NVAC NATIONAL VACCINE ADVISORY COMMITTEE

# June 15-16, 2023, 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.
Jeffrey Duchin, M.D.
Kristen R. 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.
Robert Schechter, M.D., M.Sc.
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)
Sophia Califano, M.D., M.P.H., Veteran Affairs (VA)
Uzo Chukwuma, M.P.H., Indian Health Service (IHS)
Mary Beth Hance, Centers for Medicare and Medicaid Services (CMS)
Sheena Harris, M.D., Agency for Healthcare Research and Quality (AHRQ)
David Hrncir M.D., Department of Defense (DoD)
Roxanna Diba, M.D., M.S., Health Resources and Services Administration (HRSA)
Jay Slater, M.D., Food and Drug Administration (FDA)
Melinda Wharton, M.D., M.P.H., National Center for Immunization and Respiratory Disease (NCIRD)

**NVAC Liaison Representatives**
Meredith Allen, Dr.PH., M.S., Association of State and Territorial Health Officials (ASTHO)
Courtney Londo, M.A., American Immunization Registry Association (AIRA)
Roxanna Diba, M.D., M.S., Advisory Commission on Childhood Vaccines (ACCV)
Erin Henry, B.S.N., Public Health Agency of Canada (PHAC)
Matt Bobo, M.P.H., National Association of County and City Health Officials (NACCHO)
Jean-Venable "Kelly" Goode, Pharm.D., B.C.P.S., F.A.Ph.A., F.C.C.P., American Pharmacists Association
Aleah Jensen, M.P.H., Association of Immunization Managers (AIM)
Christopher Regal, M.S., America's Health Insurance Plans (AHIP)
Kerry Robinson, Ph.D., Public Health Agency of Canada
Hana El Sahly, M.D., Vaccine and Related Biological Products Advisory Committee (VRBPAC)

**Acting 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 (FACA), its conflict-of-interest rules, and standards of ethical conduct for 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 acknowledged that June is Pride Month, dedicated to the celebration and commemoration of lesbian, gay, bisexual, transgender, queer, intersex, and asexual (LGBTQIA+) communities. ADM Levine continues to work with local leaders and state officials to promote health equity and support immunization efforts within the LGBTQIA+ communities. She thanked Dr. Demetre Daskalakis, the White House National Monkeypox (Mpox) Response Deputy Coordinator, for leading the Administration's strategy and operation to combat the Mpox outbreak. Dr. Daskalakis' collaborative initiatives with HHS, especially within LGBTQIA+ communities, resulted in a significant decline in Mpox cases and a declaration of the end of the Mpox public health emergency in January 2022. The *NVAC report on Advancing Immunization Equity* underscores the significance of vaccine efforts and the need to improve equitable access to tests and treatments, as well as spread health awareness among at-risk individuals.

Achieving equitable health care is hampered by the increased risk for mental health and wellness challenges among public health workers, due to a range of societal, cultural, structural, and organizational factors. Public health workers routinely suffer from excessive workloads, ever-increasing administrative requirements, and a lack of organizational support, which accelerates the mental health and burnout crisis. The Surgeon General of the United States, Dr. Vivek Murthy, issued an advisory that highlights the urgent need to address the health worker burnout crisis across the United States. Health workers, including nurses, doctors, community health workers, and public health staff, have long faced systemic challenges, and those were exacerbated during the coronavirus disease 2019 (COVID-19) pandemic. Therefore, collective efforts must urgently commit to protect health workers and prioritize their health, safety, and wellbeing.

Other efforts to improve public health include the continuation of the extensive, long-standing, and multifaceted vaccine safety monitoring to ensure public confidence in vaccines. ADM Levine thanked NVAC for providing vaccine safety recommendations, including new scientific strategies, advancements in technology, and approaches to shifting public and partner expectations. NVAC also developed a report with recommendations for a vaccine innovation agenda that describes priorities and actions for advancing the development of new and existing vaccines, which will optimize public health and reduce the disease burden in the United States. The Subcommittees leading the vaccine safety recommendations and vaccine innovation will provide updates on their efforts during this meeting.

ADM Levine also noted that HHS publicly released the *Sexually Transmitted Infection (STI) Federal Implementation Plan* to outline more than 200 actions undertaken by several agencies and departments across the federal government to focus their efforts on innovative and effective solutions to combat STIs. The Plan, which includes expanding access to clinical care and the development of new vaccines, focuses

on STIs with the largest impact on the U.S. public health, including human papillomavirus (HPV) infection, chlamydia, gonorrhea, and syphilis.

## Chair's Welcome—Robert Hopkins, 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 unanimously approved the minutes of the February 2–3, 2023, meeting as written.

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. NVAC is scheduled to meet next on September 21–22, 2023. (See the appendix for a list of abbreviations used in this report.)

## The Vaccine Safety Subcommittee Report Out—Stephen Rinderknecht, D.O., and Robert Schechter, M.D., M.Sc.

NVAC formed the Vaccine Safety Subcommittee (VSS) to write a report including (1) a review of the last NVAC report on vaccine safety, as well as a previous vaccine scientific agenda and vaccine safety goal in the Vaccines National Strategic Plan 2021–2025, and an outline of opportunities for continual improvement of vaccine safety activities during vaccine development, licensure, and post-market use; (2) recommendations to address current and emerging vaccine safety challenges, minimize preventable vaccine-related adverse events (AEs), and improve all the individual components needed for a strong safety system; (3) directions to improve coordination efforts and incorporate stakeholder input into the timely detection and assessment of vaccine safety signals to better inform clinical decision making and public health policies; and (4) a description of science-based activities that HHS and federal partners can use to increase knowledge and use of the vaccine safety system.

VSS has convened and reviewed several relevant reports including the 2011 NVAC report on vaccine safety. VSS has also hosted expert speakers to present on topics of interest including U.S. vaccine safety monitoring systems, safe medical practices and reporting, administration errors, international vaccine safety systems, assessment of the Agency for Healthcare Research and Quality (AHRQ) systematic review, practical solutions, and clinical trials. VSS drafted a report that includes 32 recommendations to improve infrastructure, research and development, vaccine safety monitoring, immunization information systems, vaccine administration error rates, and public communication. (See the appendix for a list of the recommendations in this report.)

### *Discussion*

Molly Howell, M.P.H., asked whether VSS considered ways to improve sharing of Immunization Information Systems (IIS) with the Food and Drug Administration's (FDA) vaccine safety surveillance system. Dr. Schechter stated that VSS can discuss potential solutions to remove legal barriers to data sharing. Ms. Howell suggested adding "schools of pharmacy" to recommendation 4 in the VSS draft, given the large role pharmacists play in vaccinations in the United States. Dr. Schechter agreed and Dr. Hopkins suggested also considering "pharmacy information systems" in the discussion of IIS.

Robert Swanson, M.P.H., asked whether VSS can recommend vaccine providers interpret and accurately present Vaccine Adverse Event Reporting System (VAERS) data to prevent misrepresentation by groups that oppose vaccines. Dr. Schechter stated that VSS has discussed the challenges in presenting VAERS data and will incorporate Mr. Swanson's comment in the VSS draft.

Jeffrey Duchin, M.D., asked if VSS estimated the cost to increase vaccine safety funding (proposed in recommendation 1) to develop and maintain a robust vaccine system within the next congressional budget

and whether any allocations have been made toward the vaccine safety programs/activities that VSS recommends. Dr. Schechter stated that VSS has preliminary estimates that can be further refined based on additional information on the scale and scope of maintaining a robust vaccine system. Drs. Rinderknecht and Schechter noted that they are not aware of the impact of the recent debt ceiling negotiations or budget allocations on the Centers for Disease Control and Prevention (CDC) and FDA budgets.

## COVID-19 Vaccine Safety Review—Robert Hopkins, M.D., M.A.C.P., F.A.A.P.

Dr. Hopkins provided the last scheduled regular review of COVID-19 vaccine safety. The objectives of the COVID-19 Vaccine Safety Technical (VaST) Work Group were to (1) review, evaluate, and interpret post-authorization/approval COVID-19 vaccine safety data; (2) serve as a central hub for technical subject matter expertise from federal agencies conducting post-authorization/approval safety monitoring; (3) advise on analyses, interpretation, and data presentation; and (4) provide updates to the Advisory Committee on Immunization Practices (ACIP) COVID-19 Vaccines Work Group and the ACIP on COVID-19 vaccine safety. VaST received COVID-19 vaccination safety data from passive and active surveillance systems, including both U.S. and international partners. VaST also reviewed numerous vaccine safety topics, from December 2020–May 2021, including anaphylaxis following mRNA vaccines, as well as thrombosis with thrombocytopenia, myocarditis and pericarditis, and Guillain-Barré syndrome following the Janssen vaccine. From June 2021–December 2021, VaST focused their efforts on mortality following COVID-19 vaccination, as well as the effects of vaccination in pregnancy and reproductive health outcomes. From January 2022–March 2023, VaST reviewed simultaneous administration of influenza and COVID-19 vaccines, COVID-19 vaccination in children, bivalent mRNA vaccine booster doses, and vaccine administration errors, as well as tinnitus, hearing loss, and ischemic stroke following mRNA vaccinations.

To satisfy their objectives and VaST member procedures included (1) review of available data on vaccine administration and AEs of special interest; (2) presentation and sharing of data by all VaST members, federal partners, and subject matter experts; (3) discussion of independent findings by VaST members; and (4) summary and interpretation of aggregate data that were provided to the ACIP Secretariat regularly. As part of these procedures, VaST has provided rapid feedback to investigators on findings and interpretation, suggested additional studies and analyses of findings that might need further investigation, and exchanged information across federal agencies, including the Department of Veterans Affairs (VA), Department of Defense (DOD), Indian Health Service (IHS), and FDA

Since March 2023, VaST transferred the review of vaccine safety data to the ACIP COVID-19 Vaccines Work Group. A summary report that describes VaST processes is currently being developed for a journal publication, and other vaccine safety groups continue to monitor COVID-19 vaccine safety data. Moreover, follow-up studies of concerns and topics identified by VaST are being coordinated through CDC, FDA, and vaccine manufacturers.

### *Monitoring COVID-19 Vaccine Safety Among Immunocompromised Persons—Anne Hause, Ph.D., M.S.P.H.*

Current recommendations for immunocompromised persons depend on patient age and COVID-19 vaccination history. Emergency use authorizations (EUAs) and licenses for mRNA COVID-19 vaccines allow for some flexibility for the number of doses, dosage, and intervals between doses. Alternative vaccine schedules may be appropriate based on individual circumstances and the clinical judgment of a patient's physician. CDC has provided many infographic resources to help providers navigate recommendations for immunocompromised persons.

***CDC Vaccine Safety Monitoring Systems***

CDC is monitoring the safety of COVID-19 vaccines through four complementary systems, V-safe, VAERS, Vaccine Safety Datalink (VSD), and Clinical Immunization Safety Assessment (CISA) Project. V-safe is a voluntary smartphone-based safety surveillance system that allows anyone to register after receiving any dose of COVID-19 vaccine. V-safe sends daily surveys during the week following each dose of vaccine. These surveys are also sent weekly through 6 weeks post-vaccination and at 36 and 12 months following each vaccine dose. Daily surveys include questions about the local injection site (e.g., pain, redness, swelling) and systemic reactions (e.g., fatigue, headache, muscle pain), as well as health impacts (e.g., inability to perform normal daily activities, missing school or work, or receiving medical care). V-safe has closed registration for COVID-19 vaccinations, and health surveys will conclude at the end of June 2023. VAERS, on the other hand, is a national passive surveillance system that is co-managed by CDC and FDA. VAERS serves as an early warning system to detect possible vaccine safety problems and continues to accept reports of AEs following COVID-19 vaccination. Individuals can submit a VAERS report regardless of relatedness to the vaccine or the clinical seriousness of the event.

***Safety Monitoring Study of COVID-19 mRNA Vaccine First Booster Doses***

To characterize the safety of the first booster doses among immunocompromised persons, aged 12 years and older, CDC conducted a study to review (1) health surveys reported to V-safe during the week after receipt of an mRNA COVID-19 first booster dose, and (2) AEs reported to VAERS after the first mRNA COVID-19 booster dose. Neither V-safe nor VAERS directly solicit information on immunocompromised status. However, individuals who received a fourth dose were presumed to be immunocompromised, as only immunocompromised persons were recommended to receive a fourth dose during the study. The study compared the odds of reporting an adverse reaction or health impact to V-safe after fourth versus third doses using a multivariable generalized estimated equation model that accounted for demographic variables, vaccine manufacturers, and repeated measures. V-safe data based on 4,015 presumed immunocompromised persons show that both local injection site and systemic reactions, as well as health impact, were less frequently reported after dose 4 compared to dose 3. Records from VAERS identified 145 presumed immunocompromised persons and summarized lists of serious and nonserious reports. Nonserious reports comprised 88 percent of all VAERS reports, with symptoms such as headache, fatigue, and pain. Serious reports are those of hospitalization, prolongation of hospitalization, life-threatening illness, permanent disability, congenital anomaly or birth defect, or death. One of the reported deaths was a patient who had preexisting pulmonary fibrosis and experienced respiratory failure.

The study has many limitations including the following: (1) V-safe is a voluntary program and data might not be representative of the entire vaccinated U.S. population; (2) VAERS is a passive surveillance system subject to reporting biases and underreporting, especially of nonserious events; (3) V-safe and VAERS do not specifically solicit information about immunocompromising health conditions; (4) vaccine recipients included in this analysis cannot be confirmed as immunocompromised; and (5) a report to V-safe or VAERS alone cannot be used to assess causality. To improve vaccine safety monitoring efforts, CDC is currently developing a new V-safe platform that incorporates immune status information and enrolls individuals who receive any new vaccines in the future.

***Discussion***

Dr. Hopkins asked if the study analyzed the time interval between that third and fourth doses and whether that affected reported reactogenicity. Dr. Hause stated the limited number of reported immunocompromised persons restricts the ability to assess varying time intervals between doses and prevents detection of any statistically significant results on reactogenicity.

Dr. Schechter asked whether the new V-safe platform will accommodate respiratory syncytial virus (RSV), influenza, and COVID-19 vaccines during Fall 2023. Dr. Hause clarified that while current efforts are focused on new vaccines for existing pathogens, the platform will not be ready by Fall 2023.

## Promoting Public Health by Combatting Misinformation—Robert Califf, M.D.

Disseminating science-based facts and medicine to the public is an integral part of the FDA's mission to help Americans make informed choices about their health. Digitization of information and the ability to accumulate and share resources via the Internet transcends previous boundaries, which has dramatically altered FDA approaches and their effectiveness. On one hand, information digitization has expanded countless opportunities to generate reliable evidence and disseminate that evidence and knowledge to most of the world. On the other hand, digitization changes have led to a constant stream of unverified information and opinions, often in the form of misinformation and disinformation, which helped undermine and erode reliance on science and trust in experts and societal institutions.

The COVID-19 pandemic is one of the greatest examples of the negative effects of medical misinformation and the continuing tragedies that resulted from the dissemination of that misinformation and people's resulting uninformed choices regarding their health and wellbeing. Despite the FDA's efforts to speedily approve and disseminate safe and effective COVID-19 vaccines, thousands of people refused these vaccines and died from COVID-19. Vaccine opposition and hesitancy phenomena have become far more dangerous as extreme vaccination opponents have disseminated their misinformation and disinformation more widely and quickly across the Internet. These false communications are often connected to a political agenda or a cultural identity, which is then tied to the delegitimization of particular scientific conclusions. The cumulative effect of this dangerous misinformation and disinformation is an unprecedented decline in the life expectancy of Americans by nearly 5 years compared to other high-income countries.

FDA aims to improve its general approach to scientific communication to the public through (1) more frequent scientific communications that explicitly implement language targeted for specific audiences, including professional societies, advocacy groups, and the public; (2) anticipation of problems that require decisions or complex actions and; (3) rebuttal of misinformation as quickly as possible to prevent broad dissemination and acceptance; (4) the commission of the Reagan-Udall Foundation to develop a long-term strategy that ensures more accurate representation of general health information in the press; and (5) evaluation of the role of artificial intelligence (AI) language models in the production and spread of misinformation. To combat false and potentially harmful information, FDA manages a Rumor Control webpage that provides specific facts about individual trending topics. Currently featured topics on the page include COVID-19, sunscreen, and dietary supplements. The page also offers several tools to help stop the spread of misinformation, such as consumer-focused videos that help users identify and report misinformation;

Combating misinformation and disinformation will require a coalition involving not only the FDA but also medical, university, and public health professionals, as well as health systems and related industries. The results of scientific, public health and regulatory work must also be conveyed in ways easily understandable by the public.

## Taking on Vaccine Fatigue: Turning up to Help Those Tuning Out

Vaccine fatigue is defined as people's inertia or inaction toward vaccine information or instruction due to perceived burden and burnout. Vaccine fatigue is not associated with anti-vaccination beliefs, but rather happens in those who hold pro-vaccination views.

### *Older Adults' Perspectives on COVID-19 Vaccine—Preeti Malani, M.D., M.S.J.*

Dr. Malani presented data from a poll, conducted by the National Poll on Healthy Aging (NPHA) at the University of Michigan, which is a recurring, nationally representative household survey of U.S. adults. NPHA helps inform the public, health care providers, policymakers, and advocates on issues related to health, health care, and health policy in a timely fashion. In October 2020, NPHA asked a national sample of adults 50–80 years of age about their interest in and opinions on the flu vaccine and a future COVID-19 vaccine. Most adults believed that getting a flu vaccine is important, especially this year (2020), and indicated that they received a flu shot during the last flu season. Moreover, 58 percent of surveyed adults indicated they would likely get a COVID-19 vaccine. When asked about their trusted sources for health information, adults ranked reported vaccine effectiveness first (80%), followed by personal research (56%), doctor recommendations (52%), public health officials (42%), and family and friends (13%). In 2022, the Poll showed that sizable percentages of the same older adults said they would not get a fall booster at all, including 23 percent of all adults aged 50–64 years. According to unpublished data, 20 percent of adults cited vaccine fatigue as one of the main reasons for their decision not to get the booster.

Dr. Malani added that, according to the Morbidity and Mortality Weekly Report (MMWR), vaccination coverage with 2 doses of measles, mumps, and rubella vaccine (MMR) fell to 93 percent nationwide in the 2021–22 school year, leaving 250,000 children unprotected against measles. This alarming decline, along with the vaccine fatigue, highlights the importance for increasing awareness in adults to protect children and communities from vaccine-preventable diseases.

### *Determinants of COIVD-19 Vaccine Fatigue—James Lewis, Pharm.D.*

Data from the NPHA highlights an increasing continuum from vaccine hesitancy into vaccine fatigue, which threatens the public trust not only in COVID-19 vaccination but also other vaccine efforts. Understanding the reasons behind vaccine fatigue is critical to minimizing the dangerous impacts of this phenomenon. According to the literature review "Determinants of COIVD-19 Vaccine Fatigue," vaccine communications (e.g., campaign messages and expert consensus), costs, incentives, and trust in government and medical institutions may all greatly impact COVID-19 vaccine uptake. For instance, rapidly changing vaccine recommendations and guidelines has fueled vaccine hesitancy and eventually led to fatigue.

Effective interventions to encourage vaccination include (1) informing health care providers about common patient questions to ensure the delivery of information is clear, concise, and consistent; (2) increasing confidence in bivalent booster efficacy; and (3) implementing education programs and non-monetary incentives. Health care providers can be empowered to increase vaccine uptake through improving access to currently available CDC tools such as electronic medical records (EMRs) and other health care informatics.

### *Practical Tips for Addressing Vaccine Fatigue—Aaron Scherer, Ph.D.*

Research on vaccine fatigue is extremely limited. A systematic review found 37 articles that featured the phrases "vaccine fatigue," "vaccination fatigue," or "immunization fatigue." However, only 5 of the 37 articles discussed vaccine fatigue that occurs after a vaccine becomes available, and only 3 articles discussed vaccine fatigue from a provider perspective.

The success of vaccine efforts hinges on the extent of trust between participating parties, including the public, health care providers, and government and medical institutes. Health care providers can promote vaccines to patients by adopting the following strategies: (1) provide a strong presumptive vaccination recommendation; (2) elicit all patient concerns to understand the breadth and the depth of these concerns and formulate a more holistic response; (3) thank patients for sharing their concerns and ask permission to share a health care provider perspective; and (4) provide accurate and credible information sources that the patient trusts (e.g., sources that align with a patient's strong social, religious, or political identity).

### *Discussion*

Dr. Hopkins praised the tip about providing a presumptive vaccine recommendation. He stated that using an active voice as a health care provider helps establish a better relationship with the patient. Dr. Scherer agreed, adding that a strong presumptive recommendation signals to the patient that health care providers view vaccines as an important part of routine care.

Ms. Aikin asked whether providing information to patients prior to their vaccine visit may help reduce hesitancy. Dr. Malani stated that creating resources that can seamlessly be incorporated into a health care provider's workflow will significantly improve vaccine uptake. These resources are especially important as the RSV, COVID-19, and flu vaccines become more urgent this coming fall. Dr. Lewis stated that vaccine efforts should focus on making resources easily available and quickly accessible to help providers navigate routine vaccine questions/challenges.

Jewel Mullen, M.D., M.P.H., asked whether effective vaccine interventions use direct-to-consumer advertising and how health care providers can help patients understand the additional benefits of vaccines such as pneumococcal and zoster (shingles). Dr. Lewis stated that direct-to-consumer advertising is an effective method that can be optimized to promote vaccine uptake. Dr. Malani noted that direct-to-consumer advertising may not be an effective approach for COVID-19 because further commercialization it may deter people from getting the vaccine. Dr. Hopkins added that engaging people through community-based organizations instead of advertisement and television will help build community demand that departs from social media and the mistrust it brings.

## Clinician Care: Post-Pandemic Immunization Insights

Even before the COVID-19 pandemic, the National Academy of Medicine found that burnout had reached crisis levels among the U.S. health care workforce, with 35–54 percent of nurses and physicians and 45–60 percent of medical students and residents reporting symptoms of burnout. Multiple stressors have negatively affected clinicians who give vaccines, especially hostility and mistrust from patients Moral injury and administrative burden are also cited as factors that impact clinician health and productivity.

COVID-19 stigma can result in part from a lack of knowledge about the virus, including how it spreads and ways to prevent exposure, and fear, which can develop due to a lack of accurate and transparent information about the virus and protection methods. Therefore, medical and public health organizations have called for swift measures to combat COVID-19-related stigma, discrimination, and violence.

### *Stigma and Stress—David Sattler, Ph.D.*

Despite their unwavering acts of kindness and compassion during the COVID-19 pandemic, health care professionals have been subject to stigma and maltreatment. Stigma involves labeling, stereotyping, and discrediting, with the perception that individuals with a given characteristic present a threat or have been rejected by others. This stigma developed during the COVID-19 pandemic, a period of unprecedented threat and stress driven by uncertainty and loss of a sense of control, predictability, and safety. Navigating the threat of illness or death and enduring job loss and economic hardship while lacking full access to social support networks (e.g., family, friends, and neighbors) negatively influenced people's interactions with health care workers.

To shed light on COVID-19 stigma and address the paucity of research examining societal responses to incidents of COVID-19 related hostility, Dr. Sattler and his colleagues investigated the relationship between economic hardship experienced during the pandemic and people's perceptions of a COVID-19 related assault. Results show that when the victim of the attack was Chinese, participants who were experiencing a high degree of COVID-19 economic hardship were less likely to endorse financially compensating the victim, and they were less likely to support legal consequences for the assailant

compared to when the victim was white. This relationship between financial hardship and perception of a COVID-19 related assault was mediated by a reduced recognition that the victim suffered emotional trauma and pain as a result of the attack. Another study examined the relationship between COVID-19 stigma and psychological distress, including the degree to which stigma experienced during the pandemic might be a contributing factor to post-traumatic stress disorder (PTSD) symptoms. Study outcomes confirmed that experiencing COVID-19 stigma, behavior change, and exclusion, as well as responding to COVID-19 stigma were associated with PTSD. Other studies reported additional adverse outcomes in response to stigma, including anxiety, depression, and worsening of preexisting mental health conditions. Stigma was also associated with intent to receive the COVID-19 vaccination. For instance, vaccinated individuals were perceived as less of a threat than those who were non-vaccinated. However, additional research is needed to assess how this perception may have evolved over the course of the pandemic.

As a result of COVID-19 stigma, health care workers have been subjected to acts that threaten their personal safety, including reports of individuals purposely spitting on, coughing at, and verbally and physically assaulting health care workers. In addition to navigating this burden of stigma, health care workers have faced challenging work conditions, including long hours and irregular shifts, staffing shortages, physically and emotionally demanding work, and risk of exposure to disease. Therefore, Dr. Sattler recommended that efforts to support health care worker well-being should focus on (1) presenting information clearly from reliable and official sources to increase mental health awareness—not fear or uncertainty; (2) consulting with behavioral scientists in developing and testing messaging to obtain useful feedback, refine information, and increase message effectiveness; and (3) researching other contributions toward health care worker stigma, especially as recommendations regarding preventive measures have evolved.

Many studies show that another manifestation of stigma can act as a barrier that prevents health care workers from seeking mental health services. A cross-sectional study during the pandemic found that U.S. health care workers reported depression, anxiety, sleep disturbances, PTSD, and emotional exhaustion. Mental health issues were associated with health fears, job stressors, perceived stigma, social stigma and avoidance, and workplace safety concerns. Hence, there is also a need for further work addressing the utility and efficacy of occupational mental health interventions for health care workers, with a special focus on stigma that acts as a barrier to treatment.

Pandemic related hardship and trauma has the potential to lead to positive outcomes such as post traumatic growth, a process through which people reflect on what gives their life meaning, their values, and shifting life priorities. Studies show that the anticipation of stigma as well as behavior change due to COVID-19 stigma were associated with post traumatic growth. Thus, reestablishing feelings of safety, stability, and control for health care workers may be necessary prerequisites to exploring meaning and purpose after trauma.

### *Burnout Trends—Marie Brown, M.D., M.A.C.P.*

The association of health worker burnout with the quality of care, turnover, reductions in work effort outcomes, and vaccine rates has had profound implications for the U.S. health care system. Before the COVID-19 pandemic, national studies reported that 35–45 percent of nurses and 40–54 percent of physicians experienced burnout. Driven by their values, health workers became strongly motivated at the beginning of the pandemic. However, the politicization of masks and vaccinations drove health care worker burnout to an all-time high. This burnout can result in medical errors, patient mistrust, referrals, increased medical costs, and suicide. Symptoms of burnout among health care workers include emotional exhaustion, depersonalization of patients, and a feeling of decreased satisfaction in the profession.

One of the main drivers of burnout is electronic health records (EHRs), which occupy physicians' work hours and distract them from caring and developing trust with their patients. A time motion study showed

that for every hour of face-to-face patient time, physicians spend 2 hours on EHR tasks. In fact, EHR documentation averages 6 hours in a 12-hour shift. In response, many physicians have become part time, or left the profession.

***Organizational system solutions***

While burnout might manifest in individuals, it originates from the organizations that can implement changes such as reducing job demands and improving resources and workflows. The American Medical Association (AMA) STEPS Forward offers a collection of engaging and interactive educational toolkits to the public that serve as practical guides to improve health professionals' practices. These toolkits address common practice challenges and offer solutions that aim to save two to three hours per day, reduce physician burnout and improve wellbeing, optimize team-based workflows, and enhance patient experiences. In addition, to reduce unnecessary and unintended burdens for health care workers, health system leaders can consider de-implementing processes or requirements that add little to no value to patients and their care teams.

## *Health Care Administration Burdens—Shawn Martin*

Health care workers fervently desire the restoration of clinical autonomy in all aspects of the practice of medicine. In addition, health care workers are advocating to remove unnecessary barriers to care including complicated routine and administrative processes. Three administrative burdens are particularly impacting the ability to consistently vaccinate the public: (1) the lack of a centralized system or information infrastructure to track vaccine information, hindering physicians' credibility and decision-making methods; (2) inconsistent reporting and documentation related to vaccinations from various settings and clinicians; and most importantly (3) the lack of inventory management in community-based primary care practices due to challenges in supply and distribution acquisition. As leaders assess their roadmaps toward more vaccine uptake efforts, they should consider solutions to these multifactorial problems.

## *Dare to: Advocate to Vaccinate?—Todd Wolynn, M.D., M.M.M.*

While most projects and funds are dedicated to vaccine research and development, very few efforts are focused on promoting vaccine communication and confidence. According to a 2023 report by Public Goods News, the United States is now the main source of vaccine disinformation that is also exported globally. Moreover, several health care providers use social media in nefarious ways that mislead their patients for personal gain. One way to control social media presence is to require boards of nursing and medical licenses to hold health care workers accountable and implement effective communication training for all health care professionals throughout their education and careers.

***Shots Heard around the World***

As the CEO of Kids+ Pediatrics, Dr. Wolynn designated a space called "evidence-based studios" that is led by a communications team. The team maintains a social media presence through podcasts and videos that are posted regularly to reach diverse audiences. In 2017, when CDC prioritized HPV vaccination, the communications team created a 90-second video called "We Prevent Cancer," in which trusted, local health care providers dispelled common vaccine myths. On one hand, the video became viral and motivated many people to schedule their vaccine appointments. On the other hand, Kids+ Pediatrics became the target of one of the first globally coordinated anti-vaccine attacks with over 10,000 attacks onto the practice's Facebook page from over 800 accounts and multiple threatening posts over 100 times per day. In response to the attacks, Kids+ Pediatrics launched a 4-pronged counter-response that involved (1) publishing research in peer-reviewed journals, (2) creating an toolkit against anti-vaccine attacks that has been translated into Spanish, French and Portuguese, (3) creating a digital cavalry, listing thousands of pro-vaccinators all over the world, and (4) promoting a vaccine awareness campaign.

The anti-vaccine industry thrives on social media because the algorithms favor sensational and voluminous disinformation. Anti-vaccination group tactics include rapid waves and organized swarms of posts and comments that use abusive language, threats, and anonymity to overwhelm, isolate, and terrorize, their targets. Often, anti-vaccine groups target health care providers with campaigns that smear provider reputation, as well as threaten and harass them. Thus, many practices and providers avoid speaking publicly or posting on social media to prevent potential vicious attacks. Health care professionals and workers, including attendings, residents, medical and pharmacy students, nurses, and public health officials are not adequately prepared to navigate politically-, financially-, or power-motivated attacks. Thus, Dr. Wolynn co-founded Shots Heard around the World, a rapid-response digital cavalry dedicated to protecting the online safety of health care providers and practices. Shots Heard aims to connect and unite, reinforce and strengthen, reassure and empower, as well as embolden and galvanize health care professionals who stand up for vaccines. As of 2020, Shots Heard is maintained by the public health nonprofit The Public Good Projects and supports a digital cavalry of over 2,000 defenders of vaccine science.

### *Physician Moral Injury: Distress, Reframing, and Repair—Wendy Dean, M.D.*

Moral injury is often mischaracterized—in combat veterans, it is diagnosed as post-traumatic stress; among physicians it is portrayed as burnout. However, without understanding the critical difference between burnout and moral injury, the wounds will never heal, and physicians and patients alike will continue to suffer the consequences. Research shows that burnout and moral injury are two equally significant but distinct concepts that often, but not always, happen together. Burnout and moral injury can influence each other, but they require different solutions. Moral injury is defined as betrayal by a legitimate authority in a high-stakes situation. Dedicated, resourceful, and resilient clinicians feel trapped between the patient-first values of their Hippocratic oath and the business imperatives of the health care system. The COVID-19 pandemic exacerbated this moral injury phenomenon and highlighted the gaps and vulnerabilities in the U.S. health care system, leaving health care workers unable to perform their duties. Betrayals to dedicated health care workers during the pandemic included retirement and benefit cuts, staff furloughs, personal protective equipment (PPE) shortages, abuse by the public, and mistrust by patients.

Changing the health care system to make it less damaging will require collective action from all parts of the health care system. The solution to moral injury lies in rebuilding communities across licensing groups to connect administrators and clinicians and reconcile the differences in their goals to rebuild trust in the system from both clinicians and patients. Creating "morally centralized" organizations that are wise and trustworthy and provide mentoring is also desperately needed in health care.

### *Discussion*

Kris Ehresmann, R.N., M.P.H., thanked the panelists and noted that burnout and moral injury extend to public health professionals—not just clinical systems. Dr. Dean agreed, adding that she also conducted a study of executives and leadership and found that 40 percent of them experienced moral injury during the pandemic. Hence, moral injury is a widespread problem that urgently needs to be addressed. Dr. Hopkins stated that the first step to addressing burnout and moral injury is initiating a common collaborative that standardizes language among all clinicians and public health professionals to help recognize burnout and moral injury and create solutions.

## Innovation in Immunization Subcommittee Update—Jewel Mullen, M.D., M.P.H. and Robert Swanson, M.P.H.

NVAC formed the Innovation in Immunization Subcommittee (IIIS) to write a report including (1) a review of both conventional and promising novel approaches for vaccine discovery and development; (2) a set of recommendations for actionable, high-impact activities; (3) an evidence-based approach for

identifying and prioritizing vaccine candidates and immunization technologies, including their criteria for prioritization that accounts for the potential impact on disease burden, population health outcomes, health equity, economy, national health priorities, and scientific feasibility; (4) a list of vaccination innovation priorities, including target antigens, molecular platforms, and immunization delivery technologies; (5) a forward-looking approach to introduce vaccines for special patient populations and neglected diseases to portray their value and importance; and (6) a scientific agenda outlining a framework of research direction that identifies scientific needs and gaps that should be addressed by the end of 2028.

IIIS has convened, reviewed disease burden data, and engaged in thoughtful discussions around its charge elements. IIIS also hosted speakers for the following topics: priorities for vaccine innovation, vaccine development ecosystems, state plans to reduce immunization exemptions in schools, vaccines to prevent antimicrobial resistant infections, and vaccine development innovations. IIIS next steps involve planning presentations on an influenza case study, equity, demand, as well as developing a report outline. IIIS is also working to (1) determine top pathogens with the highest disease burden in United States, (2) assess the status of vaccines against each priority pathogen with regard to development pipeline and marketing status and adequacy, (3) identify gaps in public health need versus available and development-stage vaccines, and (4) make recommendations regarding how to close gaps by focusing on funding innovations and technology platforms.

IIIS posed the following questions for discussion among NVAC members:

1. Advancing Immunization Equity: NVAC recently approved a report to advance immunization equity. Many of the new technologies, strategies, and vaccine development approaches could be very helpful to improving health equity. This is true for developing new and improved vaccines that could be more accessible to people, novel administration techniques that increase vaccine demand from new people, as well as improving health equity by preventing diseases that unequally affect certain groups of people. Please share your thoughts about ways we should apply a lens of equity in fulfilling the charge.
2. Challenges to Improving Existing Vaccines: iteratively improving existing vaccines or developing new vaccines to replace existing vaccines can present economic and regulatory challenges, as many improvements are required to demonstrate both improved efficacy and reduced risk of AEs compared to existing vaccines. This risk can financially disincentivize vaccine manufacturers from developing improved vaccines. What are your thoughts about the impact of public health on financial disincentives in general? How should IIIS explore various challenges in improving existing vaccines?
3. Alternative Immunization Strategies: NVAC has heard presentations on monoclonal antibodies (mAbs) as a passive immunization therapy for RSV. IIIS members discussed strategies for targeting high priority pathogens and protecting immunocompromised, very young populations, and pregnant people. Another example potentially includes immunotherapies, such as cytokines, are being worked on. What are your thoughts about new strategies such as mAbs and immunotherapies to support immunization efforts?

### *Discussion*

Ms. Ehresmann asked whether IIIS considered asking for input from members of underrepresented communities. Mr. Swanson stated that IIIS discussed vaccine equity for groups that experience the highest disease impact but has not hosted speakers from these groups.

Dr. Rinderknecht asked if there are barriers, other than financial, that prevent manufacturers from advancing new vaccines and whether IIIS has engaged representatives from the industry in their discussions. Mr. Swanson explained that many of the IIIS members are industry representatives who have

voiced several challenges, including the lack of language standardization in the development and research of vaccines.

Dr. Schecter asked about ways to convey confidence in innovative science to concerned or skeptical populations. Dr. Mullen stated that efforts should aim to demystify innovative or new advances and reframe them as "science-based" instead of "experimental" using simple language appropriate for the general public.

Dr. Hopkins noted that passive immunization must be a part of the vaccine discovery process and disease prevention efforts. Immunotherapeutic approaches have potential for growth in the coming decades, not only for infectious diseases but also for cancer. Therefore, immunizations should be considered for the betterment of public health, beyond just active immunization for infectious disease targets. Ms. Ehresmann agreed, stating that the language used in immunization efforts should be changed to acknowledge that the majority of previous efforts have been focused on active immunizations. Changing the language will help educate both vaccine partners and the public.

Ms. Howell suggested that IIIS discuss how vaccines can be made available to uninsured populations. Mr. Swanson agreed, stating that the discussion should also include the impact on immunization legislation and whether these efforts are possible in some states.

## Federal Agency and Liaison Member Updates

***Biomedical Advanced Research and Development Authority—Kim Armstrong, Ph.D., M.T.***
The Biomedical Advanced Research and Development Authority (BARDA) supports advanced research and development efforts for medical countermeasures under Project NextGen, a $5 billion program that will accelerate and streamline the development of the next generation of innovative COVID-19 vaccines and treatments. Based at HHS and led by the National Institutes of Health's (NIH's) National Institute of Allergy and Infectious Diseases (NIAID), Project NextGen will coordinate across the federal government and the private sector to advance the pipeline of new, innovative vaccines and therapeutics from laboratories into clinical trials with the intent of technology transfer to the private sector for later stage development and potential FDA authorization and approval, as well as commercialization. Project NextGen focuses on three program areas meant to support products in clinical trials and generate data that supports additional investments and commercialization: (1) advance next generation COVID-19 vaccine candidates, including broader, more durable protection, and better transmission blocking capabilities, (2) enhance mAbs to protect vulnerable populations, and (3) advance development of innovative new vaccine approaches, therapeutic platforms, and manufacturing strategies to enable faster and lower cost production, and to improve efficacy and access. BARDA is currently seeking proposals for the development of these next generation COVID-19 therapeutics, vaccines, and immune assays.

BARDA is also preparing for a potential influenza pandemic, given the high volume of avian influenza circulating globally, including in North and South America. BARDA is sponsoring a Phase 2 clinical trial to evaluate different priming and booster regimens with MF59-adjuvanted H5N8 and H5N6 cell culture-derived influenza vaccines. In addition, BARDA is supporting GlaxoSmithKline (GSK) in a Phase 1/2 observer blinded, randomized, multicenter trial to evaluate the safety and immunogenicity of different formulations of monovalent influenza A vaccine with the adjuvant system.

In addition to its ongoing support of approved recombinant protein, cell- and egg-based influenza vaccines, BARDA continues to support development of additional vaccine platforms that may further accelerate the response to a pandemic such as mRNA. BARDA has also partnered with the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), Access to

Advanced Health Institute (AAHI), and AstraZeneca to develop pandemic influenza mRNA vaccine candidates.

### *Department of Defense—David Hunter, Ph.D.*

DOD supports 400 immunization sites that provide COVID-19 vaccines. These sites will also administer the second Mpox dose, as well as vaccines normally administered in Northern and Southern hemispheres.

### *Food and Drug Administration—Jay Slater, M.D.*

The Vaccines and Related Biological Products Advisory Committee (VRBPAC) met on March 1, 2023, to discuss and make recommendations on the safety and effectiveness of AREXVY (RSV vaccine, recombinant, adjuvanted), manufactured by GSK for active immunization for the prevention of acute respiratory disease and lower respiratory tract disease (LRTD) caused by RSV-A and RSV-B subtypes in adults 60 years of age and older. On May 3, 2023, FDA approved AREXVY, the first RSV vaccine approved for use in the United States. AREXVY is approved for the prevention of LRTD caused by RSV in individuals 60 years of age and older.

On February 28, 2023, VRBPAC met to discuss and make recommendations on the safety and effectiveness of ABRYSVO, the RSV vaccine manufactured by Pfizer for active immunization for the prevention of LRTD caused by RSV in adults 60 years of age and older. On May 31, 2023, FDA approved ABRYSVO, Pfizer's RSV vaccine for adults aged 60 and older, making it the second RSV vaccine approved for use in the United States. The vaccine was approved with post-marketing requirements for pharmacovigilance studies evaluating the risk of Guillain-Barré syndrome among 1.5 million vaccine recipients.

On March 14, 2023, FDA authorized the Pfizer-BioNTech COVID-19 Vaccine, Bivalent for a single booster dose of the vaccine in children 6 months through 4 years of age at least 2 months after completion of primary vaccination with three doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine. On April 18, FDA amended the EUAs of the Moderna and Pfizer-BioNTech COVID-19 bivalent mRNA vaccines to simplify the vaccination schedule for individuals six months of age and older. On April 27, 2023, in collaboration with BARDA, FDA conducted a workshop on recombinant-protein- based COVID-19 vaccines. The goals of the workshop were to provide a forum for product sponsors to discuss progress and technical challenges and serve as an open forum for collaborative discussions to facilitate vaccine advancement.

On April 27, 2023, FDA approved PREVNAR 20, Pfizer's pneumococcal 20-valent conjugate vaccine. PREVNAR 20 is approved for: (1) the prevention of invasive disease caused by 20 Streptococcus pneumoniae strains in individuals 6 weeks and older, and (2) the prevention of otitis media caused by 7 of the 20 strains in individuals 6 weeks through 5 years. PREVNAR 20 was initially approved by FDA in 2021 for the prevention of pneumonia and invasive disease for individuals 18 years of age and older.

On April 28, 2023, FDA authorized the following uses of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent for individuals 6 months–4 years of age with certain immune deficiencies who have previously received three 0.2 mL doses (Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent): (1) a fourth dose administered at least 1 month following the most recent dose; and (2) additional doses that may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.

On May 22, 2023, Janssen BioNTech, Inc. (Janssen) submitted a request for voluntary withdrawal of the EUA for Janssen COVID-19 Vaccine. Janssen informed the FDA that the last lots of the vaccine purchased by the U.S. government have expired. There is no demand for new lots of the vaccine in the

United States and they do not intend to update the strain composition of this vaccine for emerging variants. On June 1, 2023, FDA revoked the EUA for the Janssen COVID-19 Vaccine.

VRBPAC is meeting on June 15, 2023, to discuss and make recommendations on the strain or strains that should be included in the periodic updated COVID-19 vaccines for the Fall and Winter 2023-2024 vaccination campaign.

### *Centers for Medicare & Medicaid Services—Mary Beth Hance*

The Centers for Medicare and Medicaid Services (CMS) continues to search for opportunities to emphasize the importance of routine pediatric immunizations. CMS supports the Connecting Kids to Coverage National Campaign, an initiative that provides outreach guides and toolkits to help states, community organizations, schools, health care providers, and others organize and conduct successful outreach activities. Moreover, CMS is hosting a back-to-school webinar on June 21, 2023, to help connect families, children, and teens to health coverage through Medicaid and the Children's Health Insurance Program (CHIP).

### *Health Resources and Services Administration—Roxanna Diba, M.D., M.S.*

The Advisory Commission on Childhood Vaccines (ACCV) of the Health Resources and Services Administration (HRSA) met twice in March to discuss RSV and dengue vaccines. The Division of Injury Compensation Programs (DICP) is looking to hire an attorney who is interested in vaccine-related claims.

The National Vaccine Injury Compensation Program (VICP) continues to process backlogged claims. In addition, the Countermeasures Injury Compensation Program (CICP) received approximately 11,500 claims as of April 1, 2023. As of May 5, 2023, the Bureau of Primary Healthcare has provided almost 23 and a half million vaccine COVID-19 doses.

### *Indian Health Service—Uzo Chukwuma, M.P.H.*

IHS continues to prioritize access, quality, and equity in vaccine distribution and administration for American Indian and Alaska Native tribal communities. To date, participating federal, tribal, and urban facilities within IHS authority administered over 2.3 million COVID-19 vaccines. Following the end of the public health emergency in May 2023 and the transition towards commercialization, the IHS Vaccine Task Force has been working to ensure that federal, tribal, and urban facilities can continue the administration of COVID-19 vaccines alongside other key routine immunizations. Multiple IHS facilities have launched an equity pilot project to enhance vaccine access for most vulnerable patients.

In the wake of the COVID-19 pandemic, IHS announced a new national vaccine strategy to promote vaccination coverage among its patients. IHS advocates recommending vaccines to patients with the E3 Vaccine Strategy, focusing on: (1) Every patient at (2) Every encounter should be offered (3) Every recommended vaccine when appropriate. This includes all ACIP recommended vaccines in all age groups. Efforts around this initiative include (1) extensive stakeholder engagement, (2) collaboration and quality improvement cycles to test small changes to existing systems and processes, (3) encouragement of innovation within IHS facilities and sites, (4) embracement of failure as a part of change, and (5) incentivization of work toward success using best practices developed within the system.

During the Mpox public health emergency, IHS took a proactive approach to the distribution and administration of JYNNEOS vaccine among high-risk persons in tribal communities. Recognizing the potential for exposure and illness within American Indian and Alaska Native populations, IHS was among the first of the jurisdictions to expand access to JYNNEOS vaccine as a part of a pre-exposure prophylaxis (PrEP) initiative that was implemented broadly across the IHS health care system.

IHS also conducts routine surveillance for influenza-like illness (ILI) and influenza vaccination coverage. The 2022-2023 influenza season shows a high ILI activity compared to the 2021-2022 season. The system also indicates that IHS regions with remarkably high influenza vaccination coverage rates reported lower ILI activity compared to those with low vaccination coverage rates. The IHS National Immunization Program continues to collaborate with federal and tribal partners to promote annual flu shots alongside all recommended vaccines.

### *VRBPAC—Hana El Sahly, M.D.*

On May 7, 2023, the committee met to discuss the selection of the influenza vaccine strains for the 2023-2024 influenza season. The vote was 13 "yes" and 0 "no" for the inclusion of the egg-based and cell- or recombinant-based vaccine (both are H1N1 pandemic 2009 [H1N1pdm09]-like).

On May 18, 2023, the committee met to discuss and make recommendations on the safety and effectiveness of ABRYSVO (RSV vaccine), manufactured by Pfizer, with a requested indication for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age by active immunization of pregnant individuals. The FDA has not issued its decision.

### *Association of Immunization Managers — Claire Hannan, M.P.H.*

The Association of Immunization Managers (AIM) recently concluded its Vaccine Access cooperative regional meetings, which were held to identify and address challenges to pediatric COVID-19 vaccination. During these meetings, AIM invited critical partners such as the American Academy of Pediatrics (AAP), pharmacies, and Medicaid.

AIM also created 10 focus groups on the commercialization of COVID-19 vaccines, which are currently working to implement the CDC's Bridge Access Program to provide COVID-19 vaccine for uninsured adults for a limited time after the vaccines move onto the commercial market in Fall 2023.

AIM participated in the National Adult and Influenza Immunization Summit to examine the challenges of transitioning COVID-19 vaccination programs into routine adult activities.

In celebration of the National Immunization Awareness month, AIM provides an opportunity for each jurisdiction to recognize and honor an individual who is working to increase vaccine coverage levels. Jurisdictions can submit their champion nominations throughout June, and the Champion Award winners will be announced and honored in August. Individuals interested in the nomination process should contact their state immunization program or AIM.

### *American Immunization Registry Association—Courtnay Londo, M.A.*

In December 2022, the American Immunization Registry Association (AIRA) published Guidance on Messaging Sexual Orientation and Gender Identity (SOGI). AIRA commissioned a small working group to prepare the technical guidance document to support IIS SOGI information exchange, which will support the immunization community in leveraging IIS data to further understand and address health disparities.

AIRA also supports the Recovery her Immunization Linkage Project, which links immunization registry data that is collected through state and local vaccine registries to EHRs not already shared within the EHR system. These linkages will enable scientific studies that evaluate the impact of COVID-19 vaccines on long-term outcomes of COVID-19 illness within the last six months. This project has successfully linked EHRs between the Colorado Registry and Colorado Children's Hospital.

AIRA recognizes that large provider organizations and health institutes would benefit from a standardized way to access substantial amounts of IIS data for their patients and members. Thus, AIRA partnered with

many different EHR representatives, including CDC and Office of the National Coordinator for Health IT (ONC), to develop a bulk query as an emerging standard for ways to access large amounts of data. AIRA is currently in the process of drafting the guidance and best practices for how to conduct standardized bulk queries.

The COVID-19 pandemic has highlighted the ongoing need to share participant clinical trial data with appropriate entities, particularly primary care providers. IIS can capture and include investigational study vaccines, including those for COVID-19, in participants' comprehensive vaccination records. The corresponding AIRA written report contains links to resources on considerations for capturing this type of data along with several other timely updates.

### *Association of State and Territorial Health Officials—Kim Martin, R.N.*

The Association of State and Territorial Health Officials (ASTHO) continues to support its members, the state, and territorial health officials by providing situational awareness and technical assistance. Several new resources can be found on the ASTHO website, including recent daily podcasts, blogs, and legislative updates.

ASTHO also continues to work in coordination with ONC on the Immunization Data Exchange, Advancement and Sharing (IDEAS) project to support a learning community to advance data sharing between the IIS and Health Information Exchange (HIE) programs. ASTHO recently released two reports that are available online. The first report characterizes the dynamics influencing IIS and HIE partnerships and data exchange, and the second is a legal scan that summarizes state statutes and regulations impacting public health data.

As part of the CDC Partnering for Vaccine Equity program, ASTHO is collaborating with the National Community Action Partnership and a network of partners to use locally tailored, evidence-based strategies to increase vaccine acceptance and uptake among racial and ethnic minority populations. ASTHO is currently developing a vaccine equity toolkit for community leaders and providers.

In addition, ASTHO is working in coordination with the Harvard Opinion Research Program, National Public Health Information Coalition (NPHIC), and CDC to strengthen communication and messaging during public health emergencies, including the COVID-19 pandemic. The goal of this project is to support public health agencies with actionable data that can be used to enhance communication, education, and outreach initiatives. The project includes a series of surveys about public and provider perspectives to help understand the drivers of trust in public health response and institutions. Findings from this project have been published in a recent article in *Health Affairs* and can be accessed on the ASTHO website.

### *National Association of County and City Health Officials—Matt Bobo, M.P.H.*

In January and February, the National Association of County and City Health Officials (NACCHO) conducted its National Assessment of Local Health Department Immunization Programs. The assessment results highlight the strengths and best practices of high performing immunization programs and highlight opportunities to enhance and leverage federal, state, and local resources to improve local immunization program efforts.

On April 24–27, NACCHO held the 2023 Preparedness Summit in Atlanta, Georgia. The theme of the conference was "Recover. Renew: Reprioritizing All-Hazards Preparedness," which provided an opportunity to revisit these pressing issues and share resources, shape policies, and build skills to mitigate a variety of threats.

Following the end of public health emergency on May 11, 2023, NACCHO deescalated from the Incident Command Structure (ICS) and discontinued its weekly COVID-19 updates.

On May 22, 2023, NACCHO announced a funding opportunity for a Partnering for Vaccine Equity (PAVE) demonstration site project to support local health departments in identifying inequities in adult influenza and COVID-19 vaccination coverage among racial and ethnic populations.

The NACCHO360 Annual Conference will be on July 10, in Denver, Colorado. This year's theme, "Elevating Public Health Practice for Today and Tomorrow," will explore how the local public health workforce and its stakeholders can move forward in the midst of an ongoing crisis while implementing traditional and innovative approaches to restructure a system built to protect the health of communities nationwide.

In partnership with AIM, NACCHO also continues to participate in the Equipping Local Health Departments to Address Vaccine Hesitancy project to increase the local health departments' capacity to improve adult vaccination coverage by identifying strategies to reduce racial and ethnic disparities. As part of this project, local health departments completed rapid community assessments and created work plans that will be presented at the NACCHO360 Annual Conference in July.

### *Public Health Agency of Canada—Erin Henry*

Canada's National Advisory Committee on Immunization (NACI), an External Advisory Body that provides the Public Health Agency of Canada (PHAC), recently released interim guidance on the use of bivalent Omicron-containing COVID-19 vaccines for primary series. NACI now recommends that when mRNA COVID-19 vaccines are used for the primary series, bivalent Omicron-containing COVID-19 vaccines can be used as booster doses in individuals 6 months of age and over. NACI is also releasing its fall guidance for COVID-19 vaccine programs in July.

In April 2023, NACI released the first edition of *Guidelines for the Economic Evaluation of Vaccine Programs* in Canada, marking a major milestone for the Committee as this work has been ongoing since 2018. The guidelines were established to articulate the best practices for conducting and reporting economic evaluations of vaccination programs in Canada.

As for non-COVID-19 related activities, NACI plans to focus its efforts on various policies and programs around Mpox, seasonal influenza, HPV, RSV, rabies, hepatitis A and B, herpes, zoster, and invasive meningococcal disease.

The Immunization Partnership Fund (IPF) is an equity- and evidence- based program developed in 2016 with the goal of increasing vaccination coverage in Canada. As the only one of its kind in Canada, IPF funds projects to promote education and awareness regarding the importance of vaccination. Most recently, the program demonstrated clear results with its COVID-19-specific investments, and commercialization of these product investments yielded approximately $81.5 million for IPF. The IPF will further invest $10 million in time-limited projects that continue these efforts during NACI's COVID-19 and flu vaccination campaigns in 2023.

Recognizing that outdated web content risks undermining public trust, PHAC has begun updating its vaccine preventable disease web pages, which have been dormant for the past 3 years.

### *American Pharmacists Association—Jean-Venable (Kelly) Goode, Pharm.D.*

The American Pharmacists Association (APhA) is the largest pharmacy organization representing more than 62,000 members. The organization continues to support its members with engagement, training, education, and information and resources related to vaccination strategies and uptake. For example,

APhA released a Super Heroes of COVID-19 Vaccination Coloring Book online that conveys the importance of COVID-19 vaccines and prevention for pediatric patients. In addition, APhA provided a report on the changes in vaccine-related authority for pharmacists across the United States changes based on state laws, after the expiration of the Public Readiness and Emergency Preparedness (PREP) Act. Dr. Goode thanked NVAC members for their work and noted that this will be her last meeting as the liaison member for APhA.

### *Agency for Healthcare Research and Quality—Sheena Harris, M.D., M.P.H.*

The United States Preventive Services Task Force (USPSTF) is reviewing and updating its 2018 recommendation on cervical cancer screening. USPSTF recommends screening for women aged 21–65. However, USPSTF recommends against screening for cervical cancer in women less than 21 years or most women above 65 as well as women who have had a hysterectomy for benign disease. The current AHRQ research plan finalized in March 2022, includes key questions that examine the role of HPV vaccine and cancer screening strategies, as well as the accuracy of self-collected samples. AHRQ anticipates releasing a draft recommendation statement in early 2024.

## Inflation Reduction Act (IRA): Changes to Medicaid and Medicare

On August 16, 2022, President Biden signed IRA of 2022 into law, which includes a broad package of health, tax, and climate change provisions. The law includes several provisions to (1) lower prescription drug costs for people with Medicare and reduce drug spending by the federal government, (2) strengthen the Affordable Care Act by extending customer savings on the Marketplace by an average of $800 per year on their premiums, and (3) require coverage and eliminate cost-sharing for approved, ACIP-recommended preventive adult vaccines and their administration, beginning October 1, 2023.

### *Medicare Part D Vaccine Provision—Kristina Martin*

IRA requires that all Medicare Part D plans cover ACIP-recommended adult vaccines without any cost sharing for Part D enrollees, making them free to these patients starting January 1, 2023. There is no enrollee cost sharing on the ingredient cost of the adult vaccine, or any associated sales tax, dispensing fee, or vaccine administration fee. The provision covers all categories of ACIP recommendations for adults, including those that are specified as based on shared clinical decision-making as well as those for use in limited populations and circumstances. If ACIP issues a new vaccine recommendation for use in adults during the plan year, Part D sponsors must apply the cost-sharing requirements to any applicable vaccine claims with dates of service after the issuance of such recommendation. CMS released this guidance to insurance plans on September 26, 2022, to implement this provision for the Calendar Year 2023 and issued guidance to ensure plans include this information in their plan materials for enrollees. CMS further clarified in guidance released on April 4, 2023, that in order for an adult-use-of-vaccine to be considered "ACIP recommended," such use must be approved by the CDC Director and published in the CDC's MMWR.

CMS also created social media toolkits to spread awareness about the new vaccine provision in Part D, as well as the new cost-sharing cap on insulins covered under Part D for stakeholders. The toolkits, which are available in both Spanish and English, include social media language and graphics. In addition, CMS launched a new campaign in May to promote vaccines. The vaccine campaign is live now until October—targeting people with Medicare on social, radio, and print.

### *Medicaid Vaccine Provision—Mary Beth Hance*

Beginning October 1, 2023, the IRA will require Medicaid and CHIP programs to cover ACIP-recommended adult vaccines. The Act will mandate coverage for enrollees under traditional Medicaid and CHIP beneficiaries aged 19 and older. States will receive the applicable regular Medicaid federal medical assistance percentage (FMAP) and CHIP FMAP for their expenditures on the adult vaccinations they are

required to cover under the IRA. In addition, states that, as of August 16, 2022, were covering approved, ACIP-recommended adult vaccinations, without cost sharing, can claim a 1 percentage point increase in FMAP for their Medicaid expenditures on these vaccination services for the first 8 fiscal quarters that begin on or after October 1, 2023. At the conclusion of the 8 fiscal quarters (September 30, 2025), these states' Medicaid expenditures for vaccines and vaccine administration will be return to the applicable regular FMAP. This part of the provision overlaps with the American Rescue Plan Act of 2021 that requires states to cover COVID-19 vaccines in their administration without cost sharing until September 30, 2024.

***Discussion***

Ms. Howell asked who can bill Medicaid for vaccines administered in a skilled nursing facility, particularly for adults aged 65 and older. Ms. Martin referred Ms. Howell to the online COVID-19 Public Health Emergency Unwinding Frequently Asked Questions for State Medicaid and CHIP Agencies. The webpage includes guidance resources and tools designed to help states prepare for the eventual end of the COVID-19 public health emergency.

Ms. Howell also asked how reimbursement for vaccines, especially the zoster vaccine, is determined and whether the costs will be increased to ensure adequate reimbursement for local health departments. Ms. Martin noted that she is interested in hearing more about experiences of providers in community health centers and clinics. The IRA does address drug costs and reimbursements to ensure adequate compensation and access to vaccines.

### Public Comment

No public comments were offered.

### 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. Aiken called 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. Aiken also 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 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 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, June 15, and introduced the upcoming panels. The agenda, minutes, and recordings of past meetings are available online. NVAC is scheduled to meet next on September 21–22, 2023.

## Superbugs: Vaccines Role in Stopping the Spread

### *Coordinating Action to Combat the Global Threat of Antimicrobial Resistance—Paul Plummer, D.V.M., Ph.D.*

Antimicrobial resistance (AMR) occurs when germs develop the ability to evade the drugs designed to kill them. As the pipeline for production of new antimicrobials wanes, bacteria are developing resistance faster than we are developing antibiotics. In 2019, AMR was directly attributable to 1.4 million global deaths, and an additional 5.0 million deaths were associated with AMR. Dr. Plummer emphasized AMR as a serious global health threat, discussed the importance of vaccination in addressing AMR, and provided an update on reports from the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) that could aid stakeholders in vaccine selection. In addition, he outlined the One Health concept, which aims to optimize health for humans, animals, and the environment. Addressing AMR using this framework involves improving antibiotic prescription practices and focusing on infection prevention, including vaccination, to decrease antibiotic use and maintain the efficacy of existing drugs.

Dr. Plummer is the chair of PACCARB, which was established in September 2015 by Executive Order as part of a multi-agency approach to combat antibiotic-resistant bacteria. PACCARB has produced 11 reports that include recommendations on the development of vaccines to counter AMR. In previous reports from 2017 and 2018, PACCARB recommended incentivizing the development and uptake of vaccines and streamlining interactions between sponsors and regulatory agencies. These previous reports also encouraged the use of vaccines and other therapeutic or production system interventions to reduce AMR in target animal production environments. In the 2023 report entitled *Preparing for the Next Pandemic in the Era of Antimicrobial Resistance*, PACCARB recommended investing in innovative products prior to the next public health emergency.

### *Antibiotic Use During the COVID-19 Pandemic and Beyond: The Role of Vaccines/Impact of the COVID-19 Pandemic on Healthcare-Associated Infections and Antimicrobial Resistance: A Need for New Prevention Tools—Lauri A. Hicks, D.O., F.A.C.P.*

Dr. Hicks presented data indicating the COVID-19 pandemic led to significant changes in antibiotic use in the United States. Early in the pandemic, overall antibiotic use increased in hospitals despite decreased hospital admissions. Fluctuations in hospital antibiotic use were driven by drugs used to treat bacterial pneumonia (azithromycin and ceftriaxone), with increased use of these drugs corresponding to increased COVID-19 rates. More than two-thirds of patients (77.3%) hospitalized with COVID-19 received antibiotics. Outpatient antibiotic prescribing decreased during the pandemic but rebounded in 2021 and exceeded pre-pandemic levels by 2022.

Dr. Hicks discussed several studies indicating that vaccination decreases antibiotic use. Two studies on influenza vaccination showed a 28 percent reduction in antibiotic use among adults who received influenza vaccines and a 6.5 percent decrease in antibiotic use with a 10 percent increase in the influenza vaccination rate. Studies on rotavirus, COVID-19, and RSV vaccination also demonstrated that improving uptake of existing vaccines could lead to decreased antibiotic use. Notably, in a randomized controlled trial across 11 countries, RSV vaccination of mothers reduced antibiotic prescribing for their infants by 13 percent compared to infants from mothers who had received the placebo.

Dr. Hicks also discussed the role of vaccines in reducing healthcare-associated infections (HAI) and AMR. The CDC tracks rates of HAI and AMR, and subsets AMR threats into three categories – urgent, serious, and concerning. Many HAI-associated pathogens are considered urgent or serious threats. During the pandemic, ventilator-associated events (VAEs) increased 149 percent from 2019 to 2021, which played a significant role in increasing HAI incidence during periods of high COVID-19 hospitalization rates. During the first year of the pandemic, AMR hospital-onset infections and deaths increased by 15 percent, which is likely an underestimate due to data gaps resulting from the pandemic.

The CDC has released a report describing methods to reduce AMR, including stewardship of antimicrobials, infection prevention and control, data tracking, and sanitization of appropriate environments, as well as investing in vaccines, therapeutics, and diagnostics. Currently, there are no FDA-approved vaccines targeting HAI pathogens, but Pfizer's investigational *Clostridioides difficile* vaccine was well tolerated and reduced duration and severity of disease in a Phase 3 clinical trial, although it did not meet the prespecified primary endpoint. Janssen also has an investigation vaccine for extraintestinal pathogenic *Escherichia coli*, which has an ongoing Phase 3 clinical trial.

### *The Role of Vaccines in Reducing AMR—Mateusz Hasso-Agopsowicz, MS.c., Ph.D.*

Dr. Hasso-Agopsowicz outlined numerous ways vaccines reduce AMR, including preventing drug-susceptible and resistant infections at the individual and community levels, reducing secondary infections, and decreasing antibiotic use. He described the Action Framework used by WHO to inform their decisions about vaccine usage to reduce AMR. This framework is structured around expanding the use of licensed vaccines, developing new vaccines, including AMR endpoints in vaccine clinical trials, and expanding and sharing knowledge of the impact of vaccines on AMR.

As of 2021, 61 vaccines for bacterial diseases are in active clinical or preclinical development, with the highest number of vaccine candidates for *Streptococcus pneumoniae* (16 vaccines), *Mycobacterium tuberculosis* (13 vaccines), and *Shigella flexneri* (6 vaccines). However, many pathogens, particularly those that cause HAIs, have no vaccine candidates in development. Dr. Hasso-Agopsowicz identified four classes of pathogens based on vaccine development. Class A pathogens already have licensed vaccines, and WHO recommends increasing vaccine coverage and accelerating their introduction. Class B pathogens have vaccines in late-stage clinical trials, and their development should be accelerated. Class C pathogens have vaccines in early clinical trials, and WHO recommends continuing their development while expanding knowledge on AMR impacts. Class D pathogens have few or no vaccine candidates, so other prevention or control tools should be used to prevent AMR until vaccine development advances. Dr. Hasso-Agopsowicz stressed the importance of including AMR-related endpoints in all clinical trials of vaccine candidates so the appropriate data for measuring vaccine impact on AMR could be collected.

Dr. Hasso-Agopsowicz also discussed preliminary results of analyses to assess the value of different vaccines on reducing AMR. To conduct this analysis, he used pathogen-specific data collected by the Institute for Health Metrics and Evaluation (IHME) and coupled these data with existing or hypothesized data about vaccine coverage and efficacy. Dr. Hasso-Agopsowicz then applied assumptions about vaccine profiles to the IHME dataset to estimate the impact of each vaccine on reducing AMR-associated deaths. Of all the vaccines analyzed, those for *S. pneumoniae* and *M. tuberculosis* would avert the greatest number of global deaths associated with AMR. To determine a vaccine's effect on antibiotic use, Dr. Hasso-Agopsowicz estimated the amount of antibiotic usage that was vaccine avertible based on existing literature on antibiotic use for a given syndrome caused by a particular pathogen. Of the vaccines he analyzed, an *M. tuberculosis* vaccine would avert the most antibiotic used, at approximately 1.2-1.8 billion defined daily doses. Finally, Dr. Hasso-Agopsowicz estimated the vaccine avertible economic burden of AMR by conducting systemic reviews to understand the cost of treating resistant infections and linking those with vaccine profiles. This analysis indicated that globally, vaccines could reduce annual hospital costs by over an estimated $33 billion and that *Staphylococcus aureus* and *E. coli* vaccines alone would result in the largest annual hospital costs averted with estimates of $14.5 billion and $5.7 billion, respectively.

### *Discussion*

Stephen Rinderknecht, DO, asked if there was decreased antibiotic use in vaccine groups compared to placebo groups in clinical trials of RSV vaccines. Dr. Hicks explained that in a multinational study of the RSV vaccine given to mothers there was a marked reduction in antibiotic prescribing to infants born to mothers who received the RSV vaccine compared to those born to mothers who received placebo, even

though the infants did not receive the vaccine directly. Notably, when RSV was a leading pathogen, antibiotic use increased in younger children. She predicted that clinical trials for other vaccines considered for use in the United States would also reduce antibiotic prescribing. Dr. Hasso-Agopsowicz agreed with Dr. Hicks and explained that his model of vaccine impact on antibiotic usage predicted that an RSV vaccine would result in a significant reduction in antibiotic usage. In addition, he observed that rotavirus vaccines resulted in a significant reduction in antibiotic use in children under five in low- or middle-income countries (LMICs).

Daniel Hoft, M.D., Ph.D., noted that a pathogen with a broader impact that requires a longer treatment period may have a bigger effect on collateral damage of antimicrobial use compared to other pathogens, and asked whether this concept could inform which vaccines to prioritize. Dr. Hasso-Agopsowicz discussed additional criteria he evaluated that could inform vaccine prioritization: the pandemic potential of a pathogen, the number of remaining treatment options, the rate at which a pathogen is developing resistance, and the likelihood of no available treatment options for a pathogen in the next few years. For example, *Neisseria gonorrhoeae* has few treatment options remaining, so while it is not associated with high mortality, economic burden, or antibiotic use, it should be prioritized based on limited treatment options. Dr. Hasso-Agopsowicz also stressed accounting for the length of infection and treatment when prioritizing vaccine development; for example, *M. tuberculosis* requires six months of antibiotic treatment.

Dr. Plummer explained that ensuring equity of access is another challenge to consider when prioritizing product development. Introducing a new class of antibiotics worldwide may result in less usage oversight and different resistance selection measures. He emphasized the need to incentivize both vaccine development and improving access.

Dr. Hoft also asked Dr. Hicks whether antibiotic overuse rates differ between telemedicine and in-person visits, and if researching ways to minimize antibiotic overprescribing resulting from telemedicine visits should be a priority. Dr. Hicks indicated that while telemedicine did increase access to health care during the pandemic, the CDC saw instances of antibiotic use increasing only for specific conditions, notably pharyngitis. When the Intermountain Healthcare hospital system in Utah switched to telemedicine, antibiotic prescribing increased among pharyngitis patients because they were unable to access a routine test for group A *Streptococcus* infection. Dr. Hicks stated that access to testing is a universal challenge for telemedicine, and there are minimal tools to help physicians make decisions about antibiotic prescribing in that setting. She suggested collaborating with telemedicine organizations to develop standards for antibiotic stewardship. Dr. Plummer noted that PACCARB has extensively discussed how telemedicine impacts prescribing, and these discussions are available for viewing on their website. Antibiotic prescribing also impacts One Health, especially in veterinary medicine. He noted that beginning on June 11, 2023, all antibiotics in veterinary medicine transitioned to prescription-only from being available over the counter.

Robert Schecter, M.D., M.Sc., asked whether there were any indications that deferred or decreased immunization rates in the United States during the first years of the pandemic contributed to increased antimicrobial use. Dr. Hicks explained that early in the pandemic, antibiotic prescribing initially decreased and then rebounded in the later stages of the pandemic. This rebound could be related to decreased immunization allowing for increased transmission of pathogens or increased disease severity, but Dr. Hicks indicated that she is unsure how to measure this directly.

## Vaccines and the 100 Day Mission to End Pandemics

### *The 100 Days Mission to End Pandemics: CEPI Perspective—Melanie Saville, M.D.*

Dr. Saville discussed the Coalition for Epidemic Preparedness Innovation's (CEPI's) work across the entire vaccine ecosystem during the COVID-19 pandemic and their preparation for the 100 Days Mission. Typically, vaccine development can take decades, but the COVID-19 vaccine was released for EUA 326 days after the viral sequence was published. This quick response was due to prior research on related coronaviruses as well as decades of development of mRNA technologies. To support a global end-to-end initiative for COVID-19 vaccine development and fair allocation, CEPI co-founded COVID-19 Vaccines Global Access (COVAX). CEPI-led research and development resulted in a portfolio of 11 vaccines across four technology platforms. COVAX also supported the shipment of 1.8 billion vaccine doses, of which 1.5 billion went to 92 LMICs. COVAX supported the rollout planning process by developing National Deployment and Vaccination Plans (NDVPs).

To plan for the 100 Day Mission, CEPI and McKinsey & Company interviewed stakeholders across the vaccine ecosystem to understand the innovations that contributed to the rapid vaccine response during the pandemic and identify what further innovations were necessary for future rapid vaccine responses. This research suggested further compression of the timeline of vaccine development requires a paradigm shift that significantly front-loads preparedness metrics (e.g., scientific toolkit and infrastructure and policy readiness). Additionally, after 100 days continuous data generation is needed to ensure vaccine safety and efficacy.

To drive the paradigm shift, Dr. Saville outlined five key scientific and technological prerequisites: (1) preparation of vaccine libraries representing pathogens with the greatest pandemic potential; (2) development of global clinical trial, laboratory, and manufacturing infrastructure, addressed by CEPI investment in preclinical, clinical, and manufacturing networks in the Global South; (3) identification of biomarkers indicating vaccine efficacy prior to the traditional 14 to 21 day evaluation timeline; (4) optimization of the manufacturing process for rapid initial production and scaling needs; and (5) establishment of global surveillance and laboratory networks to track pathogens and outbreaks.

### *Vaccines and the 100 Day Mission to End Pandemics: IFPMA Perspectives—Thomas Cueni, M.S.*

Mr. Cueni leads the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), which represents the pharmaceutical industry, including the companies that developed and manufactured 80 percent of the vaccines used in the COVAX project. He highlighted the important role of collaboration in accelerated vaccine development within the first 100 days of a pandemic, emphasizing that the COVID-19 vaccine success was in part a result of multistakeholder collaborations. Building those partnerships and establishing research architecture prior to a pandemic will accelerate vaccine development.

During the pandemic, the companies that partnered were the ones that delivered the most effective products (e.g., BioNTech and Pfizer, Oxford and AstraZeneca, Moderna and Lonza). Mr. Cueni noted that these partnerships were between businesses that knew of each other and worked together prior to the pandemic, allowing them to resolve issues with technology transfer beyond simple technology licensing. IFPMA is committed to driving collaboration with key stakeholders in advance of the next pandemic by building a portfolio of promising candidate vaccines and treatments for diseases, strengthening global manufacturing and clinical trial infrastructure, and building on business-to-business agreements and voluntary and early licensing or technology transfer.

Mr. Cueni noted that inequitable rollout of the COVID-19 vaccines was attributed to an initial lack of COVAX funding and a failure to share manufactured vaccines with countries in need. Mitigating these

factors in future pandemics requires accelerated funding availability and preparation for low-income countries (LICs) to enable vaccine procurement. In addition, final products as well as raw materials should be imported and exported without restrictions and there should be sustained investment in a country's public health infrastructure so that it is prepared to respond to future pandemics. However, equitable vaccine access can occur only if all stakeholders agree to participate in the social contract to share vaccines.

### *Building Greater Resilience in Vaccine Manufacturing—Tania Holt, M.Sc. & Jennifer Heller, Ph.D.*

Dr. Heller and Ms. Holt discussed the results of a McKinsey & Company survey of key stakeholders to determine how to build a more resilient vaccine ecosystem in preparation for the next pandemic. These stakeholders included academics, policy makers, regulators, global public health organizations, and vaccine manufacturers. These interviews indicated that building a more resilient vaccine manufacturing system was critical to the 100 Days Mission. Dr. Heller outlined several steps to achieve this goal: define the metrics used to evaluate a resilient vaccine ecosystem; evaluate whether local manufacturing and regulations could meet metrics of a resilient vaccine ecosystem; identify gaps in the vaccine manufacturing ecosystem, such as accessing raw materials or clinical trial networks; foster connections across all stakeholders; ensure collaborations between countries; and incentivize vaccine development and manufacturing.

Ms. Holt noted that global manufacturing is critical to reaching the 100 Day Mission equitably. Prior to the pandemic, little was known about the state of manufacturing across the world, so ongoing post-pandemic evaluations are essential to determine the degree of vaccine manufacturing readiness. Her research identified three constraining factors when estimating the required capacity of an area to supply vaccine doses: proportion of usable manufacturing capacity, production experience of manufacturing facilities, and manufacturing scale-up capabilities. Countries may need to choose which vaccine platforms they can manufacture and which vaccines are accessible via partnerships with other countries. During this selection process, countries need to consider manufacturing scale-up capabilities as well as the ability to switch manufacturing between platforms and vaccines. Global and regional collaborations will increase the ability of countries to forecast vaccine demands and increase the transparency of supply chains so raw materials can flow more easily. Additionally, regional collaborations between countries will increase their purchasing scale, thus enhancing their collective bargaining power when vaccines cannot be manufactured in that region.

### *The Global Vaccination Initiative: Accelerating Global Vaccine Access and Demand—Kathryn Bolles, M.P.H.*

Ms. Bolles explained how the Rockefeller Foundation aims to address inequities and barriers to vaccine uptake in LMICs. Some of these barriers include lack of funding, insufficient workforce to deploy vaccines or meet logistical challenges, fragmented data infrastructure for tracking vaccine delivery, and multiple barriers preventing demand for and uptake of vaccines. This low demand prevented uptake of the COVID-19 vaccine in some LMICs where the supply was available; as of January 2023, only 25 percent of people in LICs have received at least one dose, compared to 63 percent of the world population who have completed the primary series.

The Global Vaccination Initiative was launched in 2022 to help LMICs achieve national vaccination targets for vulnerable populations and is currently operating in 14 different countries. The initiative aims to build regional and country networks, improve data systems, accelerate demand through evidence-based social and behavioral approaches (e.g., social media, home visits), influence public health institutions to adopt policies that increase uptake, and build the capacity of institutions to track and generate demand for health services. Some of the Initiative's successes include reaching 64 million people through online campaigns, training 900 journalists on vaccination science, providing $20.3 million in support, and

training over 6,000 health care workers. As an example of how citizens were reached, Ms. Bolles described a two-month campaign with a popular radio DJ in Kenya that resulting in increased vaccine uptake among the listening audience by 9 percent.

COVID-19 vaccination demand has been affected by the de-prioritization of COVID-19, precedence of other health priorities, funding constraints, insufficient data collection tools that result in underreporting of vaccines administered, waning vaccine supply, cold chain issues, and trust issues among hard-to-reach groups. WHO and the United Nations Children's Fund (UNICEF) promote integrating the COVID-19 vaccine into the national immunization program and other relevant health services to enhance vaccine demand. This integration needs to be inclusive, especially of underserved populations, and sustainable. Ms. Bolles described several examples of integration from different partners. In many countries, COVID-19 vaccination was delivered with other vaccines or as part of sexual or reproductive health services. Healthcare workers were trained to communicate about and deliver the vaccines alongside other services and to work with digital tools to track vaccine administration. Several countries also integrated COVID-19 vaccine data into other health information systems.

### *Discussion*

Dr. Hopkins commented that the 100 Day Mission is a starting point rather than an end point. He reiterated the presenters' comments in support of linking preparedness efforts spanning research, large-scale manufacturing, regulation, and vaccine delivery. There were no additional comments or questions.

## Preparing for Potential Approval of Passive Immunization Products

### *Preparing for Potential Approval of Passive Immunization Products—Georgina Peacock, M.D., M.P.H., F.A.A.P.*

Dr. Peacock indicated that the Immunization Services Division (ISD) at the CDC is closely watching developments in the use of nirsevimab for treatment of RSV. The group anticipates the FDA will make its final decisions related to licensure, and ACIP will provide recommended use instructions in Fall 2023. Depending on these decisions, HHS leadership may incorporate the drug into the Vaccines for Children (VFC) program and continues to discuss the nuances of working with a product that functions as both a therapeutic and immunizing agent.

### *Preparing for Potential Approval of Passive Immunization Products—Anne Edwards, M.D., F.A.A.P.*

Dr. Edwards discussed how the American Academy of Pediatrics (AAP) was preparing for use of nirsevimab in treating RSV in children, emphasizing the potential recommendations they would make to practices delivering the immunization. Although nirsevimab is a passive immunization, the FDA Center for Drug Evaluation and Research (CDER) considers it a drug rather than a vaccine, and this will directly impact Current Procedural Terminology (CPT) coding. Dr. Edwards stressed that classification of nirsevimab as a drug would restrict the use of vaccine administration codes that include a counseling component for families with questions about the immunization. Regarding storage and handling, Dr. Edwards noted that nirsevimab requires similar storage and handling to other vaccines, for which clinical practices are already equipped. However, because nirsevimab would be classified as a drug, potential state-to-state variability in which staff can administer it may result in staffing shortages and impacts to potential workflows.

Dr. Edwards indicated that demand for nirsevimab among pediatricians is unclear, especially as the price remains uncertain. She noted that, historically, insurance payment for new products lags behind administration, which may hinder initial use. Hospitals that deliver newborns may also use nirsevimab, but its incorporation into a bundled newborn care payment remains unclear. In addition, hospitals and

primary care clinicians need to coordinate follow-up appointments. Care coordination between mothers' and infants' records would also be critical if a maternal RSV vaccine becomes available.

Dr. Edwards also addressed the immunization environment and how it relates to pediatricians. Nirsevimab use may require patient counselling to combat substantial misinformation and disinformation regarding immunizations. However, increased parental vaccine hesitancy, workforce shortages, and fatigue has resulted in mental health crises among pediatricians. To address this, AAP has established a Task Force on Well-Being & Safety to support pediatricians.

### *Discussion*

Dr. Hopkins emphasized that regulatory and practice details about nirsevimab will evolve as the product progresses through the FDA regulatory process.

Molly Howell, M.P.H., asked about the potential role for IISs in recording and tracking doses of administered nirsevimab. Dr. Peacock explained that while it would be helpful if nirsevimab could be integrated into IISs, this may not be possible in some states because of its classification as a therapeutic rather than a vaccine. Dr. Edwards indicated that IIS integration would be preferable and indicated that AAP is planning for different scenarios.

Ms. Howell also asked whether nirsevimab injection may be administered seasonally, like the influenza virus vaccine, or if providers would use it year-round like a traditional vaccine. Dr. Peacock stated that a relevant working group suggested using the drug during RSV season, but the group may also recommend that infants receive it at a birthing hospital rather than an outpatient clinic. Nirsevimab will likely be approved midseason, so usage may differ between this upcoming RSV season and future RSV seasons, especially as uptake increases. Dr. Edwards noted that, post-pandemic, RSV season timing is not well defined and it may or may not return to its traditional seasonality. She indicated that because the drug may potentially be provided to a younger cohort of infants, clinics will need to be prepared to provide the product over a longer period.

Claire Hannan, M.P.H., indicated that AIM was working to notify immunization program managers about nirsevimab availability, and it would be helpful to know in advance if it will be added to IISs. She asked if nirsevimab will be included in the VFC program. Dr. Peacock stated that a conversation about VFC inclusion was happening in HHS, but further information was required from the FDA and ACIP.

Courtnay Londo, M.A., commented that not all IISs can capture administration of passive immunity products, as those products use different code sets than those traditionally used by IISs. Since EHRs are the primary source of IIS data and use the same code sets, linking EHRs and IISs will be critical. EHR products may have to be modified locally to use different codes.

Dr. Rinderknecht commented that the practical aspects of initial nirsevimab administration are complicated. Babies born between October and April will likely receive a birth dose at the hospital, and that will need to be communicated to different offices for appropriate follow-up. The compatibility of nirsevimab with a potential maternal RSV vaccine also remains unclear. He suggested that coordination between EHRs would be challenging, especially as babies not born during this season will require doses in subsequent seasons that may occur at a different time than a scheduled wellness visit. Dr. Hopkins suggested that an additional challenge is the relatively high mobility in society; families with young children will need personal records attached to them. Dr. Peacock commented that while there are no definitive answers to these discussion topics, decreasing complexity will make vaccine uptake easier. Dr. Edwards stated that AAP is considering the practical implications and obtaining input from experts on effective implementation, which will require clear and consistent communication.

Jeffrey Duchin, M.D., asked about the role of local and state health departments and resources in implementing passive immunization products, particularly nirsevimab. Dr. Peacock stated that these roles depend on the recommendation from ACIP and whether the drug would be included in the VFC program. If it is included, resources at the state and local level would use the VFC program to support nirsevimab rollout, but if it is not included then these roles are unclear. Dr. Duchin asked if there would be an increase in available resources if nirsevimab was included in the VFC program, but Dr. Peacock could not answer that question without further information.

## The Big Catch Up: Restoring Vaccination Rates

### *Recovering from the Unprecedented Backsliding in Immunization Coverage: Learnings from Country Programming in Five Countries through the Past Two Years of COVID-19 Pandemic Disruptions—Tosin Ajayi, M.D., M.P.H.*

Dr. Ajayi presented data from the Clinton Health Access Initiative (CHAI), which supports 15 immunization programs in different countries, regarding the state of routine vaccination post-pandemic. These countries experienced a sharp decline in immunization service coverage from 2020 to 2022. In addition, the number of children who had received zero doses (ZDs) of vaccines, as measured by uptake of the first dose of diphtheria, tetanus, and pertussis (DTaP) vaccine, increased by 37 percent, with 10 countries accounting for 62 percent of these children. Measles and HPV vaccine coverage also decreased compared to 2019 rates. Many of these decreases were driven by pandemic associated disruptions, as routine immunization was temporarily suspended in many regions and many people were unable to access health facilities. Countries also significantly repurposed financial and workforce resources to respond to COVID-19.

The Big Catch Up is the global drive to immunize approximately 67 million children to return to pre-pandemic vaccination levels. This initiative focuses on 20 countries that account for 78 percent of unvaccinated or ZD children worldwide. These countries have been tasked with building recovery plans to support vaccination rate catch up. To build program resilience, these plans need to encompass a short-term strategy as well as develop systems to support long-term vaccination. Short-term catch up requires vaccinating children under the age of two as well as those who have aged out of certain cohorts, and this can be achieved through targeted and selective multi-antigen vaccination campaigns, or the Periodic Intensification of Routine Immunization (PIRI) strategy, or supplementary immunization activities (SIAs) for single or multiple antigens, irrespective of an individual's vaccination status. To ensure long-term vaccination, health and non-health stakeholders should work together to establish vaccination schedules, ensure tracking of vaccination data, and implement school and daycare vaccination checks, among other activities.

Dr. Ajayi described an article she published in which she evaluated strategies from five CHAI-supported countries (i.e., Cameroon, Kenya, Nigeria, Uganda, and Cambodia) used to restore lost coverage. She examined vaccination frequencies, vaccine catch-up approaches, strength of health information systems to capture immunization coverage, synergism of routine vaccines with the COVID-19 vaccine rollout, mobilization of resources for sustaining immunization, and restructuring of health systems to build resilience. Moving forward, CHAI will continue to support countries in developing their vaccination recovery plans, updating their policies, and securing additional vaccines and resources to reach those missed because of the pandemic. To prevent backsliding of vaccination rates, countries need to focus on ZD children by prioritizing previously unreached communities and reducing opportunities for missed vaccination by leveraging all opportunities when children contact the health system.

### *CDC's Immunization Program: Improving Vaccination Rates—Georgina Peacock, M.D., M.P.H., F.A.A.P.*

Dr. Peacock outlined the work of the CDC's ISD in ensuring a high level of coverage against vaccine-preventable diseases by provisioning federal funds to purchase vaccines, offering technical support to immunization programs, providing education, and conducting research. Vaccination equity informs all of CDC's activities and programs, and the VFC program supplies over 50 percent of all vaccines for children in the United States. Current estimates indicate VFC has prevented 472 million illnesses, saved approximately $2.2 trillion, and has helped close vaccination gaps for Black or African American/Non-Hispanic children and adolescents. In addition to the VFC, the CDC uses multiple avenues to address gaps in routine immunization, including Section 317 and the Vaccines for Adults program. Section 317 of the Public Health Service Act authorizes federal purchase of vaccines for all age groups, and vaccines purchased through this mechanism have been directed toward priority populations, such as the uninsured. The Vaccines for Adults program has been proposed in the president's budget and does not currently exist. This program would expand access to routine and outbreak vaccines for adults, especially to 24 million adults who are uninsured.

The COVID-19 pandemic significantly disrupted routine immunization. Using CDC's Vaccine Tracking System, Dr. Peacock and colleagues observed a decrease in orders of VFC-funded, ACIP-recommended non-influenza childhood vaccines and measles-containing vaccines that began after the national emergency declaration. State-level aggregated data on vaccination status for school entry of kindergartners suggested there was a steady decline in national vaccination coverage among kindergartners for two school years in a row. While this coverage corresponds to 93 percent of kindergartners being vaccinated, this is the lowest vaccination rate in the last decade and amounts to approximately 250,000 children at risk for severe disease. Dr. Peacock emphasized that while vaccination rates remain high, the downward trend is concerning. Among adolescents, there was a 25 percent decrease in orders for several vaccines, including HPV, meningococcal ACWY (Men-ACWY), and tetanus, diphtheria, and pertussis (Tdap), in 2020. While many of these vaccine orders have rebounded, HPV orders remain 10 percent lower than pre-pandemic levels. Low adult vaccinations rates were worsened by the pandemic, but these rates were relatively low prior to the pandemic, with 75 percent of adults aged 19 and older missing at least one age-appropriate routine vaccine in 2019. Improving vaccination rates in adults and increasing overall vaccine uptake is a major goal for the CDC moving forward.

Dr. Peacock described several challenges and lessons learned from the pandemic that will inform CDC's future work. A significant challenge was communicating vaccine information to the public in a timely manner, especially when health guidance was complex and changing. To that end, CDC is optimizing its data collection and review, using plain language to communicate its findings, and redesigning its website so users can find current information more easily. CDC is also partnering with local organizations to vaccinate hard-to-reach populations (e.g., people who are homebound or cannot access transportation). Two additional challenges are vaccine confidence and vaccine fatigue, which require clear communication from trusted messengers like health care providers, as well as broader accessibility to vaccination.

The CDC has several initiatives and campaigns to address declines in vaccination. Let's RISE is one such initiative, which provides strategies, resources, and data to support catch-up with routine immunizations. The Let's Play Catch Up ads have also been reactivated to deliver catch-up messages through paid media channels with the aim of keeping routine childhood vaccinations top-of-mind among parents. This campaign will run through June 2023 in select markets. A Back-to-School/"Let's Catch-Up" campaign will also run nationwide from July to September. To increase adult vaccination rates, CDC is delivering a call to action to health care providers to deliver overdue adult vaccinations, as well as providing an easily accessible resource detailing when adults should be vaccinated. Dr. Peacock emphasized the key role

health care providers play in improving vaccination, as they are still seen as trusted messengers and can implement vaccination.

Dr. Peacock also described CDC's future COVID-19 vaccine implementation efforts, which are focused on collaborating with partners during vaccine commercialization, focusing on vaccine equity, and increasing vaccine confidence. Dr. Peacock noted that the CDC will continue to work with public and private partners to ensure a smooth transition as COVID-19 vaccines are commercialized this year. The COVID-19 vaccines will remain free for most U.S. residents through a combination of the VFC program, Children's Health Insurance Program, commercial insurance, Medicare, and Medicaid. As the federal government will no longer directly allocation vaccines to pharmacies, the Federal Real Property Profile Management System (FRPP MS) partnership will change after commercialization. However, CDC will continue to support pharmacies as critical vaccine providers.

### *Post-COVID Transition—Meredith Allen, Dr.PH., M.S.*

Dr. Allen introduced ASTHO and described the organization's members and mission. She acknowledged the success of the COVID-19 vaccine response, which resulted in vaccination of 81.4 percent of the U.S. population. She noted that building on the lessons learned during the pandemic will be important for increasing routine vaccination. Some of those lessons include increasing access to vaccines, continuing to partner with health and non-health related community organizations, finding trusted messengers and engaging them to serve as vaccine champions, and expanding use of IISs. In addition, engaging a wide health care provider community by broadening the group of potential immunizers should be an important consideration for future vaccination efforts.

Post-pandemic, the public has a heightened level of vaccine awareness. ASTHO conducted polling with Harvard University and the CDC to assess public perception of vaccination and determined that health agencies are still seen as trusted sources of vaccine information, despite discourse about loss of trust. However, COVID-19 vaccines and routine vaccines are perceived differently, as routine vaccines are viewed as safe by the public. The public has also increased discussion about personal and parental rights regarding both choosing to be vaccinated and choosing to exist in an environment free from preventable disease.

Dr. Allen suggested that routine vaccination should be a prioritized public health issue but acknowledged that state agencies must also address numerous other health issues impacted during the pandemic. In addition, the legislative landscape around vaccines has changed. In 2023, over 500 bills impacting vaccine access were introduced in state legislatures, though most were not enacted. While some of these bills increased vaccine access by expanding the scope of practice, many attempted to repeal vaccine requirements for school enrollment and prevent health departments from regulating those requirements.

### *The Big Catch Up: Restoring Vaccination Rates from a Local Health Department Perspective—Matthew Bobo, M.P.H.*

Mr. Bobo highlighted the work of NACCHO, which supports approximately 3,000 local health departments. NACCHO receives funding from the CDC and transmits that funding to local health departments to help them develop best practices to increase vaccine coverage rates. Some of their initiatives include coordinating immunization activities among county and city health officials, equipping local health departments to address vaccine hesitancy and build COVID-19 vaccine confidence, supporting local health departments in reducing disparities in adult immunization, and managing the Vaccine Access and Training (VAT) Project. Some NACCHO programs include building a ChatBot that answers COVID-19 vaccine questions, organizing meetings called Salons to discuss topics such as trust and civic engagement, and setting up the Shots at the Shop program in Baltimore to provide vaccinations at barbershops. In addition, they are building maps of vaccination rates in communities so local health departments can identify vaccine deserts.

### *Getting Back to Routine: Immunization Program Environment—Claire Hannan, M.P.H.*

Ms. Hannan represents AIM, which supports immunization programs in the jurisdictions of all 64 NCIRD awardees. Immunization programs have several mechanisms to access, deliver, and track vaccines, including Section 317, the VFC program, the COVID-19 vaccination program, and IISs. Ms. Hannan reported that since 2019, 66 percent of AIM jurisdictions (42 of 64 programs) have experienced turnover among program managers, noting that this resulted in many programs being managed by people with no management experience during a time that focused on routine vaccination. She also described how supplemental funding for immunizations from investments in COVID-19 vaccine programs was waning, and AIM was concerned about maintaining the gains made with this funding, especially among adult vaccination programs. She noted that Section 317 funding, which supports most routine vaccination, does not adequately fund adult vaccination programs.

Ms. Hannan noted that routine vaccination rates have rebounded post-pandemic, but children in pandemic cohorts still need some vaccinations, especially before they begin school. She reiterated many of Dr. Peacock's comments on the decline of coverage among kindergarten students and observed that these declines were also observed among children living below the federal poverty level and in rural areas. Ms. Hannan used data from North Dakota to illustrate nationwide trends in vaccine coverage. In North Dakota, the percent of children between 19 and 35 months old up to date on their vaccine doses had rebounded for most vaccine series, except the MMR vaccine. However, the percent of adolescents who were up to date had not rebounded as quickly, especially for HPV vaccination.

Ms. Hannan discussed several AIM strategies to promote routine vaccination catch-up. AIM's Reminder/Recall Program involved mailing postcards to families in 13 jurisdictions since 2019, resulting in a 6 to 26 percent increase in target vaccines. These postcards specifically targeted adolescents as their vaccine rate had rebounded less than it had for children. Ms. Hannan also discussed the 2023 AIM Vaccine Access Cooperative (VAC) Regional Meetings, which encompassed eight in-person regional meetings that focused on pediatric vaccination. These meetings brought together key stakeholders to address challenges in vaccine uptake. Some of the key themes from these meetings included the need to create school location vaccination clinics, target education to trusted health messengers (e.g., parents, nurses, providers), and utilize peer-to-peer education to improve vaccine confidence. In addition, stakeholders deemed continued engagement of pharmacists as important for promoting routine vaccinations, but laws allowing pharmacists to provide immunizations differ among jurisdictions.

### *Discussion*

Dr. Hopkins commented that successful vaccination programs require team effort that engages public health agencies, program managers, and communities. There were no additional comments or questions.

## Public Comment

No public comments were offered.

## Adjourn Meeting

Dr. Hopkins thanked the participants and adjourned the meeting at 2:30 p.m.

# Appendix A: Abbreviations List

| | |
|---|---|
| AAHI | Access to Advanced Health Institute |
| AAP | American Academy of Pediatrics |
| ACCV | Advisory Commission on Childhood Vaccines |
| ACIP | Advisory Committee on Immunization Practices |
| AE | adverse event |
| AHIP | Agency for Healthcare Research and Quality |
| AHRQ | Agency for Healthcare Research and Quality |
| AI | artificial intelligence |
| AIM | Association of Immunization Managers |
| AIRA | American Immunization Registry Association |
| AMA | American Medical Association |
| AMR | antimicrobial resistance |
| APhA | American Pharmacists Association |
| ASH | Assistant Secretary for Health |
| ASTHO | Association of State and Territorial Health Officials |
| BARDA | Biomedical Advanced Research and Development Authority |
| CDC | Centers for Disease Control and Prevention |
| CDER | Center for Drug Evaluation and Research |
| CEPI | Coalition for Epidemic Preparedness Innovation |
| CHAI | Clinton Health Access Initiative |
| CHIP | Children's Health Insurance Program |
| CICP | Countermeasures Injury Compensation Program |
| CISA | Clinical Immunization Safety Assessment |
| CMS | Centers for Medicare & Medicaid Services |
| COVAX | COVID-19 Vaccines Global Access |
| COVID-19 | coronavirus disease 2019 |
| CPT | Current Procedural Terminology |
| DHA | Defense Health Agency |
| DICP | Division of Injury Compensation Programs |
| DOD | Department of Defense |
| DTaP | diphtheria, tetanus, and pertussis |
| EHR | electronic health record |
| EMR | electronic medical record |
| EUA | Emergency Use Authorization |
| FACA | Federal Advisory Committee Act |
| FDA | Food and Drug Administration |
| FMAP | federal medical assistance percentage |
| FRPP MS | Federal Real Property Profile Management System |
| HAI | healthcare-associated infections |
| HHS | Department of Health and Human Services |
| HIE | Health Information Exchange |
| HRSA | Health Resources and Services Administration |
| HPV | human papillomavirus infection |
| ICS | Incident Command Structure |
| IDEAS | Immunization Data Exchange, Advancement and Sharing |
| IFPMA | International Federation of Pharmaceutical Manufacturers and Associations |
| IHME | Institute for Health Metrics and Evaluation |
| IHS | Indian Health Service |

| | |
|---|---|
| IIIHS | Innovation in Immunization Subcommittee |
| IIS | Immunization Information Systems |
| ILI | influenza-like illness |
| IPF | Immunization Partnership Fund |
| IRA | Inflation Reduction Act |
| ISD | Immunization Services Division |
| JPEO-CBRND | Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense |
| LGBTQIA+ | lesbian, gay, bisexual, transgender, queer, intersex, and asexual |
| LIC | low-income country |
| LMIC | low- or middle-income country |
| LRTD | lower respiratory tract disease |
| mAb | monoclonal antibody |
| Men-ACWY | meningococcal ACWY |
| MMR | measles, mumps and rubella Vaccine |
| MMWR | Morbidity and Mortality Weekly Report |
| Mpox | monkeypox |
| NACCHO | National Association of County and City Health Officials |
| NACI | National Advisory Committee on Immunization |
| NAICP | National Adult Immunization Coordinators Partnership |
| NAVFAC | Naval Facilities Engineering Systems Command |
| NCIRD | National Center for Immunization and Respiratory Disease |
| NDVP | National Deployment and Vaccination Plans |
| NIAID | National Institute of Allergy and Infectious Diseases |
| NIH | National Institutes of Health |
| NPHA | National Poll on Healthy Aging |
| NPHIC | National Public Health Information Coalition |
| OIDP | Office of Infectious Disease and HIV/AIDS Policy |
| ONC | Office of the National Coordinator for Health IT |
| PACCARB | Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria |
| PAVE | Partnering for Vaccine Equity |
| PHAC | Public Health Agency of Canada |
| PIRI | Periodic Intensification of Routine Immunization |
| PPE | personal protective equipment |
| PrEP | pre-exposure prophylaxis |
| PREP | Public Readiness and Emergency Preparedness |
| PTSD | post-traumatic stress disorder |
| RSV | respiratory syncytial virus |
| SIA | supplementary immunization activities |
| SOGI | sexual orientation and gender identity |
| STI | sexually transmitted infection |
| Tdap | tetanus, diphtheria, and pertussis |
| UNICEF | United Nations Children's Fund |
| USDA | U.S. Department of Agriculture |
| USPSTF | United States Preventive Services Task Force |
| VA | Department of Veterans Affairs |
| VAE | ventilator-associated events |
| VAERS | Vaccine Adverse Event Reporting System |
| VaST | COVID-19 Vaccine Safety Technical |
| VAT | Vaccine Access and Training |

| | |
|---|---|
| VFC | Vaccines for Children |
| VICP | Vaccine Injury Compensation Program |
| VRBPAC | Vaccines and Related Biological Products Advisory Committee |
| VSD | Vaccine Safety Datalink |
| VSS | Vaccine Safety Subcommittee |
| ZD | zero dose |

# Appendix B: VSS Recommendations

## Infrastructure

1. New and improved scientific advances should be continually applied to support the field of vaccine safety research and surveillance. Therefore, NVAC recommends Congress increase vaccine safety funding in the next budget and consistently thereafter to nimbly evolve along with both science and new vaccine recommendations.
2. The NVAC recommends the development of a coordinating group within HHS to host regular meetings with the goal of sharing information regarding vaccine safety surveillance, research results, new methods, and other findings relevant to informing vaccine safety science and public health policies.
3. Given the important role immunization providers play in communicating vaccine safety and immunizing people, the NVAC recommends the ASH conduct a series of listening sessions with a variety of immunization providers to learn of practical ways HHS can reduce their workload to support vaccine safety monitoring.
4. The NVAC also recommends that medical schools, nursing schools, healthcare worker training programs, and public health programs develop vaccine safety monitoring courses designed to improve understanding and ensure that all immunization providers are well versed in vaccine safety monitoring methods and existing safety surveillance systems.
5. The NVAC recommends HHS works with interdisciplinary programs at academic institutions to prepare a new generation of vaccine safety experts and support the educational needs of experts in the field.
6. To increase understanding of vaccine science, the NVAC recommends HHS work with the Department of Education to add educational modules to health and science curriculums in middle schools and high schools across the country.
7. The NVAC recommends HHS work with scientific, medical, and public policy groups to develop a robust community of experts who can mentor policy experts needing vaccine safety guidance.

## Research and Development

8. The NVAC recommends the NIH and other scientists in industry and academia continue to support basic research on underlying mechanisms behind known and suspected vaccine AEs and reactogenicity.
9. The NVAC recommends academics, researchers, and scientists continue to study the clinical signs and symptoms of specific immunological biomarkers, correlates of protection, and inflammatory responses to better predict, detect, and understand clinical symptoms or AEs.
10. The NVAC recommends continued research by NIH, and other scientists, to improve knowledge of adjuvants both benefits and increasing reactogenicity.
11. With the goal of more quickly identifying rare adverse events and developing appropriate vaccine recommendations to those with complex medical histories, the NVAC recommends HHS leaders meet to discuss ways to increase assessment of prototype vaccines in subpopulations, including expanding vaccine safety clinical trials to include more pregnant people, diverse races and ethnicities, people with comorbidities or compromised immune systems, and people with allergies.
12. The NVAC recommends the ASH meet with experts from the vaccine industry, the NIH, the FDA, the CDC, and academia in the next year to find innovative solutions to both expand vaccine safety activities to be more inclusive and to reduce the costs associated in executing large, diverse clinical trials.

## Vaccine Safety Monitoring

13. The NVAC recommends HHS maintain and strengthen all the current vaccine safety monitoring systems.
14. CDC and FDA should explore scalable solutions that reduce the time and effort required by clinicians to file reports with VAERS; these solutions might be semi-automated (such as auto populating fields on the VAERS reporting form).
15. CDC and FDA should apply appropriate considerations when conducting disproportionality analysis for a vaccine of interest.
16. CDC should expand the number of health care organizations participating in the VSD to increase VSD's ability to detect potentially statistically significant associations between vaccines and AEs that warrant further investigation.
17. CDC should consider working with partners to identify potential ways to increase enrollment and responses in V-safe.
18. Given the promise held by the development of v-safe in evaluating the safety of COVID-19 vaccines, the NVAC also recommends HHS use specific funding and resources to expand this system for newly approved or authorized vaccines.
19. Vaccine safety surveillance systems and partners should seek consensus on standardized case definitions for AEs after vaccination, including search strategies for specified AEs.
20. Global vaccine safety collaborations have become increasingly valuable in detecting rare vaccine AEs. Vaccine safety experts and public health leaders in the United States should continue to collaborate with national and international partners to investigate AEs and explore potential means of anticipating AEs after vaccination.
21. The NVAC recommends investing in methods that can rapidly identify and monitor for AEs or preliminary diagnoses, as well as provide reassurance when unexpected AEs do not occur.
22. Additionally, the NVAC recommends CDC invest to expand their use of syndromic surveillance of new vaccines and further integrate this approach into vaccine safety surveillance activities.
23. HHS should invest in new methodologies, including sequential analysis for rapid detection of signals, tree-based data mining for detection of unanticipated AEs, and real-time identification of pregnancy status that can allow timely assessment of vaccination safety during pregnancy.

## Optimizing Immunization Information Systems

24. The NVAC recommends CDC and ONC meet with state groups to assess their modernization and integration needs and provide federal funding to facilitate progress in using IISs to improve vaccine safety monitoring activities.
25. The NVAC recommends CDC and ONC work together to develop model legislative language to require a bidirectional data exchange with IISs to better track immunization and AE data.

## Reducing Vaccine Administration Errors

26. As such, NVAC recommends all people responsible for vaccine storage, handling, and administering vaccines regularly educate themselves on vaccine safety measures and preventive actions and follow precautions to minimize risk to prevent errors.
27. NVAC recommends all people who give vaccines take the CDC online training course, You Call the Shots, or equivalent training, once and then review and update each year.
28. Health systems, medical directors, and practice managers should encourage, track, and incentivize providers who invest in this training with annual reviews.
29. Health systems, medical directors, practice managers, and vaccine providers should educate the entire health care team on new vaccine products, administration guidance, and vaccine recommendations when they are updated.

30. NVAC further recommends that all vaccine providers promptly report vaccine administration errors to the VAERS and that these data are analyzed to improve patient safety in a continuous improvement cycle.

## Public Communication

31. As such, the NVAC recommends continued research in vaccine safety communication, and that federal, state, local public health agencies increase testing of messages with a variety of audiences or use tested vaccine safety messages when communicating to the public.
32. The NVAC also recommends increased funding and staffing for vaccine safety communications, so messaging that has been tested and reviewed for accuracy can be provided to groups communicating about vaccine safety in a coordinated and consistent manner.