MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

JANUARY 5, 2022
SUMMARY MINUTES

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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 January 5, 2022. The meeting took place remotely via Zoom, teleconference, and live webcast. This document provides a summary of the meeting, which focused on COVID-19 safety and booster doses.

THURSDAY: JANUARY 5, 2022

WELCOME AND INTRODUCTIONS

Call to Order/Roll Call

Dr. Grace Lee (ACIP Chair) called to order and presided over the January 5, 2022 ACIP meeting. She pointed out that because this meeting was scheduled quickly, not all members could be in attendance due to responsibilities that could not be rescheduled at the last minute. She acknowledged and sincerely thanked all of the colleagues of the ACIP members who had often during the COVID-19 pandemic rescheduled their own days in order to provide coverage for many of the members, including caring for patients, so that they would be able to attend emergency ACIP meetings. ACIP recognizes that it is not only the ACIP members who are public servants, but also their colleagues, friends, and family members who enable them to serve in these roles. Dr. Lee conducted a roll call, which established that a quorum was present. No conflicts of interest (COIs) were declared. A list of Members, *Ex Officios*, and Liaison Representatives is included in the appendixes at the end of this summary document.

Announcements

Dr. Melinda Wharton (ACIP Executive Secretary, CDC) noted that copies of the slides for the day were available on the ACIP website and were made available through a ShareLink™ file for voting ACIP Voting Members, *Ex Officios*, and Liaisons. She indicated that there would be an oral public comment session prior to the vote at approximately 2:30 PM Eastern Time (ET). Given that more individuals registered to make oral public comments than could be accommodated, selection was made randomly via a lottery. Those individuals who were not selected and any other individuals wishing to make written public comments may submit them through https://www.regulations.gov using Docket Number CDC-2021-0002. Further information on the written public comment process can be found on the ACIP website.

As noted in the ACIP Policies and Procedures manual, ACIP members agree to forgo participation in certain activities related to vaccines during their tenure on the committee. For certain other interests that potentially enhance a member's expertise, CDC has issued limited COI waivers. Members who conduct vaccine clinical trials or serve on data safety monitoring boards (DSMBs) may present to the committee on matters related to those vaccines, but are prohibited from participating in committee votes. Regarding other vaccines of the concerned company, a member may participate in discussions with the provision that he/she abstains on all votes related to that company. ACIP members state any COIs at the beginning of each meeting.

ACIP Meetings Update

Dr. Amanda Cohn (CDC) wished everyone a Happy New Year, but underscored that this marked the beginning of the third year of the COVID-19 pandemic and of the ACIP deliberating on COVID vaccine recommendations. Based on a quick calculation, the ACIP met for 24 days in 2021 alone, which is extraordinary. Moving forward, consideration has been given to the best way for ACIP to continue to inform and advise the CDC Director on critical COVID-19 vaccine issues. As the vaccine landscape continues to evolve, modifications will be made by the Food and Drug Administration (FDA) to Emergency Use Authorizations (EUAs) and potentially Biologics License Applications (BLAs) based on the most current data. As these iterative changes occur, there will be times when the CDC Director approves these changes based on a data review by CDC subject matter experts (SMEs). These approvals do not deflect from the critical role that ACIP plays in advising the CDC Director on important issues and questions related to the COVID-19 vaccination program. Every effort will be made in 2022 to schedule ACIP meetings in advance so that there will be broad awareness about upcoming opportunities for ACIP to review the data and deliberate in a public, transparent setting. Upcoming meeting dates will continue to be posted to the ACIP website. Those who are signed up for announcements will receive an email notification when a new meeting is added to the ACIP website. The hope for this new year is that there will be a more feasible and sustainable approach to meetings for CDC, all of the amazing liaison and voting ACIP members, and members of the public who attended 24 days of meetings in 2021.

FDA Update

Dr. Peter Marks (FDA/CBER) extended his gratitude to FDA's CDC colleagues who worked through the holidays to keep three actions moving forward that focused primarily on children 12-15 years of age. The recent surge in COVID-19 cases, first provoked by the Delta variant and then added to by the Omicron variant, led the FDA to look carefully at any actions that could be taken to enhance the protection of the population through vaccination. They reviewed data provided to them by various companies. In the case of the Pfizer vaccine, FDA was aware of the data showing that a booster could be given at approximately 5 months after completion of the primary series. Pfizer had assessed 4.7 million individuals in a large real-world study, which showed evidence that this seemed to be effective. Among 4.1 million individuals for whom they had safety data who received the booster, the safety data also were good. The action to reduce the booster interval from 6 months to 5 months made evidence-based sense, particularly given that protection against the Omicron variant may require higher titers of antibodies that might be achieved sooner by allowing people to be boosted sooner. The second action of expanding the population who would be eligible for a third dose of the primary series to include children 5-11 years of age was straightforward based on a risk-benefit consideration and the potential need in that population of immunosuppressed individuals and those who received organ transplants or an equivalent. Eligibility had previously been expanded to children 12-15 years of age, so this essentially was a move based on reviewing the available safety data to expand eligibility to allow children 5-11 years of age who were either immunocompromised or were beginning immunosuppressing medication because of transplant to receive a third vaccine—knowing full well that that still may not restore the ability of these vaccines to provide a full level of protection. The third action involved extending the eligibility for a booster dose at 5 months post-primary series completion to children 12-15 months of age. That was based on a combination of reviewing the risk modeling previously done and evaluation of the vaccine throughout the pediatric age spectrum, as well as reviewing the data from Israel on over 6000 adolescents who received the vaccine as a booster dose at 5 months post-primary series completion. Given that there did not appear to be any safety concerns and the current surge in cases, it was felt to be a

reasonable action to extend the potential use of a booster dose down into this age range. Based on data from prior FDA work and data that emerged from other sources, it appears that the risk of myocarditis peaks at about 16-17 years of age.

Discussion Summary

Dr. Long asked whether the decision to provide a 3rd dose for children 5-11 years of age with immunocompromising conditions was based on antibody data on children from that age group to understand their responses after 2 doses or if the decision was based on supposition.

Dr. Marks indicated that this decision was based essentially the way the FDA does immunobridging to older individuals. The analogy in this case was that children 5-11 years of age would be receiving a lower dose of vaccine and would have a similar response to children 12-15 years of age, who would have a similar response as immunocompromised adults in terms of not having a good response. There also was an expectation that many of the children would be treated at transplant centers that may be using either quantitative or semi-quantitative assays to assess antibody levels, because that is the only way to know whether someone has actually responded after a 3rd dose. Antibody data are anticipated to accumulate over time.

CORONAVIRUS DISEASE 2019 (COVID-19) VACCINES

Session Introduction

Dr. Matthew Daley (ACIP, WG Chair) provided the session introduction on behalf of the ACIP COVID-19 Vaccines Work Group (WG). There have been over 56 million cases of COVID-19 in the US since the start of the pandemic. As of January 3, 2022, the case range had reached approximately 490,000 per day.[1]

On January 3, 2022, the FDA updated the EUA Fact Sheet for Pfizer-BioNTech COVID-19 vaccine to:

- ❑ Expand the use of a single booster dose to include use in individuals 12 through 15 years of age;
- ❑ Allow for a third primary series dose for certain immunocompromised children 5 through 11 years of age; and
- ❑ Shorten the time between completion of primary vaccination with the Pfizer-BioNTech COVID-19 vaccine and a booster dose to at least 5 months:
  - Memoranda were filed for Moderna and Janssen COVID-19 vaccines to allow booster doses with any product at least 5 months after completion of a Pfizer-BioNTech primary series among those eligible for each product and eligible for a booster.

Decision Memos were announced on January 4, 2021 reading as follows:

- ❑ For moderately to severely immunocompromised children 5 through 11 years of age receive an additional primary (i.e., third) Pfizer-BioNTech COVID-19 vaccine dose at least 28 days after completion of doses one and two of the primary series;

[1] https://covid.cdc.gov/covid-data-tracker/#trends_dailycases

- People aged 18 years and older receive a single homologous Pfizer-BioNTech COVID-19 vaccine booster (or heterologous as authorized for another COVID-19 vaccine for those 18 and older):

    - 5 months after completion of the primary series of a Pfizer-BioNTech vaccine
    - 6 months after completion of a primary Moderna COVID-19 vaccine series, or
    - 2 months after completion of a single dose primary series of Janssen COVID-19 vaccine; and

- People aged 16 through 17 years may receive a Pfizer-BioNTech booster 5 months after completion of a Pfizer-BioNTech primary series.

January 2022 COVID-19 Vaccine WG activity thus far included a combined call with the ACIP COVID-19 Vaccines WG and the Vaccine Safety Technical WG (VaST), during which the groups reviewed updated COVID-19 vaccine safety data and discussed updates to the booster dose vaccine policy.

On the agenda for this session were presentations on vaccine safety based on reports to the Vaccine Adverse Event Reporting System (VAERS), v-safe^{sm}, and the Vaccine Safety Datalink (VSD); updates to Clinical Considerations; updates to the EtR Framework on Pfizer-BioNTech COVID-19 vaccine booster doses in adolescents 12-15 years of age; and a vote on COVID-19 vaccine booter doses in adolescents 12-15 years of age.

Dr. Daley took a moment to thank the many colleagues of the CDC who contributed their time and expertise to the presentations they would hear throughout the day. He pointed out that something the listening audience may not be aware of is that it takes literally hundreds of hours to prepare materials for ACIP. This is not simply about preparing slides. It also involves gathering, analyzing, and interpreting data and integrating information from multiple sources. Many of the people involved were long overdue for vacations the previous week but instead, spent long hours preparing the materials for this meeting, to whom he expressed deep gratitude for their service to the nation's public health.

Israel Data: 12-15 Years of Age Booster Vaccination

Dr. Sharon Alroy-Preis (Israel Ministry of Health) described the results to date for the booster campaign among youth 12-15 years of age for whom waning immunity has been observed similar to waning in adults. Based on data from the previous week, confirmed infections have been rising steeply among individuals 12-15 years of age. In terms of vaccination coverage, persons 12-16 years of age began receiving vaccination in mid-June 2021 at the beginning of the 4th wave, but now is the leading age group with confirmed infections. Among the 300,000 vaccinated individuals 12-15 years of age, 65% had received the 1st dose, 52.5% had received a 2nd dose, and 7.2% had received a 3rd dose. The majority of the 3rd third doses administered were with Pfizer vaccine. Adverse events (AEs) reported were following a booster with Pfizer vaccine only. Methods for collecting safety data include passive surveillance from medical staff reports in the community and hospitals and active surveillance of myocarditis/perimyocarditis.

In terms of passive surveillance data gathering and processing, once reports are received from medical staff in the community and hospitals, the Ministry of Health cross-references the data with the vaccine registry and confirms the appropriate time range. Missing data are completed with data from the Ministry of Health's health maintenance organizations (HMOs) and hospitals.

Medical files are reviewed to verify medical background and differential diagnoses. Serious AEs (SAEs) are reviewed by a designated medical committee to try to link the SAE to the vaccination. Once data processing and statistical analyses are completed, anonymized data are presented. The content is presented to the public in a way that is easy to read and understand.

Active surveillance began in about February 2021 when a signal was observed for myocarditis following Pfizer vaccinations. Since that time, active surveillance has been conducted routinely. In Israel, myocarditis is a condition that requires hospitalization. Regular reporting is done by hospitals on all myocarditis hospitalizations based on International Classification of Diseases (ICD)-9 codes. Hospitals are contacted on a weekly basis to collect information on past diagnoses, misdiagnoses, assessment of association to vaccines, and medical history. All myocarditis cases, not just those following vaccination, are reviewed by a designated medical committee consisting of cardiologists and rheumatologists.

The booster safety data are very reassuring by both surveillance methods. Over 41,000 booster doses have been administered and there have been only 2 cases of myocarditis, both in males. One occurred in a male 13 years of age 3 day after his booster dose. His medical history includes pericarditis in 2019. The second occurred in a male 15 years of age 4 days post-booster dose. Neither had any compromising conditions and both were released in good condition after a few days in the hospital. Their injection sites were completely normal, there was no arrhythmia, and nothing was concerning. In addition to the 2 SAEs, there were 2 non-serious reports. One was restriction of movement in the vaccinated arm and the other was headache.

The preliminary results based on infection rates per 100,000 risk days from December 23, 2021 to January 3, 2022 confirm that unvaccinated persons 12-15 years of age have a very high rate of infection. At 1-2 months post-vaccination, there is a significant decrease of confirmed cases in this age group. However, a waning effect occurs in this group after 5-6 months and they begin having the same rates of infection as the unvaccinated group. About 7-10 after they receive a booster dose, a significant decrease is observed confirmed cases in that group.

Discussion Points

Dr. Kimberlin requested further information about the impact of boosters on severe disease and hospitalizations.

Dr. Alroy-Preis indicated that they did not have many youth 12-15 years of age with severe disease during the acute phase, which occurred primarily among the unvaccinated group. There were 2 fatalities, 1 male and 1 female, among the unvaccinated youth 12-15 years of age. There have been few hospitalizations with severe and critical conditions among this age group.

Dr. Lee asked what the major circulating variant was during the period of time that vaccine efficacy (VE) was assessed in terms of the rates of infection following booster compared to other intervals following the 2-dose series.

Dr. Alroy-Preis responded that Delta was the major variant during Israel's 4th wave. They are now seeing a combination of Delta and Omicron. Initially, there were about 10,000 Delta cases a day, which had decreased to about 500 a day. Before it was completely gone, omicron entered. There is currently a combination of Delta and Omicron, but Omicron is the predominantly circulating variant at this point.

VAERS COVID-19 Vaccine Safety Update

Dr. John Su (CDC/NCEZID) presented on reports to VAERS after a primary series of Pfizer-BioNTech COVID-19 vaccination in children and adolescents ages 5-11 and 12-15 years of age, and reports to VAERS after Pfizer-BioNTech COVID-19 booster vaccination in adolescents 16-24 years of age. As a reminder, VAERS is the nation's passive surveillance system that is designed to be an early warning system. Because it is a passive surveillance system, it is quite sensitive. Two key strengths of VAERS are that it can rapidly detect potential safety concerns, as well as previously unreported AEs. However, there are key limitations as well. VAERS is a passive surveillance system, which can result in inconsistent quality, incomplete data, and reporting biases. Most notably, VAERS data generally cannot determine cause and effect.

Moving to the data for children and adolescents 5-11 and 12-15 years of age as of December 19, 2021, ≥92% of AEs reported for either group were non-serious. Distribution by sex was similar. Data on race and ethnicity for these age groups reflects some of the limitations of VAERS in that data are most frequently reported are from those who did not report race and ethnicity and those who identify as non-Hispanic white. The 8 most frequently reported non-serious AEs to VAERS among children and adolescents 12-15 years of age include dizziness, syncope, headache, product storage error, nausea, fever vomiting, and fatigue. The top 8 ranked SAEs include chest pain, troponin increase, myocarditis, SARS-CoV-2 test negative, C-reactive protein increase, fever, echocardiogram normal, and headache. These AEs and SAEs typically reflect vaccination error, previously observed AEs, and workups for myocarditis and multisystem inflammatory syndrome in children (MIS-C). Notably, some of the SAEs include results that reflect normal findings.

For children 5-11 years of age, the 8 most frequently reported non-serious AEs after Pfizer-BioNTech vaccine include no AE, product preparation issue, incorrect dose administered, underdose, vomiting, fever, headache, and syncope. Incorrect doses administered reflect vaccination efforts and previously observed AEs. Vaccination error reports often explicitly state that no AEs occurred. The top-ranking SAEs reported include fever, vomiting, troponin increase, chest pain, echocardiogram normal, blood test, C-reactive protein increase, SARS-CoV-2 test negative, headache, fatigue, pain at the injection site, and so forth.

To walk through a hypothetical case, 2 days post-vaccination a patient develops chest pain bad enough to cause vomiting, they are seen in the Emergency Department (ED), a physician orders a battery of tests that perhaps include serologies to assess previous exposure to SARS-CoV-2, troponin, C-reactive protein due to concern for potential MIS-C, diagnostic imaging such as echocardiogram, electrocardiogram (ECG or EKG), et cetera. Some of those tests may have normal results, but the medical coder assigning standardized codes to these reports might still include them in the report itself. That is why in the SAEs reports to VAERS, normal results or negative test results may appear.

Looking more closely at reports of myocarditis among children/adolescents 12-15 years of age as of December 19, 2021, there were 317 preliminary reports of myocarditis in children in this age group. Ultimately, 265 reports were adjudicated that met the case definition of myocarditis. The median age for these reports was 14 years and much of the data reflected what has been observed in older age groups. Median time to onset was 2 days, most reports were post-Dose 2, and most were among males (90%). There were 251 patients hospitalized patients, most of whom were discharged home. There were 224 patients for whom there were known outcomes. Most of them (208; 92%) had recovered from their symptoms at time of their reports. There was a small proportion (16; 8%) who were not fully recovered at time of report, but were reported as

improved or resolved symptoms, ongoing physical restrictions, and/or still under investigation. To put this into context, 18.7 million doses had been administered to this age group during this time period. Of these, 12 were verified based on the case definition. The median age was 10 years. Similar to children 12-15 years of age, much of these data reflect what has been observed in older age groups. The median time of onset was 2 days, most reports were post-Dose 2, and most reports were for males (67%). Of these 12 reported cases, all patients were discharged home. At the time of the report, 8 were recovered of their symptoms and another 4 were still recovering at time of the report. Notably, none of the 12 reports of myocarditis reported a vaccination error. For context, approximately 8.7 million doses of vaccine had been administered to this age group at the time of this analysis.

In terms of estimated reporting rates of myocarditis per 1 million doses administered during the 7-day risk period after vaccination, about 37.8 million Doses 1 and 2 had been administered. For reference, the background incidence during the 7-day risk period ranges from 0.2 to 1.9 per 1 million persons. There was an elevated rate after Dose 1 for males 12-15 and 16-17 years of age. After Dose 2, the rate was elevated for males in age groups 5-11, 12-15, and 16-17 years of age. It is important to note that there was a very large difference between children 5-11 years of age and the other age groups. Elevated rates also were seen among females after Dose 2 for ages 12-15 and 16-17 years. Given that this is very early in vaccinations for children 5-11 years of age, it is anticipated that there may be some reporting biases at play, and these numbers are expected to vary somewhat. As the data mature, the rates should be more stable going forward.

To summarize, approximately 8.7 million doses of Pfizer-BioNTech COVID-19 vaccine have been administered to children 5-11 years of age and 18.7 million doses have been administered to children and adolescents 12-15 years of age. Regardless of the age group, most reports were non-serious. The most frequently reported AEs were known and well-characterized. There are reports of myocarditis among children 5-11 years of age. Most reports were among males and most occurred after Dose 2, which is consistent with older age groups. Reporting rates for males 5-11 years of age were substantially lower than for males of older age groups. CDC will be continuing to monitor vaccine safety among these age groups.

Moving now to booster vaccination with Pfizer-BioNTech vaccine among persons 16-24 years of age, over 95% of the reports were non-serious. Data on race and ethnicity for boosters is limited for persons 16-24 years of age, but appear to be consistent with what has been reported previously in older age groups. In this age group, the most frequently reported top 8 ranked non-serious AEs include fever, dizziness, pain, chills, headache, fatigue, nausea, and pain in extremities. The top 8 ranking SAEs reported include chest pain, myocarditis, nausea, fever, troponin increase, palpitations, chest discomfort, and blood tests.

Among these patients, 13 preliminary reports of myocarditis were identified. Of these, 4 met the case definition. To provide a brief description of the preliminary reports of myocarditis, the median age was 21 years and median time to onset was 1 day. Most were males (69%). Of the 4 reports that met the case definition, 2 of the reports were among males 16-17 years of age and 2 of the reports among 1 male and one female 18-24 years of age. All reported patients were recovered at the time of the report. During this time period, roughly 1 million doses of vaccine had been administered. It is important to remember that this is very early in the reporting for this booster vaccination campaign. As the data mature, additional data can be presented in the future.

To summarize the Pfizer-BioNTech COVID-19 booster vaccination for persons 16-24 years of age, approximately 47,000 persons ages 16-17 years of age and approximately 930,000 persons 18-24 years of age in the US have received a booster dose. Most (95%) VAERS reports were non-serious. The most frequently reported AEs largely have been known and well-characterized. There were 13 preliminary reports of myocarditis, 4 of which met the case definition. All 4 reported patients had recovered from symptoms at time of report. The characteristics seem to be consistent with what has been observed post-Doses 1 and 2. CDC will continue to monitor the safety of vaccine booster doses.

Discussion Summary

Dr. Poehling inquired as to whether there have been any deaths from myocarditis been identified from among those who met the case definition.

Dr. Su replied that 1 patient died for whom myocarditis was identified post-mortem. The role vaccination and myocarditis played in that patient's death remain under active investigation.

Dr. Daley emphasized that some parents have concerns, including concerns about myocarditis, and are perhaps waiting to see the safety profile. Though these are early reports, the rate of myocarditis seems quite a bit less in this age group. This should be reassuring to parents who would like to vaccinate but are sitting on the fence. In addition, he requested information about long-term follow-up plans for individuals diagnosed with post-vaccination myocarditis.

Dr. Su indicated that currently, a group is following up with the physicians and their patients who were identified as meeting the case definition of myocarditis who are 90 or more days out from their initial presentation to get a sense of how they are doing currently. Initial follow-up has been done with some of these patients. Those data are currently being analyzed with plans to publish those findings in the near future.

It seemed to Dr. Long that no conclusions should be made at this point about reduced occurrence of myopericarditis in children 5-11 years of age, given that it is known to be more pronounced following the second dose. It is known from the timing of the recommendations that second doses occurred in December 2021. It took as many as 8 months to get the numbers right about myopericarditis following the second dose. They must be very cautious not to overcompensate in this age group in terms of reassuring parents.

Dr. Daley agreed that it was early and recognized that there are limitations with regard to VAERS reporting.

V-Safe^{SM} COVID-19 Vaccine Safety Update

Dr. Anne Hause (CDC/NCEZID) presented a v-safe^{SM} update on safety and monitoring for COVID-19 vaccines among children and young adults. As a reminder, v-safe^{SM} is a voluntary smart phone safety surveillance system that allows a parent to enroll their child after any COVID-19 vaccine. Children less than 16 years of age must be enrolled by a parent or guardian. v-safe^{SM} allows existing participants to report receiving a booster dose of COVID-19 and new participants to enter information about all doses received and complete health surveys on their most recent dose. v-safe^{SM} health surveys are sent daily during the week following each dose of vaccine and include questions about local injection site (i.e., pain, redness, swelling) and systemic reactions (i.e., fatigue, headache, joint pain); and health impacts (i.e., inability to perform normal daily activities, missed school or work, and/or received medical care). Additional

health surveys are sent weekly for 6 weeks after vaccination and at 3, 6, and 12 months after vaccinations. As of December 19, 2021, Pfizer-BioNTech vaccination had been reported for over 115,000 v-safe[SM] participants aged 5 to 15 years. Approximately half are female, 37% were aged 5-11 years and 63% aged 12-15 years. Approximately 78% identified as non-Hispanic, while 68% identified as White.

In terms of reactions and health impact events reported at least once in days 0-7 after Pfizer-BioNTech vaccination for children and adolescents ages 5-11 and 12-15 years by dose and age group, reactions and health impacts were more frequently reported following Dose 2 than Dose 1 and more frequently reported for children aged 12-15 years. The top 5 reactions reported at least once in 0–7 days after Dose 2 of Pfizer-BioNTech vaccine for children aged 5-11 and 12-15 years included injection site reaction, fatigue, headache, myalgia, and chills. Reactions were transient and reported following vaccination in both age groups. Injection site pain, fatigue, headache, myalgia, and chills all were more frequently reported for children aged 12-15 years than children aged 5-11 years.

Now turning to booster doses for adolescents and young adults. As of December 19, 2021, over 7,000 v-safe[SM] participants aged 16-24 years reported a homologous Pfizer-BioNTech booster dose. Approximately 72% were female, 7% were aged 16-17 years, 93% were aged 18-24 years, 84% identified as non-Hispanic, and 74% identified as White. Regarding reactions and health impact events reported by v-safe[SM] participants aged 16-24 years at least once in days 0-7 after Pfizer-BioNTech vaccination by dose, Injection site reactions, systemic reactions, and health impacts (i.e., inability to perform daily activities and inability to work or attend school) all were less frequent following a booster dose and Dose 2. Receipt of medical care was reported more frequently following a booster dose. However, the difference was very small. Systemic reaction reported for v-safe participants aged 16-24 years at least once in 0-7 days after Pfizer-BioNTech vaccine were transient. In terms of the top 5 reactions reported at least once in this age group during days 0-7, pain, fatigue, headache, myalgia, and chills were frequently reported and were less common after booster than Dose 2.

These data are subject to a couple of limitations. First, v-safe[SM] is a voluntary system, and as such, is likely not to be completely representative of the vaccinated US population. Second, booster doses had only recently been authorized for persons aged 16-17 years at the time of this analysis. Other data were somewhat limited to described reactions of this age group.

To summarize, Pfizer-BioNTech vaccinations have been reported for over 115,000 v-safe[SM] participants aged 5-15 years. Reactions were generally mild to moderate and most frequently reported the day after vaccination. Reactions were more frequently reported after Dose 2 than Dose 1. Participants aged 5-11 years reported reactions less frequently than participants aged 12-15 years. However, children aged 5-11 years do receive a smaller dosage of vaccines than children aged 12-15 years. In addition, over 7,000 v-safe[SM] participants aged 16-24 years reported a homologous Pfizer-BioNTech booster dose. Reactions were generally mild to moderate and most frequently reported the day after vaccination. Also, reactions were less frequently reported after a booster dose than Dose 2.

Discussion Summary

Dr. Lee pointed out to the public that v-safe[SM] has been an incredibly helpful resource during the COVID-19 pandemic to monitor vaccine safety. She continued to encourage patients, family members, and colleagues to report into v-safe[SM] as it is incredibly helpful to have this real-time information and tracking, particularly for pediatric patients. This is still an important system to continue to support in order to ensure that everyone is able to share their vaccine safety stories through v-safe[SM] and through VAERS.

Dr. Duchin asked Dr. Hause to comment on the preponderance of female respondents in v-safe[SM].

Dr. Hause reported that approximately 70% of persons aged 16-24 years were female. This is more exaggerated than for the primary series, while it may be a reflection of females seeking booster doses compared to males. She said she would note this for the models. They also control for sex, race, and ethnicity.

VSD COVID-19 Vaccine Safety Update

Nicola Klein, MD, PhD (Kaiser Permanente Vaccine Study Center, KPNC) presented a Rapid Cycle Analysis (RCA) update from the VSD team on COVID-19 vaccine uptake and safety among persons 5-11and 12-17 years of age. As a reminder, the VSD is a collaboration between the CDC and 9 integrated healthcare organizations that include full electronic data and medical record information on more than 12.5 million of its members. The aims of the VSD RCA have been to: 1) monitor the safety of COVID-19 vaccines weekly using pre-specified outcomes of interest among the VSD members; and 2) describe the uptake of COVID-19 vaccines over time among VSD members. Surveillance began in December 2020. The VSD is monitoring numerous outcomes that have been in place since the start of this monitoring and have been applied to persons ≥12 years and over. Monitoring is now underway for children 5-11 years of age as well. This table lists the outcomes currently being monitored:

VSD COVID-19 Vaccine RCA Outcomes

#	Outcomes	Settings	Risk Interval (days)	Chart Review	Monitoring Only	Exclude if COVID-19 in the Prior X Days
1	Acute disseminated encephalomyelitis	E, I	1-21, 1-42	Yes		
2	Acute myocardial infarction – **First Ever**	E, I	1-21, 1-42			30 days
3	Acute respiratory distress syndrome	E, I	0-84		Yes	42 days
4	Anaphylaxis – **First in 7 days**	E, I	0-1	Yes	Yes	
5	Appendicitis	E, I	1-21, 1-42			
6	Bell's palsy – **First Ever**	E, I, O	1-21, 1-42			30 days
7	Cerebral venous sinus thrombosis	E, I	1-21, 1-42	Yes		30 days
8	Disseminated intravascular coagulation	E, I	1-21, 1-42			42 days
9	Encephalitis / myelitis / encephalomyelitis	E, I	1-21, 1-42			30 days
10	Guillain-Barré syndrome	E, I	1-21, 1-42	Yes		
11	Immune thrombocytopenia	E, I, O	1-21, 1-42			30 days
12	Kawasaki disease	E, I	1-21, 1-42			
13	Multisystem inflammatory syndrome in children/adults (MIS-C/MIS-A)	E, I	0-84		Yes	
14	Myocarditis / pericarditis – **First in 60 Days**	E, I	1-21, 1-42	Yes (40 years of age and younger)		30 days
15	Narcolepsy / cataplexy	E, I, O	0-84		Yes	
16	Pulmonary embolism – **First Ever**	E, I	1-21, 1-42			30 days
17	Seizures	E, I	1-21, 1-42			30 days
18	Stroke, hemorrhagic	E, I	1-21, 1-42			30 days
19	Stroke, ischemic	E, I	1-21, 1-42			30 days
20	Thrombosis with thrombocytopenia syndrome – **First Ever**	E, I	1-21, 1-42	Yes		30 days
21	Thrombotic thrombocytopenic purpura	E, I	1-21, 1-42			30 days
22	Transverse myelitis	E, I	1-21, 1-42	Yes		
23	Venous thromboembolism – **First Ever**	E, I, O	1-21, 1-42			30 days

Abbreviations: E=ED, I=Inpatient, O=Outpatient

The primary focus of this presentation centered on the outcome of myocarditis/pericarditis in the first 60 days among children and adolescents 12-17 years of age. The electronic codes used to identify cases of myocarditis/pericarditis include:

- B33.22 Viral Myocarditis
- B33.23 Viral Pericarditis
- I30.* Acute Pericarditis
- I40.* Acute Myocarditis

Selection of these codes originally was based on input received in consultation with cardiologists when designing this study over a year ago. Since that time and since monitoring much more closely, the ICD codes recently were revised based on feedback from other investigators and CDC with regard to how the codes actually are being used. With that in mind, 2 additional codes were added to the first 4:

- I51.4 Myocarditis, unspecified
- I31.9 Disease of the pericardium, unspecified

These are just for inpatient and ED settings. There was an incremental increase in the number of cases due to the addition of these 2 codes last year.

In terms of the analytic strategy, the number of outcomes observed and the risk interval of 1-21 days after COVID-19 vaccination was compared to the number expected for the primary analysis. The expected were derived from “vaccinated concurrent comparators” who were in a comparison interval of days 22-42 after COVID-19 vaccination. On each day that an outcome occurred, vaccinees who were in their risk interval were compared with similar vaccinees who were concurrently in their comparison interval. The comparisons were adjusted for age group, sex, race/ethnicity, VSD site, and calendar date.

The analysis on COVID-19 vaccine uptake and myocarditis/pericarditis among persons 12-17 years of age included data through December 25, 2021. Uptake for individuals 12-15 and 16-17 years of age was fairly well-reflected by the data on when the Emergency Use Authorization (EUA) was granted for each of these age groups. While this presentation focused on individuals 12-17 years of age, all cases of myocarditis and pericarditis are chart reviewed for individuals ≤39 years of age. This presentation focused on chart reviews through December 30, 2021 for 53/75 cases among individuals aged 12-17 years identified any time after either Dose 1 or 2 of a Pfizer COVID-19 vaccination. Following the initial chart review, all cases are adjudicated by an infectious disease clinician and/or a cardiologist to confirm that the cases are incident following vaccination, meet the CDC case definition, and evaluate the level of certainty for myocarditis. Adjudication confirmed that 47/53 (89%) were cases. Of the validated cases, 43 were among individuals 12-17 years of age with onset 0-21 days after vaccination and 39 validated cases among individuals 12-17 years of age with onset 0-7 days after vaccination.

In terms of the characteristics of the 43 chart-reviewed cases of individuals 12-17 years of age in the 21 days after vaccination, 29 (67%) were 12-15 years of age, 14 (33%) were 16-17 years of age, 37 (86%) were males, symptom onset post-vaccination was a median of 2 days. Just over half were acute myocarditis, with most of the rest being myopericarditis and just 2 cases being diagnosed as acute pericarditis. In terms of the highest level of care received by the 43 cases, 4 (9%) were treated in the ED , 28 (65%) were admitted to the hospital, and 11 (26%) were admitted to the intensive care unit (ICU). The median length of stay for the hospitalized cases was 2 days. Most stays were between 1-3 days, with a few having stays of 4-6 days. most were between one and three days, as you can see here with a few more at four days and longer. All 43 (100%) were discharged home.

The age range of the cases admitted to the ICU was 13-17 years and all were males. Race/ethnicity was 5 Hispanic, 4 White, 1 Black, and 1 Unknown. The adjudicated diagnoses were 4 acute myocarditis and 7 myopericarditis. Among those admitted to the ICU during hospitalization, the median length of stay was 5 days. The chart notes for 2 of the cases indicated that the ICU admission was preventive and 1 additional chart noted that the ICU admission was unrelated to the myocarditis.

Turning to the analyses of validated myocarditis/pericarditis among individuals 12-17 years of age in the 0-7 and 0-21 day risk interval following Pfizer COVID-19 vaccine, after Dose 2 in the 0-21 days, there was an elevated rate ratio of 15.2 (5.07 – 63.70) with a highly significant confidence interval. That was even more pronounced in the 0-7day window after Dose 2 with a rate ratio of 46.18 (15.07 – 196.40), again with a highly significant confidence interval. Notably, the excess cases were 70.2 cases per million doses after Dose 2 for both the 0-7 and 0-21 day risk intervals. This suggests that all of the risk is occurring during the 0-7 day interval. This is in contrast to the excess cases and risk after Dose 1, which for 0-7 days was 0.3 cases per one million doses.

Follow-up chart review has been ongoing for validated cases. Chart review is conducted 3 months after initial diagnosis to obtain information on symptoms and diagnostic evaluation at the most recent follow-up visit and the recovery status at the most recent follow-up visit to assess ongoing symptoms, medication, and exercise restriction. As of December 30, 2021, follow-up reviews had been completed for 32 validated cases among individuals 12-17 years of age who were time-eligible for follow-up review. Of these 32 cases, 24 had at least 1 follow-up visit at least 1 month since the initial encounter.

For these 24 cases who had at least 1 visit 1 month after diagnosis, the time of discharge to the follow-up visit had a median visit of 88.5 days (28-158 days). Only 13 (54%) had a follow-up visit of at least 3 months since the initial encounter. Another 13 (54%) had no new or worsening symptoms noted. Among those who still reported symptoms, 9 (38%) reported chest pain, pressure, and/or discomfort. Far fewer of these individuals had follow-up diagnostic studies done, with exception of EKGs, Of these cases 18 (75%) had an EKG completed and 9 (50%) had abnormal findings. In terms of the status of the most recent follow-up visits, 11 (46%) were noted to have no symptoms, medications, or exercise restrictions as of the time of the review. The remaining cases were still symptomatic, on medication, or still on exercise/physical activity restrictions.

Turning to vaccine uptake and the primary analysis for children 5-11 years of age through December 11, 2021, the timing of the recommendations and EUA for this age group coincided with a large increase in uptake for vaccinations. The RCA analyses for children 5-11 years of age used the same methods used for adults and adolescents. In the VSD, there are about 848,300 children aged 5-11 years. As of December 25, 2021, about 431,485 doses of the Pfizer vaccine had been administered in this age group. Over 257,000 were Dose 1 and almost 174,000 Dose 2. In the 1–21-day risk interval, a small number of cases were electronically identified for appendicitis (n=9), seizures (n=2), and myocarditis/pericarditis (n=2). So far, 2 potential cases of myocarditis/pericarditis have been chart reviewed. Of the 2, chart review verified 1 case of acute pericarditis in an 11-year-old at 19 days after Dose 2, and the other case was not verified as a case upon chart review. There have been no statistical signals identified to date.

To summarize the analyses of safety among individuals 12-17 years of age, the rate ratio for myocarditis/pericarditis was elevated during days 0-7 after Dose 2. The excess risk was 0.3 cases per million 1st doses and the excess risk was 70 cases per million 2nd doses. The VSD has administered 431,485 Pfizer doses to children aged 5-11 years of age. In the VSD, there have been no safety signals among children 5-11 years of age.

Discussion Summary

Referring to Slide 20, Dr. Daley asked Dr. Klein to speak to the idea that if children 5-11 years of age were going to get myocarditis, it might occur in the 7 days after vaccination, particularly after Dose 2; how quickly that would be observed within the VSD; when the peak occurs for the second dose; and whether there is enough follow-up time for these children to potentially have seen myocarditis after the second dose.

Dr. Klein said that in terms of data lag, the data are typically received quite quickly. Though each VSD site can differ depending upon their relationships with their inpatient hospitals. For instance, these data through December 11, 2021 are likely to be impacted by the holidays. There has not been a lot of follow-up time yet for Dose 2. If the pattern is the same as observed among adolescents, it typically would occur after Dose 2.

Dr. Lee called attention to the long interval for follow up. It appears that many of these children are not being followed up within a week or two post-discharge and that the mean was 88 days in these data. She would assume that the children who are followed up at 3 months post-hospitalization are probably doing their routine follow-up but are not necessarily acutely ill or would have been seen sooner.

Dr. Poehling noted that the amount of information gleaned so far was very impressive. She inquired as to whether there had been any severe cases or deaths among the cases identified.

Dr. Klein replied that there have not been any deaths. All the patients that they have been following at VSD were discharged home after their hospitalization. The best measure they have with regard to severity is the 11 children who were admitted to the ICU, of whom 2 were admitted for preventive measures and 1 was admitted for unrelated issues. While they do not have further information with regard to what occurred in the ICU, this is currently being investigated.

Dr. Daley asked Dr. Klein to explain for the broader audience what she meant by admission to the ICU for “preventive measures.”

Dr. Klein indicated that according to the chart notes, it was in case the child decompensated or had clinical deterioration to be available and ready in a setting that could manage the situation. It was not because these 2 children had the clinical indicators that require them to be in the ICU in the first place.

Public Comment

The floor was opened for public comment during the January 5, 2022 ACIP meeting at 2:50 PM ET. Given that many more individuals registered to make oral public comments than could be accommodated during this meeting, selection was made randomly via a lottery. Dr. Lee provided a gentle reminder that the ACIP appreciates diverse viewpoints that are respectful in nature and issue-focused rather than comments directed at individuals. The comments made during the meeting are included in this document. Members of the public also were invited to submit written public comments to ACIP through the Federal eRulemaking Portal under Docket No. CDC-2021-0125. Visit http://www.regulations.gov for access to the docket or to submit comments or read background documents and comments received.

Dorit Reiss, JD
Professor of Law
University of California
Hastings College of the Law

Thank you for the opportunity to comment. My name is Dorit Reiss and I'm a Professor of Law at the University of California, Hasting College of the Law. I have four points to make. I hope I can get through them. First, I want to reiterate how useful and important it is for you to have these open, transparent discussions. As Dr. Cohn has pointed out, you've met for over 24 days. I'd like to thank the committee members, the guests, and professional staff for preparing these labor-intensive presentations on vaccine safety. Thanks to you, we, the online advocates, have a good answer when anti-vaccine activists try to claim the safety [inaudible] because you provide the data and committee members ask penetrating questions to get more information about it. I know it's a lot of work. I want you to know that it really matters. Second, I'm not a scientist, but I am a parent. My kids, like millions of kids in the United States, are going back to school. Our schools are taking precautions but with Omicron, that may not be enough. And not all schools are. I know you will focus on the science, but I want to ask you to consider among the benefits the effect of children's lives and their parents' of how vulnerable they are [inaudible] school. Even if vaccinated children don't get severely ill from Omicron, their lives have been already disrupted. At least most of them don't get ill, I hope. And if a booster can reduce the risk of this disruption in a meaningful way, that matters. Third, Dr. Cohn pointed out that you're moving to have more recommendations, the CDC, without the ACIP, which given the extensive work [inaudible] done, makes sense. Yesterday, the CDC published a recommendation about two of the three things the FDA authorized, and some people asked whether the CDC has already made up its mind before hearing from the committee. It's great that the CDC's mindful of the limited number of the experts in the committee and not using that time for smaller items, but they hope you consider the messages there and make it clear when and why things go to the committee and when and why they do not. And going forward, it might be a good idea to add a line on why CDC decided that this does not need ACIP just to avoid appearances of not listening. Transparency about the process is really important right now to make things right. Finally, on process, a real problem, and this is directed more to the CDC's committee staff than the committee members, is the agenda for this meeting only went up around 8 am my time today, 11 AM Eastern Time. The public comment [inaudible] announcements came later. And

this is the second time [inaudible]. I realize it's an emergency meeting, but the federal advisory committee actually requires notice in advance for transparency, and that really matters. Anything you can do to have the agenda up one or two days in advance and have the commenting up will make a real difference. I know you're under a lot of pressure, but this really is an issue. Thank you very much.

Mr. Kermit Kubitz

Hello. My name is Kermit Kubitz and I have no conflicts. I have, as an early vaccinated person at the San Francisco Veterans Administration, been a substitute in-class IT person while teachers taught remotely and I turned on projectors and counted students at a local high school, and this experience informs my comment. I support booster doses for adolescents for three reasons. The first is the startling increase in COVID cases among children. The second reason is the benefits of vaccination in reducing infection and spread among school-aged children to others, including teachers and the unvaccinated. The third reason is the protection boosters give against existing and possible new variants, including Delta, Omicron, and future variants. First, there is a rapid increase in COVID-19. New COVID-19 cases in children in the US increased nearly 64% over the prior week, according to data published by the American Academy of Pediatrics. For the weekend being December 30th, there were more than 325,000 new cases among children—the highest count ever reported in children over the course of the pandemic. While it appears that severe illness due to COVID-19 is uncommon among children, there are still threats to immunocompromised patients and those with whom they interact. A second reason for vaccination and boosters for children and adolescents is to keep children in school and participating in sports and other group activities. Schools in Marin County have had to close gyms to spectators and schools in Chicago have had to go back to remote learning and undesirable retrogression. The final reason for boosters is to protect against both existing variants like the Delta and Omicron, and new variants such as the multi-mutation variants recently identified in France, IHU (University Hospital Institute), that causes COVID-19, also known as B.1.640.2. While its severity and infectiousness are not known, boosters would clearly produce more protection as we go forward. I thank you for the opportunity to comment as I have on previous December 1st, and December 12th, and June 24th ACIP meetings. I thank you for your work and best wishes for the new year as we get this pandemic under control through vaccination.

Joan Edelstein, RN

I'm Joan Edelstein, a Registered Nurse with a Doctorate in Public Health and faculty in the school nurse credentialing program at the California State University in Sacramento. Thank you for the opportunity to comment. I have three points to make. One, we all so value the work of this committee to truly rely on the science and evidence in making recommendations for vaccines that are clearly safe and effective and completely support the committee recommendations. Unfortunately, we have not had clear, consistent messaging from the CDC, leaving risk of decisions to individuals because of the confusion caused. That includes not following expected protocols and announcing changes before the appropriate committees meet and their recommendations. Second, I again raise the issue of the need to actively involve and model a relationship with school nurses who care for our country's pediatric, public health population to have a successful vaccine campaign. The CDC has noted school nurses are trusted vaccine ambassadors and studies of HPV vaccine, for example, a controversial vaccine,

intervention schools have higher rates of vaccination than non-intervention schools. We know that engaging parents and schools increases vaccine uptake. As in all areas of healthcare, we are losing school nursing staff at a critical juncture. The CDC should include in all school related recommendations that school nurses be actively included in assessment planning policies, programs, development implementation, and evaluation of both vaccine programs and mitigation efforts. Funding should be targeted to school nurse positions. Rather than eliminating even more school nurse positions in districts, the CDC should take the lead in recognizing the importance of including school nurses in all recommendations and enjoying state, county, and city health departments to partner with school nurses at the district school level to carry out this critical task of getting our pediatric public health population vaccinated. I ask that the CDC work directly with the National Association of School Nurses to help improve vaccine outcomes, especially in vulnerable communities with lower rates of vaccination. On CDC process, number 3, I so appreciate the work of this committee made even more difficult by the demands of the pandemic. Having the agenda posted the day of the meeting rather than in advance for both transparency and meaningful public participation would be a helpful change. In submitting a request for public comment, it feels like the CDC Oscars. Those of us who put in the request must make their acceptance speech in advance only to find out just before the meeting whether they've won. If public comments are at the beginning of the meeting, notice may arrive in the middle of the night for those of us on the West Coast. Thank you very much for this opportunity to speak. And I wish you a healthy, happy, pandemic-free year.

Dr. Julie Boom

Thank you so much. On behalf of Texas Children's Hospital, I would like to thank the CDC staff and ACIP members who have so diligently analyzed COVID-19 disease burdens, vaccine safety and efficacy data, and then so adeptly provided risk benefit assessments based on this information. Using your in-depth analyses, my colleagues and I have been able to assure families about the safety and efficacy of COVID-19 vaccines for all persons five years and older. As a general pediatrician with 26 years of experience and Director of the Immunization Project at Texas Children's Hospital, I know that vaccines are the best way to protect all persons from COVID-19 and are our best hope for ending the pandemic. As you continue your discussions today, I urge you not to minimize the disease burden and risk of COVID-19 in children and adolescents. With the arrival of the Omicron variant, children's hospitals across the nation are reporting dramatic increases in COVID-19 hospitalization. Today, almost seven million children have been diagnosed with COVID-19, resulting in over 80,000 hospitalizations and more than 1,000 deaths. Early data suggested the Omicron variant is more contagious and spreading quickly through our pediatric and adolescent population. Additionally, Omicron has resulted in breakthrough cases following full vaccination at record levels. Fortunately, early data suggests that booster doses may mitigate this phenomenon. As COVID-19 vaccine was originally approved for children 12 years and older on May 12, 2021, many adolescents could already be experiencing waning immunity and could benefit from a booster dose. As we near the two year mark of the COVID-19 pandemic, we must do everything in our power to minimize any further detrimental effects to the mental health, physical wellbeing, and education of US children. Because of Omicron surges, many educators are again facing the difficult decision regarding the safety of in-person learning for both teachers and students. For these reasons, a booster recommendation for children 12 years and older cannot come soon enough. Please give these factors your strongest consideration as you weigh the benefits and risks of COVID-19 booster doses for children 12 years and older.

Richard Paul Junghans, PhD, MD

I'm Richard Junghans. I'm a Medical Oncologist, and Hematologist, and Immunologist with 30 years' experience in the field of immunology. Title of this is, "Saving jobs, lives, and vaccines exempt prior infectees from mandatory vaccination." I am pro-vaccine. Whereas vaccinating everyone makes sense, there is a nuance to the situation with vaccine-averse people that can be exploited to everyone's benefit. Let's say 50% are vaccinated. We want to get to 100%. We provide incentives, we [inaudible] their jobs and in general try to shame people as healthcare [inaudible] to get their vaccinations done. I want to appeal to the science, not politics, not morality, not expediency. Let us find a population that is truly at risk and reduce the focus to this subset. The population at risk are those who have neither been vaccinated nor infected. So far, public health agencies have chosen to ignore prior infectees and treated them the same as the susceptible population. This is a gross error and a missed opportunity. In general, the consensus view is that natural immunity that arises from exposure to all viral proteins is superior to vaccine immunity with exposure to one viral protein. Accordingly, I propose that all prior infectees be designated the same as vaccinated as is currently being done in Israel with issued green cards. Unfortunately, the CDC has not followed the data to make this recommendation, which only favors profits of the vaccine manufacturers, subjects rare patients to medical risks, and does not increase the safety to those already naturally immunized by infection. It also decreases available doses to countries who are desperately underserved. In April 2021, CDC estimated 40% of the adult population was previously infected with a much higher likely prevalence among front-line workers, whom we disproportionately target with the mandatory vaccination. The impact, if we exempt prior infectees, this legitimately reduces the at-risk group from 50% down to 25% or 20% or lower, much more manageable numbers. Any prior positive PCR [inaudible] or antibody tests exempts them. Not everyone had proof of prior infection, but offering an antibody test to unvaccinated employees will inform, and if positive, they are exempted. This has the further benefit of engaging the employee in his or her own health choices, and more likely to be agreeable to vaccination when offered after a negative test. We follow the science and avoid aggressive, even classist, mandates that selectively impact the core economic classes with these threats. Then this proposal to treat prior infectees as vaccinated is an easy choice, respectful without caprice or arbitrariness and follows the science, not politics. In this case, I predict this proposal would increase vaccine participation while also decreasing social strains. I will post online further support of documentation.

Clinical Considerations Update

Evelyn Twentyman, MD, MPH (CDC/NCCDPHP) provided a high-level overview of some of recent updates to the Interim Clinical Considerations for Use of COVID-19 Vaccines, as well as a preview of updates to these considerations planned to follow this ACIP meeting. A number of small updates were made over the course of December 2021 to assure alignment with updated links, language, or guidance for specific providers and professionals. Many other evidence-based updates have been made to the guidance since COVID-19 vaccination began over a year ago. A list of all historical updates to the interim clinical considerations can be found by visiting the Interim Clinical Considerations page and scrolling to the bottom.[2]

[2] https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

On December 10, 2021 CDC updated its Interim Clinical Considerations to include guidance that adolescents 16-17 years of age may receive a booster dose of Pfizer-BioNTech COVID-19 vaccine at least 6 months after completion of their primary series. This decision was based on data previously reviewed by ACIP, though not specifically discussed and voted upon then as it was not relevant in the context of the EUA for Pfizer-BioNTech at that time. Given the reassuring safety data ACIP had recently reviewed,[3] the relative vaccine efficacy (RVE) for booster vaccination of more than 95% among adolescents who had received a recent booster compared with those who had not,[4] and the need for it as evidenced by the emergency of the Omicron variant and the number of adolescents who would be immediately eligible,[5] it was recommended following FDA's amendment of the Pfizer-BioNTech EUA that people aged 16-17 years may receive a booster dose based on their individual benefits and risks.[6]

On December 16, 2021, ACIP reviewed updated benefit-risk assessments pertaining to the Janssen COVID-19 vaccine in the context of identification of additional cases of thrombosis with thrombocytopenia syndrome (TTS), including deaths. In the context of increased supply of alternative mRNA vaccines in the US, ACIP voted that mRNA COVID-19 vaccines are preferred over the Janssen vaccine for the prevention of COVID-19 among those who are eligible for either mRNA or Janssen vaccine. Moving forward to December 23, 2021 just in time for the holidays, ordering opened for the newest authorized formulation of the Pfizer-BioNTech COVID-19 vaccine, nicknamed "Gray Top." CDC updated its interim clinical considerations the same day. To briefly highlight the differences between the "Gray Top" formulation for which persons ≥12 years of age are eligible and the previously released "Purple Top" formulation for the same age group, the "Gray Top" formulation does not need dilution, can be refrigerated longer, can stay at room temperature longer, and can remain in use after first puncture twice as long as its "Purple Top" predecessor.

On January 3, 2022, FDA extended authorization of a third primary dose for certain immunocompromised children 5-11 years of age. CDC followed this with the same recommendation in a Decision Memo announced on January 4, 2022. There was some sense of urgency here in the eagerness to protect children with moderate to severe immunocompromise based on the same 6 clinical symptoms listed in CDC's working definition of "moderate to severe" immunocompromise.[7] VE is lower in patients with immunocompromise.[8] CDC already recommends a third primary series mRNA vaccine dose in those ≥12 years of age with moderate to severe immunocompromise.[9] Approximately 1.4 million children in the US aged 5-17 years have an immunocompromising condition consistent with the definition of moderate to severe immunocompromise.[10] Only those immunocompromised children aged 12-17 years in this group were previously covered by this recommendation to receive a third primary series dose. In addition to this sense of urgency, there is an encouraging sense of safety based on the reassuring findings of vaccine safety surveillance for children 5-11 years of age. During administration of more than 8 million doses of Pfizer-BioNTech to this group, serious side effects were rarely reported.[11]

[3] FDA Review Memorandum, describing Israel Ministry of Health Vaccine Safety Data, 8 December 2020
[4] FDA Review Memorandum, Pfizer-BioNTech Booster for Ages 16-17, 8 December 2021
[5] CDC Vaccine Surveillance Data, 8 December 2021
[6] CDC Interim Clinical Considerations, 10 December 2021
[7] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html
[8] Embi et al *MMWR* 5 Nov 2021
[9] CDC Interim Clinical Considerations
[10] 3 Patel et al EID 2021
[11] Hause et al *MMWR* 31 Dec 2021

CDC also moved forward with a Decision Memo recommending a decreased booster interval of 5 months for those booster-eligible following completion of a Pfizer-BioNTech primary series. The sense of urgency here came from the rapid expansion of the Omicron variant and observations that people who have completed both the primary series and a booster may be better protected against symptomatic infection with the Omicron variant than those without booster.[12] In addition to that, 2 studies from Israeli document the effectiveness of Pfizer-BioNTech booster dose 5 months after primary series against severe illness[13] and death[14] secondary to COVID-19 compared to those without booster. In the US, 188 million (73%) of adults aged ≥18 years are fully vaccinated and 38% of those have received a booster.[15] Many adolescents are potentially eligible as well. Over half (4.74 million) of US adolescents 16-17 years of age are fully vaccinated with Pfizer-BioNTech COVID-19 vaccine, of whom only 6% have received a booster.[16] Turning back to the experience of Israel again for a moment for some safety-related observations of the 5-month booster interval, rare occurrences of myocarditis in people ≥16 years occurred at less than half the rate observed following second dose.[17]

To summarize COVID-19 vaccine booster dose by primary series at least 5 months after completing a Pfizer-BioNTech primary series, at least 6 months after completing a Moderna primary series, and at least 2 months after completing a Janssen primary series, people who are booster-eligible can receive any of the vaccine products for which they are eligible. Updates to the Interim Clinical Considerations include the age group eligible for Pfizer-BioNTech booster that may change based upon the outcomes of this meeting as depicted in this table:

COVID-19 Vaccine Booster Dose by Primary Series, with Interval

Primary series COVID-19 vaccine product*	Age for vaccine booster (years)	Interval between final primary dose and booster dose	COVID-19 vaccine products that may be given as booster dose*
Pfizer-BioNTech	≥16 (may change to ≥12)	≥5 months	Pfizer-BioNTech Moderna Janssen/J&J
Moderna	≥18	≥6 months	Pfizer-BioNTech Moderna Janssen/J&J
Janssen/J&J	≥18	≥2 months	Pfizer-BioNTech Moderna Janssen/J&J

*Only Pfizer-BioNTech is authorized as primary series or booster dose for people aged <18 years. For the prevention of COVID-19 in those aged ≥18 years, mRNA vaccines (Pfizer-BioNTech; Moderna) are preferred over the Janssen/J&J COVID-19 Vaccine for both primary series and booster doses.

[12] Andrews et al MedRx preprint 14 Dec 2021; Ferguson et al Report 49 16 Dec 2021
[13] Bar-On et al NEJM 23 Dec 2021
[14] Arbel et al NEJM 23 Dec 2021
[15] CDC COVID Data Tracker 4 Jan 2022
[16] CDC Immunization Data Lake 3 January 2022
[17] Israel Ministry of Health Vaccine Safety Update 15 Dec 2021

Discussion Summary

Ms. Bahta observed that the US has 3 COVID-19 vaccines with 3 different intervals, which is confounding to play out practically and feasibly. As a decision-maker, ACIP cannot do much about this. Therefore, good clinical consideration guidance is needed.

Dr. Twentyman responded that CDC endeavors to make the clinical guidance as easy to follow and as intuitive as possible for the American public and the healthcare providers who serve them. The agency will continue to do this in any context in which they are working, such as the 3 different booster intervals, and will continue to update the guidance as soon as possible for any policy or authorization updates in the future.

Dr. Long recalled that ACIP saw some data about the response of immunocompromised persons to vaccine very early on, but everything else had been tagged on. While she wants to protect children 5-11 years of age who did not respond to the first 2 doses with another dose, this is exactly the age group and the condition in which the risk of myopericarditis is significant if they responded to Doses 1 and 2 and receive a third dose in the presence of high antibody to spike protein. These are children whose hearts may be challenged by chemotherapy, steroids, various drugs, and other things. With that in mind, she asked whether the WG had seen data along the way and agreed with the changes. Many transplant centers and others are doing semi-quantitative or quantitative antibody tests. Because the CDC has said these are not accounted for because there is not a known marker of protection, this seems like a missed opportunity to know whether someone has a high antibody to spike protein and has responded to vaccine. These children may be at particular risk for myopericarditis and this is not the time to give them a dose. Based on the numbers she has seen, they either have no response and need it, or an extremely high response after the second dose. With that in mind, she wondered whether CDC had reconsidered that antibody tests are probably reproducible now, considering the use of those in immunocompromised to make the decision for the third dose at 3 months.

Dr. Wharton indicated that all of the information for the incremental extensions of recommendations would not all come to ACIP, and it is likely that fewer would come forward in the future because of the limited amount of additional information available to address those. There are a number of substantial issues that CDC would like to engage the committee to discuss, and that is likely to be an increasing direction going forward.

Dr. Lee added that as a committee, ACIP has been struggling with this. In routine scenarios, ACIP deliberates on new vaccines, indications, and/or contraindications. The goal is to ensure that ACIP is providing a timely response following FDA authorization or approval of new vaccine product or new indication. Those meetings typically occur 3 times a year and are scheduled well in advance. In the pandemic scenario, ACIP is working under a public health emergency and timeliness is essential for everyone. Based on their work as frontline clinicians or public health practitioners, ACIP members recognize that decision-making is typically in the context of uncertainty. In her view, ACIP should continue to serve the purposes it was set out to do. First and foremost, that is to provide advice and guidance to the Director of CDC regarding use of vaccines and related agents to effectively control vaccine-preventable diseases. In this instance, that is COVID-19. ACIP's second purpose is to ensure that the public has knowledge of, and an opportunity to provide public comment on, meeting topics in order to ensure transparency in its decision-making and enhanced public trust. The urgent demands of the pandemic response and the way that ACIP is structured has created challenges. They have to acknowledge those challenges and make sure that they are continuing to fulfill their function and role, while allowing public health agencies the flexibility to respond in a timely manner. She anticipates that ACIP

will be hearing from their FDA colleagues on a fairly routine basis since several decisions are anticipated to occur quickly over the next few weeks, months, and beyond. In order for ACIP to be responsive to CDC, they must focus on issues that impact the overall population benefit-risk balance and times when public discussion is critical for transparency and trust. The demands on ACIP have been above and beyond typical federal committee structure, and they will have to learn together about making sure ACIP is serving its purpose and function while also being responsive to the pandemic. It is important to recognize that every emergency meeting ACIP members, liaisons, and CDC staff attend pose an additional burden. As Dr. Cohn mentioned early on, they will continue to make this as feasible, sustainable, and impactful as possible in terms of the discussions that occur. Dr. Lee said that in her opinion, consideration must be given to enhancing the predictability of these meetings going forward in order to support a sustained response. While her hope was to be finished after a year, then after two years, it was becoming clear to her that they were heading into Year 3 and were not done by any means.

Dr. Sanchez said that his personal opinion was that he did not feel this would ever be finished and that they would have to live with it and control it by vaccination and other means. He observed that myocarditis has been a concern throughout. As he was looking at the recommendation for immunocompromised children for an additional primary series, much thought has been given to the pathogenesis and booster dosing for persons 12-15 years of age. It did not seem that there had been much myocarditis reported among the 1.4 million children with an immunocompromising/suppressive condition, and that myopericarditis is likely to be an issue with those individuals after a third dose.

Dr. Oliver noted that there had not been specific surveillance for myocarditis solely in immunocompromised populations. From a pathophysiologic standpoint, it does make sense that the children who are immunosuppressed and not having robust immune responses may not be the highest risk population for myocarditis after third doses. The consensus of the WG was exactly what Dr. Sanchez mentioned.

Dr. Shimabukuro added that all cases of myocarditis reported to VAERS are reviewed and attempts are made to follow-up, obtain medical records, and/or contact a physician as part of CDC's adjudication to ascertain whether the patient meets the case definition. He was not aware of any unusual or unexpected findings in these case reports with respect to immunocompromising conditions. He did not think there was any evidence to suggest a safety issue above and beyond what is being observed in routine surveillance for the specific immunocompromised patient population.

Dr. Poehling commented that she has received many questions about providing additional coverage for immunocompromised children who were younger than 12 years of age, so this recommendation will be welcomed news for many.

In terms of Dr. Long's comment, Dr. Daley reported that the WG had not reviewed antibody titers among immunocompromised children 5-11 years of age in the last few weeks. He emphasized that part of the process that got them to this point was the FDA's review of their interpretation of risks and benefits of vaccination of immunocompromised individuals and their assessments about whether the benefit strongly outweighs the risk. In terms of what should be put before the full ACIP, there was a lot of discussion from leadership within the CDC about what the committee should discuss. The decision was made to focus on the booster doses in persons 12-15 years of age, but that did not preclude them from thinking about, discussing, and commenting on other issues in front of them. He asked Dr. Kotton to share her perceptions about additional doses among children 5-11 years of age who are immunocompromised.

Dr. Kotton reported that what is being observed in immunocompromised patients is a marked reduction in VE and protection from disease. Omicron is different from previous variants in terms of VE and she thinks that now is the time to think about additional doses of vaccine for all immunocompromised patients, perhaps starting as early as 4 months after they complete their primary series. One thing that had not come out of the discussions during the day was the overall risk of developing myocarditis and other life-threatening conditions from the disease itself. She is seeing devastating amounts of disease in immunocompromised patients. While in general Omicron was being touted as less severe, for poorly vaccine-protected immunocompromised patients, she was seeing life-threatening disease. She has numerous patients on life support in the ICU and other patients have died. This is a horrible state of affairs for immunocompromised patients. While ACIP had been deliberating a lot about vaccine side effects, she wanted the focus also to be on the disease itself, which was occurring in astronomical proportions. The immunocompromised patients she cares for have been diligent in avoiding getting infected. The highly infectious nature of Omicron is such that patients who have been incredibly careful for the better part of the past 2 years are now getting infected, with awful outcomes. She advocated for better examination of how devastating the disease can be, especially at the rates occurring, as well as for additional doses of vaccine for all immunocompromised patients.

Updates to the Evidence to Recommendations (EtR) Framework: Pfizer-BioNTech COVID-19 Vaccine Booster Doses in Adolescents 12-15 Years of Age

Dr. Sara Oliver (CDC/NCIRD) provided updates to the EtR Framework on Pfizer-BioNTech COVID-19 vaccine booster doses in adolescents 12-15 years of age. As a reminder, this EtR Framework has been used for previous booster dose recommendations. Regarding the timeline of the recommendations for COVID-19 booster doses over the last several months, ACIP first reviewed data and voted on booster doses for the Pfizer-BioNTech vaccine in September 2021.[18] In October 2021, this expanded to the Moderna and Janssen vaccines, including recommendations for heterologous boosting.[19] In November 2021, the booster recommendations were broadened to include all persons 18 years of age and over.[20] In December 2021, this was extended down to 16 years of age.[21] In January 2022 to date, the interval was shortened between the primary series and booster dose to 5 months for the Pfizer-BioNTech vaccine.[22] During this meeting, the focus was on consideration of booster doses of Pfizer-BioNTech COVID-19 vaccine for those 12-15 years of age.

Booster doses are recommended as a “should” receive the booster for all persons 18 years of age and over. The interval between the primary series and the booster depends upon the primary series received. Those 16-17 years of age “may” receive a booster at 5 months after the receipt of their Pfizer-BioNTech COVID-19 vaccine primary series. The policy question for consideration during this session was:

> “Should individuals 12-15 years of age 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?”

[18] ACIP Meeting, September 23rd https://www.cdc.gov/vaccines/acip/meetings/slides-2021-09-22-23.html
[19] ACIP Meeting, October 21st https://www.cdc.gov/vaccines/acip/meetings/slides-2021-10-20-21.html
[20] ACIP Meeting, November 19th https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-19.html and CDC Director’s Memo: https://www.cdc.gov/media/releases/2021/s1129-booster-recommendations.html
[21] CDC’s Director’s Memo: https://www.cdc.gov/media/releases/2021/s1208-16-17-booster.html
[22] CDC’s Director’s Memo: https://www.cdc.gov/media/releases/2022/s0104-Pfizer-Booster.html

Moving to the public health problem of the EtR Framework, over 56 million cases of COVID-19 had been reported in the US between January 23, 2020 through January 3, 2022.[23] Cases rapidly increased starting in early December 2021 due to the increasing prevalence of the Omicron variant. The 7-day average reached an all-time high of nearly 500,000 cases as of January 3, 2022. As of the most recent week available ending on January 1, 2022, Omicron comprised over 95% of cases. It is important to note that the most recent estimates are drawn from a modeled forecast, Nowcast, that attempts to account for delays associated with testing and genotyping, as well as various biases in surveillance.[24]

In terms of COVID-19 incidence rates over time by age group, adolescents have had a somewhat higher incidence rate than adults over the summer and are currently experiencing the incidence increased seen across age groups due to the Omicron variant.[25] Throughout the pandemic, the pediatric and adolescent age groups have had lower hospitalization rates than adults. Regarding recent trends in persons 12-15 years of age, there is some variability in the rates from week-to-week because there are fewer events in these age groups. However, the overall trends can still be seen. There was a slight increase in hospitalization rates from the summer, but rates have remained relatively steady overall. It is important to note that these dates go through December 10, 2021 and may not reflect the significance of the Omicron variant yet.[26] The majority of COVID cases continue to occur among the unvaccinated, with unvaccinated individuals 12-17 years of age having approximately a 7 times higher risk of testing positive for SARS-CoV-2 compared to vaccinated persons 12-17 years of age.[27] Unvaccinated 12-17 year olds had an approximate 11 times higher risk of hospitalization than vaccinated 12-17 year olds.[28]

A few studies have provided early estimates of VE in this adolescent age group. The first is a prospective cohort study that followed children and adolescents 12-17 years of age in Arizona from July-December 2021 to estimate VE against SARS-CoV-2 infection. When comparing 12-17 year olds vaccinated with the Pfizer vaccine with unvaccinated 12-17 year olds, this study estimated an adjusted VE against infection of 92%.[29] The next study came from the Increasing Community Access to Testing (ICATT) Partnership. This was a test-negative study design that covered the period from July 18, 2021-October 17, 2021 that evaluated VE to prevent symptomatic infection. In a comparison of Pfizer-BioNTech VE against symptomatic infection between adolescents 12-15 and 16-19 years of age and adults 20 years of age and over, VE was highest among persons 12-15 years of age, followed by persons 16-19 years of age, then adults 20 years of age and over. VE wanes among all age groups with increasing time since vaccination. It is important to note that this analysis reflects a period with a predominance of the Delta variant.[30] Another study assessed effectiveness of the Pfizer vaccine against COVID-19 hospitalization among persons 12-18 years of age. This was a test-negative study design of children and adolescents hospitalized at 19 pediatric hospitals from 16 states from June 2021-September 2021. This study estimated that VE against COVID-19 hospitalization in persons 12-15 was 91%. Again, this study reflects the Delta dominant period.[31]

[23] CDC. https://covid.cdc.gov/covid-data-tracker/#trends_dailycases. Accessed January 2, 2022
[24] https://covid.cdc.gov/covid-data-tracker/#variant-proportions
[25] https://covid.cdc.gov/covid-data-tracker/#demographicsovertime
[26] CDC's COVID-NET, https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network
[27] https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status
[28] CDC's COVID-NET https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination
[29] Lutrick K, et al. MMWR. DOI: http://dx.doi.org/10.15585/mmwr.mm705152a2
[30] Olson SM, et al. MMWR 2021;70:1483–1488. DOI: http://dx.doi.org/10.15585/mmwr.mm7042e1
[31] DOI: http://dx.doi.org/10.15585/mmwr.mm7042e1

Dr. Oliver also highlighted data from an analysis that was soon to be published that the authors allowed to be shared from the information pre-print. This test-negative case-control design included MIS-C cases and hospital controls 12-18 years of age from July 2021-December 2021. This study showed that the VE of 2 doses of the Pfizer vaccine in this population against MIS-C was 91%. Among the children hospitalized with MIS-C, 95% were unvaccinated. The vaccine also attenuated MIS-C severity. None of the 5 vaccinated children who subsequently presented with MIS-C after SARS-CoV-2 infection required respiratory or cardiovascular support.[32]

To summarize the public health problem, the US has been experiencing a substantial increase in cases over the last month. The Omicron variant represents around 95% of recent US cases. COVID-19 cases and hospitalizations were 7 to 11 times higher in unvaccinated adolescents compared to vaccinated adolescents. VE in adolescents 12-15 years of age remains high, but may have some waning over time. However, it is important to note that the current VE estimates are primarily in the setting of the Delta variant and may not represent the current situation with the Omicron variant.

Now to think through the benefits and harms. As a reminder, when discussing recommendations for the primary series adolescents 12-15 years of age, the Pfizer-BioNTech Phase 2/3 was reviewed. This randomized controlled trial (RCT) included approximately 2,000 persons 12-15 years of age in the US. All eligible randomized participants who received all vaccinations as randomized within the pre-defined window and had no other important protocol deviations, with a data cutoff of March 13, 2021. This clinical trial for the Pfizer-BioNTech COVID-19 vaccine demonstrated efficacy against symptomatic, laboratory-confirmed COVID-19. There were no COVID-19 cases among a1001 vaccine recipients and 16 COVID-19 cases among 972 placebo recipients for a vaccine efficacy of 100%. The geometric mean ratio (GMR) for antibodies in adolescents 12-15 years of age compared to what was seen in persons 16-25 years of age was 1.76, which met the noninferiority criteria. There were no hospitalizations due to COVID-19 or MIS-C reported by any of the trial participants. SAEs were reported at a higher proportion of recipient of vaccine versus placebo (0.4% vs 0.2%), with 5 SAEs in the vaccine group and 2 in the placebo group, with none deemed to be related to the vaccine. Severe reactions were more common in vaccine recipients, with a Grade 3 or more reaction reported by 10.7% of the vaccinated versus 1.9% of the placebo recipients.[33]

Real world effectiveness data from Israel of booster doses compared to primary series from July 30, 2021-October 10, 2021 come from a study that followed 4.7 million booster-eligible individuals 16 years of age and over who received booster doses 5 months after a 2-dose Pfizer-BioNTech COVID-19 vaccine primary series. This study demonstrated efficacy against confirmed infection in all age groups. Among the participants 16-29 years of age, the rate ratio for infection comparing the non-boosted group to the boosted group was 17.2 (15.4–19.2).[34] Data from the Israeli Ministry of Health website looking at the available information across all populations as of December 15, 2021 shoe that myocarditis rates reported after the Pfizer vaccine in Israel shows that the rates of myocarditis after a third dose were lower than what is seen after the second dose. Previously, they had reported no cases of myocarditis out of 6,000 doses administered. ACIP heard earlier in the day that with over 40,000 doses administered, Israel has 2 cases of myocarditis reported in this age group.[35]

[32] Data in press for Friday, Jan 7th, upcoming *MMWR*
[33] Frenck et al., New England Journal of Medicine, 2021
[34] Bar-On et al., New England Journal of Medicine, 2021
[35] Data from: PowerPoint של מצגת (www.gov.il)

Highlighting what is known about the impact of the Omicron variant, smaller studies that have looked at neutralizing antibodies of vaccinees found that neutralization was below the limit of detection for those who received a primary series of either 2 doses of mRNA or 1 dose of Janssen vaccine. It moved above the limit of detection for those who either had a booster or who had previous infection. Given limits of detection of the assays and a lack of a correlative protection, it is difficult to determine whether these antibody titer levels translate to protection for either infection or severe disease.[36] Based on data from the United Kingdom (UK) from a study on Pfizer mRNA VE against infections with the Delta and Omicron variants, there was some waning for both variants over time. This appeared to be more pronounced with the Omicron variant. With a booster of either a Pfizer or Moderna vaccine, VE improved with both Delta and Omicron.[37]

Thinking through the potential benefits of a booster dose in adolescents 12-15 years of age, a 2-dose primary series of a Pfizer-BioNTech COVID-19 vaccine is known to provide protection against symptomatic COVID infection and hospitalization. Now data are available pertaining to MIS-C as well. VE after the primary series is high, but likely is impacted by the Omicron variant. In persons 18 years and over in the UK, VE was lower for the Omicron compared to the Delta variant. However, exact estimates of VE against Omicron in adolescents 12-15 years of age are unknown. A booster dose has been shown to increase both neutralization antibody level and VE in persons ≥18 years of age. Again, in the UK a booster dose increased VE specifically in the setting of Omicron. In terms of potential harms, the myocarditis rates among adolescents 12-15 years of age after a primary series were lower compared to rates among persons 16-17 years of age. Among over 6,000 adolescents 12-15 years of age received a third dose in Israel, no cases of myocarditis were reported. After 40,000 doses, 2 cases were reported. It is known from experience in the older age groups, the rates of myocarditis after a booster dose are lower than what is seen after a second dose.

To summarize the benefits and harms, there is likely to be lower VE in all populations in the setting of Omicron compared to what has been observed with the Delta variant. Higher antibody titers improve neutralization of the Omicron variant and booster doses of COVID vaccines can increase neutralization titers. The impact of a booster dose on neutralizing antibody or VE in adolescents 12-15 years of age specifically is unknown, but it is likely to provide additional protection. Myocarditis rates after a booster dose are likely lower than what was seen in a second dose in younger adolescents.

[36] Wilhelm et al. https://www.medrxiv.org/content/10.1101/2021.12.07.21267432v1.full.pdf; Cele et al. https://www.medrxiv.org/content/10.1101/2021.12.08.21267417v2; Roessler et al. https://www.medrxiv.org/content/10.1101/2021.12.08.21267491v1; Dejnirattisai et al. https://www.medrxiv.org/content/10.1101/2021.12.10.21267534v1; Schmidt et al. https://drive.google.com/file/d/1zjJWsybGaa3egiyn5nQqTzBtl0kmvMUu/view; Pfizer investor brief: https://investors.biontech.de/static-files/47b4131a-0545- 4a0b-a353-49b3a1d01789; Nemet et al. https://www.medrxiv.org/content/10.1101/2021.12.13.21267670v1; Ikemura et al. https://www.medrxiv.org/content/10.1101/2021.12.13.21267761v1; Lu et al. https://www.medrxiv.org/content/10.1101/2021.12.13.21267668v1; Garcia-Beltran et al. https://www.medrxiv.org/content/10.1101/2021.12.14.21267755v1/ ; Cameroni et al. https://www.biorxiv.org/content/10.1101/2021.12.12.472269v1.full.pdf ; Doria-Rose et al. https://doi.org/10.1101/2021.12.15.21267805; Planas et al. https://www.biorxiv.org/content/10.1101/2021.12.14.472630v1; Aggarwal et al. https://www.medrxiv.org/content/10.1101/2021.12.14.21267772v1; Liu et al. https://www.biorxiv.org/content/10.1101/2021.12.14.472719v1.full.pdf

[37] Andrews et al. https://khub.net/documents/135939561/430986542/Effectiveness+of+COVID19+vaccines+against+Omicron+variant+of+concern.pdf/f423c9f4-91cb-0274-c8c5-70e8fad50074

In terms of values and acceptability, vaccine uptake among teenagers increased rapidly initially. However, uptake has stalled somewhat over the last few months such that about half of parents of children 12-17 years of age reported that their teen had been vaccinated for COVID-19. Recently, around 1% said that they planned to vaccinate their teen right away. About 1 in 8 parents said that they wanted to wait to see how the vaccine is working. Notably, about 30% (3 out of 10) said that they would definitely have their children 12-17 years of age vaccinated for COVID-19. While these data indicate a slowing of vaccine uptake among teens, it is important to note that this survey was conducted prior to the emergence of the Omicron variant. As more information emerges on the potential impact of this variant on children, parents' attitudes toward vaccinating their teenagers or their younger children may change.[38]

Looking at CDC data on vaccination coverage and intent October 31, 2021-November 27, 2021 among 3 age groups (adult, adolescents, and younger children), almost 80% of adults were vaccinated against COVID-19 and around 13% reported that they were reluctant to get vaccinated. By contrast, coverage was almost 60% youth 12-17 years of age. About 20% of parents said they were reluctant to vaccinate their child. For those 5-11 years of age, 8% were vaccinated and 33% of parents said they were definitely planning to vaccinate their child. A quarter of parents reported that they were reluctant to vaccinate their children. Again, the survey was conducted in November shortly after the recommendations for children 5-11 years of age group were issued. Looking at behavioral-, social-, and access-related factors by vaccination coverage and parental intent for adolescents 12-17 years of age during the same time period, parents of adolescents who were concerned about their children getting COVID-19, were confident in vaccine safety, or had a provider recommendation to vaccinate their child were more likely for their children be vaccinated or willing to have them vaccinated soon. Parents who were reluctant to vaccinate their children were significantly less confident in vaccine safety and reported less vaccinated social networks. Across all groups, parents reported that they did not have difficulty or would not have difficulty getting the vaccine for their child.[39]

To summarize parental confidence in vaccine safety, parents were less likely to express confidence that the vaccines are safe for their adolescents or children than for the adults themselves based on the Kaiser Family Foundation (KFF) and CDC data, the top safety concerns among parents of children 12-17 years of age were assessed. Respondents were instructed to choose their main safety concern around COVID-19 vaccines. The most prominent safety concern among parents was the potential unknown long-term side effects.

In summary of values and acceptability, vaccine uptake among children 12-17 years of age for a primary series has slowed somewhat over the last few months. As more information emerges on the potential impact of the Omicron variant in children, parental attitudes may change. It is known that the parents of adolescents and children are concerned about the potential long-term side effects.

[38] KFF COVID-19 Vaccine Monitor. Winter 2021 Update On Parents' Views of Vaccines for Kids. https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-winter-2021-update-on-parents-views-of-vaccines/. Accessed January 3, 2022.
[39] CDC Preliminary & Unpublished data, National Immunization Survey, October 31, 2021 – November 27, 2021

Moving to feasibility and implementation, roughly 8.6 million of the 16.7 million children or adolescents 12-15 years of age (approximately 50%) had completed the primary COVID-19 vaccine series from June 5, 2021-January 1, 2022. Around 5 million adolescents were vaccinated more than 5 months ago and would be eligible for a booster dose.[40] Based on booster experience with other groups, it can be anticipated that about a third of adolescents may return for a booster dose shortly after the recommendation. The supply of the Pfizer-BioNTech COVID-19 vaccine is robust, and the "gray cap" described earlier will be easier to distribute and administer. At the time of this meeting, the demand for pharmacy appointments was high. Broadening eligibility could strain this further.

With respect to equity, there was variation in vaccination coverage and parental intent for children 12-17 years of age by race and ethnicity. Hispanic children were more likely to be vaccinated than either Black or White children. While there were no significant differences by the county-level Social Vulnerability Index (SVI), those in urban and suburban areas had higher vaccination coverage rates than those residing in rural areas.[41] In summary, there were noted disparities in vaccination coverage and parental intent by both recent ethnicity and geographic location.

In summary of the EtR Framework, a combined COVID-19 WG and Vaccine Safety Technical Work Group (VaST) meeting was convened on January 4, 2022. Dr. Oliver provided a summary of that meeting on behalf of VaST. VaST reviewed the most recent data for the 3 US safety monitoring systems, including data on safety after the primary vaccination series in adolescents 12-15 years of age and following booster doses among persons 16-24 years of age—the youngest age group for which booster doses have been authorized to date. No new safety signals or concerns were identified. Presently, the data did not suggest safety concerns regarding a Pfizer-BioNTech COVID-19 vaccine booster dose for youth 12-15 years of age beyond what has been identified in the older age groups.

In terms of the WG's interpretation, the WG felt that the top priority remains vaccination of unvaccinated individuals. The benefits of the COVID-19 vaccine primary series outweigh the risk in all age and sex groups. The primary vaccination series remains the best tool available against COVID-19 hospitalizations and deaths. In thinking through all COVID-19 vaccine recommendations, it is important to highlight that the goal of the COVID-19 vaccine program is prevention of severe disease, including hospitalization and death. The secondary goals are to maintain the work force and healthcare capacity, reduce infection rates and risk of transmission, instill greater confidence in in-person learning, improve mental health with more social interactions, and prevent post-COVID conditions. With all of this in mind, the WG supported the use of boosters in adolescents 12-15 years of age. The WG also emphasized the importance of clear and consistent recommendations for all adolescents, including those 16-17 years of age. As observed over many ACIP meetings throughout the last year, vaccine recommendations can and will be updated as needed—especially in a rapidly evolving pandemic.

Everyone was reminded that ACIP could vote not to recommend the intervention; recommend the intervention based on the balance of benefits and risks, which would indicate that this age group "may" receive a booster; or recommend the intervention, which would mean that this age group "should" receive a booster. The WG discussed the recommendation that adolescents 12-15 years of age "may" receive a booster dose based on the individual benefit and risk. This recommendation acknowledges that there are limited data directly on the impact to boosters

[40] https://covid.cdc.gov/covid-data-tracker/#vaccination-demographic
[41] CDC Preliminary & Unpublished data, National Immunization Survey, October 31, 2021 – November 27, 2021

and the adolescent population. In the current Omicron surge, this would provide a recommendation for boosters in a population who could have waning immunity due to time since primary series and the impact of the Omicron variant. The WG also discussed the possible advantages of a recommendation for adolescents 12-15 years of age that they "should" receive a booster dose. The WG discussed the difficulty in defining the individual benefit-risk balance with the "may" recommendation and that the way in which it varies across the population could be difficult for vaccine providers to communicate. In the current Omicron surge, prevention of infection might have larger benefits that are difficult to measure (e.g., population level protection, school attendance, mental health, et cetera).

The following highlights the language that was previously in the clinical considerations[42] pertaining to what individuals and providers could consider as they think through that benefit-risk balance with a "may" recommendation:

- Potential benefits of booster dose
  - Reduced risk of SARS-CoV-2 infection, severe disease
  - May reduce transmission of SARS-CoV-2 to others

- Potential risks of booster dose
  - Rare risks of serious adverse events (e.g., myocarditis, pericarditis, TTS, GBS, anaphylaxis)
  - Common risks of transient local and systemic symptoms

- Individual risk factors for SARS-CoV-2 infection
  - Risk of exposure in occupational and institutional settings (e.g., healthcare workers, long-term care settings)
  - Risk for infection (time since completion of primary series)

- Individual impacts of SARS-CoV-2 infection
  - Risk for severe infection (related to underlying conditions)
  - Risk associated with a person's circumstances (living with/caring for at-risk individuals or consequences of inability to meet obligations due to infection)

Dr. Oliver extended her personal gratitude to those who worked not only in a short timeframe to complete the EtR Framework assessment, but also over the holiday to make this presentation possible.

Discussion Summary

Referring to Slide 41, Ms. McNally asked whether there was anything that could be said to the public to abate the concerns regarding to potential unknown long-term side-effects.

Dr. Oliver said she thought they could highlight the recommendations for adolescents in adolescents 12-15 years of age since May 2021. There has been extensive post-authorization safety surveillance in this population and millions have been vaccinated. The ACIP meeting on myocarditis was convened in mid-June 2021. That is how rapidly this issue was identified and brought to ACIP. The rates for myocarditis observed have been stable of over time. Based on months of surveillance, VE has continued to be high. Vaccine is known to be the best tool to prevent COVID-associated disease, hospitalization, and death. As more information

[42] https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

accumulates, the benefits continue to be observed. It is now known that receipt of COVID-19 vaccine can prevent hospitalization with MIS-C. CDC continues to conduct rapid, extensive post-authorization safety surveillance that has demonstrated these vaccines to be safe and effective. Given that the information about the potential for boosters was only announced a couple of days before the meeting, it was not possible to conduct a rapid survey of acceptability specific to this potential recommendation.

Dr. Poehling noted that the hospitalization rates struck her. Her hospital is full of COVID-19 patients across all ages, with the unvaccinated being the far more representative. They also have children waiting in the ED 18 hours and longer just to get into the hospital because, given that they are so full. Parents are asking whether their children can get a booster dose like older children. Thinking about how transmissible this is, she was leaning toward a “should” recommendation.

Dr. Sanchez pointed out that the recommendation for persons 16-17 years of age was a “may” recommendation.

Dr. Oliver noted that if ACIP decided to move forward with a “may” recommendation, they could vote on individuals 12-15 years of age. If ACIP decided to recommend “should,” the vote likely would be for individuals 12-17 years of age to ensure that the two groups are harmonized.

Dr. Zimmerman said that speaking as a vaccine researcher over the decades, the human immune system responds well to boosters. Therefore, he personally supported a “should” recommendation.

Ms. Bahta also supported a “should” recommendation. However, she expressed concern that the burden of disease prevention was all falling on the vaccinated population and on getting them boosted. As they heard from one of the epidemiologists at the World Health Organization (WHO), it will not be possible to get through this pandemic by boosting. While she understood that every single tool in the disease prevention book must be used, she would like to see a much clearer direction to the general population about the other measures to prevent disease spread. She rarely saw people masking anymore, especially indoors and at gatherings. Yet, this is such an important adjunct to the tool of vaccination. They cannot place all of the burden on the people who are willing to get vaccinated. When only half of adolescents are vaccinated, that adds more burden as well.

Dr. Kimberlin (AAP Redbook) said that speaking for himself, he heard the question raised at prior ACIP meetings and among other experts around the country about what is really being asked of these vaccines. Fundamentally, he thought that question must be raised again in terms of whether the vaccines were being expected to prevent every runny nose or to prevent hospitalization and deaths. Referring to Slide 20, VE looked very good during the Delta period. These vaccines are working in what he would suggest is the only reasonable and possible way that they can. He knows of no vaccine that can prevent every respiratory infection, mildly symptomatic or asymptomatic. He suggested refocusing on what is expected of the vaccine prior to deciding whether boosters would achieve this.

Dr. Maldonado (AAP) said that in her personal opinion based on interactions with colleagues across the country, she understood what Dr. Kotton mentioned about who is getting sick and the complexity and tragic circumstances occurring among immunocompromised children. At the same time, a number of children who do not have underlying conditions also are being hospitalized and continue to impact household and school transmission. She agreed with Dr.

Kimberlin about refocusing and Ms. Bahta about considering ways to reboot their efforts to get people back to the basics. Everyone is tired, the staffing issues are horrible at this point, record numbers of people are absent from work, there is a record number of cases in children, record numbers of hospitalized children, and deaths are increasing. COVID-19 still is among the top 10 causes of death for children in this country. They cannot forget this, or that it is important to emphasize. The fact that less than 25% of children 5-11 years of age have been vaccinated and that only half of adolescents are vaccinated at this point is critical. Obviously, she thinks a booster is important. However, there remains a need to base that booster on reinforcing the need for vaccinations for others, masks, distancing, et cetera. The consequences of this whole pandemic are becoming clearer. It is not just the vaccine, but it is one tool to use to get children back to school and back into society. School districts are shutting down, teachers are refusing to go back to school, et cetera. While the overall messaging can be based on vaccines, that needs to be broadened out to ensure other steps are taken to protect children in every way possible through all safety measures possible.

Dr. Long agreed that this is a hospitalization and death avoidance vaccine. Anything else they ask of it is over the top. Although a booster dose may achieve increased antibody for a very short period of time and it may provide some protection against symptomatic infection, that will not last, and it probably will offer no protection against asymptomatic infection. She thought they were getting enamored with the Israeli study showing that boosts decreased infection rates, but that is not what the US is going to be able to accomplish. However, the US is now in the midst of a new phase in which children are affected in large numbers. Until the Omicron variant peaks, she was much in favor of a “should” boosting recommendation. That will help to understand over time whether it conferred protection against hospitalizations and deaths for those who are otherwise fully vaccinated. There is no information showing that is happening, or to know what the antibody titers look like. This will allow them to “whack-a-mole” for another month or two, but it is not sustainable, and it is not smart to think that it is necessary to continue to boost to prevent infection or mildly symptomatic infection. That is just not going to happen unless everybody in the country gets Omicron and then the US transitions to endemic and less severe disease.

Dr. Talbot disagreed for the reason of the limitations of the current medical care system. If ACIP recommends “should,” it is going to turn many providers into going backwards when they really need to move forward to get the other 50% of individuals 12-17 years of age and the other 75% of individuals 5-11 years of age vaccinated. That should be the main concern. While it is nice to have a booster in for individuals 12-15 years of age to prevent illness, most of them will be safe from a severe illness after 2 primary doses. Some of the children 5-11 years of age may be lost if ACIP recommends “should” instead of “may.” If the US had a well-funded public health system with the capacity to do everything, that would be great. Instead, she though the focus should be on children and adolescents 5-15 years of age who are not vaccinated.

Dr. Cineas agreed that the efforts need to be doubled to reach the unvaccinated. Given the current state of the surge, she also was leaning more toward a “should” recommendation. She agreed that the language should align with the older age group of persons 16-17 years of age. Given the surge, she is seeing patients in the 12-15 age group who have been vaccinated but are now having a breakthrough infection. She asked whether there was any guidance on the recommendation for boosters for those patients in terms of timing after a recent infection, or if there would be a recommendation regarding that group.

Dr. Oliver indicated that the only recommendation specifically around recent infection pertains to the time period people should be actively kind of quarantining or isolating. They definitely do not want people who test positive for COVID-19 hanging around in line at Walgreen's to get a vaccine. There is no specific minimum interval between recent infection and time to receive a booster dose.

Dr. Hogue (APhA) pointed out that this may be one of the toughest questions ACIP has faced recently. He personally was struggling deeply with the "may" versus "should" options. He was particularly struck by Dr. Kimberlin's comment about what it is they are trying to prevent (e.g., hospitalizations, deaths, breakthrough infections, et cetera). He thought they must acknowledge that in the adolescent and adult groups, the majority vaccine doses were being given in pharmacies where there is an increasing and severe shortage of staff, including Pharmacists and Pharmacy Technicians. The amount of burnout occurring in these practice sites is significant. With limited human resources, consideration must be given to what is reasonable to ask of those limited resources to be able to accomplish whatever the recommendation. In an ideal world where everything is funded as needed and there are no healthcare professional shortages, it should be okay. He realizes that every hospitalization is one too many and every death is one too many, and they want to do their best to prevent this. However, the hospitalization and death rates are very low among this age group compared to the older adult age group for whom ACIP did make a stronger "should" recommendations. Given the current stress on the existing system, he thought it was premature for ACIP to make a "should" recommendation.

Dr. Loehr expressed surprise to be in favor of a "should" recommendation. Given that this surge was greater than other surges and the number of cases were tremendously higher, he would expect to see a large number of people in the hospital just due to sheer numbers of cases. He found this concerning and agreed with Dr. Long's "whack-a-mole" analogy to whack down this variant and re-evaluate in the future.

Dr. Sanchez said that while he was torn, he agreed with his colleagues about the need to make sure that the message is to prevent serious disease. On the other hand, a "should" recommendation may bring more vaccine mandates and might change what is considered to be fully vaccinated individual down to age 5. At the same time, his struggle was that he believes in the vaccine, that it has been found safe, and that it can prevent serious infection. With the Omicron surge, even though it seems to be less severe and certainly less severe amongst vaccinated individuals, there is some waning of the antibody responses. He thought they could make the overall situation better by endorsing a vaccine that he personally believes in. Despite his struggle, he ultimately thought ACIP should make a more forceful recommendation of "should."

Dr. Cohn remind the ACIP that the federal government does not make school mandates. That happens at the state and local levels. Therefore, mandates should not be a consideration in terms of making these decisions. She also noted that CDC updated its guidance on the "fully vaccinated" language that now is "up-to-date." Use of the "up-to-date" language allows for the inclusion of booster dose recommendations. "Fully vaccinated" applies to the primary series and they should be focusing on making sure that everyone is up-to-date. Though she noted that she rarely brings her personal opinion into this, as a parent of 3 children in these age groups, she understands the burden and stress on everyone. There has been a particular challenge in this age group in terms of children being isolated and having problems with depression, anxiety, and challenges when they are sent home from school because they were positive or cannot go back to college because they are positive. All of these immeasurable potential impacts of a booster

dose, fully recognizing that it may not eliminate transmission but it may reduce the potential for a child to be positive or to be infected, could have a larger immeasurable impact on the wellbeing of these children.

Dr. Kotton strongly agreed with Dr. Cohn's comments and supported a "should" recommendation. She is seeing many families where there is transmission from children to adults. In some cases, there are devastating outcomes. Preventing as much mild to moderate disease in children as possible decrease disease in families, which seems like the way to go. The impact on a child who brings illness into a home that results in the death of a parent or a grandparent is absolutely crushing. She is seeing this clinically and the clearer ACIP can be in its recommendations, the more helpful it will be to those in the clinical trenches. Protecting immunocompromised patients and protecting children who are one of the major ways that people are being exposed currently will help prevent disease in immunocompromised patients as well.

Dr. Brooks emphasized the importance of holding these deliberations and discussions in real time, and he spoke in favor of a "should" recommendation. While it was unknown whether this booster would help with next variant, it is likely to help in some way. It will help reduce transmission, hospitalizations, and deaths though the degree to which it will do this is unknown. Something else to consider is that there may be people who are immunosuppressed who do not even know it who would get this booster, so it will protect those who have unknown conditions. A known risk of the vaccine is myocarditis, but they have not discussed within this particular deliberation that someone who gets COVID-19 has more of a chance of getting a severe myocarditis. That is mitigated by getting vaccinated. Vaccination is a tool in the toolbox. Thinking of it as a hammer, they should hit the nail hard.

Dr. Poehling agreed with her colleagues about a "should" recommendation. Hospitals are full. It is true that children are hospitalized at a less frequent rate than adults, but COVID-19 is overwhelming hospitals and children's hospitals. As Dr. Maldonado emphasized, COVID-19 is a top 10 cause of deaths among children, so this is not benign. As Dr. Brooks just mentioned, children with COVID-19 are experiencing myocarditis and severe myocarditis and there is a concern about the MIS-C to come. She too is seeing children who have lost parents. When they are quarantined, it creates undue stress and hardship on them and their families. Missing school is a big deal for children as well. Therefore, this is a tool that needs to be used to help children through this pandemic.

Dr. Talbot expressed concern about how they were talking about the children who are in a hospital in terms of whether these children being hospitalized for COVID-19 are vaccinated or unvaccinated. If they are vaccinated, that makes a big difference in the use of the boosters and a "should" recommendation would make sense. If the children being hospitalized are unvaccinated, it means they need to spend their days and nights vaccinating those who are unvaccinated. This booster will not be a hammer. This booster is going to get the nail in a millimeter, but there will be 20 millimeters to go that this hammer is not going to work on. Her thought was that if they divert public health from the unvaccinated to the vaccinated, they are not going to make a big impact. Boosters are incredibly important, but they will not solve the problem of crowded hospitals. That will be the unvaccinated.

Dr. Oliver replied that there are vaccinated children who are hospitalized, but it is known that the highest risk is among the unvaccinated. Referring to Slide 14, she pointed out that the risk is not zero among the fully vaccinated and is low among persons 12-17 years of age.

Dr. Lee expressed gratitude to everyone for sharing their opinions and agreed with nearly all of the comments her colleagues had mentioned. However, she stated a different opinion that they actually are trying to prevent infections—not just serious disease and hospitalizations. This is not dissimilar to the reasons they also continue to use tools like masking and testing. They are trying to reduce the risk of infection to protect themselves and others. She also thinks that they have burdened an entire generation of children, regardless of whether they are infected, with the impact of COVID-19. Infection and transmission are impacting the ability for individuals to function in terms of keeping schools, hospitals, businesses, and communities open. To her, all of this is critical. She sees vaccines as not the only solution, but one part of the broader public health conversation they need to continue to have around vaccines, masking, testing, et cetera to be able to manage through the pandemic. It is not just about hospitalizations. It is about the entire picture of children in terms of their physical health, mental health, socioemotional functioning, academic development, et cetera. She also truly believes that the long-term impact of COVID infection in children has not been addressed yet. They have not even scratched the surface of what they are going to see. They will continue to need more data. She expressed her hope that others would consider prevention of an infection a worthy goal.

Dr. Sanchez emphasized that everyone wants to prevent infection, but the current vaccine is showing them that it is more for serious infections. While he understood the implications for implementation of a booster, they need to do what is best for the families and children who want to be vaccinated and who want to be as protected as possible. ACIP can make that happen with a stronger “should” recommendation.

Dr. Poehling expressed appreciation for the robust discussion. She observed that the slide showing unvaccinated versus vaccinated hospitalizations was similar to what is seen in adults for whom there is a “should” recommendation. She advocated for having the same recommendation across the age groups and for improving the clarity of communication.

Dr. Daley observed that the question Ms. McNally led this discussion with regarding what is known about long-term stasis was a good one. Decades of experience with vaccines has shown that for the most part, if they cause side effects, those are in the short-term. When ACIP met in August 2021 to review the BLA for Pfizer, there were approximately 12 months of safety data from the individuals among several hundred million vaccinated adults. There are even more reassuring data now about long-term safety—more than they typically would have for any other routine vaccination. There is longer term follow-up now because the clinical trials were conducted in the summer of 2020 and ACIP met in August 2021 for the licensure for Pfizer. That provided sufficient reassurance for him that he would be comfortable voting for either “may” or “should.” He has been thinking about whether this vaccine perhaps should have been a 3-dose series all along. If that is the case, he would favor a “should” recommendation. The 2 doses spaced very closely together was dictated by the pace of the pandemic, with the observation that immunity was waning not occurring until later. It was appropriate at the time. He did not think that a “should” recommendation in individuals 12-17 years of age would take away from the public health focus on vaccinating the unvaccinated. The hard reality is that everybody who is eligible could have received a vaccine by now, so that group is going to be challenging to convince. During the WG meeting the previous day, one WG member pointed out that vaccinating persons 12-17 years of age with a booster would be worth preventing their lives from being entirely disrupted by testing positive, not being able to attend school, not being able to be around their friends, and being very isolated in the basement of their house. While the primary goal of preventing hospitals and deaths is paramount, preventing persons 12-17 years of age from suffering disruption to their lives due to the pandemic is also essential.

Dr. Lee paused the discussion to request that given ACIP's deliberations thus far, that Dr. Oliver present voted language that included "should" and changed the age range from 12-15 to 12-17. She then called upon ACIP liaison representatives to provide comments.

From the local public heath standpoint, Dr. Zahn (NACCHO) emphasized that "should" recommendations are much easier to understand, communicate, and implement than "may" recommendations. While it is not an absolute reason to make a decision, it certainly makes the communication a great deal simpler. In terms of reacting to Omicron, either recommendation has the potential to cause stress on the system. However, if ACIP thinks that this group should receive the vaccine, then local public health will use the resources they have as best they can to respond. Generally speaking, the country is experiencing a testing capacity shortage right now more so than a vaccination capacity shortage. If it is the right thing to do, public health will response. The bigger concern for Omicron is that it is transmitting rapidly through many communities and is unlikely to be lasting months. Therefore, he would not place too much emphasis on saying they are going to get people boosted to get them through Omicron. Instead, he thought they think in terms of the utility of having this population boosted, anticipating that there will Omicron and other new variants in the future. He said he could not underscore enough the disruption of COVID-19 in general in schools, but Omicron in particular has been a major disruption to the school situation. COVID-19 has been ongoing for a couple years, and they must figure out ways to keep children in school. Any measures that will make schools safer and easier to stay open during this and current surges is well worth considering.

Ms. Stinchfield (NAPNAP) supported the "should" recommendation. In terms of how to vaccinate the unvaccinated, in this age group they will just have to roll it into the standard work as is done with other vaccines for people entering schools and universities by making it an entry requirement. It is not too early to start working on this for next fall. As one of the public commenters said, conversations to engage school nurses early and work with education boards and legislators should be occurring now. She shared Dr. Poehling's concern about the data showing hospitalizations in children 0-4 years of age being so high and this age group being unprotected. The number one question she gets from parents regards when this age group will be eligible. She requested before this meeting ended that someone provide an update for the public on that timeline.

Dr. Rockwell (AAFP) said that speaking as a family physician and an AAFP representative, she supported a "should" recommendation for several reasons. The first was to keep the CDC recommendations clear and concise for physicians and other vaccine providers. She is regularly surprised by anecdotal misinformed guidance her patients have received from other healthcare professionals in her community. Second, in addressing the current state of the compromised and overburdened healthcare workforce, a "should" recommendation has the potential to result in fewer infections and hospitalizations of vaccine recipients and their family members. Therefore, a "should" recommendation may actually help reduce the burden on the healthcare workforce in a short amount of time. Third, in addressing those who have not yet been vaccinated with plenty of opportunity to do so at this point and much frustration from those who offer vaccinations, she agreed that public health efforts will not be compromised by a "should" recommendation or take away from any efforts to vaccinate the unvaccinated. She believes they need to explore other and different efforts to change the acceptance of vaccinations among the current unvaccinated population.

Dr. Duchin (IDSA) noted that a “should” recommendation clearly has advantages in the context of complicity, clarity, and consistency with other guidance. As the discussion indicated, the ACIP voting members favored that. If there were to be a “may” recommendation, it would need to be very explicit in order to give the public and healthcare providers in public health vaccine and administration programs the guidance about under which circumstances a child who “may” get it should get it. It was not clear how anyone would make the decisions that would need to be part of a “may” recommendation. The day’s discussion clearly was not informed by the amount of data that any of them would like and was an example of real-world, real-time, and real tough pandemic decision-making. He commended the ACIP members for the excellent discussion and thoughtful deliberation. He agreed with Dr. Kimberlin’s mention earlier about the need to explicitly define the goals of the national COVID-19 vaccination program with respect to prevention of infection versus serious disease. He anticipates that can happen once the country is out of the acute crisis stage of these recurrent waves.

Ms. Hayes (ACNM) reported that she has heard from many people that they are frustrated that the language coming from the CDC seems to change frequently in terms of what the recommendations are. When this recommendation is put forth, they must continue to promote that as the variants change, so must the recommendations change. She agreed that further conversation is needed about what constitutes “fully vaccinated” because there remains some confusion among the public about having 1 J&J vaccine and a booster making them fully vaccinated or whether having 3 vaccines will make them fully vaccinated. A very strong message is needed about what constitutes being “fully vaccinated.”

Ms. Arthur (BIO) noted that there is a lot of interest in better understanding the various symptoms and effects of COVID-19 infection among young people. There is little clarity and people seem to think that it is milder than it actually is. ACIP has a good understanding of that, so perhaps a *Morbidity and Mortality Weekly Report* (*MMWR*) or other publication that clearly captures the various impacts of COVID-19 itself on children in the various age groups would help to make the case for why vaccine is so important in the unvaccinated group and address the misconception that it is generally always asymptomatic or mild disease, and there have been circumstances with some of these more important side effects that are showing up in this age group that could help parents make a better informed decision.

Dr. Whitley-Williams (NMA) agreed with many of the comments that had been stated. Certainly, recommending boosters in individuals 12-17 years of age would be just one step in changing the tide of this pandemic. She agreed that another step is to encourage people who are unvaccinated to become vaccinated, which will reduce the current risk to the pediatric population. They have been overwhelmed in the last couple of weeks as demonstrated by children who are unvaccinated from families who are unvaccinated, including mothers and newborns, presenting to hospitals. The newborns have not been terribly sick, but they are starting to see that phenomenon. In light of the noted racial and ethnic disparity in vaccine coverage and parental intent, she reminded the committee that there are still social barriers in communities in color. That is not an excuse, but it is a reality of the situation. However, she assure everyone that the National Medical Association (NMA) continues to educate its membership, who primarily are African American physicians; provide care for persons in communities of color; and educate the public and persons in communities of color.

Considering the perspective at the user end, patients and the public, Dr. Kim (OIDP) asked what the message was to the public specifically the parents of children 12-15 and 16-17 years of age who were still “on the fence” about the primary series or the booster series. ACIP has an opportunity, and perhaps even an obligation, to streamline, simplify, and make concise

recommendations—strong recommendations that promote the use of vaccines to control this pandemic—and get the message out to the folks who are currently not vaccinated to ensure that there is a better chance of immunizing the community in order to get a better handle on this pandemic.

Dr. Lee emphasized that ACIP's recommendations are only the first step of this process. Much rests with implementation and communication to ensure that there is access, acceptability, and equity. She expressed extreme gratitude to ACIP's liaison partners around the virtual table who have clearly supported the implementation efforts, recognizing how difficult it has been in this dynamic pandemic. It is necessary to continually re-evaluate and ACIP appreciates the partnerships and collegiality.

Vote: COVID-19 Booster Doses

Dr. Sara Oliver (CDC/NCIRD) presented the proposed recommendations for booster doses of COVID-19 vaccine, which reflected the deliberations as follows:

> "A single Pfizer-BioNTech COVID-19 vaccine booster dose is recommended for persons aged 12-17 years of age at least 5 months after the primary series under FDA's Emergency Use Authorization."

Motion/Vote: COVID-19 Vaccine Booster Doses in Persons 12-17 Years of Age

Dr. Poehling made a motion for ACIP to approve an interim recommendation stating that, "A single Pfizer-BioNTech COVID-19 vaccine booster dose is recommended for persons aged 12-17 years of age at least 5 months after the primary series under FDA's Emergency Use Authorization." Dr. Ault seconded the motion. No COIs were declared. The motion carried with 13 affirmative votes, 0 negative votes, and 0 abstentions. The disposition of the vote was as follows:

11 Favored:	Ault, Bahta, Brooks, Chen, Cineas, Daley, Kotton, Lee, Loehr, Long, McNally, Poehling, Sanchez
0 Opposed:	N/A
0 Abstained:	N/A
0 Absent:	N/A

Discussion Points

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 stressed that she is fine with children receiving boosters, but she wants the US to move forward with vaccinating all children so that they all can return to a normal life. It did not seem fair for individuals 12-17 years of age who have been vaccinated to risk myocarditis again for unknown benefit because their colleagues will not get vaccinated. It is incredibly important to continue to follow the safety of these vaccines, immediate risk of myocarditis after the third dose, and the incremental benefit of a third vaccine in this age group. She implored parents who had not yet vaccinated their child because they had questions to please talk to a healthcare provider and not use social media where it is so easy to take things out of context in an effort to

get new Twitter followers. None of that is going to help parents protect their children. Instead, she requested that parents please talk to a pediatrician or other healthcare provider and to let them know what questions they would like answered.

Dr. Kotton said she was glad that ACIP voted in favor of this recommendation. She suggested that during upcoming ACIP meetings, consideration be given to advancing the timeframe for booster doses for immunocompromised patients. She just heard that in her own hospital, that among all kidney transplant patients with COVID-19, 25% have occurred within the past 2 weeks. This is a state of emergency crisis for which they must act soon.

Dr. Long pointed out that she was not thinking of all children taking the risk of a booster dose to protect themselves because others have not taken the risk of their primary series. She has very low concern about vaccine-related myocarditis following a booster dose. It is far enough out that the antibody levels are not such that a super spike occurs a month out. The data have shown that there is much lower risk after a booster dose, so she did not consider in her deliberation that there were any tradeoffs of anybody being a soldier when others were not. Instead, she considered the potential benefit booster doses might have in the short-term for children, especially in terms of maintaining the life that they should be able to have.

Ms. McNally thanked CDC for all of the work that went into the discussion throughout the day and her colleagues for a very robust discussion. She has 2 children in this age group who she will be taking to get boosted. She encouraged all parents with questions to seek answers to their specific questions about this vaccine, because it is so important.

Ms. Stinchfield (NAPNAP) asked whether any colleagues were present from the FDA who might be able to comment on her earlier question regarding the timeline for approval of vaccine for children 0-4 years of age.

Dr. Fink (FDA) responded that clearly, the reported increases in pediatric hospitalizations overall, including children under the age of 5 years, are concerning. As they all heard from the press release issued by Pfizer, they have an ongoing study of primary series vaccination in children 6 months to 5 years of age. They did not meet the immunobridging success criteria with their analyses. The FDA is evaluating what options are possible for moving forward with evaluating the vaccine in this age group in order to figure out how to best make safe and effective vaccines available as quickly as possible.

Dr. Gurtman (Vaccine Clinical Research and Development Group, Pfizer) added that with regard to the discussion throughout the day and the disproportionate hospitalization in children, Pfizer has a civic priority to develop a vaccine and determine the right number of doses that are safe and effective. As Dr. Fink mentioned, they did not meet the inferiority criteria in children 2-5 years of age. The criteria were met for the younger age group, which is 6 months to 2 years of age. In view of all of the information discussed throughout the day, the data are becoming available on the effectiveness of 3 doses of the vaccine for those 16 years of age and older and those 12 years of age and older. It is becoming clear that this may be a 3-dose vaccine. Therefore, the study has been amended to give a third dose to anybody less than 5 years of age, at least 8 weeks after the last vaccination. In addition, they will be providing a third dose to those who are 5-12 years of age at least 6 months after the last vaccination. At present, Pfizer anticipates having immunogenicity data on children less than 5 years of age by late in the first quarter of 2022.

CERTIFICATION

Upon reviewing the foregoing version of the January 5, 2022 ACIP meeting minutes, Dr. Grace Lee, ACIP Chair, certified that to the best of her knowledge, they are accurate and complete. Her original, signed certification is on file with the Management Analysis and Services Office (MASO) of CDC.

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ACRONYMS USED IN THIS DOCUMENT

AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatrics
ACHA	American College Health Association
ACIP	Advisory Committee on Immunization Practices
ACOG	American College of Obstetricians and Gynecologists
ACP	American College of Physicians
AE	Adverse Event
AHIP	America's Health Insurance Plans
AI/AN	American Indian/Alaskan Native
AIM	Association of Immunization Managers
AIRA	American Immunization Registry Association
AMA	American Medical Association
AOA	American Osteopathic Association
APhA	American Pharmacists Association
AR	Adverse Reaction
ASTHO	Association of State and Territorial Health Officers
BLAs	Biologics License Applications
CBER	Center for Biologics Evaluation and Research
CDC	Centers for Disease Control and Prevention
CMS	Center for Medicare and Medicaid Services
COD	Cause of Death
COI	Conflict of Interest
CSTE	Council of State and Territorial Epidemiologists
CVD	Cardiovascular Disease
DFO	Designated Federal Official
DoD	Department of Defense
DSMB	Data Safety Monitoring Board
DVA	Department of Veterans Affairs
ECG/EKG	Electrocardiogram
ED	Emergency Department
EMR	Electronic Medical Record
ET	Eastern Time
EtR	Evidence to Recommendation
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
GMR	Geometric Mean Ratio
GMT	Geometric Mean Titers
GRADE	Grading of Recommendation Assessment, Development and Evaluation
HCP	Healthcare Personnel / Providers
HHS	(Department of) Health and Human Services
HMO	Health Maintenance Organization
HRSA	Health Resources and Services Administration
ICU	Intensive Care Unit
IDSA	Infectious Disease Society of America

IHS	Indian Health Service
J&J	Johnson & Johnson
KFF	Kaiser Family Foundation
MIS-C	Multisystem Inflammatory Syndrome in Children
MMWR	*Morbidity and Mortality Weekly Report*
NACCHO	National Association of County and City Health Officials
NACI	National Advisory Committee on Immunization Canada
NAPNAP	National Association of Pediatric Nurse Practitioners
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
NCHS	National Center of Health Statistics
NCIRD	National Center for Immunization and Respiratory Diseases
NFID	National Foundation for Infectious Diseases
NHSN	National Healthcare Safety Network
NIH	National Institutes of Health
NMA	National Medical Association
OIDP	Office of Infectious Disease Policy and HIV/AIDS
PCP	Primary Care Provider/Practitioner
PHAC	Public Health Agency Canada
PIDS	Pediatric Infectious Disease Society
RCA	Rapid Cycle Analysis
RCT	Randomized Controlled Trial
RN	Registered Nurse
RNA	Ribonucleic Acid
RR	Relative Risk
RVE	Relative Vaccine Efficacy
SAE	Serious Adverse Event
SAHM	Society for Adolescent Health and Medicine
SHEA	Society for Healthcare Epidemiology of America
SME	Subject Matter Expert
SVI	Social Vulnerability Index
TTS	Thrombotic Thrombocytopenia Syndrome
UK	United Kingdom
US	United States
USG	United States Government
VA	(US Department of) Veteran’s Affairs
VAERS	Vaccine Adverse Event Reporting System
VaST WG	Vaccine Safety Technical Work Group
VE	Vaccine Efficacy
VE	Vaccine Effectiveness
VRBPAC	Vaccine and Related Blood Products Advisory Committee
VSD	Vaccine Safety Datalink
WG	Work Group
WHO	World Health Organization