NVAC NATIONAL VACCINE ADVISORY COMMITTEE

February 10-11, 2022, Virtual Meeting Minutes

Committee Members in Attendance

Robert H. Hopkins Jr., M.D., MACP, FAAP; Chair
Melody Anne Butler, B.S.N., RN, CIC
Timothy Cooke, Ph.D.
John Dunn, M.D., M.P.H.
Jeffrey Duchin, M.D.
Kristen R. Ehresmann, R.N., M.P.H.
David Fleming, M.D.
Leonard Friedland, M.D.
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.
Robert Swanson, M.P.H.

NVAC Ex Officio Members

Uzo Chukwuma, M.P.H., Indian Health Service (IHS)
Mary Beth Hance, Centers for Medicare & Medicaid Services (CMS)
Troy Knighton, M.Ed., Ed.S., LPC, Department of Veterans Affairs
Linda Lambert, Ph.D., Biomedical Advanced Research and Development Authority (BARDA)
Mary Rubin, M.D., Division of Injury Compensation Programs (DICP), Health Resources and Services Administration (HRSA)
Melinda Wharton, M.D., M.P.H. (for Sam Posner, Ph.D.), Centers for Disease Control and Prevention (CDC)

NVAC Liaison Representatives

Rebecca Coyle, M.S.Ed., American Immunization Registry Association (AIRA)
Amy Frandsen, MPH, National Association of County and City Health Officials (NACCHO)
Hana El Sahly, M.D., Vaccines and Related Biological Products Advisory Committee
Jean-Venable "Kelly" Goode, Pharm.D., BCPS, FAPhA, FCCP, American Pharmacists Association
Claire Hannan, Association of Immunization Managers (AIM)
Erin Henry, B.S.N., Public Health Agency of Canada
David Hrncir, M.D., San Antonio Military Medical Center
Kim Martin, M.Sc., Association of State and Territorial Health Officials (ASTHO)
Christopher Regal, M.S., America's Health Insurance Plans (AHIP)
Kerry Robinson, Ph.D., Public Health Agency of Canada

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

Ms. Aikin called the meeting to order at 1 p.m. ET and welcomed the participants. She briefly outlined the agenda and described key parts of the Federal Advisory Committee Act, its conflict-of-interest rules, and standards of ethical conduct for NVAC members. Ms. Aikin thanked the Office of Infectious Disease and HIV/AIDS Policy (OIDP) staff for their support in organizing the meeting and called the roll.

Opening Remarks—Admiral Rachel Levine, M.D., Assistant Secretary for Health (ASH), Department of Health and Human Services

ADM Levine said that she works every day as the ASH to improve the health and well-being of all Americans. Building a strong foundation for immunization is an important part of that goal. The National Vaccine Advocacy Committee (NVAC) provides the U.S. government (USG) with recommendations for achieving optimal prevention of human infectious diseases through vaccine development and gives direction to prevent adverse reactions to vaccines. In its first 35 years, NVAC developed recommendations and reports on a variety of topics, including supporting global immunizations, improving data exchange, and overcoming barriers to low vaccine uptake. In addition, NVAC convened multiple subcommittees that provided the government with sound science-based recommendations to address topical issues, including vaccine confidence, immunization equity, and COVID-19 vaccination. Likewise, NVAC established standards for both pediatric and adult immunization practices.

Public health officials and medical providers continue to respond to the COVID-19 crisis, protecting the public from a preventable illness and reducing the risk for spreading the SARS-CoV-2 virus that causes COVID-19. COVID-19 vaccines have a remarkable safety profile and are highly effective. NVAC and its associated organizations continue to support people in completing the series of vaccines and obtaining boosters when eligible to protect themselves, the people around them, their families, and their children, as well as any friends with compromised immune systems. ADM Levine is especially focused on building momentum toward increasing vaccine uptake. Vaccines do not accelerate progress as much as vaccinations do.

The COVID-19 vaccination program has met with incredible success in the United States. More than 535 million vaccine doses have been administered and more than 212 million people are fully vaccinated. However, distribution has not always been equitable, and future plans must center on health equity. ADM Levine was a member of the COVID-19 Health Equity Task Force that provided specific recommendations to President Biden to mitigate health inequities caused or exacerbated by the COVID-19 pandemic and to prevent such inequities in the future. The task force published its final recommendations report in October 2021. Based on these recommendations, tens of thousands of vaccination sites have opened across the United States. ADM Levine thanked the thousands of individuals and groups who have joined the COVID-19 Community Corps and have encouraged family members, friends, and people living in their community to get vaccinated. People interested in joining can do so by visiting the We Can Do This website.

NVAC has also tackled vaccine hesitancy, not only for the COVID-19 vaccine, but also for all immunizations across the lifespan. NVAC's Vaccine Confidence Subcommittee prepared a report to synthesize and summarize evidence and research, address vaccine confidence, and recommend new strategies and approaches to sustaining and increasing confidence in vaccines across the lifespan.

ADM Levine then swore in four new NVAC members: Jeffrey Duchin, M.D.; Jewel Mullen, M.D., M.P.H.; Stephen Rinderknecht, D.O.; and Winona Stoltzfus, M.D.

Chair's Welcome—Robert Hopkins, M.D., MACP, FAAP, NVAC Chair

Dr. Hopkins welcomed the participants to the virtual 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 September 14-15, 2021, 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 June 15-16, 2022.

NVAC Turns 35: Advancing the Vaccine System

The National Vaccine Advisory Committee History—Walter Orenstein, M.D., Emory University

NVAC was established as part of the National Childhood Vaccine Injury Act of 1986, which also implemented a no-fault vaccine injury compensation program, the National Vaccine Program, and the National Vaccine Program Office (NVPO, now OIDP). NVPO and NVAC coordinated the work of federal agencies involved in vaccination and immunization, from basic scientific research to vaccine development, delivery, and disease control. The second NVAC chair led the smallpox eradication effort for the World Health Organization (WHO). Facing a major measles resurgence between 1989 and 1991, NVAC provided the President with recommendations that led to the Childhood Immunization Initiative. NVAC further identified barriers to vaccination and offered potential solutions, such as creating standards for immunization practices and using federal funds to cover the cost of vaccine production and vaccination efforts.

NVAC seeks to (1) develop new and improved vaccines; (2) enhance the vaccine safety system; (3) enhance communications to inform vaccine decision-making; (4) ensure a stable supply of, access to, and use of recommended vaccines; and (5) recognize that global vaccination strategies are critical not only for humanitarian interests but also for domestic health security. To achieve these goals, NVAC has developed numerous recommendations, including the 1994 National Vaccine Plan, the 2010 National Vaccine Plan, the Section 317 Immunization Grant Program, and the Vaccine Confidence Working Group. For more detail and a more comprehensive list, Dr. Orenstein referred attendees to Dr. Kimberly Thompson's publication on the history of NVAC at its 30th anniversary.

Public-Private Partnerships: Sustaining the Research, Development, and Delivery of Vaccines for All—Amy Finan, Sabin Vaccine Institute

Public-private partnerships (PPPs) have been valuable during the COVID-19 pandemic because they can adapt more rapidly than public institutions; however, these partnerships must be remodeled for sustainability in non-crisis times, particularly to benefit people in low- and middle-income countries (LMICs) who are disproportionately impacted by both endemic disease and health crises. PPPs can future-proof economic and global health security against emerging infectious diseases and threats by distributing risk amongst multiple stakeholders, who commit to sharing diverse assets, infrastructure, and capabilities, and are especially valuable for developing vaccines against diseases primarily endemic in LMICs (i.e., vaccines of limited commercial interest or unincentivized vaccines). PPPs traditionally include stakeholders (i.e., governments, pharma, biotech companies, investors, philanthropy, nongovernmental organizations, and academia) mostly based in or representing high-income countries. To achieve the greatest success, they should recruit the same types of organizations from LMICs, particularly for increasing vaccine acceptance from LMIC residents.

Four well-known PPPs working in the vaccine and disease control space are (1) Gavi, the Vaccine Alliance, which has helped vaccinate nearly half the world's children, (2) Biomedical Advanced Research and Development Authority (BARDA), which has supported Food and Drug Administration (FDA) approval and licensure of 61 products, (3) CEPI, which has funded the development of more than 20 vaccine candidates against priority pathogens, and (4) the National Institutes of Health (NIH), which funds and guides early-stage research. PPPs serve essential and unique roles within different stages of the vaccine ecosystem. Upstream partnerships foster innovation, driving the vaccine agenda and advancing vaccine candidates. Downstream partnerships may advocate for inclusion of a vaccine in national routine immunization schedules or in a large-scale immunization program. PPPs are also critical to building trust and acceptance of vaccines in LMICs. Specific vaccines that have benefited from the involvement of PPPs include the RTSS vaccine against malaria that was recently recommended for broad use by WHO; universal influenza and HIV vaccines that are in development; and vaccines against multiple strains of Ebola that are either licensed or entering clinical trials.

Global Vaccination Efforts—Alejandro Cravioto, M.D., DTPH, Ph.D., University of Mexico, SAGE, WHO

The ability of HHS to promote the health and well-being of U.S. citizens depends in part on other countries, as observed whenever infectious diseases cross borders. Travel restrictions instituted early during the COVID-19 pandemic were ineffective against preventing millions of deaths globally. However, the immediate collaboration of research groups across the globe and the willingness to rapidly share research and tools (e.g., publications of drug and vaccine development) were critical to mitigating the disease's damage. Resource sharing and the rapid development of disease surveillance tools facilitated crucial vaccine and drug development. Funding of large-scale projects by countries such as the United States enabled companies to produce vaccines rapidly so that they were available immediately upon authorization and recommendation. Globally, 12 vaccines for SARS-CoV-2 are now either in use or under review.

However, vaccine availability has been uneven and inequitable. The COVAX initiative established by Gavi and UNICEF has supported many countries' efforts to launch their vaccination programs, regardless of financial compensation. Supply is expected to increase,

which will improve vaccine distribution and enable countries to request vaccines according to needs and population size. Reliant on donations from vaccine-rich countries, the COVAX initiative has not been able to meet its coverage goals to date.

Health policies seek to increase resiliency during public health crises, but most policies have failed when put into practice during the COVID-19 pandemic, because they do not consider personal factors (e.g., health, demographics) and relationships between individuals and with governments. Trust in government and fellow citizens, as well as beliefs about government corruption, have been more relevant to the effectiveness of vaccines to reduce the case fatality rate in 171 countries than many of the interventions established to address the COVID-19 pandemic. More so than other interventions, health promotion to modify risks and community investment to increase trust have been associated with a reduction of COVID-19-related deaths and thus should be prioritized among pandemic preparedness measures.

Strong international leadership and a single health policy are needed to ensure global health. Preparedness requires the support and financing of international organizations such as WHO, because parallel national organizations may only increase bureaucracy and decrease the efficiency necessary to confront and control future pandemics.

Past, Present, and Future Vaccine Challenges—Kathryn Edwards, M.D., Vanderbilt University

At NVAC's inception in 1983, only three pediatric vaccines were routinely provided: diphtheria/tetanus/pertussis vaccine (DTP), oral polio vaccine, and measles/mumps/rubella (MMR). Since then, another 11 vaccines have been added to the routine pediatric schedule, resulting in many positive outcomes. However, neonatal deaths from sepsis and pneumonia remain common, and preventing these deaths requires maternal vaccinations to facilitate transplacental antibody transfer. Opportunities exist for NVAC to increase its role in promoting maternal vaccinations.

Recent advancements during the COVID-19 pandemic have facilitated development of new vaccines, for example mRNA and viral vector vaccines. Researchers and medical providers rely on vaccine safety monitoring systems to track unexpected adverse events (e.g., thrombocytosis) related to new vaccines. For example, the Vaccine Adverse Event Reporting System (VAERS) receives many reports of temporally correlated adverse events without regard to causation in order to detect signal of potential adverse effects. Vaccine Safety Datalink (VSD) provides near real-time datalinks and databases with precise metrics of vaccines administered and adverse events reported. The Clinical Immunization Safety Assessment (CISA) national network of vaccine safety experts, medical research centers, and other partners provides a comprehensive vaccine safety public health service to the nation. One system, V-Safe, was launched specifically for SARS-CoV-2 vaccines and has been critical to uptake in pregnant people. However, the ability of these systems to inform providers and the public about SARS-CoV-2 vaccine safety and effectiveness has been challenged by the rapidly emerging variants that resist existing vaccines and booster doses (e.g., Delta, Omicron) as well as by the natural waning immunity of the vaccines themselves.

Vaccine hesitancy is not equally distributed across the population. For example, only 45 percent of Black or African American individuals have received at least one dose of a SARS-CoV-2

vaccine, compared to nearly 70 percent of American Indian and Alaska Native individuals. Further, vaccine uptake has been lower in southeastern states than in northwestern and northeastern states. The most common reason for vaccine refusal is concern about side effects; thus, NVAC should strive to recruit messengers to better communicate the rarity of side effects and to reassure the public that all severe side effects are evaluated by experts.

NVAC Turns 35: Looking to the Future—Robert Hopkins, M.D., MACP, FAAP, NVAC Chair
NVAC's work beyond its 35th anniversary will be shaped by four driving themes: innovation, vaccine equity, vaccine confidence, and collaboration. Innovation is critical in the search for and development of safe and effective vaccines against known and potential vaccine-preventable diseases. NVAC should encourage innovative research to develop and optimize adjuvants, vaccine delivery platforms (e.g., microneedle or needle-free delivery systems, mucosal or topical immunization), and technologies that evade cold-chain delivery. Innovation is strengthened by collaborations across the globe, as was clearly exhibited during the SARS-CoV-2 pandemic.

The pandemic has also highlighted the issue of vaccine equity—that is, the provision of safe and effective vaccines to all people in need to maximize their benefits in a healthy society. NVAC efforts toward vaccine equity will focus on restoring routine vaccination lost to the pandemic, minimizing missed opportunities in childhood vaccination, and addressing access and coverage gaps.

NVAC can help to enhance vaccine confidence by communicating true and reliable information about vaccines and vaccination to the public in an evidence-based manner and by labeling misinformation and false rhetoric as such. NVAC can help the general population to learn that vaccination is important and that safe and effective vaccines are available. NVAC must address the growing challenge of vaccine hesitancy and support collaborations to address the impact of anti-science and anti-vaccine misinformation in communities, media, and social media.

To achieve these goals, NVAC will leverage the expertise of OIDP staff, the broad representation of NVAC members across public health, academia, and industry, and its partnerships with agencies across the United States and around the world. Dr. Hopkins closed by stating that NVAC's meetings should remain open to the public and that public comments help to guide the NVAC's work.

Discussion
Timothy Cooke, Ph.D., noted that the COVID-19 pandemic has dramatically expanded the funding landscape for vaccines and has influenced vaccine modality innovation. In addition, Dr. Cooke praised NVAC for its response to the pandemic.

David Fleming, M.D., asked which issues important to immunization intersect with the issues that NVAC can influence. Drs. Orenstein and Hopkins agreed that NVAC should continue to focus on vaccine implementation, increasing vaccine confidence, reducing barriers to vaccination, and increasing support for adult immunization. Making NVAC recommendations more accessible requires collaboration with state and local health departments to increase publicity.

Dr. Duchin asked how NVAC could support local health departments that are integrating vaccine confidence, access, and acceptance into efforts to address community health needs. Dr. Hopkins responded that these concerns intersect neatly with recent discussions about the best way to frame messaging about the heavy burden of COVID-19 hospitalizations and deaths on people with chronic diseases. Rather than focusing on the burden, that messaging should focus on reducing the impact of disease through prevention, including not only vaccination but also addressing of social determinants of health.

Protecting the World Through Immunization

Addressing Global Immunization Disruptions: Recovery and Resilience—Anita Shet, M.D., Ph.D., Johns Hopkins University

The global coverage of a third dose of DTP or DTaP (DTP3) increased steadily between 1980 and 1990 before plateauing. In 2009, global coverage was 83 percent; in 2019 it was 86 percent. However, the 2020 global coverage of DTP3 was 83 percent—a loss of 10 years of progress in a single year. Most countries experienced some routine vaccination disruption during the COVID-19 pandemic, with a large drop in immunization services during the first half of 2020 and partial recovery of these services in the second half of 2020. However, recovery has been uneven with two vaccines: DTP3 and MMR. Reported reasons for immunization disruption include public fears about disease transmission, restrictions during severe lockdowns, health facility closures, health care worker shortages, supply chain disruptions, and health facility reassignment to COVID-19-care only. Based on those observations, a team consisting of researchers from WHO, Gavi, UNICEF, the Johns Hopkins Bloomberg School of Public Health, and others agreed upon several specific actions to increase and sustain immunization progress, including:

- Focus on catch-up vaccinations for children who had missed routine vaccines.
- Strengthen health immunization information systems (IIS).
- Ensure resource mobilization from global agencies and also from local sources.
- Leverage the SARS-CoV-2 vaccine rollout, which established valuable systems.
- Establish best practices to build health system resilience around the world.

Vaccine campaigns are also critical strategies, especially for vaccines against diseases for which reducing transmission depends on filling immunity gaps (e.g., measles and polio). Efforts to eradicate polio are under way; the disease is now endemic only to Pakistan and Afghanistan. Another disease that public health officials hope to eradicate through widespread vaccination is measles, which showed a long decline in cases before an increase starting in 2017 and a large outbreak in 2019. Incidence rates have again declined since; however, 22 million children have missed their first dose of a measles vaccine. Both facility-based immunization programs and outreach-based immunization programs have faced disruptions during the pandemic, particularly those that have historically vaccinated more vulnerable populations. As a USG committee, NVAC is primarily focused on domestic concerns, but it must also attend to global and distant regions for the following reasons:

- Immunization contributes to community immunity.
- Pathogens do not respect international boundaries.
- Pathogens evolve and may escape immunity.

- Vaccination is a useful strategy for reducing the risk of antimicrobial resistance development.
- And many vaccine-preventable infections have pandemic potential (e.g., Dengue and Japanese encephalitis).

Dr. Shet referred attendees to the Immunization Agenda 2030 for further information.

Antipoverty Vaccines for Neglected Tropical Diseases—Peter Hotez, M.D., Ph.D., Baylor College of Medicine

Neglected tropical diseases (NTDs) are classified as diseases that are highly prevalent among individuals with low income, ancient diseases described in ancient texts, typically chronic and disabling rather than fatal, stigmatizing, and poverty promoting. Initially, this classification consisted primarily of diseases that were endemic to rural areas of low-income countries; however, these diseases have become more common in urban areas. Historically, pharmaceutical companies have limited their research and development on these diseases because they are complex targets without obvious financial returns. Among the 20 currently recognized NTDs are intestinal roundworm, hookworm, and schistosomiasis. Most people who live in extreme poverty have at least one of these conditions. Dr. Hotez and his team established a program that will ship donated medicines for mass treatment of NTDs until vaccines are developed; to date, this program has treated 200 million individuals each year.

Yet, prevention is preferred to treatment. Dr. Hotez co-heads the Center for Vaccine Development at Texas Children's Hospital, where researchers strive to develop vaccines against schistosomiasis, hookworms, Chagas disease, and leishmaniasis. One vaccine targets both hookworm and schistosomiasis, which are major causes of anemia, inflammation, and impaired child growth and productivity, and have significant epidemiologic overlap in sub-Saharan Africa and the poorest areas of Latin America. A recent vaccine in clinical trials to prevent schistosomiasis showed promising results in Phase I and Phase II clinical trials; however, the extensive funding required for Phase III trials has not been secured and production at industrial scale warrants further consideration. Through a partnership called HOOKVAC, the team developed a bivalent vaccine against hookworms that has completed Phase I clinical trials, and it is now planning a path toward Phase III trials. The team has also developed a Chagas disease vaccine that is entering clinical trials in New York.

The team also developed a COVID-19 vaccine that is genetically engineered in yeast or bacteria and produced via microbial fermentation. Microbial fermentation is inexpensive ($1.90 per dose), is considered Halal, and uses a process already used to produce recombinant Hepatitis B vaccines around the world. This vaccine can address the COVID-19 vaccine equity gap and support vaccination of the African continent and Southeast Asia. This vaccine was licensed with no patents, and the team transferred ownership to developing country vaccine manufacturers. Upon production on an industrial scale, the companies own the vaccine and must manage regulatory plans independently. The vaccine was released for emergency use in India, and 250 million doses have been produced, with rapid progression toward 1 billion doses.

Digitalizing Routine Immunization and Personal Immunization Cards as WHO SMART Guidelines—Garrett Mehl, WHO

In 2020, WHO member states endorsed a 5-year Global Digital Health Strategy focused on collective actions to support international digital health system transformation. The strategy is designed to facilitate data exchange through digital health approaches that rely on interoperability standards, the importance of security and privacy of health data, equitable data-sharing for research, and citizen access to their personal health records in digital formats. Countries invest heavily in digital health systems to optimize and address persistent challenges with implementing guidelines for clinical and public health interventions however; translation and operationalization of digital tools is extremely challenging for most countries, resulting in few digital systems with up-to-date recommended WHO algorithms. In 2021, WHO published its SMART guidelines for optimizing country-level use of it guideline recommendations in the digital age, alongside derivative products focused on digitalization and interoperability of routine information systems. SMART guidelines consist of knowledge layers to support all stakeholders in the digitization process.

The first knowledge layer, Layer 1 (Narrative), provides guidance for personal home-based records including immunization documents. This layer enhances traditional guidelines, such as routine vaccination schedules, with unique identifiers to track recommendation updates. nenprovides. Layer 2 (Operational) translates narrative guidelines into a digital adaptation kit whose components include workflow, diagrams, data for collection, decision points, priority performance monitoring indicators, and health worker functionalities. Full development of this kit may take months or years; WHO aims to provide 80 percent generic content to enable countries to focus on 20 percent adaptation. Layer 3 (Machine Readable) translates the Layer 2 components into computable and interoperable content with structured logic, data requirements, and calculations mapped to the International Classification of Diseases and Health Level Seven (HL7)/Fast Healthcare Interoperability Resources (FHIR) standards. Layer 4 (Executable) manifests guidelines in a point-of-care software application that can be integrated into a country's digital health system and deployed in the field. This layer can also lead to the development of reference software, which not only enables backend data management but also enables patients to retain their own records. For example, the vaccination record sets the foundation for an internationally recognized personal record that could also document, for example, lab test results, risk factors, and allergies to support continuity of care. Standardized health content with consistent metadata enables reuse of data captured in clinical workflows for secondary purposes, such as the patient-mediated exchange of personal health records, including decision support and adverse event reporting, without concerns that any new system will not be able to read their records. Traveling patients will be supported by an inter-operable digital network supported by consistent metadata and digital health solutions with consistent standards.

Discussion

John Douglas, M.D., asked Dr. Hotez about his team's ability to meet the existing or future need for COVID-19 vaccines given the approaches employed. Dr. Hotez answered that the feasibility of Phase III trials decreases as more people are immunized or infected. In addition, placebo controls become unethical, necessitating superiority studies. WHO has yet to determine exactly what should happen with next-generation COVID-19 vaccines and continues to request large placebo-controlled Phase III trials.

Daniel Hoft, M.D., Ph.D., asked Dr. Hotez which factors most contributed to his team's success in developing vaccines against NTDs. Dr. Hotez stated that maintaining a consistent team over time has been important. Funders, however, must be diversified, which is difficult to achieve because they tend to be deterred by the long timeframes for vaccine development.

Robert Schechter, M.D., asked whether the vaccine hesitancy prompted by COVID-19 vaccination has increased hesitancy toward routine vaccinations. Dr. Shet said that, although this question could not be answered with certainty, current evidence does not suggest that hesitancy toward COVID vaccines transferred to routine vaccines.

Rebecca Coyle, M.S.Ed., observed that digital health practices have faced political resistance within the United States because they use QR codes, and some jurisdictions prohibit generation of health cards from IISs. She asked the panelists whether WHO has observed this issue in other countries, and if so, whether that concern is restricted to vaccines. Dr. Mehl noted that these digital records often serve to identify the source of the vaccination, and thus often appear where countries and jurisdictions have established international agreements—for example, within the European Union and the East African community. Some states in the United States have also chosen to use these records. One group working within the United States to facilitate COVID certificates across states is the Verifiable Credentials Initiative, which will also aid international travelers.

Leonard Friedland, M.D., noted that between January 2020 and July 2021, Americans missed an estimated 37 million more of their recommended vaccines than during 2019.

Data Digest: COVID-19 Vaccination Effectiveness

COVID-19 Incidence and Death Rates by Vaccination Status During Periods of Delta and Omicron Variant Emergence—Commander Heather Scobie, Ph.D., M.P.H., CDC
Previous reports of COVID-19 case, hospitalization, and death rates by vaccination status indicated that protection against infection and serious COVID-19 illness for some groups declined with the emergence of Delta due to waning vaccine-induced immunity. Thus, CDC recommended additional primary COVID-19 vaccine doses for immunocompromised patients and booster doses for people aged 18 years and older. By December 25, 2021, the Omicron variant accounted for 72 percent of all sequenced SARS-CoV-2 samples.

CDC evaluated COVID-19 incidence and death rates among unvaccinated and fully vaccinated adults with and without booster doses during the periods of Delta and Omicron variant emergence. CDC analysts used weekly case, death, and incidence rates to estimate vaccine effectiveness. They found that rates of COVID-19 cases and deaths were lowest among people fully vaccinated with a booster dose, higher in people without a booster dose, and much higher in unvaccinated people. Unvaccinated people had 14 times the risk of COVID-19 infection during the pre-Delta period compared to fully vaccinated people. They also had 9 times the risk of infection during Delta emergence, 5 times the risk during Delta predominance, and 3 times the risk during Omicron emergence. Finally, unvaccinated people had more than 15 times the risk of COVID-19-associated death before and after the emergence of Delta.

This analysis has several limitations. Because of lags in reporting death data, the influence of Omicron on COVID-19-associated deaths by vaccination status in December 2022 could not be

evaluated. Additional doses in immunocompromised people and booster doses could not be distinguished. Further, the analysis lacked multivariable adjustments, and causality could not be determined. Other factors (e.g., prevention behaviors) may partially explain the differences in rates between groups. In addition, the analysis used national variant prevalence estimates for all localities. Temporal changes, as well as testing or reporting, may have affected trends. Finally, the data represent only 62 percent of the overall U.S. population. Still, the data strongly suggest that all individuals should obtain booster doses per recommendation.

Associations Between County-level Vaccination Rates and COVID-19 Outcomes Among Medicare Beneficiaries—Ben Sommers, M.D., Ph.D., Lok Wong Samson, and Wafa Tarazi, HHS

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) conducted a study to identify associations between the county-level vaccination rates in early 2021 and COVID-19 infections, hospitalizations, and deaths among Medicare fee-for-service beneficiaries within the first 5 months of the COVID-19 vaccine rollout. The study defined county-level vaccination rates as the proportion of people in each county who were fully vaccinated according to CDC data, divided into two age groups: aged 18-64 years and aged 65 years and older. The study team used Medicare claims from January to May 2021 to identify a cohort of 25.3 million Medicare fee-for-service beneficiaries, and conducted analyses with complex covariates (e.g., hospitalization, secondary, underlying comorbidities, demographic characteristics, and local county characteristics). To capture COVID-19 outcomes in 2020, prior to the availability of vaccinations, the study team developed a model using Medicare claims beginning in September 2020. These analyses found an association between higher county-level vaccination rates and reduced risk of COVID-19 outcomes in Medicare beneficiaries. Results suggested that high vaccination rates for adults aged 18-64 were protective against severe outcomes in Medicare beneficiaries, independent of vaccination rate among adults over age 65. Vaccinations were associated with 107,000 fewer infections (i.e., 18 percent reduction), 43,000 fewer hospitalizations (i.e., 21 percent reduction), and 18,000 fewer deaths (i.e., 22 percent reduction) in the study cohort. States with higher vaccination rates had greater reductions in COVID-19 outcomes, and the greatest benefit of additional vaccination occurred in states beginning with lower vaccination rates.

Among racial and ethnic groups, American Indian and Alaskan Native Medicare beneficiaries experienced the greatest percentage reduction in COVID-19 outcomes (25 percent) due to vaccination. Because White beneficiaries comprised 81 percent of the study cohort, the largest reductions in negative COVID-19 outcomes by number were observed in this group due to vaccination. The study found that vaccination was associated with 5,600 fewer deaths among long-term nursing home residents, who are also at high risk of COVID-19 outcomes. ASPE plans to update this analysis using data from the second half of 2021 to assess population-level effects of rising vaccination rates amid the Delta and Omicron surges. In addition, the study team will include state mitigation effots, mobility data, vaccination rates in nursing homes, and interaction effects between vaccination rates and subgroups. Finally, the study team aims to estimate the savings to Medicare from the reductions in hospitalizations.

Discussion

John Dunn, M.D., M.P.H. commented that the research presented informs vaccine confidence messaging strategies by identifying groups that would most support public health. In addition, he requested access to the ASPE reports.

Dr. Mullen noted that Texas and Hawaii were not included in the ASPE analysis because county-level data were not available and pondered how such data could be made available for future analyses. She also asked about the completeness of available race and ethnicity data. Dr. Samson stated that Medicare data are relatively complete in terms of race and ethnicity data, but imputation methods exist to improve data quality where needed.

Dr. Duchin praised ASPE's work and expressed enthusiasm for its plan to extend the analysis into the second half of 2021. In addition, he asked about the differential effect observed between "fully vaccinated" and "fully vaccinated and boosted." In the Medicare dataset, those data could not be analyzed. Dr. Scobie noted that a strong differential effect between the two cases was observed in her study, which will be published on the CDC COVID Data Tracker. However, the primary differential effect remains for hospitalization rather than infection. Data on reductions in deaths during the Omicron period will soon be available. Dr. Duchin added that a national discussion about the purpose of the vaccination program—that is, to reduce severe outcomes or to reduce infections—may be necessary.

Prohibiting Discrimination in COVID-19 Vaccination Programs—Lisa Pino, OCR, HHS

In December, the HHS's Office of Civil Rights (OCR) issued guidance to ensure equity in the distribution of COVID-19 vaccines in adherence with Title VI of the Civil Rights Act of 1964 and Section 1557 of the Affordable Care Act. Recipients of federal funds (e.g., state and local agencies, hospitals, and health care providers) must adhere to these civil rights tenets. Nonetheless, years of systemic discrimination have contributed to longstanding health care disparities and have been a driver of disparities in COVID-19 infections, hospital admissions, and death rates, particularly among people of color. Policies and practices with discriminatory effects must be eliminated. OCR has received complaints alleging that some covered providers are not meeting legal obligations to make information accessible to people who do not speak English (e.g., by not translating material or not providing interpreter services), which may indirectly discriminate against people based on national original or race. As another example, a vaccination program that requires online registration and is designed to distribute vaccines only at pharmacies could limit vaccine access to communities of color who live in pharmacy deserts or experience the digital divide.

To ensure an equitable pandemic response and recovery, President Joseph Biden issued Executive Order (EO) 13995 in January 2021 to guide the administration's efforts to mitigate the health equities caused or exacerbated by the COVID-19 pandemic and to prevent such inequities in the future. The EO requires federal agencies to assess pandemic response plans and policies through a civil rights lens and to determine, for example, whether personal protective equipment, COVID-19 tests, vaccines, therapeutics, or other resources are allocated equitably. The EO also mandates that agencies strengthen enforcement of anti-discrimination requirements pertaining to the availability and access to COVID-19 care and treatment. OCR's December guidance also offers many best practices for increasing access to and equity in vaccine programs. As HHS's

civil rights law enforcement agency, OCR has a particularly important role in ensuring that equity is at the center of all its enforcement efforts.

Towards a Vaccinated Workforce

The Role of Employers in COVID-19 Vaccination—Emily Gee, Center for American Progress
Employers can promote safer workplaces through a variety of means. Vaccine promotion is critical, but employers can also help to improve vaccine access by providing on-site vaccination clinics or transportation to offsite locations and paid time off for vaccination and for recovery from side effects for both employees and dependents. Employers can also address vaccine hesitancy by providing educational materials at work, as well as incentives to workers (e.g., monetary rewards) and customers (e.g., discounts) to encourage vaccine uptake throughout the community. In addition, employers may require vaccination for workers and for customers. Regardless of approach, employers can increase equity of vaccination uptake by combining requirements and incentives with improved access and ensuring that workers have good information from trusted messengers.

Workplace-based initiatives for COVID-19 vaccination support both the workplace and public health. From the employer and employee perspective, such initiatives protect the health of customers, patients, students, and children who may not yet be vaccine eligible and supports community health and economic activity. From the policymaker and public perspective, such initiatives raise population vaccine rates and level the playing field for business activity and the labor market.

Approximately two-thirds of the U.S. population has been fully vaccinated and 40 percent has been boosted. However, many workers who provide essential goods and services remain unvaccinated (e.g., 22 percent of hospital staff, 22 percent of childcare workers). Although vaccination requirements are appropriate for all workplaces, mandates are particularly critical in four settings: health care, schools and childcare settings, high-risk facilities (e.g., meat processing plants, groups homes, shelters), and first responders/essential workers in contact with unvaccinated individuals.

Employers disagree on whether mandates aid or hinder employee retention. However, respondents to an employer survey by Willis Towers Watson indicated that 71 percent of employers with vaccine mandates did not experience increased turnover and only 4 percent did. Among respondents, 33 percent were concerned about losing employees if a vaccine mandate were implemented, but 50 percent believed that a mandate could help recruit and retain employees. In workplaces with mandates, greater than 90 percent of employees have been vaccinated.

Vaccinating the Workforce—Lorraine Martin, National Safety Council
The National Safety Council (NSC) is focused on reducing preventable death and injury related to the workplace, and it has recognized COVID-19 as the most important workplace safety hazard in recent years. To prevent COVID-19 infection among its employees, NSC has worked remotely for approximately 100 weeks and has promoted vaccination. Business has become the world's most trusted institution, and, as such, business leaders should support employees as they learn how to protect themselves from COVID-19. Businesses can reach approximately 157

million Americans with safety- and health-related information, including on vaccination and other countermeasures.

NSC supports vaccine requirements and mandates. If vaccinations cannot be required, workplaces should use risk-based approaches focused on high-risk environments and utilize incentives and other tools to encourage vaccination. At workplaces with employer encouragement, 73 percent of workers received at least one COVID-19 vaccine, compared to 41 percent of workers at workplaces without employer encouragement. NSC achieved 100 percent vaccination and lost less than 1 percent of its staff as a result of its vaccine requirement. As COVID-19 becomes endemic, employers can continue to protect their employees by setting vaccine requirements for in-person events, reduce barriers to vaccination, reduce barriers to using sick time, and upgrade ventilation.

Toward a Vaccinated Workforce—Michelle Hood, American Hospital Association
Throughout the COVID-19 pandemic, the American Hospital Association (AHA) has distributed print material to members, physicians, and clinicians about the different vaccines available. It has supported its more than 5,000 member hospitals and health systems in their efforts to contact communities and trusted community leaders to improve COVID-19 vaccine messaging, as well as to create pop-up vaccination sites. Fundamentally, AHA has focused on providing individualized support to members because many one-size-fits-all strategies fail. In addition, AHA's vast communication network facilitates replication of ideas that may succeed at other member sites. AHA also worked with the White House Response Team to standardize approaches to vaccination at various points in the care continuum—for example, offering vaccination to patients entering emergency departments and educating patients and their families about vaccine safety and importance throughout recovery and at discharge.

Nonetheless, frontline health care workers are too overwhelmed with patient care to focus on vaccine messaging. Therefore, AHA started to build partnerships with other groups to improve communication strategies; for example, AHA partnered with the National Urban League to identify contacts within the African American population and UnidosUS to identify trusted vaccine spokespeople within the Hispanic American population. AHA leveraged its longstanding relationship with CDC to increase vaccination rates by focusing on building trust, empowering health care workers, and creatively engaging communities in ways that reflect and respond to community and culture. Through this effort, AHA recruited 43 frontline official ambassadors to communicate COVID-19 talking points, science, information, guidance, and best practices to their communities. AHA encouraged clinics and hospitals to contribute to social media and multi-channel media messages and encourages creativity in information sharing. AHA has also hosted several webinars that are directed to different audiences—including educating clinicians to be spokespersons—and community events supporting layperson community educators. AHA has shared some its best practices for community outreach, with a focus on local organization. Finally, AHA focused on collecting data on vaccine hesitancy, which will support tailored messaging in the future.

Discussion
Dr. Duchin asked whether changing perspectives on the greatest benefit of COVID-19 vaccines (i.e., preventing severe disease instead of preventing infection) may change employers' or policymakers' decisions regarding mandatory vaccinations. Ms. Martin suggested that changing

perspectives may complicate messaging; however, employers should communicate that they not only want to avoid their employees becoming ill but want to continue the employment relationship should they become ill anyway. Dr. Gee added that, although more breakthrough infections occurred during Omicron, businesses learned that even mild variants have the potential for major economic disruption and thus should support vaccines that *may* reduce the chance of preventing infection.

Dr. Mullen asked how NVAC can support broadening workplace vaccine incentives (e.g., adding influenza vaccination requirements). Dr. Hood stated that all AHA member hospitals maintain an influenza vaccine mandate and that greater than 50 percent mandate COVID-19 vaccination. Ms. Martin noted that flu vaccine clinics have become common, but flu vaccination is largely voluntary outside of health care. NSC and the Occupational Safety and Health Administration (OSHA) have discussed a standard approach to infectious disease prevention for all workplaces. Dr. Gee added that vaccine politicization and state legislation prohibiting COVID-19 vaccination requirements may extend to non-COVID-19 vaccinations. However, other tools (e.g., education) remain available.

Dr. Duchin asked how employers have responded to requirements for booster dose documentation. Ms. Martin noted that because CDC defines "fully vaccinated" as including the primary series only, most employers do not require boosters and capturing booster dose data has been challenging. She noted that changing the definition would benefit her organization. Dr. Gee noted that her organization requires booster doses, and some states require boosters for health care workers.

Dr. Duchin also asked about promotion of more holistic approaches to improving COVID-19 safety (e.g., improved ventilation). Ms. Martin answered that OSHA, NSC, and National Institute for Occupational Safety and Health support improved ventilation and have issued guidelines for employers. Dr. Gee suggested that employers should also increase paid sick leave, which would promote staying home when infectious. In addition, she promoted fostering a culture in which remote work is possible and removing the stigma around not working when ill.

Public Comment

Theresa Wrangham, Executive Director of the National Vaccine Information Center (NVIC), noted that her organization's co-founders worked with Congress to pass the 1986 Act that created the National Vaccine Advisory Commission, so that when Americans choose to vaccinate, they are vaccinating with the safest vaccines possible. She noted that NVAC's comments on vaccine hesitancy aligned with many highlights from Institute of Medicine reports relating to adverse event causality and the prevention of adverse events, and she added that these comments belied a lack of research being done today, which is a huge reason for vaccine hesitancy. Ms. Wrangham stated that because COVID-19 vaccines are vaccines with emergency authorizations, they have not gone through the same safety testing measures as a regular vaccine and that this causes concern.

Ms. Wrangham expressed disappointment that the presentation by OCR did not state that Title VII and Title I protects unvaccinated-by-choice employees from discrimination and that these Titles require that such employees be allowed reasonable accommodations. She added that NVIC has received many complaints from individuals that felt harassed to get vaccinated and forced to

choose between a job and a vaccine, which NVIC argues is coercion, discrimination, and a violation of human rights. While NVIC supports access to vaccines and believes that those who want to vaccinate should not face any barriers (e.g., language, financial), NVIC also maintains that choice is necessary, because vaccines are not entirely without risk. Ms. Wrangham also noted that—while VAERS is a passive system—it is receiving a historically high rate of reports associated with COVID-19 vaccines. Ms. Wrangham emphasized an importance to studying each report not only against the background population, but at the bench to discern any associations to vaccines and to potentially include these reported events on the Vaccine Injury Table for compensation.

Adjourn

Dr. Hopkins thanked the participants and OIDP staff and recessed the meeting for the day at 5:39 p.m.

Day Two

Chair's Welcome—Robert Hopkins, M.D., MACP, FAAP, NVAC Chair

The meeting resumed at 1:00 p.m. on February 11, 2022. Dr. Hopkins summarized the proceedings of day one and reviewed the agenda for day 2.

Correlates of Protection

Urgent Need for the Immunocompromised—Samantha Finstad, Ph.D., National Cancer Institute

A correlate of protection (CoP) is a measure of an immune response related to protection against infection or disease. CoPs allow researchers and clinicians to identify a minimum threshold at which they can predict protection against a given disease. At a population level, CoPs provide insight into public health measures, such as when vaccine boosters or prophylactic (i.e., disease prevention) strategies may be needed. To identify CoPs, data such as longitudinal serum measurements are critical; such studies appeared early during the COVID-19 pandemic, often funded by the National Cancer Institute (NCI). These studies followed healthy cohorts as well as immunocompromised patients (e.g., cancer patients, transplant recipients, and autoimmune disease patients) to identify CoPs of COVID-19. One challenge to identifying CoPs is that they may differ between people whose immune reactions are caused by infection as opposed to vaccination. Immune reactions may vary based on vaccination timing, variants of concern, mucosal immunity, cellular or T-cell immunity, and ratios of binding to neutralizing antibodies. CoPs may also differ between healthy people and immunocompromised people.

Researchers often first test antibodies as potential CoPs because they are easy to measure and have been successfully implemented as indicators of immunity against other diseases. Phase III vaccine studies indicated a correlation between two types of antibodies (neutralizing and binding) and protection against severe COVID-19; however, no specific threshold could be identified. Another potential CoP for COVID-19 is functional T cell and antibody effector functions, which may help to control disease severity. However, these functions currently cannot be measured easily because existing assays are specialized, labor intensive, and costly. Finally, many vaccine efficacy trials collected serology measurements, and although measurements were

not standardized, the National Serology Standard can be used to standardize these measures and enable direct comparisons between studies.

Because of the differences in immune response between individuals with and without compromised immune systems, most Phase III vaccine studies exclude immunocompromised patients. Patients may be immunocompromised for several reasons, and a CoP identified for one group of immunocompromised patients may not fit another. However, immunocompromised patients more frequently experience severe outcomes from infection. Therefore, study of the quality and durability of the immune response in immunocompromised patients (e.g., cancer patients) is critical. Cancer patients often lack a robust immune response; however, in one study, cancer patients showed measurable T-cell immune response to COVID-19 vaccination, even in the absence of a robust antibody response. Furthermore, patients with higher T-cell counts were more likely to recover from COVID-19, suggesting that T-cell immunity facilitates recovery from COVID-19. Further research is necessary to support immunocompromised patients through the COVID-19 pandemic, as well as to provide guidance to clinicians on whether these patients should receive additional or higher vaccine doses, additional or alternative treatment, or prophylactic monoclonal antibody treatment. These patients may also require special guidance regarding social distancing and mask-wearing.

Research Findings on Correlates of Protection and Implications for Boosting Protection—Kizzmekia Corbett, Ph.D., Harvard University

When patients first received marketed COVID-19 vaccines, they exhibited strong antibody responses; however, those responses declined dramatically over time in an age-dependent manner (i.e., patients above age 55 experienced a greater decline in antibody response than those under age 55). In addition, antibody effectiveness decreased with the emergence of new SARS-CoV-2 variants. Many experiments support the addition of a booster dose to the COVID-19 vaccine series, which could also overcome waning immunity or failure to respond appropriate to new mutations.

Dr. Corbett's team used a non-human primate (NHP) model to understand SARS-CoV-2 vaccine-relevant immunogenicity. The NHPs received both the initial Moderna mRNA COVID-19 vaccine series and a booster dose 6 months later. As in humans, antibody responses decreased over the 6 months following the initial two doses. After administering the booster, the team observed an increase in the antibody response beyond the peak observed after the initial series. Notably, this response increased against the wild-type virus (i.e., the initial variant that emerged in China in late 2019), but also against other variants of concern available for testing (e.g., Delta). A recent preprint supported these data for Omicron. In addition, regardless of receiving the booster or only the initial two-dose series, the vaccinated NHPs were largely protected against severe disease and cleared SARS-CoV-2 virus from the lower respiratory tract and lung within 4 days of infection with the Beta variant. However, the virus was not cleared from the nose.

Vaccine dose escalation studies utilizing a challenge design provided a means of identifying potential CoPs for SARS-CoV-2 in NHPs. Results suggested that higher vaccine doses correlated with greater antibody responses. Notably, the level of protection required for the lower airway protection differed from the level (e.g., lung) required for the upper airway (e.g., nose). To evaluate antibodies as CoPs, researchers extracted antibodies from NHPs and transferred them

into a hamster model. The researchers found that antibodies from vaccinated NHPs were sufficient to protect hamsters from symptomatic infection.

To test the durability of immunity after two doses of a COVID-19 vaccine, Dr. Corbett's research team conducted a challenge study using the NHP models 1 year following a regular two-dose vaccine series. Regardless of booster status, NHPs cleared the virus in the lower airway within 4 days of infection. Notably, although the most relevant CoP measurement shortly after vaccination appears to be antibody levels, these CoPs do not apply after 1 year, indicating that CoPs may change over time.

Efforts to Identify Correlates of Protection for USG-sponsored COVID-19 Vaccines—Christopher Houchens, Ph.D., HHS Coordination, Operations, and Response Element Immune Assays Team

The HHS Coordination Operations and Response Element (H-CORE), formerly known as Operation Warp Speed, was initially established to accelerate the process to clinical combat SARS-CoV-2. To support the USG's vaccine development efforts, H-CORE's Immune Assay Working Group aimed to identify CoPs for each vaccine developed under H-CORE. Generally, developing vaccines involves large, randomized, placebo-controlled, Phase III clinical trials lasting more than 6 months and tens of thousands of subjects. However, a robust CoP can shrink the sample size and shorten the study length while accurately predicting vaccine efficacy, a critical component of vaccine development. Notably, smaller studies are inherently more likely to occur when other vaccines are commercially available during study recruitment; thus, CoP identification is immediately valuable.

To identify correlates for USG-supported COVID-19 vaccines, the Immune Assay Working Group built a network of labs to develop assays for testing samples from participants vaccinated during Phase III trials. Labs used the samples to establish correlates between antibody levels in vaccinated and unvaccinated individuals and monitored participant infection status for several months. The team will follow the subjects for up to 2 years to establish individual vaccine durability and CoPs against evolving variants. Because the USG-supported vaccines have included three distinct platforms (i.e., mRNA, viral vector, and recombinant protein-based vaccines), the Immune Assays Working Group expects rich datasets regarding CoPs associated with different vaccine types. These CoPs, identified for a diversity of vaccine types, will support more rapid evaluation of next-generation COVID-19 vaccines.

H-CORE has published potential CoPs for the Moderna vaccine, Spikevax. Patients with the highest antibody levels 4 weeks after the second dose were least likely to have symptomatic COVID-19 infections over the next 4 months. However, vaccinated people with the lowest antibody levels were less likely to be infected than unvaccinated people, implying that this CoP does not fully account for the mechanism of this vaccine—it was estimated to explain about two-thirds of the protective effectiveness and is judged useful for future vaccine evaluation.

Discussion

Dr. Hoft asked about the existence of any NHP research studying mucosal vaccination, which may provide protection against upper airway replication and viral transmission. Dr. Corbett stated that some studies are in progress, but results are not yet available. Dr. Hoft also asked whether T cells are sufficiently protective in an NHP model to defend an animal against potential

reinfection after depletion of antibody-producing B cells. Dr. Corbett stated that causing B-cell depletion is technically challenging in NHPs; however, some data support the importance of anamnestic T cells (i.e., T cells that remember a previously contracted virus) to these responses. Dr. Finstad added that measuring T-cell CoPs is difficult in humans because of the variety of T-cell types, but studies are under way.

Dr. Hoft asked whether vaccination had been studied in B-cell-deficient people. Dr. Finstad noted that NCI and Albert Einstein College of Medicine researchers are pursuing research regarding immune response kinetics in patients with B-cell depletion.

Dr. Duchin asked when a commercially available assay may exist to provide reliable evidence of immunity in people with prior COVID-19 infection. Dr. Houchens answered that current research has not been directed toward developing a commercially usable tool. Dr. Duchin also asked how the results of CoP testing may influence dosing schedules of COVID-19 vaccines (e.g., number of doses or timing of doses). Dr. Houchens stated that population-based studies should answer whether COVID-19 vaccine schedules should adapt for people with prior infection, and, if so, how the adaptation should be implemented.

Dr. Schechter asked whether CoPs can be generalizable to new and emerging variants. Dr. Corbett noted that immune responses that neutralize SARS-CoV-2 typically target the spike protein's receptor binding domain (i.e., how the virus enters cells and causes infection). Evolutionary adaptations lead new variants to avoid antibodies that target that region of the spike protein quickly. In addition, Dr. Corbett stated, although titer measures are useful indicators, they should never be considered as reliable thresholds for individuals.

Dr. Cooke asked whether any formal mechanism exists for collaborating with FDA, given that CoPs will be added into the regulatory processes. Dr. Houchens stated that the H-CORE Immune Assay Working Group meets weekly with FDA to discuss issues of study conduct and statistical analysis.

Expanding Immunization Information Exchange

Interoperability to Support Public Health—Micky Tripathi, Ph.D., M.P.P., National Coordinator for Health Information Technology, HHS

The Office of the National Coordinator for Health Information Technology (ONC) coordinates federal government agencies and collaborations between those agencies and the private sector to create a nationally interoperable, open, standardized infrastructure for clinical data exchange. ONC certifies electronic health records (EHRs) used by greater than 95 percent of hospitals and 80 percent of ambulatory providers. Certified EHR systems share a set of standardized data elements (e.g., demographic variables that facilitate health equity research) to improve interoperability between health care providers. For example, a company called HL7 standardizes reports of lab results to be delivered across the country in structured documents. Interoperability will be further improved by a new standard called FHIR that focuses, in part, on enabling customizable, app-based, health information and record access. ONC has requested that every health system have a FHIR-compliant app available by the end of 2022. This move would also enable ONC to make EHR systems accessible to authorized entities (e.g., patients).

By increasing health record interoperability, ONC has created an environment in which public health officials can accurately compare records from multiple sources. For example, USG has not endorsed a standard for vaccination credentials during the COVID-19 pandemic, but private-sector vendors and health care organizations independently developed a standardized interoperable vaccination credential that aligns with ONC guidelines for EHR systems. In addition, ONC and CDC jointly launched an FHIR accelerator that directly applies FHIR standards to public health use cases. ONC is also working with HL7 to identify use cases for FHIR to improve public health interoperability and develop a nationwide public health data model. Lastly, ONC is working with CDC to develop a cloud-based data governance structure to support public health research and management.

Immunization Data Sharing Partnerships During COVID-19: Lessons Learned and Future Directions—Katie Greene, M.P.P., Duke University

Immunization Information Systems (IISs)—or immunization registries—serve to record immunizations. IISs are regulated and governed at the state, territorial, or local level. IISs benefit patients in accessing their own immunization records, which may otherwise be challenging if those immunizations occurred in other jurisdictions. In addition, IISs can increase vaccine uptake by informing trusted health care communicators (e.g., school nurses, home-based care organizations) about the vaccine status of their communities. Functioning IISs also support vaccine manufacturers and regulators by providing access to real-world data, enabling better evaluation of safety and effectiveness and thereby supporting rapid vaccine development in the next pandemic.

The COVID-19 pandemic catalyzed public health and health care provider partnerships, leading to investments in IIS infrastructure and capacity. One such partnership, Maryland CRISP (Chesapeake Regional Information System for Our Patients), launched a vaccine tracker service that enables health care providers to access a list of their patients with associated vaccination status and also provides summary reports on the vaccine status of their patients by age, race, geography, or chronic condition. Data-driven partnerships also emerged between state IISs, state Medicaid programs, and managed care entities. Ohio and Michigan have used such collaborations to encourage patients to seek vaccination, and Medicaid programs have used the newly available data to set quality benchmarks for how well Medicaid plans vaccinate patients against COVID-19.

Challenges to IIS bidirectional data sharing include differing state-level laws and regulations governing data sharing and technical challenges. For example, during the COVID-19 pandemic, these systems have received a tenfold increase in queries, which has stressed old and underdeveloped systems. Although ONC has begun supporting transition to cloud-based services, the transition will take time to complete.

Future State Strategy for IIS—Lynn Gibbs-Scharf, MPH, National Center for Immunization & Respiratory Diseases

The United States has 64 individuals IISs, all of which were leveraged to support decision making during the COVID-19 pandemic. Prior to the pandemic, no national database of immunization data was available, despite long-term foundations developed on local and state levels. During the COVID-19 pandemic, IISs began to provide daily updates on COVID-19 vaccinations and detailed information across local, state, and federal public health organizations.

These organizations have also incorporated data from pharmacies and other commercial partners to develop a complete impression of COVID-19 vaccination coverage across the United States.

These successes have also highlighted additional opportunities for improvement, such as standardizing systems and processes for all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines. The immunization community has long promoted standardized data exchange, and the standards must evolve with technology to reduce limitations in analysis (e.g., incomplete data, lack of bandwidth). To facilitate improved exchange and linkage for both routine immunizations and future public health emergency immunizations, IISs need to be improved, modernized, and evaluated for sustainability. No system can function on technology alone; IISs require a large, prepared workforce that can evolve with the rapidly changing pace of technology and data analytics. CDC has established several immediate priorities to support improved IISs as part of its Vaccines for Children program. It will continue to improve data quality by providing resources, such as the IIS Data Quality Blueprint, expanding the use of technologies such as privacy preserving record linkage tools, and improving data sharing via CDC's Immunization Gateway.

Vaccine Administration Standard—Rhonda Facile, CDISC

The Clinical Data Interchange Standards Consortium (CDISC) aims to streamline the flow of data and identify pathways to transition real-world data sources to submission datasets in order to accelerate FDA review and approval of new treatments, biologics, and medications. CDISC standards are required for submissions to the U.S. and Japanese regulatory agencies and are preferred but not required for submissions to China's regulatory authority. These standards ensure the accessibility, interoperability, and reusability of data to improve the meaningfulness and efficiency of research. CDISC provides specific standards to several fields (e.g., virology) and subfields of research. Notably, CDISC developed and released provisional standards for COVID-19 research data by adapting a core set of vaccine research concepts.

CDISC then applied its experience with data submission standards to the development of a digital vaccine administration record. In collaboration with the Learning Health Community, CDISC drew guidance from European health guidelines and focused on a core set of 20 data elements, including the data necessary for facilitating interoperability across international mobile applications (e.g., vaccine batch and lot number). These data often included personally identifiable patient information (e.g., names, addresses) for which CDISC had no standards for incorporating. Thus, CDISC drew from HL7's existing data standards for personal patient information. Although not yet implemented, multiple app developers have contacted CDISC about using this approach.

Expanding Immunization Information Exchange—Rebecca Coyle, American Immunization Registry Association

Although IISs have improved dramatically in recent years and serve a valuable purpose, older IISs would benefit from technical, operational, and policy improvements. Critically, older IISs should transfer to Cloud-based operating systems; those that already have transitioned report an increase in capacity and functionality. In addition, IISs must adapt to enable bulk queries (i.e., accessing immunization records for many patients simultaneously from one IIS). However, to reduce the likelihood of overwhelming the primary system with massive bulk queries, IISs should also expand data lakes and data warehouses, which function as secondary databases or

parallel environments with near-real team data updates that large entities (e.g., payers, health systems) can access. These updates may necessitate improvements to technical onboarding processes for providers. Technologically, many IISs have added new capabilities over time without addressing critical infrastructure or committing the investment needed to maintain systems on an ongoing and long-term basis. These adaptations are especially important as new types of providers (e.g., skilled nursing facilities), which may have different standards for EHRs, request access to IISs.

IISs also require operational upgrades. Staffing increases would enable IISs to better respond to requests for access and to onboard and educate new partners. Additional staff are also needed to use and analyze the data in innovative and functional ways. Further, some parts of the IIS workflow could benefit from automation. One of these parts may be onboarding and connecting with EHRs at different medical facilities. Some facilities may already have access to their jurisdictional IIS and be unaware of this access due to programming complexities. However, operations must also be able to clearly communicate who is not authorized to have access to IISs.

Recent policy changes have impacted IISs. The COVID-19 vaccine is the first vaccine that the USG has required mandatory provider reporting, leading to large increases in quantity and quality of data in IISs. These increases have greatly improved public health officials' understanding of real-time experiences of the pandemic within the United States. However, data sharing can and should be further improved. Although CDC's Immunization Gateway is a valuable tool, federal partners do not always report their data. The availability and quality of these depend on the submitters. A national commitment to develop uniform, harmonizable data would greatly improve IIS and Immunization Gateway functionality.

Discussion
Dr. Howell noted that many state IISs began to encounter difficulty with accessing funds for maintenance and interoperability, particularly from by Medicaid, which will require remediation from CMS.

Dr. Dunn asked how NVAC can facilitate preparations for IISs and thereby close the remaining gap in U.S. immunization practices. Dr. Coyle suggested that NVAC should advocate for policy standardization regarding IISs.

Vaccine Safety

COVID-19 Vaccine Safety Technical Work Group: Safety Assessment—Robert Hopkins, M.D., MACP, FAAP, NVAC Chair

The Vaccine Safety Technical Work Group (VaST) seeks to:

- review, evaluate, and interpret post-authorization/approval COVID-19 vaccine safety data,
- serve as the central hub for technical subject matter expertise from federal agencies conducting post-authorization/approval safety monitoring,
- advise on analyses, interpretation, and presentation of vaccine safety data,
- and provide updates to the ACIP COVID-19 Vaccines Work Group and the entire ACIP on COVID-19 vaccine safety.

These data sources include both U.S.-based and international passive and active surveillance systems (e.g., VAERS, VSD) and the Global Advisory Committee on Vaccine Safety. VaST has conducted several special evaluations. For example, since the September NVAC meeting, VaST revisited and reviewed reports of thrombosis with thrombocytopenia syndrome. This review led VaST to recommend preferential use of mRNA vaccines due to indications of a stronger correlation and more evidence for a causal relationship between the Janssen vaccine and the thrombosis events. In addition, VaST has extensively discussed the occurrence of myocarditis following mRNA COVID-19 vaccination and found that VAERS and VSD reports both indicate high chances of hospitalization with rapid recovery following vaccine-induced myocarditis. The data also indicate that adolescents and young adults are at low risk of myocarditis from mRNA COVID-19 vaccines, and the myocarditis resulting from vaccination is clinically mild.

VaST also conducted two additional data reviews. The first was a review of the VAERS reports for the nearly 26 million doses of mRNA vaccine booster doses and 334,000 Janssen booster doses administered. The Spikevax booster was more reactogenic according to this dataset than the Pfizer-BioNTech booster (i.e., Comirnaty), regardless of initial vaccine series. From this review, VaST determined that the adverse events of interest after booster doses occur at similar or lower rates than after dose two and that the safety profile of booster doses is encouraging. VaST also reviewed safety data on more than 7.1 million doses of Comirnaty administered to children aged 5-11 years. Based on V-Safe, VAERS, and VSD data, VaST determined that data regarding vaccination in this age group are encouraging. Adverse events of interest appear similar to or less frequently in this population than in older children.

COVID-19 Vaccine Safety Updates: Primary Series in Children 5-11 Years—Anne Hause, Ph.D., MSPH, CDC

As previously noted, VAERS reports can be submitted by any individual regardless of the plausibility of the vaccine causing the reported event, meaning that reporting cannot determine causality but can support rapid detection of safety issues and rare adverse events. As of February 6, 2022, nearly 15 million doses of COVID-19 vaccines had been administered to children aged 5-11 years. VAERS had received 6,564 reports, with a median age of 8 years. Of these reports, 97 percent were for non-serious adverse events, reflecting rates both for COVID-19 vaccines and all vaccines. The most commonly reported non-serious adverse events were related to vaccine administration—which was expected given that this age group was the first to receive the smaller dose of mRNA vaccine—however, most of these administration errors did not cause any adverse events. Common clinical outcomes included expected systemic reactions to mRNA vaccines and syncope (i.e., temporary loss of consciousness), a common side effect among adolescents following any vaccination. Some serious clinical outcomes reported to VAERS were consistent with myocarditis, of which 14 were verified to meet CDC definition of myocarditis, with a median age of 9 years and a median time to onset of 3 days. As of the last follow-up, all children were discharged to home and 10 had fully recovered. This case count of myocarditis amounts to fewer than 1 case per million doses administered.

V-Safe is a voluntary smartphone-based safety surveillance system with which a parent or guardian can complete regular health surveys following their child's receipt of any dose of any COVID-19 vaccine, regardless of the parent's own participation in V-Safe. As of February 6, 2022, 48,000 children enrolled through V-Safe had received Pfizer-BioNTech COVID-19 vaccinations. Reactions occurred more commonly after Dose 2 and were generally mild to

moderate. However, data were not yet available for Dose 2 for 20 percent of participants. At the beginning of vaccine rollout, approximately 20 percent of vaccine recipients participated in V-Safe, and participation decreased over time. Further, participation among children aged 5-15 years is only about 1 percent. To promote V-Safe participation by parents for children in this age group and in the 6 months to 4 years age group, clinicians should verbally direct parents to visit the V-Safe website or provide V-Safe information sheets, preferably prior to vaccination.

COVID-19 Vaccine Safety in Context—Grace Lee, M.D., MPH, Stanford University
Vaccine experts encounter multiple challenges when communicating vaccine safety to the public. COVID-19 vaccine safety surveillance has been extremely intensive, including passive surveillance and active surveillance. Integrating data from multiple systems with unique populations and differing capabilities comes with several challenges, but also enables experts to rapidly identify potential safety concerns. Some systems may capture certain patient populations more effectively than others, and differences in data types, population sizes, reporting, and outcome definitions may influence findings and cause variations in conclusions. This variation may be especially challenging for communicators (e.g., researchers, public health officials, clinicians, lay vaccine advocates) to clarify. Communicators may also experience difficulty clarifying that any safety signals detected require further evaluation before conclusions are drawn.

Vaccine safety is often understood as a balance of benefits and risks. National discussions typically focus on preventing deaths, hospitalizations, and symptomatic infection due to COVID-19, and balancing the risks of adverse events following vaccination. However, as specific adverse events (e.g., myocarditis) are highlighted, the lack of corresponding specificity for benefits can complicate effective communication with patients. For example, communicators should highlight the risk of myocarditis following vaccination compared to the risk of myocarditis following disease. Communicators should also compare the rates of adverse events experienced by vaccinated and unvaccinated patients.

Based on data regarding adverse events, some countries developed vaccination policies with preferential vaccination recommendations based on age group or gender. This variability depends on country-specific factors (e.g., risk estimates, COVID-19 burden, timing of product availability, risk perceptions, broader policy response, and non-vaccine-related COVID-19 mitigation methods). In addition, distinct countries identified differences in effectiveness and safety based on dosing interval for the primary series for mRNA vaccines. These findings contributed to varying recommendations on timing, despite some of these differences being driven by limited supply and country-specific allocation policies. These differing policies may add to public confusion regarding population-level risks and benefits.

Discussion
Hana El Sahly, M.D., asked whether VAERS reports of pediatric rashes showed a particular pattern or heterogeneity. Dr. Hause answered that the rashes were likely heterogenous, but further analysis is needed to confirm. She added that rashes were among the least frequently reported adverse events following COVID-19 vaccination in children aged 5-11 years.

Dr. Schechter agreed with Dr. Lee's assertion that risk estimates introducing myocarditis following COVID-19 immunization should include myocarditis following COVID-19 disease.

Dr. Douglas commended Dr. Lee's comparison of adverse events between vaccinated and unvaccinated individuals and asked whether this approach could be routinized to address vaccine disinformation. Dr. Lee stated that the approach has been particularly beneficial for COVID-19 and is relevant to patients. Dr. Hopkins agreed that more transparent data on baseline rates can alleviate concerns and illustrate that not every negative outcome is related to vaccination.

Ms. Coyle asked how clinicians should speak with parents about recommendations for booster doses for children who experienced non-serious adverse events. Dr. Hopkins acknowledged the fear associated with the event (e.g., fever, rash, swollen lymph node), but added that those events should not be considered a barrier to boosters because the alternative (e.g., hospitalization with COVID-19) may be far worse. Dr. Lee added that many people express concern about the long-term safety of vaccines, but few people discuss the long-term effects of infection (i.e., long COVID). While death from COVID-19 is rarer in children than in adults, COVID-19 is currently the eighth leading cause of death in children aged 5-11 years.

Federal Agency and Liaison Representative Updates

Advisory Commission on Childhood Vaccines—Mary Rubin, M.D.
ACCV conducted its 119th quarterly meeting by Zoom on December 2, 2021. The meeting began with program updates from the Division of Injury Compensation Programs and the Department of Justice. ACCV also received program updates from the Immunization Safety Office, the National Institute of Allergy and Infectious Diseases, the Center for Biologics Evaluation and Research, and OIDP. ACCV proposed the establishment of a Work Group focused on vaccine safety research, the formation of which will be subject to a vote during ACCV's March 2022 meeting.

Association of Immunization Managers—Claire Hannan
AIM developed a "legislative roundup" regarding the nearly 500 legislative proposals concerning vaccination from states and jurisdictions across the United States in 2021 for program managers to reference. It held listening sessions for the COVID-19 vaccine rollout among children aged 5-11 years and discussed lessons for enrolling providers and messaging to parents. AIM developed a video for HPV Awareness Day on March 4, 2022, that promotes the benefits of HPV vaccination. AIM also partnered with the National Association of School Nurses and developed school-based vaccine clinics.

American Immunization Registry Association—Rebecca Coyle
AIRA developed SMART health cards and invested further in IISs. It published guidance on incorporating immunizations acquired during a clinical trial into an IIS. AIM also collaborated with CDC and Healthcare Information and Management Systems Society (HIMSS) on the Immunization Integration Program to foster teamwork across the data exchange spectrum to tackle key issues; this program aims to facilitate bulk query use. AIRA also launched new initiatives related to data use, specifically to support those that have used Microsoft Power BI.

American Pharmacists Association—Jean-Venable "Kelly" Goode, Pharm.D., BCPS, FAPhA, FCCP
APhA, in cooperation with CDC, aims to increase vaccine confidence through pharmacist activities and video testimonials. APhA offers webinars to provide education and training for

pharmacists; for example, it developed a COVID-19 vaccine algorithm practice tool to help determine patient eligibility timing for COVID vaccines for primary, additional, or booster doses.

Association of State and Territorial Health Officials—Kim Martin
ASTHO launched a new website in February 2022 with resources to support its members. It is working with key partner organizations to reduce disparities in adult immunization programs and plans to strategically fund communities with low adult vaccination rates and high levels of racial and ethnic disparities to improve immunization uptake during 2022. In 2021, ASTHO coordinated with CDC to provide full-time disability and preparedness specialists in 17 jurisdictions and has published a new report outlining the opinions of those specialists regarding vaccine hesitancy in the disability community. Finally, ASTHO developed a short brief describing practical strategies for improving trust, communication, and advanced policies.

National Association of County and City Health Officials—Amy Frandsen, MPH
As part of its Vaccine Confidence Project, NACCHO developed the Vaccine Confidence Health Equity Action Lab, a training based on tools and resources developed by the Institute of Healthcare Improvement. The Action Lab is an adaptable model that uses a set of activities to bring together a diverse group of community stakeholders to pursue vaccine equity and uptake. Through its Support Local Health Departments to Increase Vaccine Uptake Project, NACCHO partnered with the National Rural Health Association to produce two webinars on supporting rural health departments to increase vaccine uptake. On January 31, 2022, NACCHO hosted the SARS-CoV-2 Vaccines Information Equity and Demand Creation Project (COVIED) webinar, which provided a guided introduction to the materials and tools developed by the COVIED project—a consortium aiming to increase COVID vaccine uptake in vulnerable populations. NACCHO will host the 2022 Preparedness Summit with a theme of Re-imagining Preparedness in the Era of COVID-19 from April 4 to April 7 in Atlanta, GA. NACCHO will host its annual NACCHO 360 conference from July 19 to July 21 in Atlanta, GA, with a theme of Looking to the Future: Reshaping the Public Health System.

Public Health Agency of Canada—Erin Henry, B.S.N.
The Canadian population is highly vaccinated, with 88.6 percent of the eligible population aged 5 years and older having received at least one dose and 83.5 percent fully vaccinated as of February 10, 2022. The Government of Canada's domestic focus is on pediatric immunization and COVID-19 booster rollout. Among 5- to 11-years old, 55 percent have received one dose and 22 percent are fully vaccinated; among individuals at least 18-years-old, 52 percent have received a booster dose, and among individuals older than 70 years, 81 percent have received a booster dose. Canada has approved Spikevax and Comirnaty as well as COVID-19 vaccines from AstraZeneca and Janssen. Novavax and Medicago's vaccines are expected to be authorized soon. Canada's National Advisory Committee on Immunization has released guidance for off-label use for boosters for children aged 12-17 years at high risk of severe COVID-19 outcomes and has provided recommendations for intervals between previous COVID-19 infection and vaccinations. The Public Health Agency of Canada anticipates strong public health measures to bring patients up to date on routine vaccinations to prevent future outbreaks of other vaccine preventable diseases.

Vaccines and Related Biological Products Advisory Committee—Hana El Sahly, M.D.
In September 2021, VRBPAC approved an emergency use authorization (EUA) of a booster dose for Comirnaty at least 6 months after the primary series for individuals aged 65 years and older, individuals younger than age 65 but at risk for severe COVID-19 or have institutional or occupational exposure to SARS-CoV-2. On September 30, 2021, VRBPAC met again to review the research program at the Laboratory of Bacterial Polysaccharides, Division of Bacterial, Parasitic, and Allergenic Products at the Center for Biologics Evaluation and Research, as well as to select strains for inclusion in the influenza vaccine for the 2021-2022 Southern Hemisphere influenza season, which resulted in recommended changes to two strains compared to the previous seasons.

On October 14 and 15, 2021, the committee met to discuss the issuance of an EUA of Spikevax for an additional dose following the completion of the primary series. VRBPAC voted in favor of an EUA of a third dose at least 6 months after the initial vaccine series for individuals aged 65 years and older, aged 18-64 years and at risk of severe COVID-19, or aged 18-64 years old and at high-risk of frequent SARS-CoV-2 exposure due to institutional or occupational background. In addition, VRBPAC voted in favor of an EUA for a booster dose of the Janssen vaccine at least 2 months following the first dose in individuals aged 18 years and older. On October 26, 2021, VRBPAC met to discuss a potential EUA for the use of Comirnaty in children aged 5-11 years. It voted in favor of the EUA for a two-dose series of 10µg each 3 weeks apart.

Biomedical Advanced Research and Development Authority—Linda Lambert, Ph.D.
BARDA continues to support and collaborate with the Department of Defense (DOD) on its international donations of COVID-19 vaccines. In addition, BARDA continues its projects for Ebola, smallpox, anthrax, Zika, pandemic influenza, and needle-free vaccine delivery. Finally, BARDA recently updated its website, making it easier to find its support for medical countermeasures against COVID-19.

Centers for Medicare & Medicaid Services—Mary Beth Hance
CMS updated its Medicaid vaccine toolkit on February 11, 2022. On December 2, 2021, CMS announced that state Medicaid agencies are required to cover vaccine counseling visits during which a vaccine is not administered for most children enrolled in Medicaid up to age 21 under the Early and Periodic Screening Diagnostic and Treatment Benefit. CMS will now consider certain COVID-19 vaccine counseling visits for children and youth to be COVID-19 vaccine administration, for which state expenditures can be fully federally matched for a set amount of time detailed in the approval. In December, CMS also issued the federal FY2020 Medicaid and Children's Health Insurance Program (CHIP) child and adult chart packs, which provide summaries of state reporting on health care financing for children and adults enrolled in Medicaid and CHIP and primarily reflect care provided in 2019. These chart packs include reporting on immunization quality measures.

Centers for Disease Control and Prevention—Melinda Wharton, M.D., MPH, CDC
On February 9, 2022, the U.S. Department of Agriculture confirmed highly pathological avian influenza H5N1 viruses in a commercial turkey flock in Indiana, following detection of very similar viruses in wild bird in recent weeks. CDC considers the risk to the general public to be low, but outbreaks in domestic poultry in addition to infections in wild birds may result in increased exposure in some groups of people, especially poultry workers.

Cumulative reductions in routine vaccine coverage for children since the beginning of the COVID-19 pandemic has surpassed 12 million doses in the United States. Although these numbers are less easily calculated for adults, routine adult vaccinations are likely severely impacted as well. CDC issued guidance on how to combat delayed routine immunizations, but solving the issue will require sustained and substantial effort of clinicians and public health officials alike.

Department of Defense Health Agency, Immunization Healthcare Division—David Hrncir, M.D.
As of February 1, 2022, DOD administered 6.8 million doses of FDA-approved or -authorized COVID-19 vaccinations globally, and 91 percent of active duty Service Members are fully vaccinated. DOD also connected VAERS reports to its own health care record system to enable follow-up with patients and investigation of reported adverse events. DOD operates an all-hours immunization-related Support Center for questions related to adverse events.

DOD is optimistic about an upcoming ACIP meeting regarding a tick-borne encephalitis vaccine that it would use for beneficiaries that live in or Service Members deployed to countries in which the disease is endemic. Finally, DOD supported the medical needs of Afghan families relocated to U.S. Safe Haven locations as part of Operation Allies, which includes routine immunizations; as the Operation reaches completion, DOD is working to ensure that remaining vaccines are not wasted.

Health Resources and Services Administration—Mary Rubin, M.D.
As of January 28, 2022, more than 8 million COVID-19 vaccine doses had been administered through the Bureau of Primary Health Care's Health Center COVID-19 Vaccine Program, 76 percent of which to people in racial and ethnic minority groups. Health centers administered seasonal influenza vaccines to more than 4 million patients. Health centers also administered select immunization doses to more than 3 million patients for hepatitis A, Haemophilus influenza B, pneumococcal, DTaP, DTP, DT, MMR, poliovirus, varicella and hepatitis B.

The National Vaccine Injury Compensation Program (VICP) is processing an increased number of claims in FY2022. As of January 1, 2022, petitioners filed 245 claims with the program and nearly $33.8 million was awarded to the petitioners, inclusive of their attorney's fees and costs. As of January 18, 2022, VICP has a backlog of 1,482 claims alleging vaccine injury awaiting review. As of December 1, 2021, the Countermeasures Injury Compensation Program had 5,630 claims alleging injury or death from COVID-19 countermeasures, including 2,969 claims alleging injuries from COVID-19 vaccines. Approximately 148 claims are in medical review.

Indian Health Service—Uzo Chukwuma, M.P.H.
IHS maintains its COVID vaccine task force, initiated in September 2020 to facilitate the agency-wide allocation, distribution, and administration of COVID-19 vaccines within the IHS or graded facilities, the Tribal Health programs, and urban Indian organizations. As of February 2, 2022, IHS reports distribution of about 2.7 million COVID-19 vaccines within IHS-operated facilities, Tribal Health programs, and urban Indian organizations. Of the total population served by these facilites, 51 percent have received at least one dose of COVID-19 vaccine, 40.4 percent are fully vaccinated, and 27.9 percent have received a booster dose. IHS is working to update its EHR vaccine forecasting capabilities to implement the ACIP-recommended additional dose for

immunocompromised persons and booster doses for people at recommended ages and intervals. The IHS vaccine taskforce promotes COVID-19 vaccine safety among American Indians and Alaskan Natives via VAERS and the IHS Safety Tracking and Response System (ISTA), and routinely monitoring surveys from participating IHS vaccine sentinel sites. IHS also tracks pediatric immunization coverage and has detected a decline in immunization coverage for 2-year-old children with a further decrease since the onset of the COVID-19 pandemic. To combat this decline, IHS launched an initiative called "Safeguard Our Future, Protect Tomorrow, Vaccinate Today." Prior to this initiative, vaccine coverage among 2-year-olds was at 57 percent in Q2 of FY2021; by the end of Q4 of FY2021, it had improved to 57.8 percent. IHS plans to leverage its COVID-19 vaccine strategies to implement the new 20-valent pneumococcal vaccine recommendations, the Zoster vaccine in immunocompromised individuals 19 years and older, and an expanded hepatitis B vaccine recommendation.

Department of Veteran's Affairs—Troy Knighton, M.Ed., Ed.S., LPC
VA promotes vaccination and prevention for all vaccine-preventable diseases. Since August 2021, VA vaccinated about 1.55 million veterans; approximately 40 percent received an enhanced influenza formulation. Although the 2021-2022 influenza season vaccine uptake has increased over the previous season, it is lower than pre-pandemic seasons. About 46,000 veterans were vaccinated through community partnership programs by retailers and other providers. As of February 2022, approximately 4 million veterans were fully vaccinated against COVID-19 and 1.5 million have received a booster dose. VA also vaccinated its own health care personnel, employees of other federal agencies, and caregivers and spouses of veterans through the Strengthening and Amplifying Vaccination Efforts to Locally Immunize All Veterans and Every Spouse Act—the SAVE LIVES Act.

Written updates were provided by NIH, FDA, America's Health Insurance Plans, and the Agency for Healthcare Research and Quality.

Public Comment

Theresa Wrangham suggested that when VAERS and V-Safe data are reported, researchers should consider how V-Safe data will or will not be incorporated into various datasets. She stated that integrating V-Safe data into VAERS would increase public trust and transparency by making those data publicly accessible. However, Ms. Wrangham also noted that many NVIC supporters who are vaccinated, unvaccinated, and selectively vaccinated have expressed concern that IIS systems and EHR systems may violate privacy. These supporters say that these requirements center public health to the detriment of patient concerns, ignoring that sensitive medical data associated with individuals are involved. NVIC fears that these data may be used to limit movement in society by individuals who have chosen not to be or are unable to be vaccinated. These individuals state that data sharing systems are stigmatizing and traumatizing. Ms. Wrangham advocated for allowing patients and individuals to choose when, how, and with whom their personal health information is shared outside of a public health emergency and stressed that there should be careful crafting around how it is shared during a public health emergency. NVIC's supporters fear that their health information has been combined into big data over which they have no control, and that is broadly shared via an automatic opt-in system. While Ms. Wrangham acknowledged benefits to data sharing, she also advocated respecting individuals to whom those data belong.

Adjourn Meeting

Dr. Hopkins thanked the participants and NVAC members and adjourned the meeting at 4:47 p.m.

Appendix: Abbreviations List

ACCV	Advisory Commission on Childhood Vaccines
ACIP	Advisory Committee on Immunization Practices
AHA	American Hospital Association
AIM	Association of Immunization Managers
AIRA	American Immunization Registry Association
APhA	American Pharmacists Association
ASPE	Office of the Assistant Secretary for Planning and Evaluation
ASTHO	Association of State and Territorial Health Officials
ASH	Assistant Secretary for Health
BARDA	Biomedical Advanced Research and Development Authority
CDC	Center for Disease Control and Prevention
CDISC	Clinical Data Interchange Standards Consortium
CHIP	Children's Health Insurance Program
CMS	Centers for Medicare & Medicaid Services
CoP	correlate of protection
COVID-19	Coronavirus disease 2019
CRISP	Chesapeake Regional Information System for Our Patients
DTP	Diphtheria, Tetanus, and Pertussis vaccine
DTP3	third dose of DTP or DTaP
EHR	electronic health record
EO	Executive Order
EUA	emergency use authorization
FDA	Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
H-CORE	HHS Coordination Operations and Response Element
HHS	Health and Human Services
HIMSS	Healthcare Information and Management Systems Society
HL7	Health Level Seven
IHS	Indian Health Service
IIS	Immunization Information System
LMICs	low- and middle-income countries
MMR	measles/mumps/rubella vaccine
NACCHO	National Association of County and City Health Officials
NCI	National Cancer Institute
NHP	non-human primate
NIH	National Institutes of Health
NSC	National Safety Council
NTDs	Neglected tropical diseases
NVAC	National Vaccine Advocacy Committee
NVIC	National Vaccine Information Center
NVPO	National Vaccine Program Office
OCR	Office of Civil Rights
OIDP	Office of Infectious Disease and HIV/AIDS Policy
ONC	Office of the National Coordinator for Health Information Technology

OSHA	Occupational Safety and Health Administration
PPP	Public-private partnerships
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus disease 2019
USG	U.S. Government
WHO	World Health Organization
VA	Department of Veterans Affairs
VAERS	Vaccine Adverse Event Reporting System
VaST	Vaccine Safety Technical Work Group
VRBPAC	Vaccines and Related Biological Products Advisory Committee
VSD	Vaccine Safety Datalink