MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

APRIL 20, 2022
EXECUTIVE SUMMARY

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MEETING PURPOSE

The United States (US) Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) convened a meeting of the Advisory Committee on Immunization Practices (ACIP) on April 20, 2022. The meeting took place remotely via Zoom, teleconference, and live webcast. This document provides an Executive Summary of the meeting, which focused on updates on vaccine effectiveness (VE) and safety of a COVID-19 booster dose, Vaccine Safety Technical Subgroup (VaST) assessment, updates to the Evidence to Recommendations (EtR) Framework for COVID-19 vaccine booster doses in adults ≥50 years of age and immunocompromised persons, CDC guidance for a second COVID-19 booster dose, and a framework for future COVID-19 doses.

EXECUTIVE SUMMARY

Session Overview

Dr. Matthew F. Daley (WG Chair) reported that there were 80,476,479 total COVID-19 cases and 986,123 total deaths between January 23, 2020 – April 17, 2022. On March 29, 2022, FDA authorized a second booster dose of either the Pfizer-BioNTech or Moderna COVID-19 vaccine for older people and immunocompromised individuals. A second booster dose of the Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine may be administered to individuals 50 years of age and older at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine. A second booster dose of the Pfizer-BioNTech COVID-19 vaccine may be administered to individuals 12 years of age and older with certain kinds of immunocompromise at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine. A second booster dose of the Moderna COVID-19 vaccine may be administered to individuals 18 years of age and older with certain kinds of immunocompromise at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine.

On March 29, 2021, CDC issued Emergency Use Instructions (EUI) for the use of both mRNA COVID-19 vaccines stating that people ages 18–49 who received Janssen COVID-19 vaccine as both their primary series dose and booster dose may receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the first Janssen booster dose. The EUI allows CDC to permit emergency use of FDA-approved medical products. EUI are provided as fact sheets for healthcare providers and recipients and include information about such products' approved, licensed, or cleared conditions of use under circumstances that go beyond the scope of the approved labeling under the Emergency Use Authorization (EUA). Dr. Daley explained the difference between an EUA and an EUI and summarized the recommendations by primary series product and age among people who are not moderate to severely immunocompromised.

Between February-April 2022, the COVID-19 Vaccine WG has reviewed the following: VE data for COVID-19 vaccines in children ages 5-11 years, COVID-19 vaccine safety updates in children ages 5-11 years, survey data for intent to receive COVID-19 vaccines among children, safety and efficacy of Novavax COVID-19 vaccine, infection-induced and hybrid immunity to COVID-19, VE for booster doses, safety data for COVID-19 vaccine booster doses, policy discussions around booster doses, and the framework and data needs for future doses of COVID-19 vaccines.

Updates on VE of a COVID-19 Booster Dose

Ruth Link-Gelles, PhD, MPH (CDC/NCIRD) presented evidence on VE during Omicron in terms of the outcomes of infection, emergency department (ED)/urgent care (UC), and hospitalizations. Based on data from the Increasing Community Access to Testing (ICATT) Partnership and data from the United Kingdom (UK), VE looks different for recipients of J&J vaccine in that it is lower overall than regimens that include at least 1 mRNA dose. There is evidence of slight waning against infection for 3 mRNA doses by 2-4 months after the last dose. Early VE data from the UK show similar VE for the BA.1 and BA.2 sub-lineages of the Omicron variant. As seen previously with Delta for which there was higher VE for more severe outcomes, these data also show the clear benefit of a third dose over a second dose during Omicron, and the highest VE of 94% with 3 doses for critical illness and death up to a median 60 days of follow-up. VE remained high against hospitalization among non-immunocompromised individuals for 4 to 6 months after the booster dose. As previously observed, there was limited protection and faster waning with 2 doses of mRNA vaccines against infection. This assessment showed higher VE and less waning with 3 doses of mRNA vaccines for all outcomes among non-immunocompromised individuals. While it was not possible to estimate VE for all outcomes among immunocompromised individuals, a similar pattern was observed as with non-immunocompromised persons with higher VE for worst outcomes. However, immunocompromised individuals have lower VE than non-immunocompromised persons, which lead to the earlier additional dose recommendation.

Updates on Safety of COVID-19 Booster Dose

Nicola Klein, MD, PhD (KPNC) presented an update on the safety of a COVID-19 booster dose in which she described the preliminary findings of a Vaccine Safety Datalink (VSD) Rapid Cycle Analysis (RCA) chart review analysis of myocarditis and pericarditis following the first booster dose of COVID-19 vaccine. Pre-specified surveillance outcomes were assessed during weekly sequential monitoring after the first COVID-19 booster vaccination. The analyses assessed the risk of pre-specified outcomes within 1–21 days following a booster vaccination compared with boosted individuals who are within 22–42 days following the booster dose, adjusting for age, sex, race/ethnicity, VSD site, time since primary series, and calendar time. Weekly sequential analyses will continue through 2022, with a one-sided p-value threshold for signaling of 0.01. Due to the association of myocarditis/pericarditis with primary mRNA vaccination, myocarditis/pericarditis cases after the first booster also were chart-reviewed and adjudicated using the CDC case definitions.

In weekly surveillance, the only safety signal has been for myocarditis/pericarditis in the 21 days after a first booster dose. There have been no other safety signals in weekly monitoring of pre-specified outcomes. Myocarditis/pericarditis differed between persons 12–39 years of age and 40+ years of age. Most persons 12–39 years of age experienced myocarditis and myopericarditis with onset <7 days after the first booster. Those over 40+ years had mostly pericarditis and the cases were more spread out in the 3 weeks after the first booster dose. For persons 12–39 years of age, the rate ratios for myocarditis/pericarditis 0–7 days after the first booster dose were elevated. The rate per million first booster doses administered was not higher than after the primary series of 2 doses of mRNA COVID-19 vaccination. For persons aged 40 years and older, the rate ratios for myocarditis/pericarditis were elevated, but less so in the 0–7 and 0–21 days after the first booster dose compared with persons ages 12–39 years of age.

Tom Shimabukuro, MD, MPH, MBA (CDC/NCEZID) provided an update on adverse events (AEs), serious adverse events (SAEs), and myocarditis/pericarditis following a first booster dose from the Vaccine Adverse Event Reporting System (VAERS) and v-safe[SM] monitoring. After 93 million first doses of mRNA COVID-19 booster vaccinations in the United Sates (US) in VAERS monitoring, local and systemic reactions are most commonly reported following first booster dose. There have been 110 verified reports of myocarditis and 38 of pericarditis. Myocarditis reporting rates were highest among young males aged 12–29 years. Reporting rates for persons aged 12–29 years following the first booster exceeded background, but were lower compared to post-dose 2 rates with the primary series. Pericarditis reports were relatively rare and were distributed evenly among males and females and among varied age groups. More myocarditis (82%) than pericarditis (39%) case patients were hospitalized. Follow-up varies based on the timing of the report and the availability of healthcare records. Most hospitalized patients had recovered from symptoms at the time of follow-up. Among 729,720 v-safe[SM] participants aged ≥18 years who reported a booster dose, no unusual or unexpected findings or new safety concerns were identified.

In summary, active surveillance in VSD and passive surveillance in VAERS suggests an increased risk of myocarditis/pericarditis following the first mRNA COVID-19 booster vaccination. For myocarditis, the findings are consistent with those observed with primary series vaccination, but the risk appears to be lower following the first booster dose compared to Dose 2 of the primary series. Risk of myocarditis is highest in younger males with onset clustering within 0–7 days of the first booster vaccination. Pericarditis is less common, more evenly distributed between males and females, and more evenly distributed across age groups. Local and systemic reactogenicity and health impacts appear similar or attenuated for the first mRNA COVID-19 booster vaccination compared to Dose 2 of the primary series. Monitoring is ongoing.

VaST Assessment

H. Keipp Talbot, MD MPH (VaST Chair) presented the findings from VaST on its safety assessment of booster doses. As a reminder, the objectives of VaST are to: 1) review, evaluate, and interpret post-authorization/approval COVID-19 vaccination safety data; 2) serve as the central hub for technical subject matter expertise from federal agencies conducting post-authorization/approval safety monitoring; 3) advise on analyses, interpretation, and presentation of vaccine safety data; and 4) provide updates to the ACIP COVID-19 Vaccines WG and the entire ACIP on COVID-19 vaccine safety. VaST has convened 44 meetings to review vaccine safety data from December 21, 2020 to the present.

VaST has provided assessments on booster dose safety during 4 ACIP meetings. The presentation during this session included VaST's assessment of data from the VSD, v-safe[SM], VAERS, and Veteran's Affairs (VA). The findings from this assessment were that reactogenicity is similar to or lower than that seen after the primary series. Myocarditis risk appears lower than after Dose 2 from a primary series. Further work and analyses are needed to understand pericarditis risk. While available data do not suggest safety concerns beyond those previously identified, VaST will carefully monitor data on myocarditis and pericarditis after booster doses and will review further safety regarding booster doses as those data become available, collaborate with global vaccine safety colleagues on key issues, and provide updates to the ACIP COVID 19 Vaccines WG and the full ACIP during future meetings.

Updates to the EtR Framework: COVID-19 Vaccine Booster Doses in Adults Ages ≥50 years and Immunocompromised Individuals

Sara Oliver, MD, MSPH (CDC/NCIRD) provided updates to the EtR Framework on a second COVID-19 booster dose in adults ≥50 years of age and immunocompromised individuals. The policy question for this analysis was, "Do the balance of benefits and risks warrant an update to COVID-19 vaccine policy, allowing adults aged ≥50 years and persons with moderate to severe immunocompromise aged ≥12 years to receive a second booster of an mRNA COVID-19 vaccine?"

To summarize the public health problem, the current 7-day average of COVID-19 cases is approximately 4% of the peak seen during the Omicron surge. COVID-19 related hospitalization admissions and deaths also continue to decline from the recent winter Omicron surge. COVID-19 cases, hospitalizations, and deaths have been 2 to 20 times higher in unvaccinated individuals in recent months compared to vaccinated individuals. VE for 3 doses (e.g., primary series + booster) in immunocompetent older adults remains high, especially for more severe outcomes.

In summary of the benefits and harms, data from Israel demonstrate increased immune response after a fourth dose of COVID-19 vaccine. Higher rates of infection and severe illness have been observed in 3-dose recipients compared to 4-dose recipients. The greatest benefit from vaccination is achieved from receipt of the primary series and the first booster dose. Additional benefits may be achieved through receipt of a second booster dose. Known and possible benefits outweigh risks, including theoretical risks, in terms of individual factors that influence the magnitude of benefits for a second booster. Additional data will be monitored to inform theoretical risks.

To summarize values and acceptability based on surveys regarding booster doses, 60% to 80% of adult respondents stated that they may get a second booster dose. This varied by age and race/ethnicity. Approximately 20% of boosted adults ≥50 years of age stated that they would prefer a vaccine focused on new variants, while 10% stated that they either would get a vaccine now or in the Fall, but not both. Strong healthcare provider (HCP) recommendations were found to be influential in the decision to receive additional COVID-19 vaccine doses.

In terms of feasibility, among people who are fully vaccinated, approximately 52% of people 50-64 years of age and 67% of people ≥65 years of age have received a COVID-19 vaccine booster dose. At the time of authorization, approximately 30 million people were eligible at least 4 months after their previous dose (e.g., about 10 million eligible individuals 50-64 years of age and about 20 million eligible individuals ≥65 years of age). Based on the timing of recommendations, people with immunocompromised conditions would not be eligible for second booster (5 total doses) until May 13, 2022 at the earliest. The number of people reportedly getting vaccinated has nearly tripled since the authorization of second booster doses to an average of 447,000 per day in the week ending April 8, 2022 compared with 160,000 per day in the week ending March 29, 2022. As of April 19, 2022, approximately 1.1 million second COVID-19 vaccine booster doses have been given in adults 50–64 years of age and 3.2 million second booster doses have been given in adults ≥65 years of age since authorization.

Racial and ethnic minority groups are under-represented in the population ≥65 years of age, both overall and among those with COVID-19-associated hospitalizations. COVID-19-associated hospitalizations among adults 50-64 years of age are more consistent with the underlying population. Underlying medical conditions are more prevalent in racial and ethnic minority groups. A second booster recommendation for adults ≥50 years of age may prevent COVID-19 among persons from racial and ethnic minority groups and persons with underlying medical conditions.

The COVID-19 Vaccine WG's interpretation is that the primary goal of COVID-19 vaccines is prevention of severe disease. The secondary goals are maintaining workforce and healthcare capacity, reducing infection rates and risk of transmission, improving mental health with more social interactions, and prevention of post-COVID conditions. COVID-19 vaccines continue to offer high levels of protection against severe disease, especially for individuals who have received a booster dose. While vaccines are a critical aspect of protection against severe COVID-19, monoclonal antibodies and antivirals are also essential. Continued research into vaccines that may also have prolonged protection against SARS-CoV-2 infection (e.g., mucosal vaccines) is important.

In terms of adults ≥50 years of age, the risk of COVID-19 increase with age. A second booster (4 total doses) for older adults can help ensure that those at risk are protected from severe disease. Current VE data shows limited waning for immunocompetent adults after a third dose. Although there are lower COVID-19 case counts and hospitalization rates currently, there may be recommendations for additional COVID-19 vaccines in the future. The WG supported recommendation that adults ≥50 years of age may receive a second COVID-19 vaccine booster dose.

For immunocompromised individuals ≥12 years of age, the WG interpretation was that the earliest eligibility for the second booster (5th dose) would be mid-May based on the timing of previous recommendations. VE data are currently available from a third dose in the primary series, but there are no VE data from the currently recommended first booster (4th dose). There are lower COVID-19 case counts and hospitalization rates currently; however, immunocompromised individuals likely remain at higher risk for severe outcomes. Therefore, it is important that immunocompromised individuals receive all doses of the primary series including additional doses and a first booster dose. The WG supported the recommendation that immunocompromised individuals ≥12 years of age may receive a second COVID-19 vaccine booster dose.

Recommendations that individuals may receive a COVID-19 vaccine second booster reflect current conditions in the pandemic, including that there is wide availability of COVID-19 vaccines, high protection against severe disease from a primary series and first booster dose, low rates of COVID-19 cases and hospitalizations, and use of antivirals and monoclonal antibodies for SARS-CoV-2. As the second booster is already authorized and available, recommendations can be rapidly adjusted if the COVID-19 epidemiology changes in the future. The current recommendation allows for flexibility in terms of giving patients and providers access to this vaccine dose and the ability to decide based on individual factors and timing.

CDC Guidance for a Second COVID-19 Booster Dose

Elisha Hall, PhD, RD (CDC/NCIRD) discussed CDC's interim clinical guidance for a second COVID-19 booster dose, The Interim Clinical Considerations provide guidance that some populations may receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the first booster dose. This includes people ≥50 years of age, people ≥12 years of age who are moderately or severely immunocompromised, and people ages ≥18 years of age who received Janssen vaccine as both primary and booster doses. The second booster dose should be an mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech or Moderna). Janssen COVID-19 vaccine is not authorized for use as a second booster. Booster doses may be heterologous, but eligible people 12–17 years of age can receive only Pfizer-BioNTech COVID-19 vaccine. The dosage is the same as the first booster dose: Pfizer-BioNTech (gray or purple cap) 0.3 mL (30 mcg) or Moderna (red cap): 0.25 mL (50 mcg).

CDC recommends everyone get up-to-date (UTD) with their COVID-19 vaccinations. Being UTD means a person has received all recommended doses in their primary vaccine series and a booster dose when eligible. Receipt of a second booster dose is not necessary to be considered UTD at this time.

Eligible people who may consider getting a second booster dose as soon as possible include:

- People with certain underlying medical conditions that increase the risk of severe COVID-19 illness
- People who are moderately or severely immunocompromised
- People who live with someone who is immunocompromised, at increased risk for severe disease, or who cannot be vaccinated due to age or contraindication
- People at increased risk of exposure to SARS-CoV-2, such as through occupational, institutional, or other activities (e.g., travel or large gatherings)
- People living or working in an area where the COVID-19 community level is medium or high

Eligible people who may consider waiting to receive a second booster include:

- People with recent SARS-CoV-2 infection within the past 3 months
- People who may be hesitant about getting another recommended booster dose in the future, as a booster dose may be more important in the fall and/or if a variant-specific vaccine is needed

To reinforce what was mentioned earlier, 2 of the 3 groups are authorized under EUA, people 50 years of age and older and people 12 years of age and older who are moderately or severely immunocompromised. The third group, people 18 years of age and older who received 2 doses of Janssen vaccine, are authorized through EUI. Regardless of the regulatory mechanism, a second booster may be given to a person from any of these 3 groups. CDC will be creating educational materials for providers and the public to facilitate a conversation around the second booster dose based on individual circumstances.

Framework for Future COVID-19 Doses and Next Steps

Sara Oliver MD, MSPH (CDC/NCIRD) presented a framework for future doses of COVID-19 vaccine doses for each of the EtR domains. Regarding the public health problem, COVID-19 epidemiology has been unpredictable to date, without a defined seasonality. Winter surges have been noted in the last 2 years, but it likely will be difficult to predict the timing of future surges. With regard to benefits and harms, it will be important to define the goal of future doses of COVID-19 vaccines in terms of prevention of infection/transmission versus prevention of severe disease. Prevention of infection/transmission is time-limited and would require timing of vaccine roll-out just prior to any increase in COVID-19 cases. A focus on prevention of severe disease is more durable and would allow more flexibility in timing of future vaccine rollouts. Preserving the capacity of healthcare infrastructure in winter is likely to be important. Data may support different recommendations for general population and vulnerable populations. Vaccines that prompt a diverse immune response likely provide better protection against current and possible future SARS-CoV-2 variants. Considerations for diverse immune response from COVID-19 vaccines include the time between recommended doses of COVID-19 vaccines, possibly expanding vaccines to include additional SARS-CoV-2 variants, and possibly expanding to include different COVID-19 vaccine platforms (e.g., protein subunit vaccines).

Regarding feasibility, it is important to have COVID-19 vaccine policy that is simple. Policies that differ by type of vaccine for current and previous doses are difficult. For many vaccines, recommendations are not dependent on the type of vaccine received previously. Vaccines based on timing (e.g., annual boosters) may be easier to communicate than number (e.g., second booster, fourth dose, et cetera). For every COVID-19 vaccine dose recommended, uptake declines. It is important to ensure that acceptability and uptake are higher when the public health need for protection from a COVID-19 vaccine is more critical.

To summarize the WG's considerations, policy around future doses requires continued evaluation of COVID-19 epidemiology and VE, including the impact of both time and variants and the ability of doses to improve protection. Evolution of COVID-19 vaccines will be important as SARS-CoV-2 virus evolves. This may involve evolution of the strains included in the vaccines as well as the vaccine platform. Vaccine policy that is simple and easy to communicate and implement will be important to optimize uptake and should balance simplicity with need to provide optimal protection to vulnerable populations. Consideration must be given to the impact of each COVID-19 vaccine recommendation in terms of time and resources of pharmacies, providers, and public health staff; the effect on vaccine confidence and uptake; incremental balance of benefits and risks; and monitoring for any negative impact of repeated boosting on antibody titers.

Regarding next steps, FDA and CDC will continue to partner for future discussions. ACIP will continue to review additional data on COVID-19 epidemiology, genomic surveillance, and VE and manufacturer data on safety, immunogenicity, and possible efficacy of variant-specific vaccines. Discussions around feasibility, implementation, and balance of benefit and risks by age group and population will inform the timing and populations for future doses of COVID-19 vaccines.

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ACRONYMS USED IN THIS DOCUMENT

ACIP	Advisory Committee on Immunization Practices
AE	Adverse Event
CDC	Centers for Disease Control and Prevention
ED	Emergency Department
ET	Eastern Time
EtR	Evidence to Recommendation
EUA	Emergency Use Authorization
EUI	COVID-19 Vaccine Emergency Use Instructions
FDA	Food and Drug Administration
HCP	Healthcare Personnel / Providers
HCW	Healthcare Workers
HHS	(Department of) Health and Human Services
ICATT	Increasing Community Access to Testing Partnership
J&J	Johnson & Johnson
RCA	Rapid Cycle Analysis
SAE	Serious Adverse Event
UC	Urgent Care
UK	United Kingdom
US	United States
VA	(US Department of) Veteran's Affairs
VAERS	Vaccine Adverse Event Reporting System
VaST	Vaccine Safety Technical Subgroup
VE	Vaccine Efficacy
VE	Vaccine Effectiveness
VSD	Vaccine Safety Datalink
WG	Work Group