MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

JUNE 26-28, 2024
MEETING SUMMARY

Trade names are used for identification purposes only and do not indicate endorsement.

WEDNESDAY: JUNE 26, 2024

WELCOME AND INTRODUCTIONS

Call to Order

Dr. Keipp Talbot, ACIP Chair, called to order and presided over the June 26-28, 2024, Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) meeting.

Announcements

Dr. Melinda Wharton, ACIP Executive Secretary, CDC, made opening announcements about the availability of presentation slides on the ACIP website and scheduled oral public sessions as well as the written public comment process. She reviewed conflict of interest policies for ACIP members and indicated that CDC is currently soliciting applications and nominations for candidates to fill upcoming vacancies on the ACIP for 4-year terms beginning July 2025. 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 15, 2024.

She welcomed the following 3 new members who were joining the ACIP meeting for the first time and the new ACIP Chair:

- ❑ Denise Jamieson, MD, MPH who is the Vice President for Medical Affairs, Dean of the Carver College of Medicine, and Professor of Obstetrics and Gynecology at the University of Iowa. Her scientific work is focused on emerging infections and vaccines in pregnancy.

- ❑ Robert Schechter, MD, MSc who is Chief of the California Department of Public Health (CDPH) in the Immunization Branch where he has worked for over 20 years. He has served previously on the National Vaccine Advisory Committee (NVAC) and on a number of ACIP Work Groups (WG), including COVID-19, Influenza, and other vaccines.

- ❑ Albert Shaw, MD, PhD, FIDSA who is Professor of Medicine in the Section of infectious Diseases at the Yale School of Medicine. Dr Shaw is an infectious disease physician whose field of expertise is changes in the immune system function in older adults.

- ❑ Keipp Talbot, MD who is the new ACIP Chair. Dr. Talbot has been on ACIP since 2018 and is well known to most of the ACIP members. Dr. Talbot is Professor of Medicine and Health Policy in the Division of Infectious Diseases at Vanderbilt University.

Roll Call

Dr. Keipp Talbot, ACIP Chair, conducted a roll call, 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. No conflicts of interest (COIs) were identified for the first day of this meeting.

PRESENTATIONS

Dr. Camille Kotton, Chair of the ACIP Adult Respiratory Syncytial Virus (RSV) Work Group, began the session by introducing the incoming chair of the work group, Dr. Albert Shaw. Dr. Kotton reminded the committee of the current recommendation for use of RSV vaccine in adults that had been voted on by the committee in June 2023, that adults aged 60 years and older may receive a single dose of RSV vaccine, using shared clinical decision-making (SCDM). This recommendation was not product-specific, and whichever vaccine was available could be administered. She reviewed what had been covered at the February 2024 ACIP meeting, including an analysis comparing the estimated magnitude of public health benefit and potential risk of Guillain-Barré syndrome (GBS) associated with protein subunit RSV vaccination in adults aged 60 years and older. ACIP recommended that adults 60 years and older who remain unvaccinated were encouraged to receive RSV vaccine in the late summer or early fall to optimize public health benefits.

Since the June meeting, the work group had discussed use of Moderna's mRESVIA® in adults aged 60 years and older (approved by FDA May 31, 2024); use of GSK's AREXVY in adults aged 50-59 years at increased risk of severe RSV disease (approved by FDA June 7, 2024); safety of protein subunit RSV vaccines, including risk of GBS; and shifting from a shared clinical decision-making recommendation to an age-based recommendation for adults 75 years of age and older; a risk-based recommendation for adults 60-74 years of age; and a risk-based recommendation for adults 50-59 years of age. These proposed changes were informed by feedback received from healthcare providers on the challenges of implementing a recommendation based on shared clinical decision-making.

Dr. Jim Donahue from the Marshfield Clinic Research Institute provided an update on the Vaccine Safety Datalink's (VSD's) rapid cycle analysis of RSV vaccines in older adults. The VSD is a collaborative project between CDC and 13 integrated healthcare organizations which have data on approximately 13.5M persons. Rapid cycle analysis (RCA) permits rapid assessment of vaccine safety by looking at the incidence of pre-specified outcomes in vaccinated persons compared to the incidence of those outcomes in a comparator group. Sequential analytic methods are used to detect "statistical signals" while maintaining a pre-defined type 1 error rate. Statistical signals are interpreted as potential associations. The RSV RCA looked at persons ≥60 years of age who received an RSV vaccine, with a surveillance period from August 1, 2023, through May 31, 2025. This RCA uses vaccinated concurrent comparators, who are RSV vaccinees who on the same day as the exposed case in a risk interval, were in the same demographic stratum, but in a comparison interval. The RCA looked at both GSK and Pfizer RSV vaccines, with and without simultaneous vaccination and 14 pre-specified outcomes were evaluated. From August 1, 2023 to May 25, 2024, 385,729 doses of RSV vaccine were administered in the VSD sites, of which 87.7% was the GSK vaccine. A statistical signal was detected for immune thrombocytopenia (ITP) among recipients of the GSK vaccine without simultaneous vaccination, but most of the cases were not incident cases. The RCA team plans to do more detailed chart review of ITP cases. There was no statistical signal for GBS (few cases were observed) or atrial fibrillation. Surveillance for all outcomes will continue through May 2025.

Dr. Patricia Lloyd from the Office of Biostatistics and Pharmacovigilance, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA), presented an update on FDA's evaluation of Guillain-Barré syndrome following RSV vaccination among adults 65 years of age and older in fee-for-service Medicare.

The risk of GBS following both GSK's and Pfizer's RSV vaccines was evaluated using a retrospective cohort design with a 2022 historical comparator. The estimated observed incidence rates were compared to the historical comparator rates to obtain incidence rate ratios (IRRs) with 95% confidence intervals. An adjustment for the positive-predictive value (PPV) of a GBS diagnosis code was made using an estimate of PPV of 71%, based on chart review. An elevated IRR was observed for GBS following RSV vaccination. In the PPV-adjusted analysis, only the association for the Pfizer vaccine was statistically significant. This is a crude method that utilized aggregate historical comparator rates, increasing the potential for confounding; statistically significant results of GBS do not establish a causal association between RSV cases and GBS. A self-controlled case series analysis was then undertaken. Current results were based on an analysis of early-season vaccination. An elevated IRR was observed for GBS following the Pfizer vaccine in two analyses that had the least adjustments; results additionally adjusted for PPV were no longer statistically significant. These analyses do not provide clear, conclusive evidence of an elevated risk of GBS and an elevated risk cannot be ruled out; FDA is conducting medical chart review on GBS cases and will continue to evaluate the safety of RSV vaccines as more data are available.

Dr. Diya Surie from the Coronavirus and Other Respiratory Viruses Division (CORVD), CDC, presented on the effectiveness of adult RSV vaccines, 2023-2024. In the IVY Network of 26 hospitals in 20 states, a test-negative, case-control design was used with an analysis period of October 1, 2023 to March 31, 2024. Vaccine effectiveness (VE) was high against RSV-associated hospitalization and similar among adults aged 60-74 years and ≥75 years. In the VISION multi-site network of 245 emergency rooms and 230 hospitals, a test-negative design analysis was done based on electronic health records. VE was high against RSV-associated emergency department (ED) visits, hospitalization, and critical illness. VE was similar among adults aged 60-74 years and ≥75 years for both outcomes. VE point estimates decreased with increases in time since RSV vaccination with limited follow-up time within the season. Across outcomes, VE was similar between GSK and Pfizer RSV vaccines and RSV vaccines provided protection against RSV-associated hospitalizations among people with immunocompromise. The Veterans Administration used a target trial emulation that compared RSV vaccination (GSK or Pfizer) with no RSV vaccination for the prevention of documented RSV infection and RSV-associated ED/urgent care (UC) visits or hospitalization among veterans ≥60 years of age. Enrollment was September 1-December 31, 2023, and follow up was extended through March 31, 2024. VE was high against documented RSV infection, RSV-associated ED or UC visit, and RSV-associated hospitalization and did not differ between the two products. An analysis of Medicare fee-for-service data for persons ≥65 years of age with end-stage renal disease (ESRD) showed that RSV vaccination provided protection against RSV-associated hospitalization among adults with ESRD on dialysis. Under real-world conditions, RSV vaccination (GSK or Pfizer) provided protection against severe RSV disease among US adults aged ≥60 years in this first season of use. These results provided evidence of VE against RSV-associated ED visits, hospitalizations, and critical illness and demonstrated protection in a population that more closely represents those at high-risk of severe RSV disease.

Dr. David Hutton from the University of Michigan presented an economic analysis of RSV vaccination in adults 50 years and older. The analysis looked at U.S. adults aged ≥50 years, stratified by age and chronic medical conditions and assumed that VE was reduced by half in immune compromised populations, compared with others. The base case incremental cost-effectiveness analysis showed for all adults 75 years+ with protein subunit vaccines $51,447 per quality-adjusted life-year (QALY) and with Moderna's RSV vaccine $66,287 per QALY; for adults 60-74 years of age with at least one risk condition, $60,933 for the protein subunit vaccines and $80,953 for the Moderna vaccine; and for adults 50-59 years of age with at least 1 risk condition, $154,501 per QALY. Cost per QALY was much higher in all age groups among persons without underlying risk conditions. Longer duration of protection (36 months rather than 24 months) or higher baseline RSV disease burden made all policy options more cost effective.

Dr. Hutton presented a second analysis that compared the estimated benefits of RSV vaccination and the potential risk of GBS after protein subunit RSV vaccination (GSK or Pfizer). This analysis found that the estimated numbers of avertable deaths are much larger than potential GBS cases for adults 75 years of age and older and for adults 60-74 years of age with at least one risk condition. The estimated numbers of avertable deaths are larger, but more similar in magnitude, than potential GBS cases for adults 50-59 with at least one chronic condition and adults 60-74 without chronic conditions.

Dr. Ismael Ortega-Sanchez, CDC, presented a summary comparing economic models from GSK, Moderna, and the University of Michigan (UM) with CDC. Differences in key inputs and assumptions among the three models explain differences in results. The resulting incremental cost-effectiveness ratios vary by age and high-risk group. For vaccinating all adults ≥75 years against RSV, Moderna and UM-CDC models reported societal costs between $51K and $66K per QALY saved. For vaccinating adults aged 60-74 years at higher risk of severe RSV disease, Moderna and UM-CDC models reported societal costs between $61K to $89K per QALY saved. For vaccinating adults aged 50-59 years at higher risk, the results were more discrepant, ranging from societal cost-saving (GSK) to $154K per QALY saved (UM-CDC).

The Evidence to Recommendations Framework (EtR) for RSV vaccination in adults aged 50-59 years, 60-74 years, and 75 years and older was presented by Drs. Amadea Britton and Michael Melgar and Ms. Lauren Roper, CORVD. The work group interpretation was that RSV was a public health problem for adults ≥60 years of age. The annual rate of RSV-associated hospitalization increases with increasing age, with a steep rise at age 75 years. Certain chronic medical conditions also increase risk of RSV-associated disease; age and chronic medical conditions are independently associated with increased risk. RSV is associated with severe disease and has significant post-hospitalization sequelae among older adults. Evidence for benefits and harms was presented, and the work group interpretation was that desirable effects outweighed undesirable effects for both protein subunit and Moderna's RSV vaccine in adults ≥75 years of age and in adults 60-74 years at increased risk. The evidence for values, acceptability, feasibility, and resource use also supported use of RSV vaccines in both groups, and the work group felt that RSV vaccine would likely have a positive impact on health equity in both groups, with support overall for use of RSV vaccine in both groups. The work group felt that there was sufficient information to move forward with a recommendation, and recommended that adults 75 years of age and older receive a single dose of RSV vaccination, and adults 60-74 years of age who are at increased risk for severe RSV disease receive a single dose of RSV vaccination.

Next the EtR for use of RSV vaccine in adults 50-59 years at increased risk of severe RSV disease was presented. The work group felt that RSV in this group was or probably was a public health problem but thought that it was unclear whether or not desirable effects outweighed undesirable effects. As of the June 2024 ACIP meeting, the work group majority had concluded that there is currently insufficient evidence to make a recommendation regarding RSV vaccination in adults 50-59 years of age. Before making a recommendation for adults 50-59 years, the work group would like to review additional data, including at least one complete season of safety surveillance data; immunobridging data in adults with immune compromise; and data on duration of protection and immune response after revaccination.

Clinical considerations included discussion of chronic medical conditions associated with increased risk of severe RSV disease. These included lung disease; cardiovascular disease; moderate or severe immune compromise; diabetes mellitus with end-organ damage; severe obesity; neurologic or neuromuscular conditions; advanced chronic kidney disease; liver disorders; hematologic disorders; and other chronic medical conditions that a healthcare provider determines increase the risk of severe disease due to respiratory infection. This might include residence in a nursing home or other long-term care facility; frailty; or other individual factors determined by the clinician to increase risk of severe respiratory infection. In accordance with CDC's General Best Practices for Immunization, coadministration of RSV vaccines with other adult vaccines is acceptable.

Dr. Jamie Loehr moved that ACIP recommend that adults who are 75 years of age and older receive a single dose of RSV vaccine. The motion was seconded by Dr. Sara Long. Dr. Loehr moved that ACIP recommend adults 60-74 years of age who are at increased risk of severe RSV disease, as described in CDC's clinical guidance, receive a single dose of RSV vaccine. The motion was seconded by Dr. Camille Kotton.

The next topic was preferential use of Combined Diphtheria and Tetanus Toxoids and Acellular Pertussis, Inactivated Poliovirus, *Haemophilus influenzae* Type B Conjugate, and Hepatitis B vaccine (VAXELIS®) in American Indian and Alaska Native (AI/AN) infants. Dr. Jamie Loehr, Chair of the ACIP Hib/Meningococcal Vaccines Work Group, opened the session with background on the existing recommendation for use of PRP-OMP (PedvaxHIB®) in AI/AN infants because it provides a protective antibody response after the first dose and historically, Hib meningitis peaked at an earlier age among AI/AN infants. VAXELIS® (DTaP-IPV-Hib-HepB) did not have a preferential recommendation for AI/AN infants because it contains PRP-OMP in a lower amount than in PedvaxHIB® and post-dose 1 immunogenicity data were not previously available. At the February ACIP meeting, clinical trial data on post-dose 1 immunogenicity of VAXELIS® vs. PedvaxHIB® were presented along with preliminary work group considerations.

The EtR for use of VAXELIS® among AI/AN infants was presented by Dr. Jennifer Collins, CDC. The work group determined that invasive Hib disease is a public health problem among AI/AN populations and that the desirable effects outweighed the undesirable effects, favoring use of VAXELIS® or PedvaxHIB®. Dr. Collins described a listening session with tribal communities that NCIRD held in collaboration with CDC's Office of Tribal Affairs and Strategic Alliances in January 2024. Key questions and concerns raised by participants for work group consideration were whether or not VAXELIS® would provide the same protection as PedvaxHIB®; the need to monitor for possible breakthrough cases, and safety and side effects. The work group felt that available evidence in the domains of values, acceptability, feasibility, and resource use were supportive or probably were supportive, and that the impact of using VAXELIS® among AI/AN infants on health equity were moderate or large.

The majority of the work members judged that the desirable consequences probably outweigh undesirable consequences in most settings and proposed that ACIP recommend that DTaP-IPV-HepB (VAXELIS®) should be included with PRP-OMP (PedvaxHIB®) in the preferential recommendation for AI/AN infants based on the *Haemophilus influenzae* type b (Hib) component.

Dr. Loehr made a motion that ACIP recommend that DTaP-IPV-HepB (VAXELIS®) should be included with PRP-OMP (PedvaxHIB®) in the preferential recommendation for AI/AN infants based on the *Haemophilus influenzae* type b (Hib) component. Dr. Long seconded the motion.

Dr. Jeanne Santoli, Immunization Services Division, CDC, then presented a proposal to update the Recommended Vaccination Schedule and Intervals section of the Vaccines for Children (VFC) resolution to add a preference for VAXELIS® in children who are AI/AN and to better align with the existing ACIP recommendations.

Dr. Loehr made a motion to approve the VFC resolution for vaccines to prevent *Haemophilus influenzae* type b (Hib) and it was seconded by Dr. Sybil Cineas.

PUBLIC COMMENTS

Overview

The floor was opened for public comment on June 26, 2024 at 3:40 PM EDT. Members of the public also were invited to submit written public comments to ACIP through the Federal eRulemaking Portal under Docket Number ID CDC-2024-0043. Visit regulations.gov to read background documents and comments received.

Public Comments

Mr. Noah Louis-Ferdinand
Communications Coordinator
Voices for Vaccines

Mr. Louis-Ferdinand made comments about the shared clinical decision-making recommendation for RSV vaccine for people 60 and over, which he said was confusing. SCDM doesn't really give clear guidance on what people should or shouldn't do, on top of recommendations for updated COVID-19 vaccines, which people also find confusing. Clear messaging would be very helpful it would go a long way to have that clear recommendation, given that this is a serious and burdensome disease for the public.

Dorit Reiss, PhD
Professor of Law
University of California (UC) Law San Francisco

Ms. Reiss spoke in favor of combination vaccines as a parent, because fewer injections are required. She agreed with the previous commenter about the need for simplicity and clarity in recommendations. Because the Vaccine for Adults program is not on the immediate horizon, taking away shared clinical decision-making for adults under 75 will create serious equity issues for those who cannot afford a $400 vaccine. She mentioned two recent legal decisions that might affect the committee's or CDC's work. In a recent decision in Braidwood v Becerra, the Fifth Circuit implied at least that it may consider previous ACIP recommendations as unconstitutional, given the lack of approval. In Murthy versus Missouri, the Supreme Court rejected the challenge to CDC's and other agencies' communications with government and social media on the grounds that they didn't show the communication led directly to effects, which could open the door to more communication between CDC and social media platforms.

Elias Kass, ND
Naturopathic Physician
Pediatric Primary Care and Vaccine Hesitancy

Dr. Kass spoke in favor of including babies and young children in this fall's updated COVID vaccine recommendations and asked that primary care offices be supported in distribution and administration of these vaccines as most young children cannot be vaccinated in pharmacies. Dr. Kass also expressed his hope that the authorization for Novavax authorization would be extended down to 6 months because many families in his practice who otherwise enthusiastically vaccinate are still apprehensive about mRNA vaccines and their children are experiencing multiple COVID infections as there are no other options for this age group. He called on CDC to emphasize layered prevention, including engineering controls like clean indoor air as well as individual controls like masks and not rest on a vaccine only approach. These approaches would also help with other respiratory viruses like RSV. The rollout of nirsevimab in the 2023-2204 season was eagerly anticipated and incredibly frustrating; he expressed hope that this year will be smoother and that it was exciting to have ABRYSVO® for use in pregnancy, as RSV disease in infants remains a significant burden and contributes to a lifetime of complications.

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

Ms. Clarke stated that when the ACIP delays a vote because they think they need more data, the committee is inadvertently hampering vaccine data collection because new vaccines won't be used without an ACIP recommendation. Ms. Clarke said that ACIP should get rid of its RSV and pneumococcal vaccine shared clinical decision-making recommendations for older adults. A report that was recently released by Champions for Vaccine Education, Equity, Progress (CVEEP) found that SCDM vaccine recommendations create complex and unnecessary access hurdles, particularly for underserved communities. She also stated that her organization would like to see ACIP vote on a universal RSV vaccination for all adults ages 60 and older and for the RSV vaccine that received FDA approval for expanded use in adults ages 50 and older. Additionally, ACIP should vote on a universal pneumococcal vaccine recommendation for adults ages 50 and older.

She also asked the committee to continue to support a preferential recommendation for enhanced flu vaccines and to vote as soon as possible after the FDA approves or authorizes the 2024-2025 COVID-19 vaccines; her organization would like to see updated vaccines available in August on the same timeframe as annual flu vaccines.

VOTES

Dr. Keipp Talbot, ACIP Chair, requested that the language for the votes be displayed for the recommendation and VFC votes.

Vote #1: RSV Vaccine in Adults ≥75 Years of Age

Dr. Talbot read the following proposed ACIP voting language into the record for RSV vaccine in adults ≥75 years of age:

> *ACIP recommends adults 75 years of age and older receive a single dose of RSV vaccine.*[a,b]
>
> *a. RSV vaccination is recommended as a single lifetime dose only. Persons who have already received RSV vaccination are NOT recommended to receive another dose.*
> *b. This recommendation would supplant the current recommendation that adults 60 years of age and older may receive RSV vaccination, using shared clinical decision-making. Adults 60–74 years of age who are not at increased risk of severe RSV disease would NOT be recommended to receive RSV vaccination.*

Motion/Vote #1: RSV Vaccine in Adults ≥75 Years of Age

Dr. Loehr made a motion to approve the proposed recommendation RSV vaccine in adults ≥75 years of age as written stating:

"ACIP recommends adults 75 years of age and older receive a single dose of RSV vaccine.[a,b]

a. RSV vaccination is recommended as a single lifetime dose only. Persons who have already received RSV vaccination are NOT recommended to receive another dose.
b. This recommendation would supplant the current recommendation that adults 60 years of age and older may receive RSV vaccination, using shared clinical decision-making. Adults 60–74 years of age who are not at increased risk of severe RSV disease would NOT be recommended to receive RSV vaccination."

Dr. Long seconded the motion. No COIs were declared. The motion carried with 11 favoring, 0 opposing, and 0 abstaining. The disposition of the vote was as follows:

11 Favored: Brooks, Chen, Cineas, Daley, Jamieson, Kotton, Loehr, Long, Schechter, Shaw, Talbot
0 Opposed: N/A
0 Abstained: N/A

Vote #2: RSV in Adults 60–74 Years of Age at Increased Risk of Severe RSV Disease

Dr. Talbot, ACIP Chair, read the following proposed ACIP voting language into the record for adults 60–74 years of age who are at increased risk of severe RSV disease:

> *ACIP recommends adults 60–74 years of age who are at increased risk of severe RSV disease[c] receive a single dose of RSV vaccine.[a,b]*
>
> *a. RSV vaccination is recommended as a single lifetime dose only. Persons who have already received RSV vaccination are NOT recommended to receive another dose.*
> *b. This recommendation would supplant the current recommendation that adults 60 years of age and older may receive RSV vaccination, using shared clinical decision-making. Adults 60–74 years of age who are not at increased risk of severe RSV disease would NOT be recommended to receive RSV vaccination.*
> *c. CDC will publish Clinical Considerations that describe chronic medical conditions and other risk factors for severe RSV disease for use in this risk-based recommendation.*

Motion/Vote #2: RSV Adults 60–74 Years of Age at Increased Risk of Severe RSV Disease

Dr. Loehr made a motion to approve the proposed recommendation in adults 60–74 years of age at increased risk of severe RSV disease as written stating:

"ACIP recommends adults 60–74 years of age who are at increased risk of severe RSV diseasec receive a single dose of RSV vaccine.[a,b]

a. RSV vaccination is recommended as a single lifetime dose only. Persons who have already received RSV vaccination are NOT recommended to receive another dose.
b. This recommendation would supplant the current recommendation that adults 60 years of age and older may receive RSV vaccination, using shared clinical decision-making. Adults 60–74 years of age who are not at increased risk of severe RSV disease would NOT be recommended to receive RSV vaccination.
c. CDC will publish Clinical Considerations that describe chronic medical conditions and other risk factors for severe RSV disease for use in this risk-based recommendation."

Dr. Kotton seconded the motion. No COIs were declared. The motion carried with 11 favoring, 0 opposing, and 0 abstaining. The disposition of the vote was as follows:

11 Favored: Brooks, Chen, Cineas, Daley, Jamieson, Kotton, Loehr, Long, Schechter, Shaw, Talbot
0 Opposed: N/A
0 Abstained: N/A

Dr. Talbot invited voting members to make comments following the votes.

Dr. Loehr said he realized when talking to people that the general public might not know why the ACIP is so concerned about GBS. For those who do not know, he explained that GBS is a neurological disorder with ascending paralysis. Patients who have it often end up in the hospital for 3 to 4 months, might be intubated, and might die. Therefore, it is not a small consequence. It is not fevers or a febrile seizure. This is why the ACIP has such significant concerns about the possible risk of GBS with RSV vaccine. That is why he was much more comfortable with the risk-based rather than the age-based recommendation for persons 60—74 years of age.

Dr. Daley noted that when Dr. Talbot was reading the language, he felt like adding “at this time” to both of those sentences. He just wanted to acknowledge that and make sure it is conveyed because that is based on what is known at this time. To Dr. Loehr’s point for the listening public, GBS is quite a serious condition. Fortunately, it is rare and more data are being gathered about it. For those who are recommended for an RSV vaccine at this time, that recommendation is because they will receive substantial benefit and avoid a serious illness that may put them in the hospital. There are many opportunities for disease prevention that should be implemented.

Vote: DTaP-IPV-Hib-HepB (VAXELIS®)

Dr. Keipp Talbot, ACIP Chair, read the following proposed ACIP voting language into the record for DTaP-IPV-Hib-HepB (VAXELIS®):

> *ACIP recommends DTaP-IPV-Hib-HepB (Vaxelis®) should be included with PRP-OMP (PedvaxHIB®) in the preferential recommendation for American Indian and Alaska Native infants based on the Haemophilus influenzae type b (Hib) Hib component.*

Motion/Vote: DTaP-IPV-Hib-HepB (VAXELIS®**)**

Dr. Loehr made a motion to approve the proposed recommendation for chikungunya vaccines stating, “ACIP recommends DTaP-IPV-Hib-HepB (VAXELIS®) should be included with PRP-OMP (PedvaxHIB®) in the preferential recommendation for American Indian and Alaska Native infants based on the *Haemophilus influenzae* type b (Hib) Hib component.” Dr. Long seconded the motion. No COIs were declared. The motion carried with 11 favoring, 0 opposing, and 0 abstaining. The disposition of the vote was as follows:

11 Favored: Brooks, Chen, Cineas, Daley, Jamieson, Kotton, Loehr, Long, Schechter, Shaw, Talbot
0 Opposed: N/A
0 Abstained: N/A

Vote: VFC Resolution for DTaP-IPV-Hib-HepB (VAXELIS®)
Dr. Keipp Talbot, ACIP Chair, read the following proposed ACIP voting language into the record for the VFC Resolution for diphtheria, tetanus, and pertussis vaccines:

> *Approve the Vaccines for Children (VFC) Resolution for vaccines to prevent Haemophilus influenzae type b (Hib).*

Motion/Vote: VFC Resolution for Diphtheria, Tetanus, and Pertussis Vaccines

Dr. Loehr made a motion to approve the proposed recommendation for the VFC Resolution stating, "Approve the Vaccines for Children (VFC) Resolution for vaccines to prevent *Haemophilus influenzae* type b (Hib)." Dr. Cineas seconded the motion. No COIs were declared. The motion carried with 11 favoring, 0 opposing, and 0 abstaining. The disposition of the vote was as follows:

11 Favored: Brooks, Chen, Cineas, Daley, Jamieson, Kotton, Loehr, Long, Schechter, Shaw, Talbot
0 Opposed: N/A
0 Abstained: N/A

The next session began with a report from the ACIP Chikungunya Vaccines Work Group presented by Dr. Wilbur Chen. The work group has been developing policy options for ACIP's consideration for use of chikungunya vaccine among U.S. persons at risk of chikungunya, including travelers, laboratory workers, and residents of U.S. territories and states with risk of transmission. In February 2024 the work group recommended use of the live attenuated chikungunya vaccine among U.S. travelers and laboratory workers.

Dr. Susan Hills, Division of Vector-Borne Diseases (DVBD), CDC, then provided an update on chikungunya vaccines. Bavarian Nordic has reported that their Biologics License Application (BLA) for their virus-like particle vaccine has been filed with FDA and the product could be licensed in the first half of 2025. They are requesting licensure of a single dose schedule for adolescents and adults ≥12 years of age. Valneva's chikungunya vaccine, IXCHIQ, was licensed by FDA in November 2023 for use in a single dose schedule in adults ≥18 years.

Dr. Hills also provided an update on the epidemiology of chikungunya in U.S. territories and states with risk of transmission. Chikungunya is a mosquito-borne disease; key vectors are *Aedes aegypti* and *Aedes albopictus* mosquitoes. Chikungunya typically occurs in tropical and subtropical regions where it periodically causes large outbreaks, often with high attack rates. Virus transmission is usually highest during the wet season of the year. Acute chikungunya virus infection is a febrile illness typically with severe arthralgia (joint pain), which can be debilitating. Other symptoms can include headache, rash, myalgia, and anorexia. In the absence of specific antiviral treatment, the approach to management typically involves rest, fluids, and use of analgesics and antipyretics. Serious complications are rare but can include myocarditis, hepatitis, and neurologic illnesses such as Guillain-Barré syndrome and meningoencephalitis. Deaths are also rare and are reported mostly in older adults, particularly those with comorbidities, and young infants infected perinatally or by mosquito bites. Acute symptoms of chikungunya usually resolve in about 7 to 10 days. However, some patients have a continuation or relapse of their joint symptoms in the months after acute illness and experience other symptoms such as fatigue.

Up to one-half of patients might have ongoing arthralgia of variable severity at 3 months after infection and up to about 30% at 12 months after infection.

In the Caribbean region, chikungunya emerged in December 2013 with the first case reported in Saint Martin island. Subsequently there was a rapid increase in countries and territories reporting virus transmission. In Puerto Rico, the first locally acquired, laboratory-confirmed case of chikungunya occurred in early May 2014. There was a rapid increase in the number of cases with the outbreak peaking in September 2014. In 2015 there was a small increase in cases in the middle of the year when the weather in Puerto Rico is hot and humid and rainfall is heaviest but there was no substantial transmission after 2014. In Puerto Rico in terms of age groups, there was a higher percentage of cases in children aged 0-19 years (42%) and lower but similar percentages of cases in the other age groups, although the higher percentage of cases in children might have been biased by laboratory testing practices. Cases occurred in almost all areas of the island. Seroprevalence surveys suggest that about a million persons were infected during the outbreak, translating to an estimated 650,000-850,000 clinical cases of chikungunya.

The first locally acquired case of chikungunya in the U.S. Virgin Islands was in June 2014 on the island of Saint Thomas. The outbreak in Saint Thomas was followed by outbreaks on St. John and on St. Croix. The last laboratory-positive case was in February 2015. A seroprevalence survey approximately oe year after the outbreak ended showed that 31% of persons had evidence of past infection, translating to an estimate of 33,000 persons infected and 21,000-28,000 clinical cases during the 8-month outbreak period.

In American Samoa, an outbreak began in June 2014. The extent of the outbreak is unclear, but unconfirmed reports suggested at least 823 suspected cases occurred. The duration of the outbreak is also unclear but there was no evidence of ongoing transmission by the end of 2015 when a Zika outbreak began there. Chikungunya has not been reported in the other U.S. territories, Guam and the Commonwealth of the Northern Mariana Islands. An outbreak occurred in the Federated States of Micronesia in Yap State August 2013 to August 2014. An attack rate of 155 clinical cases per 1,000 population was reported; about 15% of the population sought care for suspected illness. An outbreak began in the Marshall Islands in February 2015; the duration and extent are unclear but there may have been >1,000 suspected cases.

In summary, among 8 US territories or affiliated states, 3 territories and 2 affiliated states have had outbreaks of chikungunya. When outbreaks occurred, they were explosive and spread rapidly. For Puerto Rico and USVI, where information is available, seroprevalence surveys suggest about 30% of the population was infected, which equates to about 20-25% of the population having clinical illness, with most cases occurring during a peak transmission period of about 6 months. All outbreaks in the US territories and freely associated states began from 2013–2015, and the last evidence of any ongoing confirmed transmission was in 2017 in Puerto Rico and was much earlier in the smaller island nations. Finally, the timing of future transmission or outbreaks is unknown, and the likely patterns of transmission in future cannot be predicted with certainty.

The first local transmission of chikungunya virus in the continental United States occurred in Florida in 2014. This occurred at the time an extensive outbreak of chikungunya was ongoing in the Americas and the US had seen a dramatic increase in chikungunya cases among travelers returning to the United States. After the first locally acquired case was identified in June, 11 additional cases were reported, and all occurred in four counties in southern Florida. Two patients lived with 1,500 feet of each other and were assumed to be linked as part of a cluster, and the others all appeared to be sporadic cases.

No local transmission of chikungunya virus in Florida has been reported since that time. An additional case of locally acquired chikungunya occurred in Cameron County, Texas, in November 2015. The county is on the border with Mexico, but the patient denied any international travel prior to illness onset. No additional cases were identified.

Dr. Kelly Kilburn, CDC, presented an analysis of the cost-effectiveness of using a single dose of the live attenuated chikungunya vaccine among the population aged 18 years and older living in US territories that previously experienced an outbreak. A population-based model was used with an analytic time horizon of 30 years. There are little data on the time between chikungunya outbreaks in island nations or territories. A modeling study in the Philippines estimated an average of 17 years between outbreaks. Since the last outbreaks in the territories were in 2014, it was assumed that there would be one chikungunya outbreak in 2034. Two strategies, routine vaccination with 20% annual vaccination coverage and outbreak vaccination were evaluated. The outbreak strategy averted 67% of health outcomes and the routine strategy averted 90% of health outcomes. More doses are delivered during the 30-year time horizon in the routine strategy, resulting in higher vaccination costs of $436 million while the outbreak strategy has a cost of $356 million. In terms of total societal costs, vaccination in either strategy leads to lower net costs than without vaccination because of the large number of health outcomes averted.

Dr. Hills then provided an overview of next steps for the work group, which will continue gather data and discuss use of chikungunya vaccine in at-risk U.S. territories, including acceptability and value of vaccine to providers and relevant populations and feasibility of administration. The work group will also be considering recommendations for residents of U.S. states with risk and recommendations for use of the virus-like particle vaccine in travelers, laboratory workers, residents of U.S. territories with risk, and residents of U.S. states with risk.

The next session was on dengue vaccines. It began with an update from Dr. Nicholas Bergren, Sanofi, who provided an update on the discontinuation of Dengvaxia®, Sanofi's dengue vaccine. Dengvaxia® was indicated for the prevention of dengue disease caused by dengue virus serotypes 1, 2, 3 and 4 and was approved for use in individuals 6 through 16 years of age with laboratory-confirmed previous dengue infection and living in endemic areas. In 2021, ACIP recommended vaccination with the Dengvaxia® vaccine for children aged 9–16 years having evidence of a previous dengue infection and living in areas where dengue is endemic. Dengvaxia® wss recommended as a 3-dose vaccination series, administered 6 months apart (at month 0, 6, and 12) for the selected pediatric population. Evidence of previous dengue infection, such as confirmation with previous laboratory-confirmed infection or a highly specific serodiagnostic test, was required among eligible children before vaccination. Dengvaxia® is being discontinued due to low demand; the decision was not due to any concerns regarding quality, safety, or efficacy. Dengvaxia® will continue to be distributed through public (e.g., VFC) and private markets globally (including Puerto Rico where it is currently recommended by the ACIP) through product expiry. The last doses of Dengvaxia® will expire at the end of August 2026. Given the 3-dose, 1-year series needed for full immunization, individuals should start the Dengvaxia® immunization series no later than August 31, 2025.

Dr. Joshua Wong, Dengue Branch, DVBD, NCEZID, then provided an update on dengue vaccines and epidemiology. Many countries including the U.S. have reported locally acquired dengue cases during the period March 2023 to April 2024. As of June 25, 2024, nearly 10 million cases have been reported in the Americas in 2024. Dengue is endemic in 6 U.S. territories and freely associated states. Puerto Rico declared a public health emergency due to a dengue outbreak in March 2024; dengue infections have been above the epidemic threshold for 21 weeks. Dengvaxia® was used in Puerto Rico, beginning in September 2022.

Since that time, 264 doses have been administered to 145 individuals, only 32 of whom completed the three dose series. With the requirement for laboratory confirmation of prior infection, multiple visits to healthcare providers were required to determine eligibility and start vaccination; this greatly complicated implementation. Major barriers to update included prevaccination testing, complex billing processes, and limited messaging about the vaccine. CDC has updated its website with information about the discontinuation of Dengvaxia®.

No dengue vaccines will be available in the U.S. after the discontinuation of Dengvaxia®. Takeda voluntarily withdrew TAK-003 (Qdenga) from FDA review in July 2023. The TV003/TV005 dengue vaccine is in late-stage phase 3 trials. This vaccine was developed by the U.S. National Institutes of Health and was licensed to Merck in the U.S. and the Instituto Butantan in Brazil. Phase 3 trials in Brazil are ongoing. Data from the first two years of follow-up have been published, showing high efficacy and safety. DENV-3 or DENV-4 have not been observed during this period, limiting evaluation of VE against these serotypes. Five-year follow-up data are expected later this year. The ACIP Dengue Vaccines Work Group will be paused until new dengue vaccines are submitted to FDA for approval. Vaccines are just one part of a multilayered approach to reducing morbidity by dengue; people can continue to protect themselves and their families from dengue by preventing mosquito bites and controlling mosquitoes in and around their homes.

With no additional business posed for the day, the ACIP meeting stood in recess until 8:00 AM on June 27, 2024.

THURSDAY: JUNE 27, 2024

WELCOME AND INTRODUCTIONS

Call to Order

Dr. Keipp Talbot, ACIP Chair, called to order and presided over the second day of the June 26-28, 2024 ACIP meeting.

Announcements

Dr. Melinda Wharton (ACIP Executive Secretary, CDC) welcomed and introduced the 4th new member of the ACIP, Yvonne (Bonnie) Maldonado, MD. Dr. Maldonado is Chief of the Division of Infectious Diseases in the Department of Pediatrics at Stanford University, Director of Stanford's Global Child Health Program, and serves as Medical Director for Infection Prevention and Control at the Children's Hospital at Stanford University.

Dr. Wharton also acknowledged the long service of Dr. William Schaffner from Vanderbilt University who recently concluded a more than 40-year engagement with the ACIP. Dr Schaffner started his service in the early 1980s when he was a member of the ACIP from 1982 to 1986. Following, he served as a liaison representative for the American College of Physicians (ACP), the American Hospital Association (AHA), the Infectious Diseases Society of America (IDSA), and the National Foundation for Infectious Diseases (NFID). Dr. Schaffner responded that his long association with the ACIP continues to be one of the most rewarding aspects of his professional career.

Roll Call

Dr. Keipp Talbot, ACIP Chair, conducted a roll call, 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 COI was identified: Dr. Maldonado is the Stanford Principal Investigator (PI) for the COVID vaccine trials.

AGENCY UPDATES

Centers for Disease Control and Prevention

Demetre Daskalakis, MD, MPH highlighted CDC's activities in seasonal respiratory viruses, with the commercialization of the COVID-19 vaccine, launch of multiple RSV products, and the agency's staple work in seasonal influenza. While the times have been exciting, there also have been some significant challenges and important issues that continue to need to be addressed. As of May 11, 2024, 22.5% of adults ≥18 years of age and 14.4% of children 6 months to 17 years of age were reportedly up to date with the 2023-2024 COVID-19 vaccine. Vaccination coverage increased by age and was highest among adults, with receipt of at least 1 updated 2023-2024 COVID-19 vaccine reaching 41.5% among adults ≥ 75 years. The Bridge Access Program, launched in Fall 2023, provides no-cost COVID-19 vaccines to adults without health insurance and adults whose insurance does not cover all COVID-19 vaccine costs. Approximately 1.5 million doses have been provided through this program from September 2023 through May 2024. This temporary program will end in August 2024.

There are other respiratory viruses that continue to be the focus of attention at CDC, including avian influenza A(H5N1). CDC's current A(H5N1) bird influenza human health risk assessment for the general public remains low. CDC continues to respond to the public health challenge posed by a multistate outbreak of avian influenza A(H5N1) virus in dairy cows and other animals in the US. To date, there have been 3 human cases in the US associated with an ongoing multistate outbreak of A(H5N1) in dairy cows. All 3 cases were mild, and all had direct contact with infected cows. CDC is working in collaboration with the US Department of Agriculture (USDA), FDA, state public health and animal health officials, and other partners using a One Health approach to continue to monitor the impact on public health.

Measles represents another ongoing public health threat. As of June 6, 2024, a total of 151 measles cases were reported by 22 jurisdictions in the US in 2024. This is in comparison to 2023, during which a total of 58 measles cases were reported by 20 jurisdictions. Jurisdictions at highest risk for measles continue to be those containing communities with persistently low vaccination coverage and importations from locations with measles outbreaks.

In terms of Mpox, a report in a May *MMWR* showed that infection after receipt of 2 JYNNEOS doses is estimated to have occurred in <1% of fully vaccinated persons and comprises a small proportion of national cases. Among persons who experienced infection after having received a complete 2-dose series and for whom complete data were available, infections have been milder than those among unvaccinated persons. Disparate time intervals from vaccination to infection among fully vaccinated persons suggest that immunity is not waning.

Regarding anthrax, Emergent BioSolutions Inc. announced in July 2023 that FDA had approved CYFENDUS or Anthrax Vaccine Adsorbed, Adjuvanted, for post-exposure prophylaxis of disease following suspected or confirmed exposure to *Bacillus anthracis* in persons 18–65 years of age when administered in conjunction with recommended antibacterial drugs. This vaccine is comprised of the previously FDA-approved Anthrax Vaccine Adsorbed (AVA) and an additional adjuvant, CpG7909. It has been demonstrated that by using an additional adjuvant, 2 doses administered over 14 days elicit protective levels of immune response, as opposed to 3 doses over 4 weeks required for AVA to illicit an adequate immune response. AVA Adjuvanted vaccine is currently a component of the US government's (USG's) Strategic National Stockpile (SNS) for use in an anthrax public health emergency and will replace AVA as it expires. ACIP will soon convene an Anthrax WG to review data and provide recommendations for its use to the ACIP committee.

Though not necessarily thought of as vaccine-preventable, antimicrobial resistance (AMR) is another important topic. In September 2024, the USG will have an opportunity to demonstrate US leadership in combatting AR at the second United Nations General Assembly High-Level Meeting on Antimicrobial Resistance 2024. The USG has set ambitious goals to reduce healthcare-associated infections (HAIs), including those caused by antimicrobial-resistant germs, and protect patients and healthcare personnel (HCP).

Centers for Medicare and Medicaid Services

Mary Beth Hance reported that in February 2024, CMS released an updated *Coverage and Payment of Vaccines and Vaccine Administration Under Medicaid, the Children's Health Insurance Program, and Basic Health Program*.[1] She amplified that CMS continues to share with all of its partners and stakeholders to highlight coverage of vaccines and amplify activities that are being undertaken by Medicaid agencies and other partners throughout the country to really encourage uptake of vaccines and increase vaccination, particularly for pediatric vaccines. CMS will continue to look for these opportunities to amplify this and emphasize coverage of vaccines throughout the Medicaid, Medicare, and Marketplace.

Food and Drug Administration

Dr. David Kaslow, FDA, reported that since the last FDA agency report during the February 2024 ACIP meeting and that apropos to this convening of ACIP, FDA's Vaccines and Related Biologics Products Advisory Committee (VRBPAC) convened twice and the Office of Vaccines Research and Review (OVRR) took several major regulatory actions, of which Dr. Kaslow briefly highlighted 3 actions.

In March, VRBPAC met in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2024 to 2025 influenza season in the Northern Hemisphere. Having discussed the need to transition from quadrivalent to trivalent influenza vaccines at several previous VRBPAC meetings, committee members generally agreed on transitioning to trivalent influenza vaccines only, for use in the US starting in the 2024-2025 respiratory virus season, and US-licensed quadrivalent vaccines for ex-US distribution purposes only. There also was general agreement among VRBPAC members for changing the H3 components but maintaining the currently recommended H1 and B components.

[1] https://www.medicaid.gov/medicaid/quality-of-care/downloads/vacines-coverage-payment.pdf

VRBPAC again met in open session in June to discuss and make recommendations on the selection of the 2024-2025 formula for COVID-19 vaccines for use in the US beginning in Fall 2024. VRBPAC unanimously voted to recommend a monovalent JN.1-lineage vaccine composition and discussed considerations for the selection of a specific strain, be it JN.1 or KP.2. Subsequently, FDA communicated advice to manufacturers of licensed and authorized COVID-19 vaccines on use of these 2 specific strains for the 2024-2025 Formula.

In terms of 3 major regulatory actions taken since February, on June 7, RSV Vaccine, Adjuvanted was approved for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV. On June 17, pneumococcal 21-valent conjugate vaccine was approved for active immunization for the prevention of invasive disease caused by 22 *Streptococcus pneumoniae* serotypes in individuals ≥18 years of age and was approved under accelerated approval for active immunization for the prevention of pneumonia caused by *Streptococcus pneumoniae* serotypes in individuals ≥18 years of age.

Health Resources and Services Administration

CDR Reed Grimes, MD, MPH provided a Health Resources and Services Administration (HRSA) update on 3 important vaccination efforts that HRSA undertakes to support the nation's public health. First, HRSA's Health Center Program is a cornerstone of the country's health care system, providing affordable, high-quality, comprehensive primary care services to more than 30 million medically underserved people nationwide, especially for individuals and families who are uninsured; enrolled in Medicaid; living in rural, remote, or underserved areas; struggling to afford their health insurance co-pays; experiencing homelessness; residing in public housing; or otherwise finding it hard to find a doctor or pay for the cost of care. Today, the nearly 1,400 HRSA-funded health centers operate more than 15,000 health care sites, as well as mobile clinics, community outreach events to engage patients in accessible settings, and other satellite sites. HRSA's Health Center Program has been essential in vaccine uptake for COVID-19 vaccine doses. As of April 2024, more than 24 million vaccine doses have been administered by all health centers, with 70% to racial and/or ethnic minority patients.

Second, the Countermeasures Injury Compensation Program (CICP) continues to make unprecedented progress in reviewing claims alleging injuries from medical countermeasures (e.g., Mpox vaccine, anthrax vaccine, COVID-19 vaccine) deployed in response to pandemic, epidemic, and security threats. As of June 1, 2024, CICP has specifically rendered decisions on 2,814 COVID-19 claims and continues to work through the backlog of claims filed following the extraordinary deployment and administration of over 676 million COVID-19 vaccines in response to the pandemic. More information about the CICP can be found on the website.[2]

Third, the National Vaccine Injury Compensation Program (VICP) continues to actively process claims. In FY 2024, as of June 1, 2024, petitioners have filed 783 VICP claims, nearly $119 million was awarded to petitioners, and over $34 million was awarded to pay attorney's fees and costs. In addition, the VICP has approximately 600 claims alleging vaccine injury awaiting activation for review. More data about the VICP can be obtained on its website.[3]

[2] https://www.hrsa.gov/cicp
[3] https://www.hrsa.gov/vaccine-compensation/data/index.html

Indian Health Services

Matthew Clark, MD, FAAP, FACP emphasized that the Indian Health Service (IHS) continues to prioritize vaccination as its number one clinical and public health prevention priority. As part of IHS's ongoing national E3 vaccine strategy, they offer every patient at every encounter every ACIP-recommended vaccine, when appropriate. To date, they have designated 29 E3 Champion Pilot sites in 9 IHS Areas. In the past several months, utilizing a grassroots approach, the pilot sites have shared and IHS has disseminated innovative strategies to promote vaccine acceptance and improve vaccine coverage rates in Tribal communities.

Under the leadership of IHS Chief Medical Officer, Dr. Loretta Christensen, last month as recently recognized by partners at CMS, IHS announced its E3 Champions Pilot Community Development Project to cross-pollinate the IHS system of care with multidisciplinary best practices. IHS has recently designated 3 IHS E3 Champions including one federal, one tribal, and one urban site in 3 IHS Areas who have demonstrated excellence by exceeding established thresholds to improve vaccine coverage rates for AI/AN people. Dr. Clark drew particular attention to the outstanding work of one of these IHS E3 Champions, its Tribal partners in the YK Delta region of Alaska.
The YK region is a landmass roughly equivalent in size to the State of Oregon and larger than half of the states in the country. Serving a population of 23,000 Indigenous people in 58 remote tribal communities off the road system, the YK Delta historically has the highest rate of severe RSV disease in the US and arguably in the world.

During the 2023-2024 respiratory viral season, with support from the VFC program and a supplemental allocation from IHS, the Yukon Kuskokwim Health Corporation (YKHC) vaccine team conducted regular bush-plane flights to remote tribal villages, sometimes up to 3 villages a day, to administer nirsevimab and other recommended vaccines to eligible infants and toddlers, with a vaccine acceptance rate of over 60%. In addition, among newborn infants born in the YK Delta region during this first season of availability, immunization with nirsevimab approached 100% with an obstetric delivery rate of roughly 30 to 35 newborns per month. Notably, preliminary data analysis, pending publication, indicates that no single infant in the YK Delta region who had been effectively immunized with nirsevimab experienced severe disease, including hospitalization. Indicative of a virtuous cycle resulting from proactive efforts to promote RSV protection among this high-risk service population, IHS's tribal partners at YKHC also managed to raise baseline composite immunization rates among infants ages birth to 1 year by over 10% for all ACIP-recommended vaccines. Working in collaboration with immunization exemplars like their tribal partners in the YK Delta region of Alaska, the IHS will continue to mitigate the risk of vaccine preventable illness in Indian Country.

National Institutes of Health

Dr. John Beigel, NIAID, NIH, provided several updates for the National Institutes of Health (NIH). NIH continues to support multiple areas of vaccine research for multiple pathogens, a few of which he highlighted that he thought would be of interest to the ACIP. In response to the human and bovine A(H5N1) cases, the NIH released an A (H5N1) influenza research agenda that describes NIH's ongoing and planned efforts to meet 4 key objectives: 1) increasing understanding of the biology of H5N1 viruses and the factors that influence their ability to transmit and cause disease; 2) developing and evaluating prevention strategies, such as vaccines; 3) advancing existing and novel treatments, including antivirals and monoclonal antibodies; and 4) supporting strategies for detecting H5N1 virus. The agenda can be found on the NIH website and will be provided in NIH's written updates.[4]

Regarding Ebola and NIH's continuing efforts to advance vaccines for pandemic and preparedness, scientist at the Vaccine Research Center (VRC) evaluated a heterologous prime-boost strategy for Ebola. This was done in a Phase 1 trial in the US and in Uganda. The strategy uses a ChAd3-EBO-Z with an MVA boost, The heterologous prime-boost regimen was well-tolerated and induced a robust immune response, which persisted up to a year. The results were published in *npj vaccines*.[5]

For malaria, the NIH published interim trial results showing an injected dose of an experimental malaria monoclonal antibody was 77% effective at preventing disease in children in Mali during the country's 6-month malaria season. Monoclonals are seen as a possible component to minimize morbidity and mortality from malaria. In efforts toward an HIV vaccine, there have been some important advances in the development of broadly neutralizing antibodies. A class of broadly neutralizing antibodies called 10E8 is a priority for HIV vaccine development because they can bind to conserved regions in glycoprotein Gp41.
This has been difficult to advance previously. Germline targeting is an approach that guides naïve B cells to develop into B cells that can produce these broadly neutralizing antibodies. Recently, a scientist described an approach to germline targeting that was done in mice that develop broadly neutralizing antibodies to this Gp41. The findings published in *Nature Immunology* are encouraging.[6] It is an incremental step, but an incremental and important step in developing a preventive HIV vaccine.

Office of Infectious Disease and HIV/AIDS Policy

Dr. Chinedu Okeke, Office of Infectious Disease and HIV/AIDS Policy (OIDP), reported that the National Vaccine Advisory Committee (NVAC) met on June 12-13, 2024. During this meeting, Admiral Rachel Levine, the Assistant Secretary for Health at HHS, charged the committee with providing guidance and recommendations to support the development of the next 5-year National Vaccine Strategic Plan (NVSP). This plan provides a vision for the nation and helps to ensure continued responsiveness to an evolving vaccine and immunization landscape.

The next NVAC meeting will take place on September 12-13, 2024, in-person and as a live webcast. The meeting will be made available on the meeting page later this summer on hhs.gov.

[4] https://www.nih.gov/news-events/news-releases/nih-releases-h5n1-influenza-research-agenda
[5] https://www.nature.com/articles/s41541-024-00833-z#citeas
[6] https://www.nih.gov/news-events/news-releases/novel-vaccine-concept-generates-immune-responses-could-produce-multiple-types-hiv-broadly-neutralizing-antibodies

In terms of planning for the next iteration of the NVSP 2026–2030 updates, the OIDP, in collaboration with the HHS Interagency Vaccine Work Group (IVWG) has started planning data gathering and engagement efforts for the next iteration of the NVSP for the 2026–2030. The NVAC report and its recommendation is a process which will form an inclusive and robust consultation process that will include listening sessions with stakeholders and other inputs. They are putting together a request for information to be released very soon. ACIP members were encouraged to actively submit feedback and recommendations during this process.

In terms of responding to the Senate Appropriation Committee, OIDP prepared a report that just went into official clearance in response to the request from the Senate Appropriation Committee that encouraged the OASH, in partnership with CDC, to lead the development of a government-wide coordinated effort to ensure the implementation of the ACIP's recommendation that all adults between 19 and 59 years of age be vaccinated for Hepatitis B. The Senate Appropriation Committee requested this report be prepared before the end of fiscal year 2024.

PRESENTATIONS

The COVID-19 vaccine session began with an update from the ACIP COVID-19 Vaccines Work Group by Dr. Matthew Daley, Work Group Chair. He reminded the committee of the 2023-2024 COVID-19 vaccine recommendations, which in September 2024 were recommended as authorized under EUA or approved by BLA for persons ≥6 months of age. In February 2024, ACIP recommended that adults 65 year and older receive an additional dose of 2023-2024 COVID-19 vaccine. At that meeting, the committee discussed next steps for the COVID-19 vaccine program, including shifting to a vote at the June ACIP meeting for future vaccine updates.

The work group had started their discussions with considerations for an age-based versus a risk-based recommendation. The work group consensus was to proceed with deliberations for an age-based recommendation for everyone ages ≥6 months for the 2024-2025 season.

On June 5, 2024, FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to discuss strain selection for 2024-2025 COVID-19 vaccines. Based on the totality of the evidence presented, FDA advised manufacturers to develop monovalent JN.1 lineage COVID-19 vaccines, with a preference for the KP.2 strain, if feasible.

Dr. Fiona Havers, CORVD, CDC, presented an update on COVID-19 hospitalizations from COVID-NET, a population-based surveillance system that collects data from more than 300 acute care hospitals in 98 counties across 13 states. Racial and ethnic disparities in COVID-19 hospitalizations persist, with the highest hospitalization rates among non-Hispanic American Indian and Alaska Native persons. From October 2023 through May 2024, adults ages 65 years and older comprised 67% of all COVID-19 hospitalizations captured in COVID-NET, with adults 75 years and older comprising almost half of all COVID 19 hospitalizations. Children and adolescents ages 17 years and younger comprised 4% of all COVID-19-associated hospitalizations. Infants <6 months had recent cumulative hospitalization rates that are approximately 6 times that of hospitalization rates in children ages 6 months to 4 years, the pediatric age group with the second highest rates. Overall, 50% of hospitalized infants, children, and adolescents ages have no underlying medical conditions, but the prevalence of underlying medical conditions in children hospitalized with COVID-19 increases with increasing age.

The majority of hospitalized children <2 years have no underlying medical conditions. Only 5% of children and adolescents hospitalized with COVID-19 received the 2023–2024 vaccine dose, the most recent available, prior to hospitalization, and the vast majority of hospitalized children had not received the vaccine available in fall 2023 or in the preceding year. Only 11% of COVID-19-associated hospitalizations among adults ages 18 years and older received a 2023–2024 vaccine dose and the majority had not received any COVID-19 vaccine after August 2022. Among adults, underlying conditions increase risk for hospitalization, but age remains strongly associated with risk for hospitalization.

Dr. Ruth Link-Gelles, CORVD, CDC, presented an update on the effectiveness of 2023-2024 COVID-19 vaccines. 2023-COVID-19 vaccination provided increased protection against symptomatic SARS-CoV-2 infection and COVID-19-associated ED/UC visits and hospitalizations compared to no 2023-2024 vaccine dose. Waning patterns appeared similar to previous COVID-19 vaccine formulations; the most durable protection appeared to be for critical illness, though statistical power was lacking in the longest time period since vaccination. As with previous COVID-19 vaccine formulations, effectiveness was similar across age groups. Receipt of 2023-2024 COVID-19 vaccine provided protection against JN.1 and other circulating variants, though may be lower than protection provided against XBB sublineage variants.

Dr. Jonathan Duffy, Immunization Safety Office, Division of Healthcare Quality Promotion (DHQP), CDC, presented an update on COVID-19 vaccine safety surveillance for the 2023-2024 season. The Vaccine Safety Datalink (VSD) identified two statistical signals for mRNA COVID-19 vaccines during the 2023-2024 season. There was a statistical signal for Guillain-Barré syndrome (GBS) following Pfizer COVID-19 vaccine among people aged ≥65 years. No association between mRNA COVID-19 vaccines and GBS had been observed prior to this season in VSD or other systems. The increased rate ratio observed during the 2023-2024 season may or may not represent a true risk; if there is a true risk, it is estimated to be similar to what is considered acceptable for other adult vaccines. There also was a statistical signal for ischemic stroke following Moderna (aged ≥65 years) and Pfizer (aged 50-64 years) COVID-19 vaccines. The VSD previously observed a statistical signal for ischemic stroke during 2022-2023 for bivalent Pfizer COVID-19 vaccine (aged ≥65 years). Available data do not provide clear and consistent evidence of a safety problem for ischemic stroke with mRNA COVID-19 vaccines. No other new or unexpected safety concerns were identified for the 2023-2024 COVID-19 vaccines; any real or theoretical risks of vaccine adverse events need to be placed in the context of the benefits of COVID-19 vaccines in preventing COVID-19 and its potentially serious complications.

Dr. Lisa Prosser, University of Michigan (UM), presented an economic analysis of COVID-19 vaccination. According to the model developed by the UM team, COVID-19 vaccination averts morbidity and mortality in all age groups, but with substantial variation in impact by age. In adult age groups, the current model projects somewhat less favorable results overall due to declining burden of illness. ICERs for vaccination in the 65 years+ age group ($23,000 per QALY) are robust to changes in parameter inputs across plausible ranges (cost saving to $117,000 per QALY). ICERs for vaccination of 18-49 year old ($212,000 per QALY) and 50-64 year old ($113,000 per QALY) age groups are sensitive to changes in parameter inputs, including vaccine cost. In pediatric age groups, ICERs for vaccination of 5-11 year old ($200,000 per QALY) and 12-17 year old ($203,000 per QALY) age groups are very sensitive to changes in parameter inputs. The evidence base of pediatric age groups overall is less robust, and the estimated results reflect a higher degree of uncertainty compared with adult age groups.

Dr. Lakshmi Panagiotakopoulos presented the EtR Framework for 2024-2025 COVID-19 vaccines in persons ≥6 months of age. ≥The work group interpretation was that COVID-19 continued to be a public health problem, with COVID-19 COVID-19-associated hospitalizations and deaths occurring all year round, but peaking in December – February. COVID-19-associated hospitalizations and deaths are highest in adults aged 75 and older. Among children hospitalized for COVID-19, 50% had no underlying medical conditions; of those, 18% were admitted to the ICU. Racial and ethnic differences in COVID-19 hospitalization rates persist.

The work group concluded that the balance between desirable and undesirable effects favored the intervention (2024-2025 COVID-19 vaccine). The 2023-2024 COVID-19 vaccine was effective in preventing ED/UC visits and preventing severe outcomes related to COVID-19 (e.g., hospitalization or death). COVID-19 vaccines continue to have a favorable safety profile as emonstrated by robust safety surveillance over 3 years of COVID-19 vaccine use. The statistical signals observed in the VSD (ischemic stroke and GBS) are not clear or consistent, and are seen in the age groups (adults ≥ 50 years and adults ≥ 65 years, respectively) with the highest burden of disease that would benefit the most from updated COVID-19 vaccination. Modeling projects more hospitalizations averted when 2024-2025 COVID-19 vaccines are universally recommended compared to no recommendation or recommended only for those at high risk.

For the values domain of the EtR, the work group thought that people recommended to receive 2024-2025 COVID-19 would have variable assessments of whether or not the benefits outweighed the risks of vaccination. Approximately 30% of parents of children ages 6 months – 17 years reported concern about their child getting COVID-19, but confidence in COVID-19 vaccine safety and vaccine importance was highest among parents of adolescents. Adults ages 65 years and older were more concerned about COVID-19 disease and had higher confidence in vaccine safety and vaccine importance than those <65 years.
Racial and ethnic minority groups, older adults, and those with lower incomes are more concerned about getting COVID-19 than other groups.

For the acceptability domain, the work group thought that acceptability of the intervention would be variable. Vaccine coverage with at least 1 dose of 2023-2024 COVID-19 vaccine was approximately 20% in adults aged ≥ 18 years. From August 2021 to February 2024, the percentage of adults who report being up to date with COVID-19 vaccination has decreased from 69% to 28%. Concern about side effects is the most likely reason for not being vaccinated. Less than 30% of people report having received a healthcare provider recommendation for the 2023-2024 COVID-19 vaccine. COVID-19 vaccine coverage varies by age, race and ethnicity, metropolitan statistical area, insurance status and household income.

The work group judged that implementation was probably feasible or that feasibility was variable. The 2024 – 2025 COVID-19 vaccine will continue to consist of single dose vial presentations and smaller minimum order quantities and storage and handling requirements are unchanged. The increasingly complex routine vaccination schedule, which includes immunizations for three seasonal viral respiratory diseases, presents potential barriers to implementation such as limited storage space due to more vaccines, more opportunities for vaccine administration errors and the need for increased education among vaccine providers. Vaccines will continue to be accessible; however, the end of the temporary Bridge Access Program will result in decreased vaccine access for underserved populations.

The work group felt that 2024-2024 COVID-19 probably was a reasonable and efficient allocation of resources, or that it was variable. Base case ICERs ranged from $23,308 per QALY in adults aged ≥65 years to $212,225 per QALY in adults aged 18-49 years. Cost-effectiveness estimates in those ages ≥65 years were robust to input changes across plausible ranges. Cost-effectiveness estimates in those 5-17 years and 18-64 years were sensitive to changes in inputs. COVID-19 vaccination is most cost-effective in older adults in which disease burden is highest compared to younger adults; COVID-19 vaccination is likely more cost-effective in populations with risk factors, such as underlying conditions, which increase their probability of hospitalization due to COVID-19. ICERs would be more favorable in younger age groups if the cost of vaccination was lower.

Based on the evidence reviewed the work group judged that 2024-2025 COVID-19 vaccine should be recommended. The work group acknowledged that the benefits of COVID-19 vaccination vary by age and risk status. Under a universal recommendation, 2024-2025 COVID-19 vaccines will be available to all persons ages ≥6 months. Additional implementation efforts should be targeted toward those that will receive the most benefit from COVID-19 vaccination, including people ≥65 years old, people with underlying conditions including immunocompromise, and pregnant people to protect themselves and their infants. The Work Group will continue to evaluate COVID-19 vaccine policy, including the need for a universal recommendation, particularly as COVID-19 epidemiology continues to change. The work group's proposed vote was to recommend 2024-2025 COVID-19 vaccines as authorized or approved by FDA in persons ≥6 months of age. Dr. Daley moved to approve the proposed vote language, and the motion was seconded by Dr. Brooks.

Dr. Jamie Loehr, Chair of the ACIP Influenza Vaccine Work Group, introduced the influenza session. Dr. Vivien Dugan, Influenza Division, CDC, provided an update on influenza A(H5N1). Highly pathogenic avian influenza A H5N1 [HPAI A(H5N1)] was detected in birds in 1996. Sporadic HPAI A(H5N1) virus infections of mammals have been reported since 2003-2004. A(H5N1) clade 2.3.4.4b viruses emerged in wild birds in 2020 and 29 human cases of HPAI A(H5N1) have been detected globally since January 2022, of which 4 were in the United States. USDA has confirmed A(H5N1) virus infections of dairy herds in >100 farms across 12 states, with clade 2.3.4.4b virus and high levels of virus in raw milk. Infection of other animal species (wild birds, cats, racoon, opossums) have been reported in association with infected dairy herds in the United States. Since April, a number of human cases have been reported among adults working at dairy farms and in contact with cows. None had severe illness and no human-to-human transmission has been detected. Available candidate vaccine viruses are expected to provide good protection against this virus. Overall the risk to the public remains low, but there is increased risk with exposure to infected animals or environment (occupational, recreational). Exposed individuals should monitor for symptoms after first exposure and for 10 days after last exposure.

Dr. Lisa Grohskopf presented updates, work group considerations, and proposed recommendations for the 2024-25 influenza season. All influenza vaccines marketed in the United States for the 2024-25 season will be trivalent; there will be no influenza B/Yamagata component, following no confirmed detections of wild-type influenza B/Yamagata viruses since March 2020. U.S. influenza vaccine composition for 2024-25 includes an update to the influenza A(H3N2) component: an A/Victoria/4897/2022 (H1N1)pdm09-like virus for egg-based vaccines or an A/Wisconsin/67/2022 (H1N1)pdm09-like virus for cell and recombinant vaccines; an A/Thailand/8/2022 (H3N2)-like virus for egg-based vaccines or an A/Massachusetts/18/2022 (H3N2)-like virus for cell and recombinant vaccines; a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.

For the 2023-2024 influenza season, ~158 million doses of influenza vaccine distributed in United States. No new safety concerns were identified for influenza vaccines.

On behalf of the work group, Dr. Grohskopf summarized evidence on use of higher dose and adjuvanted influenza vaccines for solid organ transplant (SOT) recipients. More than 45,000 solid organ transplants were performed in the U.S. in 2023. American Society for Transplantation (AST) states that high-dose or boosted dosing might be preferable post-transplant, but ACIP has recommended that SOT recipients should receive an age-appropriate inactivated or recombinant influenza vaccine (i.e., an IIV or RIV). An evidence review was undertaken for use of high-dose inactivated, adjuvanted inactivated, and/or recombinant influenza vaccines as an option for influenza vaccination of solid organ transplant recipients who are younger than the approved age indication (i.e., <65 years for high-dose and adjuvanted influenza vaccines, and <18 years for recombinant influenza vaccine). The work group judged that influenza in SOT recipients is a public health problem; manifestations of influenza can be more severe in this population. For benefits and harms, the work group felt that desirable effects outweighed undesirable effects, favoring the intervention. The domains of values, acceptability, resource use, and feasibility were supportive of the intervention ("probably yes") and the work group felt that the intervention would probably increase health equity, leading to a proposed recommendation that all persons should receive an age-appropriate influenza vaccine (i.e., one approved for their age), with the following exception: solid organ transplant recipients aged 18 through 64 years on immunosuppressive medication regimens may receive either HD-IIV3 or aIIV3 as an acceptable option (without a preference over other age-appropriate IIV3s or RIV3). Additionally, the work group proposed that ACIP reaffirm the recommendation for routine annual influenza vaccination of all persons aged ≥6 months who do not have contraindications. Dr. Kotton made a motion to reaffirm the recommendation for annual influenza vaccination and this was seconded by Dr. Daley. Dr. Kotton made a motion for use of HD-IIV3 or aIIV3 as an acceptable option in SOT recipients aged 18 through 64 years and Dr. Loehr seconded the motion.

The pneumococcal vaccines session opened with an update from the ACIP Pneumococcal Vaccine Work Group Chair, Dr. Jamie Loehr, who reminded the committee that during the COVID-19 pandemic, invasive pneumococcal disease (IPD) rates reached a historically low level in all age groups. During 2021-2023, new pneumococcal conjugate vaccines PCV15 and PCV20 were recommended for both adults and children. A 21-valent pneumococcal conjugate vaccine (CAPVAXIVE™, Merck) containing 8 serotypes not in other pneumococcal vaccines was approved by the FDA for adults aged ≥18 years on June 17, 2024. Additional higher-valence pneumococcal conjugate vaccines are currently in clinical development. PCV21 includes serotypes accounting for 81% of IPD cases in 19-64 year olds with a risk-based indication for pneumococcal vaccine and 85% of cases among those ≥65 years, compared with 58% and 54%, respectively, for PCV20. An increase in serotype 4 (included in PCV15 and PCV20 vaccines, but not in PCV21) has been seen in certain subpopulations (e.g., adults experiencing homelessness, especially in the western U.S., and adults in Alaska, especially Alaska Native adults). The following groups are currently recommended to receive a dose of pneumococcal conjugate vaccine (PCV): adults aged ≥65 years who have not received a PCV; adults aged 19–64 years with certain underlying conditions or risk factors who have not received a PCV; and certain adults who have received PCV13 but have not received PCV20. Among adults vaccine coverage is generally lower for risk-based recommendations compared with age-based recommendations. The work group is proposing that ACIP recommend PCV21 as an option for adults aged ≥19 years who currently have a recommendation to receive a dose of PCV.

Dr. Charles Stoecker, Tulane University School of Public Health and Tropical Medicine, presented an economic assessment of PCV21 in U.S. adults. Based on the models presented, replacing PCV20 with PCV21 at age 65 increases QALYs with modest increases in cost. Simulations range from $4,000 to $28,000 per QALY in several scenarios. Replacing PCV20 with PCV21 is results in lower QALYs and more costs in a scenario where serotype 4 disease accounts for 30% of pneumococcal disease. Replacing PCV20 with PCV21 at diagnosis of IC or CMC before age 65 is cost-saving. Cost is $110,000 per QALY in a scenario where serotype 4 disease accounts for 30%. At serotype 4 disease proportions of 35% or above it results in decreased QALYs. Moving PCV21 vaccination from age 65 to age 50 increases case counts and deaths, but also results in gains in QALYs. Disease burden is shifted from younger adults to older adults who have lower background QALY values. Vaccinating at both age 50 and age 65 costs $300,000 per QALY, with sensitivity analyses range from $200,000 per QALY to $400,000 per QALY. Vaccinating with PCV21 at age 19 instead of age 50 results in less health (both lower QALYs and more cases) and increased costs. Supplemental PCV21 at age 65 that includes all adults that previously had PCV20 (at age 65 or at CMC/IC) costs $400,000/QALY; if the supplemental dose is delayed until age 70 the cost drops to $300,000/QALY. Supplemental PCV21 for the CMC/IC population ranges from $200,000 to $300,000 per QALY in the base case. Cost per QALY is 5-30% lower if PCV21 is delayed 5 years after PCV20 vaccination rather than 1 year afterward. Assuming no herd immunity from childhood PCV20 program is associated with the lowest cost per QALY.

Dr. Andrew Leidner, Immunization Services Division, CDC, provided a summary of three economic analyses on the use of PCV21 among adults in the U.S. The three models were the Tulane-CDC model; a model developed by Merck, the manufacturer of the PCV21, PCV15 and PPSV23 vaccines; and a model from a team at the University of Pittsburgh. As modeled, most strategies improved health, although age-based vaccination at 19 years instead of 50 years in the Tulane-CDC model did not improve health. Several strategies were cost-saving, but there was variability in estimates across models for age 50 and supplemental dose strategies.

Dr. Miwako Kobayashi, Division of Bacterial Diseases, CDC, presented the work group's EtR and policy options for use of PCV21 in adults. For the question of should PCV21 be recommended for U.S. adults aged ≥19 years who currently have a recommendation to receive a PCV, the work group felt that "desirable consequences clearly outweigh undesirable consequences in most settings". For the question of should PCV21 be recommended for U.S. adults aged 50-64 years who currently do not have a risk-based pneumococcal vaccine indication, there was not a clear consensus of the work group. Of the available options, "Desirable consequences probably outweigh undesirable consequences in most settings" was most frequently selected by WG members, but did not reach the majority. Some selected "Desirable consequences clearly outweigh undesirable consequences" and "The balance between desirable and undesirable consequences is closely balanced or uncertain", but few believed that undesirable consequences outweighed desirable consequences. For the third policy question, should PCV21 be recommended for U.S. adults aged 19-49 years who currently do not have a risk-based pneumococcal vaccine indication, the majority of WG members selected "undesirable consequences probably outweigh desirable consequences in most settings."

For the equity domain, Dr. Kobayashi presented data on invasive pneumococcal disease (IPD) by race/ethnicity. Racial disparities in IPD incidence have long existed, but disparities due to PCV13-type IPD decreased after 2010, when PCV13 was introduced in the pediatric population. Most of the remaining disparities are due to non-PCV13-type disease.

In Black adults, IPD rates peak at a younger age at 55 to 59 years compared with non-Black adults who have a steady increase in IPD rates with increasing age; the IPD rates for Black adults 50 years and older exceeds the IPD rate for all adults 65 years and older. This is likely due to multiple factors, but differences in prevalence of underlying medical conditions that increase the risk of pneumococcal disease may be one contributing factor. Adults 19-64 years with a risk-based indication of pneumococcal vaccination have had lower vaccine coverage compared with adults 65 years and older with an age-based vaccine recommendation, and disparity in vaccine coverage by race and ethnicity exists. Within adults 65 years and older, the proportion with receipt of any pneumococcal vaccine was significantly lower in Black and Hispanic adults compared with white adults.

An increase in serotype 4 IPD cases has been reported in certain adult populations in recent years. Serotype 4 is contained in previous pneumococcal vaccines but not in PCV21. Serotype 4 IPD cases had nearly been eliminated after PCV7 use in children but IPD clusters have been reported in certain populations (e.g., people experiencing homelessness). In certain areas, increase in serotype 4 IPD cases observed in routine surveillance in recent years, especially post-2020, after near elimination; increases have been reported in the western United States (Alaska, Navajo Nation, Active Bacterial Core Surveillance sites in Colorado, New Mexico, and Oregon). Serotype 4 appears to primarily affect adults aged <65 years with risk-based pneumococcal vaccine indications.

In summary, the work group agreed that available evidence supports PCV21 use for adults currently recommended to receive a PCV. The work group could not reach a consensus on whether the age-based recommendation for PCV21 should be lowered from ≥65 years to ≥50 years; the work group did not support lowering the age-based recommendation for PCV21 to age 19 years. The majority of work group members believed there was insufficient evidence to support lowering the age-based recommendation for currently recommended vaccines.

Dr. Loehr shared his observations on the work group discussions. The work group recognized that lowering the age-based recommendation down to 50 years would result in a significant improvement in equity but at significant cost. The duration of protection is a key variable that would greatly impact the cost-effectiveness. The work group also recognized that lowering the age down to age 50 for PCV21 but for other pneumococcal vaccines would be very confusing. He stated that the work group welcomes the committee's feedback and thoughts on these issues because the work group could not come to a consensus.

Dr. Talbot asked about data on coverage of ≥1 dose of any pneumococcal vaccine among adults 50-64 years of age with a risk-based indication and Dr. Kobayashi stated that the only data she had been able to find was for PCV20, which is a relatively new vaccine and would not be helpful to address this question. Dr. Talbot asked if the age-based recommendation were lowered to age 50, would it be for both PCV21 and PCV20. Dr. Kobayashi replied that the work group was not supportive of lowering the age-based recommendation for other pneumococcal vaccines. Dr. Loehr asked what proportion of 50-64 year olds are already included in the current risk-based recommendation. Dr. Kobayashi answered that it depends on the data source, but ranges from 30 to 50 percent.

Dr. Jamieson stated that she shares the concern about how confusing the recommendations are so she would not be on favor of lowering the age-based recommendation to age 50 years but would be supportive of recommending PCV21 as an option for adults currently recommended to receive a PCV.

Dr. Daley expressed his appreciation for the conversation. He stated that ACIP always has to make recommendations with some uncertainty and that the economic analysis helped highlight the critical issue of whether or not vaccination at age 50 would provide protection for longer than 15 years. Clarity of policy leads to clarity of implementation and operationalization. Having different recommendations for people 50 to 64 years of age with and without high-risk conditions could not be implemented by primary health care providers. He observed that vaccine recommendations do tend to settle over time as knowledge accumulates but is not sure that that is true in this case because of continued introduction of new vaccines. With information about duration of protection, ACIP can make better decisions. Dr. Daley stated that with the IPD burden in Black Americans 50 to 59 years of age being comparable to that in the overall population ≥65 years of age, the committee is missing something by not deciding. He agreed with the work group on not deciding on the age-based recommendation at this meeting but expressed his hope that the committee could get there soon given the existing racial and ethnic disparities in incidence of IPD.

Dr. Brooks stated his support for lowering the age-based recommendation down to age 50 years. Given the rates of IPD in the Black population 50-64 years of age, it would be very helpful to have a universal recommendation. Many are already included in the existing risk-based recommendation but are not getting vaccinated.

Dr. Kotton expressed concern about collateral damage on other vaccines. Providers are overwhelmed by choices and changes and some people feel like they have had enough vaccines. She pointed out some people would definitely benefit from pneumococcal vaccination at age 50 but not everyone; it would be great if persons at highest risk could be better targeted by vaccination programs. She stated that she would prefer to focus efforts on vaccines for which there might be more benefit.

Dr. Long stated that she thought that an age-based recommendation down to age 50 years would decrease equity because lower risk people would be disproportionately vaccinated compared to the populations at higher risk of IPD. The burden of disease data does not support lowering the age to 50 years for PCV20, so if only PCV21 were recommended, that would be a preferential recommendation and might impact the availability of PCV20. Clinical effectiveness data are unavailable for either PCV20 or PCV21, and it's unclear what's going on with serotype 4. If PCV20 were no longer available, that could adversely impact other populations, and this is a reason not to lower the age for PCV21.

Dr. Shaw asked about availability and supply for PCV21.

Dr. Cineas stated that she favored an age-based recommendation from 50-64 years because of the high prevalence of underlying conditions in this age group. Implementation of risk-based recommendations is difficult and she believed that an age-based recommendation would help reduce disparities.

Dr. Loehr replied that the supply would come, but it takes a year for insurance companies to be required to cover a new vaccine recommendation. Because PCV20 would still be used in children, he is less concerned about that vaccine not being available. He stated that he believed that an age-based recommendation down to age 50 would improve health equity.

Dr. Matthew Clark, *Ex Oficio* member from the Indian Health Service, expressed support for PCV21 but that it was important that other vaccines remained available. Despite the availability of pneumococcal vaccines, the burden of IPD remains 2 to 4 times higher among AI/AN adults

compared to the general U.S. population. This is primarily due to serotypes not covered by currently available vaccines, but in the last few years, serotype 4 has emerged as a substantial contributor to IPD in adults in Alaska and in the Navajo Nation, which are the two places in the U.S. with robust IPD surveillance in AI/AN populations. Most cases occurred in people who had not received pneumococcal conjugate vaccine but who had a risk factor indication to be vaccinated. This is especially true among adults 18-49 years of age. In April the IHS Chief Medical Officer Dr. Christensen issued a call to action to administer PCV20 to all AI/AN adults with an indication. PCV21 has a great potential to prevent IPD in AI/AN adults and provides excellent coverage for the serotypes causing disease in those ≥65 years of age, but does not contain serotype 4, so it's important to retain a serotype 4-containg vaccine as an option, especially for AI/AN adults 18 to 49 years of age with risk factors for IPD. Neither PCV20 nor PCV21 is perfectly matched to protected against the circulating serotypes in tribal communities, but where data are available, clinicians serving AI/AN patients may be able to tailor their vaccine recommendations to the local epidemiology. The burden of IPD increases at a younger age among AI/AN adults, and historically IHS has been more successful implementing age-based rather than purely risk factor-based indications. A recommendation for PCV21 that includes those ≥50 years of age would be a benefit in the AI/AN population that IHS serves.

Ms. Phyllis Arthur, liaison representative from BIO, expressed concern with the idea that increased coverage in one group would have a negative impact on equity for others. Increasing vaccination in all groups will result in an overarching improvement in vaccination status. Industry is focused on bringing interventions to populations that will raise equity while still offering great options for all populations regardless of equity.

Dr. Rick Zimmerman, liaison representative from the Association for Prevention Teaching and Research, said that he had recently been part of a team that had published a piece on the societal cost in adults of racial inequity in pneumococcal disease and the cost is $673 million for adults aged 50 and older. In another paper, the strategy that reduced IPD cases and deaths the most in the Black population was vaccination with PCV21 at ages 50 and 65 and in the non-Black population with PCV21 at ages 50 and 65.

Dr. Bob Hopkins, liaison representative from NFID, expressed strong support for recommending PCV21 for those ≥50 years with and without risk factors.

Dr. Jason Goldman, liaison representative from ACP, spoke in support of an age-based recommendation beginning at age 50. Many of his patients 60 to 65 year age range are not working but not yet Medicare-eligible and don't have medical insurance. A recommendation at age 50 would be easier to implement and also could improve equity by allowing patients in that 50 to 60 year old age range who are working and insured to be vaccinated.

Dr. Randall Morgan, liaison representative for NMA, spoke in support of an age-based recommendation for pneumococcal vaccine beginning at age 50. The life expectance for Black persons, especially Black men, is much lower than for other minorities and for whites. The poor clinical outcomes for Black people also create systemic challenges associated with earlier, longer, and mre serious hospitalization stays as well as possible deaths so pneumococcal vaccine recommendation beginning at age 50 years will certainly improve the lives of many Black patients and enhance the population health of the community.

Dr. Rick Haupt from Merck Vaccines thanked the committee for the thorough review. He reminded the committee that PCV21 was developed as an adult-specific pneumococcal vaccine that due to its serotype composition addresses most of the residual pneumococcal disease in adults. The expansion of a routine age-based recommendation that includes 50- to 64-year-olds could have substantial public health impact. While the majority of IPD cases and pneumonia in this age group occur among adults who have risk conditions, the current vaccine uptake in this group is far too low. There are significant racial disparities in pneumococcal disease risk and in the prevalence of risk conditions. Implementation of a routine age-based recommendation could improve access to and uptake of pneumococcal vaccines and reduce disparities in adults 50-64 years of age with risk conditions. Lowering the age-based recommendation down to age 50 would likely improve vaccination coverage rates in all populations and could have a far greater impact on reducing disparities and improving equity; this opportunity would be lost if no expansion of the age-based recommendation occurs. The occurrence of clusters of serotype 4 disease does not diminish the overall positive overall population impact expected for PCV21 in adults 50 years of age and older. ACIP can make a much simpler recommendation that will make implementation much easier through an age-based recommendation. Merck has built a supply that is adequate for a broad recommendation.

Dr. Luis Jodar from Pfizer Vaccines reminded the committee that they previously had considered an age-based recommendation for PCV20 starting at age 50 but ultimately voted for an age-based recommendation for adults ≥65 years of age and risk-based recommendations for adults 19 to 64 years of age, so the current policy question proposes the use of PCV21 in populations that have no recommendations for use of any PCVs. Having one PCV recommended for healthy adults ≥50 years of age and other PCV vaccines or other ages or risk conditions would likely complicate rather than simplify implementation of these recommendations. All PCVs licensed for use in adults ≥18 years and older should be considered as options for routine vaccination of all adults ≥50 years of age.
Dr. Kobayashi presented the work group's proposal that ACIP recommend PCV21 as an option for adults aged ≥19 years who currently have a recommendation to receive a dose of PCV and the accompanying implementation guidance.

Dr. Long said that the rationale for the age-based recommendation for PCV21 down to age 50 apparently was that doctors couldn't understand and implement a risk-based recommendation, and she thought it would be a better investment of resources to educate doctors to do that better. This recommendation for PCV21 down to age 50 would cost $270,000 per QALY. She stated that the committee should not consider PCV20 down to age 50 so they match up because that's $630,000 per QALY; $270,000 per QALY is unacceptable but $630,000 is outrageous.

Dr. Talbot asked Dr. Goldman if the problem for internists in vaccinating those at high risk between 50 and 64 years of age is lack of education, or are there other reasons? Dr. Goldman responded that internal medicine specialists are able to read the vaccine schedule and understand the patients' chronic conditions. The barriers are beyond the control of physicians – the Federal government, the reimbursement, the storage, the insurance companies that create barriers to care, preventing physicians from being able to take care of the patients the way they need to as well as the administrative burdens that are created by the system. He stated that he believes it is imperative to have a simplified process so that physicians can delegate with standing orders to their staff to make sure that patients are screened appropriately and that they are giving the vaccines that are needed. It would be very simple to stock both PCV20 and PCV21 in the office and be able to implement both of them; he sees them as two separate and useful vaccines that are both needed.

Lowering the age to 50 years would simplify the process because of the system dynamics that make it a barrier to patient care. He said that while he appreciates the expenditure to society, he always has to go back to the only patient that matters is the one sitting in front of him, until he sees the next patient, and then that's the most important patient in the world. He understood that the committee has to look at the cost to society, but as a practicing physician, he has to look at what is most beneficial to his patient, and he would be in favor of making sure they have access to both vaccines.

Dr. Schechter asked if a single dose could be given at age 50 due to either durable immunity or a change in the epidemiology of the disease due to childhood and adult vaccination, what would be the cost effectiveness implications? Dr. Kobayashi responded that in the Tulane-CDC model, vaccination with PCV21 at age 50 was cost saving, but with the caveat that there was more disease due to waning, and so an additional dose was added at age 65.

Dr. Daley said that he thought it would be problematic to have a recommendation for PCV21 down to age 50 but not for the other high valency vaccines such as PCV20 even though he was clear that PCV21 was a very different vaccine that was expected to provide broader protection. He asked if the work group would bring the full proposal to ACIP in October for lowering the age-based recommendation to age 50 for high valency pneumococcal vaccines because he felt like he did not have the information today for that big of a decision. He acknowledged that there was an opportunity cost but the data had not been presented for all high valency pneumococcal vaccines down to age 50; it's an important question to answer, and it needs to be answered soon.

Dr. Sandra Fryhofer, liaison representative from the American Medical Association, stated that pneumococcal vaccination for adults is the most complicated vaccination recommendation and that she thought that having a different age recommendation for PCV20 and PCV21 would add much confusion. She stated that she supported Dr. Daley's suggestion to come back to this issue in October.

Dr. Long stated that she thought it would be good for the work group to look at this again and to address the question about the duration of protection from polysaccharide conjugate vaccines; the data that the work group saw provided no indication for protection after 12 to 15 years. Making a decision to vaccinate at 50 is most likely a decision to vaccinate again at 65, which is very expensive.

Dr. Brooks stated that he would ask that the work group come back with a proposal for PCV20, but that that would not preclude a vote today on PCV21.

Dr. Kotton said that she appreciated Dr. Goldman's comments about the "patient in front of him" but that she does feel the need for some financial stewardship and she is concerned about the magnitude of the costs we are incurring, both with RSV vaccine which is quite expensive and with this vaccine, which is $319 plus administration fees. She stated that she thought that the committee really needed to think about cost that is being added to American healthcare.

Dr. Schechter said that there's a case for a reinforcement of pediatric vaccination. Introduction of new higher valency pneumococcal vaccines in adults before children misses an opportunity to both protect children directly and protect adults through indirect effects. Whatever the committee decides today, he hoped that there was a way to expedite access to children of vaccines that protect against additional serotypes.

Dr. Loehr made a motion that ACIP recommends PCV21 as an option for adults aged ≥19 years who currently have a recommendation to receive a dose of PCV. The motion was seconded by Dr. Jamieson.

PUBLIC COMMENTS

Overview

The floor was opened for public comment on June 27, 2024 at 3:40 PM EDT. Members of the public also were invited to submit written public comments to ACIP through the Federal eRulemaking Portal under Docket Number ID CDC-2024-0043. Visit regulations.gov to read background documents and comments received.

Public Comments

Ms. Chloe Humbert
Private Citizen

Ms. Humbert spoke in favor of better vaccine promotion campaigns from the government. The recommendation for a Spring COVID vaccine boost for seniors was not well-promoted. She expressed concern that the recommended additional dose in the spring excluded 50- to 64-year-olds with underlying conditions—people clearly at risk of hospitalization or death.
She stated that this lack of a vaccine campaign is persistent failure and antivaccine sentiment has been coming from inside of government. She spoke very critically about the antivaccine campaign implemented outside the United States by the Department of Defense. She stated that this disinformation campaign was reported to have undermined vaccination and also masking and testing. Even though the campaign was forbidden by law from targeting Americans, in an interconnected world during a global pandemic, the idea of undermining public health abroad without harming Americans is ridiculous on its face and harming innocent civilians abroad during a global health crisis is not itself defensible. CDC officials may think that this is not the fault or responsibility of the CDC, but that's false. Real people are counting on the CDC. Leadership cannot rest on laurels or point fingers elsewhere. Infectious disease doesn't recognize geopolitical boundaries or federal agency silos. CDC should have a distinct and purposeful goal of actually promoting public health and leading vaccination promotions with an active campaign.

Meghan Rapp
Private Citizen

Ms. Rapp expressed her appreciation to ACIP members for their important work in making vaccine recommendations. She shared her concerns as a mother of 2 young children about the timing, access, and frequency of COVID boosters for young children. In the South, schools start in August. All populations, including children, need access to the updated COVID-19 vaccines as soon as possible so that there's time to get children into the pediatrician's office or health department before August; October is not acceptable timing. She asked for an increase in vaccine options available for young children, including Novavax for under 12 years of age. She stated that she knows many parents who would prefer that option and that its availability would help with vaccine uptake among young children. She also described challenges of access to vaccination sites faced by parents because pharmacies may not be able to or be willing to vaccinate younger children.

It takes more time to visit a pediatrician's office and not all pediatricians offices will carry COVID shots. It would increase the vaccine uptake rate if COVID boosters for children were available in July when these back-to-school appointments are beginning. She also requested that the recommended frequency of boosters be increased for all ages. With waning immunity following vaccination, changes in variants, the inability of small children to mask, and states banning masks, fewer prevention strategies are available.

Dr. Brian Koffman
Co-Founder and Executive Vice President
Chronic Lymphatic Leukemia (CLL) Society

Dr. Koffman introduced himself as a retired family doctor and a chronic lymphatic leukemia (CLL) patient. He explained that all CLL patients are immunocompromised regardless of their treatment status and like other immunocompromised communities, CLL patients were disproportionately affected by COVID-19. He stated that it is also well-documented that the response of immunocompromised persons to vaccines is less predictable and robust than that of the general population and expressed appreciation to ACIP for recognizing the immunocompromised as a special category requiring specific recommendations. He pointed out that often the evidence to make these recommendations is weaker than that for other vaccine recipients for whom data from randomized clinical trials are available; immunocompromised persons are often excluded from these trials, so decisions end up being made by expert consensus. He requested that ACIP, when appropriate, push to include the immunocompromised in clinical trials so higher quality data are available to inform recommendations.
He asked ACIP to coordinate its efforts to integrate every available immune measure, including vaccines and pre-exposure prophylaxis, with disease-specific monoclonal antibodies to offer the immunocompromised their best package of protection, including both active immunity through vaccination and passive through antibodies. He also requested that ACIP revisit the near universal prohibition against live vaccines in the immunocompromised and to find ways to explore the safety and efficacy of live vaccines rather than dismiss them all as too risky and leave immunocompromised persons completely unprotected.

Stanley Plotkin, MD
University of Pennsylvania

Dr. Plotkin stated his support for the development of more combination vaccines. Combination vaccines decrease the amount of time post-vaccination when an unrelated illness could be ascribed to a vaccine, decrease required medical visits, and could increase collaborations among manufacturers. He stated that he hoped the ACIP would express enthusiasm for combined vaccines to induce manufacturers to work together and also to advance vaccine coverage. He also said that he was happy to see that chikungunya vaccine was under consideration. Chikungunya can be devastating to those infected, even if mortality is low. He reminded the committee that chikungunya is now a worldwide disease and as global warming increases, it will inevitably spread Northward. Dr. Plotkin stated that he has been a consultant to Valneva about their chikungunya vaccine and said he was happy to see it progress to licensure. He stated that the best way to prevent outbreaks is to produce an immune human population. Waiting for an outbreak and responding only then is a recipe for increased individuals with chronic problems due to chikungunya. He expressed his hope that ACIP would eventually recommend prophylactic vaccination in areas where there are *Aedes* mosquitoes.

Jamie Schanbaum
J.A.M.I.E. Group

Ms. Schanbaum shared her experience as a survivor of meningitis. She was a college student and like many meningitis patients, came out of the hospital as an amputee. She stated that she was hospitalized for 7 months and at discharge weighed 80 pounds and had lost all of her hair. She expressed regret that she went to college without having been vaccinated and almost lost her life to it. She said that she knew people whose children had not survived meningitis, and she wanted to be the voice for them. She reminded the committee that meningitis is commonly misdiagnosed due to the initial nonspecific symptoms and said that she had known someone in whom the diagnosis was initially missed, and when they returned to the hospital, they were declared brain dead within 18 hours from their first symptom of meningitis. Ms. Schanbaum said that was why she was speaking, because she didn't want anyone to go through what she had gone through. She said that she recently had her leg re-amputated 2 years ago because of an ill-fitted prosthetic. She thanked the committee for listening.

Don Ford
Organizing for a Better Tomorrow

Mr. Ford said that the role of the CDC is to set guidance that will protect people from disease, but a large amount of anti-vaccine propaganda, state representatives trying to ban conventional masking, and mutating variants, it's a challenging time for people to protect themselves. The diseases discussed today are a risk to everyone, not simply the immunocompromised. Looking only at mortality underestimates impact when any single infection can destroy someone's quality of life forever. He stated that people need to do everything they can to limit the risks.
He advocated for an earlier vaccine rollout, recommendations for both mRNA and protein subunit COVID-19 vaccines, and for two dose recommendations due to development of new variants and imprinting in response to previous vaccination. CDC and FDA should consider meeting twice a year to discuss variants and recommend updates to vaccines if needed. As the Bridge Program is expiring, access to insurance is the only way that people can access these lifesaving vaccines. New recommendations determine not only if people can access them, but whether insurance will cover the once free but now cost-prohibitive vaccines. He spoke in support of authorization of Novavax for children. He expressed concern about state legislatures banning masks or other personal airborne protections under the guise of security. He also said that H5N1 should be taken more seriously, that it is a ticking time bomb that needs to be diffused before it goes off.

Ashlie White
Amputee Coalition

Ms. White spoke on behalf of The Amputee Coalition, which supports and advocates on behalf of the 5.6 million Americans with limb loss and limb difference and their families, caregivers, and clinicians. She appreciated the opportunity to comment about the important role vaccines play in protecting their community. Well over half of the more than 5.6 million individuals missing limbs in the US have serious underlying health conditions, including diabetes, peripheral arterial disease, and cancer—illnesses that have been shown to be the most likely causes of limb loss and of themselves are significant risk factors in increasing anyone's vulnerability. Limb loss patients have additional burdens. There is impact on patient health from living with reduced mobility, as well as the challenge of obtaining medical services, as travel can often present both physical and economic barriers to seeking care. “Limb difference” is the phrase used to describe differences in the size, shape, or structure of a limb when compared to what is considered medically normal. Limb loss and limb difference patients need to be able to know about, understand, and easily access the vaccines which CDC recommends for them. Ensuring our communities understand the vaccines that are available to them and have easy access to get them can really make a difference; however, confusion over CDC recommendations, insurance coverage, or having to make multiple trips to a provider to get vaccinated for one condition at a time can present real and formable burdens to our community members. She urged the committee to consider this community when developing vaccine recommendations and to make sure that recommendations are as clear and broad as possible to support and increase awareness and access by those who would most benefit.

VOTES

Vote: COVID-19 Vaccines
Dr. Keipp Talbot, ACIP Chair, read the following proposed ACIP voting language into the record for COVID-19 vaccines:

> *ACIP recommends 2024–2025 COVID-19 vaccines as authorized or approved by FDA in persons ≥6 months of age.*

Motion/Vote: COVID-19 Vaccines

Dr. Daley made a motion to approve the proposed recommendation as written stating, "ACIP recommends 2024–2025 COVID-19 vaccines as authorized or approved by FDA in persons ≥6 months of age" Dr. Brooks seconded the motion. Dr. Maldonado declared a COI due to serving as the Stanford PI for the Pfizer pediatric COVID-19 and RSV vaccine trials and adult varicella vaccine trials. No other COIs were declared. The motion carried with 11 favoring, 0 opposing, and 1 abstaining. The disposition of the vote was as follows:

11 Favored: Brooks, Chen, Cineas, Daley, Jamieson, Kotton, Loehr, Long, Schechter, Shaw, Talbot
0 Opposed: N/A
1 Abstained: Maldonado

Vote: Pneumococcal Vaccines
Dr. Talbot, ACIP Chair, read the following proposed ACIP voting language into the record for pneumococcal vaccines:

> *ACIP recommends PCV21 as an option for adults aged ≥19 years who currently have a recommendation to receive a dose of PCV.*

Motion/Vote: Pneumococcal Vaccines

Dr. Loehr made a motion to approve the proposed recommendation as written stating, "*ACIP recommends PCV21 as an option for adults aged ≥19 years who currently have a recommendation to receive a dose of PCV.*" Dr. Jamieson seconded the motion. Dr. Maldondo declared a conflict due to serving as the Stanford PI for the Pfizer RSV and COVID-19 vaccine trials and adult varicella vaccine trials. No other COIs were declared. The motion carried with 11 favoring, 0 opposing, and 1 abstaining. The disposition of the vote was as follows:

11 Favored: Brooks, Chen, Cineas, Daley, Jamieson, Kotton, Loehr, Long, Schechter, Shaw, Talbot
0 Opposed: N/A
1 Abstained: Maldonado

Vote #1: Influenza Vaccines
Dr. Talbot, ACIP Chair, read the following proposed ACIP voting language into the record for the first influenza vaccines vote:

> *ACIP reaffirms the recommendation for routine annual influenza vaccination of all persons aged ≥6 months who do not have contraindications.*

Motion/Vote #1: Influenza Vaccines

Dr. Kotton made a motion to approve the proposed recommendation as written for influenza vaccination stating, "ACIP reaffirms the recommendation for routine annual influenza vaccination of all persons aged ≥6 months who do not have contraindications." Dr. Daley seconded the motion. Dr. Maldonado declared a COI as the Stanford PI for Pfizer pediatric RSV and COVID-19 vaccine trials and adult varicella vaccine trials. No other COIs were declared. The motion carried with 11 favoring, 0 opposing, and 1 abstaining. The disposition of the vote was as follows:

11 Favored: Brooks, Chen, Cineas, Daley, Jamieson, Kotton, Loehr, Long, Schechter, Shaw, Talbot
0 Opposed: N/A
1 Abstained: Maldonado

Vote #2: Influenza Vaccines
Dr. Talbot, ACIP Chair, read the following proposed ACIP voting language into the record for the second influenza vaccines vote:

> *ACIP recommends high-dose inactivated (HD-IIV3) and adjuvanted inactivated (aIIV3) influenza vaccines as acceptable options for influenza vaccination of solid organ transplant recipients aged 18 through 64 years who are receiving immunosuppressive medication regimens, without a preference over other age-appropriate IIV3s or RIV3.*

Motion/Vote #2: Influenza Vaccines

Dr. Kotton made a motion to approve the proposed recommendation as written stating, "ACIP recommends high-dose inactivated (HD-IIV3) and adjuvanted inactivated (aIIV3) influenza vaccines as acceptable options for influenza vaccination of solid organ transplant recipients aged 18 through 64 years who are receiving immunosuppressive medication regimens, without a preference over other age-appropriate IIV3s or RIV3." Dr. Loehr seconded the motion. Dr. Maldonado declared a COI as the Standford PI for Pfizer pediatric COVID-19 and RSV vaccine trials and adult varicella vaccine trials. No other COIs were declared. The motion carried with 11 favoring, 0 opposing, and 1 abstaining. The disposition of the vote was as follows:

11 Favored: Brooks, Chen, Cineas, Daley, Jamieson, Kotton, Loehr, Long, Schechter, Shaw, Talbot
0 Opposed: N/A
1 Abstained: Maldonado

Dr. Talbot invited ACIP members to make comments following the votes.

Dr. Loehr commented that there have been recommendations for 18 to 64 years of age and for ≥19 to 64 years of age. He wondered if this could be consistent in the future if there is a rationale for one versus the other. It is confusing because the VFC considers through age 18, which may be the reason why sometimes there is confusion.

Dr. Wharton indicated that this also may have to do with the data that are available for certain diseases in terms of when historically the recommendations were originally put together, but it is an inconsistency that does create another type of challenge.

Dr. Talbot reminded everyone that it was mentioned earlier in the day that insurance has a year to pay for vaccines. It is interesting that the ACIP has a mandate to review and vote on a vaccine very quickly after FDA licensure, but insurance has a year. It seems just as imperative for insurance companies to have an abbreviated time following an ACIP vote to start paying for these vaccines. This should be considered in the near future.

Dr Kotton seconded the concern about insurance companies. Given that it is CMS policy that gives insurers a year, CMS would need to alter its policy, which would then influence private insurance.

Ms. Hance from CMS clarified that this would require a modification of the Affordable Care Act (ACA) that gave private insurance a year after a vaccine is recommended.

Dr. Kotton said that similarly, she would like to ask that CMS and other regulatory bodies consider how vaccines are being supplied and the fact that many of practitioners cannot give vaccines that are covered under Medicare Part D in their offices. The minute the patient leaves a clinic with a recommendation to go to a commercial pharmacy, they often do not get the vaccines they need. This is a major impediment toward broad vaccination of adults. As they had seen during the first 2 days of this meeting, there are missed opportunities to prevent vaccine-preventable illnesses. Support on the regulatory aspects of vaccine coverage would be much appreciated.

Dr. Brooks pointed out that regarding the discussion about PCV being moved down to be universally recommended at age 50 in the interim while the ACIP further deliberates on this, they could focus on those who already have the indication for the vaccines that are now available who are not getting vaccinated—the 30% to 50% who are of high risk who are unvaccinated in that age group.

With no additional business posed for the day, the ACIP meeting stood in recess until 8:00 AM on June 28, 2024.

FRIDAY: JUNE 28, 2024

WELCOME AND INTRODUCTIONS

Call to Order/Roll Call

Dr. Keipp Talbot, ACIP Chair, called to order and presided over the third day of the June 26-28, 2024 Centers for CDC ACIP meeting. She conducted a roll call, 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. One COI was declared by Dr. Maldenado, who is the Stanford PI for the pediatric COVID vaccine and RSV vaccine trials, and adult varicella trials. Dr. Talbot noted that this was the last meeting for several ACIP members, including Dr. Chen, Dr. Daley, Dr. Kotton, and Dr. Long. Each of them shared a few thoughts about their tenure on the ACIP.

PRESENTATIONS

The meningococcal vaccines session began with an introduction by Dr. Jamie Loehr, Chair of the ACIP Meningococcal/Hib Vaccines Work Group. The work group is reviewing GSK's combination MenABCWY vaccine, which could be licensed soon, as well as continuing to consider changes to the adolescent meningococcal vaccine schedule. The policy questions under consideration by the work group for GSK's MenABCWY vaccine are: should the pentavalent vaccine be included as an option for MenACWY/MenB vaccination in people currently recommended to receive both vaccines at the same visit; should the pentavalent vaccine be included as an option for people currently recommended to receive MenACWY only; and should the pentavalent vaccine be included as an option for people currently recommended to receive MenB only. Dr. Loehr shared that the work group anticipates presenting GRADE and the Evidence-to-Recommendations (EtR) framework along with an economic analysis for the GSK MenABCWY vaccine at the October ACIP meeting in preparation for a possible vote in February 2025, if the vaccine is licensed by that time.

Ms. Amy Rubis, Division of Bacterial Diseases, CDC, presented an update on the epidemiology of meningococcal disease in the United States. Meningococcal disease cases are reported to CDC through the National Notifiable Diseases Surveillance System (NNDSS). Additional serogroup and outcome information along with other clinical characteristics are collected from all jurisdictions through Enhanced Meningococcal Disease Surveillance (EMDS). All available isolates are also submitted to CDC for whole genome sequencing. Meningococcal disease surveillance data are typically finalized in the fall of the following year; 2023 data are still preliminary. Meningococcal disease incidence in the US declined dramatically between 1996 and 2019, with further declines in 2020 and 2021. In 2022 to 2023, reported cases have rebounded. Based on preliminary 2023 data, 423 cases have been reported, which equates to the highest incidence since 2014. The 2023 increase was predominantly due to a dramatic increase in *Neisseria meningitidis* serogroup Y (NmY). In many jurisdictions, the increases are primarily due to NmY sequence type (ST) 1466 (clonal complex CC174), which is susceptible to all treatment and prophylaxis antibiotics. Of cases for which data are available, 64% are among Black or African American persons. Sixty-two percent of cases presented with bacteremia. Only 4 cases were in individuals who received MenACWY vaccine, and none were up to date with MenACWY according to ACIP recommendations.

Cases associated with NmY ST-1466 were almost all among adults and have been detected across the U.S. but seem to be concentrated on the East Coast. For 2024, as of June 11, 251 cases have been reported to CDC, compared to 164 cases as of this date in 2023. Of those with known serogroup, 103 (57%) are NmY.

Looking at overall meningococcal disease epidemiology during the period 2012 to 2021, incidence and serogroup distribution vary by age group with the highest incidence observed in children aged less than 2 years and adults aged greater than 85 years. A peak in incidence is also observed among adolescents and young adults aged 16-20 years. Serogroup B is the predominant serogroup in children aged less than five years; in children and adolescents aged 5-20 years, serogroup B accounts for approximately half of cases and in adults aged greater than 20 years, serogroups C, W, and Y cause the majority of disease. Incidence was lower across age groups in 2022 and 2023, but there was a peak in disease in 26-64 year olds, driven by the ST-1466 NmY cases. In 2022 and 2023 an increase in incidence among Black or African American persons consistent with the demographic characteristics of the ST-1466 cases driving the increase in incidence in these years. From 2015 to 2023, incidence rates among 11-20 year olds were highest for Black or African American persons and by ethnicity, for non-Hispanic persons.

Both penicillin resistant and ciprofloxacin and penicillin resistant cases that are mostly serogroup Y are being identified. This strain is not related to the ST-1466 cases; these are mainly sequence type 3587 with some isolates in closely related STs. This strain is disproportionately affecting Hispanic individuals. Ciprofloxacin-resistant only cases are also being seen; these are mostly sporadic cases and not related to the ST-3587 strain. In 2023 and 2024 there have been increases cases due to penicillin resistant as well as ciprofloxacin and penicillin resistant *N. meningitidis*. An increase in ciprofloxacin resistant only cases is also being seen. Most of the dual resistant and penicillin resistant cases are NmY or have an NmY backbone and they appear to be genetically related. CDC has recently provided guidance to avoid the use of ciprofloxacin for prophylaxis of close contacts of patients with meningococcal disease in areas with ciprofloxacin resistant cases.

Since 2022, 9 outbreaks have occurred, including a large serogroup C outbreak among men who have sex with men; a small serogroup C outbreak among people experiencing homelessness; a small serogroup B outbreak in a college and surrounding community; a large statewide serogroup Y ST1466 outbreak; a serogroup W community outbreak; an outbreak of serogroup B in an Amish community; another outbreak among people experiencing homelessness, this one serogroup Y; one outbreak in a correctional facility; and an outbreak associated with travel to the Kingdom of Saudi Arabia.

In summary, incidence of meningococcal disease increased in 2023 to above prepandemic levels, and this increase was primarily driven by serogroup Y ST-1466 cases. The increasing burden of disease driven by ST-1466 NmY is being observed primarily among those aged 30-60 years. We don't know if that is just the epidemiology of this strain or if the adolescent vaccination program is successfully protecting the preteens, teens, and young adults. Ciprofloxacin resistance is increasing both domestically and in imported cases, and multiple jurisdictions have moved away from using ciprofloxacin for prophylaxis of close contacts of patients with meningococcal disease. A growing number of the isolates resistant to ciprofloxacin are serogroups other than Y. ST1466 is predominately affecting Black or African American persons, leading to an increasing disparity in incidence among Black persons compared to other racial groups.

There have been a large number of outbreaks since 2022, and in many cases these outbreaks are affecting minorities (e.g., Black or Muslim communities) or disadvantaged populations (people experiencing homelessness or people who are in prison).

Dr. Wendy Sohn, GSK, presented immunogenicity and safety data on GSK's MenABCWY vaccine. GSK's vaccine is built on the components of MenACWY (Menveo) and MenB-4C (BEXSERO), with licensure of the combined product anticipated in 2025. The proposed indication for MenABCWY is for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroups A, B, C, W, and Y in individuals 10 through 25 years of age, with 2 0.5 mL doses administered intramuscularly at least 6 months apart. Dr. Sohn presented an overview of GSK's clinical program, with a summary of study results that demonstrated the safety and immunogenicity of MenABCWY in adolescents and young adults. MenABCWY was non-inferior to MenACWY-naïve and -primed participants. Investigators were also able to demonstrate an immune response against a diverse group of serogroup strains that was non-inferior to MenB-4C. Persistence of antibody response to MenB strains was demonstrated at 24 months. Solicited local and systemic adverse events within 7 days were monitored after MenABCWY, MenB-4C or MenACWY; reported adverse events were generally mild-to-moderate, with mean duration of 1-4 days, depending on the adverse event. Adverse events occurred at similar rates after MenABCWY and MenB-4C, and higher than after MenACWY. No differences in adverse events were observed between the 1st and 2nd dose of MenABCWY.

Dr. Sarah Schillie, Division of Bacterial Diseases, CDC, then presented work group considerations regarding MenABCWY vaccine and on potential risk groups for MenB vaccination. In their review of GSK's clinical development program, they noted that the demographics of the clinical trial participants may not be reflective of that of the U.S. population but rather reflective of the countries in which the trials occurred. The work group found that the safety profile of pentavalent vaccine was favorable and similar to that of MenB (and more adverse events occurred for pentavalent compared to MenACWY). Regarding immunogenicity, pentavalent was non-inferior to MenACWY in most study groups. The comparison of 1 dose pentavalent vs. 1 dose MenACWY in naïve recipients was not powered for noninferiority, although results were favorable for all serogroups except A. MenABCWY was non-inferior to MenB based on GSK's endogenous complement human bactericidal antibody assay. MenABCWY was non-inferior to MenB 0,2 months for 3 components (fHbp, NadA, NHBA) and MenB 0,6 months for 2 components (fHbp, NadA) based on hSBA. After 24 months, titers waned substantially for serogroup A and for B components fHbp, NHBA, and PorA. A robust booster response was elicited. The work group was concerned about the drop in protection at 2 years for serogroup B.

Options for revising the adolescent meningococcal vaccine schedule were presented to ACIP in February. With the current schedule, MenACWY is recommended at 11-12 years and at 16 years, and MenB vaccine is recommended at 16-23 years based on SCDM. Options under consideration include, in addition to the current schedule, keeping MenACWY as in the current schedule and either recommending MenB for all adolescents at age 16 years and again at age 17-18 years, or for adolescents at higher risk for MenB at those same ages. The dose of MenACWY recommended at 11-12 years could be dropped and a single dose given at age 16 years, with Men B at 16 years and 17-18 years either for all adolescents or for those at higher risk. Finally, MenACWY could be given at 15 years and 17-18 years and Men B (2 doses) at 17-18 years. Because changing the MenB recommendations to risk-based is under consideration, the work group has considered groups of adolescents at higher risk for MenB, based on congregate living settings.

This would include adolescents planning to attend college and adolescents in a congregate living setting (e.g., congregate foster care, boarding school, correctional facility, etc.) who are anticipated to remain in this setting long enough to complete the MenB vaccine series. Additionally, any adolescent who desires protection may receive MenB vaccine, even if they are unsure of their future plans which may inform congregate living risk.

Dr. Sarah Long opened the session on maternal and pediatric RSV with a report from the ACIP Maternal/Pediatric RSV Work Group. Dr. Long reminded the committee of the current recommendations for either vaccination in pregnancy or administration of nirsevimab for protection of infants from severe RSV disease. Vaccine administration errors have been reported to the Vaccine Adverse Event Reporting System, including reports of pregnant persons receiving GSK's vaccine for older adults; reports of children receiving RSV vaccine instead of nirsevimab or of young children receiving the wrong dose of nirsevimab. CDC has made additional educational materials available to healthcare providers to support appropriate use of these products.

Dr. Shannon Stokley, Immunization Services Division, CDC, provided an update on implementation and uptake of nirsevimab and the maternal RSV vaccine. In the Vaccine Safety Datalink, 17.8% of pregnant persons had received the maternal RSV vaccine by January 31, 2024. Vaccination coverage varied by race and ethnicity, ranging from 10.3% among Black pregnant persons to 24.8% among Asian pregnant persons. According to the March 2024 National Immunization Survey, 41% of infants <8 months of age received nirsevimab during the 2023-2024 season. Fifty-one percent of infants are estimated to have been protected from RSV by either receipt of nirsevimab or maternal RSV vaccination. For the 2024-2025 season, maternal immunization should resume in most of the continental U.S. on September 1, and nirsevimab administration should resume in the same areas on October 1; nirsevimab is expected to be broadly available by that time. During the 2023-2024 season there were a number of challenges with maternal RSV vaccination including cost and reimbursement issues, access issues (e.g., lack of supply at many OBGYN offices, requirement for a prescription at pharmacies), lack of data on coadministration, and lack of linkage of maternal and infant immunization records; for nirsevimab, the timing of licensure and ACIP recommendations provided little time for planning of distribution and rollout, and there were uncertainties about insurance coverage and demand rapidly outpaced supply. Due to the limited supply, CDC issued a Health Advisory via the Health Alert Network recommending that available doses be prioritized to younger and high-risk infants. By January, demand had decreased and additional supply was available, allowing return to the original recommendations. Jurisdictional immunization programs have targeted birthing facilities for enrollment in the VFC program to facilitate administration of nirsevimab to VFC-eligible newborns; birthing hospitals can enroll in VFC as "specialty providers," only offering nirsevimab and the hepatitis B vaccine birth dose.

Dr. Pedro Moro, Immunization Safety Office, DHQP, presented to the committee on maternal RSV vaccine safety surveillance. In clinical trials among pregnant persons at 24–36 weeks' gestation, more preterm births were noted among Pfizer RSV vaccine recipients compared to placebo, although the differences were not statistically significant. Post-licensure safety surveillance of the Pfizer RSV vaccine in pregnant persons was initiated during the 2023-2024 season. The patterns of reported local and systemic (e.g., headache) symptoms in V-safe and VAERS after maternal Pfizer RSV vaccine were consistent with its pre-licensure safety profile. Among reports received in VAERS after maternal Pfizer RSV vaccine, the most frequent adverse events reported were pregnancy-specific conditions (e.g., preterm delivery), as expected for a vaccine recommended at 32-36 weeks' gestational age.

Preliminary findings in the VSD observed that the incidence of preterm births is 4.1% among pregnant persons who received Pfizer RSV vaccine during the 2023-2024 respiratory season. This was within the expected range of the incidence of preterm births at 32-36 weeks' gestation (3.1 - 6.1%) before introduction of this vaccine. CDC and FDA will continue to monitor maternal RSV vaccine safety in VAERS, V-safe and VSD.

Dr. Amanda Payne, Coronavirus and Other Respiratory Viruses Division, CDC, provided an update on post-licensure effectiveness of nirsevimab. A test-negative design analysis of first season nirsevimab product effectiveness against RSV-associated emergency department (ED) encounters and hospitalization was conducted in VISION, a multi-site network of electronic health records, including 127 emergency rooms and 107 hospitals. In this analysis infants aged less than 8 months as of October 1, 2023, or those born after October 1, 2023 who visited a participating ED for or were hospitalized with RSV-like illness (RLI) and were tested for RSV were included. Cases were those with RLI and a positive RSV antigen or nucleic acid amplification test (NAAT), and controls were those with RLI and a negative RSV NAAT test. Encounters during October 8, 2023, through March 31, 2024, were included. Encounters were excluded if they were aged less than 7 days at the time of their encounter, maternal RSV vaccination history could not be verified, there was evidence of maternal RSV vaccination or palivizumab administration, unrecommended nirsevimab doses were received, there was less than 7 days between the nirsevimab dose and the RLI encounter, or the RSV test result was indeterminate. The adjusted odds ratio comparing the odds of immunization among the case versus the controls was estimated using multivariable logistic regression, and product effectiveness (or PE) was calculated as 1 minus the adjusted odds ratio times 100%. Nirsevimab was effective against RSV-associated ED encounters and hospitalization among infants in their first RSV season. Among about 5,000 ED encounters for RSV-like illness among infants in their first RSV season, 442 had evidence of nirsevimab receipt 7 days more prior to the encounter, with a median time since dose of 53 days. RSV percent positivity was lower among those that had evidence of nirsevimab receipt compared with those without evidence of nirsevimab receipt, and the adjusted estimate of product effectiveness was 77%, with a confidence interval from 69% to 83%. Among 1,000 hospitalizations for RSV-like illness among infants in their first RSV season, 93 had evidence of nirsevimab receipt 7 days or more prior to the hospitalization, with a median time since dose of 48 days. The adjusted estimate of product effectiveness against RSV-associated hospitalization was 98%, with a confidence interval from 95% to 99%.

Another study using test-negative design was done in the New Vaccine Surveillance Network, a prospective, population-based surveillance network for pediatric acute respiratory illness (ARI) at 7 U.S. medical centers. Nirsevimab was effective against medical-attended RSV-associated ARI episodes and RSV-associated hospitalization. Among nearly 1,700 ARI episodes among infants in their first RSV season, 120 had evidence of nirsevimab receipt 7 days more prior to symptom onset, with a median time since dose of 42 days. RSV percent positivity was lower among those that had evidence of nirsevimab receipt compared with those without evidence of nirsevimab receipt, and the adjusted estimate of product effectiveness was 89%, with a confidence interval from 77% to 94%. Among 870 hospitalizations for ARI among infants in their first RSV season, 63 had evidence of nirsevimab receipt 7 days or more prior to ARI symptom onset, with a median time since dose of 38 days. The adjusted estimate of product effectiveness was 91%, with a confidence interval from 79% to 96%.

Together these data indicate nirsevimab was effective against RSV-associated ED encounters and hospitalization among infants in their first RSV season during the 2023-2024 RSV season. However, due to the timing of authorizations and recommendations of RSV prevention products and RSV activity during the 2023-2024 RSV season, these results should be interpreted with caution. US-based analyses may be subject to residual confounding due to prioritization of nirsevimab doses, and the short time between nirsevimab administration and outcomes limited the ability to assess duration of protection. Further, there was limited ability to assess effectiveness of maternal RSV vaccines during the 20230-2024 RSV season. CDC will continue monitoring post-licensure product effectiveness.

Dr. Jefferson Jones, Coronavirus and Other Respiratory Viruses Division, CDC, shared considerations from the ACIP Maternal/Pediatric RSV Work Group. For the 2024-2025 season, no supply/demand mismatch is anticipated for the maternal RSV vaccine. There will be limited availability of nirsevimab beginning early September, and the product is expected to be broadly available by October 1. The original ACIP recommendations for nirsevimab apply for 2024-25 RSV season; all infants are recommended to be protected by either maternal RSV vaccination or nirsevimab. Dr. Jones summarized the post-licensure safety data for the maternal RSV vaccine. There have been no verified reports of Guillain-Barré syndrome following RSV vaccination in pregnancy and a preliminary analysis of preterm births in the Vaccine Safety Datalink suggest that the incidence of preterm births following Pfizer's RSV vaccine is within the expected range. Nirsevimab safety is monitored through FDA's drug safety surveillance system. The most frequently reported adverse events involved patients who reportedly developed breakthrough RSV infections despite receiving nirsevimab, and included signs, symptoms, or complications of these infections (e.g., bronchiolitis). Cases of serious hypersensitivity reactions with nirsevimab were identified in the post-marketing setting and the product labeling was updated in February 2024. The work group found the safety data on nirsevimab and maternal RSV vaccine reassuring, but population-based studies with comparison groups are needed and pending. Because of U.S. recommendation that Pfizer maternal RSV vaccine be given at 32–36 weeks gestation, U.S. data on safety of vaccine given earlier in pregnancy is unlikely to become available. The work group also noted, in their discussion of the nirsevimab safety findings, that hypersensitivity reactions in young infants are rare and can be difficult to discern from startle reactions or vasovagal reactions.

The effectiveness of nirsevimab against RSV-associated hospitalization was 91% in NVSN and 98% in VISION; effectiveness against any medically attended RSV-associated ARI episode in NVSN was 89%, and effectiveness against RSV-associated ED visits was 77% in VISION. These estimates are consistent with studies in Europe. Longer follow up time is needed to determine duration of protection. There has been to far limited impact on RSV hospitalization burden, likely because of late administration. Substantial decreases in RSV-associated hospitalizations in young infants reported in Spain, Luxembourg, and Italy with early implementation and high coverage. It has not been possible to estimate maternal RSV vaccine effectiveness during the 2023-24 season due to limited uptake of maternal RSV vaccine, early onset of the 2023-2024 RSV season, and timing of the vaccine rollout; CDC will continue to monitor maternal RSV vaccine effectiveness in future seasons.

The work group found that the available evidence shows nirsevimab to be highly effective, but the duration of protection from nirsevimab and maternal vaccination remains unknown. A number of important studies are needed for 2024-25 season and future RSV seasons, of maternal vaccine effectiveness; nirsevimab effectiveness with longer follow up time, which should be available with earlier widespread availability; nirsevimab effectiveness among children aged 8–19 months with increased risk for severe disease during their second RSV season; and the impact on RSV burden when nirsevimab and maternal vaccine are given with earlier administration and potentially increased uptake.

On the subject of revaccination during subsequent pregnancies, Dr. Jones reminded the committee that ACIP recommendations for Pfizer RSV maternal vaccine state that "Currently, no data are available on either the efficacy of the first lifetime dose to protect infants born after subsequent pregnancies or the safety of additional doses given during subsequent pregnancies. Additional data are needed to determine whether additional seasonal doses during subsequent pregnancies are indicated, and ACIP might update recommendations in the future, as data become available." There still are no data on additional RSV vaccine doses in subsequent pregnancies and there are potentially people who received an RSV vaccine during pregnancy for the 2023-24 RSV season who could have a subsequent pregnancy during the 2024-2025 RSV season. The work group found it concerning that data in older adults suggest that revaccination does not restore antibody levels to those after first dose. Antibody levels are particularly important for maternal vaccination since infants are protected through transplacental transfer of antibodies. The work group also noted that RSV vaccine differs from Tdap vaccine; maternal RSV vaccine has a potential safety concern for preterm birth and hypertensive disorders of pregnancy, and an alternative product, nirsevimab, exists that can protect infants from severe RSV for subsequent pregnancies. The work group concluded that additional data are needed prior to recommending RSV vaccine during each pregnancy (i.e., during subsequent pregnancies), including antibody data in pregnant people and infants with vaccination during subsequent pregnancies; safety data (e.g., reactogenicity) with vaccination during subsequent pregnancies; and safety data of RSV vaccine during the first pregnancy it is administered, particularly regarding outcomes of preterm birth and hypertensive disorders of pregnancy.

The final topic on the agenda was an introduction of the ACIP Human Papillomavirus (HPV) Vaccines Work Group, from work group chair, Dr. Oliver Brooks. Dr. Brooks reminded the committee of the evolution of HPV vaccine recommendations in the U.S., starting in 2006, with the initial recommendation for use in females at 11 or 12 years, or as early as age 9 years, with catch-up vaccination through age 26 years, using a three-dose schedule. In 2011, the recommendation was extended to males, with catch-up vaccination through age 21 years. In 2015, the schedule was changed to 2 doses for those receiving the first dose before age 15 years, and in 2019, catch-up was harmonized through age 26 years, and vaccination was recommended for some adults 27 through 45 years of age with shared clinical decision-making. Over this time period, the U.S. transitioned from using the 4- and 2-valent HPV vaccines to using the 9-valent HPV vaccine. The HPV Vaccines work group will consider the number of doses in the recommended HPV vaccination series; the wording of the age for routine vaccination; and guidance regarding persons in the "shared clinical decision-making" age range (27-45 years). There is accumulating evidence on efficacy of HPV vaccination with fewer doses. In 2022, the World Health Organization recommended a two-dose schedule for persons aged 9 years or older and, as an off-label option, a single-dose schedule can be used for those aged 9–20 years. For the wording of the age for routine HPV vaccination, there is support among some stakeholders for starting vaccination at age 9 years, which is consistent with current ACIP recommendations, but there is thought that modification of wording could allow more flexibility.

For the guidance regarding persons in the “shared clinical decision-making” age range, this recommendation was made in 2019, and there’s interest in providing more guidance for subgroups in this age range. The first meeting of the work group is planned for July 2024, and the work group expects to present on the number of doses in the HPV vaccination schedule and the routine age recommendation wording at the October 2024 ACIP meeting.

With no additional business posed, the June 2024 ACIP meeting was officially adjourned.

ACIP MEMBERSHIP ROSTER

CHAIR
TALBOT, Helen Keipp, MD
Professor of Medicine
Vanderbilt University
Nashville, TN
3/5/2024 – 6/30/2025

EXECUTIVE SECRETARY
WHARTON, Melinda, MD, MPH
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
Atlanta, GA

MEMBERS
BROOKS, Oliver, MD, FAAP
Chief Medical Officer
Watts HealthCare Corporation
Los Angeles, CA
Past President, National Medical Association
Term: 7/26/2021 – 6/30/2025

CHEN, Wilbur H, MD, MS, FACP, FIDSA
Professor of Medicine
Center for Vaccine Development and Global Health
University of Maryland School of Medicine
Baltimore, MD
Term: 12/23/2020 – 6/30/2024

CINEAS, Sybil, MD, FAAP, FACP
Associate Professor of Medicine,
Pediatrics, and Medical Science
(Clinical)
The Warren Alpert Medical School
of Brown University
Associate Program Director
Brown Combined Residency in
Internal Medicine and Pediatrics
Providence, RI
Term: 9/28/2021 – 6/30/2025

DALEY, Matthew F, MD
Senior Investigator
Institute for Health Research, Kaiser Permanente Colorado
Associate Professor of Pediatrics
University of Colorado School of Medicine
Aurora, CO
Term: 1/4/2021 – 6/30/2024

JAMIESON, Denise J., MD, MPH
Vice President for Medical Affairs
Dean, Carver College of Medicine
University of Iowa
Term: 3/4/2024 – 6/30/2027

KOTTON, Camille Nelson, MD, FIDSA, FAST
Clinical Director, Transplant and Immunocompromised Host Infectious Diseases
Infectious Diseases Division, Massachusetts General Hospital
Associate Professor of Medicine, Harvard Medical School
Boston, MA
Term: 12/23/2020 – 6/30/2024

LOEHR, Jamie, MD, FAAFP
Owner, Cayuga Family Medicine
Ithaca, New York
Term: 7/26/2021 – 6/30/2025

LONG, Sarah S, MD
Professor of Pediatrics
Drexel University College of Medicine
Section of Infectious Diseases
St. Christopher's Hospital for Children
Philadelphia, Pennsylvania
Term: 12/24/2020 – 6/30/2024

MALDONADO, Yvonne (Bonnie), MD
Senior Associate Dean for Faculty Development and Diversity
Taube Endowed Professor of Global Health and Infectious Diseases
Professor of Pediatrics and of Epidemiology and Population Health
Interim Chair, Department of Medicine
Stanford University School of Medicine
Medical Director, Infection Prevention and Control and Attending Physician
Lucile Packard Children's Hospital at Stanford
Department of Pediatrics
Palo Alto, CA
Term: 3/4/2024 – 6/30/2027

SCHECHTER, Robert, MD, MSc
Chief, Immunization Branch
California Department of Public Health
Richmond, CA
Term: 3/6/2024 – 6/30/2027

SHAW, Albert C., MD, PhD, FIDSA
Professor of Medicine
Section of Infectious Diseases
Yale School of Medicine
New Haven, Connecticut
Term: 3/4/2024 – 6/30/2027

EX OFFICIO MEMBERS

Centers for Medicare and Medicaid Services (CMS)
HANCE, Mary Beth
Senior Policy Advisor
Division of Quality, Evaluations and Health Outcomes
Children and Adults Health Programs Group
Center for Medicaid, CHIP and Survey & Certification Centers
for Medicare and Medicaid Services
Baltimore, MD

Food and Drug Administration (FDA)
KASLOW, David C., MD
Director, Office of Vaccines Research and Review
Center for Biologics Evaluation and Research (CBER)
Silver Spring, MD

Health Resources and Services Administration (HRSA)
GRIMES, Reed, MD, MPH
CDR, USPHS
Director, Division of Injury Compensation Programs
Health Systems Bureau
Health Resources and Services Administration
Rockville, MD

Indian Health Service (IHS)
CLARK, Matthew, MD, FAAP, FACP
Physician
Chair, IHS National Pharmacy & Therapeutics Committee
Durango, CO

Office of Infectious Disease and HIV/AIDS Policy (OIDP)
OKEKE, Chinedu, MD
Chief Medical Officer
Department of Health and Human Services
Washington, DC

National Institutes of Health (NIH)
BEIGEL, John, MD
Associate Director for Clinical Research
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases (NIAID)
Bethesda, MD

LIAISON REPRESENTATIVES

American Academy of Family Physicians (AAFP)
MORRIS, Laura, MD, MSPH
Professor
Clinical Family and Community Medicine
Associate Program Director of Family and Community Medicine Residency
University of Missouri
Columbia, Missouri

American Academy of Pediatrics (AAP)
O'LEARY, Sean, MD, MPH
Professor of Pediatrics
Pediatric Infectious Diseases
General Academic Pediatrics
Children's Hospital Colorado/University of Colorado School of Medicine

American Academy of Pediatrics (AAP)
Red Book Editor
KIMBERLIN, David, MD
Professor of Pediatrics
Division of Pediatric Infectious Diseases
The University of Alabama at Birmingham School of Medicine
Birmingham, AL

American Academy of Physician Assistants (AAPA)
LÉGER, Marie-Michèle, MPH, PA-C
Senior Director, Clinical and Health Affairs
American Academy of Physician Assistants
Alexandria, VA

American College Health Association (ACHA)
LEE, Sara, MD
Assistant Vice President of University Health and Counseling Services
Chief Health Officer
Case Western Reserve University
Cleveland, OH

American College Health Association (ACHA) (alternate)
HALBRITTER, Ashlee, MPH
Executive Director, Public Health and Wellbeing
University of Pennsylvania
Philadelphia, PA

American College of Nurse Midwives (ACNM)
HAYES, Carol E., CNM, MN, MPH
Lead Clinician
Clinical Quality Compliance and Management
Planned Parenthood Southeast Atlanta, GA

American College of Nurse Midwives (ACNM) (alternate)
MEHARRY, Pamela M., PHD, CNM
Midwifery Educator, Human Resources for Health
In partnership with University of Rwanda and University of Illinois, Chicago

American College of Obstetricians and Gynecologists (ACOG)
SWAMY, Geeta K., MD
Associate Vice President for Research
Vice Dean for Scientific Integrity
Haywood Brown, MD Distinguished Professor of Women's Health
Duke University
Durham, NC

American College of Physicians (ACP)
GOLDMAN, Jason M, MD, FACP
Affiliate Assistant Professor of Clinical Biomedical Science, Florida Atlantic University, Boca Raton, Florida
Private Practice
Coral Springs, FL

American Geriatrics Society (AGS)
SCHMADER, Kenneth, MD
Professor of Medicine-Geriatrics Geriatrics
Division Chief
Duke University and Durham VA Medical Centers
Durham, NC

America's Health Insurance Plans (AHIP)
GRUBB, Jessica, MD
Medical Director, Infectious Diseases
Elevance Health Companies/Carelon
Charleston, SC

American Immunization Registry Association (AIRA)
COYLE, Rebecca, MSEd
Executive Director, AIRA
Washington, DC

American Immunization Registry Association (AIRA) (alternate)
LONDO, Courtnay, MA
Senior Program Manager
Washington, DC

American Medical Association (AMA)
FRYHOFER, Sandra Adamson, MD
Adjunct Associate Professor of Medicine Emory
University School of Medicine
Atlanta, GA

American Nurses Association (ANA)
RESNICK, Barbara, PhD, RN, CRNP, FAAN, FAANP
Professor, Organizations Systems and Adult Health
University of Maryland, Baltimore
Baltimore, MD

American Osteopathic Association (AOA)
MAHMOUDI, Massoud, DO, PhD, MS
President, American Osteopathic College of Allergy and Immunology
Clinical Professor, Department of Medicine, Division of General Internal Medicine
University of California San Francisco
San Francisco, CA

American Pharmacists Association (APhA)
GOODE, Jean-Venable "Kelly" R., PharmD, BCPS, FAPhA, FCCP
Professor and Director, PGY1 Community-Based Pharmacy Residency Program
School of Pharmacy, Virginia Commonwealth University
Richmond, VA

Association of Immunization Managers (AIM)
HOWELL, Molly, MPH
Immunization Program Manager
North Dakota Department of Health
Bismarck, ND

Association for Prevention Teaching and Research (APTR)
ZIMMERMAN, Richard, MD, MPH
Professor
University of Pittsburgh School of Medicine
Department of Family Medicine and Clinical Epidemiology
Pittsburgh, PA

Association of State and Territorial Health Officials (ASTHO)
JUTHANI, Manisha, MD
Commissioner
Connecticut Department of Public Health
Hartford, CT

Biotechnology Industry Organization (BIO)
ARTHUR, Phyllis A, MBA
Senior Director, Vaccines, Immunotherapeutics and Diagnostics Policy
Washington, DC

Council of State and Territorial Epidemiologists (CSTE)
HAHN, Christine, MD
State Epidemiologist
Office of Epidemiology, Food Protection and Immunization Idaho
Department of Health and Welfare
Boise, ID

Canadian National Advisory Committee on Immunization (NACI)
TUNIS, Matthew, PhD
Executive Secretary, National Advisory Committee on Immunization (NACI)
Centre for Immunization Programs (CIP)
Public Health Agency of Canada, Government of Canada

Infectious Diseases Society of America (IDSA)
MUNOZ-RIVAS, Flor, MD, MSc
Chief and Medical Director
Transplant Infectious Diseases
Texas Children's Hospital
Houston, TX

Infectious Diseases Society of America (IDSA) (alternate)
MCAULEY, James B., DTM&H, MD, MPH
Clinical Director
Whiteriver Indian Hospital
Whiteriver, AZ

International Society for Travel Medicine (ISTM)
BARNETT, Elizabeth D, MD Professor of
Pediatrics
Boston University School of Medicine
Boston, MA

National Association of County and City Health Officials (NACCHO)
ZAHN, Matthew, MD
Medical Director, Epidemiology
Orange County Health Care Agency
Santa Ana, CA

National Association of Pediatric Nurse Practitioners (NAPNAP)
DESHON, Dana, DNP, APRN, CPNP-PC
Order of Saint Francis Medical Group
Morton Pediatrics
Morton, IL

National Foundation for Infectious Diseases (NFID)
HOPKINS, Robert H., Jr., MD, MACP
Professor of Internal Medicine and Pediatrics
Chief, Division of General Internal Medicine
University of Arkansas for Medical Sciences
Little Rock, AR

National Foundation for Infectious Diseases (NFID) (alternate)
DALTON, Marla, PE, CAE
Executive Director & CEO
National Foundation for Infectious Diseases (NFID)
Bethesda, MD

National Medical Association (NMA)
WHITLEY-WILLIAMS, Patricia, MD Professor and Chair
University of Medicine and Dentistry of New Jersey Robert Wood
Johnson Medical School
New Brunswick, NJ

Pediatric Infectious Diseases Society (PIDS)
PAULSEN, Grant, MD
Associate Professor of Pediatrics
Pediatric Infectious Diseases
Cincinnati Children's Hospital Medical Center
Cincinnati, OH

Pediatric Infectious Diseases Society (PIDS) (alternate)
ROSS, Shannon A, MD, MSPH
Professor of Pediatrics
Birmingham School of Medicine
University of Alabama
Birmingham, AL

Pharmaceutical Research and Manufacturers of America (PhRMA)
ROBERTSON, Corey, MD, MPH
Senior Director, US Medical, Sanofi Pasteur
Swiftwater, PA

Society for Adolescent Health and Medicine (SAHM)
MIDDLEMAN, Amy B, MD, MSEd, MPH
Professor of Pediatrics
Chief, Section of Adolescent Medicine
University of Oklahoma Health Sciences Center
Oklahoma City, OK

Society for Healthcare Epidemiology of America (SHEA)
MEHROTRA, Preeti, MD, MPH
Senior Medical Director
Infection Control/Hospital Epidemiology
Beth Israel Deaconess Medical Center
Adult and Pediatric Infectious Diseases
Harvard Medical School
Boston, MA

Society for Healthcare Epidemiology of America (SHEA) (alternate)
DREES, Marci, MD, MS
Chief Infection Prevention Officer & Hospital Epidemiologist
ChristianaCare
Wilmington, DE
Associate Professor of Medicine
Sidney Kimmel Medical College at Thomas Jefferson University
Philadelphia, PA