ACIP Update to the Evidence to Recommendations for a Pfizer-BioNTech CO Ages 5-11 Years

Question: Should individuals ages 5-11 years receive a Pfizer-BioNTech COVID-19 vaccine booster dose at least 5 months after completion of the primary series, based on the balance of benefits and risks?

Population: Individuals ages 5-11 years

Intervention: A Pfizer-BioNTech COVID-19 vaccine booster dose in children ages 5-11 years who received a primary series dose at least 5 months ago

Background:

The emergence of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), has led to a global pandemic with substantial societal and economic impacts on individual persons and communities. In the United States, more than 82 million cases and more than 998,000 COVID-19-associated deaths have been reported as of May 16, 2022. Persons of all ages are at risk for infection and severe disease. While children <18 years of age infected with SARS-CoV-2 are less likely to develop severe illness compared with adults, children are still at risk of developing severe illness and complications from COVID-19 and contribute to transmission in households and communities. A disproportionate burden of COVID-19 infections and deaths occur among racial and ethnic minority communities, including among children. Non-Hispanic Black, Hispanic/Latino and American Indian/American Native persons have experienced higher rates of disease, hospitalization and death compared with non-Hispanic Whites. This is likely related to inequities in social determinants of health that put racial and ethnic minority groups at increased risk for COVID-19, including income disparities, reduced access to healthcare, or higher rates of comorbid conditions.

On October 29, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Pfizer-BioNTech COVID-19 vaccine in persons ages 5-11 years for prevention of COVID-19. The vaccine was safe and met non-inferiority criteria for immunobridging compared with young adults ages 16-25 years in a randomized controlled clinical trial that included 2,268 participants randomized 2:1 to receive either vaccine or placebo.

On May 17, 2022, the FDA amended the Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine, authorizing the use of a single booster dose for administration to individuals 5 through 11 years of age at least five months after completion of a primary series with the Pfizer-BioNTech COVID-19 vaccine. Following FDA's regulatory action, CDC expanded eligibility of COVID-19 vaccine booster doses to everyone 5 years of age and older on May 19, 2022.

Additional background information supporting the ACIP recommendation on the use of additional or booster doses of COVID-19 vaccine can be found in the relevant publication of the recommendation referenced on the ACIP website.

Updates to the EtR framework are presented below to address the evidence supporting a booster in children ages 5-11 years:

Problem

Criteria	Evidence	Additional Information

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Is the problem of public health importance?	**Incidence:** As of May 16, 2022, there were 82,522,948 cases of COVID-19 reported in the United States.[1] As of May 8, 2022, there were >4.8 million COVID-19 cases reported among children 5-11 years of age in the United States. COVID-19 cases among the pediatric population, including children ages 5-11 years, were much higher during the Omicron predominant period compared to any previous time during the pandemic.[2] Seroprevalence in all age groups increased substantially during the Omicron wave as well. Since October 2021, children ages 5-11 years have had the highest seroprevalence of all age groups; and by February 2022, 77% of children ages 5-11 years had serologic evidence of previous SARS-CoV-2 infection.[3] During the Omicron predominant period, COVID-19 incidence rates among unvaccinated children ages 5 – 11 years were 1.3X higher than rates in children vaccinated with a primary series.[4] **Hospitalization:** COVID-19 Associated Hospitalization Network (COVID-NET), a population-based surveillance system, reports a cumulative hospitalization rate among children ages 5-11 years of 55.9 per 100,000 population as of May 7, 2022. While hospitalization rates for children ages 5-11 years remained low when compared to the overall hospitalization rate of 978.7, there is an increase in hospitalizations for this age group during the Omicron predominant period.[5] Furthermore, during the Omicron predominant period of December 19, 2021 – February 28, 2022, COVID-19-associated hospitalization rates among unvaccinated children ages 5-11 years were twice as high as rates in children vaccinated with a primary series.[6,7]A recent COVID-NET MMWR described COVID-19-associated hospitalizations in children ages 5-11 years throughout the pandemic. Focusing on the Omicron predominant period, during which COVID-19 vaccination was recommended in this age group, 87% of hospitalized children were unvaccinated. Among unvaccinated hospitalized children, 53% were Black or Hispanic. One-third of hospitalized children had no underlying medical conditions and 27% required ICU admission. No significant differences were found for severe outcomes by vaccination status, which might be due to low numbers of hospitalized vaccinated children, however no vaccinated children required higher level O2 (or oxygen) support.[7] Additionally, after examining hospitalization rates by vaccination status among adolescents, as they are recommended to receive a booster dose 5 months after their primary series, analysis found that during March 2022, the monthly COVID-19-associated hospitalization rates among unvaccinated adolescents ages 12-17 years were 2.5X higher compared to rates among adolescents vaccinated with a primary series plus a booster or additional dose.[8] **Mortality:** As of May 7, 2022, there were 189 COVID-19-related deaths among children ages 5-11 years reported to the National Center for Health Statistics (NCHS), which made up 2.5% of all deaths among children in this age group.[9] Additionally, according to NCHS, COVID-19 was the 11th leading cause of death among children ages 5-11 years.[10] **Multisystem Inflammatory Syndrome in Children (MIS-C):** MIS-C is a serious hyperinflammatory syndrome occurring 2-6 weeks after acute SARS-CoV-2 infection, resulting in a wide range of manifestations and complications. The condition often requires intensive care and can be fatal, as approximately 60-70% of patients are admitted to intensive care and 1-2% die.[11,12] The incidence early in the COVID-19 pandemic (from April – June 2020) was approximately 1 case of MIS-C per 3,000 SARS-CoV-2 infections in persons <21 years. Incidence is highest among racial and ethnic minority children and adolescents, including non-Hispanic Black and Hispanic or Latino children and adolescents.[13] As of May 2, 2022, 8,210 cases of MIS-C and 68 deaths have been reported to CDC among persons less than 21 years of age. Reports of MIS-C typically follow increases in COVID-19 cases. However, following the Omicron surge, reports of MIS-C did not increase to the same level as occurred following prior waves of COVID-19 cases.[14] Additionally, children ages 5-11 years are the most common age group affected by MIS-C. As of May 2, 2022, among children 5-11 years of age, there have been 3,809 MIS-C cases with 16 deaths.[15] **Post-COVID conditions in children:** Post-COVID conditions occur in children, though it appears to be less common in children than in adults. A national survey in the UK found 7-8% of children with COVID-19 reported continued symptoms >12 weeks.[16] Post-COVID conditions can appear after mild to severe infections, and after MIS-C. The most common symptoms include fatigue, headache, insomnia, trouble concentrating, muscle and joint pain, and cough.[17,18] These conditions also have an impact on quality of life including limitations of physical activity, feeling distressed about symptoms, mental health challenges and decreased school attendance/participation.[17] A prospective cohort study examined post-COVID conditions among children who had been previously hospitalized for COVID-19 between April and August of 2020 and highlights the risk factors for post-COVID conditions and symptoms experienced by these children. Compared to the youngest children, those ages 6-11 years and 12-18 years have a higher risk of post-COVID conditions. Children with a history of allergic diseases (i.e., atopy) are also more likely to report post-COVID conditions compared to those without a history of allergic diseases. Additionally, many of the common symptoms experienced by adults are also experienced by children, with fatigue being the most common, followed by sleep problems. Similar to adults, symptoms decrease over time.[19] Moreover, non-hospitalized children who experience milder acute infection also report post-COVID conditions.	**COVID-19-related K-12 school disruptions:** Another important impact of COVID-19 on children is disruption in in-person learning in school, with disruptions defined as school moving away from regular in-person instruction caused in some way by the pandemic. COVID-19 related school disruptions have continued through the 2021-2022 school year, specifically during the Omicron surge.[24] **Indirect impacts of COVID-19 pandemic on children:** There are other indirect impacts of the COVID-19 pandemic on children including worsening of mental or emotional health, widening of existing education gaps, decreased physical activity and increased body mass index, decreased healthcare utilization, decreased routine immunizations, and an increase in adverse childhood experiences. **Vaccination:** Vaccination coverage is highest among older age groups and decreases among younger ages. Currently, coverage is lowest among children ages 5-11 years, of whom 35.4% received at least one dose and 28.8% were fully vaccinated as of May 14, 2022.[25] Additionally, vaccination coverage declines as age decreases, with the highest 2 dose coverage at 32% among children ages 10-11 years and the lowest at only 25% among 5-year-olds.[26]

Criteria	Evidence	Additional Information
How substantial are the desirable anticipated effects?	An analysis of immunogenicity data from an open label continuation of the Pfizer phase 2/3 randomized controlled trial and among children ages 5-11 years in the United States, observed waning of antibody levels after completion of a 2-dose primary series; however, booster doses achieved antibody levels higher than after the primary series. At 1 month post dose 2 the Geometric Mean Titers (GMTs) increased sharply but decreased substantially by the sampling point prior to dose 3. However, at 1 month post dose 3, the GMTs were twice as high as observed following dose 2.[1] Overall, a 3rd dose of Pfizer-BioNTech vaccine elicited robust neutralizing antibody titers; and the GMTs observed 1-month post-dose 3 (2720.9) were substantially higher than GMTs observed prior to dose 3 vaccination (271.0).[1] Additionally, analyzing the impact of booster dose mRNA vaccines during Omicron in adults ≥18 years, receipt of a booster dose increases protection across all outcomes, including infection, emergency department/urgent care, hospitalization, and critical illness/death. Moreover, booster dose vaccine effectiveness remains high among immunocompetent individuals ages ≥65 years, 4-6 months after receiving a booster dose. Receipt of a primary series of COVID-19 vaccines remains important and continues to provide protection against severe COVID-19 outcomes, but based on information from other age groups, providing booster doses can increase protection against both COVID-19 infection and severe disease.	Immunogenicity data consists of 67 children who received a 10µg booster dose and 67 participants randomly selected from the previously analyzed dose 2 population. Immunogenicity analyses were based on immune responses at each time point with descriptive comparison of immune responses at 1-month post-dose 3 compared with immune responses at 1-month post-dose 2. All participants who received dose 3 received the booster dose ≥7 months after dose 2, most commonly between 8- and 9-months post-dose 2.[1] **COVID-19 vaccines and seropositivity:** In the clinical trials for children ages 5-11 years, 5.5% of the children in the booster safety population were baseline SARS-CoV-2 positive and almost 9% of the children in the primary series trial were baseline SARS-CoV-2 positive. According to recent studies done in the United States, approximately 77% of children ages 5-11 years have evidence of prior SARS-CoV-2 infection. However, seropositivity should not be interpreted as protection from future infection, as prior infection can result in protection against infection, but not 100% and likely decreases over time. Omicron-wave surges of pediatric COVID-19 hospitalizations occurred even with high seroprevalence, suggesting this alone is not sufficient to provide broad protection. There were no concerns identified in safety surveillance with vaccination of seropositive individuals. A recent update to Clinical Considerations states that people who recently had SARS-CoV-2 infection may consider delaying their COVID-19 vaccine booster by 3 months from symptom onset or positive test. An increased time between infection and vaccination may result in an improved immune response to vaccination and low risk of reinfection has been observed in the weeks to months following infection. **Predicted hospitalizations prevented vs. myocarditis cases per million 2nd doses among children ages 5-11 years during the Omicron surge:** In the 3 months after primary series recommendations in this age group, it is estimated that per 1 million 2nd doses, 133 hospitalizations, 30 ICU admissions, and 0 to 1 deaths were prevented, while 1 to 2 myocarditis cases were expected. Among the 7.5 million fully vaccinated children, approximately 1,000 hospitalizations may have been prevented during the Omicron surge.[3]
How substantial are the undesirable anticipated effects?	An analysis of safety data from an open label continuation of Pfizer's Phase 2/3 randomized controlled trial observed no serious adverse events reported among trial participants. Additionally, there were no deaths, cases of anaphylaxis or myocarditis. Cases of lymphadenopathy, including palpable lymph node axillary mass, were reported by 2.5 participants. The frequency of lymphadenopathy after dose 3 in children ages 5 to 11 years was higher than was observed post dose 2 (0.9%) but almost half of what was observed in adults (5.2%) post dose 3. All cases of lymphadenopathy reported after dose 3 were mild. Most of the cases were identified as occurring in axillary or cervical nodes, had an onset within 2 days of booster vaccination and were reported as resolved within roughly 1 week after onset.[1] In relation to local reactogenicity, injection site pain was the most common reaction after a 3rd dose, with roughly 75% of participants reporting this local symptom. Additionally, 16% of participants reported swelling or redness at the injection site following dose 3. These local reactions were comparable to reactions following doses 1 and 2.[1] For systemic reactions, fatigue was commonly reported among children ages 5-11 years after every dose. Roughly, 46% of participants reported this reaction post dose 3, which was also a similar reporting frequency to dose 2. Other commonly reported systemic reactions were headache and	Safety data consists of 401 participants ages 5-11 years who received a 10 ug booster dose. Of the 401 boosted participants, 5.5% were baseline SARS-CoV-2 positive. Data are through March 22, 2022; and include a median 1.3 months of follow-up time.[1] **COVID-19 vaccine booster dose safety:** After 93 million 1st mRNA COVID-19 booster vaccinations in the United States in individuals ages 12 years and older, local and systemic reactogenicity and health impacts appear similar or slightly less for 1st mRNA COVID-19 vaccination compared to dose 2 of the primary series. In relation to myocarditis, findings are consistent with those observed with the primary series, but the risk appears to be lower following the 1st booster dose compared to dose 2 of the primary series. Risk of myocarditis is highest in younger males, with onset clustering within 0-7 days of the 1st booster vaccination. An increased risk of pericarditis has also been detected after the 1st booster dose administration, but is less common, more evenly distributed between males and females, and more evenly distributed across age groups.[2] **Vaccine-associated myocarditis:** Identified rates of myocarditis after the primary series in children ages 5-11 years are lower than what is seen in those ages 12-17 years. In other age groups, rates of myocarditis are

Values and Acceptability

Criteria	Evidence	Additional Information
Does the target population feel that the desirable effects are large relative to undesirable effects?	Since little was known about U.S. parental attitudes, beliefs, and intentions surrounding COVID-19 vaccines for children prior to their introduction, an online cross-sectional nationally representative survey of U.S. parents/guardians of children less than 18 years of age was conducted using the Ipsos KnowledgePanel.® The goals and objectives of the project were to: • Assess parental attitudes and beliefs about SARS-CoV-2-related disease and COVID-19 vaccines • Gauge parental acceptance of COVID-19 vaccines for children • Characterize parents who reported willingness to vaccinate their child against COVID-19 • Evaluate factors that might influence parental willingness to vaccinate.[1] A longitudinal sample of respondents (N=2,265) completed wave 1 of the survey in February 2021, which analyzed predictors of respondents' willingness to have their children receive a COVID-19 vaccine. The analysis showed that parent's or guardian's willingness to vaccinate themselves was the most important predictor of COVID-19 vaccine acceptance for their children. Additionally, before data on pediatric vaccines were widely available and vaccine rollout to 16-and 17-year-olds began, 66% of parents intended to vaccinate their children.[1] A longitudinal sample from wave 2 was fielded from October 26 – November 30, 2021, which consisted of 3,042 respondents. As it pertains to attitudes and beliefs about COVID-19 vaccines, rough 60% of respondents "very strongly/strongly agree" that their child's healthcare provider is a reliable and trustworthy source of information about COVID-19 vaccines. Furthermore, as it relates to the likelihood and timing of vaccinating children, compared to 70% of adolescents ages 12 -17 years, the likelihood of vaccination among children ages 5-11 years was 54%, with 36% very likely and 18% somewhat likely. Finally, considering net predictors for vaccine acceptance and factors influencing parents' decision to get their child vaccinated, the belief in benefits of COVID-19 vaccination and acceptance of routine childhood vaccines were the most important predictors of COVID-19 vaccine acceptance for their children. Positive predictors also included the perception that pediatric COVID-19-related disease is severe for children, parents of Hispanic ethnicity being more prone to having their children vaccinated and parental COVID-19 vaccination. Additionally, the desire to protect their child from COVID-19 and protect their children against new variants were the primary determining factors toward parents' decision to get their child vaccinated.[1]	The survey instrument was based on the WHO's Vaccine Hesitancy Scale and survey questions were designed based on the Health Belief Model.[1] The primary outcomes for wave 2 were parental vaccine acceptance broken down by age of the child, which were dichotomized as "already received or very/somewhat likely" vs. "somewhat/very unlikely" for each age group. Questions were centered around beliefs about, and experiences of SARS-CoV-2 related disease and beliefs about COVID-19 vaccines unchanged. Questions were also included regarding influences on COVID-19 vaccine decision-making broken down by age of the child.[1] In relation to parental characteristics and household composition, roughly 60% of parents had more than one child in the household. The average age of parents in the survey was 40 and the modal level of education was a bachelor's degree or higher. Furthermore, 55% of parents in the survey identified as female. Moreover, 86% of parents were accepting of routine childhood vaccines and 71% were vaccinated against COVID-19 themselves.[1]
Is there important uncertainty about or variability in how much people value the main outcomes?	Considering the results from wave 1, perceived barriers to COVID-19 vaccination were a negative predictor, as respondents were unlikely to accept COVID-19 vaccination for their children. Furthermore, those who were very or somewhat unlikely to vaccinate their children most frequently reported that school and travel requirements would make them more likely to vaccinate. Additionally, those who were somewhat likely to vaccinate their children most frequently reported that healthcare provider recommendation, school requirements, and peer influence would make them more likely to vaccinate. Conclusively, all groups reported that more serious or severe side effects would make them less likely to vaccinate, even those who were very likely to vaccinate.[1] Regarding results from wave 2, roughly 50% of respondents "very strongly/strongly agree" that they are concerned about possible serious and rare side effects; and more than a quarter "very strongly/strongly agree" that vaccines may not work or are not needed for their children. Additionally, in relation to the expected timing of vaccination, nearly 41% of parents of children ages 5-11 years wanted to wait until other children had been vaccinated.[1]	

Feasibility and Implementation

Criteria	Evidence	Additional Information
Is the intervention feasible to implement?	As of April 27, 2022, 35.4% of children ages 5-11 years reportedly received at least one dose of the COVID-19 pediatric vaccine.[1] In relation to the weekly number of COVID-19 vaccine first doses administered to children ages 5-11 years, although nearly 10 million first doses have been administered since November 3rd, very few doses are being initiated now.[2] As it pertains to parent-reported place of COVID-19 vaccination among children ages 5-11 years from November 2021 to February 2022, based on results from the National Immunization Survey-Child COVID-19 Module, medical place and pharmacy were the highest reported places of COVID-19	

Criteria	Evidence	Additional Information
What would be the impact on health equity?	After reviewing the weekly rates of completed primary series for children ages 5-11 by race/ethnicity, there was an initial peak following an Emergency Use Authorization (EUA) followed by a small peak in early January, likely due to the Omicron surge. The highest rates of completed primary series were among non-Hispanic, Asian children and the lowest rates of primary series completion were among Non-Hispanic, Black children.[1] Additionally, with regard to the percent of children with a completed primary series by race/ethnicity, 57% of non-Hispanic Asian and 35% of American Indian and Alaska Native children have completed their primary series.[2] Furthermore, assessing the percent of children ages 5-11 years with at least one dose of the COVID-19 pediatric vaccine, by Social Vulnerability Index (SVI) of the county of residence from November 3, 2021 to April 27, 2022, the highest vaccination rates were among those residing in low SVI counties at 37%, whereas the lowest rates were among those residing in high SVI counties at 31%.[3] Moreover, there is a relatively large gap in the percentage of children with at least one dose of the COVID-19 vaccine between those who reside in large urban areas (40%) and rural areas (14%).[3] Regarding vaccination coverage and parental intent for children ages 5-11 years, the lowest intent is among those who reside in rural areas (54% definitely will not get vaccinated, 6% intend), uninsured individuals (52% definitely will not get vaccinated, 13% intend) and among White, non-Hispanic individuals (48% definitely will not get vaccinated, 4% intend).[4] Taking a look at disparities in COVID-19 vaccination coverage between urban and rural counties across the United States, COVID-19 vaccination coverage was lower in rural counties than in urban counties. Compared with previous estimates, urban-rural disparities among those now eligible for vaccination, have increased more than twofold through January 2022, despite increased availability and access to COVID-19 vaccines. Additionally, among all age groups, vaccination coverage with ≥1 dose was lower in rural counties, with the largest difference in pediatric populations.[5] There are multiple factors that may have contributed to increasing disparities in pediatric COVID-19 vaccination coverage in urban and rural counties. Parents in rural communities were approximately twice as likely to state that their child will definitely not get a COVID-19 vaccine compared with those in urban communities. Notably, 76% of parents in rural communities indicated that their trusted source of vaccination for their children is their health care provider. However, nearly 40% of rural parents reported that their child's pediatrician did not recommend a COVID-19 vaccine, compared with only 8% of parents in urban communities. Health care providers remain a trusted source of information for parents, and vaccine recommendations from a health care provider are strong predictors of COVID-19 vaccination. The reported disparity between urban and rural pediatricians highlights the importance of partnering with health care providers and provider organizations to reduce vaccine hesitancy and increase vaccination coverage.[5] Methods to address vaccine equity consist of: • Developing and disseminating culturally and linguistically appropriate messaging through trusted channels, identified by partners working closely in the communities of interest • Implementing targeted digital, radio, and out of home media buys to reach parents or caregivers representing groups and areas with low vaccination coverage among children • Promoting new webpages for clinicians and families focused on children with disabilities and special healthcare needs • Supporting rural vaccine communication and education partnerships • Developing a rural addendum to *COVID-19 Vaccination Field Guide: 12 Strategies for Your Community*	

Work Group Interpretation Summary

Receipt of a primary series provides protection against COVID-19, especially against severe disease. While myocarditis after COVID-19 vaccines in children ages 5-11 years is rare, only 29% of children within this age group are fully vaccinated with a primary series. Future surges will continue to impact children, with unvaccinated children remaining at higher risk of severe outcomes. Overall, the benefits of COVID-19 vaccines continue to outweigh the risks and receipt of COVID-19 vaccine primary series continues to be important.

Additionally, COVID-19 vaccine booster doses have been shown to increase protection against all outcomes in those ages 12 years and older. Although, there is a waning of protection over time after 2 doses for those ages 12 years and older, there has been limited time to detect waning in children ages 5-11 years. However, for each age, myocarditis after booster doses of COVID-19 vaccines were lower than after receiving a 2nd dose in the primary series. It is likely that children ages 5-11 years will benefit from a COVID-19 vaccine booster dose.

The Work Group discussed vaccine policy where children ages 5-11 years 'may receive' or 'should receive' a COVID-19 vaccine booster dose:

Type of recommendation	PROS	CONS
Standard recommendation **"Should receive"**	• Simple to communicate • Consistent with booster recommendations in other age groups • Likely that all ages will benefit from 3 doses of mRNA COVID-19 vaccines	• Limited numbers of children ages 5-11 years received booster in clinical trial • Uncertainty around future of fall boosters • Many children recently infected with SARS-CoV-2 during Omicron surge
Recommended for individuals based on assessment of benefits and risks **"May receive"**	• Reflects uncertainty around fall epidemiology and variant booster • Allows access for children who would benefit the	• More complicated to communicate • Not consistent with booster recommendations for other age groups

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Benefits and harms:

1. Open label continuation of Pfizer phase 2/3 randomized controlled trial (unpublished, data obtained from sponsor)
2. Klein, N & Shimabukuro, T. Safety update of 1st boost mRNA COVID-19 vaccination. Presentation to ACIP. April 20, 2022. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-04-20/03-COVID-Klein-Shimabukuro-508.pdf
3. Source: Hospitalization rates during 11/27/2021-2/12/2022, calculated using a 90 day time horizon

Values and Acceptability:

1. Hammershaimb, et al., University of Maryland Baltimore (UMB), Children's Hospital Colorado (CU/CHCO), and Ipsos (unpublished)

Feasibility and Implementation:

1. Immunization Data Lake. Data as of April 27, 2022
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3. CDC unpublished data
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