MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

MAY 19, 2022
EXECUTIVE SUMMARY

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MEETING PURPOSE

The United States (US) Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) convened a meeting of the Advisory Committee on Immunization Practices (ACIP) on May 19, 2022. The meeting took place remotely via Zoom, teleconference, and live webcast. This document provides an Executive Summary of the meeting, which focused on COVID-19 vaccines among children 5-11 years of age in terms of vaccine effectiveness (VE) and safety, a Vaccine Safety Technical Subgroup (VaST) assessment, safety and immunogenicity of booster doses, Evidence to Recommendations (EtR) Framework on booster doses, and a vote on booster doses in this age group.

EXECUTIVE SUMMARY

Session Overview

Dr. Matthew F. Daley (WG Chair) reported that there were 82,522,948 total COVID-19 cases and 997,215 total deaths between January 23, 2020 – May 16, 2022. Unvaccinated people ≥5 years of age had 10 times the risk of dying from COVID-19 in February compared to people vaccinated with at least the primary series. Unvaccinated people ≥12 years of age had 20 times the risk of dying from COVID-19 in February compared to people vaccinated with a primary series and booster dose. A new analysis predicts that vaccines could have prevented at least 318,000 COVID-19 deaths between January 2021 and April 2022.

On May 17, 2022, the Food and Drug Administration (FDA) expanded eligibility for a Pfizer-BioNTech COVID-19 vaccine booster dose to children 5-11 years of age. 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 5 months after completion of a primary series with the Pfizer-BioNTech COVID-19 vaccine. The current recommendations for COVID-19 vaccines in children 5-11 years of age should receive 2 doses of Pfizer-BioNTech vaccine 3 weeks apart. Children 5-11 years of age who are moderately to severely immunocompromised should receive 2 doses 3 weeks apart followed by a third dose 4 weeks after the second dose.

Between April-May 2022, the COVID-19 Vaccine WG has reviewed the following: vaccine response by type of immunocompromise in adults, seroprevalence of infection-induced SARS-CoV-2 antibodies, COVID-19 epidemiology in children 5-11 years of age, safety and immunogenicity for a Pfizer-BioNTech COVID-19 vaccine booster dose in children ages 5-11 years, VE data for COVID-19 vaccines in children 5-11 years of age, safety data for COVID-19 vaccines in children 5-11 years of age, and policy around booster doses for children 5-11 years of age.

Updates on VE of COVID-19 Vaccines in Children 5-11 Years of Age

Ruth Link-Gelles, PhD, MPH (CDC/NCIRD) presented on COVID-19 VE during Omicron for children and adolescents. She described data from the Pediatric Research Observing Trends and Exposures in COVID-19 Timelines (PROTECT), Increasing Community Access to Testing (ICATT) Partnership, the VISION Network, and unpublished preliminary data from CDC. To summarize some of the findings, in terms of infection, 2-dose VE declined quickly in children and adolescents, following a similar pattern that occurred among adults during Omicron. A

booster dose in adolescents significantly improved VE at least 6 weeks to 3 months after the third dose. With regard to emergency department/urgent care (ED/UC) visits, 2-dose VE was higher for ED/UC visits compared to infection but declined 60 days after the second dose for adolescents. A booster dose in persons 12-15 years of age significantly improved VE. Regarding severe disease, 2-doses provided protection for children and adolescents against hospitalizations and multisystem inflammatory syndrome in children (MIS-C). However, there some waning evident for hospitalization in adolescents. There were not enough data to assess waning in children 5-11 years of age or the impact of a booster dose in persons 12-15 years of age.

Updates on Safety of COVID-19 Vaccines in Children 5-11 Years of Age

Tom Shimabukuro, MD, MPH, MBA (CDC/NCEZID) provided an update from post-authorization safety monitoring for the primary series of Pfizer-BioNTech (COMIRNATY) COVID-19 vaccination in children 5–11 years of age from the Vaccine Adverse Event Reporting System (VAERS), v-safe[SM], and the Vaccine Safety Datalink (VSD).

To summarize the VAERS findings, since authorization, 18.1 million doses of Pfizer-BioNTech vaccine have been administered to children 5-11 years of age in the United States (US). Most VAERS reports (8750/9001, 97%) were non-serious. The most frequently reported adverse events (AEs) for non-serious reports were known and well-characterized AEs associated with Pfizer-BioNTech vaccination, including potential allergic reactions. The most frequently reported AEs for serious reports were consistent with MIS-C. There were 20 reports of myocarditis verified to meet the CDC case definition among children 5-11 years of age. There was male predominance of myocarditis reports that occurred mostly after Dose 2. This is similar to older age groups. There was one death in a male with symptom onset 12 days after Dose 1. The clinical course was rapid and there was histopathologic evidence of myocarditis on autopsy. The reporting rates for males 5-11 years of age are lower than for males 12-15 and 16-17 years of age, especially after Dose 2. Reporting rates for males after Dose 1 and for females after either Dose 1 or Dose 2 are within background rates using the 0–7-day risk interval. CDC will continue monitoring COVID-19 vaccine safety among this age group and is following up on VAERS case reports of myocarditis to assess functional status and clinical outcomes at least 90 days after the onset of myocarditis symptoms.

As a reminder, v-safe[SM] is a voluntary CDC smart phone-based monitoring program for COVID-19 vaccine safety in the US that uses text messaging and web surveys to check in with vaccine recipients after vaccination. It solicits participants' reports on how they feel after COVID-19 vaccination in terms of local injection site reactions (e.g., pain, redness, swelling), systemic reactions (e.g., fatigue, headache, joint pain), and health impacts (unable to perform normal daily activities, missed school or work, or received care). To summarize the findings from v-safe[SM] reports after Pfizer-BioNTech vaccination among children 5-11 years of age, there have been a total of 49,396 v-safe[SM] among children 5-11 years of age. Reactions were generally mild to moderate and were most frequently reported the day after vaccination. Generally, reactions were more frequently reported after Dose 2 than Dose 1. Patterns are generally similar to those observed in people ≥12 years of age.

To summarize the VSD Rapid Cycle Analysis (RCA) analyses for children 5-11 years of age as of April 23, 2022, there are approximately 877,855 children ages 5-11 years in the VSD and 786,202 total doses of Pfizer-BioNTech vaccine have been administered in this age group. About 41% of children 5-11 years of age have completed the primary series. No statistical signals have been identified to data for any outcomes. There were 10 potential cases of

myocarditis or pericarditis identified in the 98 days post-vaccination, 6 (60%) of which were verified through chart review and included the following:

- Male age 7 years with acute myocarditis 16 days after dose 1
- Male age 11 years with acute pericarditis 19 days after dose 1
- Female age 9 years with acute pericarditis 14 days after dose 1
- Male age 8 years with acute myocarditis 3 days after dose 2
- Male age 9 years with acute myocarditis the day of vaccination after dose 2
- Male age 10 years with acute myocarditis 2 days after dose 2

Of the 10 cases reported, 4 were determined not to be cases. There were 2 cases with a history of myocarditis, 1 with a congenital heart defect, and 1 with chest pain but normal troponin and electrocardiogram (ECG). There were 3 verified anaphylaxis cases identified on Days 0-1 after vaccination. Anaphylaxis rates in children ages 5-11 years are consistent with rates observed in people ≥12 years of age.

There were 12 potential cases of MIS-C identified after vaccination. Of these, 8 were verified as meeting the CDC case definition (7 Brighton Collaboration Level 1, 1 Brighton Collaboration Level 4) and 4 were ruled out. Of the verified cases, 5 (63%) were in males and 6 (75%) occurred following Dose 1. All 8 cases were admitted to the hospital, with 5 (63%) admitted to the intensive care unit (ICU). The median length of stay was 3 days (range 1-7 days). The median time from vaccination to symptom onset was 19.5 days. Of the 8 cases, 6 had both documented COVID-19 infection and COVID-19 vaccination before diagnosis, 3 had infection <12 weeks prior to vaccination followed by vaccination and then MIS-C, 1 had vaccination followed by infection and then MIS-C, 2 had unclear timing but with infection and vaccination prior to MIS-C diagnosis, and 2 had vaccination followed by a known exposure to COVID-19 and then MIS-C.

In terms of the overall summary of safety following the primary series of Pfizer-BioNTech COVID-19 vaccination in children 5-11 years of age, findings from post-authorization safety monitoring of Pfizer-BioNTech primary series vaccination are generally consistent with those from the clinical trials. Systemic and local reactions are relatively common, with more systemic reactions after Dose 2. The reporting rate for myocarditis in VAERS in males after Dose 2 is slightly elevated when compared to background incidence; otherwise, reporting rates are below background incidence. No statistical signal for myocarditis has been observed in VSD RCA. Anaphylaxis rates in children 5-11 years of age following Pfizer-BioNTech COVID-19 vaccination are comparable to rates in people ≥12 years of age. MIS-C cases detected in the VSD following vaccination had a history of COVID-19 infection or a known exposure to COVID-19 prior to their MIS-C diagnosis. Enhanced safety monitoring continues, including following up on recovery status and longer-term outcomes in myocarditis case reports.

VaST Assessment

H. Keipp Talbot, MD MPH (VaST Chair) reminded everyone the objectives of VaST are to: 1) review, evaluate, and interpret post-authorization/ approval COVID-19 vaccination safety data; 2) serve as the central hub for technical subject matter expertise from federal agencies conducting post-authorization/approval safety monitoring; 3) advise on analyses, interpretation, and presentation of vaccine safety data; and 4) provide updates to the ACIP COVID-19 Vaccines WG and the entire ACIP on COVID-19 vaccine safety. VaST has convened 57 meetings to review vaccine safety data from December 21, 2020 to the present.

VaST reviewed the most recent data from 3 US safety monitoring systems to assess safety after the primary vaccination series in children 5-11 years of age and after booster doses in adolescents 12-15 years of age. Adolescents 12-15 years of age are the youngest group for which boosters were previously authorized. A total of 18.1 million doses of Pfizer-BioNTech vaccine have been administered to children aged 5-11 years of age in the US. In VAERS, the reporting rate for myocarditis among males was lower among children 5-11 years of age versus adolescents 12-15 years of age. In the VSD RCA, no statistical safety signals have occurred after more than 778,000 doses Pfizer-BioNTech vaccine in children 5-11 years of age. Data do not suggest potential safety concerns regarding a Pfizer-BioNTech COVID-19 vaccine booster dose for children 5-11 years of age beyond those previously identified in older age groups.

In terms of a VaST assessment of mortality following COVID-19 vaccination in the US, the CDC Immunization Safety Office (ISO) and FDA have standard and systematic methods for following up on all reported deaths following vaccination. Because of the importance of mortality as a potential AE following vaccination, VaST has reviewed mortality data as they have become available from several systems. Population-based studies conducted to date have not identified increased risk of death following COVID-19 vaccination. Spontaneous reporting to VAERS has not identified any unusual reporting or patterns of causes of death (CODs). In a cohort of 6.4 million COVID-19 vaccinees and 4.6 million demographically similar unvaccinated persons, no increased risk was identified of mortality among COVID-19 vaccine recipients. Among over 20,000 nursing home residents in 284 facilities, no increases were identified in 7-day mortality following COVID-19 vaccination. Among deaths reported to VAERS following COVID-19 vaccination, Bayesian data mining identified no signals other than mortality due to COVID-19 disease following the Ad26.COV2.S vaccine in adults. No unusual clustering of CODs has been associated with US-authorized COVID-19 vaccines.

VaST will continue to review vaccine safety data from multiple US safety systems, in specific age groups, and after primary series and booster doses; collaborate with global vaccine safety colleagues on key issues; and provide updates to the ACIP COVID-19 Vaccines WG and ACIP during future meetings.

Safety and Immunogenicity of BNT162b2 Booster (Third) 10 µg Dose in Children 5-11 Years of Age

Charu Sabharwal, MD, MPH (Pfizer) reviewed the safety and immunogenicity of a 10µg booster dose of BNT162b2 in children 5 to <12 years of age in terms of the data that was agreed upon with the FDA for safety and tolerability in 401 participants with follow-up from Dose 3 to 1 month post-Dose 3; a subset of the first 130 participants to complete 1 month post-dose 3 by March 15, 2022 who contributed to the overall descriptive immunogenicity assessment against the SARS-CoV-2 wild-type; an 67 participants from a 2-dose series population to conduct a robust 1 month post-Dose 2 comparison; and 30 of the 130 participants at 1 month post-Dose 3 to analyze their immune response against the Omicron variant.

In terms of the study design and timeline, this originally was a placebo-controlled observer-blinded study evaluating a 2-dose primary series. On June 7, 2021, the Phase 2/3 2-dose series was initiated. Enrollment was completed on September 10, 2021, with approximately 4,500 participants randomized in a 2:1 ratio to achieve a safety database of 3,000 actively vaccinated participants. On October 29, 2021, the EUA authorization was expanded to include this group based on immunogenicity, safety, and descriptive efficacy. The immunogenicity criteria for the primary immunogenicity objective were to immunobridge the immune response elicited by participants in this age group to that of the participants 16-25 years of age in the landmark

efficacy trial up to 1 month after the second dose. Only 450 of the randomly selected participants in the trial had a 1-month post-Dose 2 blood draw. With the EUA authorization, participants in this age group became eligible for unblinding. On January 4, 2022, the protocol was amended to include a third dose for all participants to maximize protection against variants of concern, including Delta and Omicron. On January 31, 2022, booster doses were initiated in this age group among existing participants. The data cutoff period was March 22, 2022.

Of the 401 participants to receive the booster dose at the 10µg dose, the overall demographics were representative of participants in the trial. Slightly more than 50% were male, 70% were White, 7% were African American or black, 12% were multi-racial, and 22% were Hispanic. The mean age was 8 years at the time of Dose 1. While none of the participants reported a history of COVID-19 at that time, 5.5% had a baseline positive test for SARS-CoV-2. In terms of the follow-up time for the booster dose, 86.8% occurred approximately 8 to 9 months after Dose 2. The range was from approximately 5 to 9 months.

In terms of the Dose 3 mean follow-up time of 1.3 months in the 5 to <12 years of age safety population, pain at the injection site was the most commonly reported local reaction. Most local reactions were mild or moderate in severity. Severe reactions were infrequent and occurred at <1%. The median onset for all local reactions after any dose of BNT162b2 10µg was 1 to 2 days. All events resolved with a median duration of 1 to 2 days after onset. Most systemic events were mild to moderate. Fatigue and headache were the most commonly reported across the 3 doses. Overall, the rates of fever were low and there were no fevers >40.0 °C. In addition, chills also remained low. There were no Grade 4 systemic events at Dose 3 and severe reactions remained infrequent and occurred at less .2%. The overall number of AEs were small, with 9% percent of participants reporting an AE. Of these, 4.7% were reported to be related to the vaccine. Most of these were related to reactogenicity events. There were no related serious adverse events (SAEs), withdrawals due to AEs, or deaths. This was consistent with the 2-dose series data.

In terms of the breakdown of the 9% AEs that occurred from Dose 3 to 1 month after Dose 3 that occurred in ≥1.0% of participants by system organ class, these events were consistent with reactogenicity events and included general disorders (2.2%), blood and Lymphatic system disorders (2.0%), respiratory/thoracic/mediastinal disorders (1.5%), gastrointestinal disorders (1/5%), nervous system disorders (1.0%), and infections and infestations (1%). There were few AEs of clinical interest corresponding to those requested by the FDA or CDC in terms of the list of AEs of special interest (AESIs). No events of anaphylaxis, myocarditis/pericarditis, Bell's palsy (or facial paralysis/paresis), or appendicitis were reported in BNT162b2 recipients up to the data cutoff point. From Dose 3 to cutoff, there was 1 event of mild facial rash that was considered to be unrelated to vaccine by the investigator that was attributable to wearing a face mask. The onset was 11 days post-Dose 3 and resolved 4 days later.

Lymphadenopathy post-Dose 3 occurred in 10 (2.4%) of BNT162b2 participants compared to 0.9% in post-Dose 2 recipients and 5.2% of post-Dose 3 adults who received a 30µg dose. Lymphadenopathy occurring in participants 5 to <12 years of age was mild overall and considered to be related to the vaccine by the investigator. Overall, these events were mild and occurred primarily in the axillary or cervical nodes. Onset was within 2 days of receipt of a booster vaccination, and they were reported as resolved within 1 week of onset.

In terms of overall safety conclusions, the safety data from 401 participants who received a booster (3rd) dose of BNT162b2 at the 10µg dose did not identify any new safety concerns. Reactogenicity was mostly mild to moderate and short-lived after the third dose and was generally comparable to that observed after the second dose. AESIs were limited to the 1 case of rash.

With regard to the descriptive immunogenicity analysis that compared the immune responses at 1-month post-Dose 3 to 1-month post-Dose 2, not all participants in the trial had a blood draw at 1-month post-Dose 2. As mentioned, 130 participants did complete 1-month post-Dose 3 by March 15, 2022. Of those, 123 received the 10µg dose. These participants were with and without evidence of infection. Of those participants, 30 were part of the 1-month post-Dose 2 immunobridging subset. Of the 103 participants who completed 1-month post-Dose 3, 67 did not have evidence of infection. Of the 30, 29 did not have evidence of infection. This contributed to the Omicron analysis. In addition, the 2-dose set included an additional 67 participants without evidence of infection who were randomly selected from the 1-month post-Dose 2 evaluable population.

Among participants without evidence of infection, using the combined 2-dose and 3-dose datasets, there were substantial increases in the SARS-CoV-2 neutralizing titers against wild-type SARS-CoV-2 after Dose 3 compared to after Dose 2. The geometric mean ratio (GMR) comparing 1-month post-Dose 3 to 1-month post-Dose 2 was 2.17 (1.76, 2.68). In addition, the overall geometric mean titers (GMTs) and GMRs were similar to this in participants when those with and without evidence of infection were included. There also were high seroresponses against SARS-CoV-2 wild-type after Dose 3 at 98.5%. Seroresponses were high in participants with and without evidence of infection as well at 99.1%.

Regarding the supportive analysis that was conducted using participants from the 3-dose set to assess responses to Omicron, robust neutralizing titers were elicited after Dose 3 at 614.4 (410.7, 919.2) compared to Dose 2 at 27.6 (22.1, 34.5) for a GMR of 22. In terms of the wild-type reference, similarly improved GMTs occurred after Dose 3 compared to Dose 2, with a GMR of 5. Among the evaluable population with and without evidence of infection in this supportive analysis, an increase in GMTs was noted 1 month after the third dose. They were higher than the previous 992.7 (675.9, 1458.1) compared to Dose two at 27.3 (22.0, 33.9), for a GMR of 36. Similarly, an increase was seen in the wild-type reference strain with a GMR of 6.

The immunogenicity conclusions are that among participants with and without evidence of prior infection, administration of a booster (3rd) dose of BNT162b2 10µg elicited robust neutralization titers against SARS-CoV-2 wild-type. In addition, a booster (3rd) dose of BNT162b2 10µg elicited neutralizing titers against SARS-CoV-2 Omicron in participants with and without evidence of infection. Overall, the immune response associated with a booster (3rd) dose of BNT162b2 10µg given at least 6 months after the second dose is expected to confer protection against COVID-19, including that due to Omicron.

Updates to the EtR Framework: COVID-19 Vaccine Booster Doses in Children 5 to 11 Years of Age

Sara Oliver, MD, MSPH (CDC/NCIRD) provided updates to the EtR Framework on Pfizer-BioNTech COVID-19 boosters in children aged 5-11 years. The policy question for this analysis was, 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?"

To summarize the evidence relevant to the public health problem, children ages 5-11 years are at risk of severe illness from COVID-19. There have been over 4.8 million reported cases and >15,000 hospitalizations to date. In 2020, COVID-19 was a leading COD in children ages 5-11 years. Children who have received a COVID-19 vaccine primary series have better outcomes than children who are unvaccinated, particularly against severe illness. A total of 28.8% of children ages 5-11 years have completed their primary series.

In summary of the benefits and harms evidence, waning of antibody levels have been observed after completion of the 2-dose primary series. Booster doses achieve antibody levels higher than after the primary series. Reactogenicity reported after a booster dose is similar to what was reported after the primary series. Rates of myocarditis after the primary series in children ages 5-11 years is considerably lower than rates in adolescents. Rates after booster doses are likely even lower. Receipt of a primary series of COVID-19 vaccines remains important and continues to provide protection against severe COVID-19 outcomes. Based on information from other age groups, providing booster doses can increase protection against both COVID-19 infection and severe disease.

In terms of values and acceptability based on surveys regarding booster doses, about half of parents are worried about rare and serious side effects of the COVID-19 vaccines, but many also are worried about how new variants will affect children. Slow COVID-19 vaccine uptake can be expected in children 5-11 years of age as about 4 in 10 (41%) parents plan to "wait and see." Ultimately, 63% of parents of children 5-11 years of age intend to vaccinate their children at some point. Most parents trust their children's healthcare provider (HCP) as a source of information about COVID-19 vaccines.

Regarding the evidence supporting feasibility, 35.4% of children 5-11 years of age have received at least 1 dose of the COVID-19 pediatric vaccine. Nearly 10 million first doses have been administered since November 3, 2021. Medical facilities and pharmacies were the highest reported place of vaccination among children ages 5-11 years. Efforts to strengthen the provider network and mitigate barriers to provider participation is crucial to improving pediatric COVID-19 vaccination coverage. Booster dose coverage is lower among adolescent and young adult populations.

With respect to equity, there are noted disparities in vaccination coverage and parental intent for children ages 5-11 years by race and ethnicity, income, and geographic location. Addressing barriers to vaccination in rural areas is critical to achieving vaccine equity, reducing disparities, and decreasing COVID-19-related illness and death in the US. Additional outreach is critical to improve vaccine confidence and increase coverage rates among children ages 5-11 years, especially in high Social Vulnerability Index (SVI) areas. Disseminating culturally and linguistically appropriate messaging through trusted channels is pertinent to reaching parents and caregivers who reside in areas with low vaccination coverage among children.

Regarding the COVID-19 Vaccine WG's conclusions, prior to COVID-19 vaccine authorization for children in this group, among US children ages 5-11 years, there were 1.9 million cases 8,300 hospitalizations, 3,070 MIS-C cases, 94 deaths related to COVID-19. Since authorization of COVID-19 vaccines for children ages 5-11 years of age, there have been 2.9 million cases, 6,700 hospitalizations, 739 MIS-C cases, and 95 deaths. This is in the context of approximately 90% of the children hospitalized overall being unvaccinated and 93% of MIS-C cases being unvaccinated.

Receipt of a primary series provides protection against COVID-19, especially against severe disease. Myocarditis after COVID-19 vaccines in children ages 5-11 years is rare. Given that only 29% of children ages 5-11 years are fully vaccinated with a primary series, future surges will continue to impact children and unvaccinated children will remain at higher risk of severe outcomes. The benefits of COVID-19 vaccines continue to outweigh the risks. Receipt of a COVID-19 vaccine primary series continues to be important.

COVID-19 vaccine booster doses have been shown to increase protection against all outcomes in those ages 12 years and over. Waning of protection over time after 2 doses has been noted for those 12 years of age and over. Notably, there has been limited time to detect waning in children 5-11 years. For each age, myocarditis after booster doses of COVID-19 vaccines is lower than after Dose 2 in the primary series. It is likely that children ages 5-11 years would benefit from a COVID-19 vaccine booster dose.

The WG discussed vaccine policy in which children ages 5-11 years "may receive" or "should receive" a COVID-19 vaccine booster dose, with the pros and cons considered shown in this table:

Work Group Interpretation

Type of recommendation	PROS	CONS
Standard recommendation **"Should receive"**	• Simple to communicate • Consistent with booster recommendations in other ages 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 most from a booster dose • Flexibility to adjust to a stronger recommendation in the fall	• More complicated to communicate • Not consistent with booster recommendations for other age groups • Likely that all ages will benefit from 3 doses of mRNA COVID-19 vaccines

Overall, the WG supported the current recommendation that children ages 5-11 years "may receive" a COVID-19 vaccine booster dose. This would allow flexibility to adjust to a stronger recommendation in the Fall if the epidemiology warrants this or if newer vaccines become available. This was not unanimous. Both viewpoints were represented on the WG.

Vote: COVID-19 Vaccine Booster Doses in Children 5-11 Years of Age

Sara Oliver, MD, MSPH (CDC/NCIRD) presented the proposed recommendations for a Pfizer-BioNTech COVID-19 vaccine booster dose for individuals 5-11 years of age, which read as follows:

> "A single Pfizer-BioNTech COVID-19 vaccine booster dose is recommended for persons ages 5-11 years at least 5 months after the primary series under the FDA's Emergency Use Authorization."

Motion/Vote: COVID-19 Vaccine Booster Doses for Individuals 5-11 Years of Age

Dr. Loehr made a motion for ACIP to adopt the verbiage of the recommendation stating that, "A single Pfizer-BioNTech COVID-19 vaccine booster dose is recommended for persons ages 5-11 years at least 5 months after the primary series under the FDA's Emergency Use Authorization." Dr. Brooks seconded the motion. No conflicts of interest (COIs) were declared. The motion carried with 11 affirmative votes, 1 negative vote, and 1 abstention. The disposition of the vote was as follows:

11 Favored:	Bahta, Bell, Brooks, Cineas, Daley, Kotton, Lee, Loehr, Long, McNally, Poehling
1 Opposed:	Talbot
1 Abstained:	Ault

Discussion Summary

Subsequent to the vote, Dr. Lee invited ACIP members to make a statement about the rationale for their vote and/or to share any additional general comments:

Dr. Talbot emphasized that she wants children to be vaccinated. However, if only 30% of children have received only 1 dose, there is a need to spend time and effort on educating the 70% who have not been vaccinated. Boosters are great, but everyone getting their primary series in this age group first needs to be a priority.

Dr. Loehr said that while he supported this recommendation, he wanted to add his voice to the public comments provided during the meeting and the written public comments posted to the docket by requesting that FDA expedite the review of the EUA application for immunizations for children less than 5 years of age. He thinks this is an important priority, especially given that many parents and many of his personal patients are asking for that.

Dr. Kotton emphasized the importance of making sure that immunocompromised children and adult receive all of their vaccines. The vast majority of immunocompromised patients she is seeing are not fully protected. She encouraged everyone to take the opportunity to be as well-protected as possible and encouraged the CDC to provide as much advertising and clarity on this topic as possible so that people can be as well-protected as possible against this horrible infection.

Ms. McNally said she felt very strongly that this recommendation should send a clear message regarding the importance of this vaccine. She voted for a “should” recommendation for the reasons stated in Dr. Oliver’s presentations pertaining to the available evidence on benefits and harms. She encouraged parents with questions about this vaccine and the booster to review the information on waning immunity, reactogenicity, rates of myocarditis being considerably lower with the booster dose, and the fact that the booster will offer increased protection.

Dr. Poehling agreed that the pros of a booster dose in this age group are strong and that benefits are seen for many outcomes, which is why she voted yes for a “should” recommendation. She stressed that only 28% of 5-11 years of age are fully vaccinated and that it is very important to enhance protection of all children by making sure that all who are eligible receive their primary series and booster—both are equally important.

Dr. Daley emphasized the importance of communicating to parents. In addition to encouraging parents to review the data Ms. McNally suggested, he also would encourage them to talk to their child’s HCP as a trusted advisor. These are complicated decisions and providers need to meet families where they are in terms of their questions and concerns. While HCP will not have all of the answers, they can share their thoughtful opinions based on knowing their patients. This hopefully will go a long way toward improving vaccination coverage among the large proportion of families who have not yet vaccinated their children.

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ACRONYMS USED IN THIS DOCUMENT

ACIP	Advisory Committee on Immunization Practices
AE	Adverse Event
AESI	Adverse Events of Special Interest
CDC	Centers for Disease Control and Prevention
COD	Causes of Death
ED	Emergency Department
ET	Eastern Time
EtR	Evidence to Recommendation
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
GMR	Geometric Mean Ratio
GMT	Geometric Mean Titers
HCP	Healthcare Personnel / Provider
HHS	(Department of) Health and Human Services
ICATT	Increasing Community Access to Testing Partnership
ICU	Intensive Care Unit
J&J	Johnson & Johnson
MIS-C	Multisystem Inflammatory Syndrome in Children
PROTECT	Pediatric Research Observing Trends and Exposures in COVID-19 Timelines
RCA	Rapid Cycle Analysis
SAE	Serious Adverse Event
SVI	Social Vulnerability Index
UC	Urgent Care
US	United States
VAERS	Vaccine Adverse Event Reporting System
VaST	Vaccine Safety Technical Subgroup
VE	Vaccine Efficacy
VE	Vaccine Effectiveness
VSD	Vaccine Safety Datalink
WG	Work Group