COVID-19 cases nationally. Although a recent prepublication report summarizing surveillance data from New York State during the Omicron surge revealed that vaccination in 5- to 11-year-olds may be less effective against infection compared with effectiveness among adolescents,<sup>10</sup> national data from CDC vaccine effectiveness studies have revealed

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similar patterns of vaccine effectiveness in children aged 5 to 11 years compared with individuals aged  $\geq 12$  years.<sup>11</sup> Moreover, the vaccination of children aged 5 to 11 years continues to demonstrate substantial protection against more severe outcomes, including emergency department or urgent care visits and hospitalizations.<sup>12</sup> Additionally, the COVID-19 vaccine was shown to be  $>90\%$  effective at preventing the development of MIS-C in children aged 12 to 18 years during the Delta wave<sup>13</sup>; preliminary data support protection against MIS-C in children aged 5 to 11 years during Omicron (CDC, unpublished data).

Describing the benefit–risk balance of COVID-19 vaccination in children by comparing the number of COVID-19 hospitalizations prevented with myocarditis cases can help providers as they counsel parents regarding COVID-19 vaccines. Per million fully vaccinated children aged 5 to 11 years, it is estimated that 133 hospitalizations, 30 ICU admissions, and 0 to 1 COVID-19 deaths would be averted by vaccination, using hospitalization rates from the Omicron surge. Since authorization, 7.5 million children aged 5 to 11 years have been fully vaccinated. Therefore, based on this benefit-risk assessment,  $\sim 1000$  COVID-19 hospitalizations may have been prevented during the  $\sigma$  surge among fully vaccinated children aged 5 to 11 years. Fifteen verified cases of myocarditis were reported among vaccine recipients aged 5 to 11 years, approximately the same number expected in an unvaccinated group of similar size. Overall, the benefits of COVID-19 vaccination in children far outweigh the possible risks.

Despite these compelling data on vaccine safety and effectiveness,

COVID-19 vaccination rates among children aged 5 to 11 years remain substantially lower than other age groups; 33% of 5- to 11-year-olds have received at least 1 COVID-19 vaccine dose and only 26% are fully vaccinated. As demonstrated by Hause et al, the Pfizer-BioNTech COVID-19 vaccine is safe in children aged 5 to 11 years. Meanwhile, numerous studies reveal COVID-19 vaccines continue to meet their primary goal among children and adults: prevention of hospitalizations and severe outcomes of COVID-19.<sup>12–14</sup> As evidence from adolescents and adults reveals, protection against severe disease remains durable after 2 doses and can be improved after 3 doses.<sup>12–15</sup> On May 17, 2022, FDA expanded eligibility for a Pfizer-BioNTech COVID-19 vaccine booster dose to children ages 5–11 years, and on May 19, 2022, CDC recommended that children ages 5–11 years should receive a booster shot 5 months after their initial vaccination series. COVID-19 vaccine clinical trials in children  $<5$  years of age are ongoing; data around safety, immunogenicity, efficacy, and the impact of vaccination to prevent severe COVID-19 in this youngest age group will also be reviewed. In anticipation of the next wave or variant, unvaccinated individuals continue to be the most vulnerable to severe disease. Vaccination remains the single best way to protect all children aged 5 to 11 years against COVID-19, including the prevention of MIS-C, hospitalization, and severe disease.

#### ABBREVIATIONS

CDC: Centers for Disease Control and Prevention

COVID-19: coronavirus disease 2019

MIS-C: multisystem inflammatory syndrome in children

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