MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

JUNE 21-23, 2023
MEETING SUMMARY

CONTENTS

WEDNESDAY: JUNE 21, 2023

WELCOME AND INTRODUCTIONS

Call to Order/Roll Call

Dr. Grace Lee (ACIP Chair) called to order and presided over the June 21-23, 2023 Advisory Committee on Immunization Practices (ACIP) meeting. Dr. Lee conducted a roll call each day, which established that a quorum was present. A list of Members, *Ex Officios*, and Liaison Representatives is included in the appendixes at the end of this summary document. The following conflicts of interest (COIs) were identified:

- ❑ Dr. Camile Kotton is involved in a clinical trial for Takeda for an investigational antiviral agent for cytomegalovirus (CMV) that does not involve vaccine.

Announcements

Dr. Melinda Wharton (ACIP Executive Secretary, CDC) noted that copies of the slides for the meeting were available on the ACIP website and were made available through a ShareLink™ file for ACIP Voting, *Ex Officios*, and Liaisons Members. The ACIP is, at its heart, a public body. Engagement with the public and transparency in all of its processes are vital to the committee's work. She indicated that there would be 2 oral public comment sessions during this meeting, which were scheduled for 4:15 Eastern Time (ET) on June 21, 2023 and 4:50 pm on June 22, 2023 ET. To create a fair and more efficient process, individuals interested in making an oral comment were asked to submit a request online in advance of the meeting. Priority is given to these advance requests. If more people make requests than can be accommodated, a blind lottery is conducted to determine who the speakers will be. Speakers selected in the lottery for this meeting were notified in advance of the meeting. Members of the public also may submit written comments via https://www.regulations.gov using Docket Number ID CDC-2023-0035. Information on the written public comment process, including information on how to make a comment, can be found on the ACIP meeting 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 while serving on the committee, CDC may issue 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 those members are prohibited from participating in committee votes on issues related to those vaccines. 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. Applications are being solicited for applications and nominations of candidates to fill upcoming ACIP vacancies. Detailed instructions for submission of names of potential candidates to serve as ACIP members are now available on the ACIP website. The deadline for applications is August 1, 2023 for the 4-year terms beginning July 2024.

RESPIRATORY SYNCYTIAL VIRUS VACCINES: ADULT

Brief Summary

During the RSV session, Dr. Alejandra Gurtman (Pfizer) presented Pfizer data on season 2 safety and efficacy and on co-administration with influenza vaccine. Dr. Leonard Friedland (GSK) presented GSK season 2 safety and efficacy and co-administration with influenza vaccine. Dr. David Hutton (University of Michigan) presented updated cost-effectiveness of the Pfizer and GSK vaccines, known as the main CDC model. Dr. Ismael Ortega Sanchez (CDC/NCIRD) provided a comparison of cost-effectiveness results of the main CDC model and each manufacturer model (e.g., Pfizer and GSK). Dr. Michael Melgar (CDC/NCIRD) presented the updated EtR Framework including GRADE (Grading of Recommendation Assessment, Development and Evaluation) and clinical considerations for the Pfizer and GSK vaccines. The following language was proposed for votes:

- ❑ Vote #1: Adults 65 years of age and older are recommended to receive a single dose of RSV vaccine.
- ❑ Vote #2: Individual adults aged 60–64 years may receive a single dose of RSV vaccine, using shared clinical decision-making based on risk assessment.

Discussion Points for Clarification Prior to the Vote

Dr. Loehr made a motion to approve the first vote as stated, “Adults 65 years of age and older are recommended to receive a single dose of RSV vaccine.” Dr. Brooks seconded the motion.

Dr. Loehr made a motion to approve the second vote with a revision to state, “Individual adults aged 60–64 years may receive a single dose of RSV vaccine, using shared clinical decision-making. Dr. Poehling seconded the motion.

Dr. Sanchez made a motion to amend the first vote to “Adults 65 years and older may receive a single dose of RSV vaccine using shared clinical decision-making.” Dr. Long seconded the motion.

Dr. Kotton, as the WG Chair, reminded the ACIP members that the WG for people 65 years of age and over thought that there was moderate data for desirable anticipated effects, that the undesirable anticipated effects were low, and the majority opinion was that the WG favored the intervention. The WG spent many months, virtually every week in recent times, reviewing a large amount of data and research that went into the original proposed vote language. Although they were having an amazing, interesting, and vigorous conversation at this time, she suggested that the members contemplate that slides 46, 47, 48, and 49 reflected what the WG spent time doing rather than perhaps changing opinions now. She also emphasized that along with others, she had major concerns about cost, and thought the companies who make these vaccines are beholden to share cost with the ACIP. She personally found it upsetting that GSK virtually doubled the cost of vaccine in recent times and wondered what the future holds.

Following the public comments and prior to the vote, Dr. Wharton indicated that they heard back from their colleague at the Center for Medicare and Medicaid Services (CMS), Mary Beth Hansen, regarding questions the ACIP raised earlier who indicated that should the older adult RSV vaccine be recommended by ACIP, coverage would be through Part D for Medicare beneficiaries.

Dr. Leonard Friedland (GSK) clarified that the rationale for the price range reviewed during this session and for which the ACIP requested additional information on pricing, the price range reviewed reflected AREXVY's efficacy over 2 full RSV seasons, which resulted in better cost-effectiveness versus GSK's previously submitted analyses. The original price range was based on clinical data over 1 season only. To aid in the committee's decision-making, GSK could confirm that the price of its RSV vaccine would fall within a narrow range of $200 to $295. This reflects the totality of the GSK data reviewed earlier concluding that AREXVY provides durable efficacy for at least 2 full seasons in the 60 and over population, including in those with underlying comorbidities and across advancing age. This reinforces GSK's confidence in AREXVY's potential to make a significant public health impact. The price of AREXVY will be based on cost-effectiveness analyses to ensure efficient allocation of resources.

Donna Altenpohl (Pfizer) indicated that as was stated earlier in the day, to support the cost-effectiveness analyses as part of the US CDC's EtR framework, Pfizer provided CDC a price range of $180 to $270. Pfizer has been consistent with its price range since they first provided their cost-effectiveness analyses early this year. According to the CDC cost-effectiveness model shared during this session, even at the highest end of the Pfizer range of $270, the Pfizer RSV vaccine would have a cost per quality-adjusted life year (QALY) of under $180,000. This is not a guarantee, as Pfizer is in the midst of competitive price negotiations and has not set its list price.

Regarding a question that arose about reports of 2 possible cases of acute disseminated encephalomyelitis (ADEM) related to RSV vaccines, Dr. James Sejvar (CDC) said that it appeared that there was some equating of ADEM with Guillain-Barré Syndrome (GBS). He clarified that although both are inflammatory neurologic diseases, GBS and ADEM are fundamentally different diseases. Although they can see sporadic cases of ADEM in the setting of prior vaccination within the 42-day window, association of causality is sometimes hard to establish. The other point about the 2 cases in question, for the data presented about the RSV vaccines, these were preliminary diagnoses of ADEM without the diagnostic testing that neurologists would like to see to substantiate a diagnosis. Apparently, these 2 cases were based upon clinical observations only without substantiating neuroimaging or cerebrospinal fluid tests. It is difficult, if not impossible, to come to a definitive diagnosis of ADEM in the absence of confirmatory neuroimaging or cerebrospinal fluid (CSF) studies.

Dr. Lee reminded everyone that based on the rules of order, the ACIP would first vote on the amended Vote #1. If it passed, this would be the recommendation. If not, they would return to the original vote.

Vote #1: RSV Vaccines for Adults ≥65 Years of Age (Amendment)

Dr. Lee (ACIP Chair) showed the proposed vote language following the public comment period. The vote was combined with the RSV session for ease of reading:

> Adults 65 years of age and older may receive a single dose of RSV vaccine, using shared clinical decision-making.

Motion/Vote #1: RSV Vaccines for Adults ≥65 Years of Age (Amendment)

Dr. Poeling made a motion to approve the recommendation as stated, which Dr. Talbot seconded. No COIs were declared. The amended motion carried with 10 affirmative votes, 4 negative votes, and 0 abstentions. The disposition of the vote was as follows:

10 Favored: Bahta, Bell, Cineas, Daley, Lee, Loehr, Long, McNally, Poehling, Sanchez
4 Opposed: Brooks, Chen, Kotton, Lee, Talbot
0 Abstained: N/A

Vote #2: RSV Vaccines for Adults 60–65 Years of Age

Dr. Lee (ACIP Chair) showed the proposed vote language following the public comment period. The vote was combined with the RSV session for ease of reading:

> Individual adults aged 60–64 years may receive a single dose of RSV vaccine, using shared clinical decision-making based on risk assessment.

Motion/Vote #2: RSV Vaccines for Adults 60–65 Years of Age

Dr. Poeling made a motion to approve the recommendation as stated, which Dr. Talbot seconded. No COIs were declared. The motion carried with 14 affirmative votes, 0 negative votes, and 1 abstention. The disposition of the vote was as follows:

14 Favored: Bahta, Bell, Brooks, Chen, Cineas, Daley, Kotton, Lee, Loehr, Long, McNally, Poehling, Sanchez
0 Opposed: N/A
1 Abstained: Talbot N/A

POLIO VACCINE

Introduction

Oliver Brooks, MD, FAAP introduced the Polio Vaccination WG, which was formed approximately a year ago. The WG's Terms of Reference (TOR) are to consider the following policy topics under consideration:

1. Whether more specific guidance on adult vaccination, including use of adult booster doses, can be provided in the context of circulating poliovirus.

2. Whether adults who are immunocompromised should be recommended an additional adult booster of a polio-containing vaccine.

3. Whether fractional doses of IPV (fIPV), as prequalified by WHO, should meet polio vaccination requirements, including for people immigrating to the United States.

4. Consider criteria under which novel Oral Polio Vaccine type 2 (nOPV2) might be used in areas with outbreaks or persistent circulation of poliovirus.

During this session, the WG presented on TOR #1 for the WG's consideration, deliberation, and vote.

Recommendations for Adult Polio Vaccination

Sarah Kidd, MD, MPH (CDC/NCIRD) presented on behalf of the Polio Vaccination WG, indicating that the 2 main objectives for this session were to: 1) summarize the WG's deliberations on adult polio vaccination specifically for recommendations for unvaccinated and incompletely vaccinated adults and recommendations for booster doses of IPV; and 2) present the WG's proposed language for an ACIP vote. She presented the WG's deliberations using the ACIP EtR Framework with the standard domains of: Public Health Problem, Benefits & Harms, Values, Acceptability, Resource Use, Equity, and Feasibility. As background, the most recent ACIP statement on adult polio vaccination was published in 2000, and it contains some ambiguous and outdated language. The 2000 statement is as follows:

2000 Recommendations for Inactivated Polio Vaccine (IPV) Vaccination of Adults[1]

- *Vaccination is recommended for certain adults who are at greater risk for exposure to polioviruses than the general population*

- *Unvaccinated adults who are at increased risk of exposure should receive a primary vaccination series with IPV*

- *Adults who have had a primary series of oral polio vaccine (OPV) or IPV and who are at increased risk of exposure can receive another dose of IPV*

Multiple problems and questions about the recommendations came to light last year when a New York polo paralytic case was identified. First, the 2000 statement focuses almost exclusively on adults at increased risk of poliovirus exposure. It was unclear how increased risk should be defined in a setting of circulating vaccine-derived poliovirus (cVDPV) in the US. In addition, there was no clear guidance for unvaccinated adults who were not known to be at increased risk of exposure, and there was uncertainty about vaccinated adults and when and if a booster was advised. With that in mind, the first policy question the WG addressed was as follows:

Policy Question #1
Should completion of a primary polio vaccination series with IPV be recommended for unvaccinated and incompletely vaccinated adults in the US?

The population of interest was unvaccinated and incompletely vaccinated US adults (with tOPV or IPV) US adults aged ≥18 years. The intervention was completion of a primary vaccination series with IPV. The comparison group was no vaccination or partial series completion. The most important outcomes of interest were prevention of paralytic poliomyelitis; serologic

[1] https://www.cdc.gov/mmwr/preview/mmwrhtml/rr4905a1.htm

immunity to polioviruses Types 1, 2, and 3; SAEs following vaccination; and indirect effects (e.g., community transmission and impact on health systems). The current definition of fully vaccinated, an adult is conserved fully vaccinated if they have received the following:[2]

- ❑ A primary series of at least ≥3 doses of tOPV or IPV in any combination administered ≥4 weeks apart

AND

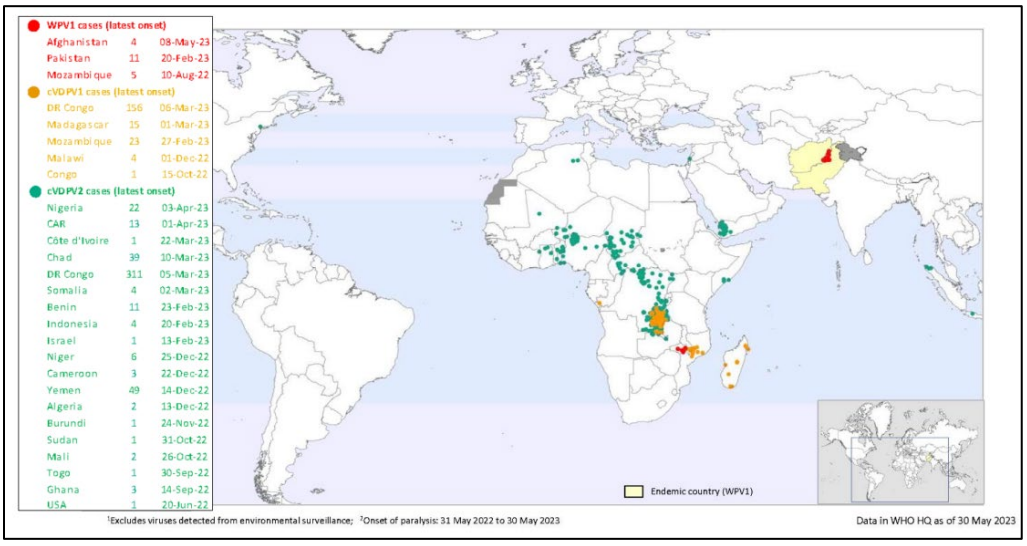
- ❑ The last dose in the series was given on or after the 4th birthday

AND

- ❑ The last dose in the series was given ≥6 months after the previous dose

In terms of the Public Health Domain, poliovirus infection can cause poliomyelitis and lifelong paralysis. Paralytic disease occurs in fewer than 1% of infections, with the exact frequency varying by serotype. Non-paralytic clinical illness occurs in approximately 25%, including 1%–5% with aseptic meningitis. Most (75%) poliovirus infections are asymptomatic. The incidence of paralytic polio decreased rapidly in the US after introduction of the Salk IPV in 1955, quickly followed by the Sabin OPV in 1961. The Sabin OPV vaccine was used for routine childhood immunization in the US for decades. In 1997, an enhanced-potency IPV was introduced as part of a sequential schedule with IPV followed by OPV. In 2000, the US moved to an IPV-only schedule, and IPV has been the only polio vaccine recommended in the US since that time.

Wild-type poliovirus Type 1 (WPV1) and cVDPV are still circulating in certain parts of the world. This map shows the distribution of the almost 700 paralytic polio cases that have been identified in the last 12 months (note that environmental detections from wastewater are not shown in this map:[3]



[2] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5830a3.htm
[3] https://polioeradication.org/polio-today/polio-now/

A case of paralytic polio caused by vaccine-derived poliovirus Type 2 (VDPV2) was confirmed in an unvaccinated young adult from Rockland County, New York in July last year. Genetic sequencing has indicated a linkage to polioviruses collected in wastewater in Israel, the UK, and Canada. Of note, Rockland County has reported overall low vaccine coverage for over 20 years. In Summer 2022, just 60% of children under age 2 had received 3 doses of IPV. Zip code level coverage was as low as 37% in some areas. Fortunately, no additional paralytic cases have been identified. Poliovirus related to the case was detected in wastewater in several other New York counties and New York City. Retrospective testing detected poliovirus in the area as early as April 2022, indicating circulating and asymptomatic infections in the area at least since that time. Related virus continued to consistently be detected in wastewater until the beginning of November of last year. Only 2 samples have been positive for poliovirus since November 1st, with the most recent being collected on February 22nd in Rockland County. Samples collected in the last 15 weeks all have been negative.

Looking at the pattern of wastewater detections in each affected county by week, there was just one paralytic polio case identified. But the presence of that case and the pattern of wastewater detections indicate that there were likely at least 1,000 to 2,000 mostly asymptomatic infections in the area. Circulating poliovirus poses a risk of paralytic polio to those who do not have immunity. In the US, most people are protected from paralytic polio because they have been vaccinated. National Salk IPV vaccination campaigns in the late 1950s targeted all persons up to 40 years of age. In terms National US Immunization Survey (USIS) data[4] for Salk IPV vaccination coverage by September 1961 by age and race, campaign coverage was highest among children 5—14 years of age in 1961. This would be birth years 1947—1956. Also of note, estimates of coverage were higher among whites than non-whites in all age groups. In comparison to children and adolescents, coverage was lower in adults ≥20 years of age. Not many adults ≥40 years of age were vaccinated in the campaigns.

After that USIS household survey, subsequent surveys focused on coverage among preschool-aged children.[5] It is important to note that data from 3 different national surveys for 3-dose polio vaccination coverage among children used different methodologies and have different limitations. The USIS was based on parental recall and is thought to underestimate actual coverage by as much as 20% when compared to actual vaccination records. In contrast, the National Immunization Survey (NIS) data, come from actual vaccination records. While coverage levels, especially in the 1970s and 1980s, might be cause for concern.

It is interesting to contrast those coverage data with serosurveys that indicate that a large majority of Americans have protective antibodies to poliovirus. In a National Health and Nutrition Examination Survey (NHANES) survey conducted in 2009—2010,[6] seroprevalence varied by poliovirus serotype but was high in all the age groups studied. Seroprevalence for Type 3 was consistently the lowest but remained high even in the oldest age group. Of note, there were some small differences in seropositivity by race ethnicity group, but none of these were statistically significant among the younger age groups. Among older adults, differences by race and ethnicity generally were not statistically significant with a few exceptions where Mexican-

[4] Morris, Public Health Reports 1964

[5] Sources: Simpson et al, AJPM 2001 Forty years and four surveys: How does our measuring measure up? – ScienceDirect. CDC, MMWR 2001 National, State, and Urban Area Vaccination Coverage Levels Among Children Aged 19--35 Months --- United States, 2000 (cdc.gov). CDC, MMWR 2006 National, State, and Urban Area Vaccination Coverage Among Children Aged 19--35 Months --- United States, 2005 (cdc.gov). CDC, MMWR 2011 National and State Vaccination Coverage Among Children Aged 19--35 Months --- United States, 2010 (cdc.gov). Hill et al, MMWR 2016 Vaccination Coverage Among Children Aged 19–35 Months — United States, 2015 | MMWR (cdc.gov). Hill et al, MMWR 2018 Vaccination Coverage Among Children Aged 19–35 Months — United States, 2017 | MMWR (cdc.gov).

[6] Wallace et al, BMC Public Health 2016

American adults had slightly lower seroprevalence of Type 2 antibodies compared to non-Hispanic Blacks in those 20–39 years of age and compared to non-Hispanic Whites in individuals 40–49 years of age. They also had lower levels of Type 3 antibodies compared to non-Hispanic Whites in individuals 40–49 years of age. Unfortunately, there are no seroprevalence data for older age groups by race and ethnicity.

To summarize the problem, the US remains at risk of poliovirus importations as long as there is ongoing transmission of poliovirus globally. Data indicate that most US adults have serologic immunity to polioviruses Type 1, 2, and 3. However, unvaccinated and incompletely vaccinated adults remain susceptible to paralytic polio if exposed to poliovirus. In response to the question for the EtR domain, the WG agreed that paralytic polio is a problem of public health importance.

Regarding the Benefits and Harms domain, the effectiveness of enhanced-potency IPV has been established. The presence of detectable neutralizing antibodies is an accepted correlative protection against paralytic disease. However, immunity against paralytic disease can be present even in the absence of detectable antibodies. Studies of serologic immunogenicity among infants and children show that 70% to 100% are seropositive after 2 IPV doses and 88% to 100% are seropositive after 3 doses. There are limited data on VE against paralytic polio, but estimates range from 36% to 89% for 1 dose and 89% to 98% for 2 doses. However, because this is a routine childhood vaccine, there is a paucity of data for previously unvaccinated adults who receive a primary series.[7]

In addition to serologic immunity, which protects against severe disease and paralysis, it also important to consider mucosal immunity and the potential effect of IPV on transmission. IPV does not decrease the proportion of people who will shed poliovirus when exposed. Multiple studies have shown that there is no significant difference between IPV and unvaccinated individuals in terms of the odds of shedding. However, several studies indicate that IPV may reduce the quantity and perhaps duration of shedding. Although a recent modeling study indicated no impact of IPV. There are fewer data on nasopharyngeal immunity following IPV, but data from 2 studies suggest that rates of nasopharyngeal shedding are similar and low at 0% to 4% among both OPV and IPV vaccinees.[8]

The safety of IPV also is well-established and IPV is well-tolerated. Local reactions at the injection site were reported during clinical trials and up to a third reported erythema, induration, or tenderness at the injection site. Combining IPV with other vaccines has not been associated with increased frequency or severity of reported AEs, compared to when the other vaccines are administered alone. No SAEs have been causally associated with the use of the current formulation of IPV.[9] In a paper that looked at 2000–2012 data from VAERS during a period when more than 250 million IPV doses were distributed during 2000-2012, 41,792 AEs were submitted for IPV-containing vaccines. Most of these were non-serious and 95% were among persons less than 7 years of age. Most events were associated with IPV that was co administered with other vaccines and standalone IPV accounted for just 0.5% of reports.[10] It is important to remember that VAERS is a passive reporting system cannot assess causal associations between vaccination and AEs. However, the lack of a signal in VAERS after decades of IPV use is reassuring.

[7] Vidor et al review, PIDJ 1997. Stoeckel et al, Rev Infect Dis 1984. CDC, MMWR 1988. John, Rev Med Virol 1993.
[8] Hird and Grassly meta-analysis, PLoS Pathogens 2012. Kok et al, Bulletin of WHO 1992. Onorato et al, JID 1991. Brouwer et al, J R Soc Interface 2022.
[9] : Sanofi Pasteur Package Insert - IPOL (fda.gov) . Vidor et al, PIDJ 1997. Murdin et al, Vaccine 1996. Wattigney et al, Pediatrics 2001. IOM 1994.
[10] Iqbal et al, Lancet ID 2015.

For the ErR domain of Benefits and Harms, the WG interpretation was that taking into account both the individual- and population-level effects, the desirable anticipated effects of completing a polio vaccination series are large, the undesirable anticipated effects are minimal, and the anticipated benefits of completing a primary polio vaccination series outweigh the anticipated harms.

In terms of the Values domain, an Annenberg Science Knowledge (ASK) survey[11] was conducted in October 2022 that included questions about polio, so there are some data about what the general public thinks about polio recently. In this survey, 59% of people said it would be "extremely bad" to have polio and an additional 26% said it would be "very bad" to have polio. This was a higher proportion of the population than for other diseases surveyed, including long-COVID, Mpox, or measles. There is evidence that the general public values polio prevention, at least at the individual level. In addition, 85% of respondents said that they were likely to recommend that an eligible person in their household get vaccinated with the polio vaccine, indicating relatively high acceptability of the vaccine among the general public. However, when thinking about the values of the specific population in question, unvaccinated or incompletely vaccinated adults, it is likely that this is a heterogeneous group that consists of persons whose family chose for them to not be vaccinated as children and persons who missed opportunities to be vaccinated as children. There is a lack of data on how these populations currently perceive their risk of paralytic polio and how they perceive the anticipated positive versus negative effects of polio vaccination. Additional acceptability considerations include the pros that the context of global polio eradication efforts and the prevention of paralytic polio have been a public health priority for decades. In practice, there currently are many competing priorities for clinicians and local public health departments. The cons are competing priorities for clinicians and local public health departments and uncertainty about eligibility for vaccination and the true level of risk to adults in the US also could undermine acceptability.

The WG thought that whether the target population of unvaccinated or incompletely vaccinated adults feel that the described effects of vaccination are large relative to the undesirable effects likely varies because of the heterogeneity of this group. The WG also felt that there is probably important uncertainty or variability in the values of the target population. In contrast, for acceptability of key stakeholders overall, the WG felt that providing a primary series to unvaccinated or incompletely vaccinated adult was probably acceptable to key stakeholders.

Moving to the Feasibility domain, there currently is just one US-licensed manufacturer of standalone IPV (e.g., Sanofi). There are 3 US-licensed manufacturers of combination vaccines that include IPV (e.g., Sanofi, Merck, GSK). However, these combination vaccines are currently not indicated for adults. The potential demand for IPV is difficult to quantify. There are no data on the number of adults who know they are unvaccinated or incompletely vaccinated, so it is difficult to quantify potential demand. In practice, it is possible to learn from New York's experience last summer. New York State and New York City did not experience any significant IPV supply issues despite identification of a polio case, persistent wastewater detections in the area, national media attention and calls, and a concerted effort by the health department to vaccinate unvaccinated persons, including adults.

[11] https://www.annenbergpublicpolicycenter.org/what-u-s-adults-know-and-believe-about-polio-and-the-bivalent-covid-booster/

Other resource and feasibility considerations include issues with access. Adult medicine offices typically do not stock IPV, so access to vaccination sites that do stock IPV could be a barrier to implementation. Also, there are concerns about the potential effects on health systems and their vaccine screening and patient recall algorithms. However, the WG felt that these concerns could be mitigated with clear guidance for who is eligible for vaccination with these recommendations. The WG talked at length about the feasibility of implementing risk-based recommendations, particularly if risk of exposure in the population changes over time. Overall, the WG felt that vaccination of adults who are known or suspected to be unvaccinated or incompletely vaccinated was probably or was a reasonable and efficient allocation of resources. They also felt that it was probably feasible to implement.

For the Equity domain, there are different rates of childhood vaccination and poliovirus immunity in different communities. Having an opportunity to receive catch-up polio vaccination as an adult likely increases equity. There are no known differences in VE among immunocompetent persons in the US setting. Assuring equitable access to vaccination sites with IPV will be an important consideration for implementation. Overall, the WG felt that providing polio vaccination for adults known or suspected to be unvaccinated or incompletely vaccinated probably would increase equity.

For the overall balance of consequences, taking into account all of the EtR domains just presented, the WG considered 2 different populations of unvaccinated adults. For unvaccinated and incompletely vaccinated adults known to be at increased risk of poliovirus exposure, the WG's judgment was that the desirable consequences clearly outweigh undesirable consequences in both settings. For unvaccinated and incompletely vaccinated adults who are not specifically known to be at increased risk of poliovirus exposure, the WG's judgement was that desirable consequences probably outweigh undesirable consequences in most settings.

Most of the WG's deliberations focused on whether the recommendations for unvaccinated adults should be a risk-based recommendation or a uniform recommendation for all unvaccinated adults. Currently, situations that are considered to put adults at increased risk of poliovirus exposure include international travelers, laboratory and healthcare workers, and healthcare workers or other caregivers. In addition, unvaccinated or incompletely vaccinated adults whose children will be receiving an OPV and unvaccinated adults or incompletely vaccinated adults who are living or working in a community where poliovirus is circulating are considered to be at increased risk of exposure and vaccine is recommended. It became clear to the WG that most of these situations pose risk at the individual level and there would be an opportunity to anticipate the risk and vaccinate prior to the potential exposure. A situation for unvaccinated and incompletely vaccinated adults in a community where poliovirus is circulating was different. The situation affects an entire population, and the community already is at increased risk at the time the risk is recognized. This means there potentially would be missed opportunities for vaccination prior to exposure if the recommendation remains solely a risk-based recommendation.

Additional challenges with the current risk-based recommendation came to light in 2022 when CDC, New York City, and state health departments received numerous questions about which adults were at increased risk of exposure. For instance, in which of these counties with wastewater detections or adjacent to wastewater detections are unvaccinated adults considered at increased risk of exposure? Are counties with a single wastewater detection of poliovirus considered to be at increased risk of exposure? When are unvaccinated adults in these counties no longer at increased risk of exposure? Are unvaccinated adults traveling to these counties at increased risk of exposure? As wastewater surveillance becomes more common, it is possible

that other jurisdictions might experience sporadic detections of poliovirus in their wastewater. These are the types of challenges that arise when trying to implement a risk-based recommendation.

With these factors in mind, the pros of a uniform recommendation are that it allows unvaccinated adults and their healthcare providers to take advantage of opportunities to get vaccinated before they are at increased risk of exposure. It also brings adult polio vaccination policy closer in line with other routine childhood vaccines such as MMR and varicella vaccines. It is a less complicated policy to communicate, understand, and implement in that the recommendation does not change based on the latest wastewater data. The cons are that most adults in the US still have a low risk of poliovirus exposure and paralytic polio and most adults received their primary polio vaccination series as children. Another other con is that demand for IPV potentially could exceed supply, particularly if a large number of adults without documentation of polio vaccination status were to assume that they were not vaccinated. However, the WG felt that this issue could be mitigated by providing guidance for this group in the clinical considerations.

Ultimately, the majority of the WG supported a uniform recommendation. However, a substantial minority favored the current risk-based recommendation with the addition of language specifically addressing unvaccinated adults who are not known to be at increased risk of exposure. The proposed recommendation language and important Clinical Considerations follow:

Proposed Language for Policy Question #1
Adults who are known or suspected to be unvaccinated or incompletely vaccinated against polio should complete a primary vaccination series with IPV.

Important Context to Be Included in Clinical Considerations
In general, unless there are specific reasons to believe they were not vaccinated, most adults who were born and raised in the United States can assume they were vaccinated against polio as children. Polio vaccination has been part of the routine childhood immunization schedule for decades and is still part of the routine childhood immunization schedule. Adults who received any childhood vaccines almost certainly were vaccinated for polio.

The second policy question addressed by the WG was as follows:

Policy Question #2
Should a booster IPV dose be recommended for adults at increased risk of poliovirus exposure who have previously completed a primary polio vaccination series?

The specific population being considered was US adults ≥18 years if age who are at increased risk of poliovirus exposure who have also completed a primary polio vaccination series with trivalent OPV, IPV, or a combination of both. The intervention was a booster dose of IPV and the comparison group was adults who competed a primary series, but did not receive a booster dose. Again, the main outcomes of interest were: prevention of paralytic polio; serologic immunity to poliovirus Types 1, 2, and 3; SAEs following vaccination; and indirect effects (e.g., community transmission and impact on health systems. The 2000 booster statement follows:[12]

[12] CDC MMWR 1977; CDC MMWR 1986

2000 Statement

Adults who have had a primary series of OPV or IPV and who are at increased risk [of exposure to poliovirus] can receive another dose of IPV. Available data do not indicate the need for more than a single lifetime booster dose with IPV for adults.

In terms of the rationale, this has been a long-standing recommendation since tOPV was used in routine immunization. However, the actual need for a supplementary dose has not been established. It has been thought that "there is value in assuring protection against infection with wild polioviruses when exposure can reasonably be expected." (1977 ACIP Statement). Of note, there were at least 2 reported cases of paralytic polio in adult travelers who had completed a primary series with Salk IPV and/or tOPV. However, further details on these cases are not available and it is unknown whether a booster dose would have prevented these cases.
The 2000 guidance was complicated in 2014 when CDC issued interim guidance in response to new WHO Polio International Health Regulations (IHR) Emergency Committee Temporary Recommendations. The WHO recommendations were for travelers who were departing countries with poliovirus circulation in order to prevent exportation. They applied to residents and travelers who were staying in the country for more than 4 weeks. If implemented by a country, proof of polio vaccination (IPV or tOPV) within the last 12 months could be required prior to leaving the country. This recommendation or a similar recommendation is still included in the most recent polio IHR statement. In response to this new WHO recommendation in 2014, which differed from ACIP recommendations, CDC published interim guidance in 2014 that stated:[13]

> "Adults who have completed a routine series of polio vaccine are considered to have lifelong immunity to poliovirus but data are lacking. As a precaution, persons aged ≥18 years who are traveling to areas where there has been WPV circulation in the last 12 months and who have received a routine series with either IPV or OPV in childhood should receive another dose of IPV before departure. For adults, available data do not indicate the need for more than a single lifetime booster dose with IPV."

It is unclear whether previously vaccinated adults need an IPV booster for protection. Results from the NHANES serosurvey showed that seroprevalence of neutralizing antibodies were high for all 3 serotypes and in all age groups studied.[14] There are no data on the comparative VE of a primary series plus booster compared to a primary series alone, but serologic studies in adults with heterogeneous pre-booster vaccination histories and heterogeneous seropositivity have shown that 98% to 100% are seropositive 1 month after receiving an IPV-containing booster. One study also followed up trial participants 10 years later and 98% to 100% were still seropositive at that time.[15] In terms of the safety of IPV, combining IPV with other vaccines has not been associated with increased frequency or severity of reported adverse reactions compared to when other vaccines are administered alone, and no SAEs have been causally associated with the current formulation of IPV.[16]

[13] Wallace MMWR 2014; Statement of the thirty-fifth Polio IHR Emergency Committee (who.int)
[14] Wallace et al, BMC Public Health 2016
[15] Sources: Broderick et al, Vaccine 2015; Domenicus et al, Vaccine 2014; Fukushima et al, Vaccines 2022; Grimprel et al, Vaccine 2005; Kovac et al, Vaccine 2015; Larnaudie et al, Human Vaccines 2010; Zimmermann et al, Vaccine 2013.
[16] Sources: Sanofi Pasteur Package Insert - IPOL (fda.gov) . Vidor et al, PIDJ 1997. Murdin et al, Vaccine 1996. Wattigney et al, Pediatrics 2001. IOM 1994.

For the EtR domain of Benefits and Harms, the WG determined that for adults at increased risk of exposure, the desirable anticipated effects of receiving an IPV booster were small to moderate, the undesirable effects were minimal, and the anticipated benefits outweighed the anticipated harms.

Considering target population values, the results of that ASK survey conducted in 2022 showed the majority of adults surveyed thought that having polio would be “extremely bad” or “very bad” and that 85% said they were likely to recommend that someone in their household get vaccinated against polio if they were eligible.

In terms of the Value domain, the WG thought that the target population, meaning previously vaccinated adults who were at increased risk of exposure, probably felt that the desirable effects of a booster were large compared to the undesirable effects. However, this was split with a significant portion of the WG also saying that they did not know based on the limited data available. The WG thought there probably was not important uncertainty or variability in terms of target population values.

When considering acceptability, feasibility, and resources for IPV boosters, the WG noted that the current recommendation that adults who have had a primary series of OPV or IPV and who are at increased risk of exposure to poliovirus can receive another dose of IPV, that this recommendation is long-standing, and it is generally considered accepted and feasible. However, if the at increased risk of exposure group were to be expanded, for instance to include previously vaccinated adults in certain US areas with poliovirus circulation, feasibility might be affected in the future. Again, the experience of New York State and New York City in 2022 is helpful in that even in the context of a polio case and media attention, IPV supply was not a significant issue.

The WG agreed that providing a booster IPV dose to adults at increased risk of exposure “probably” is or “is” acceptable to key stakeholders, “probably” is a reasonable and efficient allocation of resources, and “probably” or “is” feasible to implement.

To address the Equity EtR domain, there are no known differences in response to a primary series or need for a booster by socioeconomic group in the US setting. No groups or settings are known to be disadvantaged by the current recommendation. However, the WG thought that there is a potential for increased equity by boosting immunity in persons at increased risk of exposure, especially persons with potential occupational exposures to poliovirus. On that basis, the WG thought that boosters for those at increased risk of exposure “probably” would result in increased equity.

For the overall WG judgment, taking into account all of the EtR domains, the WG thought the desirable consequences of an IPV booster probably outweigh the undesirable consequences in most settings for previously vaccinated adults who are at increased risk of poliovirus exposure. The majority of the WG agreed with the current ACIP recommendation for adult boosters and recommended a vote to reaffirm this language. This recommendation is risk-based and based on shared clinical decision-making, and the proposed language includes some slight evidence to modernize the language compared to the 2000 statement.

Proposed Language for Policy Question #1
Adults who have received a primary series of tIPV or OPV in any combination and who are at increased risk of poliovirus exposure may receive another dose of IPV. Available data do not indicate the need for more than a single lifetime booster dose with IPV for adults.

Clinical Considerations
Situations that put adults at increased risk of poliovirus exposure include:

- ❑ **Travelers** who are going to countries where polio is epidemic or endemic (For additional information, see Polio: For Travelers).
- ❑ **Laboratory and healthcare workers** who handle specimens that might contain polioviruses.
- ❑ **Healthcare workers or other caregivers** who have close contact with a person who could be infected with poliovirus.

Vote #1: Polio Vaccination Unvaccinated and Incompletely Vaccinated Adults

Sarah Kidd, MD, MPH (CDC/NCIRD) displayed and read the proposed vote language following the public comment period. The vote was combined with the Polio Vaccine session for ease of reading:

> Adults (aged ≥18 years) who are known or suspected to be unvaccinated or incompletely vaccinated against polio should complete a primary vaccination series with IPV.
>
> *Important Context to Be Included in Clinical Considerations:*
> *In general, unless there are specific reasons to believe they were not vaccinated, most adults who were born and raised in the United States can assume they were vaccinated against polio as children. Polio vaccination has been part of the routine childhood immunization schedule for decades and is still part of the routine childhood immunization schedule. Adults who received any childhood vaccines almost certainly were vaccinated for polio.*

Motion/Vote #1: Adult Polio Vaccination

Dr. Poeling made a motion to approve the recommendation as stated, which Dr. Talbot seconded. No COIs were declared. The motion carried with 14 affirmative votes, 0 negative votes, and 0 abstentions. The disposition of the vote was as follows:

14 Favored: Bahta, Bell, Brooks, Chen, Cineas, Daley, Kotton, Lee, Loehr, Long, McNally, Poehling, Sanchez, Talbot
0 Opposed: N/A
0 Abstained: N/A

Vote #2: Polio Vaccination Unvaccinated and Incompletely Vaccinated Adults

Sarah Kidd, MD, MPH (CDC/NCIRD) displayed and read the proposed vote language following the public comment period. The vote was combined with the Polio Vaccine session for ease of reading:

> Adults who have received a primary series of tIPV or OPV in any combination and who are at increased risk of poliovirus exposure may receive another dose of IPV. Available data do not indicate the need for more than a single lifetime booster dose with IPV for adults.

Motion/Vote #2: Adult Polio Vaccination

Dr. Poeling made a motion to approve the recommendation as stated, which Dr. Cineas seconded. No COIs were declared. The motion carried with 14 affirmative votes, 0 negative votes, and 0 abstentions. The disposition of the vote was as follows:

14 Favored: Bahta, Bell, Brooks, Chen, Cineas, Daley, Kotton, Lee, Loehr, Long, McNally, Poehling, Sanchez, Talbot
0 Opposed: N/A
0 Abstained: N/A

INFLUENZA VACCINE

Introduction

H. Keipp Talbot, MD, MPH (ACIP, WG Chair) reported that recent WG activities have included preparation of the proposed 2023-2024 Influenza Statement and discussion of the safety of influenza vaccination of persons with egg allergy. She indicated that this session would include presentations focused on influenza vaccination of persons with egg allergy, including: 1) Background, WG Considerations, and an EtR Framework Discussion; and 2) Proposed recommendations for the 2023-24 influenza season.

WG Considerations and Proposed Recommendations

Lisa Grohskopf MD, MPH (CDC/NCIRD) presented the EtR discussion and WG considerations for influenza vaccination of persons with egg allergy, particularly those with a history of severe allergic reaction to egg. Beginning with some background, egg allergy is a relatively common food allergy affecting approximately 1% to 3% of children by 3 years of age.[17] It resolves for many during later childhood and adolescence. In one study, 68% have developed a tolerance by 16 years of age.[18] Reactions range from mild to life-threatening. Diagnosis is generally done by a clear history of immediate allergic reactions to egg or egg-containing foods, as well as skin prick testing (SPT) or estimation of egg-specific IgE levels.[19] Of the 9 influenza vaccines that are currently available in the US, 7 are produced through the propagation of viruses in

[17] Eggesbo M et al. Allergy 2001;56(5):403-411; and Erlewyn-Lajeunesse M et al. BMJ 2009;339:b3680
[18] Savage JH et al. J Allergy Clin Immunol 2007;120(6):1413-7
[19] Eggesbo M et al. Allergy 2001;56(5):403-411

embryonated eggs. These vaccines can and generally do contain residual amounts of egg proteins (e.g., ovalbumin). For 5 of the 7 egg-based vaccines, the egg ovalbumin content is listed in the package insert and is generally low, under about 1 mcg/dose. For 2 of the 7 egg-based vaccines, ovalbumin is not listed. There are 2 egg-free vaccines, Flucelvax Quadrivalent, which is a cell culture-based inactivated vaccine (ccIIV4), and Flublok Quadrivalent. While these 2 vaccines are considered egg-free, only Flucelvax Quadrivalent is approved for children <18 years of age.

ACIP currently recommends,[20] and has for a number of years, that all persons with egg allergies should receive influenza vaccine and that it is not necessary to receive an egg-free vaccine. Any influenza vaccine that is otherwise appropriate for the person's age and health status can be used (i.e., any IIV4, RIV4, or LAIV4). For those who have a history of severe allergic reaction to egg, and for the purposes of the ACIP guidance, this is defined as follows:

> "If a vaccine other than ccIIV4 or RIV4 is used, the selected vaccine should be administered in an inpatient or outpatient medical setting, including but not necessarily limited to hospitals, clinics, health departments, and physician offices. Vaccine administration should be supervised by a health care provider who is able to recognize and manage severe allergic reactions."

No specific post-vaccination observation period is recommended. The primary focus of this session concerned the language pertaining to severe allergic reaction in terms of whether this additional recommendation no longer needs to be made for people with severe egg allergy. Some of the reasoning behind this has to do with guidance from other professional organizations. The recommendations of the Joint Task Force (JTF) of the American Academy of Asthma, Allergy & Immunology and the American College of Asthma, Allergy & Immunology (Joint Task Force AAAAI/ACAAI) differ from the ACIP and American Academy of Pediatrics (AAP) recommendations. Since the 2016-2017 season, AAP has recommended no additional measures for persons with egg allergy.[21] The AAP 2022-2023 Influenza Prevention and Control Guidance states that "Children with egg allergy can receive any influenza vaccine without any additional precautions beyond those recommended for all vaccines."[22] The Technical Report that accompanies the recommendations indicates that measures such as the use of specific vaccines, observation periods, or restricting vaccination to specific medical settings and screening for egg allergy are not warranted and constitute a barrier to vaccination.[23] The AAAAI/ACAAI similarly state that, "No special precautions beyond those recommended for the administration of any vaccine to any patient are necessary for administration of influenza vaccine to egg-allergic individuals."[24]

Severe allergic reactions to vaccines overall are uncommon and anaphylaxis is rare, but given their potential seriousness, preparation for such reactions is recommended when administering any vaccine to any recipient. The *General Best Practices Guidelines for Immunization* in the chapter entitled "Managing Adverse Reactions" notes that allergic reactions are uncommon, and anaphylaxis following vaccines is rare, but also notes that vaccination settings should be prepared for potential serious reactions, noting that epinephrine and equipment for managing

[20] CDC/ACIP. MMWR Recomm Rep 2022;71(No. RR-1):1–28
[21] Recommendations for Prevention and Control of Influenza in Children, 2016–2017 | Pediatrics | American Academy of Pediatrics (aap.org)
[22] Recommendations for Prevention and Control of Influenza in Children, 2022–2023 | Pediatrics | American Academy of Pediatrics (aap.org)
[23] AAP. Technical Report for the 2022-23 Recommendations for the Prevention and Control of Influenza in Children, 2022-23
[24] Greenhawt M et al. Ann Allergy Asthma Immunol 2018;120:49-52

airways should be available for immediate use.[25] As a last piece of background, there are several past approaches to influenza vaccination of persons with egg allergy that are not currently recommended, including the following:

- ❑ Vaccine skin testing prior to vaccination:[26]
  - Skin prick and/or intradermal testing with dilution of vaccine
  - If positive, vaccination deferred or administered via alternative dosing protocol

- ❑ Graded administration of vaccine:[27]
  - Incrementally increasing volumes, often in 5 to 6 steps, sometimes with dilutions in early steps
  - 0.05 mL of 1:100 dilution→0.05 mL of 1:10 dilution→0.05 mL→0.1 mL→ 0.15 mL→0.2 mL, with observation periods after each dose (e.g., 15 minutes)
  - In the literature, these also are referred to "desensitization protocols"

- ❑ Split dosing of vaccine:[28]
  - Most commonly 10% of dose volume→observation period→remaining 90% of dose volume, often with additional observation after final dose.

The policy question the WG addressed for this analysis regarded whether to no longer recommend additional safety measures for persons with egg allergy of any severity, beyond what is recommended for any other persons presenting for influenza vaccination. In the discussion that follows, the proposed intervention was to no longer make the recommendation regarding vaccination setting for those with a history of severe allergic reaction to egg. With that background in mind, Dr. Grohskopf summarized the WG's discussion of the EtR Framework.

Beginning with the Public Health Importance domain regarding whether vaccination of egg-allergic persons is an issue of public health importance, influenza vaccination is important and recommended for all persons 6 months and older. Come individuals are at increased risk of severe illness due to influenza and some egg-allergic individuals might fall into this category. For example, egg allergy is more common in younger age groups, sometimes resolves as children get older, and frequently co-exists with asthma. In one cross-sectional survey of 38,408 children,[29] asthma prevalence was higher among children with egg allergy (46.5%) than with the other 8 most common food allergies (33.2%). Younger children and people with asthma are groups that are recognized as being at increased risk for severe influenza illness and are populations for which barriers to vaccination might be more consequential.

In the WG discussion, a number of points were raised related primarily to potential increased risks for some people with egg allergy in terms of how consequential the potential barriers may be or if they even exist. On the one hand, current recommendations might be a real or perceived barrier to vaccination (e.g., by promoting hesitancy based on safety concerns, or providing a reason to decline vaccination). This could be detrimental to egg allergy persons who are at increased risk of severe influenza. No data specifically examining or confirming that the current recommendations as they stand are an actual barrier, but the existence of a real or perceived barrier is plausible. Conversely, some WG members raised the point that current recommendations might be less of a barrier now than they were previously since the cell

[25] Kroger AT et al. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
[26] Bierman CW et al. J Infect Dis 1977;136:S652-S655; and Miller JR et al. J Allergy Clin Immunol 1983;71:568-173
[27] Murphy KR et al. J Pediatr 1985;106(6):931-933
[28] James JM et al. J Pediatr 1998;133:624-628
[29] Samady W, Warren C, Wang J, et al. Egg allergy in US children. J Allergy Clin Immunol Pract. 2020;8(9):3066-73

culture-based egg-free vaccine, Flucelvax Quadrivalent, is currently approved for individuals ≥6 months of age. Until relatively recently, it was only for 4 years and older. Now it goes to the youngest age group that probably has the highest prevalence of egg allergy. However, it is important to consider that there is only 2 vaccine that is egg-free that is licensed for children <18 years of age compared with 4 other vaccines that are egg-based. In polling on this question, 95% of the WG responded either “yes” or “probably yes” vaccination of egg-allergic individuals is an issue of public health importance, with only 6% of the total responding “probably no.”

For the second domain of Benefits and Harms, a systematic literature view was conducted, and a GRADE analysis was performed. There was somewhat of a disconnect because it seemed unlikely that data would be found directly addressing the question of whether having the additional recommendation was consequential. Therefore, the review focused on the safety of influenza vaccine in this population, addressing the question, “Does the available evidence concerning the safety of influenza vaccine in persons with a history of egg allergy favor routine vaccination without additional safety measures, regardless of severity of previous allergic reaction to egg?” Because all egg allergy individuals are currently recommended to get influenza vaccine and they were are not looking at the question of whether to vaccinate or whether to choose specific vaccines, this review focused solely on harms and did not include review of efficacy or effectiveness data.

In terms of the PICO question, the population was persons of any age with a history of allergy to eggs, or who had an allergic reaction to influenza vaccine believed to be secondary to egg allergy. The interventions included any influenza vaccine. The comparators of interest included placebo, non-egg-based influenza vaccine, non-influenza control vaccines, no vaccine, or no comparator. Within 4 hours of vaccination, the critical outcomes of death, anaphylaxis meeting Brighton Criteria Levels 1—3, anaphylaxis otherwise classified, and allergic symptoms requiring hospitalization. The 2 anaphylaxis outcomes were combined. Important outcomes included allergic reaction symptoms requiring outpatient or emergency department (ED) medical attention. This category included instances that were described as being treated with medications, without explicit mention of whether there was outpatient or ED care. The second important outcome was allergic reaction including cardiovascular symptoms, respiratory symptoms, angioedema, or generalized urticaria. The basis for inclusion of this set of reactions was that they fall short of anaphylaxis, but nonetheless might be considered worrisome.

The systematic review yielded a total of 47 reports describing 52 studies. There was only 1 randomized study, which was a comparison of full-dose with the 10%/90% split dosing of vaccine. There was 1 VAERS report summary. The remainder were retrospective and prospective cohort studies and case series and 2 involved only recombinant vaccine, which is egg-free. Of interest none of the studies included a relevant comparison group (e.g., an alternative intervention such as no intervention or a different vaccine, an egg-free vaccine, or no vaccine). In general, these studies administered vaccine to a population of individuals with egg allergy and then followed them for reactions. Of the reports, 14 were abstracts only, with no related paper found and relatively limited information. All of the papers, reports, and studies were reviewed descriptively. However, 28 reports encompassing 31 studies were included in the GRADE analysis. The studies included in GRADE were of egg-based seasonal and monovalent pandemic vaccines only and included full- or split-dose administration. Those 2 administration methods were combined in the data because after consultation with an allergist, it was determined that these 2 administration routes were similar from the point of view of risk of an adverse reaction. For the randomized study that compared full- versus split-dose, those 2 experimental groups were combined, and this study was treated as a cohort study. Data with unknown or unclear vaccine type, unspecified administration protocols, that used a graded

protocol of ≥3 steps to administer vaccine, or which had an unknown or unclear denominator were excluded. Since there were no comparators, the data were summarized as frequencies.

This table summarize frequency of the events that occurred by vaccine type for persons with egg allergies of all severities, with the results stratified these results by Seasonal IIVs*, Monovalent IIVs*, and live-attenuated influenza vaccine (LAIV):

Outcome	Seasonal IIVs*	Monovalent IIVs*	LAIV	Importance	Certainty
Death	0/1591 (0%)	0/5235 (0%)	0/1129 (0%)	Critical	Very low
Anaphylaxis	0/1591 (0%)	0/5235 (0%)	0/1129 (0%)	Critical	Very low
Reaction requiring hospitalization	0/1591 (0%)	0/5235 (0%)	0/1129 (0%)	Critical	Very low
Reaction requiring outpatient/ED attention (includes those given symptomatic medications)	3/1591 (0.2%)	77/5235 (1.5%)	0/1129 (0%)	Important	Very low
Allergic reaction including cardiovascular symptoms, respiratory symptoms, angioedema, or generalized urticaria	5/1591 (0.3%)†	33/5235 (0.6%)	10/1129 (0.8%)	Important	Very low

*Includes several papers for which vaccine type not explicitly stated, but presumed based upon season, study location, and/or use of graded/split dosing. Seasonal IIV data include one paper describing a virosomal vaccine.
†One study reported 6 instances of reactions including "wheezing, eczema exacerbation, or hives on chest", but not specifying number with each symptom. If assumed that all six included wheezing, frequency would be 11/1591=0.7%

All of the LAIV work was with seasonal vaccine. The seasonal IIV group included one virosomal vaccine, which was not available in the US. It was a study from Europe. GRADE and evidence certainty for every vaccine and outcome were assessed separately. However, the results were all the same. Therefore, only one column was included for space considerations. Certainty levels were very low across the board. With regard to the event frequencies, the included papers reported no occurrences of the three critical outcomes death, anaphylaxis, or hospitalization across vaccine type. For reactions requiring outpatient or ED attention, frequencies were 0.2% for seasonal IIV, 1.5% for monovalent IIV, and 0% for LAIV.

Instances that involved treatment with symptomatic medications were included, which was the majority of these. There were only 2 that referred explicitly to transfer to an ED. For reactions including cardiovascular symptoms, respiratory symptoms, angioedema, or generalized urticaria, the frequencies were 0.3% for seasonal IIV, 0.6% for monovalent IIV, and 0.8% for LAIV. Again, certainty across the board was very low. These studies generally were all observational studies, so they started with a certainty of low, so downgrading even for one characteristic would bring the certainty to very low. This work overall was downgraded mainly for methodological quality and for imprecision. Because these data reflected data for people with egg allergy of all severities and not just those who had a history of anaphylaxis to egg, it also was downgraded for indirectness.

This table summarize frequency of the events that occurred by vaccine type for a subset of persons with anaphylaxis to eggs, with the results stratified these results by Seasonal IIVs*, Monovalent IIVs*, and live-attenuated influenza vaccine (LAIV):

Outcome	Seasonal IIVs*	Monovalent IIVs*	LAIV	Importance	Certainty
Death	0/1591 (0%)	0/5235 (0%)	0/1129 (0%)	Critical	Very low
Anaphylaxis	0/1591 (0%)	0/5235 (0%)	0/1129 (0%)	Critical	Very low
Reaction requiring hospitalization	0/1591 (0%)	0/5235 (0%)	0/1129 (0%)	Critical	Very low
Reaction requiring outpatient/ED attention (includes those given symptomatic medications)	3/1591 (0.2%)	77/5235 (1.5%)	0/1129 (0%)	Important	Very low
Allergic reaction including cardiovascular symptoms, respiratory symptoms, angioedema, or generalized urticaria	5/1591 (0.3%)†	33/5235 (0.6%)	10/1129 (0.8%)	Important	Very low

*Includes several papers for which vaccine type not explicitly stated, but presumed to be IIV based upon season, study location, and/or use of graded/split dosing.

This subset of individuals in these studies were found to have reported a history of anaphylaxis to egg. Since the policy question focuses on people who have a history of severe egg allergy, this group was important to the WG and they were hoping to find as much as possible and the data were stratified where possible. Overall, the numbers are lower. Some studies did not include people with severe egg allergy, did not mention whether people with severe egg allergy were included, did not state the numbers of these people in the study, or did not report the findings specifically for that subgroup. They might have reported reactions, but then did not go on to say whether they occurred or how many of them occurred in people with anaphylaxis to egg. There were no events for any of the outcomes of interest for any vaccine type in this subset. This is likely due, at least in part, to small sample sizes. Certainty for these outcomes was rated as very low for each vaccine type as well, with downgrading primarily for methodological quality and imprecision.

To summarizes, the certainty of evidence for the 3 critical and 2 important outcomes of interest was very low for all 3 vaccine types. While studies without denominator data and those for which the vaccine was unclear were not included in the GRADE analysis, one particular report bears noting in this discussion. This was a report of Brighton Level 1 anaphylaxis that occurred in a person with “possible” egg allergy within 30 minutes of receiving monovalent vaccine. It was reported in a paper summarizing VAERS reports of AEs to monovalent pandemic vaccine during the 2009-2010 season.[30] The information presented on the case in this paper is limited and it is unclear from the way it is described whether the recipient was documented to be egg allergic. It is referred to as a case of “possible” egg allergy. The reactions were included in the counts in the GRADE evidence profiles because there was not a defined denominator, given that these were VAERS data. While the paper states that approximately 127 million doses of influenza vaccine were distributed that season; however, the number of doses that were actually administered is unknown. Other reactions among egg-allergic persons reported in this paper included 2 described as respiratory hypersensitivity and 1 as a sensation of throat closure.

[30] Halsey NA, et al. Vaccine. 2013 Dec 9;31(51):6107-12. doi: 10.1016/j.vaccine.2013.09.066. Epub 2013 Oct 8. PMID: 24120547.

The papers related to egg-free vaccine discuss reactions following recombinant influenza vaccine were from Woo, et al 2015 and 2017. These are summaries of VAERS reports following administration of recombinant influenza vaccine. They include reports of serious allergic reactions following RIV, some of which occurred among persons with egg allergy. RIV is egg-, gelatin-, antibiotic-, and preservative-free. Because RIV is an egg-free vaccine, these reactions cannot be assumed to be a manifestation of egg allergy. However, this literature brings up a couple of points that probably are important. One that the authors note is that the occurrence of such reactions might reflect an underlying predisposition to atopy among egg-allergic individuals. Also, it highlights the importance of thinking about the unpredictability of severe allergic reactions and the importance of being prepared in all vaccination settings for all recipients and with all vaccines.

There are a number of limitations to this review and the literature retrieved, which were discussed within the WG. These were observational data with no comparator groups meeting criteria. Not only are the data observational, but also most of the cohort studies essentially were case series because there was no comparator group. It is important to note that about 4 studies included a comparator group of non-egg-allergic people, but that was not the kind of comparator group that was going to provide the information needed. Some of the data were available only from abstracts, which had relatively limited details compared with the paper. Many of the papers, particularly the older papers, employed skin testing with egg proteins and/or vaccine prior to deciding to vaccinate or deciding how to vaccinate (e.g., full- versus split-dose). Therefore, it is possible that there could have been some kind of selection bias caused by that procedure. There is considerable variability in the level of detail in which outcomes are described, particularly in abstracts for which descriptions are scant. Even among the full papers there is variability in the level of detail.

It is probably reasonable to assume that serious reactions, such as death or anaphylaxis, are more likely to be reported than less serious ones. Even among less serious ones, there was some variability. Most studies had a follow-up period for delayed reactions to be reported by parents or caregivers, perhaps 24 to 72 hours after discharge from the vaccination setting, but it is easy to see how some of these reactions might not be described as well and instances of outpatient care or hospitalizations might be missed. The observation time post-vaccination varied and often was not reported for the delayed reactions. While the WG was trying to be conservative with the 4-hour window after vaccination, observation times ranged between 30 minutes and 2 hours across the board. Even authors who reported delayed vaccinations often did not report the elapsed time post-vaccination, which made the data difficult to use. Ovalbumin content was not reported or was unknown in most instances. Some authors did report it, relying on either the package insert or having the vaccine assayed themselves. In most instances where noted, it was under 1 microgram per dose and substantially less in some cases. In particular, the monovalent vaccine Arepanrix™ was used in some of the studies. Arepanrix™ has as unusually low ovalbumin content as did the virosomal vaccine, which was in one of the studies. It is difficult to know how this compares with current vaccines, since the package inserts for current vaccines express this information as an upper limit. A number of papers have shown that the quantity of ovalbumin can vary from lot-to-lot. Finally, and perhaps most important, data specifically for people with anaphylaxis to egg were very limited. Not all studies specified included them and some did not include them. Where they were included, the data were not always reported specifically for that population.

In terms of egg allergy and anaphylaxis reports after IIVs in VAERS between 2017–2022, colleagues in the Immunization Services Office (ISO) did a brief review of VAERS reports for egg allergy and anaphylaxis for the 2017–2022 period. In the review of VAERS reports, there were 178 anaphylaxis reports after IIVs, 18 of which were reported to have an egg allergy. Clinical review of these reports revealed 7 reports of anaphylaxis and egg allergy(4 among children, 3 among adults), all of which occurred in the 2017–2018 season. There were 4 Brighton Level 1, 1 Brighton Level 3, and 2 that did not meet Brighton. Associated influenza included Fluarix Quad in 2 instances, Fluzone Quadrivalent in 2 instances, Fluvirin Trivalent in 1 instance, Flucelvax Quadrivalent in 1 instance, and Flublok Quadrivalent in 1 instance. It is difficult to assess whether the reaction was due to egg protein in these instances due to limited laboratory data.

With regard to the question of benefits and harms, because this review focused solely on safety literature, only 1 of the benefits and harms questions was addressed. For the question of how substantial the undesirable anticipated effects are, 83% of respondents (N=18) selected either “small” at 44%, or “minimal” at 39%. There was 1 vote (6%) for “moderate” and 11% selected “varies.”

Moving to the Values domain and the question regarding whether the target population feels that the desirable effects are large relative to the undesirable effects, no direct evidence was found to support any conclusions. It was raised that a change in the recommendations might be reassuring to some who have wanted to be vaccinated but were hesitant or perceived it to be unsafe. It also was raised that it might be a source of concern for some people, with 1 WG member expressing that the change might be viewed unfavorably if it was perceived as a tradeoff between safety versus increasing coverage and reducing missed opportunities to vaccinate. For this question, there was not a majority opinion for any single answer, but half of respondents responded indicated “Don't Know” probably reflecting lack of information to inform this particular question. There was considerable dispersion among the other options, although none selected “No.” Regarding whether there is important uncertainty about or variability in how much people value the main outcomes, no direct evidence was found to support conclusions here. Presumably, greater value might be attached to the more serious outcomes, such as death, anaphylaxis, and hospitalization, which were the critical outcomes. But again, no data were found to support this. For the values question whether there is important uncertainty about, or variability in, how much people value the main outcomes, there was a clearer majority of responses, with 67% indicating that they felt that there was “probably not important uncertainty or variability” in how people value the main outcomes. However, 28% selected that there is “probably important uncertainty or variability.”

Regarding the Acceptability domain, no direct evidence was found from stakeholders. However, there was some information that speaks indirectly to the possibility of acceptability. Some information speaking for acceptability includes the fact that several US professional societies (AAP, AAAAI, ACAAI) already recommend that no special measures, screening, observation periods, selection of specific vaccines, or specific vaccination settings are needed for those with egg allergy. A potential factor against acceptability is that as of 2022–2023, packaged inserts for egg-based vaccines continue to carry a contraindication for severe hypersensitivity reactions to any vaccine components which for egg includes egg-based vaccines. This could cause confusion among providers and consumers. However, this is a contraindication that has been in place for quite some time and ACIP has recommended influenza vaccination for a number of seasons with any appropriate vaccine, including egg-based vaccines for people with egg allergy regardless of severity to reaction to egg. Therefore, there is probably not an a priori reason to assume that a change in recommendations would affect acceptability substantially. In further

discussion with the WG, considerations regarding acceptability included the idea that alignment of recommendations among public health organizations and professional societies facilitates consistent messaging to providers and patients. However, some expressed the concern that some settings might not be prepared to manage severe reactions, even though the guidelines state that preparation should be in place, and further that acceptability could be severely negatively impacted if the anaphylaxis occurs in a setting unprepared to manage it—particularly if there is a bad outcome. The same WG member raised the importance of stressing that every setting must be prepared to manage anaphylaxis or should not be administering any vaccine to any recipient. Finally, there was concern for potential liability issues. With regard to whether a change in recommendations would be acceptable, 44% of 18 respondents indicated "Yes" while 56% indicated "Probably Yes," with no responses in the negative.

For the Resource Use domain, following consultation with the NCIRD Health Economist, no economic analysis was conducted for this review. One reason was that the target population is small. There also is lack of data for some factors that would be important in constructing the needed assumptions for an economic model. For example, there is not a reliable estimate on the proportion of those with egg allergy who have had severe reactions to egg. The proportion of individuals with egg allergy by age, particularly in older age groups, is uncertain. Importantly, there is little information on the proportion of persons with egg allergy who are receiving egg-based versus egg-free vaccines. Finally, the primary emphasis of this review was on safety rather than cost. While the intervention discussed here is not really one that has to do with the vaccines per se and the WG did not discuss whether to recommend some vaccines over others, the point was raised that a change in recommendations with regard to setting could lead to influenza vaccination of egg-allergic persons being achieved in a more widespread manner in more settings, and that could lead to a change in the balance of use of egg-free versus egg-based vaccines in this population. With that in mind, the WG examined cost data. While average wholesale cost data were not available, some information was obtained from CMS payment allowances and the VFC. This table reflects these data, rounded to the nearest dollar:[31]

Vaccine (based on 0.5mL dose)	CMS Rate 2022-23[1]	VFC List 2023-24[2]
Egg-based		
Average for egg-based vaccines for ≥6 mos: Multidose	$20.00	$20.00
Average for egg-based vaccines for ≥6 mos: Preservative-free	$22.00 (IIV4s) $27.00 (LAIV4)	$21.00 (IIV4s) $24.00 (LAIV4)
Fluzone High-Dose Quadrivalent: Preservative-free (≥65 yrs only)	*$70.00*	-
Fluad Quadrivalent: Preservative-free (≥65 yrs only)	*$72.00*	-
Egg-free		
Flucelvax Quadrivalent: Multidose (≥6 mos)	$31.00	$29.00
Preservative-free (≥6 mos)	$32.00	$30.00
Flublok Quadrivalent Preservative-free (≥18 yrs only)	*$70.00*	-

Overall, CMS payment allowances and VFC costs are higher for the egg-free vaccines that are approved for children. In particular for both the multi-dose and preservative the single-dose formulations of Flucelvax Quadrivalent, the egg-free subculture based vaccine costs are about 9 to 11 dollars higher than the average corresponding presentation for the egg-based inactivated vaccines.

[31] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-drugs/McrPartBDrugAvgSalesPrice/VaccinesPricing; and CDC Vaccine Price List (Private sector cost per dose)

The WG considerations around the issue of resource use included that removing existing restrictions possibly could result in a more efficient allocation of resources if the data suggests no or minimal increase in AEs. Conversely, a change in recommendations and lower cost of egg-based vaccines might lead to their increased use, which might be associated with increased cost if there is increase in reactions that require medical attention. With regard to whether the intervention is a reasonable and efficient allocation of resources, of 18 respondents, 1 was excluded who selected 2 options. Of the 17 remaining, 76% responded "Yes" and 24% responded "Probably Yes."

Regarding the Equity domain, no direct evidence was identified that would affect conclusions in this particular population of egg-allergic individuals. However, some indirect evidence concerning the risk of some populations to severe influenza illness and the prevalence of egg allergy are raised here as potential indirect lines of evidence. For example, some racial and ethnic groups are at increased risk of severe influenza illness, highlighting the importance of influenza vaccination. One paper recently reported that influenza-associated hospitalization and ICU admission rates were higher among Black, Hispanic, and AI/AN children under 4 years of age compared with white children.[32] Additionally, some studies indicate that some groups are more likely to have food allergies. For example, Black children were disproportionately represented among children with egg allergy in one series.[33] If current recommendations are a real or perceived barrier to vaccination, the intervention potentially could improve equity with regard to risk of severe influenza illness in this population.

Issues related to trust in the healthcare system were raised by a couple of WG members as potentially negative impacts. Again, this is not about recommending egg-based versus non-egg-based vaccines. Instead, this point brings together the issues of cost, equity, and trust. The proposed recommendation focuses on language related to vaccination setting. People with egg-allergy are currently recommended to receive any vaccine that is otherwise appropriate, even if it is egg-based. However, a change in recommendations might mean that the vaccination occurs more widely in more settings than previously. Perhaps with increased use of egg-based influenza vaccines rather than egg-free vaccines in some settings could be influenced by their relative cost. The fact that egg-based vaccines are less expensive might reinforce the belief that vaccination providers do not care to use the necessary resources to provide a potentially safer vaccine. With regard to impact on health equity, the WG responses were dispersed. This possibly reflects uncertainty given the lack of specific data. However, 50% of the 18 respondents expressed that equity would be "Probably Increased."

For the last domain of Feasibility, a number of considerations were raised. Considerations favoring feasibility are that the proposed change is a simplification of the previous recommendation. It involves removal of an extra recommendation for 1 subgroup, and it makes the recommendations for vaccination of egg-allergy persons uniform regardless of severity and basically similar to the recommendations for vaccination of any person against influenza. It also does not specify particular vaccines and does not change recommendations for emergency equipment and resources in vaccination settings. As noted, the General Best Practices already indicate that equipment and medicines to manage potential severe allergic reactions should be available in all vaccination settings.[34] A consideration against feasibility is that there might be some vaccination settings that are not already prepared to manage severe allergic reactions, and such settings would need to address these needs. Again, all settings already are recommended to be prepared for severe allergic reactions when administering any vaccine to

[32] O'Halloran et al JAMA Netw Open. 2021 Aug 2;4(8):e2121880
[33] Samady W et al. J Allergy Clin Immunol Pract. 2020 Oct;8(9):3066-3073.e6. doi: 10.1016/j.jaip.2020.04.058
[34] Kroger AT et al. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

any recipient. With regard to whether the intervention is feasible, 89% of the 18 respondents answered “Yes” and 11% answered “Probably Yes.”

In terms of the balance of consequences and sufficiency of information, 61% of the 18 respondents indicated that the “Desirable consequences clearly outweigh undesirable consequences in most settings” and 39% responded that the “Desirable consequences probably outweigh undesirable consequences in most settings.” With regard to whether there is sufficient information to move forward with a vaccination, 100% of the 18 respondents answered “Yes” and 0% responded “No.”

Influenza Vaccine Safety Update and Proposed Recommendations for the 2023-2024 Influenza Season

Lisa Grohskopf MD, MPH (CDC/NCIRD) presented a brief influenza vaccine safety update and the proposed recommendations for the votes. Approximately 173 million doses of influenza vaccines were distributed in the US for the 2022-2023 season.[35] In VAERS, which is co-managed by CDC and FDA, no new safety concerns were identified for influenza vaccines. In the VSD, which is a collaboration between CDC and 9 integrated healthcare organizations within the VSD, approximately 5.5 million doses of influenza vaccine were distributed for the season. No new safety concerns were identified in influenza vaccine monitoring.[36] However, a statistical signal for ischemic stroke after Pfizer-BioNTech Bivalent mRNA COVID-19 vaccine in persons ≥65 years of age that was detected in a VSD analysis for COVID-19 vaccine safety monitoring.[37] Post-signal analyses in VSD found an elevated rate ratio for ischemic stroke after simultaneous vaccination with Pfizer-BioNTech Bivalent mRNA COVID-19 vaccine and high-dose or adjuvanted influenza vaccine, which has attenuated over time. Separate analyses did not detect elevated rate ratios for ischemic stroke after influenza vaccine administered without bivalent mRNA COVID-19 vaccine.

To provide an overview of the proposed recommendations for 2023-2024, vaccination of all persons ≥6 months of age who do not have contraindications continues to be recommended. Additionally, no changes were proposed for the recommendations regarding timing of vaccination compared to the past season. Proposed changes include the updated US influenza vaccine composition for 2023-2024 and proposed changes to the recommendations for vaccination of persons with egg allergy. As noted, the timing of vaccination recommendations are unchanged from last season. Because this information is important for programs in terms of planning their influenza vaccine campaigns for the upcoming season, Dr. Grohskopf reviewed them briefly. The overarching recommendation is that for most persons who need only 1 dose of influenza vaccine for the season, vaccination ideally should be offered during September or October. The reason that is the case and not earlier is because of concerns about waning of immunity during the season. However, vaccination among vaccinated persons should continue after October and throughout the season as long as influenza viruses are circulating and unexpired vaccine is available. Vaccination during July and August are not recommended for most groups due to concerns for waning immunity. Considerations for July and August vaccination are noted for adults, children, and pregnant persons.

[35] Weekly Flu Vaccination Dashboard | FluVaxView | Seasonal Influenza (Flu) | CDC
[36] Outcomes monitored in VSD: acute disseminated encephalomyelitis, anaphylaxis, Bell’s Palsy, encephalitis, Guillain-Barré syndrome, seizures, transverse myelitis
[37] Shimabukuro T, ACIP presentation on April 19, 2023 mRNA COVID-19 bivalent booster vaccine safety update (cdc.gov)

For most adults, particularly adults ≥65 years of age, and for pregnant persons in the first or second trimester, vaccination during July and August should be avoided unless there is concern that vaccination later in the season might not be possible (e.g., concern that an opportunity to vaccinate at all might be missed). This is because, particularly for adults ≥65 years of age, there is a concern about waning immunity over the course of the season that has been documented in all age groups but appears to be the most pronounced among older adults. There are 2 recommendations for children. Children who require 2 doses who are ≥6 months─8 years of age who have an unclear or unknown influenza vaccination history or who have not received a lifetime total of 2 doses should receive their first dose as soon as possible, including during July and August if vaccine is available, to allow for the second dose that is to be administered 4 weeks later to be given ideally by the end of October. For children who require only 1 dose, vaccination during July and August can be considered. This is because waning has been documented in all age groups, although there are less data currently for children. Moreover, school-aged children commonly present to HCP in the late summer months for preschool physicals, which presents a vaccination opportunity that should be considered if that child is not expected to be seen again prior to the season. For pregnant people in the third trimester, vaccination during July and August can be considered because vaccination might reduce risk for influenza illness in their infants during the first months after birth when they are too young to receive influenza vaccine. This has been documented in a number of studies.

In terms of the US influenza vaccine composition for 2023-2024, there is only 1 proposed change that comes from the FDA. FDA's VRBPAC met in early March as usual to select the recommended composition for the next season.[38] All vaccines available expected to be available in the US for the next season will be quadrivalent. The 2023-2024 composition includes updated influenza A(H1N1)pdm09 components for both egg-based and non-egg-based vaccines. Interestingly, this has caused some confusion and questions because the A(H1N1)pdm09 components last year also were an influenza A/Victoria and an influenza A/Wisconsin, but they were different with slightly different numbers in their taxonomy. The components for the H3N2 and both B viruses are the same as last season. All US-licensed influenza vaccines will include hemagglutinin derived from the following:

- ❑ An influenza A/Victoria/4897/2022 (H1N1)pdm09-like virus (egg-based vaccines)
  An influenza A/Wisconsin/67/2022 (H1N1)pdm09-like virus (cell and recombinant vaccines)

- ❑ An influenza A/Darwin/9/2021 (H3N2)-like virus (egg-based vaccines)
  An influenza A/Darwin/6/2021 (H3N2)-like virus (cell and recombinant vaccines)

- ❑ An influenza B/Austria/1359417/2021-like virus (B/Victoria lineage)

- ❑ An influenza B/Phuket/3073/2013-like virus (B/Yamagata lineage)

[38] https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-march-7-2023-meeting-announcement

The proposed recommendation language for vaccination of persons with egg allergy was drafted for the ACIP's consideration and editing as appropriate:

- ❑ All persons aged ≥6 months with egg allergy should receive influenza vaccine unless a contraindication exists. Any influenza vaccine that is otherwise appropriate for the recipient's age and health status can be used (egg based or non-egg based).

- ❑ Egg allergy in and of itself necessitates no additional safety measures for influenza vaccination beyond those recommended for any recipient of any vaccine, regardless of severity of previous reaction to egg.

- ❑ Severe and life-threatening reactions to vaccines can rarely occur with any vaccine and in any vaccine recipient, regardless of allergy history. Providers are reminded that all vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of acute hypersensitivity reactions are available. All vaccination providers should be familiar with their office emergency plan and be certified in cardiopulmonary resuscitation.

VFC Resolution

Jeanne Santoli, MD, MPH (CDC/NCIRD) indicated that the purpose of this resolution was to: 1) update the product table in the IIV component of the resolution; 2) revise the eligible groups section in the LAIV component of the resolution; and 3) add/update the links in the contraindications and precautions section of both components of the resolution. The eligible groups are all children 6 months–18 years of age. There are no changes to the vaccine schedule and recommended dosage intervals are as follows:

- ❑ 6 months through 8 years: 1 or 2 doses, as noted in the current ACIP recommendations
- ❑ 9 through 18 years: 1 dose
- ❑ Minimum age: 6 months
- ❑ Minimum interval between dose 1 and dose 2 (where applicable): 4 weeks

This table lists the currently approved IIVs in the VFC program, including the age indication for each vaccine, with the only change being removal of a product that is no longer available in the US:

Brand Name	Presentation	Age Indication
Afluria (Quadrivalent)	0.5 mL pre-filled syringe	≥ 36 months
Afluria (Quadrivalent)	5.0mL multi-dose vial	≥ 6 months
Fluarix (Quadrivalent)	0.5 mL pre-filled syringe	≥ 6 months
Flucelvax (Quadrivalent)*	0.5 mL pre-filled syringe	≥ 6 months
Flucelvax (Quadrivalent)*	5.0mL multi-dose vial	≥ 6 months
Flulaval (Quadrivalent)	0.5 mL pre-filled syringe	≥ 6 months
Fluzone (Quadrivalent)	0.5mL prefilled syringe/single-dose vial	≥ 6 months
Fluzone (Quadrivalent)	5.0mL multi-dose vial	≥ 6 months

Note: The use of brand names is not meant to preclude the use of other comparable licensed vaccines.
*All IIVs and LAIV are egg-based, with the exception of Flucelvax Quadrivalent, which is cell culture-based.

Recommended Dosage Refer to product package inserts available at:
https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states

For the contraindications and precautions, some guidance was removed about the use of vaccine in egg-allergic individuals that was thought to be potentially confusing. Instead, a link was added to the details about the contraindications and precautions.

Contraindications:
1. For egg-based IIV: History of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine (other than egg) or after previous dose of any influenza vaccine.
2. For cell culture-based IIV: History of severe allergic reaction (e.g., anaphylaxis) to cell culture-based IIV or any component of the vaccine.

Precautions:
1. Moderate or severe acute illness with or without fever
2. GBS within 6 weeks following a previous dose of influenza vaccine
3. For cell culture-based IIV only: History of severe allergic reaction to any other influenza vaccine.

Details of contraindications and precautions can be found at Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022–23 Influenza Season | MMWR (cdc.gov).

For the LAIV section, the eligible groups were reworded to remove reference to potential precautions for vaccination and instead indicate that the eligible groups are non-pregnant children and adolescents aged 2 through 18 years. The recommended vaccination schedule and dosing intervals were unchanged:

- ❑ 2 years through 8 years: 1 or 2 doses, as noted in the current ACIP recommendations
- ❑ 9 through 18 years: 1 dose
- ❑ Minimum Age: 2 years
- ❑ Minimum interval between dose 1 and dose 2 (where applicable): 4 weeks

The dosage and contraindications and precautions section was unchanged except for an update to the link in this section to match the latest published statement. The statement regarding updates based on published documents did not change from the following:

[If an ACIP recommendation regarding influenza vaccination is published within 6 months following this resolution, the relevant language above (except in the eligible groups sections) will be replaced with the language in the recommendation and incorporated by reference to the URL].

Vote #1: Influenza Vaccination Recommendation

Dr. Lee (ACIP Chair) displayed and read the proposed vote language following the public comment period. The vote was combined with the Influenza Vaccine session for ease of reading:

> All persons ages ≥6 months with egg allergy should receive influenza vaccine. Any influenza vaccine (egg based or non-egg based) that is otherwise appropriate for the recipient's age and health status can be used.

Motion/Vote #1: Influenza Vaccination Recommendation

Dr. Poeling made a motion to approve the recommendation as stated, which Ms. Bahta seconded. No COIs were declared. The motion carried with 14 affirmative votes, 0 negative votes, and 0 abstentions. The disposition of the vote was as follows:

14 Favored: Bahta, Bell, Brooks, Chen, Cineas, Daley, Kotton, Lee, Loehr, Long, McNally, Poehling, Sanchez, Talbot
0 Opposed: N/A
0 Abstained: N/A

Vote #2: Influenza Vaccination *MMWR* Recommendations and Reports

Dr. Lee (ACIP Chair) displayed and read the proposed vote language following the public comment period. The vote was combined with the Influenza Vaccine session for ease of reading:

> Affirm the updated *MMWR* Recommendation and Reports, "Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2023-24 Season."

Motion/Vote #2: Influenza Vaccination *MMWR* Recommendations and Reports

Dr. Poeling made a motion to approve the recommendation as stated, which Dr. Daley seconded. No COIs were declared. The motion carried with 14 affirmative votes, 0 negative votes, and 0 abstentions. The disposition of the vote was as follows:

14 Favored: Bahta, Bell, Brooks, Chen, Cineas, Daley, Kotton, Lee, Loehr, Long, McNally, Poehling, Sanchez, Talbot
0 Opposed: N/A
0 Abstained: N/A

Vote #3: Influenza Vaccine VFC Resolution

Dr. Lee (ACIP Chair) displayed and read the proposed vote language following the public comment period. The vote was combined with the Influenza Vaccine session for ease of reading:

Approve the Vaccines for Children (VFC) resolution for influenza vaccines.

Motion/Vote #3: Influenza Vaccine VFC Resolution

Dr. Poeling made a motion to approve the recommendation as stated, which Dr. Daley seconded. No COIs were declared. The motion carried with 14 affirmative votes, 0 negative votes, and 0 abstentions. The disposition of the vote was as follows:

14 Favored:	Bahta, Bell, Brooks, Chen, Cineas, Daley, Kotton, Lee, Loehr, Long, McNally, Poehling, Sanchez, Talbot
0 Opposed:	N/A
0 Abstained:	N/A

PUBLIC COMMENTS

Overview

The floor was opened for public comment on June 21, 2023 at 4:15 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 Number ID CDC-2023-0035. Visit http://www.regulations.gov for access to the docket or to submit comments or read background documents and comments received. The public comment session occurred prior to the votes, but the votes were connected back with their respective sessions for ease of reading.

Public Comment

Lindsay Clarke, JD
Senior Vice President
Health Education and Advocacy
Alliance for Aging Research

Good afternoon and thank you to the committee for this opportunity to comment. My name is Lindsay Clarke. I am the Senior Vice President of Health Education and Advocacy at the Alliance for Aging Research. One of the educational campaigns that I lead at the Alliance is the "Our Best Shot" campaign. Over the years, this campaign has produced dozens of educational resources focused on raising awareness about the importance of vaccines in older adults, how

they work, which ones are recommended by this committee, how the Medicare program covers vaccines, and more. The resources have included a focus on influenza, pneumonia, shingles, and COVID. In this past year, we've produced educational films on RSV in older adults, emphasizing to viewers that RSV is not just a pediatric disease. While we know that older adults are especially vulnerable to serious complications from RSV, we also know that adults ages 60 to 64 living with asthma, congestive heart failure, COPD are all at high risk for RSV related hospitalizations and deaths. Additionally, studies from the CDC and others presented at the ReSViNET conference in January demonstrate that a higher proportion of adults ages 60 to 64 who were hospitalized and/or experienced severe outcomes due to RSV were Black, Hispanic, or American Indian/Alaskan Natives. These racial and ethnic defenses are critical to consider when determining age recommendations for the new RSV vaccines. Earlier and higher rates of asthma, congestive heart failure, or COPD in communities of color due to structural racism led to earlier RSV onset and higher risk of hospitalization, severe outcomes, including deaths, and must be considered as part of the age recommendations. Once the recommendations are determined, we urge publication in the *MMWR* without delay. While respiratory surges are no longer limited to the traditional cold and flu season, we know that the surges of influenza, COVID, pneumonia, RSV, and other respiratory illnesses continue to flood and overwhelm our healthcare system in the fall and winter months. Being able to start administering these vaccines for the fall season will undoubtedly save lives. Lastly, we urge the federal government to make sure that the safety of co-administering multiple vaccines like RSV, influenza, COVID, and pneumonia is clearly communicated. We know from our education and outreach that misinformation about the safety of receiving multiple vaccines at once persists and clear communication from the FDA, CDC, and other agencies is critical in the distribution of reliable and trustworthy information on vaccination and specifically on co-administration. We are excited about the new RSV vaccines, and while general awareness and prevention will remain a priority for the Alliance, we look forward to being able to encourage older adults and all adults at high risk to receive an RSV vaccine to protect themselves and their loved ones. Thank you again for this opportunity to comment.

Erica DeWald
Chief Communication Officer
Vaccinate Your Family

Thank you and good afternoon. I am the Chief Communication Officer at Vaccinate Your Family, an organization you will hear about from my colleague, Serese Marotta, in just one moment. Thank you for the opportunity to comment. I wanted to thank the ACIP voting members and liaisons for all of their hard work in recent years. While many in the general public first became aware of ACIP during the pandemic, our organization has held the ACIP in the highest regard for decades. Our policies specifically stipulate that Vaccinate Your Family follow the recommendations of this committee. This week's meeting showcases the depth and the breadth of the work you do. ACIP serves a critical role in ensuring the safety and efficacy of our vaccine schedule in the US. As independent experts, your review of the available data presents an unbiased view of how best to protect people in this country. Science and the data it creates should always lead the way on vaccination recommendations. As you consider votes on pneumococcal and RSV vaccines as well as the reformulation of the COVID-19 vaccines, Vaccinate Your Family urges you to continue to consider the available data. Too often in recent years, politics have attempted to replace science. The ACIP has remained firm in their commitment to follow the data. We hope others will in turn continue to follow the ACIP and respect their independent review of the safety and effectiveness of new and existing vaccines. Thank you again for the opportunity to comment.

Serese Marotta
Director of Advocacy and Education
Vaccinate Your Family

Good afternoon. Hello, I'm Serese Marotta, Director of Advocacy and Education at Vaccinate Your Family. On behalf of Vaccinate Your Family, thank you for the opportunity to comment today. Established 30 years ago, Vaccinate Your Family works to protect people of all ages from vaccine-preventable diseases through advocacy, education, and policy. As evidenced by the COVID-19 pandemic, there is still much work to do to improve health equity and this is a priority for our organization. While we recognize that ACIP is discussing several important topics this week, my comments will focus primarily on respiratory syncytial virus, also known as RSV. Our organization is pleased that the committee will be considering recommendations for RSV vaccines for older adults, and we sincerely appreciate the robust discussions this morning. RSV infections in older adults result in 60,000 to 160,000 hospitalizations and 6,000 to 10,000 deaths every year in the United States. Recent studies found that the economic burden of RSV infections on healthcare systems was substantial, with RSV hospitalizations resulting in a national direct cost burden of $1.5 to $4.0 billion dollars for adults greater than 60 years old. Given the public health and economic burdens of RSV on older adults in the US, it is imperative that we have preventive measures like vaccines available as early as possible to help protect older adults from this disease. RSV can also be serious for infants and young children. Every year in the US, 58,000 to 80,000 children younger than 5 years old are hospitalized with RSV, and an estimated 100 to 300 children younger than 5 lose their lives to it. RSV not only causes a significant public health burden for young children, but also it creates a serious economic burden for families. According to a recent national survey, more than 2/3 of parents said that RSV caused a financial burden or crisis to their family. RSV has disproportionate impacts on Black and Hispanic/Latino infants as well as those on Medicaid, which is why it is so important that we have equitable access to preventive measures, including tools like monoclonal antibodies and maternal vaccinations. The past '22—'23 seasons saw a resurgence of RSV, along with other respiratory diseases like flu and COVID, resulting in a triple-demic that puts serious strains on our healthcare systems. We urge ACIP to follow the science and, if possible, provide timely recommendations prior to the start of the next RSV season this Fall. This means the inclusion of passive immunizations in the VFC program and the timely publication of the *MMWR*.

Martha Nolan, JD
Senior Policy Advisor
HealthyWomen

Good afternoon. My name is Martha Nolan. I am the Senior Policy Advisor for HealthyWomen, an advocacy organization committed to educating women so they can make informed health choices, advocate for themselves, and prioritize their health and wellness. For thousands of women across the country, we are a trusted source for credible, up-to-date information relevant to their mental and physical well-being and we believe a critical aspect of business preventive care. We understand the vital role that vaccines play in protecting against severe disease and are a strong proponent of ensuring that women and their families have the information they need to make informed decisions about their vaccine options. Last year's unexpected influx of RSV cases, on top of the already active flu, COVID, and pneumonia season, presented a stark reminder of why continued innovation in vaccines is so necessary. At the time, many adults were learning about the risk of RSV for older Americans for the first time, and there were no vaccines available to protect themselves. We know that on average, as many as 160,000 adults 65 and older are hospitalized for RSV, and up to 10,000 older adults die each year from the

virus. These numbers do not capture the many more Americans who may not require hospitalization but suffer at home from this illness. Given the considerable increase in respiratory threats facing the older population over these past few years, the need for preventive tools to defend against them cannot be overstated. It is also worth noting that the majority of care is provided by women, with 1 in 4 women reporting being caregivers and over a 1/3 of these women reporting that they are caring for a parent and a parent in-law, according to the CDC. Caregiving is a challenging and demanding responsibility and involves spending an extensive amount of time with those caring more and can put older Americans at greater risk of contracting a virus like RSV given the intergenerational aspect of a woman's caregiving roles. That is why we are so encouraged to be here today speaking about not just 1 but 2 FDA-approved vaccines for this virus after decades of having no protection. This is truly an important step forward and we are eager to share this committee's recommendations with our communities, so that all those who are eligible can benefit from this critical protection. HealthyWomen is grateful for this committee's work to ensure that these new protections are made available to those most vulnerable to serious illness and death. We ask that you provide as clear and simple guidance as possible on who should consider receiving these vaccines because, as you know, that is not the final step before older Americans can access these vaccines. So, in order to ensure everyone who is eligible for the need of protection has broad and equitable access to the vaccine before the start of yet another respiratory season this Fall, we ask for the process for publishing this guidance to be done in a timely and straightforward manner to ensure potential timely coverage by CMS. HealthyWomen appreciates the opportunity to address this important issue and we look forward to communicating the CDC's guidance to our communities so that everyone who is eligible for the vaccines understands the value they play in protecting their long-term well-being. Thank you.

Michael Hoerger, PhD, MSCR
Clinical Health Psychologist
Health Scientist and Health Strategist
Runs a Health Science PhD Program

Thank you all for your service during this difficult time. I'm Mike Hoerger. I run a Health Science PhD program in the Deep South. I'm a Clinical Health Psychologist, Health Scientist, and Health Strategist. I'm also in the sandwich generation with 3 young children at home and older relatives nearby. I have a few comments about COVID. We know from national wastewater data that SARS-CoV-2 transmission is lower now than during 75% of the pandemic, of course, higher than 25% of the pandemic. But during this time of lower transmission, it's important for organizations and families to hopefully catch their breath and reflect on their COVID strategy. I appreciate how receptive you all were to oral comments last time. I have a few strategic suggestions about COVID vaccines. First, transparency. I think we need more transparency and balanced framing. We need to be clear on vaccine efficacy, while also acknowledging that benefits wane substantially after 2 to 4 months, not annually, and they do less to protect against long COVID than we might hope, with cumulative risk increasing upon each reinfection. My family is highly vaccinated, and we would get more today if possible, but we need to avoid overpromising on any particular tool. Second, agility. We need faster COVID vaccine updates based on emerging variants so we're skating to where the puck is going, not to where it was months ago. We need to open up Novavax to all Americans 6 months and older, regardless of vaccine history or ability to pay. We desperately need next-generation vaccines that substantially reduce transmission. Third, we need a multi-layered strategy. SARS-CoV-2 viral and aerosol particles linger in the air like smoke, infect people when inhaled, and can cause severe damage to multiple organ systems. In addition to vaccines, we need to emphasize the use of high quality, well-fitting masks. Some of the best N95s are now only .09 cents each and

are readily available. We also need to emphasize the importance of air cleaning through ventilation and filtration, particularly given the forthcoming ASHRAE building standards. Babies under 6 months cannot mask or get COVID vaccines, so we need safe spaces in healthcare and at vaccination sites. A year ago, my twins were newborns and we had to navigate through a large health system to receive recommended medical care. We passed 70 clinicians who were unmasked. That's extremely dangerous. We need masks in health and in dental care, particularly for patients who must be unmasked at times for care. Finally, we need to do more on outreach and education. Nationally, uptake of the bivalent booster has been lower than we would hope, and particularly so in my part of the country in the Deep South, often even among older adults. We needed to reach out to the community, retail pharmacy chains, and clinicians. Again, I appreciate you all working hard during the ongoing pandemic, particularly when you and your families may be dealing with illness, trauma, moral distress, bereavement, and other stressors. The work you are doing is very important. Thank you for your time.

Ms. Sarah Berry
Independent Pro-Vaccine Advocate
42believer

Hello, CDC ACIP members. Thank you for your attention today. My name is Sarah Berry, also known as 42believer online. I am an independent pro-vaccine advocate who splits my time between gathering critical information on anti-vaxxers for numerous journalists and volunteering my time with pro-vaccine individuals and groups. One of them is Safe Communities Coalition, a nonprofit focused on educating legislators about vaccine policy issues, although there are many more that I like to talk to when possible. My purpose in giving a comment today is to talk about the stifling of innovation when anti-vaccine talking points embed themselves in the mainstream. We see this in low uptake for flu vaccines, which aside from the HPV vaccine, were the most commonly attacked vaccine prior to the pandemic. Some people, even those who I know personally, have hesitations about the necessity of the flu shot. So, how do we reach the average person about the flu vaccine? I have one talking point I use when speaking to friends who are genuinely hesitant about the flu vaccine, which is to bring up a sadly not unheard of but very serious consequence to flu infection, quadruple amputation. I recently, very recently, just yesterday, had a conversation with 2 friends about this and even shared pictures showing children as young as 5 needing this kind of intervention and they were absolutely shocked. Their faces said everything. I think we've gotten too used to seeing influenza trivialized, partially because of COVID, partially because of anti-vaxxers prior to COVID, but many people do suffer or die from flu every year. We can save some of them by being more upfront about the dangers of not vaccinating against flu. Prior to the pandemic, anti-vaxxers also used fear about the flu vaccine to push a bill in my home state that would have banned flu vaccine requirements in healthcare facilities. The thorough discussions around all future vaccines that have been discussed today are eventually going to be stifled by the overtaking of anti-vaccine viewpoints, both on a legislative level and a cultural one. As you all might have seen the fantastic Dr. Hotez, who researches new vaccines without relying on typical pharmaceutical funding that anti-vaxxers hate so much, has faced attempts at having his innovation stifled by simply calling out the influence of anti-vaccine talking points in our culture. This is my takeaway. We need to be more specific. We need to be specific about what happens when people don't vaccinate. We need to show people examples and videos and feature these people, so they know that this is a real potential outcome, and we need more people like Dr. Hotez being specific about why anti-vaccine grifters should not be trusted. I've been following this topic since 2017. If you need help with that, please reach out at 42believer@gmail.com. Thank you for your time.

Kelly Moore, MD, MPH
Chief Executive Officer

Good afternoon. I'm Dr. Kelly Moore, the CEO of Immunize.org and a former ACIP member. Immunize.org is a 32-year-old national nonprofit that supports implementation of ACIP recommendations and advocates for health policies that remove barriers to immunization. It's great to be at the threshold of having immunizations recommended to mitigate the under-valued burden of RSV disease in older adults and soon, hopefully, in infants. After today's vote, though, please continue public updates to the ACIP early and often on effectiveness and safety. We need evidence of the impact of these vaccines on the frail elderly in long-term care and elsewhere among the 80 plus population. In addition, as noted, the inflammatory neurologic disease cases observed are, for now, an uninterpretable signal—maybe something, maybe not. Either way, confidence in implementation will be helped by regular updates as you learn more. As an aside, it is notable to me that the debate between shared clinical decision-making and routine recommendation seems to weigh more than usual on Medicare logistics and less on the interpretation of efficacy and safety data, and also that today's decision must be made without the final prices. That issue at least seems fixable. After today's votes comes the need to address RSV in infants. We'll have to work fast to make a difference for babies this fall, and I urge the committee and the CDC to make decisions concerning maternal vaccination and infant immunization as soon as feasible and to publish an *MMWR* without delay. Timing is going to be a crunch. In addition, we want affordable infant RSV protection to be within the reach of every family. To that end, if judged an effective use of resources by ACIP, we encourage you to vote to include the new long-acting monoclonal antibodies, or mAbs, in the VFC program so newborns are not denied access due to a family's inability to pay. Thank you to those working to update our regulatory policy making payment processes to support the use of passive immunization for population health. Experts like Vanderbilt's Jim Crowe tell me that long acting mAbs could be the quickest tool to make to protect the population from the next pandemic virus, beating vaccines by months. In light of that, now is a great time to standardize the process to evaluate, approve, and recommend passive immunizations with population-wide application and to establish the expectation that they, like active vaccinations, should be affordably accessible to all in the interest of public health. Thank you for all your hard work today. I miss you.

THURSDAY: JUNE 22, 2023

AGENCY UPDATES

Centers for Disease Control and Prevention

José R. Romero, MD noted that throughout this meeting, the ACIP would receive the most current and comprehensive information on many of CDC's efforts, so he would keep his CDC updates brief and only share high-level updates on COVID-19, influenza, measles, and efforts to maintain childhood vaccination coverage. COVID-19 remains a key public health priority. COVID-19 hospitalizations and deaths continue to decline from the seasonal peak of January 2023. These peaks were far lower than those seen during the 2 previous winters. CDC provides weekly updates on COVID-19 vaccine distribution and administration on the CDC COVID-19 Tracker website. As of June 11, 2023, greater than 56 million individuals have received an updated bivalent COVID-19 vaccine dose. Since the recommendation of the Pfizer-BioNTech COVID-19 vaccine for children aged 5–11 years, greater than 9 million individuals aged 5–11 years have completed the primary series. While most Americans continue to pay nothing out-of-pocket for COVID-19 vaccine due to their insurance coverage, 25 million uninsured American

adults are at risk of losing access to affordable vaccines for COVID-19 and treatments when these transition to the commercial marketplace. In April 2023, HHS announced the Bridge Access Program for COVID-19 vaccines and treatment. This public-private partnership provides under- and un-insured adults with access to COVID-19 vaccines and treatments at no cost from Fall 2023 to the end of 2024. Turning now to seasonal influenza, following a moderately severe influenza season that peaked earlier than usual in late fall and early winter, influenza vaccination provided substantial protection this season. CDC again partnered with the Ad Council and the American Medical Association (AMA) for their annual "Get My Flu Shot" Campaign. The campaign encouraged the American public, with an emphasis on Black and Hispanic audiences, to get vaccinated against the influenza for the season 2022-2023. Planning for a new campaign for the 2023-2024 season is underway. With regard to avian influenza, the currently circulating influenza A(H5) viruses remains low. However, CDC and others remain very vigilant for this. An A(H5) candidate vaccine was developed by CDC and made available to vaccine manufacturers in early 2022. CDC continues to work with international, national, state and local partners to detect H5, and to prevent transmission through enhanced surveillance and guidance for people who may be exposed to infected birds. CDC continues to analyze viral sequence data for genetic markers associated with greater disease severity, more efficient infectivity, transmissibility to humans, reduced susceptibility to antiviral drugs, and impact on candidate vaccines and diagnostics. With regard to measles, with declines in measles vaccination rates globally during the COVID-19 pandemic, measles outbreaks are occurring in all World Health Organization regions. The United States has seen an increase in measles cases from 49 in 2021 to 121 in 2022. All have occurred among children who are not fully vaccinated, including the outbreaks in Minnesota and Ohio. Jurisdictions at highest risk for measles continue to be those contained communities with persistently low vaccination coverage and importations from locations with measles outbreaks. In terms of CDC's current efforts to maintain childhood vaccination coverage, the agency launched the "Let's Rise Campaign" to address pandemic-related declines in routine immunizations and equip partners and health care providers with actionable strategies, resources, and data to support getting all Americans back on schedule with their routine immunizations. More information about "Let's Rise" and access to routine immunization resources and data can be found on CDC's website.

Centers for Medicare and Medicaid Services

Mary Beth Hance reported that a CMS continues to emphasize the importance of routine pediatric immunizations. One way they have done this is through the Connecting Kids to Coverage National Campaign, which provides materials that can be used or rebranded to outreach grantees and a variety of partners who include government agencies, community organizations, health care providers, schools, and others. There are many tools available related to vaccines on the Connecting Kids to Coverage National Campaign. In addition, a Back-to-School webinar was held on Tuesday of this week that emphasized, among other things, the importance of immunizations and of getting caught up on immunizations before school. Shifting to follow-up from the previous day's adult RSV vaccines conversation, Ms. Hance confirmed from her colleagues on the Medicare side of CMS that if this vaccine is recommended, it will be included in Part D of the Medicare Program.

Food and Drug Administration

David Kaslow, MD reported that since the February 2023 ACIP meeting, 2 RSV vaccines with proposed indications for use in adults 60 years of age and older were reviewed by Vaccines and Related Biological Products Advisory Committee (VRBPAC), which subsequently approved both in May 2023. In addition, VRBPAC also met to review an RSV vaccine with the proposed indication for the prevention of lower respiratory tract disease and severe lower respiratory tract disease caused by RSV in infants from birth through 6 months of age by active immunization of pregnant individuals. Also reviewed by ACIP the previous day were VRBPAC's recommendations in March on the selection of strains to be included in the influenza virus vaccines for the 2023-2024 influenza season. In April, FDA amended the Emergency Use Authorizations (EUAs) of the 2 COVID-19 bivalent mRNA vaccines to simplify the vaccination schedule for most individuals and to authorize the current bivalent vaccine containing original and Omicron BA.4 and BA.5 strains for all doses administered to individuals 6 months of age and older. A week ago, VRBPAC met to discuss and make recommendations on the selection of strains to be included in the periodic updated COVID-19 vaccines for the 2023-2024 vaccination campaign. The committee unanimously voted to update the vaccine composition to a monovalent COVID-19 vaccine with an Omicron XBB lineage and expressed a preference for the XBB.1.5 sublineage. On June 16, 2023, FDA advised manufacturers who will be updating their COVID-19 vaccines that they should develop a vaccine with a monovalent XBB.1.5 composition for the 2023-2024 formula of COVID-19 vaccines in the US. In April 2023, FDA co-hosted with Biomedical Advanced Research and Development Authority (BARDA) a workshop on recombinant protein-based COVID-19 vaccines to review and discuss overcoming challenges faced by recombinant protein vaccine platforms in timely strain updates and pandemic readiness. Highlighted in that workshop was the timely availability of additional updated COVID-19 vaccines beyond the current nucleic acid-based vaccines approved for use at the onset of periodic vaccination campaigns. A number of regulatory actions are anticipated in the coming months. As reflected in the current ACIP meeting agenda, the magnitude of the current submissions under review is unprecedented. On behalf of FDA's Office of Vaccines Research and Review (OVRR) and Center for Biologics Evaluation and Research (CBER), Dr. Kaslow thanked the ACIP and the many ACIP WGs for their partnership in the work on this very large portfolio vaccine and vaccine candidates.

Health Resources and Services Administration

CDR Reed Grimes, MD, MPH reported that the National Vaccine Injury Compensation Program (VIPC) continues to process a high volume of claims in Fiscal Year 2023. As of June 1, 2023, petitioners have filed 747 claims with the VICP and $119.6 million has been awarded, including awards to petitioners for their attorney fees and costs. In addition, the VICP is working on a backlog of 1,363 claims alleging vaccine injury. More data about the VICP can be obtained at www.hrsa.gov/vaccinetackcompensation/data/index.html. As of June 1, 2023, 11,806 claims alleging injuries or death from COVID-19 countermeasures have been filed with the Countermeasures Injury Compensation Program (CICP), including 8,372 claims alleging injuries from COVID-19 vaccines. CICP has rendered decisions on 919 COVID-19 claims. Of the countermeasures claims, 25 have been determined medically eligible for compensation, 20 claims are pending a review of the eligible expenses, 4 have been compensated, and 1 did not have eligible expenses for reimbursement. A total of 894 COVID-19 countermeasure claims have been denied compensation because of various reasons. More information about the CICP can be found at www.hrsa.gov/CICP.

Indian Health Service

Matthew Clark, MD, FAAP, FACP reported that the IHS continues to prioritize access, quality, and equity in vaccine distribution and administration for American Indian and Alaska Native tribal communities served by the IHS system of care. Following expiration of the Public Health Emergency (PHE), the IHS has remained committed to its efforts to promote COVID-19 vaccination in all age groups in every region. They are currently implementing a national vaccine strategy for the tribal communities served by IHS federal, tribal, and urban Indian organization programs. The E3 Vaccine Strategy is designed to promote access for every patient at every encounter to every recommended vaccine when appropriate. This includes all ACIP-recommended vaccines in all age groups. Working in collaboration with key stakeholders, especially its tribal and urban Indian organization partners, IHS is committed to improving general vaccination rates in tribal communities. The E3 Operational Plan includes a bottom-up approach to encourage innovation, incentivize effort, and recognize success drawing on the adaptability of the IHS's comprehensive health care system to cross-pollinate federal, tribal, and urban Indian programs using best practices developed in Indian country for Indian country. Following rollout of the E3 Champions Pilot Program in Spring 2023, Dr. Clark said he was pleased to report that over 2 dozen federal, tribal, and urban Indian programs have applied for and received designation as an IHS E3 Champion Pilot site. IHS looks forward to continued collaboration with its tribal, urban, and federal partners to ensure access to safe and effective vaccines and to reduce morbidity and mortality from vaccine-preventable illness across the age spectrum for American Indian and Alaska Native people served by the IHS.

National Institutes of Health

John Beigel, MD reported that the NIH continues to support basic and clinical research to improve human health. A large part of what the NIH does is centered around new and better vaccines, for which he highlighted a few studies and other updates that may be of interest to ACIP. For COVID-19, although currently available vaccines are highly effective at preventing severe disease, infection and death, there is significant interest in mucosal vaccines that could potentially reduce transmission of the virus and/or asymptomatic disease. In November, the National Institute of Allergy and Infectious Diseases (NIAID) co-hosted a workshop on the science of developing mucosal vaccines for SARS-CoV-2. The workshop highlighted what is known, gaps in the field, and a potential path forward. A link to the manuscript that summarizes the workshop will be provided in the written comments. Related to the need for advancing next generation vaccines, Project NextGen was announced in May 2023. Project NextGen is a coordinated effort through which NIAID and BARDA will work with the private sector to advance a pipeline of new innovative vaccines into clinical trials. NIAID's efforts are going to focus on a structured program evaluating multiple next-generation COVID-19 vaccines in Phase 1 and Phase 2 clinical trials. A link will be provided in the written comments, but it can also be found just by searching "NIAID Project NextGen." Shifting to tuberculosis (TB), a clinical trial testing a freeze-dried, temperature-stable TB vaccine was found to be safe and effective in simulated antibodies, as well as the cellular immune response. A non-stable temperature form had previously been studied, but this is the first time any subunit TB vaccine in a temperature-stable form has been evaluated, which is critical in terms of thinking about how to roll out a TB vaccine. For influenza, a clinical trial of an experimental mRNA universal influenza vaccine developed by NIAID's Vaccine Research Center (VRC) began enrolling volunteers at Duke. This is the first investigational universal influenza vaccine candidate tested by the Collaborative Influenza Vaccine Innovation Center (CIVIC) Program, which is a program to advance more durable, broadly protective and longer lasting influenza vaccines. The approval of RSV vaccines marks

an important step toward protecting the nation from this serious respiratory disease. It is important to highlight that that accomplishment is a result of decades of scientific discovery and research funded by the NIH and many other groups. The development of effective vaccines takes time. It is a series of incremental discoveries and steps, but good science is fundamental to getting effective vaccines like the ACIP voted on the previous day. For HIV, May 18, 2023 marked 26th anniversary of HIV Vaccine Awareness Day. An effective, safe, long-lasting HIV vaccine remains crucial for ending the HIV pandemic worldwide. However, HIV continues to pose a formidable challenge to vaccine development due to its ability to mutate rapidly and heighten reservoirs that the immune system cannot reach. The NIH applauds efforts of the global community of scientists, advocates, study participants, and funders enabling unprecedented levels of innovation and adaptation in pursuit of a highly effective HIV vaccine. There are several other updates and links for which he referred listeners to the written comments.

Office of Infectious Disease and HIV/AIDS Policy

CDR Valeria Marshall, MPH, PMP reported that in the National Vaccine Program, housed within the Office of Infectious Disease and HIV/AIDS Policy (OIDP), is working on the progress report for the "Vaccines Federal Implementation Plan" and will work with federal agencies over the summer to provide their progress across goals and strategies. The National Vaccine Advisory Committee (NVAC) convened on June 16-17, 2023. In an effort to be responsive to emerging challenges and immunization, select agenda topics included preparing for the potential approval of passive immunization products, restoring vaccination rates in the post-pandemic period, and addressing clinician fatigue. The committee updated their progress on 2 ongoing charges, including the charge on vaccine innovations and vaccine safety.

PNEUMOCOCCAL VACCINES

Introduction

Katherine A. Poehling, MD, MPH (ACIP WG Chair) reminded everyone that pneumococcal vaccines currently recommended for use in the US include PCV13 and PCV20 for adults. PCV13 and PCV15 are recommended for children. PPSV3 has a risk-based recommendation for children. PPSV3 is recommended for adults who previously received PCV13 or PCV15, but not for those receiving PCV2020. The goal is to move forward with fewer differences. As a reminder, all children under 2 years of age have the same pneumococcal vaccine recommendation for 3 primary series and a booster, often known as the 3 + 1 schedule. The primary series doses are administered at 2, 4, and 6 months and the booster is given at 12 to 15 months later. Currently, either PCV13 or PCV15 can be given to US children. Children with certain underlying conditions are recommended to receive PPSV23. Children with chronic medical conditions (CMC), cerebrospinal fluid (CSF) leak, and cochlear implants are recommended to receive PPSV23 ≥8 weeks after the conjugate vaccine. Children with immunocompromising conditions are recommended to receive PPSV23 ≥8 weeks after the conjugate vaccine. Then ≥5 years later, a second dose of PPSV23 is recommended. Children 6–8 years of age with CMC can receive PPSV23 if they did not receive pneumococcal conjugate vaccine. Of note, CMC includes chronic heart disease (CHD), chronic lung disease (CLD),and diabetes mellitus (DM).

An extended indication for PCV20 use among children was approved on April 27, 2023. Pediatric PCV15 use was approved in June 2022. Both PCV15 and PCV20 were approved based on safety and immunogenicity data compared with PCV13. There are no direct PCV15 vs PCV20 comparisons. Unknown clinical implications include numerically lower antibody responses vs PCV13 and numerically higher antibody response against serotype 3 in PCV15 vs PCV13.

With all of this in mind, the WG considered the following policy questions:

- ❑ Should PCV20 be recommended as an option for pneumococcal conjugate vaccination according to currently recommended dosing and schedules for US children aged <2 years?

- ❑ Should PCV20 without PPSV23 be recommended as an option for pneumococcal vaccination for US children aged 2─18 years of age with underlying medical conditions that increase the risk of pneumococcal disease?

Presentations during this session focused on and economic analysis and public health impact of PCV20 use in children presented by Dr. Charles Stoecker (Tulane University); a comparison of cost-effectiveness analyses on PCV20 use in children by Dr. Ayabina Diepreye (CDC/NCIRD); a summary of the WG's interpretation on EtR and policy options presented by Dr. Miwako Kobayashi (CDC/NCIRD); the VFC Resolution presented by Dr. Jeanne Santoli (CDC/NCIRD); and the following 5 votes:

Vote #1: Routine PCV Use for All Children aged <24 Months

Miwako Kobayashi, MD, MPH (CDC/NCIRD) displayed and read the proposed vote language following the public comment period. The vote was combined with the Pneumococcal Vaccine Session for ease of reading:

> Use of either PCV15 or PCV20 is recommended for all children aged 2–23 months according to currently recommended PCV dosing and schedules.

Motion/Vote #1: Routine PCV Use for All Children aged <24 Months

Dr. Cineas made a motion to approve the recommendation as stated, which Ms. Bahta seconded. No COIs were declared. The motion carried with 14 affirmative votes, 0 negative votes, and 0 abstentions. The disposition of the vote was as follows:

14 Favored: Bahta, Bell, Brooks, Chen, Cineas, Daley, Kotton, Lee, Loehr, Long, McNally, Poehling, Sanchez, Talbot
0 Opposed: N/A
0 Abstained: N/A

Vote #2: Catch-Up PCV Doses for Children Aged 24–71 Months with an Incomplete PCV Vaccination Status

Miwako Kobayashi, MD, MPH (CDC/NCIRD) displayed and read the proposed vote language following the public comment period. The vote was combined with the Pneumococcal Vaccine Session for ease of reading:

> For children with an incomplete PCV vaccination status, use of either PCV15 or PCV20 according to currently recommended PCV dosing and schedules for:
> - Healthy children aged 24–59 months
> - Children with specific risk conditions* aged 24–71 months
>
> *Risk conditions include: cerebrospinal fluid leak; chronic heart disease; chronic kidney disease (excluding maintenance dialysis and nephrotic syndrome, which are included in immunocompromising conditions); chronic liver disease; chronic lung disease (including moderate persistent or severe persistent asthma); cochlear implant; diabetes mellitus; immunocompromising conditions (on maintenance dialysis or with nephrotic syndrome; congenital or acquired asplenia or splenic dysfunction; congenital or acquired immunodeficiencies; diseases and conditions treated with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and solid organ transplant; HIV infection; and sickle cell disease and other hemoglobinopathies).

Motion/Vote #2: Catch-Up PCV Doses for Children Aged 24–71 Months with an Incomplete PCV Vaccination Status

Dr. Daley made a motion to approve the recommendation as stated, which Dr. Long seconded. No COIs were declared. The motion carried with 14 affirmative votes, 0 negative votes, and 0 abstentions. The disposition of the vote was as follows:

14 Favored: Bahta, Bell, Brooks, Chen, Cineas, Daley, Kotton, Lee, Loehr, Long, McNally, Poehling, Sanchez, Talbot
0 Opposed: N/A
0 Abstained: N/A

Vote #3: Children Aged 2–18 Years with Any Risk Condition Who Have Completed Their Recommended PCV Doses Before Age 6 Years

Miwako Kobayashi, MD, MPH (CDC/NCIRD) displayed and read the proposed vote language following the public comment period. The vote was combined with the Pneumococcal Vaccine Session for ease of reading:

> For children aged 2–18 years with any risk condition who have received all recommended doses before age 6 years:
> - Using ≥1 dose of PCV20: No additional doses of any pneumococcal vaccine are indicated. This recommendation may be updated as additional data become available.
> - Using PCV13 or PCV15 (no PCV20): A dose of PCV20 or PPSV23 using previously recommended doses and schedule is recommended.

Motion/Vote #3: Children Aged 2–18 Years with Any Risk Condition Who Have Completed Their Recommended PCV Doses Before Age 6 Years

Dr. Long made a motion to approve the recommendation as stated, which Ms. Bahta seconded. No COIs were declared. The motion carried with 14 affirmative votes, 0 negative votes, and 0 abstentions. The disposition of the vote was as follows:

14 Favored: Bahta, Bell, Brooks, Chen, Cineas, Daley, Kotton, Lee, Loehr, Long, McNally, Poehling, Sanchez, Talbot
0 Opposed: N/A
0 Abstained: N/A

Vote #4: Children Aged 6–18 Years with Any Risk Condition Who Have Not Received Any Dose of PCV

Miwako Kobayashi, MD, MPH (CDC/NCIRD) displayed and read the proposed vote language following the public comment period. The vote was combined with the Pneumococcal Vaccine Session for ease of reading:

> For children aged 6–18 years with any risk condition who have not received any dose of PCV13, PCV15, or PCV20, a single dose of PCV15 or PCV20 is recommended at least 8 weeks after the most recent dose of pneumococcal vaccine. When PCV15 is used, it should be followed by a dose of PPSV23 at least 8 weeks later if not previously given.

Motion/Vote #4: Children Aged 6–18 Years with Any Risk Condition Who Have Not Received Any Dose of PCV

Dr. Sánchez made a motion to approve the recommendation as stated, which Dr. Daley seconded. No COIs were declared. The motion carried with 14 affirmative votes, 0 negative votes, and 0 abstentions. The disposition of the vote was as follows:

14 Favored: Bahta, Bell, Brooks, Chen, Cineas, Daley, Kotton, Lee, Loehr, Long, McNally, Poehling, Sanchez, Talbot
0 Opposed: N/A
0 Abstained: N/A

Vote #5: VFC Resolution

Jeanne Santoli, MD, MPH (CDC/NCIRD) displayed and read the proposed vote language following the public comment period. The vote was combined with the Pneumococcal Vaccine Session for ease of reading:

> Approve the Vaccines for Children (VFC) resolution for pneumococcal pneumonia.

Motion/Vote #5: VFC Resolution

Ms. Bahta made a motion to approve the recommendation as stated, which Dr. Sánchez seconded. No COIs were declared. The motion carried with 14 affirmative votes, 0 negative votes, and 0 abstentions. The disposition of the vote was as follows:

14 Favored: Bahta, Bell, Brooks, Chen, Cineas, Daley, Kotton, Lee, Loehr, Long, McNally, Poehling, Dr. Sánchez, Talbot
0 Opposed: N/A
0 Abstained: N/A

DENGUE VACCINE

Brief Summary

The Dengue Vaccines schedule included a session introduction by Dr. Wilbur Chen (ACIP, WG Chair); introduction of policy questions for TAK-003 by Dr. Alfonso Hernandez (CDC/NCEZID); presentation of a cost-effectiveness analysis and the health impacts of routine vaccination with TAK-003 dengue vaccine in Puerto Rico by Dr. Guido Espana (University of Notre Dame); a summary of two economic models for dengue vaccine TAK-003 use in Puerto Rico by Dr. RajReni Kaul (CDC/NCIRD); and a presentation of the partial EtR framework for TAK-003 by Dr. Joshua Wong (CDC/NCEZID). No votes were taken on this topic during this meeting.

CHIKUNGUNYA VACCINE

Brief Summary

The Chikungunya Vaccine session included a session introduction by Dr. Beth Bell (ACIP, WG Chair); a presentation on the value of chikungunya vaccine to US travelers and providers by Ms. Nicole Lindsey (CDC/NCEZID); and presentations on chikungunya virus infection among laboratory workers, a large chikungunya outbreak in Paraguay, and WG plans and timelines by Dr. Susan Hills (CDC/NCEZID). No votes were taken on this topic during this meeting.

RESPIRATORY SYNCYTIAL VIRUS VACCINES: PEDIATRIC/MATERNAL

Brief Summary

The Respiratory Syncytial Virus Vaccines: Pediatric/Maternal session included a session introduction by Dr. Sarah Long (ACIP, WG Chair); a presentation on an economic analysis of RSVpreF in pediatric populations by Dr. David Hutton (University of Michigan); a presentation on the EtR of Pfizer maternal RSV vaccine by Dr. Katherine Fleming-Dutra (CDC/NCIRD); a presentation on an economic analysis of the combined use of nirsevimab and maternal RSVpreF vaccine by Dr. David Hutton (University of Michigan); and a presentation on clinical considerations for RSV maternal vaccine and nirsevimab by Dr. Jefferson Jones (CDC, NCIRD). No votes were taken on this topic during this meeting.

PUBLIC COMMENTS

The floor was opened for public comment on June 22, 2023 at 4:50 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 Number ID CDC-2023-0035. Visit http://www.regulations.gov for access to the docket or to submit comments or read background documents and comments received. The public comment session occurred prior to the votes, but the votes were connected back with their respective sessions for ease of reading.

Mr. Joaquín Beltrán
Biden/Harris 2020 Regional Director
Small Retail Investor of Novavax Vaccine

Thank you for having me. Full transparency, I was a Biden/Harris 2020 Regional Director and currently am a small retail investor of Novavax vaccine's ongoing availability, vaccinated with 2 Pfizers, 1 Novavax, and never had COVID. My name is Joaquín Beltrán. Today I am calling on the CDC to fulfill its specific mission to control and prevent disease. Here are the specific actions to take: 1) make Novavax's updated XBB.1.5 booster available upon manufacturing completion; 2) update booster guidelines for equal access and allow for multiple boosters to improve protection; 3) expand Novavax access to everyone 6 months and up; 4) bring back mask requirements in healthcare savings; and 5) bring back testing and data. Here are some stories on why these actions are important. My friend Robbie, who has been suffering from long-COVID for years, her mother was recently in the hospital for a non-COVID issue. She acquired COVID in the hospital and died from that very infection—a tragic and preventable death. My grandma and my dad, who both have long COVID, my grandma for whom I am a caregiver—they have been experiencing long-COVID after their infections. Both have circulation issues and their quality of life has not been the same. Other friends, in trying to protect themselves, many have had to lie or go out of state, or the country even, to obtain a Novavax vaccine because of current language in the guidelines, specifically the line that reads, "but have not previously received a COVID-19 booster and if they cannot or will not receive mRNA vaccines." This language should be removed immediately. Other friends have lost all sources of income due to disability and others are currently in this very moment being evicted from their homes because of long-COVID. These stories are not unique to people I know. Millions are suffering and going through this suffering from long-COVID and through this financial hardship. Moreover, hospitals are collapsing from shortages, from thousands of healthcare workers who have died from COVID, many more who have become disabled, and from increased overall morbidity in the population from the CDC's de facto mass reinfection policy that creates cumulative risk—cumulative risk of heart attacks, stroke, brain damage, Type 1 diabetes in children, immune dysregulation, and much more. I am urging the CDC to take immediate action to protect our families and communities by: 1) making Novavax's updated XBB.1.5. booster available upon manufacturing completion; 2) updating booster guidelines for equal access and allow for multiple boosters to improve protection; 3) expanding Novavax access to everyone 6 months and older; 4) bringing back mask requirements in healthcare settings; and 5) bringing back testing and data. Thank you so much for your time.

Dorit Reiss, JD, PhD
Professor of Law
University of California San Francisco

Hello, my name is Dorit Reiss. I am a Professor of Law at UC San Francisco. Thank you for the opportunity to again comment to the committee. I have 3 points to make first following the committee's careful critical discussion of RSV vaccines both yesterday and today, the penetrating question about the data, and the thoughtful way of the discussion. Frist, I'd like to thank both the committee and the WGs for their extensive work on this. This meeting always shows the extensive data and work behind every vaccine decision, with reams of information provided, though you have to boil it down to relatively short presentation. More than ever, I think this meeting shows us how hard it is to make decisions when you don't have full information, which you rarely do, but this is a little more extreme than usual. It's exactly in this situation where we need the expert input of a committee like ACIP even more than when the data is clear. I'd like to reinforce the committee members' comments that we need data before the committee gets to a vote, but I would like to finish by reminding the committee and CDC on this point that the vaccine-recommended under "shared clinical decision-making" may be treated by doctors as less important and not recommended. I hope that any materials sent out will remind doctors of the risk of the diseases and vaccines they're recommending for in this way and set out clearly that at least a discussion of the vaccine is recommended. The shared clinical decision-making shouldn't be "don't talk about it," but should be "at least talk about it." Second, since we discussed dengue and chikungunya vaccine today, and following yesterday's discussion of the reemergence of polio, I want to use those to remind everyone of the importance of covering these diseases and looking for the safety of the citizens of our territories as much as of the states, and generally, the importance of addressing so-called neglected tropical diseases, which are not really tropical, including by funding and promoting vaccination against them. Thank you for highlighting the larger burden of these outbreaks both in deaths and in other ways they are harming, and of course, in this age of climate change and travel, diseases don't stay. They will be coming beyond their borders, and we need to look at them for more selfish reasons as well. A bit off topic, this is a chance to remind everyone of the importance of protecting our vaccine scientists from harassment. To build on this last point, I want to remind people that although anti-vaccine harassment has always been part of the reality of people responding to this information, as several of our scientists can testify, it's been going more extreme, more virulent, and the volume has grown. Although CDC and ACIP have an important role in providing good information, they're not going to be in the front of line of debunking. But I hope CDC makes sure that its scientists and ACIP experts have the support and protection they need to do the job safely and with resources and answers when harassed, and I would encourage other institutions to support scientists to speak up as well. Thank you.

Patricia Neuenschwander, PNP
Pediatric Nurse Practitioner

Good evening. I would love to stand before you and commend this committee on their rigorous evaluation of high-quality studies used to make recommendations, but I can't. I am a nurse who was a defender of vaccine safety and efficacy, a nurse who dutifully vaccinated her children and herself, confidently trusting that the CDC recommendations were based on a rigorous evaluation of high-quality studies. I now know that was a lie. I sat yesterday listening to Dr. Talbot express her legitimate concerns over the RSV studies. When those concerns were not addressed, she did not vote "no." She abstained. This is not scientific discourse. It is a pressure cooker for experts in the field to vote unanimously for anything that is put forward giving the illusion of consensus. I want to focus the remainder of my comments specifically on the

inadequate RSV vaccine science used yesterday and that is being used today with pregnant women. They did not study the people who would potentially benefit—people over 75, nursing home patients, patients with the usual amount of comorbid conditions, or the immune compromised. Applying the questionable data from one healthy group to another group that has far more risk and yet not studied, is scientifically unsound. Immunogenicity trials are inadequate. There are no established immune correlates of protection. We know nothing about additional doses or the coadministration with vaccines other than a small number who received a flu vaccine. The factual evidence presented from the GRADE evaluations did not show benefit with hospitalization, severe illness, or death, probably because the population used was healthy. We will never know now, but I'm sure that you will use suboptimal, biased observational studies in the future to try and show it does. The actual science shows that it *may* reduce hospitalization for RSV illness, but the effect is very uncertain and a very low-evidence type. It *may* impact severe RSV illness requiring supplemental oxygen and other support, but the effect is very uncertain and a very low-evidence type. Yet you'll tell providers and the American people that it prevents severe disease and hospitalizations. These issues are not unique to the RSV vaccine trials. I have watched again and again as ACIP gave blanket approvals to COVID vaccines and boosters with equally questionable data. This is why you have anti-vaxxers. You are losing credibility and trust with frontline healthcare workers, and you have lost credibility and trust with the majority of Americans because you are allowing junk science and industry influence to determine your decisions. The CDC has settled too long for data that is poor, inadequate, or no data. It's time to modernize, demand rigorous science, embrace transparency, and engage in free and open debate or the entire vaccine program will die. Thank you.

David Wiseman, PhD
Research Bioscientist
Synechion, Inc.

Thank you very much. Please see our written remarks. FDA has just advised developing XBB.1.5 COVID monovalents. This strategy seems destined to fail with the currently low death rate despite the 17% bivalent uptake. Do people agree with Dr. Offit that chasing variants is a losing game? Already 3 months after introduction, the bivalents were alarmingly evaded by XBB according to Wang and other studies omitted from FDA's January brief. Cleveland Clinic noted that they were not alone in finding a possible association with more vax doses and higher risk of COVID, and last week, that COVID risk is lower in out-of-date than up-to-date adults. CDC interprets otherwise, but their data echoes others with rapid waning to negative [unclear] suggesting immune compromise. Rouzine in *Nature* and FDA's brief suggest vaccination influences evolution and natural selection of escaped variants. Recall Dr. Long's comments in January 22 that "repeated whack-a-mole boosting was unsustainable." Let's chase safety, not variants. Temporal associations between vax coverage and all-cause mortality persist. Why did it take until March for myocarditis to appear in Janssen's factsheet and CDC and FDA to report this potential safety concern in the Wu paper? We flagged this signal to ACIP in late 2021. Why can't they find a stroke signal outside of VSD when it appears in CDC's VAERS FOIA release in January? That same release shows cancer signals, but still no cancer genotoxic or mutagenicity studies, and yet the National Cancer Institute shows reverse transcription is possible. NIH showed message and spike into the nucleus. Episomal transmission does not need integration. FDA's Dr. Peden writes "DNA can be oncogenic." There are reports of possibly replication-competent residual plasmid template DNA with antibiotic-resistance and undisclosed SV40 promoter sequences at levels above guidelines, suggesting adulteration. Excluding these gene therapies from guidance does not change biology or safety concerns. FDA extrapolates further the chasm between EUA "may be effective" and the regular safe and effective standards. The bivalents yield novel heterotrimers with untested tox and likely misbranding. Dr. Sanchez's

question last year about spike kinetics remains unanswered, with no FDA insistence for these studies. Lipid nanoparticles widely distribute, spike persists for up to 4 months, mRNA up to 28 days. If you can't say where and for how long these gene therapies induce spike production, you shouldn't be asking people to vax. Dr. Fauci, in *Cell*, writes "vaccines have never effectively controlled these sorts of vaccines, and are not expected to do so." Dr. Marks, in *JAMA*, questions incrementally modifying variant-specific vaccines. Regulate these products as gene therapies, no free passes to poorly understood platforms. Thank you very much.

Mr. Burton Eller
Executive Director of Advocacy
National Grange

My name is Burton Eller. I'm the Executive Director of Advocacy for the National Grange. Founded in 1867, the Grange is the oldest national organization advocating for Americans living in rural and small-town America. Our mission is to work together to support and advance the safety, health, economic security, and well-being of those who have chosen a rural way of life. We are here today to continue our effort to highlight the vulnerability of our communities to respiratory diseases, and to share our support for ensuring that older Americans most vulnerable to RSV have access to the newly FDA-approved vaccines before the start of the respiratory season. As you may know, rural Americans face an elevated risk of serious illnesses from respiratory diseases. These are due to a number of factors, including the fact that rural Americans are less likely to have health insurance and have less access to healthcare as more and more rural hospitals are closing their doors. A lack of reliable broadband also limits rural Americans' ability to access healthcare services. Additionally, rural areas have a higher percentage of Americans aged 65 and older versus urban areas. While the COVID-19 pandemic, in ways, helped shine light on the positive aspects of living outside of cities, the resulting migration of urban residents to rural areas has also put an added strain on our already limited resources. As we saw more adults suffering from RSV last fall and winter, it was almost reminiscent of the beginning of the COVID pandemic. News outlets throughout the country were once again reporting the challenges that remaining rural hospitals faced as they tried to cope with the influx of patients needing care, with no space to offer them. Fortunately, with long-awaited development and approval of an RSV vaccine, we have the tools to protect ourselves. We thank the committee for your thoughtful consideration of who would be the best served by these vaccines, but we are concerned that these vote for the shared clinical decision-making may create a rather disproportionate impact on rural seniors. Rural providers are stretched thin, and their patients tend to be older and sicker. In urban areas, there are 31 physicians for every 10,000 people, compared to just 13 physicians in rural areas, and there are fewer clinical facilities like clinics and pharmacies. While we believe every American should have the choice of whether to receive a vaccine, we also want to ensure equitable access to the information of what vaccines are available and why they are so important. For rural seniors who do not have easy access to their clinician, any extra step, we fear, could reduce the likelihood that these patients will gain access to these protections. Regardless, we are encouraged by those aged 60 years and older who will have the opportunity to consider a protection against RSV, and hope the recommendations are reconsidered in the future as we have more data to indicate whether these most vulnerable communities are truly and adequately being served. Thank you.

Miss Elizabeth Ditz
Potential RSV Vaccine Recipient

My name is Liz Ditz and I live in San Mateo County, California. Thank you all and to the committee for the time and expertise that you donate to the nation to improve public health. I'm especially grateful to Dr. Camille Nelson Kotton this morning for sharing on Twitter the key benefits of the RSV vaccine. I am speaking as a potential RSV vaccine recipient. I'm over 65 and have other risk factors for infection with RSV. I am grateful that the committee voted to approve the vaccine, and I'm disappointed that the recommendation is that my age cohort "may" get the vaccine with shared decision-making rather than we "should" get the vaccine. Here's why. I've been an advocate for vaccines in my community, both in-person and online, for over 20 years. Until relatively recently, I had no idea that RSV was a significant health risk for people over 60. I thought it was only a risk for infants, especially those born prematurely. It's hard to sell a health intervention like a vaccine if the intended recipient has no idea that the disease prevented is a risk for the recipient. Most people in my age cohort that I know were eager to get the Shingrix vaccine because the suffering caused by shingles is common knowledge. Most people in my age cohort that I know have been vaccinated against pneumococcal disease because of the significant drop in quality of life and hospitalization for pneumonia is common knowledge. Most people in my age cohort that I know do take an annual flu vaccine because a risk of flu in our age group is common knowledge. And yes, many in my age cohort do get their flu vaccines and others through vaccine clinics or pharmacies. In other words, the vaccine recipient drives the decision to get the vaccine—not a physician or other healthcare provider. We are in a dangerous era where influential sources are blatantly anti-science. What is the plan to explain to older Americans that this is a disease that does not just kill, but significantly impairs their quality of life? After an ICU stay and hospitalization, it takes a while to return to pre-illness baseline quality of life, independence, and mobility. Because these vaccines will be covered under Medicare Part D and thus administered in pharmacies rather than physicians' offices, what is the plan to educate not just the vaccine-giving pharmacists, but all client-facing pharmacy staff have to educate elders? I appreciate that the committee voted for "may" rather than "shall" because of a lack of data. What is the plan to collect post-approval data, especially in the 80-and-over age cohort? What's the plan for this committee to reconsider this data and to change "may" to "shall?" Again, thank you all for your hard work, and I hope that this vaccine will be reconsidered soon.

Shinsuke Yamamoto
Member, Protect Our Future

Hi, thank you. My name is Shin Yamamoto. I'm a husband, father of 2 kids ages 3 and 9, and a member of the group Protect Our Future, a nonprofit advocating for equitable healthcare and COVID-19 vaccine access for children of all ages. We've led a fairly cautious lifestyle since March 2020 between waiting for vaccinations for all of us and trying to reduce adverse outcomes for my wife, who is now on B-cell depletion therapy for her relapsing and remitting multiple sclerosis. Considering the problems of autoimmune disease and other chronic illnesses in this country, I don't think we're an isolated case. Many like us have had to make hard choices and accept an elevated level of risk that comes with reintegrating into society. I support and welcome the updated COVID-19 vaccine boosters coming from various manufacturers. I would, however, like to see simultaneous availability across all ages, which we have not had up to now. This is the most equitable option and one that will ultimately help those of us most at risk who still have to balance our health and the daily lives of our families. Accessibility for pediatric vaccines has been an issue, and I would like to see that addressed as well. Finding a vaccine for your kids should not be as difficult as finding a popular Christmas toy in stock. The same

thought applies for any vaccination for RSV, which was a cause for so many sick kids in 2022. That is all. Thank you.

FRIDAY: JUNE 23, 2023

MPOX VACCINES

Brief Summary

The Mpox Vaccines session included a session introduction by Dr. Pablo Sanchez (ACIP, WG Chair); updates from the 2022/2023 US Mpox Outbreak: Epidemiology, Vaccine Safety, and Vaccine Effectiveness by Dr. Faisal Minhaj (CDC/NCEZID); and presentations on clinical guidance for the use of JYNNEOS during Mpox outbreaks and considerations for long-term protection against Mpox by Dr. Agam Rao (CDC/NCEZID). No votes were taken on this topic during this meeting.

MENINGOCOCCAL VACCINES

Brief Summary

The Meningococcal Vaccines Session included a session introduction by Dr. Kathy Poehling (ACIP, WG Chair); a presentation on a cost-effectiveness analysis by Dr. Ismael Ortega-Sanchez (CDC/NCIRD); and presentations on GRADE/EtR and a summary and WG considerations by Dr. Sam Crowe (CDC/NCIRD). No votes were taken on this topic during this meeting.

VACCINE SAFETY

Brief Summary

The Vaccine Safety Session included a presentation of the background on the CDC Immunization Safety Office (ISO) and ISO efforts to evaluate studying the safety of the childhood immunization schedule by Dr. Tom Shimabukuro (CDC/NCEZID); a presentation on the childhood immunization schedule and safety from studies in the Vaccine Safety Datalink (VSD) by Dr. Matthew Daley (Kaiser Permanente Colorado); and a presentation on the preliminary evaluation of aluminum content in childhood vaccines and the risk of asthma in a Danish nationwide cohort by Dr. Anders Hviid (Statens Serum Institut, Copenhagen, Denmark). No votes were taken on this topic during this meeting.

COVID-19 VACCINES

Brief Summary

The COVID-19 Vaccines Session included a session introduction by Dr. Matthew Daley (ACIP WG Chair); a presentation of updates to COVID-19 epidemiology and vaccine effectiveness (VE) by Dr. Fiona Havers (CDC/NCIRD), Dr. Romeo Galang (CDC/NCCDPHP), and Dr. Ruth Link-Gelles (CDC/NCIRD); a presentation on infection-induced and hybrid immunity by Dr.

Jefferson Jones (CDC/NCIRD); and a summary and presentation of WG considerations by Dr. Megan Wallace (CDC/NCIRD. No votes were taken on this topic during this meeting.

CERTIFICATION

Upon reviewing the foregoing version of the June 21-23, 2023 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
ABCs	Active Bacterial Core Surveillance System
ACA	Affordable Care Act
ACHA	American College Health Association
ACIP	Advisory Committee on Immunization Practices
ACOG	American College of Obstetricians and Gynecologists
ACP	American College of Physicians
ADE	Antibody-Dependent Enhancement
ADHD	Attention Deficit Hyperactivity Disorder
AE	Adverse Event
AESI	Adverse Event of Special Interest
AHIP	America's Health Insurance Plans
AI/AN	American Indian/Alaskan Native
AIDP	Acute Inflammatory Demyelinating Polyneuropathy
aIIV	Adjuvanted Influenza Vaccine
AIM	Association of Immunization Managers
AIRA	American Immunization Registry Association
AMA	American Medical Association
AMETHST	American **T**ransformative **H**IV **S**tudy
AMIS	American Men's Internet Survey
AOA	American Osteopathic Association
AOM	Acute Otitis Media
APhA	American Pharmacists Association
AR	Adverse Reaction
ARI	Acute Respiratory Illness
ASPR	Administration for Strategic Preparedness and Response
ASTHO	Association of State and Territorial Health Officers
AUC	Area Under the Curve
BARDA	Biomedical Advanced Research and Development Authority
BEST System	Biologics Effectiveness and Safety System
BLA	Biologics License Application
CBER	Center for Biologics Evaluation and Research
CBO	Community-Based Organization
ccIIV4	Cell-Culture Based Vaccine
CDC	Centers for Disease Control and Prevention
CHD	Chronic Heart Disease
CHIKV	Chikungunya Virus
CHIP	Children's Health Insurance Program
CICP	Countermeasures Injury Compensation Program
CISA	Clinical Immunization Safety Assessment Project
CLD	Chronic Lung Disease
CLI	COVID-Like Illness
CMC	Chronic Medical Conditions
CMS	Center for Medicare and Medicaid Services

CMV	Cytomegalovirus
COI	Conflict of Interest
CONUS	Continental United States
COPD	Chronic Obstructive Pulmonary Disease
COVID-NET	Coronavirus Disease 2019 (COVID-19) Hospitalization Surveillance Network
CSF	Cerebrospinal Fluid
CSTE	Council of State and Territorial Epidemiologists
CVD	Cardiovascular Disease
cVDPV2	Circulating Vaccine-Derived Poliovirus Type 2
DCAC	Dengue Case Adjudication Committee
DENV	Dengue Virus
DFO	Designated Federal Official
DM	diabetes mellitus
DoD	Department of Defense
DSMB	Data Safety Monitoring Board
DUA	Data Use Agreement
DVA	Department of Veterans Affairs
eCRF	Electronic Case Report Form
ED	Emergency Department
EIND	Emergency Investigational New Drug
EMA	European Medicines Agency
EMDS	Enhanced Meningococcal Disease Surveillance
EMR	Electronic Medical Record
ET	Eastern Time
EtR	Evidence to Recommendation
EU	European Union
EUA	Emergency Use Authorization
FAERS	FDA Adverse Event Reporting System
FAS	Freely Associated States
FDA	Food and Drug Administration
FluSurv-NET	Influenza Hospitalization Surveillance Network
FQHC	Federally Qualified Health Centers
FRN	Federal Register Notice
FRPP	Federal Retail Pharmacy Program
GACVS	Global Advisory Committee on Vaccine Safety
GBS	Guillain-Barré Syndrome
GDP	Gross Domestic Product
GISAID	Global Initiative on Sharing All Influenza Data
GMC	Geometric Mean Concentrations
GMT	Geometric Mean Titers
GPEI	Global Polio Eradication Initiative
GRADE	Grading of Recommendation Assessment, Development and Evaluation
HCP	Healthcare Personnel / Providers
HD-IV	High-Dose Influenza Vaccine
HHS	(Department of) Health and Human Services
HIV	Human Immunodeficiency Virus
HRSA	Health Resources and Services Administration
HSCT	Hematopoietic Stem Cell Transplant
HZ	Herpes Zoster

IC	Immunocompromising Conditions
ICERs	Incremental Cost Effectiveness Ratios
ICU	Intensive Care Unit
IDMC	Independent Data Monitoring Committee
IDSA	Infectious Disease Society of America
IHS	Indian Health Service
IIS	Immunization and Infectious Diseases
IIS	Immunization Information System
IIV	Inactivated Influenza Vaccine
ILINet	Influenza-like Illness Surveillance Network
IM	Intramuscular
IMD	Invasive Meningococcal Disease
IPD	Invasive Pneumococcal Disease
IPV	Inactivated Polio Vaccine
IRA	Inflation Reduction Act of 2022
ISD	Immunization Services Division
IV	Intravenous
IVIG	Intravenous Immune Globulin
IVWG	Federal Interagency Vaccine Workgroup
IVY	Investigating Respiratory Viruses in the Acutely Ill
LGBTQ+	Lesbian, Gay, Bisexual, Transgender, Queer or Questioning, or Other
LRTD	Lower Respiratory Tract Disease
LRTI	Lower Respiratory Tract Illness
LTCF	Long-Term Care Facilities
MAAEs	Medically Attended Adverse Events
MACDP	Metropolitan Atlanta Congenital Defects Program
MATISSE	Maternal Immunization Study for Safety and Efficacy
MELODY	Prevention of Medically Attended Lower Respiratory Tract Infection Due to Respiratory Syncytial Virus in Healthy Late Preterm and Term Infants
MFS	Miller Fisher Syndrome
MICH	Maternal, Infant, and Child Health
MIS-C	Multisystem Inflammatory Syndrome in Children
MMWR	*Morbidity and Mortality Weekly Report*
MoH	Ministry of Health
MSM	Men Who Have Sex with Men
NACCHO	National Association of County and City Health Officials
NACI	National Advisory Committee on Immunization Canada
NAMCS	National Ambulatory Medical Care Survey
NAPNAP	National Association of Pediatric Nurse Practitioners
NBP	Nonbacteremic Pneumonia
NCCDPHP	National Center for Chronic Disease Prevention and Health Promotion
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NCHS	National Center of Health Statistics
NCIRD	National Center for Immunization and Respiratory Diseases
NDC	National Drug Code
NDCMC	Newly Diagnosed Chronic Medical Conditions
NFID	National Foundation for Infectious Diseases
NHANES	National Health and Nutrition Examination Survey
NHP	Non-Human Primate

NHSN	National Healthcare Safety Network
NIAID	National Institute of Allergy and Infectious Diseases
NICU	Neonatal Intensive Care Unit
NIH	National Institutes of Health
NIS	National Immunization Survey
NMA	National Medical Association
NNDSS	National Notifiable Diseases Surveillance System
nOPV2	Novel Oral Polio Vaccine, Type 2
NP	Nasopharyngeal
NREVSS	National Respiratory and Enteric Virus Surveillance System
NSSP	National Syndromic Surveillance Program
NSTEMI	Non-ST-Elevation Myocardial Infarction
NVAC	National Vaccine Advisory Committee
NVPO	National Vaccine Program Office
NVSN	New Vaccine Surveillance Network
NVSS	National Vital Statistics System
NYS	New York State
OASH	Office of the Assistant Secretary for Health
ODPHP	Office of Disease Prevention and Health Promotion
OGC	Office of General Council
OIDP	Office of Infectious Disease and HIV/AIDS Policy
OP	Oropharyngeal
OPA	Opsonophagocytic Activity
OPV	Oral Polio Vaccine
PCP	Primary Care Provider/Practitioner
PCR	Polymerase Chain Reaction
PCV	Pneumococcal Conjugate Vaccines
PEP	Post-Exposure Prophylaxis
PFFS	Private Fee-For-Service
PHAC	Public Health Agency Canada
PHE	Public Health Emergency
PHEIC	Public Health Emergency of International Concern
PICO	Population, Intervention, Comparison, Outcomes
PIDS	Pediatric Infectious Disease Society
PK	Pharmacokinetics
POTS	Postural Orthostatic Tachycardia Syndrome
PPSV23	Pneumococcal Polysaccharide Vaccine
PPV	Positive Predictive Value
PR	Puerto Rico
PrEP	Pre-Exposure Prophylaxis
QALY	Quality-Adjusted Life Year
QIV	Quadrivalent Inactivated Influenza
RCA	Rapid Cycle Analysis
RCT	Randomized Controlled Trial
RESP-NET	Respiratory Virus Hospitalization Surveillance Network
RSV-NET	Respiratory Syncytial Virus Hospitalization Surveillance Network
SAB	Spontaneous Abortion
SAE	Serious Adverse Event
SAHM	Society for Adolescent Health and Medicine

SD-IIV	Standard-Dose Unadjuvanted Influenza Vaccines
SES	Socioeconomic Status
SHEA	Society for Healthcare Epidemiology of America
SME	Subject Matter Expert
SMFM	Society for Maternal-Fetal Medicine
SNF	Skilled Nursing Facilities
STIs	Sexually Transmitted Infections
SVD	Sudan Virus Disease
TIA	Transient Ischemic Attack
TOR	Terms of Reference
UK	United Kingdom
US	United States
USG	United States Government
USVI	US Virgin Islands
VAERS	Vaccine Adverse Event Reporting System
VDPV	Vaccine-Derived Poliovirus
VE	Vaccine Efficacy
VE	Vaccine Effectiveness
VEPP	Vaccine Equity Pilot Program
VFC	Vaccines For Children
VFIP	*Vaccines Federal Implementation Plan*
VICP	National Vaccine Injury Compensation Program
VNSP	Vaccines National Strategic Plan
VRBPAC	Vaccines and Related Biological Products Advisory Committee
VSD	Vaccine Safety Datalink
VZV	Varicella-Zoster Virus
WG	Work Group
WGS	Whole Genome Sequencing
WHO	World Health Organization
WPV	Wild Poliovirus
ZIKV	Zika Virus