NVAC NATIONAL VACCINE ADVISORY COMMITTEE

September 13-14, 2024, Virtual Meeting Minutes

Committee Members in Attendance
Robert H. Hopkins Jr., M.D., M.A.C.P., F.A.A.P.; Chair
Melody Anne Butler, B.S.N., R.N., C.I.C.
Kristen Ehresmann, R.N., M.P.H.
Daniel F. Hoft, M.D., Ph.D.
Molly Howell, M.P.H.
Jewel Mullen, M.D., M.P.H.
Stephen Rinderknecht, D.O.
Winona Stoltzfus, M.D.
Geeta Swamy, M.D.
Robert Swanson, M.P.H.

NVAC Ex Officio Members
Kimberly Armstrong, Ph.D., MT (ASCP) Administration for Strategic Preparedness and Response (ASPR)
Karin Bok, Ph.D., United States Food and Drug Administration (FDA)
Uzo Chukwuma, M.P.H., Indian Health Service (IHS)
Andrew Ford, M.P.H., National Institutes of Health (NIH)
Mary Beth Hance, Centers for Medicare & Medicaid Services (CMS)
Brenda Holbrook, N.P., Health Resources and Services Administration (HRSA)
Nicole Hsu, M.D., M.P.H., Department of Defense (DOD)
Troy Knighton, M.Ed., Ed.S., L.P.C., Department of Veterans Affairs
Justin A Mills, M.D., M.P.H., F.A.A.P., Agency for Healthcare Research and Quality (AHRQ)
Mandy Paust, M.A., United States Agency for International Development (USAID)
Melinda Wharton, M.D., Centers for Disease Control and Prevention (CDC)

NVAC Liaison Representatives
Rebecca Coyle, M.S.Ed., American Immunization Registry Association (AIRA)
Claire Hannan, M.P.H., Association of Immunization Managers (AIM)
Erin Henry, B.S.N., Public Health Agency of Canada (PHAC)
Ericka McGowan, M.S., Association of State and Territorial Health Officials (ASTHO)
Christopher Regal, M.S., America's Health Insurance Plans (AHIP)
Mitch Rothholz, R.Ph., M.B.A., American Pharmacists Association (APhA)
Judy Shlay, M.D., National Association of County and City Health Officials (NACCHO)
Hana El Sahly, M.D., Vaccines and Related Biological Products Advisory Committee (VRBPAC)

Designated Federal Officer
Ann Aikin, M.A., Communications Director, Office of Infectious Disease and HIV/AIDS Policy (OIDP), Department of Health and Human Services (HHS)

Proceedings

Day One

Call to Order and Rules of Engagement—Ann Aikin, Acting Designated Federal Officer, NVAC

Ms. Aikin called the meeting to order at 9 a.m. ET and welcomed the participants. She briefly outlined the agenda and described key parts of the Federal Advisory Committee Act, its conflict-of-interest rules, and standards of ethical conduct for the National Vaccine Advisory Committee (NVAC) members. Ms. Aikin noted that statements made during the meeting do not necessarily reflect those of the Department of Health and Human Services (HHS) or NVAC and called the roll.

Opening Remarks—Admiral Rachel Levine, M.D., Assistant Secretary for Health (ASH), HHS

ADM Levine welcomed meeting participants and thanked NVAC members for their time and dedication to the committee and for promoting increased immunization.

ADM Levine noted the surge of COVID-19 infections in summer 2024 and the role of COVID-19 vaccines in combatting these surges. HHS recently launched the "Risk Less. Do More" campaign to raise awareness of vaccines to prevent serious respiratory illnesses such as COVID-19 and respiratory syncytial virus (RSV). Although this campaign seeks to promote vaccination among the public, it specifically focuses on populations with increased risk of serious respiratory illnesses, including older adults, residents of long-term care facilities, pregnant people, and people who experience structural barriers to accessing health care information and services.

This campaign is part of larger HHS efforts to increase vaccinations for respiratory diseases in preparation for the upcoming 2024–2025 respiratory disease season. During the 2023–2024 respiratory disease season, only 57.4% of children (aged 6 months through 17 years) and 46.9 percent of adults were vaccinated for influenza. During this same period, 44,900 people in the United States died from influenza. Similarly, a survey conducted during the 2023–2024 respiratory disease season identified multiple reasons for the relatively low vaccine uptake for RSV, COVID-19, and influenza, including lack of health care provider recommendation for vaccines, concerns, or lack of knowledge about potential vaccine side effects, mild side effects from vaccination, and lack of time or forgetting to get vaccinated.

ADM Levine called on NVAC members and meeting participants to address these reasons for vaccine hesitancy. She suggested multiple approaches, including the following:

- Refer people with vaccine safety concerns to vaccines.gov and cdc.gov, which have credible information on vaccine safety and answers to common questions.
- Engage with others to encourage them to get vaccinated.
- Support people where they are in their vaccination decision (i.e., degree of certainty regarding vaccines) rather than arguing with them. This support may include asking them to discuss their concerns with the health care provider or sharing stories about how vaccinations have been personally helpful.

ADM Levine concluded her remarks by thanking Dr. Hopkins, Ms. Butler, and Dr. Swamy for their service on NVAC.

Chair's Welcome—Robert H. Hopkins, Jr., M.D., M.A.C.P., F.A.A.P., NVAC Chair

Dr. Hopkins welcomed the participants to the hybrid virtual and in-person public meeting, which was accessible to the public by live webcast and telephone. He outlined the agenda for this meeting. NVAC members then unanimously approved the minutes of the June 13–14, 2024 meeting.

Dr. Hopkins described the procedure for delivering public comments during the meeting. Written comments can be sent to NVAC for consideration by e-mail (nvac@hhs.gov). The agenda, minutes, and recordings of past meetings are available online.

Actions for Elimination: Hepatitis B Vaccine Recommendation Implementation

Hepatitis B Virus Screening, Testing, and Vaccination and Opportunities to Impact Syndemics—Melissa Nyendak, M.D., M.H.S.

Viral hepatitis is a public health crisis, including an epidemic of undiagnosed hepatitis B virus (HBV) and hepatitis C virus (HCV) infections. Approximately 660,000 people in the United States are estimated to have HBV—50% of whom are unaware of their infection. Similarly, more than 2.4 million people in the United States are estimated to have HCV—33% of whom are unaware of their infection. Untreated chronic HBV and HCV infection can lead to liver damage, liver cancer, and death.

Vaccination for HBV infection began in 1982 for people at greater-than-average risk of HBV infection and was then expanded to all U.S. infants in 1991 and all children up to age 18 in 1999. This expansion corresponded with a significant decline in HBV incidence over the past 40 years. However, HBV infection remains prevalent among some groups, including people born outside of the United States, injection drug users, and people with multiple sexual partners who engage in unprotected sexual intercourse. Chronic HBV infections and hepatitis B mortality also disproportionately impact some populations, including Asian and Pacific Islander populations and older adults.

Following updates in 2023 to HBV screening and testing recommendations, the Centers for Disease Control and Prevention (CDC) recommends screening for the following groups:

- all adults aged 18 and older screened at least once per lifetime
- anyone who requests HBV screening
- all pregnant persons, with screening during each pregnancy
- anyone with a history of HBV infection risk (e.g., previous or current incarceration)
- periodic testing of people with ongoing hepatitis B risk (e.g., people with history of HCV or sexually transmitted infections)

The Advisory Committee on Immunization Practices (ACIP) recommends that all adults aged 19–59 and adults aged 60 or older with risk factors for hepatitis B should be vaccinated for HBV. Adults aged 60 or older without hepatitis B risk factors may also vaccinated for HBV. ACIP recommends that people who are screened for HBV should be vaccinated in the same visit or an associated follow-up visit.

To prevent perinatal transmission of HBV, CDC recommends testing all pregnant people for hepatitis B surface antigen (HBsAg) with each pregnancy and administering antiviral therapy for HBsAg-positive pregnant people. Infants born to HBsAg-positive people should be tested for hepatitis B immune globulin and vaccinated for HBV within 12 hours of birth. Post-vaccination serologic testing for HBsAg and antibodies to HBsAg should be completed 9–12 months after birth, or 1–2 months after the final dose in the series if completion is delayed.

HBV infections and chronic hepatitis B are increasingly occurring in syndemics with other diseases such as substance use disorder (SUD), chronic illnesses (e.g., diabetes), and HCV. Responding to these syndemics requires a population-centered HBV prevention and vaccination approach across multiple settings, including SUD treatment clinics, correctional settings, Federally Qualified Health Centers (FQHCs), emergency departments, and STI clinics. Efforts across these settings can reach many populations who are disproportionately impacted by hepatitis B.

Forum Symposium on HBV Elimination and Universal Adult Vaccination in the U.S.—Mitchell Leus, M.P.H.

The Forum for Collaborative Research, based out of the School of Public Health at the University of California, Berkeley, helps accelerate drug development and regulatory science for unmet medical needs. The Forum provides an independent and neutral venue for different stakeholders (e.g., patient and community advocates, industry partners, regulatory government agencies) to facilitate consensus and decision-making on drug development and regulation.

As part of its Policy Series, the Forum hosted a symposium in 2022 on HBV elimination and increasing adult hepatitis B vaccination among adults, particularly those at higher-than-average risk of HBV infection. This symposium convened 110 discussants from government agencies, professional societies, health departments, harm reduction organizations, and community organizations. The agenda for this symposium was developed based on outputs from 15 stakeholder consultation meetings conducted by the Forum, including a meeting with the CDC Division of Viral Hepatitis.

Key discussion points from this symposium are summarized in a conference report by Leus and colleagues (2024). This conference report identifies four areas of recommendations:

- **Leverage electronic health records (EHRs) to increase hepatitis B vaccinations.** Potential approaches in EHR systems may include real-time messaging and patient referrals to HBV specialists; routine opt-out screening for HBV, HCV, and HIV; and one-click options for ordering HBV serology tests.
- **Embed HBV health care services in different health care settings,** including harm reduction organizations, rural health clinics, and carceral settings.
- **Use Public Health Service Act Sections 317 and 340B programs (hereafter referred to as "Section 317" and "Section 340B," respectively) to expand insurance coverage for hepatitis B vaccines**, including the expansion of these programs under the Inflation Reduction Act.
- **Build vaccine confidence among impacted communities** by employing trusted community leaders for HBV health education and addressing concerns around hepatitis B vaccination. This education and outreach should occur in different community settings (e.g., faith-based settings, community markets).

Coordination of Government-Wide Implementation of the Adult Hepatitis B Vaccine Recommendations—Darcy Cherlin, M.P.H.

The Senate Appropriations Committee tasked the Office of Infectious Disease and HIV/AIDS Policy (OIDP) within the Office of Assistant Secretary for Health to lead the development of a government-wide coordinated effort to ensure the implementation of the ACIP recommendations on hepatitis B vaccines. The Senate Appropriations Committee also requested a report on this effort by the end of fiscal year (FY) 2024.

As part of these efforts, OIDP led the development of the Viral Hepatitis National Strategic Plan 2021–2025 and the Vaccines National Strategic Plan 2021−2025. OIDP also leads the Syndemic Steering

Committee to identify strategies for integrating hepatitis B vaccination across health care settings and to address syndemics of HBV, sexually transmitted infections, SUD, and HIV.

To coordinate implementation of these strategic plans and recommendations of the Syndemic Steering Committee, OIDP held a webinar on May 23, 2022, titled "Federal Implementation of the Updated Adult Hepatitis B Vaccination Recommendations." This webinar featured presentations from multiple federal agencies (e.g., CDC, Centers for Medicare & Medicaid Services [CMS], Health Resources and Services Administration [HRSA], Substance Abuse and Mental Health Administration [SAMHSA]) on how those agencies plan to implement recommendations for increasing hepatitis B vaccine uptake. This event was followed by a subsequent webinar on May 30, 2023, titled "Federal Implementation of Updated Viral Hepatitis Screening and Vaccination Recommendations." This webinar focused on lessons learned from implementing updated HCV screening recommendations, updates on recommendations for hepatitis B vaccines, and plans for integrating HBV screening and vaccination recommendations across federal agencies.

Recent federal efforts by federal departments and agencies to implement hepatitis B vaccination recommendations are shown in the table below.

Department / Agency	Recent Hepatitis B Vaccination Effort
CDC	Provided funding to 17 state and local health departments and syringe services programs to support hepatitis-related services
CMS	Proposed two updates related to coverage and payment of hepatitis B vaccination
Federal Bureau of Prisons (BOP)	Implemented guidelines to offer hepatitis B vaccination to all adults in custody
U.S. Food and Drug Administration (FDA)	Initiated process to reclassify HBV assays from Class III to Class II
HRSA	Provided education and training on hepatitis B prevention and vaccination
Indian Health Service (IHS)	Implemented the Immunization Calculation Engine
OIDP	Developed financing recommendations to improve integration of viral hepatitis prevention and care services
SAMHSA	Incorporated hepatitis B vaccination as required or allowable activity in grant programs
Department of Veterans Affairs (VA)	Offered hepatitis B vaccination to previously unimmunized Veterans in care aged 19–59 years

Based on discussions and coordination with multiple federal departments and agencies, OIDP has identified multiple opportunities for increasing hepatitis B vaccination, including

- coordination of government-wide implementation, including an integrated public awareness campaign about hepatitis B vaccination and policy alignment;
- increased vaccine procurement through a federal Vaccines for Adults program;
- expanded insurance coverage for hepatitis B screening and vaccination by aligning U.S. Preventive Services Task Force (USPSTF) preventive care recommendations with CDC recommendations for hepatitis B screening;
- funding syndemic-based approaches for whole-person health care;
- widespread usage of immunization information systems (IISs) to improve monitoring and measurement of hepatitis B vaccination coverage;

- EHR clinical decision support tools for HBV screening and vaccination, including EHR prompts, tasks lists, and order sets; and
- bolstering of health care workforce on multiple topics, including vaccine provider education and training, patient education, and culturally appropriate messaging.

Local Health Department Approaches to Increasing Adult Hepatitis B Vaccination—Judith C. Shlay, M.D., M.S.P.H.

The National Association of County and City Health Officials (NACCHO) serves more than 3,300 local health departments (LHDs) across the United States by providing professional resources, training, and events. NACCHO focuses on six key focus areas: advocacy; partnerships; funding; training and education; networking; and resources, tools, and technical assistance.

NACCHO has identified multiple approaches for increasing hepatitis B vaccination, including

- community-based vaccination clinics for all vaccines, including hepatitis B vaccines;
- support of health agencies to provide hepatitis B vaccination among adults; and
- provision of hepatitis B vaccination as part of health care for homeless clinics.

NACCHO recently published the 2023 Immunization Profile Study comparing immunization-related activities by LHDs between 2017 and 2022. Compared to 2017, LHDs significantly increased immunization-related activities in 2022, particularly conducting outreach for adult vaccinations and addressing vaccine hesitancy for adult vaccinations. Since 2022, LHDs must increasingly respond to multiple competing demands, including increasing COVID-19 and mpox vaccinations and responding to outbreaks of hepatitis A, meningococcal disease, and measles.

Dr. Shlay provided an example of hepatitis B vaccination efforts by LHDs. The Public Health Institute at Denver Health has a team that provides hepatitis B vaccinations at multiple locations, including SUD treatment centers and at the Denver Health's Infectious Diseases Clinic. This team is also conducting outreach to new entrants about vaccinations and has administered more than 1,200 vaccines to new entrants as part of this effort. Because of limited LHD resources, Denver Health prioritized hepatitis B vaccination efforts for populations at increased risk of HBV infection, including persons with HIV, adults who previously initiated but did not complete the hepatitis B vaccination series, persons with any type of liver disease, and persons who use injection drugs.

Similar examples include the following:

- Orange County, NY: The county LHD is offering hepatitis B vaccines at sexual health clinics.
- Madison County, NY: The county LHD is providing hepatitis B information and education for women in various settings, including the county jail, organizations that provide services for pregnant people, and prenatal services groups.
- Minneapolis, MD: The Healthcare for Homeless Clinics are including assessments and provision of hepatitis B vaccines to its clients.

Insurance coverage remains a significant challenge for LHDs to provide hepatitis B vaccines. Most LHDs can bill public insurance (e.g., Medicaid), but few are able to bill private insurance. Many patients going to LHDs are uninsured or underinsured, and significant cuts to Section 317 funding has reduced the available supply of hepatitis B vaccines to these patients. Similarly, limited funding for LHDs also limits hepatitis B vaccination efforts. Most LHDs receive inadequate or no funding for the prevention and control of hepatitis. According to a 2020 NACCHO survey, 73% of respondents indicated that limited funding is a key barrier to the provision and scale-up of hepatitis services. This limited funding often

forces many LHDs to prioritize hepatitis B vaccination for specific populations at higher risk of HBV infection rather than providing hepatitis B vaccines for all adults.

Implementing Universal Hepatitis B Vaccination Across the U.S.—Kelly L. Moore, M.D., M.P.H.

A key challenge to increasing hepatitis B vaccination among adults is shifting clinical practices and insurance coverage from a risk-based paradigm (i.e., vaccinating only individuals at higher risk of HBV infection) to universal vaccination of all adults. The largest barrier to universal hepatitis B vaccination is differences in insurance coverage between vaccination and screening. Although vaccination for hepatitis B is commonly covered for patients at greater-than-average risk of HBV infection, screening these patients for HBV is usually not covered. Clinicians also face additional challenges, including previously vaccinated younger adults testing negative for anti-HBV antibodies, lack of vaccination records for HBV, and limited awareness and confusion regarding interpretation of HBV serology results.

One potential solution is integrating HBV screening and vaccination into EHR system workflows. A recent publication by Kim and colleagues (2024) provides a framework for integrating screening and vaccination in workflows. This framework includes

- EHR system prompts that identify patients at greater-than-average risk of HBV infection,
- workflows that facilitate ordering of vaccines and HBV screening sets,
- proper documentation and follow-up for patients at greater-than-average risk of HBV infection,
- answers to common questions from health care providers with limited hepatitis B familiarity, and
- support for interpreting hepatitis B serology results.

Successfully implementing universal hepatitis vaccination requires many additional actions, including

- widespread hepatitis B vaccination of adults who were not vaccinated during childhood,
- alignment of USPSTF preventative care recommendations with CDC recommendations for hepatitis B screening and vaccination recommendations to broaden insurance coverage,
- greater awareness among health care providers and the public on the value of hepatitis B vaccination, and
- consistent use of IISs to prevent unnecessary revaccination of adults.

Discussion

Role of Pharmacies in Vaccination

Mitch Rothholz noted that pharmacists play a significant role in administration of vaccines, but which vaccines they may administer and whether those vaccines are covered by insurance vary significantly between states. Some payers (e.g., Medicare Part B) allow hepatitis B vaccination in medical settings (e.g., physician offices) but not pharmacies, creating barriers for expanding hepatitis B vaccination. Dr. Shlay agreed and noted the importance of expanding coverage under both public and private payers for hepatitis B vaccines at pharmacies.

Inadequate Funding for Vaccine Programs

Clare Hanna emphasized the need for additional funding for vaccinating uninsured and underinsured adults. Funding for the Section 317 program has not increased enough to account for inflation and additional recommended vaccines. FQHCs can provide vaccinations under Section 340B, but this

program also has inadequate funding. She reiterated the need for additional funding as part of a broader Vaccines for Adults program.

USPSTF Recommendations

Justin Mills stated that USPTF makes it recommendations for vaccines and screening based upon published evidence rather than whether its recommendations will influence insurance coverage. For hepatitis B, much of the published research on vaccination and screening is in populations at greater-than-average risk of HBV infection, so USPTF confined its hepatitis B recommendations to these populations. More research is needed on the benefits of universal screening and vaccination for hepatitis B among adults.

Risk Less. Do More: An Overview of the New Evidence-Based Campaign from HHS to Prevent Respiratory Illness

2024-2025 Pan-Respiratory Virus Public Education Campaign—May Malik, M.A.

The "Risk Less. Do More." public education campaign is a national integrated effort led by HHS to increase awareness, confidence, and uptake of vaccines that reduce severe illness from influenza, COVID-19, and RSV in populations at greater-than-average risk for severe illness. This campaign was launched on August 19, 2024, and seeks to limit the spread of influenza, COVID-19, and RSV by informing people about effective prevention measures (e.g., vaccination). The campaign uses research-based messaging to promote vaccination through paid, earned, and owned media, including TV, radio, print, social, digital, and out-of-home (e.g., billboards, transit ads) advertising. HHS is also partnering with national, state, and local organizations for further outreach.

The "Risk Less. Do More." campaign has multiple goals, including increasing vaccination uptake through informed decision-making, increasing public trust in vaccines, cultivating vaccine literacy, and enhancing awareness of vaccine accessibility. The campaign's primary audience is adults over age 60, long-term care residents, and health navigators for these populations. Additional secondary audiences include pregnant people as well as health care providers and family members of adults over age 60.

The campaign's messaging recognizes that some populations live with a greater-than-average risk of serious respiratory disease and frames vaccines to reduce this risk, enabling these populations to live their lives and continue participating in activities they enjoy. As such, many ads use hopeful imaging of people engaging in hobbies, spending time with family, and engaging in physical activities. This messaging was based upon previous engagement by HHS with health care providers for older adults to identify what factors were most likely to motivate target populations to get vaccinated.

This campaign also seeks to engage with people at their current level of vaccine confidence and involves health care providers in addressing questions or concerns about vaccine safety and efficacy. The campaign does not seek to correct or address all potential vaccine misinformation or misunderstanding but rather focus on which concerns are most likely to impact vaccination. For example, HHS has rapid response frequently asked question (FAQ) ads to quickly address vaccine misinformation and misunderstandings online (e.g., false belief that people can get influenza from influenza vaccines).

The campaign has two stages: "Cultivate Confidence," which focuses primarily on education regarding RSV vaccination, and "Motivate Action," which focuses on motivating the public to get vaccinated for RSV, COVID-19, and influenza and addresses potential concerns regarding vaccine safety. The campaign is currently in the "Cultivate Confidence" stage, which will continue through January 2025. The "Risk Less. Do More." website has been launched, which includes campaign ads, resources for health care

providers, and a "Contact Us" form for partners to request additional resources. Resources for health care providers include the following:

- "What You Should Know About Flu, COVID-19 and RSV Vaccines" explains to patients which populations are the highest risk for severe influenza, COVID-19, and RSV infections and why vaccination is important.
- The "Addressing Common Concerns About Flu, COVID-19, and RSV Vaccines" fact sheet can be used by health care providers to address common patient concerns about influenza, COVID-19, and RSV vaccines.
- A poster for health care provider offices lists reasons to vaccinate against influenza, COVID-19, and RSV.

The "Motivate Action" stage is scheduled to begin in November 2024 to coincide with winter months and the holiday season. This stage will employ many different channels of advertising, including social media, television and radio ads, and out-of-home advertising. The campaign will also share new social media graphics and messages for partners to use on Facebook Instagram, X, and LinkedIn. This stage will also have updated campaign talking points for partners.

Discussion

Opportunities for Partner Organizations

Dr. Hopkins asked about opportunities for partner organizations (e.g., LHDs) to reinforce campaign messaging. Ms. Malik noted that partner organizations can share ads and promotional materials through different channels, including newsletters, social media, and email listservs. HHS can facilitate presentations by subject matter experts from CDC and other HHS agencies on vaccinations and provide campaign talking points to partner organizations for their own outreach activities.

Messaging for Payers

Mr. Rothholz asked whether the campaign has messaging targeted toward payers, noting that inadequate coverage for vaccines may be a barrier to increasing vaccine uptake. Ms. Malik responded that the campaign's messaging does not specifically target payers, but HHS engages with CMS as well as pharmacy retailers to develop messaging and campaign strategy.

Bundling of RSV, COVID-19, and Influenza Vaccines

Mr. Rothholz noted that many health care providers face challenges discussing COVID-19, RSV, and influenza vaccines during the same patient visit and asked whether the campaign has any resources or materials on which of these vaccines to prioritize. Ms. Malik responded that the "Risk Less. Do More." Campaign encourages co-administration of these three vaccines, and HHS is collaborating with pharmacy organizations and long-term care facilities to co-administer vaccines. The "Motivate Action" stage of the campaign also addresses concerns regarding RSV, influenza, and COVID-19 vaccines.

Mr. Hoft asked whether skepticism and disinformation about COVID-19 vaccines may reduce confidence about RSV and influenza vaccines. Ms. Malik responded that, based upon research conducted by HHS, much of the skepticism about COVID-19 vaccines is due to misunderstandings and lack of consistent messages rather than disinformation. The campaign seeks to address many of these misunderstandings, including on vaccine-associated risks, through its rapid response FAQ ads. HHS is also partnering with local community messengers and state, local, tribal, and territorial health departments to ensure consistent messaging.

Beyfortus

Dr. Rinderknecht asked whether this campaign plans to promote Beyfortus for protection against RSV among young children. Ms. Malik responded that the campaign is focusing on older adults rather than young children, but materials developed by partner organizations may include information on Beyfortus and other relevant medications for young children.

Investing in Vaccine Equity Pays Off: Two Innovative Projects

Civic Heart Community Services—Sam Brown

Since 2022, Civic Heart Community Services has participated in the Partnering for Vaccine Equity (P4VE) program to promote vaccine equity and increase vaccine uptake in Harris and Waller Counties in Texas. In both counties, Civic Heart Community Services helped navigate residents to relevant services (e.g., vaccine administration), educated residents on health impacts of COVID-19 and influenza, and collaborated with community leaders to promote vaccination for COVID-19 and influenza.

In both counties, Civic Health Community Services encountered stigma and misinformation regarding vaccines, including

- beliefs that Black people are immune to SARS-CoV-2 infection;
- mistrust of vaccines and vaccine providers among Black residents, many of whom have a historic mistrust of the medical profession;
- beliefs that COVID-19 pandemic was planned by the federal government or the Democratic Party (i.e., "plandemic"); and
- mixed messages about COVID-19 and vaccines from news outlets and social media channels.

To counter these beliefs and misinformation, Civic Heart used information provided by the CDC Foundation's Vaccine Resource Hub, Civic Heart's Wellness community advisory board, and the City of Houston to formulate culturally relevant messages. These messages were then disseminated to stakeholders through social media platforms and by community leaders to ensure consistent messaging across channels. Civic Heart also partnered with vaccine providers to provide education, vaccine navigation, and additional prevention and wellness services and incentives to increase vaccine uptake.

Southeast Arizona Health Education Center—Christine Ashimwe

The Southeast Arizona Health Education Center (SEAHEC) was established in 1985 to recruit, place, and retain culturally competent health professionals in Cochise, Pima, and Santa Cruz Counties in Arizona. SEAHEC now supports five rural counties in Arizona: Cochise, Pima, Santa Cruz, Graham, and Greenlee Counties. SEAHEC's mission is to enhance the health of rural, migrant, and border populations through advocacy, education, and action. SEAHEC supports multiple programs, including (a) Santa Cruz County Overcoming Substance Addiction Consortium, (b) Gila Valley Food Coalition, (c) the SEAHEC Community Partnerships to Advance Science for Society program, (d) Southeastern Arizona Governments Organization Area Agency on Aging, and (e) SEAHEC Migrant Healthcare Coordination Program.

SEAHEC's Migrant Healthcare Coordination Program connects migrants with health and other services, both locally around Tucson, AZ, and in their destination communities throughout the United States through SEAHEC's team of community health workers. This program, which is based at the Pima County Respite Shelter, provides multiple services for migrants, including assistance with obtaining prescription and over-the-counter medications, meals for migrants who require special diets (e.g., diabetics), and

health education. Migrants in this program come from a variety of geographic areas (e.g., Latin America, Africa, South Asia) and many speak languages other than English or Spanish. Thus, health education campaigns are offered in a variety of languages, including Spanish, French, Portuguese, Arabic, Haitian Creole, Persian, and Punjabi.

SEAHEC's community health workers increase vaccine confidence through multiple approaches, including

- providing culturally and linguistically appropriate health education materials on vaccines and other health topics to migrants in the Pima County Respite Shelter;
- coordinating logistics for follow-up care at migrants' final destinations and providing lists of partner agencies, LHDs, vaccination sites, and other services at these destinations;
- providing information on low-cost and affordable linguistically appropriate resources in migrants' destination communities;
- hosting and attending health promotion events, health fairs, and awareness campaigns;
- distributing educational materials to inform migrant families about safety and effectiveness of vaccines, addressing concerns, and promoting trust;
- developing unique communication and health education communication materials (e.g., brochures, flyers, WhatsApp messages) that promote vaccination in multiple languages; and
- collaborating with local health care providers to ensure that free vaccination services are accessible and offer vaccines that meet rigorous safety standards.

SEAHEC's efforts in promoting vaccination and health education among migrants has resulted in multiple successes, including increased vaccine uptake and community trust, an improved understanding of reasons behind vaccine hesitancy, tailored health education across all age groups, and an expanded network of partners. However, SEAHEC continues to face multiple challenges, including language barriers, misinformation about vaccines, challenges in working with foreign populations with a variety of immigration statuses, and different cultural beliefs about vaccines.

Discussion

Dr. Mullen noted the importance of health care centers for migrants and the SEAHEC model of care for providing equitable access to essential health care in border regions, including continuity of care across borders.

Immunization Equity: Lessons and Evaluation Approaches

Research Update: Establishing the Evidence Base Needed to Implement Effective Vaccine Equity Interventions—Stefanie Friedhoff

In response to two 2021 recommendations (4.4 and 4.5) from NVAC, the National Adult and Influenza Immunization Summit Vaccine Equity Group created a report (will be released soon) on key considerations for vaccine equity. Vaccine equity is defined as providing access to and generating demand for established vaccines and new vaccines for all populations, with a priority on those populations who need the protection from a given vaccine the most. Examining differences in vaccination rates between racial and ethnic groups is essential but only one of many ways for conceptualizing, measuring, and understanding vaccine equity. For example, not all populations are equally impacted by specific diseases. Thus, many vaccine strategies focus on groups disproportionately impacted by a disease rather than seeking parity across all populations.

Studies on vaccine equity have made significant progress over the past 4 years, including the number and types of studies. Vaccine equity can be studied using a broad range of research approaches, including community-based participatory research, quasi-experimental designs, mixed-methods studies, and implementation science frameworks (e.g., Reach, Effectiveness, Adoption, Implementation, and Maintenance [RE-AIM]).

Vaccine equity can be measured using two different approaches: measuring outputs (e.g., vaccine doses administered, number of vaccine clinic visits and measuring outcomes (e.g., changes in vaccination rates and vaccine confidence in specific populations). Relevant qualitative measures can include community focus groups, pre- and post-intervention surveys, and semi-structured interviews. Relevant quantitative measures can include number of vaccinations administered, vaccination rates, number of vaccination appointments scheduled, and number of communication activities (e.g., social media posts, emails).

Recent research on vaccine equity suggests that too many interventions focus exclusively on reducing vaccine hesitancy without understanding the larger structural factors (e.g., lack of childcare or paid sick leave) that often prevent people from getting vaccinated. Thus, many successful interventions focus on these structural barriers to make vaccines easier to access. Successful interventions also understand each population of focus and that population's challenges and priorities, and these interventions work with community-based partners who are already serving those populations.

Additional recommendations from the Vaccine Equity Group include the following:

- Conduct granular research that can better identify specific factors that influence the success of vaccine equity efforts and relevant contextual factors.
- Identify and measure moderating variations (e.g., role of existing community relationships) in the success of vaccine equity efforts.
- Include requests or requirements for cost-effectiveness studies in funding announcements (e.g., Requests for Proposals) for vaccine equity programs.
- Identify opportunities for blending and combining funding mechanisms to support vaccine equity programs.
- Generate and sustainably archive evaluation toolkits and other resources for implementation of vaccine equity programs.

University of Washington Population Health Initiative—Ali H. Mokdad, Ph.D.

The University of Washington Population Health Initiative conducted a mixed-methods study using data from the National Immunization Survey (NIS)-Child to examine childhood immunization equity between 2007 and 2019 for three childhood vaccines: measles-mumps-rubella (MMR); hepatitis B; and diphtheria, tetanus toxoids, and acellular pertussis (DTaP). This study examined nine representative counties each in Washington state, North Carolina, and Arizona and identified qualitative factors in these counties that have most effectively improved vaccine equity between racial and ethnic groups and across income levels.

This study found that uptake rates differed significantly between specific vaccines, with DTaP vaccination rates lower than MMR and hepatitis B vaccination rates. Disparities in vaccination rates between racial and ethnic groups also varied based on specific vaccine and family income level. For example, racial and ethnic disparities in MMR vaccine uptake rates are greater than disparities in hepatitis B and DTaP vaccines, with the greatest disparities among children of low-income families.

Qualitative interviews identified multiple factors that impact equity for childhood vaccine equity and coverage, including

- population-specific programming and communications (e.g., accounting for potential differences in English fluency between children and their parents/guardians);
- ability to address common barriers such as ensuring vaccine services accessible to working parents;
- State Medicaid expansion;
- policies regarding exemptions to childcare and school vaccine requirements;
- universal purchasing that enables health care providers to vaccinate children regardless of insurance coverage;
- state budget allocations for vaccine programs, including logistics and vaccine reimbursement rates; and
- immunization data quality, including IIS funding and requirements for recording and tracking vaccinations in IISs.

Qualitative interviews also identified multiple attributes of resilient and equitable programs. First, these programs are built on trust and address historical trauma caused by government and health care systems to many disadvantaged groups. Second, these programs are tailored to specific communities and their needs. Third, these programs are community-led based on that community's expertise and lived experience. Fourth, these programs promote learning and coordination across all levels of government, health care, and partner organizations.

The study resulted in four recommendations:

- **Enhance data systems.** Improve the collection, tracking, sharing, and disaggregation of immunization data at the state and local levels.
- **Promote equitable policy priorities.** Measure policy success and ensure policies and promote equity, reduce patient costs, improve access, increase funding and capacity.
- **Engage communities.** Develop population-specific programming and interventions that support proactive outreach and increase community capacity.
- **Boost vaccine confidence.** Disseminate accessible, reliable, and community-centric information that improves health literacy and vaccine confidence.

Dr. Mokdad outlined five key takeaways from this study:

- Despite efforts to reduce costs and address inequities in immunization, racial disparities persist in vaccination rates.
- Vaccine attitudes and beliefs are complex. Programs and policies must account for the cultural, historical, and contextual factors affecting uptake.
- Data limitations hinder our ability to adequately identify and address racial disparities in vaccination at a local level.
- State and local health agencies wield significant power over the success of vaccination efforts through policy, program implementation, and funding.
- Structural barriers to vaccination cannot be overcome solely by increasing motivation to get vaccinated.

CDC Adult Immunization Evaluation Overview—Tara C. Jatlaoui, M.D., M.P.H.

In 2022, CDC funded the National Opinion Research Center (NORC) at University of Chicago to conduct a mixed-methods evaluation of CDC's adult immunization activities. This evaluation drew on several evaluation frameworks, including RE-AIM, the CDC Framework for Program Evaluation in Public Health, and the Culturally Responsive Evaluation framework. For the core evaluation, CDC extracted

progress report data from CDC's major award mechanisms for 497 awardees and 883 reports. Elements extracted included key populations of interest, area of focus (e.g., vaccine uptake, equity), interventions implemented, types of education materials offered, and languages of communication products.

To understand strategies that increase adult vaccine uptake and vaccine equity, NORC, CDC, and the Association of Immunization Managers (AIM) conducted a qualitative substudy that examined case studies from state, local, tribal, and territorial jurisdictions, including interviews with CDC awardees and partners. This substudy sought to identify the key elements of successful routine adult immunization programs and determine which of these elements had the greatest impact on COVID-19 vaccine uptake.

The Administration of Community Living (ACL) conducted a retrospective survey to examine the impacts of Aging and Disability Resource Center Vaccine Access and Older Americans Act Vaccine Access grants on COVID-19 vaccination rates among older adults and people with disabilities. This substudy sought to examine (a) which approaches improved vaccine uptake among older adults and people with disabilities, (b) the extent to which these approaches promoted vaccine equity, (c) how CDC funding affected the implementation of ACL activities around COVID-19 vaccination, and (d) promising practices and lessons learned.

NORC also conducted a cost analysis of five professional associations and nonprofit organizations that were awarded CDC grants to conduct vaccine clinics, develop or engage vaccine partnership networks, or partner with vaccine ambassadors/champions. The cost-analysis aimed to understand awardee approaches to fulfilling requirements of specific funding mechanisms (e.g., grant programs), identify associated cost drivers for awardee approaches to strategies of interest, and identify lessons learned and considerations for future cost analyses.

Based on results from these analyses, NORC is developing a range of communication products, including a special report, comprehensive presentation decks, a manuscript on evaluation findings, and an infographic. These products are scheduled to be released in January or February 2025.

Moving forward, CDC will continue monitoring and evaluating its funded partner activities to ensure ongoing improvement and support for partner organizations; inform funding announcement development; identify successes, barriers, and promising practices for improving vaccine equity; and demonstrate the value of partnerships in reaching adult immunization goals. Findings from these future studies will be shared through various channels, including publications and reports to policymakers.

Immunization Partnership Fund: Evaluating Vaccine Equity Programs—Erin Henry

The Immunization Partnership Fund (IPF) was established in 2016 to support action on Canada's National Immunization Strategy by providing grants and contributions to programs that increase vaccine confidence, access, and uptake. From 2016 to 2021, IPF focused on increased vaccination rates among communities or populations experienced social or structural inequities, including (a) Black, Indigenous, and other racial and ethnic minorities; (b) sexual and gender minorities; (c) people with disabilities or chronic illnesses; and (d) people experiencing housing insecurity and poverty. During this period, IPF focused on building capacity of health care providers; community-based vaccination education, promotion, and outreach; and capacity for evidence-based communication about vaccines.

IPF was originally intended to sunset in 2021, but in response to the COVID-19 pandemic, IPF was expanded and became a key mechanism for the roll-out of Canada's COVID-19 vaccination campaign. Between 2021 and 2023, projects funded by IPF connected with nearly 1.5 million people in Canada through in-person vaccine education, confidence, and vaccine administration activities. Since 2021, more than 368,700 individuals have received a vaccine because of the direct efforts of IPF funding recipients.

IPF-funded projects used multiple approaches to reduce barriers to vaccination, including (a) culturally, religiously, and linguistically safe care; (b) support for booking and attending vaccination appointments; (c) community and social events, incentives, and outreach; (d) extended hours at mobile and pop-up vaccination clinics; and (e) trauma-informed care.

Ms. Henry highlighted two programs as examples of equity-promoting approaches. First, the Dr. Peter Centre administered 37 microgrants to low-capacity community organizations. These microgrants had relatively low barriers to receiving funding. The micrograntees organized 130 vaccination clinics, resulting in more than 7,800 vaccinations in accessible and familiar community spaces. Micrograntees stated that the microgrant model was crucial for enabling these small groups to serve priority populations.

Second, the Alberta International Medical Graduates Association trained medical graduates as vaccine navigators to promote vaccination among new entrants in Calgary. These navigators used their medical expertise and cultural fluency to build trust with new entrants and reduce language barriers for vaccination services. The association is now seeking to continue vaccine literacy and uptake of respiratory disease vaccines among new entrants in Calgary.

Multiple promising practices have emerged from IPF-funded projects, including

- trust and relationship building, including the involvement of community members in the planning and implementation of vaccination programs and recruitment and training of community ambassadors;
- establishment of strong partnerships to increase the quality of resources and services, increase reach to intended audiences, and promote program sustainability;
- flexibility and responsiveness, including information transparency and sensitivity to audience needs; and
- messaging based on people's current level of vaccine confidence (i.e., "meeting people where they are at"), including demonstrating an understanding of the historic and current barriers to vaccinations faced by communities and tailoring communications and vaccine initiatives based on this understanding.

In 2023, IPF was renewed until 2026. Over the next 2 years, IPF will explore software options to facilitate data collection and analysis, support further evaluation of IPF-funded activities, and evolve the IPF logical model and data collection tool to reflect the current vaccination landscape and emerging threats (e.g., mpox).

Discussion

Dr. Hopkins emphasized the need for both qualitative and quantitative measures for assessing effectiveness and efficacy of vaccine programs. Program evaluation should also be a continuous process to enable program improvements.

New Approaches for an Old and Ongoing Threat: Tuberculosis Vaccine Innovation

Tuberculosis: A Primer—Jonathan Wortham, M.D.

Tuberculosis (TB) is a disease of global public health concern caused by the pathogenic bacteria *Mycobacterium tuberculosis*, which clinically manifests as a prolonged cough, fever, weight loss and other non-specific symptoms. TB is one of the most common infectious causes of mortality. According to the World Health Organization (WHO), in 2022, TB caused an estimated 1.3 million deaths and 10.6 million infections, demonstrating an increase in TB cases from 2021. This caseload is likely an

underestimate due to incomplete disease reporting in regions where incidence is highest, which depends on factors such as geographic location and social, demographic, or medical risk factors. WHO also estimates that 2 billion people have latent, asymptomatic TB infections.

TB can be challenging to diagnose and treat. TB is diagnosed through an administered TB skin test or interferon gamma release assay and often results in abnormal chest radiographs, especially for patients with pulmonary TB. However, a negative skin test does not necessarily exclude the possibility of TB infection. An additional challenge is that treatment for TB can last anywhere for 4 to 9 months and initially involves at least three different medications. The Bacille Calmette-Guérin (BCG) vaccine typically given to infants has demonstrated efficacy against severe forms of TB that occur primarily in children, but it does not prevent pulmonary TB.

Although TB incidence rates in the United States are relatively low in comparison to other countries, case numbers have increased from 8,331 in 2022 to more than 9,000 in 2023, according to provisional data from CDC's 2023 annual report. These numbers far exceed the elimination threshold goal of less than 1 case per million population, or 330 cases per year. Similar to global patterns, TB incidence in the United States varies by geographic location and demographic characteristics: typically, 50% or more of U.S. TB cases are reported in five or six states, and TB prevalence increases with age, with most cases occurring in people aged 45 and older. TB also disproportionately affects people born outside of the United States, with non-U.S.-born individuals experiencing a TB incidence rate 17 times that of U.S.-born persons. Data from 2022 show that 30% of non-U.S.-born individuals with TB were diagnosed within 5 years of U.S. arrival, with over half of those infections occurring within the first year of living in the United States. These cases therefore likely represent progression of TB infection acquired prior to entering the country.

Most U.S. cases of TB are pulmonary only, which introduces transmission risk of latent tuberculosis infection (LTBI), or inactive TB. LTBI does not cause symptoms but is estimated to have caused 13 million infections based on a CDC study conducted from 2011 to 2012. USPSTF recommends LTBI screening in adults that were born in or former residents of countries with increased TB prevalence, have lived in high-risk congregate settings such as correctional facilities and emergency shelters, or are members of other groups that may experience social or medical factors that increase their risk for TB.

The Tuberculosis Vaccine Pipeline—Mike Frick, M.Sc.

Emerging TB vaccines are being developed in the context of other existing and evolving preventative interventions, including infection control, BCG vaccination, preventative treatments, anti-retroviral therapy for people living with HIV, and adequate nutrition, all while considering social protection, human development, universal health coverage, and respect for human rights. However, selecting the appropriate antigens to target from the very large genome of *M. tuberculosis* remains a significant obstacle to TB vaccine development.

TB vaccine development is guided by three overarching strategies: prevention of infection, prevention of disease, and prevention of recurrence. Prevention of disease vaccines aim to prevent microbiologically confirmed pulmonary TB disease and are the primary strategy of focus. Prevention of disease vaccines are seen as having the greatest likelihood of licensure because of their precisely defined endpoint and potential beneficial impact on public health. Several vaccine platforms are being explored, including viral vectors, protein/adjuvant subunits, mRNA, and killed whole cell or extracted forms or live recombinant or attenuated forms. The field is working on multiple Phase III trials across these delivery platforms that collectively will enroll 80,000 people. Future Phase II and III trials will aim to enroll individuals that represent diverse populations at risk of TB. These trials have been registered in 28 different countries. Together, these efforts will collect hundreds of thousands of human participant samples, which can guide next-generation vaccine development as well as immunology and other basic science research. The TB

vaccine pipeline currently contains 15 vaccine candidates across clinical trials in different phases. One notable candidate entering Phase III trials is M72/AS01E, a subunit protein/adjuvant vaccine that combines two *M. tuberculosis* antigens, Mtb32A and Mtb39A, with an AS01E adjuvant. This candidate will be evaluated for its ability to prevent bacteriologically confirmed pulmonary TB among HIV-negative participants who are TB positive. Enrollment for this study opened in March 2024, and results will be available in 4 to 5 years. Another vaccine candidate in Phase III trials is MTBVAC, a live attenuated mycobacterial vaccine based on an *M. tuberculosis* clinical isolate. Attenuation is achieved by deletion of genes *PhoP* and *fadD26*, which code for two major virulence factors. MTBVAC is being tested in infants as a replacement for BCG, and participants are currently being recruited for this study. This candidate will also be tested in adolescents and adults, and the trial has been registered with clinicaltrial.gov in preparation for open enrollment. In addition, several groups are working toward developing an mRNA vaccine for TB. BioNTech has registered two Phase I clinical trials of two investigational mRNA vaccines, BNT164a1 and BNT164b1, which will be evaluated for safety, reactogenicity, and immunogenicity across four dose levels on a three-dose schedule. Preclinical evaluations of mRNA TB vaccine constructs are being performed by the mRNA Technology Transfer Hub Programme and Moderna in partnership with the International AIDS Vaccine Initiative®, and various other organizations are also developing these vaccine platforms.

The science behind TB vaccine development is promising, but financial resources are limited. While the United Nations calls for $1.25 billion for TB vaccine research and development each year, only $1.4 billion in total was spent between 2009 and 2022. The United States only contributed $145 million in FY22. Funding should be increased to maximize progress in addressing TB.

Additional information on TB vaccine candidates is provided the *TB Vaccines Pipeline Report,* published annually by the Treatment Action Group, the Stop TB Partnership Working Group on New TB Vaccines website, and WHO's *Global TB Report*.

Collaboration in Tuberculosis Vaccine Research and Development—Ann Ginsberg, M.D., M.P.H.

Key stakeholders in TB vaccine development, from early researchers tasked with discovery to manufacturers responsible for creating sustainable vaccine supply, are involved at multiple stages of this end-to-end process. Collaborations between these stakeholders are critical for TB vaccine research, development, implementation, and uptake.

One prominent stakeholder is The Collaboration for TB Vaccine Discovery (CTVD), an international network of scientists and experts dedicated to fostering innovation, cooperation, and collaboration in upstream TB vaccine discovery, translational research, and product development. Founded in 2015 and managed by the Gates Foundation, this organization includes more than 375 members from 86 different institutions worldwide that engage in small working groups as well as an annual national meeting. CTVD members have identified scientific gaps that have slowed TB vaccine development, including in protective antigen identification, validated and predictive animal models, understanding of the human protective immune responses and correlates of protection, and a robust pipeline of next-generation candidates. Addressing such gaps has enabled CTVD to accelerate discovery, advance the most promising clinical and preclinical candidates, and implement new and improved tools to help the field advance toward accessible and effective TB vaccines. Individuals interested in contributing to CTVD should contact Dr. Ginsberg.

Another important stakeholder is the Stop TB Partnership Working Group on New Vaccines, which was established in 2001 to facilitate research and development of new TB vaccines by providing an inclusive forum for stakeholders to engage in scientific exchange, build consensus on key issues, and advocate for

greater support and investment in TB vaccine research and development. This informal network of TB research and development stakeholders involves a variety of constituencies including academics, product developers, clinicians, advocates, funders, policymakers, and affected communities. Membership is open to anyone interested in being involved with TB vaccine research and development and can be obtained by completing a sign-up form on the "Become A Member" page of the organization's website.

The WHO TB Vaccine Accelerator Council is also a key stakeholder. The Council is an informal, voluntary network managed by the office of WHO's Chief Scientific Officer. Council participants can exchange views, share information, and enhance technical and political cooperation, especially as they relate to late-stage TB vaccine candidates. This network was founded in 2023 to facilitate the licensing and use of effective novel TB vaccines by catalyzing high-level alignment between funders, global agencies, governments, and end users in identifying and overcoming barriers to TB vaccine development. The ministerial board primarily comprises health and finance ministers and support staff from not only the global north but also high-burden TB countries. The Council is establishing technical and strategic working groups to address potential vaccine distribution challenges upon immunization licensure, and these small groups will report relevant progress to the principal working group and ministerial board. Such challenges include global coordination and consensus on goals and expectations; finance across the value chain; manufacturing; awareness and alignment on vaccine candidates for adults and adolescents, need and impact, and timelines; country-specific data for adults and adolescents; and delivery, health systems readiness, and engagement.

Conventional Versus Unconventional Approaches in Tuberculosis Vaccine Development—Maziar Divangahi, Ph.D.

Novel TB vaccine design has been hindered by poor understanding of TB immunity. *M. tuberculosis* infects individuals via respiration, reaching the lower airways through uptake by alveolar, or residential, macrophages into interstitial tissue. Innate and adaptive immune cells, including monocyte-derived macrophages from the bone marrow, then form granulomas, which prevent bacterial dissemination by trapping bacteria within this structure. However, the distinct roles of residential versus infiltrating macrophages in fighting TB infection remain poorly understood. Studies have shown that the metabolism of naïve human alveolar macrophages becomes compromised upon infection with *M. tuberculosis* strain H37Ra, whereas the metabolism of monocyte-derived macrophages increases. Another study demonstrated the ability of *M. tuberculosis* to travel to the bone marrow within 10 days of infection, where it preferentially inhibited generation of myeloid lineage stem cells, including monocyte-derived macrophages, while expanding lymphoid lineage cells such as B and T cells. Furthermore, *M. tuberculosis* access to bone marrow resulted in transcriptomic reprofiling of hematopoietic stem cells such that they are no longer able to clear the bacterial infection.

The steps of natural immunity have traditionally set the foundation for vaccine development. Many delivery platforms including viral vectors and mRNA result in the overexpression of a pathogen-associated antigen, leading to the generation of memory T and B cells that produce antibodies that will neutralize the pathogen. However, as evidenced by the studies described, natural immunity to TB neither eliminates bacteria nor generates a protective memory response that will prevent subsequent reinfection. Most developed TB vaccines elicit antigen-specific T cell responses, particularly in CD4+ T cells, although these approaches have not been successful in either preclinical or clinical trials. Such failures are likely because of the potential for T cells to promote TB pathogenesis, as suggested by the literature. Although animals infected with *M. tuberculosis* demonstrate increased numbers of CD4 and CD8 T cells, increased levels of antigen-specific T cells did not correlate with protection against, and in fact increased susceptibility to, TB. These data support the notion that conventional T cell function in TB may be different when compared to other pathogens such as viruses and thus traditional approaches to vaccination may be unsuitable for TB.

While a significant body of work has focused on adaptive immunity mechanisms to combat TB infections, epidemiological data suggest a role for innate immunity in TB pathogen elimination. Approximately 20% of individuals living in TB hyperendemic areas show negative TB skin tests and TB resistance, as do 30-50% of close household contacts of active TB patients. Innate immune responses to TB also exhibit the capacity to be trained through epigenetic programming. A 2024 study was in performed in which intravascular, rather than intradermal, administration of BCG in humans resulted in hematopoietic stem cell programming within the bone marrow that generated monocyte-derived macrophages capable of providing protection against TB. These results recapitulated previous studies performed in mice. Future TB vaccine approaches should consider intravascular administrations of BCG as well as the power of innate immune responses to develop effective TB preventions and treatments.

Conventional and Unconventional Tuberculosis Vaccine Targets and Role of Controlled Human Challenge Models—Daniel Hoft, M.D., Ph.D.

Although latency is the largest reservoir of *M. tuberculosis*, it has not been a strong focus of TB vaccinology efforts, in part because vaccine candidates targeting latent infection are challenging to test. Many latent pathogens reside in macrophages found in granulomas, which reduces the immune access required to clear the bacteria. Major targets for TB vaccine development are CD4+ TH-1 cells that make interferon (IFN) γ, tumor necrosis factor and interleukin (IL) 2, which are key for protective immunity, but these cells have limited efficacies. Other cells including CD8 cells and CD4+ TH7 cells that make IL-17 may have therapeutic potential by inducing mucosal protection against TB infection.

Conventional vaccine approaches target αβ T-cell receptor (TCR)+ T cells that are human leukocyte antigen restricted. This approach requires many differing epitopes to induce responses in different individuals. To overcome this challenge, an unconventional vaccine approach targeting αβTCR+ and γδTCR+ T cells that are not human leukocyte antigen restricted has resulted in the emergence of donor-unrestricted T cell (DURT) inducing vaccines. DURT cells can recognize a diverse array of antigens and thus have the potential to induce a protective response in many people. DURT vaccines are considered universal because the restriction elements required to activate these cells are ubiquitously expressed in humans and are non-polymorphic. Two such examples of DURTs are γ9δ2 T cells and mucosal-associated invariant T (MAIT) cells.

γ9δ2 T cells have demonstrated capacity for memory development after vaccination. These cells respond to methyl glucose lipopolysaccharide (MGLP), a component of the *M. tuberculosis* cell wall, and can recognize TB-infected human monocytes to inhibit intracellular *M. tuberculosis* replication. Although MGLP is typically difficult to obtain for vaccine development purposes, early studies assessing immune response induction of MGLP antigen-based TB vaccines elicited induction of a γ9δ2 cell population in both the blood and lungs of treated NHPs. These responses resulted in reduced bacterial load and decreased clinical pathology. Within the past 6 months, the active portion of MGLP required to induce such a response has been synthesized and is undergoing evaluation for potential to expand γ9δ2 cells to inhibit intracellular microbacteria in vitro.

MAIT cells, particularly those restricted by the non-polymorphic restriction element NR1, are activated in LTBI patients upon oral BCG vaccination. While intradermal vaccination induced strong immune responses in the blood, oral vaccination elicited the strongest response in the lung. Further analysis of transcriptomal data revealed expression of several genes associated with MAIT cell functions, implicating the involvement of MAIT cells in this response.

Work is being done to develop a human challenge model based upon intradermal BCG granulation. Intradermal administration of BCG causes ulcerative lesions and prolonged shedding of live BCG, which

can be quantified over time. Evaluation of the peak and variance in BCG shedding can be combined with assessing correlations between shedding patterns and immunogenomic data to reveal potential biomarkers. This approach has shown promise in a feasibility study in which tolerable doses were identified, lesions were safely generated, and BCG shedding patterns were successfully observed. This study also demonstrated that men have significantly higher BCG shedding than women, potentially because women demonstrated four-fold higher gene expression that may prevent pathogen replication. This model is also being used in an ongoing study assessing vaccination timeline effects on BCG shedding.

Although unconventional vaccine approaches show promise, challenges remain in developing novel TB vaccines. Preclinical results need to be translated into human studies, which will require prolonged and expensive clinical efficacy trials. Funding inadequacy continues to slow progress, especially for lower income, hyperendemic areas that are most affected by uncontrolled infection. Future TB vaccine development efforts should focus on increasing understanding of TB protective immune correlates, using challenge models for early screening of TB candidates, and financially investing in TB research to make such work possible.

The Investment Case for TB Vaccines—Lois Privor-Dumm, M.B.A.

Although TB remains a global threat, this area of study continues to lack funding and effective vaccines. New vaccines for pre-and post-exposure situations are needed by 2025 to end the TB pandemic by 2030, according to "An investment case for the new tuberculosis vaccines," a technical document published in 2022 by WHO. To achieve this goal, TB vaccine development needs to be accelerated.

Drug resistance to TB poses significant societal and financial costs. TB accounts for one in three antimicrobial resistance (AMR)-related deaths globally. A 2015 report from the U.K. Parliamentary Group on TB estimates that multidrug-resistant TB will cause 75 million more deaths in the next 35 years. The report further projects that AMR will cost the global economy $16.7 trillion. The United States spent $502 million to treat drug resistance in the year 2020 alone. Development of TB vaccines would reduce antibiotic use, thus combatting AMR.

New vaccine developments provide important lessons that can help inform TB-focused work. Effective vaccines should be available, acceptable, and accessible. Vaccine availability requires multisector collaborations, a thorough understanding of local disease burden, especially those at higher risk for TB, and resource planning such as supply and delivery to ensure both production and accessibility of available doses. Accessibility involves flexible delivery strategies as well as utilization and optimization of existing health infrastructure. Acceptability addresses vaccine confidence through community sensitization and education, potentially through trusted local leaders, and robust communication strategies as informed by social science research. Vaccine accessibility is particularly relevant to ensuring health equity. TB disproportionately impacts low-income families, and one in two households worldwide spend more than 20% of their income on TB treatment costs. These individuals may experience preexisting medical conditions, transportation challenges, or concerns about treatment costs, especially because catastrophic expenses can force people living in lower economic quintiles below the poverty line. While more U.S.-focused studies are needed to demonstrate vaccination value for specific populations, broad economic studies in low- and middle-income countries have shown significant returns on investment, with the potential to return $7 for every $1 invested in TB vaccine development.

Although the investment case for TB vaccines on a global basis is clear, additional evidence is needed to refine a TB vaccine development strategy in the United States. Such work should focus on

- defining target populations and optimizing delivery strategies to reach these groups,

- performing cost-benefit and return-on-investment analyses to establish the broader value of vaccination given various priorities,
- increasing understanding of potential impact on AMR and multidrug-resistant TB
- resource planning,
- determining supply and investment strategies to reach both national and international goals,
- performing social science studies and stakeholder mapping in target communities, and
- engaging in political advocacy for the continued support of global priorities.

Provider Payment: Addressing Barriers and Increasing Confidence

Medicare Vaccine Coverage—Susan Janeczko

CMS manages Medicare, a federal health insurance program for adults aged 65 and older as well as for some younger adults with disabilities or end-stage renal disease. Medicare Part A covers inpatient care, while Medicare Part B covers outpatient care (e.g., outpatient physician visits, preventive services). Medicare Part C (i.e., Medicare Advantage) provides similar services as Parts A and B but is administered by private insurers. Medicare Part D covers prescription medications.

Medicare vaccine coverage falls under both Parts B and D, and the conditions and extent of this coverage is determined by Medicare statute and relevant laws and regulations. For example, the Medicare statute requires Part B to cover the cost of both the vaccine and vaccine administration for pneumococcal, influenza, hepatitis B and COVID-19 vaccines for all Medicare beneficiaries, but limits coverage of the hepatitis B vaccine to beneficiaries who are at high or immediate risk of HBV infection.

Some preventive vaccines (e.g., zoster and RSV vaccines) are covered under Part D, which has different pricing regulations than Part B. CMS is prohibited by statute from conducting cost negotiations with pharmaceutical manufacturers, pharmacy benefit managers, and pharmacies. CMS is also prohibited from establishing a pricing structure under Part D for vaccines and other drugs. Thus, pricing for vaccines covered under Part D may significantly differ from vaccines covered under Part B.

The Inflation Reduction Act of 2023 has increased vaccine access for Medicare beneficiaries. For example, under this act, patients with Medicare Part D coverage pay no out-of-pocket costs for adult vaccines recommended by ACIP, which has so far saved Part D beneficiaries more than $400 million in out-of-pocket costs. RSV vaccines account for the majority of increased vaccination uptake resulting from the expanded coverage under the Inflation Reduction Act.

Vaccine Coverage under 2025 Proposed Rule for Medicare Part B—Rachel Radzyner

In 2024, CMS issued a proposed rule for the 2025 physician fee schedule for Medicare Part B that includes multiple proposed changes to vaccine coverage. The proposed rule expands Part B coverage for hepatitis B vaccines to include pharmacies in addition to physician offices and allows for roster billing for hepatitis B vaccines by pharmacies and other nontraditional vaccine providers (e.g., public health clinics, senior centers). The proposed rule would also revise the definition of "intermediate risk" of HBV infection to include beneficiaries who have not completed the hepatitis B vaccine schedule or whose previous vaccination history is unknown. Unlike for other vaccines (e.g., COVID-19, influenza), Part B requires a physician to assess a patient's risk of contracting HBV prior to coverage of a hepatitis B vaccine. This requirement prevents Medicare from covering mass or universal hepatitis B vaccination programs. In addition, the proposed rule would change payments for vaccines at Rural Health Clinics and FQHCs to 100% of reasonable cost to streamline payment under Part B in these settings. Under the proposed rule, claims by Rural Health Clinic and FQHCs for Part B-covered vaccines would be paid using established Part B payment rates, which will be annually reconciled with actual vaccine costs.

The formal comment period for the proposed rule recently closed. CMS is seeking to finalize this rule by November 2024. If adopted, the proposed rule will take effect on July 1, 2025.

Vaccine Coverage Under Medicaid and Children's Health Insurance Program—Mary Beth Hance

In addition to Medicare, CMS manages Medicaid and the Children's Health Insurance Program (CHIP). Medicaid provides health care coverage to approximately 80 million Americans, including adults with low income, people with disabilities, pregnant people, and older adults. CHIP provides health care coverage to children and families whose incomes are above the maximum threshold for Medicaid but insufficient to afford private health insurance. Both Medicaid and CHIP are joint federal and state programs that operate within regulations established by CMS.

Under the Inflation Reduction Act, most Medicaid and CHIP beneficiaries have access to ACIP-recommended vaccines without cost sharing. CMS issued guidance to states in June 2023 about the increased coverage for vaccines under the Inflation Reduction Act. In February 2024, CMS issued an updated vaccine toolkit for state governments with information on vaccine coverage under Medicaid and CHIP, including vaccine administration fees and coverage for childhood vaccines under the CDC Vaccines for Children (VFC) program.

CMS strongly encourages states to use multiple programs and approaches in Medicaid and CHIP to increase immunization rates. For examples, states can examine Medicaid and CHIP claims data to identify areas with low immunization rates, and then partner with LHDs and community organizations to increase immunization in those areas. CDC, CMS, and HHS have pre-built communication and promotional materials for states and nongovernmental organizations to use to ensure consistent messaging about vaccines and coverage. For example, the Connecting Kids to Coverage National Campaign has pre-built communications materials in English and Spanish on childhood vaccine access through Medicaid and CHIP.

Health Plans: Promoting Equitable Vaccine Access—Chris Regal

Section 2713 of the Public Health Services Act requires insurers—both public and private—to provide coverage for vaccines without cost-sharing for vaccines that are routine use (i.e., listed on CDC immunization schedules), recommended by ACIP, and provided by in-network providers. For newly recommended vaccines, the requirement goes into effect at the start of the next calendar year (i.e., January 1) *following* the 1-year anniversary of ACIP recommending the vaccine. For example, if ACIP recommended a vaccine in September 2024, coverage without cost-sharing would not be required until January 1, 2026.

The Inflation Reduction Act expanded coverage for vaccines and vaccine administration under Medicare Part D, Medicaid, and CHIP. For Medicare Part D, coverage for ACIP-recommended vaccines began on January 1, 2023, regardless of when ACIP issued its recommendations. Similarly, Medicaid and CHIP were required to begin coverage of ACIP-recommended vaccines on October 1, 2023, regardless of the ACIP recommendation dates. The Inflation Reduction Act also expanded coverage under Medicare Part D, Medicaid, and CHIP from only routine-use vaccines to any ACIP-recommended vaccines.

Legal requirements and ACIP recommendations for RSV vaccines are complex. Because ACIP recommended RSV vaccines in June 2023, private insurers are not required to cover these vaccines without cost-sharing until January 1, 2025. Some RSV vaccines are recommended for specific populations (e.g., older adults, pregnant people); for example, ACIP has recommended three different RSV vaccines—Arexvy, mResvia, and Abrysvo—for older adults, but only Abrysvo has been

recommended for pregnant people. Confusion has arisen among many health care providers and insurance plans about whether newborns should be given nirsevimab prior to hospital discharge or at outpatient clinics.

ACIP recommendations for RSV vaccination among older adults recently changed from shared clinical decision-making for all adults aged 60 and over to risk-based vaccination for adults aged 60-74 and all adults aged 75 and older. Some payers have not updated their processes to reflect this change and continue to use shared decision-making for RSV vaccines. Among older adults, nirsevimab is recommended on a seasonal basis between October and March. Many health care providers seek to provide nirsevimab to patients outside of this period, which can lead to denial of coverage.

ACIP recommendations for pneumococcal vaccines are similarly complex. Since 2013, different pneumococcal vaccines (e.g., 13-, 15-, 20-, 21-, and 23-valent vaccines) have been recommended for different populations (e.g., adults aged 65 and over, children younger than 5 years). Some ACIP recommendations superseded previous recommendations made prior to requirements for coverage under the Public Health Service Act, creating further confusion among health care providers and insurers.

Mr. Regal outlined multiple potential solutions to these challenges:

- ACIP should continue to make recommendations based on evidence and communicate its recommendations as clearly as possible.
- Medical coding practices for various vaccines and populations should be clearly communicated.
- Health care stakeholders need to collaborate to effectively implement ACIP recommendations across different populations.
- Payers should communicate with their members about ACIP recommendations and ways to access recommended vaccines.

Overview of Provider Payment for Vaccination—Mitchell Finkel

Administration of vaccines by health care providers includes multiple processes and steps before as shown in the table below:

Pre-Vaccination	During Vaccination	Post-Vaccination
• Establishing vaccination infrastructure and supplies (e.g., specialized equipment) • Training for vaccinating patients • Acquisition of vaccine doses	• Counseling patients on vaccines • Answering patient questions and concerns • Sharing information from Vaccine Information Sheet	• Submitting claims to patient's insurance for vaccine and administration

Ideally, payment policies and reimbursement rates account for all these steps and processes, including vaccine acquisition, administration, counseling, and maintenance of vaccine infrastructure. However, reimbursement policies and levels are influenced by multiple factors, including coverage for specific vaccines and populations; relevant medical coding for vaccines, patient conditions, and health care provider services; and payment policies. Most payment rates (e.g., rates for commercial plans, Medicare Part B, and Medicare Advantage) are negotiated between health care providers and payers, and these rates are not public. All these factors can introduce significant variability in vaccine reimbursement rates.

Within the past 15 years, many health care stakeholders have focused on improving reimbursement rates for pediatric vaccines, including development of the American Academy of Pediatrics *Business Case for*

Pricing Vaccines and improved medical coding for pediatric vaccine administration. However, reimbursement rates for adult vaccines has received less attention than pediatric vaccines.

In 2018, Lindley and colleagues published findings from a survey of adult health care providers on providers' perceptions of the adequacy of reimbursements for vaccines. Providers reported that commercial and Medicare reimbursement rates were adequate, but Medicaid reimbursement rates were not. Recent analyses of Medicare claims data by Avalere confirm providers' perceptions about low Medicaid reimbursement amounts. Most state Medicaid programs reimburse all vaccines except for COVID-19 below Medicare's preventive vaccine reimbursement rate. The median Medicaid vaccine administration rate is $14.70 per vaccine, which is approximately 71% of the national payment rate of $20.64 per vaccine and 45% of the Medicare Part B rate of $32.57.

Health care stakeholders have outlined multiple potential policy solutions improve Medicaid reimbursement rates, including

- CMS implementation of federal payment regulations for vaccines and their administration under Medicaid and CHIP;
- increasing the Medicaid Federal Medical Assistance Percentage for adult vaccines;
- establishment of coverage and reimbursement parity among all health care provider types (e.g., physicians, pharmacists, nurses);
- reforms to Medicare Part B preventive benefits, to which many Medicaid programs match their reimbursement rates; and
- reforms to coding (e.g., Current Procedural Terminology [CPT] code structure) for adult vaccines.

Discussion

Access to Medicaid Reimbursement Rates

Mr. Rothholz noted that Medicaid reimbursement rates for vaccines vary significantly between states, and these state-specific rates are not available in a single source or reference and thus often challenging to locate. He asked whether CMS plans to compile these rates into a single, publicly available source. Ms. Hance responded that CMS makes Medicare Part B fee-for-service data publicly available. She added that while though Medicare Advantage rates are proprietary, vaccine reimbursement rates under Medicare Advantage are likely similar to Medicare Part B rates. Unlike Medicare, Medicaid programs are joint federal–state programs, so states' Medicaid programs maintain the data on Medicaid reimbursements for vaccines.

Coordination between ACIP Recommendations and Payer Coverage

Mr. Rothholz noted that HHS is emphasizing the importance of RSV vaccines as part of its "Risk Less. Do More." campaign, but coverage for these vaccines is not yet required for all payers. He expressed concern that patients may seek RSV vaccines, only to be turned away or unable to afford the copay for these vaccines. He asked whether HHS agencies (e.g., CDC, CMS, FDA) could change regulations to more closely coordinate ACIP recommendations for vaccines and payer coverage. Mr. Regal noted that America's Health Insurance Plans (AHIP) members have previously met with CDC to address gaps between ACIP recommendations and insurance coverage. Mr. Rothholz agreed to send examples of patients unable to access RSV vaccines due to lack of coverage to Mr. Regal.

Counseling for Low Vaccine Confidence

Within the past 10 years, many health care providers require additional appointment time to address low vaccine confidence and misinformation about vaccines, but many medical coding systems (e.g., ICD-10-CM) do not have codes for this type of patient counseling. Mr. Rothholz emphasized the need for medical coding systems to have specific codes for this type of counseling. He also asked whether this counseling is included in covered vaccine administration costs under the Public Health Service Act. Mr. Regal responded that coverage for this type of counseling likely varies between individual health plans.

Bundled Billing for Nirsevimab

Ms. Howe noted that nirsevimab is not included in many hospitals' bundled reimbursement rates, which often presents a barrier to administering nirsevimab to patients, and she asked what steps are necessary to ensure coverage of nirsevimab at hospitals. Mr. Regal responded that the negotiation of rates for nirsevimab often lags behind ACIP recommendations, and AHIP hopes to have this issue addressed by the 2025–2026 respiratory disease season.

Ms. Howe asked whether Medicare Advantage plans cover vaccine administration at LHDs and other public health sites. Mr. Regal responded that Medicare Advantage plans are required to provide similar benefits to Medicare Parts A and B. Because most LHDs are considered out-of-network providers by Medicare Advantage plans, vaccines covered under Medicare Part B (e.g., hepatitis B) would not be covered by Medicare Advantage plans. Vaccines covered under Medicare Part D (e.g., RSV) are governed by Part D requirements rather than Medicare Advantage requirements.

National Strategy Charge Working Session— Ann Aikin, Acting Designated Federal Officer, NVAC

NVAC has been charged with reviewing the 2020–2025 National Vaccines Strategic Plan (NVSP) to inform development of the 2026–2030 NVSP. The NVSP provides a roadmap for coordinating new vaccine development and addressing new challenges (e.g., emerging diseases). This plan uses a lifespan approach with defined goals, objectives, strategies, and indicators, many of which are overlapping. The current NVSP currently has 5 goals, 10 indicators, and 3 developmental indicators. Of the 10 indicators, 5 are pediatric, 4 are for adults, and 1 is for people aged 6 months and older.

The overall goals for the National Strategy Charge Working Sessions on Days 1 and 2 were to (a) discuss whether to change or propose new goals and indicators and (b) recommend and prioritize three objectives within each goal that will likely make the greatest impact on the U.S. immunization system over the next 5 years. For the Day 1 session, NVAC members discussed the five goals:

Goal 1: Foster innovation in vaccine development.

Dr. Swamy expressed concern that this goal—as presently worded—does not show a clear linkage with public health. She suggested that this goal should remain in the NVSP but not be listed as the first goal.

Goal 2: Maintain the highest possible levels of vaccine safety.

Dr. Karin Bok asked why the 2026–2030 NVSP includes vaccine safety as a goal. Multiple NVAC members noted that public concerns about vaccine safety increased during the COVID-19 pandemic. This goal also includes messaging about vaccine safety to increase vaccine confidence.

Goal 3: Increase knowledge of and confidence in routinely recommended vaccines.

Dr. Mullen asked whether this goal is limited to routinely recommended vaccines or seeks to increase confidence in all vaccines and the overall immunization system. Dr. Hopkins responded that this goal seeks to improve the confidence and acceptance (i.e., uptake) of routinely recommended vaccines, similar to the focus of Goal 4. Goal 3 focuses more on relevant communication, whereas Goal 4 focuses on improving access.

Dr. Rinderknecht noted that "routinely recommended" is vague, particularly in shared clinical decision-making models, and many recommendations are also for specific populations. Vaccine recommendations may also vary between agencies (e.g., CDC, FDA) and other health care stakeholders. Dr. Melinda Wharton responded that CDC typically uses "routine" to refer to vaccines on its immunization schedules, including age-based and travel-based immunization schedules.

Goal 4: Increase access to and use of all routinely recommended vaccines.

NVAC members agreed to change "access to and use" to "vaccination and immunization" to reflect the importance of increasing uptake as well as access. "Immunization" was included to reflect types of immunization therapeutics other than vaccines (e.g., monoclonal antibodies).

Goal 5: Protect the health of the nation by supporting global immunization efforts.

NVAC members agreed that this goal should remain in the 2026–2030 NVSP.

Additional Considerations

Multiple NVAC members expressed concern about the lack of focus on vaccine equity in the current goals. They recognized that the goals are broad and include equity components, but they suggested that at least one goal explicitly include "equity" to ensure sufficient emphasis on vaccine equity.

NVAC members suggested reordering the goals as follows in descending order of priority:

1. Increase knowledge of and confidence in routinely recommended vaccines (previously Goal 3).
2. Maintain the highest possible levels of vaccine safety (previously Goal 2).
3. Increase access to and use of all routinely recommended vaccines (previously Goal 4).
4. Foster innovation in vaccine development (previously Goal 1).
5. Protect the health of the nation by supporting global immunization efforts (remains Goal 5).

Public Comment

Mr. Timothy Cestaro, father of son with altered immunocompetence, provided a public comment. Mr. Cestaro emphasized the importance of ensuring that vaccines are safe, and that many members of the public have serious doubts about vaccine safety. He suggested that paying health care providers on a per-vaccine basis may incentivize these providers to over-vaccinate. Mr. Cestaro claimed that his son sustained severe brain damage due to a live attenuated virus vaccine, which Mr. Cestaro maintained should not have been given based on CDC guidance. He agreed to provide additional remarks on Day 2.

Adjourn

Dr. Hopkins thanked the participants and recessed the meeting for the day.

Day Two

Call to Order and Rules of Engagement—Ann Aikin, Acting Designated Federal Officer, NVAC

Ms. Aikin called day 2 of the meeting to order at 9:00 a.m. and welcomed meeting participants. She reminded participants that the meeting was being recorded and would be made publicly available. Ms. Aikin then briefly outlined the key parts of the Federal Advisory Committee Act, its conflict-of-interest rules, and standards of ethical conduct for NVAC members.

Chair's Welcome—Robert H. Hopkins, Jr., M.D., M.A.C.P., F.A.A.P., NVAC Chair

Dr. Hopkins welcomed the participants to the hybrid virtual and in-person public meeting, which was accessible to the public by live webcast and telephone. He described the procedure for asking questions and delivering public comments during the meeting. Written comments can be sent to NVAC for consideration by e-mail (nvac@hhs.gov).

Dr. Hopkins outlined his thoughts on the meeting highlights from the previous day, September 12, and introduced the upcoming panels. He reminded attendees that the agenda, minutes, and recordings of past meetings are available online. Scheduling information for the next NVAC meeting will be announced at a later date.

Dr. Hopkins noted that this meeting will be his last serving as NVAC Chair and thanked the NVAC community for their shared experiences and continued efforts.

Agency and Liaison Updates

Association of Immunization Managers (AIM)

From May 2024 to July 2024, AIM hosted eight regional vaccine access cooperative meetings that brought together teams and partners such as Medicaid representatives, pharmacies, family physicians, public health immunization program managers, and other coalitions. Together, these groups created action plans focused on improving influenza and COVID-19 vaccination rates in birthing parents, individuals in long-term care facilities, and the adult population. AIM plans to release a report about these efforts later this year and will continue to track these cohorts to assess the effectiveness of this initiative.

In August 2024, AIM announced the 2024 Immunization Champion Award winners as part of National Immunization Awareness Month. These awards recognize individuals that go above and beyond to promote and foster immunization efforts in their communities. This year, 46 awardees were nominated and selected from a pool of public health professionals, community advocates, and other immunization leaders. The awardees are profiled on the AIM website and are being celebrated in their jurisdictions.

On October 1, 2024, AIM and its partners will host a webinar to celebrate the 30th anniversary of the VFC program launch. This event will feature distinguished guests and discuss the success of the program in preventing more than 508 million cases of illness, 32 million hospitalizations, and 1 million deaths due to vaccines and VFC-facilitated vaccinations.

AIM plans to release two additional resources before the end of the year. The first is the 2023–2024 State Legislative Session Report, which is a comprehensive review of all proposed, considered, enacted, and vetoed vaccine-related legislation. This resource is primarily designed for program managers but will be posted on the AIM website. The second is a white paper about opportunities and challenges in pharmacy

participation in the VFC program. This publication is a collaborative effort between AIM Immunization Program Managers and pharmacies and will be posted to the AIM website upon release.

American Immunization Registry Association (AIRA)

AIRA launched a new e-learning course about Health Level Seven (HL7) immunization messaging. To date, 185 individuals have registered for the course, and 46 have completed it. To facilitate the onboarding process for the e-learning course, AIRA has updated onboarding templates and uploaded them to the AIRA website for jurisdictional and external partner access. These templates can be personalized, modified, and updated based on evolving guidance to meet the specific needs of each jurisdiction.

AIRA has released a series of technical advisory bulletins on its website that provide updates related to HL7 messaging and clarifying next-of-kin phone number and address details, where this information should be located in messages sent between systems, and what expectations exist for returning certain message components.

AIRA will host its national meeting from April 28, 2025, to May 1, 2025, in Spokane, WA.

American Pharmacists Association (APhA)

APhA released vaccine preparedness informational pieces to help providers effectively communicate details about upcoming influenza immunizations, such as explaining differences between trivalent and quadrivalent vaccines. APhA has also been working with other partners to increase birthing parent RSV vaccination access and to answer patient or provider questions about these immunizations. Another resource recently developed by APhA is the "My Vaccine Action Plan" tool, which enables providers to discuss and plan immunization timelines with their patients.

APhA is continuing to work with providers and public health partners to identify and address barriers and challenges to vaccine accessibility through payment network engagement, understanding current vaccination recommendations, and building and strengthening collaborations across immunization communities. As part of these efforts, APhA has been collaborating with AIM to bolster the VFC program.

During the August 2024 NIC and National Adult and Influenza Immunization Summit, APhA provided updates on its work with pharmacy community members to address vaccine confidence and pharmacy utilization. The pharmacy community released an executive summary report regarding potential recommendations to increase pharmacy engagement in the VFC program. This report has been shared with Ms. Aikin to distribute to NVAC.

APhA provided additional updates in its written report, including highlights from the June 2024 ACIP meeting and program launch strategies for expanding adult vaccinations.

Association of State and Territorial Health Officials (ASTHO)

ASTHO's recent initiatives have been directed at supporting National Immunization Awareness Month. ASTHO provided situational awareness and technical support through a series of newscasts focused on topics including AIM's Immunization Award, RSV, advancing vaccine equity, vaccine barriers for people with disabilities, and vaccine misinformation. ASTHO published two blog posts detailing how state legislatures can reshape public health legal authority and how state policies impact access to new immunizations products.

ASTHO held a two-part policy academy for state and regional health leaders to improve capacity to identify, develop, and implement policies that address vaccine hesitancy. The first academy discussed legislative trends, while the second focused on policies concerning vaccine-like products such as nirsevimab. The academies highlighted the benefits of early engagement, evidence-based advocacy, and transparent communication from stakeholders. ASTHO presented these highlights, as well as state legislative trends, at the August 2024 National Immunization Conference.

As part of P4VE, ASTHO worked with the National Community Action Partnership, five community action agencies, and a network of other partners to increase vaccine acceptance and uptake among people from racial and ethnic minority groups by using locally tailored, evidence-based strategies. ASTHO and the National Community Action Partnership also supported community partners in developing long-term strategies for vaccine equity sustainability.

ASTHO will participate in the upcoming National Foundation for Infectious Diseases 2024 Awards Gala and Silent Auction as well as the October 2024 VFC anniversary events.

National Association of County and City Health Officials (NACCHO)

NACCHO held its annual conference, NACCHO360, on July 23–26, 2024. During this event, local public health department immunization program staff gathered to discuss recent accomplishments, current challenges, and future priorities and needs. Identified needs include additional and flexible grant funding, tools and training to address mis- and disinformation, support for data collection and sharing, and expanded vaccine access through development of language translation services and other community advocacy resources.

Several projects funded by NACCHO and CDC reached completion at the end of July 2024. The resources created and lessons learned from these projects will be shared on the NACCHO website and blog. Links to these sites are included in the written report.

NACCHO is currently preparing for fall respiratory virus season by updating relevant resources for local health departments. Additionally, NACCHO will hold a webinar in October 2024 to discuss effective strategies to mitigate the health impacts of respiratory viruses. Registration information for the webinar will be shared through NACCHO communications platforms.

Public Health Agency of Canada (PHAC)

PHAC is working with provinces, territories, and international partners, including WHO, to monitor Mpox both domestically and internationally and will donate up to 200,000 doses of Imvamune for global use. Mpox risk in Canada remains low despite case numbers increasing from 70 in 2023 to 164 in 2024. However, Canada is experiencing the highest number of pertussis cases since 1959, with 12,000 cases reported as of the end of August 2024. Jurisdictions have therefore increased pertussis immunization opportunities and outreach.

For the 2024–2025 respiratory virus season, the Canadian government plans to launch communications that aim to increase confidence in and uptake of seasonal influenza, COVID-19, and RSV vaccines. PHAC will host a webinar for health care providers to give an overview of the National Advisory Committee on Immunization (NACI) recommendations related to the upcoming respiratory virus season as well as a description of the current vaccine landscape in Canada.

For RSV vaccines, NACI recommends building toward a universal program that allows all infants to receive nirsevimab. Plans for infant RSV programs across Canada vary by jurisdiction. Some provinces

and territories will offer universal programs, while others will focus on high-risk programs this year and plan to implement the full program in the future. Regarding adult RSV immunizations, NACI recommends vaccinations for adults aged 75 and over at risk for severe disease and adults aged 60 and over who are residents of nursing homes or other chronic care facilities. Five provinces will have publicly funded programs for fall 2024, whereas other jurisdictions will offer RSV solely to adults aged 60 and older living in retirement homes and other long-term care facilities.

Vaccines and Related Biological Products Advisory Committee (VRBPAC)

VRBPAC held a meeting in June 2024 following the previous NVAC meeting. The committee strongly endorsed using the monovalent JN.1 lineage vaccine for the 2024–2025 COVID-19 vaccine formula. The committee emphasized the importance of a strong ACIP recommendation for COVID-19 vaccines to prevent severe disease caused by emerging variants and the need for immunization with the most up-to-date vaccines, especially in unvaccinated individuals. The committee also identified the need for safety data presentations about updated COVID-19 vaccines, called for a clinically meaningful correlate of protection threshold, and requested consideration of the three-step antigen update iteration more than once a year.

America's Health Insurance Plans (AHIP)

AHIP and several partners recently launched "Promoting Health Through Prevention," a coordinated campaign that promotes the availability and uptake of no-cost preventative services recommended under the Affordable Care Act, such as vaccines. In June 2024, participating organizations issued reminders to their audiences about recommended preventative services as well as how to access them through the Office of Disease Prevention and Health Promotion's "My Health Finder" tool. This tool allows users to query service recommendations based on age and gender and leverages community health center data to help users identify proximal public health sites. The second phase of the initiative will provide additional messaging regarding preparation for the upcoming open enrollment period. Organizations interested in participating in this campaign can direct inquiries to cregal@ahip.org.

Agency for Healthcare Research and Quality (AHRQ)

AHRQ is funding an ongoing influential trial to develop and evaluate an in-patient vaccination program to improve influenza vaccination rates among hospitalized children. Questions about this study should be directed to the principal investigator or the designated AHRQ point of contact. Additionally, USPSTF is working to update cervical cancer screening recommendations for women aged 21–65. The task force is awaiting results of in-progress studies that will inform these recommendations and plans to have a draft document ready for public comment by early 2025.

Biomedical Advanced Research and Development Authority (BARDA)

BARDA is working with Merck to provide more than 1 million doses of ERVEBO®, a single-dose Ebola vaccine, that were manufactured and delivered to the U.S. government. BARDA is also coordinating with WHO, Gavi, and the United Nations Children's Fund to address the global supply of Ebola vaccines.

The United States is in the process of rebuilding its supply of preventative smallpox vaccine JYNNEOS, which also possesses a label indication for Mpox and is now commercially available.

BARDA is supporting Moderna's Zika virus vaccine development and manufacturing platform through clinical development toward licensure. Following dose selection based on Phase I clinical trial results, Moderna completed a Phase II study to assess the mRNA-1893 vaccine in adult participants living in

endemic and nonendemic flavivirus areas. A clinical study report synthesizing these results was submitted in June 2024 to FDA, which has since granted fast-track status to this vaccine candidate. Moderna recently announced that the Zika program will not advance into studies beyond Phase II because of the absence of funding.

BARDA is preparing for potential public health interventions against influenza virus strain H5N1. Although risk to human health is low, and vaccination is not recommended for any segment of the population at this time, BARDA is continuing preparedness activities under the National Pre-Pandemic Influence of Vaccine Stockpile should vaccine recommendations change. As part of these efforts, BARDA is filling approximately 4.8 million doses of previously manufactured bulk vaccine, which equates to 2.4 million courses because this is a two-dose vaccine. BARDA is also sponsoring a Phase II randomized double-blind clinical trial to assess safety and immunogenicity of Santa Fe's H5-inactivated monovalent influenza vaccines at different antigen dose levels adjuvanted with AS03 or MF59. Enrollment for this trial began in August 2024. BARDA also continues to support approved recombinant cell- and egg-based influenza vaccines as well as development of vaccine platforms such as mRNA that may further accelerate responses to influenza. Under the Rapid Response Partnership Vehicle, BARDA has awarded Moderna a transaction agreement to rapidly develop and license mRNA-based pandemic influenza vaccines. Moderna will assess the capabilities of an mRNA seasonal influenza vaccine candidate in late-stage development to function as a pandemic vaccine. This project will focus on Phase III clinical trials to collect data supporting regulatory approval and to establish mechanisms for rapid response to an influenza public health emergency.

Centers for Medicare & Medicaid Services (CMS)

CMS is emphasizing back-to-school and seasonal messaging that communicates the importance of vaccinations. CDC has spoken on a Medicaid all-state call and will do so again in late September 2024 to provide information about seasonal vaccines. CDC and Office of Assistant Secretary for Health representatives also attended a CMS staff meeting to discuss the importance of immunizations and ongoing National Immunization Awareness Month efforts. CMS continues to seek ways to optimize and expand consistent messaging about the importance of vaccines.

On September 12, 2024, CMS released an issue of the Medicaid Learning Network Connects® Newsletter that provides coding and pricing information about the 2024–2025 COVID-19 vaccine. This newsletter was distributed to NVAC committee members and can also be obtained from Ms. Aikin. Any questions related to this newsletter should be directed to CMS personnel.

Department of Defense (DOD)

For its 2024–2025 Northern Hemisphere influenza vaccine campaign, DOD has purchase more than 3 million doses to cover service members and their beneficiaries working in the military health system. DOD requires uniformed personnel and health care professionals working in these facilities to receive an annual influenza vaccine.

DOD is engaged in interagency meetings with HHS partners to synchronize a messaging strategy across federal organizations for this year's respiratory virus vaccine campaign. DOD also continues to work with CDC to enhance biosurveillance and immunization data sharing efforts among federal partners. In May 2023, DOD joined CDC and the Veterans Health Administration to launch the Immunization Gateway Project with the goal of connecting DOD electronic medical records with IISs in Washington state, the project pilot site. In 2024, DOD expanded engagement to add IISs in eight additional states. Engagement with this project enhances the completeness of vaccine records for service members and their dependents. All immunizations documented in the DOD electronic medical record will be prospectively sent to state

IISs, and health care providers can query their respective state registries for beneficiaries, including service members.

Food and Drug Administration (FDA)

Since the COVID-19 vaccine strain selection, FDA has been working to approve and authorize all COVID-19 vaccines to prepare for their distribution and use. In August 2024, FDA approved and authorized the Pfizer and Moderna mRNA vaccines and the Novavax vaccine. FDA has also updated the vaccination schedule for Bexsero, the GlaxoSmithKline (GSK) meningitis B vaccine, to 6 months.

A VRBPAC meeting in September 2024 will discuss how to regulate formulations of next-generation pertussis vaccines that demonstrate efficacies and safety profiles like cellular pertussis vaccines. Meeting participants will also assess the possibility of using controlled human infection models as a potential approach for vaccine evaluation.

Health Resources and Services Administration (HRSA)

In July 2024, the Advisory Commission on Childhood Vaccines (ACCV) conducted two meetings that received updates from the Division of Injury Compensation program and a briefing from the National Academies of Science, Engineering, and Medicine (NASEM) committee on its recent report, *Evidence Review of the Adverse Events of COVID-19 Vaccination and Intramuscular Vaccine Administration*. AACV members discussed findings from the NASEM report and passed three motions that

- established a working group to amend the vaccine injury table, qualifications, and aids to interpretation to address conclusions and information provided by NASEM on shoulder injuries;
- added an agenda item to the next ACCV meeting with input from HRSA and HHS about potential research areas of interest regarding shoulder injuries; and
- added an agenda item to the next ACCV meeting to hear an overview of Vaccine Safe from CDC.

ACCV has several vacancies and is currently seeking nominations. Individuals interested in participating can access more information on the AACV webpage at HRSA.gov.

In August 2024, the Bureau of Primary Healthcare released 2023 Uniform System Data, which captures immunization rates for children aged 2 years and younger based on the CDC-10 series. The Bureau is also collaborating with CDC to communicate the various tools and resources being developed to promote immunization efforts.

The National Vaccine Injury Compensation Program (VCIP) is a no-fault alternative to the traditional legal system for resolving vaccine injury petitions. VCIP aims to stabilize vaccine supply and protect the nation's public health by expeditiously processing claims. Between October 2022 and August 2024, VCIP reduced the number of claims activated by the U.S. Court of Federal Claims and awaiting medical review from 1,100 to 74. Over this time, wait times for HRSA medical review decreased from more than 12 months to fewer than 30 days. In FY 2024, VCIP received 971 petitions and adjudicated more than 1,100 claims, ultimately awarding more than $133 million to petitioners and more than $40 million for attorney fees and costs. Additional VCIP data can be found on the Vaccine Injury Compensation Data webpage.

As of August 2024, more than 13,000 claims have been filed with the Countermeasures Injury Compensation Program (CICP) alleging cases of injury or death from COVID-19 countermeasures. CICP has made decisions on more than 3,000 of these claims. Although CICP continues to make progress reviewing and providing payment for compensable cases, additional resources are required to aid this process. More information about CICP is available on the HRSA.gov website.

Indian Health Service (IHS)

IHS remains committed to immunization as its foremost clinical and public health prevention priority and continues to promote efforts that improve vaccination rates in American Indian and Alaskan Native (AI/AN) populations. Through the IHS National E3 Vaccine Strategy, IHS offers patients all appropriate ACIP-recommended vaccines at each patient encounter, regardless of age. As part of this strategy, IHS also implemented the E3 Vaccine Pilot Program, which has established 28 designated Vaccine Champion pilot sites in nine IHS service areas. These pilot sites have shared best practices about information, technology, and community engagement within clinical settings and pharmacies, such as identifying vaccine ambassadors to organize vaccine clinics in communities, villages, and other remote locations and assessing clinical practice processes to maximize the ability to offer vaccines.

To promote a seamless implementation of ACIP recommendations in Indian Country during respiratory virus season, IHS is involved in a series of activities and engagements. IHS's 2024–2025 Viral Vaccine Campaign is focused on ensuring that providers have access to information about vaccine recommendations, establishing informatics infrastructure for implementation, and bolstering partnerships with state immunization programs to improve AI/AN population access to recommended vaccines. IHS is collaborating with CDC and the Administration for Children and Families (ACF) on an initiative to protect AI/AN infants from RSV by developing a toolkit that compiles communication material and information resources about recommended RSV prevention methods. IHS, CDC, and ACF are also hosting a webinar series to increase the awareness and knowledge of tribal communities, home visitors, and programs regarding new immunization products for pregnant people, infants, and AI/AN children. The webinar will provide vaccine champions, providers, and families with the opportunity to learn how to use the RSV toolkit. Finally, IHS is partnering with CDC and state immunization programs to facilitate and ensure access to nirsevimab vaccines for AI/AN infants.

Through the IHS Immunization Program, IHS is working with regional immunization coordinators to increase AI/AN adult uptake of the pneumococcal vaccine (PCV). Pneumococcal disease burden is 2–4 times higher in AI/AN adults than the general population, and this burden is further complicated by the recent surge in invasive pneumococcal disease resulting from serotype 4 infections in IHS regions such as Alaska and the Southwest. In April 2024, the IHS Chief Medical Officer issued a call to action to administer PCV 20 to all AI/AN adults not only in anticipation of ACIP recommendations for PCV 21, which has no coverage for serotype 4, but also in recognition of the unique needs of tribal communities for both PCV 20, which does have coverage for serotype 4.

National Institutes of Health (NIH)

The National Institute of Allergy and Infectious Diseases (NIAID) is funding a Phase I clinical trial, which is the first to be conducted as part of HHS's Project NextGen. The trial will explore the safety of an experimental nasal vaccine that may provide enhanced protection against emerging COVID-19-causing viral variants. This investigational vaccine has been designed and tested preclinically by NIAID scientists. The Phase I trial aims to enroll 60 adult participants that have previously received at least three doses of an FDA-approved or authorized mRNA COVID vaccine. Scientists conducting the study will assess both vaccine candidate tolerance and its potential to elicit immune response in participant noses and blood.

Two other NIH-funded trials are being co-led by investigators from both NIAID and University of Sciences, Techniques, and Technologies of Bamako, Mali. These studies have demonstrated the safety and efficacy of a radiation-attenuated malaria vaccine in Malian adults. In one trial, which enrolled 300 healthy women aged 18–38 who anticipated becoming pregnant soon after immunization, the vaccine candidate conferred a significant degree of protection from infection and clinical malaria. This protection was sustained over the span of 2 years without the need for a booster dose. Exploratory analyses of

women who conceived during this study showed that the vaccine candidate significantly protected them against malaria during pregnancy.

U.S. Agency for International Development (USAID)

USAID has partnered with Pfizer to distribute 568 million Pfizer vaccines, an endeavor that is close to completion. USAID is also involved in global efforts to eradicate polio by providing vaccinations and monitoring new cases, including those in Gaza. USAID continues to work to strengthen international health systems, with specific foci on 30 countries. USAID provided additional updates in their submitted written report.

Department of Veterans Affairs (VA)

VA continues to be involved in the exchange of vaccine data through the IIS Immunization Gateway, maintaining established relationships with more than 47 states and jurisdictions, reporting more than 6.5 million vaccinations to these partners, and receiving more than 14 million records in return. In partnership with DOD, VA has initiated bidirectional data exchange in nine states and jurisdictions with four or five more to be added this winter.

VA offers influenza, RSV, and COVID-19 vaccines and has updated its clinical guidance for these immunizations according to ACIP and CDC guidelines. VA also has continued a partnership with more than 65,000 community agencies in the United States to provide no-cost vaccines and other care to enrolled veterans, which has expanded access to multiple vaccines such as influenza, COVID-19, RSV, and PCV. To further increase vaccination uptake, VA updated its national clinical reminders for influenza and hepatitis A and has been actively promoting CDC's "Wild to Mild" and HHS's "Risk Less. Do More." campaigns.

Centers for Disease Control and Prevention (CDC)

CDC provided a written report and did not give a verbal presentation during the meeting.

Future Forward Insights: RSV Immunization Across the Lifespan—Evelyn Twentyman, M.D., M.P.H.

RSV is a prominent health threat throughout the human lifespan. RSV not only is the leading cause of infant hospitalization in the United States but also globally infects more than 64 million people, causing more than 160,000 deaths across all ages each year. However, data show that RSV vaccination rates are much lower than those for influenza or SARS-CoV-2, indicating that many individuals are not receiving the health benefits of RSV immunization, especially those at higher risk for negative outcomes, such as older adults.

To improve RSV vaccination uptake, CDC has revised its guidance for children and older adults. According to ACIP recommendations, pregnant people may receive the RSV vaccine at 32–36 weeks gestation if they have not received this immunization during a previous pregnancy. CDC recommends that all infants under age 8 months and children aged 8–19 months with risk factors receive nirsevimab unless a birthing parent RSV vaccine was administered. CDC also recommends that adults over age 75 and adults aged 60–74 with identified risk factors should receive the RSV vaccine. Older adults may self-attest to having these conditions and do not need to provide documented proof to be eligible to receive the RSV vaccine. Adults aged 18–59 who are not pregnant are not currently recommended to receive RSV immunization.

Many health insurance entities cover RSV immunizations. Most private insurance companies are required to cover RSV vaccines without charging a copayment or coinsurance when given by an in-network provider, and both Medicare and Medicaid cover ACIP-recommended vaccines without cost-sharing. Importantly, patients who receive the RSV vaccine through Medicare Advantage or Part D must receive this immunization at an in-network provider or pharmacy. More information about State Medicaid vaccine coverage may be found in the Vaccine Toolkit released by CMS in February 2024, which also includes information about CHIP and Basic Health Program coverage. The VFC program also provides free vaccines to eligible children. VFC encompasses nirsevimab administration for Medicaid-eligible, Medicaid-enrolled, underinsured, or uninsured as well as AI/AN children.

CDC is working to improve vaccine access and thus RSV vaccination uptake by expanding birthing hospital enrollment in VFC, which enables timely immunization of infants for RSV. By working with jurisdictional immunization awardees and other partners, CDC identifies birthing hospitals and other facilities with the highest percentage of Medicaid births and encourages them to enroll in VFC. CDC also aims to reduce barriers to VFC enrollment by allowing birthing hospitals to enroll virtually as specialty providers, if approved by their respective jurisdictions. These efforts have proven effective; between July 2023 and May 2024, VFC enrollment of birthing hospitals increased by 24%. Furthermore, this work helps prioritize communities with low vaccine access.

In addition to improving RSV vaccine access for children, CDC is working to support health care providers in immunizing adult patients. Because ordering and offering immunizations in clinics is one of the most effective ways to improve vaccine confidence and increase immunization rates, CDC has launched a new tool to facilitate ordering immunizations. This resource provides estimated launch dates, links to pre-ordering and early reservation programs, details on the product type, and return policies for unused products. Additionally, CDC remains engaged in outreach to health care providers by hosting events and calls to help them prepare for respiratory virus season and protect their patients through vaccination. Finally, CDC has been involved with the successful HHS "Risk Less. Do More." public education campaign, which focuses on increasing vaccine awareness, confidence, and uptake for vaccines that reduce severe illness from influenza, COVID-19, and RSV in at-risk populations.

Discussion

Increasing Birthing Hospital VFC Enrollment

Dr. Hopkins expressed surprise at the low number of birthing hospitals enrolled in VFC and inquired about ongoing efforts to increase enrollment. Dr. Twentyman detailed the current two-fold approach, which focuses on increasing active outreach and reducing barriers to enrollment. To increase outreach, CDC is working with P4VE partners to prioritize engagement with birthing hospitals across all 64 immunization jurisdictions in the United States. These efforts aim to engage more providers, especially nontraditional providers such as rural pharmacies, to ensure RSV vaccine access in locations with low uptake. To reduce barriers to enrollment, CDC is allowing birthing hospitals to enroll in VFC as specialty providers, which would permit these facilities to only provide certain vaccines such as RSV if granted exemptions from jurisdictional immunization programs that would otherwise require the full vaccine complement for children to be offered. Jurisdictional partners have informing birthing hospitals of their ability to enroll in VFC as specialty providers. In addition, CDC has developed virtual methods for both VFC enrollment and vaccine inventory. If birthing hospitals enroll in the VFC program as specialty providers, they may do so virtually without the need for site or CDC visits. Virtual vaccine inventory will reduce logistical barriers introduced by previous practices that required the maintenance of separate refrigerators for VFC vs. non-VFC vaccines.

Mr. Rothholz asked whether virtual enrollment could also be used for non-birthing hospital VFC providers. Dr. Twentyman responded that virtual enrollment most likely cannot be used for these providers at this time because only specialty providers can enroll virtually, but she will follow up with Mr. Rothholz after speaking to VFC leads to confirm.

Cost Equity of RSV Vaccine Access

Dr. Geeta Swamy highlighted existing challenges regarding the vaccine care bundle and billing. She noted that providers cannot bill for administering individual vaccines, but different facilities face different patient needs, even within the same health system. For example, one hospital may treat patients who are mostly covered by Medicaid or are uninsured, while another hospital may treat a patient population with completely different coverages. She stated that such circumstances can be challenging for providers and create equity issues, because decisions are often made by assessing individual costs at each specific location. Dr. Twentyman recognized the difficulty for providers and patients in these situations and confirmed that CDC is actively working to address these equity challenges through its ongoing partnership with CMS through the CDC-CMS Public Healthcare Payment Integration Team. Dr. Twentyman also noted that confidence in reimbursement facilitates uptake; if providers are confident that they will be reimbursed for administering a vaccine, they are more likely to complete the entire vaccine process, that is, ordering, advising, and administering the vaccine.

Dr. Stephen Rinderknecht acknowledged that many non-VFC providers were able to administer hepatitis B vaccines as part of the Section 317 Immunization Program. Dr. Rinderknecht wondered whether this approach would be possible for RSV vaccines but supposed that cost differences between the two vaccines would negatively impact feasibility. Dr. Twentyman stated that immunization jurisdictions have discretion over which vaccines can be purchased with Section 317 funds. She noted that, while doing so for RSV vaccines would not be impossible, the concern about RSV immunization cost would remain. Dr. Twentyman suggested that enrolling in VFC might be a way for birthing hospitals to provide nirsevimab more easily and with a broader base of financial support and surmised that facilities providing hepatitis B vaccines through Section 317 are likely VFC-eligible. She offered to connect providers mentioned by Dr. Rinderknecht with their jurisdictional counterparts to facilitate VFC enrollment.

Payer Knowledge of Self-Attestation for Underlying Conditions

Mr. Rothholtz asked whether the use of patient self-attestation for underlying conditions that make them eligible for RSV vaccine coverage has been communicated to payers to avoid audits of providers. Dr. Twentyman affirmed that patient self-attestation is being thoroughly communicated to different entities including payers to help reduce barriers to RSV vaccine access. Dr. Twentyman pointed to COVID-19 as a valuable example of the effectiveness of self-attestation for increasing patient access to vaccines. During the COVID-19 pandemic, payers were not initially contacted in this process due to the U.S. government acting as the sole purchaser and distributor of COVID-19 vaccines. However, once vaccine distribution expanded, payers were made aware of self-attestation policies regarding vaccine coverage, and the same procedure is occurring with RSV vaccine–related patient self-attestation.

Science Review: New Research to Inform Future HIV Vaccine Development

Status of HIV Vaccine Research for HIV Prevention—James G. Kublin, M.D, M.P.H.

HIV remains a significant global public health issue. According to WHO, 39.9 million people were estimated to be living with HIV at the end of 2022, 65% of whom were in the WHO African Region. In 2023, more than 630,000 people died from HIV-related causes, and 1.3 million were estimated to have acquired HIV in that year alone. Although the total number of HIV infections has decreased, the number

of existing HIV cases exceeds the 2023 target set by the Joint United Nations Programme on HIV/AIDS (UNAIDS). HIV also has significant financial impacts on society. The U.S. government investment in domestic response to HIV has increased to more than $28 billion per year, and the global HIV drugs market size is poised to grow from $32.26 billion in 2023 to $44.49 billion by 2031. Average lifetime HIV-related medical costs for people living with HIV in the United States is estimated to be $420,285 discounted or $1,079,999 undiscounted, and these costs far exceed those of any other preventive communicable or non-communicable disease.

Challenges in the development of an HIV vaccine remain, as initially identified by Dan H. Barouch in his 2008 *Nature* review, "Challenges in the development of an HIV-1 vaccine." HIV exhibits extensive viral clade and sequence diversity and can establish multidimensional latent viral reservoirs in early infection as a retrovirus that integrates into the genome of resting cells in many different tissues around the body. Immune correlates of protection remain unclear, and HIV can evade host humoral and cellular immune responses. Antibody responses elicited are type-specific, and no method exists to elicit broadly reactive neutralizing antibodies, even if progress has been made toward this goal in the past decade. No confirmed early small animal models that are directly applicable to humans exist, and pharmaceutical interest in pursuing an HIV vaccine is minimal. Furthermore, HIV envelope protein trimer Env, a neutralizing antibody target of interest, displays significant variability in both amino acid sequence and sugar moiety identity of glycosylated surface regions. Env also exhibits low density on the virion surface, which makes inter-spike crosslinking characteristic of neutralizing antibodies a rare occurrence.

Regardless, many experts uphold the value of HIV vaccine development and believe this goal can be achieved. According to modeling studies, HIV vaccines, even those that are only partially efficacious, would dramatically reduce the number of new HIV infections in a cost-effective manner, especially when combined with pre-exposure prophylaxis (PrEP). Additionally, HIV vaccine research and development efforts benefited COVID-19 vaccine production during the pandemic, and researchers believe that these resources can be leveraged to realize the goal of developing an effective HIV vaccine.

Recent progress toward achieving HIV vaccine development is due in part to the HIV Vaccine Trials Network (HVTN), the world's largest publicly funded clinical trials program dedicated to finding effective HIV and TB vaccines. The goal of HVTN is to fully characterize the safety, immunogenicity, and efficacy of HIV vaccine candidates as rapidly as possible for global prevention of HIV infection. HVTN prioritizes global collaborations that span a variety of disciplines including sociobehavioral science, vaccinology, and immunology, and is funded largely by the Division of AIDS within NIAID with specific projects funded by the Bill and Melinda Gates Foundation, South African Medical Research Council, and Janssen Vaccines and Prevention. The Discovery Medicine Program is a series of studies within HVTN that aim to assess the ability of candidate immunogens to induce germline binding. The program aims to design a vaccine that can induce two or three epitope-specific lineages with high breadth for Env. Five Env epitope sites have been identified as targets for HIV immunization and are being investigated for their potential to induce immune response production of broadly neutralizing antibodies (bnAbs). BnAbs are naturally produced antibodies triggered by both infections and vaccinations to defend against a pathogen that is very diverse. Induction of HIV bnAb production occurs almost 2 years after initial viremia in individuals that have acquired HIV and only in a minority of these individuals. Although there are currently no active HIV vaccine efficacy trials, ongoing efforts are focused on developing active HIV vaccination strategies that can elicit bnAb production.

Stepping Toward an HIV Vaccine with Germline-targeting Vaccine Design—William R. Schief, Ph.D.

HIV vaccine development remains a relevant scientific priority. According to the 2024 UNAIDS Fact Sheet, about 9 million of the 40 million people living with HIV are not receiving ART, which puts them

at risk of HIV-related health impacts and transmission to other individuals. Although PrEP can be highly effective and should be maximally deployed, challenges to access and feasibility of long-term use persist. Despite these ongoing challenges, global funding for AIDS response is less than what is needed and continues to decrease.

HIV vaccine development candidate Env is a potential target of neutralizing antibodies. However, its protein structure, glycosylation profile, and amino acid sequence variation pose major challenges to the binding and thus neutralizing potential of bnAbs being developed to target this protein. Many ongoing efforts to develop HIV bnAbs that neutralize diverse isolates have demonstrated the potential of these antibodies to protect against HIV infection in both humans and non-human primates (NHPs). Different classes of existing HIV bnAbs bind to different epitopes on HIV Env, including PCT64/PG9, which binds the V2 apex; VRC01, which targets the CD4 binding site; BG8+PGT130, which binds the V3 glycan; and 10E8, which binds to the membrane-proximal external region (MPER). An effective HIV vaccine will likely need to induce multiple bnAb classes to achieve sufficient neutralization potency and breadth to protect against diverse HIV isolates circulating among humans. An HIV vaccine also needs to trigger expansion of human naïve precursor B cells and drive them to maturity through accumulation of B cell receptor somatic hypermutations that permit tight antibody binding to specific Env epitopes. However, bnAb-producing B cells are rare, exhibit a variety of specific genetic features that lead to production of numerous distinct bnAbs, and are difficult to activate with wild type HIV proteins.

To address these challenges, researchers have pursued germline-targeting vaccine design, an approach not yet used in human licensed vaccines but that provides the opportunity to optimize the engineering of B cells throughout their maturation process. The strategy focuses on the development of an immunogen that can find and prime bnAb-producing B cells to create a pool of germinal center (GC) memory B cells. This GC pool can then be triggered with additional immunogens that are closer in structure to native HIV Env, eventually resulting in induction of the desired bnAb profile in a pool of memory B cells. Success for this strategy will likely require a priming immunogen that can target a diverse precursor pool for a particular class of bnAb, ensuring that all vaccine recipients can produce bnAbs upon immunization.

The lead project for this approach is focused on VRC01-class bnAbs, which interact with Env at the CD4 binding site. Although VRC01-class bnAbs bind at this site with specific regions, they otherwise exhibit significant diversity in their heavy and light chains. One immunogen that induces VRC01-class bnAb production is eOD-GT8, a self-assembling nanoparticle presenting 60 copies of an engineered Env outer domain, gp120. eOD-GT8 primes VRC01-class responses in humanized mouse models and induces VRC01-class memory responses that can be boosted toward bnAb development in mice. The eOD-GT8 60mer also induced VRC01-class precursor production in 97% of vaccine recipients in a clinical trial, establishing proof-of-principle for germline-targeting vaccine priming in humans. The one patient who did not exhibit bnAb production lacked the heavy chain alleles required to interact with the CD4 binding site, underscoring the importance of inducing multiple bnAb classes for optimal HIV vaccine efficacy.

Two additional clinical trials have been performed with corresponding manuscripts awaiting publication. The first assesses heterologous boosting of bnAbs in humans and demonstrates that different immunogens can advance desired maturation of B cells. The second describes testing of priming in Rwanda and South Africa, which helps establish these research milestones in Africa where a vaccine is needed the most. Future work will investigate bnAb induction in humans for one class as well as multiple classes in parallel. Utilization of mRNA to accelerate HIV vaccine development is also being explored in partnership with Moderna.

Informing Vaccine Design by Defining the Rules of Antibody Responses—Facundo D. Batista, Ph.D.

Effective HIV vaccines should induce priming and boosting steps to shepherd B cell differentiation to produce bnAbs with high affinity for Env epitopes. Classical responses to vaccines involve short GC cycles in which B cells typically accumulate only three or four mutations. However, generation of B cells that produce bnAbs requires anywhere from 12–25 mutations, which cannot be achieved with a single round of vaccination.

Previous work has shown that the eOD-GT8 60mer can trigger the correct B cell precursors in humanized mouse models, in which antibody binding sites in mice are replaced by human B cell receptors. These humanized mouse models enable recreation of the rare human naïve B cell precursors, large-scale immunogen testing, and the ability to follow both early and late GCs after priming and boosting events. Produced antibodies can then be probed to determine mutation count and diversification, observe binding site details through structures obtained via cryo-electron microscopy, and evaluate the binding affinity changes occurring throughout antibody maturation.

Humanized mouse model development has enabled extensive preclinical validation of multiple immunogens to induce bnAbs similar to the V3-glycan–targeting bnAb BG18. Xie et al. (2024) revealed N332-GT5 as a good candidate immunogen for priming BG18 precursors and showed that B cell responses elicited by this immunogen can be boosted either through mRNA or protein delivery. This study identified B16 and B11 as potential boosting candidates and showed that mRNA and membrane configuration immunogens have superior priming and boosting capabilities to those of proteins. Wang et al. (2024) demonstrated that GT8-60mer protein immunization elicits robust epitope-specific, high-affinity antibodies that can prime and guide precursor B cell lineages to produce VRCO1-like bnAbs, with GT8-60mer mRNA and eOD-GT8 proteins eliciting similar responses. Finally, Ray et al. (2024) showed that germline-targeting immunogens could induce MPER-targeting antibodies and that B cell residency in GCs may be regulated by a precursor-competitor affinity gap. Undesired competitor cells initially play a role in GC residency, but immunogens that have higher affinities for desired B cells can guide them to and keep them in GCs for prolonged periods so that they may accumulate desired somatic mutations. Although substantial progress has been made on priming and boosting to guide B cells toward maturation, more HIV vaccine development work is needed to finish characterizing bnAbs in the late stages of immune response.

Vaccine Priming of Rare HIV Broadly Neutralizing Antibody Precursors—Jon M. Steichen, Ph.D.

BG18 is a V3-glycan epitope binding bnAb that neutralizes 63% of global HIV isolates through contact of the HCDR3 loop with Env via a class-defining amino acid sequence motif. Although BG18 precursor antibodies are present in most humans, these precursors occur at low frequency, in part because of HCDR3 dependence. Because HCDR3-dependent antibodies represent a canonical antibody binding mode, an effective strategy to generate HCDR3-dependent bnAbs could be leveraged to develop vaccines against not only HIV but also other relevant pathogens.

Steichen and colleagues (2024) developed the priming immunogen N332-GT5 using a validated immunogen design strategy for HCDR3-dependent germline targeting in rhesus macaques. BG18 germline targeting has been challenging in NHP models because BG18 class antibody frequencies are eight-fold lower than in humans. Nevertheless, rhesus macaques have antibody genes that are similar enough to humans and represent a realistic, if challenging, animal model for vaccine development studies. Eight rhesus macaques were given an exponentially increasing dose of immunogen N332-GT5 over 2 weeks as well as a boost at Week 10, with saponin/monophosphoryl lipid A nanoparticles (SMNP) given

as an adjuvant. BG18 B cells were found in the lymph nodes or blood in the eight animals, indicating that BG18 response priming occurred in all tested NHPs. Structural determination of three NHP BG18-class antibodies in complex with the immunogen demonstrated HCDR3 loop binding characteristics comparable to BG18 itself, confirming the existence of an effective BG18 antibody class. BG18 antibody antigen binding affinity increased by four orders of magnitude from Week 3 to Week 10 post-immunization, and BG18 antibody somatic hypermutation levels increased to 7%.

Although the HIV vaccine assessed in this study also boosted production of other antibodies without the capacity to become bnAbs, these off-target antibodies did not bind to boost candidates. Thus, the tested boosting candidates deflected off-target antibodies. Future studies will focus on developing a sequential boosting regiment to elicit BG18-class bnAbs in NHPs and evaluating vaccine priming of BG18-class antibodies in humans. Vaccine priming in humans is currently in progress as part of the HVTN 144 clinical trial, which is testing administration of N332-GT5 + SMNP as a fractionated escalating dose and as a bolus.

Rational Design of Epitope-Scaffolds That Induce Broadly Neutralizing Antibody Precursors to HIV gp41—Torben Schiffner, D.Phil.

MPER is a highly conserved region of HIV Env that is not part of most soluble native-like trimers. Because of the conservation of this region, MPER-binding bnAb 10E8 can bind greater than 98% of global HIV isolates with good potency, engaging the target epitope using a binding motif found within an HCDR3 loop. However, the 10E8-binding epitope is occluded in the Env trimer context. To overcome this challenge, Dr. Schiffner and colleagues employed epitope scaffolding, which involves removing an epitope from its native environment and stabilizing it with a scaffold protein to maintain the antibody-bound confirmation. Combining epitope scaffolding with germline targeting mutations enables engagement of diverse precursors.

To test this epitope-scaffolding germline-targeting approach, B cells isolated from humans were sorted to obtain a pool that demonstrated immunogen binding, and antibodies were sequenced and assessed for 10E8-like characteristics. Results from these experiments showed an enrichment for bound 10E8 motif-containing antibodies as well as centralization of HCDR3 amino acid lengths around those of 10E8, indicating that 10E8-GT scaffolds isolate 10E8-class human naïve precursor B cells. Additional studies in stringent mouse models and NHPs demonstrated activation of 10E8-class HCDR3 responses in response to immunization with 10E8-GT scaffolds. Mice immunized with immunogen candidates GT10 and GT12 showed the same HCDR3 length patterns as 10E8 and demonstrated an enrichment of 10E8-like B cells. Together, these data show that B cells can be primed using epitope-scaffold germline-targeted nanoparticles.

Boosting is required for B cell precursors to fully mature into bnAbs. Two boosting candidates have shown promise in animal models. Mice immunized with a priming candidate as well as boosting candidate 10E8-B1.1 demonstrated an enrichment of 10E8-class B cells. In a pilot study in which NHPs were immunized with priming immunogen 10E8-GT12 24mer and then boosted with 10E8-B1 24mer, 10E8-class B cells were observed in all immunized animals, and these cells demonstrated an increased affinity for 10E8 immunogens. Future studies will continue to work on boosting primed B cells toward bnAb maturation.

Discussion

Dr. Daniel Hoft inquired about the potential for high titer induction of bnAbs in humans to create selective pressure for targeted epitope sites that escape antibody binding and neutralization. Dr. Batista responded that the goal is to develop a vaccine that can target multiple epitopes to ensure redundancy and

reduce the opportunity for viral evasion. Dr. Batista likened this approach to treatments of people living with HIV in which three monoclonal antibody regimens are administered simultaneously. Dr. Batista also described data from an ongoing study being prepared for publication that show concurrent priming of different HIV bnAb classes in mice, which supports the possibility of incorporating multiple immunogen classes in the same vaccine to maximize efficacy. Dr. Kublin voiced his agreement with Dr. Batista and noted that much of the monoclonal antibody work, including antibody-mediated prevention studies, have revealed information about target bnAb in vivo levels and the critical thresholds needed to develop effective combined bnAb approaches.

Dr. Hoft also asked whether CD8 T-cells could be pursued as an additional strategy. Dr. Batista noted the increasing popularity of that approach and remarked that it would be ideal to use a combined approach that involves both bnAbs and T- and natural killer cells. Dr. Kublin added that HVTN has nearly completed HVTN 142, a study focused on evaluating the safety and immunogenicity of the cytomegalovirus vector, which can solicit specific MHC-E-restricted presumptive responses from CD8 T-cells. The goal of the study is to help inform an approach that combines the cytomegalovirus vector with the bnAb-inducing antigens discussed in this session.

National Strategy Charge Working Session Continued—Ann Aikin, Acting Designated Federal Officer, NVAC

During the Day 2 working session on the National Strategy Charge, the committee discussed potential language refinements and prioritized three objectives within each of the goals that they believe would make the greatest impact on the U.S. immunization system in the next 5 years. Comments about the strategy or inquiries regarding participation in a listening session can be directed to syndemics@hhs.gov.

Goal 1: Foster innovation in vaccine development

Prioritization of Goals

On Day 1, several committee members suggested prioritizing safety above all else (written as Goal 2 at the time of the meeting). Although Dr. Hoft agreed with moving safety to Goal 1, he expressed his desire to maintain innovation as Goal 2 and expand its breadth, potentially by stating it as "Foster innovation in vaccine development, implementation, and equitable uptake." If this goal is changed to include this suggested language, Dr. Hoft recommended the addition of a third objective relating to equitable uptake.

Ms. Aikin considered incorporating funding to achieve this goal. Dr. Hopkins noted that "foster" is a broad word and could have intellectual and financial meanings, depending on the level of granularity with which the committee wishes to define terms. Dr. Rothholz supported the idea of facilitating resources to support technology development.

Objective 1.1: Support the development of innovative, safe, and effective vaccines to prevent infectious disease of public health significance

Dr. Howell wondered whether this objective should exclude the word "infectious" or incorporate other language to capture discussions from the previous NVAC meeting about cancer vaccines. Dr. Hopkins voiced his inclination to have separate objectives discussing vaccinations against infectious vs. other diseases because they have different implications. Dr. Hopkins also noted that development of monoclonal antibodies would fall under innovation and should be one part of the larger vaccination model alongside traditional anti-infective vaccine processes and potentially therapeutic vaccines.

Objective 1.2: Support the development and uptake of technologies to improve vaccine manufacturing, storage, distribution, and delivery mechanisms.

Dr. Rothholz suggested adding "usage" after the word "delivery."

Dr. Karin Bok noted the existing gaps in data from special patient populations including birthing parents and immunocompromised individuals and observed that addressing these data needs could be possible under this objective.

Goal 2: Maintain the highest possible levels of vaccine safety

Several committee members voiced their desire to add to or change the word "maintain" and discussed replacement language that more accurately articulates the goal. Dr. Hopkins expressed his appreciation of the current U.S. vaccine safety system and suggested including two verbs to convey not only the strengths of the systems in place but also the importance of continuous quality improvement into the future. Dr. Hoft suggested "maintain and enhance," and Dr. Jewel Mullen suggested "uphold."

Dr. Bok recommended thinking about changing Objectives 2.1 and 2.2 to improve their potential to be measured. Dr. Hopkins noted the aspirational nature of Objective 2.1 but agreed that Objective 2.2 provides the opportunity for measurability. Ms. Aikin noted that the indicators discussed later in the working session offer other ways to measure progress toward Goal 2.

Goal 3: Increase knowledge of and confidence in routinely recommended vaccines

General Discussion

Dr. Coyle suggested incorporating language, either within existing objectives or as a new objective, about soliciting public feedback to recognize the importance of bidirectional communication.

Objective 3.3: Ensure key decision- and policymakers receive accurate and timely information on vaccines and strategies to promote vaccine uptake

Dr. Hopkins proposed different language: "Communicate the value, efficacy, and safety of vaccines in order to increased confidence in vaccination to benefit our society." Dr. Stephen Rinderknecht suggested changing "increase knowledge" to "improve knowledge of and increase confidence in routinely recommended vaccines" to emphasize both increasing the knowledge base and the vaccine confidence of the public.

Objective 3.4: Reduce disparities and inequities in vaccine confidence and acceptance

Dr. Mullen considered modifying this objective so that it provides a concrete goal to reducing structural factors responsible for disparities and inequities in vaccine confidence and acceptance. Dr. Hopkins highlighted the potential measurability of confidence and acceptance in Objective 3.2 and suggested considering data-driven assessments of structural barriers and inequities, as well.

Dr. Rothholz suggested combining this objective with Objective 3.1 if the number of objectives under Goal 3 needs to be reduced. Dr. Mullen voiced concern that doing so might dilute both of their meanings. Ms. Aikin noted that each goal can have more than three objectives and reiterated that the committee was tasked to prioritize the top three objectives rather than consolidate to three.

Goal 4: Increase access to and use of all routinely recommended vaccines

Objective 4.3: Strengthen data infrastructure, including Immunization Information Systems, to track vaccine coverage in the United States and conduct surveillance of vaccine-preventable diseases

Dr. Coyle noted that this objective should include language emphasizing the importance of provider and patient data access so that both parties can make more informed decisions. Dr. Rothholz agreed with Dr. Coyle and recommended the addition of "increase usage" after "strengthen" to emphasize data usage. Dr. Howell suggested leaving this objective as is but adding language to Goal 3 that mentions provider and public usage of IIS data in a clinical setting.

Objective 4.4: Reduce financial and systems barriers for providers to facilitate delivery of routinely recommended vaccines

Dr. Rothholz advised adding language focused on sustaining community-based providers, especially financially. Dr. Bok recommended combining this objective with Objective 4.5 by using the terms "delivery" and "access" to encapsulate both providers and patients.

Goal 5: Protect the health of the nation by supporting global immunization efforts

General Discussion

Ms. Mandy Paust expressed appreciation for this goal and suggested further defining the word "support" that is written across these objectives. Dr. Howell proposed assessing the effectiveness of vaccine surveillance systems in other countries to bolster global vaccine safety surveillance collaborations.

Objective 5.2: Support global partners in efforts to combat vaccine misinformation, disinformation, and hesitancy worldwide

Ms. Paust recommended changing "hesitancy" to "confidence" and that this term be used moving forward. Ms. Paust also requested that "global partners" include governments of partner countries and not just organizations such as United Nations Children's Fund and WHO. Dr. Hopkins noted the opportunity to measure engagement with other countries, nongovernmental organizations, and the public.

Objective 5.3: Support global partners to strengthen immunization systems

Dr. Mullen recalled previous conversations focused on the meaning of global equity when planning for the Vaccine Innovation Report and highlighted the opportunity to recognize global equity within this goal. To achieve this recognition, Ms. Aikin suggested adding the word "equity" to the end of this objective, which was supported by both Dr. Mullen and Ms. Paust.

Pediatric Indicators

The committee reviewed baseline data as well as the 2025 and 2030 targets for five measurable, data-supported pediatric indicators (with data source):

- Percentage of children aged <6 years whose immunization records are in a fully operational, population-based IIS (IISAR)
- Percentage of children enrolled in kindergarten who received two or more MMR doses (ASAR)
- Percentage of children who received four or more DTaP doses by their second birthday (NIS-Child)

- Percentage of kindergarten population with a nonmedical exemption from school vaccination requirements (ASAR)
- Percentage of adolescents aged 13–17 years who receive recommended human papillomavirus vaccine doses (NIS-Teen)

Dr. Hopkins highlighted the utility of these indicators and the feasibility of data collection, and he expressed interest in using registry data in addition to survey data to inform progress. Dr. Hopkins noted the focus on decreasing rates of adverse health effects and pondered how they might be measured more effectively.

Dr. Coyle recommended adding an indicator that measures the percentage of adolescents whose immunization records are in a fully operational, population-based IIS. Dr. Coyle also clarified that, to have records in IIS, a patient needs to receive a certain number of immunizations: two or more for pediatric and adolescent patients, and one or more in adults. Dr. Hopkins suggested focusing on measures that address the most prevalent gaps in immunization rates, such as MMR for children and human papillomavirus for adolescents.

Public Comment

Mr. Timothy Cestaro, a former service member of the U.S. Navy and father of son with altered immunocompetence, provided a public comment. Mr. Cestaro expressed his gratitude about discussions surrounding vaccine safety, especially regarding Objective 2.1 under Goal 2 of the National Strategy Charge, which reads "Minimize preventable vaccine-related adverse events." Mr. Cestaro believes that health care providers are given too much discretion and are not practicing appropriate caution when providing live virus vaccines to infants, especially those that may have altered immunocompetence such as his youngest son. Mr. Cestaro feels that such situations are unsafe and can lead to erosion of public trust.

Mr. Cestaro briefly outlined his son's medical history and experiences, including recurrent skin and ear infections that he cited as being signs of primary immune deficiency and references information provided by CDC, Mayo Clinic, and Boston Children's Hospital. He recounted that his son was given antibiotics to treat these infections and was administered the MMR vaccine 2 days after finishing a course of amoxicillin. Mr. Cestaro claimed that his son sustained brain damage because he received this live vaccine, which Mr. Cestaro maintained should not have been given based on CDC guidance. Mr. Cestaro stated his belief that doctors are being pressured to vaccinate according to a timeline that provides them with incentives but does not allow for proper assessment or treatment of immunocompromised pediatric patients.

Mr. Cestaro provided a handful of potential solutions he thinks would be helpful to avoid these situations in the future. He recommended training pediatricians to refer patients exhibiting signs of primary immune system deficiencies to immunologists so that CDC-recommended panels can be performed. Mr. Cestaro also suggested spreading out childhood vaccinations to allow for adequate time for identification of children with altered immunocompetence. Mr. Cestaro remarked that improving verbiage surrounding current CDC vaccination guidelines and requirements may remove pressure on health care providers to adhere to a vaccine schedule to receive monetary incentives and instead encouraging them to approach pediatric patients with more caution. Mr. Cestaro thanked the committee members for their time and encouraged them to reach out to him via email to involve him in this process in the future.

Adjourn Meeting

Dr. Hopkins thanked the participants, offered his gratitude for the opportunity to serve as Chair, and adjourned the meeting at 1:10 p.m.

Appendix A: Abbreviations List

ACF	Administration for Children and Families
ACIP	Advisory Committee on Immunization Practices
ACL	Administration of Community Living
AHIP	America's Health Insurance Plans
AHRQ	Agency for Healthcare Research and Quality
AIAN	American Indian and Alaskan Native
AIM	Association of Immunization Managers
AIRA	American Immunization Registry Association
AMR	antimicrobial resistance
APhA	American Pharmacists Association
ASAR	Active Surveillance System for Adverse Reactions
ASTHO	Association of State and Territorial Health Officials
BARDA	Biomedical Advanced Research and Development Authority
BCG	Bacille Calmette-Guérin
bnAbs	broadly neutralizing antibodies
BOP	Federal Bureau of Prisons
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CICP	Countermeasures Injury Compensation Program
CMS	Centers for Medicare & Medicaid Services
CTVD	Collaboration for TB Vaccine Discovery
DOD	Department of Defense
DTaP	diphtheria, tetanus toxoids, and acellular pertussis vaccine
ED	emergency department
EHR	electronic health record
Env	HIV envelope trimer
FAQ	frequently asked question
FDA	Food and Drug Administration
FQHC	Federally Qualified Health Center
FY	fiscal year
GC	germinal center
GT	germline-targeting
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCV	hepatitis C virus
HHS	Department of Health and Human Services
HL7	Health Level Seven
HRSA	Health Resources and Services Administration
HVTN	HIV Vaccine Trials Network
IHS	Indian Health Service
IIS	immunization information system

IISAR	Immunization Information Systems Annual Report
IL	interleukin
IPF	Immunization Partnership Fund
LHD	local health department
LTBI	latent tuberculosis infection
MGLP	methyl glucose lipopolysaccharide
MMR	measles-mumps-rubella vaccine
MPER	membrane-proximal external region
NACCHO	National Association of County and City Health Officials
NACI	National Advisory Committee on Immunization
NHP	nonhuman primate
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NIS	National Immunization Survey
NORC	National Opinion Research Center
NVAC	National Vaccine Advisory Committee
NVSP	National Vaccines Strategic Plan
OIDP	Office of Infectious Disease and HIV/AIDS Policy
P4VE	Partnering for Vaccine Equity
PCV	pneumococcal vaccine
PHAC	Public Health Agency of Canada
PrEP	pre-exposure prophylaxis
RE-AIM	Reach, Effectiveness, Adoption, Implementation, and Maintenance
RSV	respiratory syncytial virus
SAMHSA	Substance Abuse and Mental Health Services Administration
SEAHEC	Southeast Arizona Health Education Center
SMNP	saponin/monophosphoryl lipid A nanoparticles
SOSA	Santa Cruz County Overcoming Substance Addiction
SUD	substance use disorder
TB	tuberculosis
TCR	T-cell receptor
UNAIDS	United Nations Programme on HIV and AIDS
USAID	United States Agency for International Development
USPSTF	U.S. Preventive Services Task Force
VA	Department of Veterans Affairs
VCIP	National Vaccine Injury Compensation Program
VFC	Vaccines For Children
VRBPAC	Vaccines and Related Biological Products Advisory Committee
WHO	World Health Organization