



June 16–17, 2021, Virtual Meeting Minutes

Committee Members in Attendance

Robert H. Hopkins Jr., M.D., MACP,
FAAP; Chair
Debra Blog, M.D.
Melody Anne Butler, B.S.N., RN, CIC
Timothy Cooke, Ph.D.
John Dunn, M.D., M.P.H.
Kristen R. Ehresmann, RN, M.P.H.
David Fleming, M.D.
Leonard Friedland, M.D.
Daniel F. Hoft, M.D., Ph.D.
Molly Howell, M.P.H.
Cody Meissner, M.D., FAAP
Robert Schecter, M.D.
Geeta Swamy, M.D.
Robert Swanson, M.P.H.

NVAC Ex Officio Members

Uzo Chukwuma, M.P.H., Indian Health
Service (IHS)
Mary Beth Hance (for Jeffrey a. Kelman,
M.D., M.M.Sc.) Centers for Medicaid
and Medicare Services (CMS)
David Hrnecir, M.D., (for COL Tonya Rans,
M.D.) Department of Defense (DoD)
Troy Knighton, M.Ed., Ed.S., LPC,
Department of Veterans Affairs (VA)
Linda Lambert, Ph.D., Biomedical
Advanced Research and Development
Authority (BARDA)
LTC Valerie Marshall, M.P.H. (for Marion
Gruber, Ph.D.), Food and Drug
Administration (FDA)
Justin A. Mills, M.D., M.P.H., Agency for
Healthcare Research and Quality
(AHRQ)
Barbara Mulach, Ph.D., National Institutes
of Health (NIH)

Mary Rubin, M.D., Division of Injury
Compensation Programs, 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

Kimberly Martin (for James S.
Blumenstock), Association of State and
Territorial Health Officials (ASTHO)
Gina Charos, Public Health Agency of
Canada (PHAC)
Rebecca Coyle, M.S.Ed., American
Immunization Registry Association
(AIRA)
John Douglas, M.D., National Association
of County and City Health Officials
(NACCHO)
Hana El Sahly, M.D., Vaccine and Related
Biological Products Advisory
Committee (VRBPAC)
Jean-Venable “Kelly” Goode, Pharm.D.,
BCPS, FAPhA, FCCP, American
Pharmacists Association (APhA)
Aleah Jensen (for Claire Hannan),
Association of Immunization Managers
(AIM)
Christopher Regal, M.S., America’s Health
Insurance Plans

Designated Federal Officer

Ann Aiken, 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, M.A., NVAC Designated Federal Officer, Communications Director, OIGP, HHS

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 OIGP staff for their support in organizing the meeting and called the roll.

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

Dr. Levine said her goal as ASH is to work to improve the health and well-being of all Americans. Building a strong foundation for immunization is an important part of that goal, and vaccines are among the most effective public health tools available. Other priorities include improving health equity (as COVID-19 exposed how deep health disparities run in the United States), integrating behavioral and physical health services, addressing the opioid and overdose crisis, ending HIV, and establishing a new HHS office on climate change and health equity.

With thanks to NVAC members among many others, 310 million doses of safe, effective COVID-19 vaccines have been distributed, and more than half of the U.S. adult population has received at least one vaccine dose. Hospitalizations and deaths from COVID-19 have slowed since their peak in January, but the United States cannot afford to become complacent. Vaccination rates have slowed, and efforts are needed to make vaccines even more accessible. Now is the time for intensive action to achieve President Biden's goal of ensuring that 70 percent of the U.S. adult population has received at least one vaccine dose by July 4.

Dr. Levine stressed that even more important than boosting the numbers is spreading the message that the COVID-19 vaccines are safe, effective, and accessible. The World Health Organization declared the new delta variant of COVID-19 a variant of concern that may be more transmissible and more severe than previous variants. Therefore, Dr. Levine encouraged public health partners and other stakeholders to expand their outreach and efforts to address vaccine hesitancy—for example, by joining the COVID Community Corps. To increase accessibility, HHS and its partners are providing free health care to vaccinated people, extending pharmacy hours for vaccination, offering incentives, and setting up vaccination clinics in nontraditional settings.

Existing COVID-19 vaccines were recently approved for use in children as young as 12 years old, and clinical trials are underway involving younger children. HHS is part of the critical effort to increase COVID-19 vaccination around the world.

Among the lessons learned so far from the pandemic is the realization of how interconnected people are and how big a role social determinants of health play. Dr. Levine said that addressing systemic barriers to health can reduce health care disparities, including disparate vaccination rates, and promote health equity. One step is better data collection to provide a better understanding of disparities and inequities.

With funding from the American Rescue Plan, HHS announced \$250 million to build a community-based workforce to increase confidence in the COVID-19 vaccines and address barriers to vaccination, especially for people in medically underserved areas. To succeed, the

effort must be culturally responsive and involve a diverse group of local, State, and Federal stakeholders. Dr. Levine thanked NVAC for its ongoing work to address immunization equity.

Dr. Levine also appreciated NVAC for raising awareness about the need to augment routine vaccinations for children and adults given the slowdown during the pandemic. She noted that thanks to the introduction of *Haemophilus influenzae* B vaccine, new pediatricians and medical residents almost never see the consequences of invasive *H. influenzae*, which had been common when she was a resident treating children in New York. Orders for measles vaccine have declined during the pandemic, and combined with vaccine hesitancy, the country has gone from having no measles cases in 2000 to thousands in the past few years.

Dr. Levine said downward trends in vaccinations for all ages must be reversed. Communities are healthier and stronger when immunization rates are high, she added. Dr. Levine praised NVAC's work to build vaccine confidence and increase vaccine acceptance across the life span. Strong recommendations from trusted health care providers are key to acceptance, she emphasized. Dr. Levine said NVAC members' commitment and expertise are invaluable to her, the department, and the country.

Chair's Welcome—Robert H. Hopkins Jr., 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 approved the minutes of the February 4–5, 2021, meeting as written, unanimously.

Dr. Hopkins described the procedure for delivering public comments during the meeting. Written comments can be sent to NVAC for consideration by e-mail (nvac@hhs.gov). The agenda, minutes, and recordings of past meetings are available [online](#). NVAC is scheduled to meet next on September 15–16, 2021. (See the appendix for a list of abbreviations used in this report.)

Vaccine Confidence Subcommittee Update—John Dunn, M.D., M.P.H., and Cody Meissner, M.D., FAAP, Co-Chairs

In June 2019, the ASH charged the Subcommittee with creating a report on what affects vaccine confidence over a lifetime, how HHS can increase vaccine confidence, and how to foster confidence based on evidence. The Subcommittee has been discussing the scope of its recommendations and report, with particular focus on defining vaccine confidence. Dr. Dunn noted that hesitance can be limited to a specific vaccine.

Guest speakers have presented to the Subcommittee on CDC's Racial and Ethnic Approaches to Community Health program, strategies for improving adult immunization, COVID-19 vaccine confidence in the military, the Vaccine Education Project's efforts to engage middle school students as vaccine advocates, and CDC's most recent State of Vaccine Confidence Insight Report.

The Subcommittee is drafting its report and recommendations for planned review by NVAC members in August, followed by a public comment period. The final report will be presented to NVAC for approval at an upcoming meeting. Dr. Dunn said the recommendations will cast a wide net, recognizing that no single intervention or group can fully address vaccine hesitancy.

Equity First: Resolving Emerging Issues

Vaccine Equity—Walter Orenstein, M.D., Emory University

Inequity in vaccine uptake results from lack of access, lack of awareness, and hesitancy. Adequate funding and research are needed to tackle all three. Dr. Orenstein described the success of the Childhood Immunization Initiative under President Clinton, which successfully closed the gap in measles vaccination rates between white children and children of color by creating the Vaccines for Children (VFC) program to remove financial barriers. The project also invested in community engagement to identify and address the barriers to access, awareness, and uptake highlighted by stakeholders at the local level.

Efforts to increase COVID-19 vaccine uptake among people of color (POC) have identified specific barriers (e.g., distrust in the health care system, lack of transportation), engaged trusted messengers, and expanded outreach to youth. Racial disparities in immunization are longstanding. Dr. Orenstein called for more measurement of disparities, better dissemination of available data, and more accountability for reducing disparities. Data show that POC are more likely than white people to have concerns about long-term and serious side effects of COVID-19 vaccine. More POC than white people believe that the vaccine can cause COVID-19.

More support is needed to enable national partnerships, local and community organizations, and State and local health departments to gather data, identify needs, understand community concerns, and address them. Successful approaches include targeted partnerships in areas of need, tailored media messages, linguistically appropriate outreach, and pop-up clinics. The strategies for overcoming barriers to vaccination are well known, but they require a combination of communication, infrastructure, and funding to succeed.

***The National Academies of Sciences, Engineering, and Medicine (NASEM)
Framework for Equitable Allocation of COVID-19 Vaccine—Helene Gayle, M.D.,
M.P.H., The Chicago Community Trust***

The Framework represented the first NASEM effort to create guidance centered around equity that took into account the structures that perpetuate inequity and racism in employment, housing, transportation, and health care. Equity issues were embedded in all of the goals, allocation criteria, and phases, all resting on the foundational principle that all lives have equal value. NASEM's recommendations for equitable allocation of COVID-19 vaccine call for appropriately funding a risk communication and community engagement program.

Dr. Gayle outlined the Chicagoland Vaccine Partnership, which targeted the significant disparities in health faced by POC in Chicago. Longstanding, entrenched racial disparities were reflected in early COVID-19 vaccination rates; even among health care workers, white people were far more likely to be vaccinated than POC. Concentrated efforts have helped increase vaccination rates among all racial and ethnic groups, but white people continue to have the highest rates. Geographic disparities persist, with those in wealthy, majority-white neighborhoods having much higher vaccination rates and lower death rates than those in poor, majority-Black neighborhoods.

The Chicagoland Vaccine Partnership is mobilizing community members to strengthen the public health workforce and increase equitable access to vaccines. It is coordinating people and resources to improve the public health infrastructure for the area. It is working across sectors to break down barriers to equity. Among the group's programs are a vaccine ambassador course, a speaker's bureau, an educators' round table, media education about public health storytelling, and a health justice school. The Partnership has mechanisms to evaluate its efforts, learn from them, disseminate the data and lessons learned.

The Conversation—Rhea Boyd, M.D., M.P.H., The Commonwealth Fund

The Conversation is an online information repository that aims to answer questions from minority communities about COVID-19 vaccines. It was created before any of the vaccines were authorized for use and anticipated the public’s concerns about safety, efficacy, and side effects.

The Conversation was promoted by television host W. Kamau Bell and received input from such high-profile sources as the White House COVID-19 Task Force. Since its initial launch campaign, it has expanded to include a Spanish version. The Conversation specifically addresses misinformation targeting minority communities. Creators partnered with large social media platforms to combat misinformation spread via those platforms. Starting early, anticipating the distrust among POC of health care information, and cultivating and nourishing partnerships were key to the successful rollout. The Conversation reflects the value of pairing digital strategies to combating disinformation and misinformation with a strong community engagement effort on the ground with influential organizations and partners.

To increase the number of children who receive COVID-19 vaccination, The Conversation will focus on family vaccination—which includes administering vaccine to the whole family at one visit and assisting with catch-up vaccines. Dr. Boyd observed that not all of those who are not yet vaccinated are hesitant; many face barriers or have legitimate concerns that have not yet been addressed. She added that all of the content produced by The Conversation is free for use.

Black Coalition Against COVID-19—Reed Tuckson, M.D., Black Coalition Against COVID-19

To improve health equity, distrust in the health care system must be addressed. Despite the recognition of racism in health care (from the Tuskegee experiments to the early approaches to HIV), nothing has been done to address the inequity or restore Black people’s trust in health care research, delivery, or policy, said Dr. Tuckson. Few POC hold positions of authority and visibility in science, medicine, and health. Increasing the number of minority health professionals, for example, can help build confidence in the system.

Although the importance of engaging community and faith-based organizations is recognized, those organizations always find themselves begging for money from large organizations run by white people who receive the funding, said Dr. Tuckson. More minority-led organizations should be funded directly. In addition, public health infrastructure must be sustained. Public health entities that receive Federal funding should be required to gather the kind of data that can be used to track progress.

Scientific and health literacy among minority students must be improved by collaborating with organizations such as national associations of science and math educators. There is little support for science education in schools that discourage teaching the theory of evolution, for example. Dr. Tuckson concluded that advocates have been too polite; the pandemic revealed how ineffective a polite approach has been, so it is time to become much more assertive.

COVID in the Queer Community—Mardi Moore, Out Boulder County

Few public health data exist about people who are lesbian, gay, bisexual, transgender, or queer (LGBTQ), so Out Boulder County of Colorado surveyed its community about immediate needs early in the pandemic. The survey found surprisingly low rates of COVID-19 vaccine uptake among LGBTQ people, often linked to concerns about safety, lack of trust in the vaccine, and lack of specific information. For example, many sought to understand the potential interaction of the vaccine with hormone therapies or HIV medications but found no clinical data. Despite the

fact that LGBTQ people make up a significant portion of the population, they are still invisible in population data, and their unique concerns are overlooked.

With input from the community and funding from CDC and national and local foundations, Out Boulder County set up COVID-19 vaccination clinics where LGBTQ people were recognized and welcomed, including banners identifying the location of “equity clinics,” use of nametags with preferred pronouns, and staff trained in topics of gender identity and language. Vaccinated people were identified with stickers and became ambassadors for promoting vaccination among peers.

The group also disseminated the data it gathered and took part in a local vaccine coordination committee to ensure the LGBTQ community was addressed. Messaging was crafted with a trauma-informed mindset. Ms. Moore pointed out that the LGBTQ community has high rates of chronic disease and mental health conditions, but no government data set validates those findings, so the community remains invisible. Requests to address the community’s unmet needs are rejected because they are seen as too costly, but, Ms. Moore noted, failing to address them is far more expensive.

Equity in COVID-19 Vaccination in the Disability Community—Linda Mastandrea, Federal Emergency Management Agency (FEMA)

The success of the national effort to achieve the goal of 200 million COVID-19 vaccinations within the first 100 days of the Biden presidency resulted from an integrated approach among all partners to establish vaccine centers, accelerate State efforts, and communicate broadly. FEMA’s disability advisors used community data to identify needs and coordinate services for people with disabilities and ensured that vaccine centers were physically accessible. FEMA convened an advocacy group to develop a civil rights checklist to ensure accessibility.

The COVID-19 pandemic was the first time in recent history in which the entire country experienced the same disaster at once, so interagency cooperation was vital. FEMA’s Office of Disability Integration and Coordination focused on meeting the needs of people with disabilities. It defined disabilities for the purpose of Federal data collection, worked with CDC to create sign-language interpreted videos about COVID, launched a community hotline, and held stakeholder outreach to provide current information.

Novel approaches to serving people with disabilities included Deaf Vaccine Day in Philadelphia, expedited service and private treatment areas at large vaccine clinics, and mobile vaccine clinics. Ensuring that people with disabilities have information about and access to COVID-19 vaccines is a key component of equity, Ms. Mastandrea stated.

Health Center COVID-19 Vaccine Program—Sue Lin, Ph.D., M.S., HRSA

HRSA’s health centers play a crucial role in equitable vaccine distribution because they provide high-quality health services to a number of vulnerable populations, such as the homeless, people in public housing, migrant and seasonal agriculture workers, and people with limited English proficiency. HRSA health centers have tracked vaccination rates among vulnerable populations since the outset of vaccination efforts. They began tracking adolescent vaccinations as soon as vaccines were approved for this group. HRSA also has data on vaccinations by the race and ethnicity of its clients. Vaccination rates have steadily climbed across all of the groups.

During the pandemic, health centers have organized mobile vaccine clinics, pop-up clinics, and school-based clinics, working with community organizations and emergency and public health entities at all levels of government. Health centers have administered COVID-19 vaccines

through more than 12,000 community events since April 2021. As of mid-May, they had administered more than 11 million vaccine doses, exceeding HRSA's initial goals.

Provider Hesitancy: The Problem and Implementing Promising Practices

Unpacking Vaccine Hesitancy/Acceptance Amongst Health Care Providers—Noni MacDonald, M.D., FRCPC, Dalhousie University and Canadian Centre for Vaccinology

Many factors influence decision making about vaccines, including lived experience, peer influences, dismissal of evidence that does not support beliefs, a focus on negative information, and a preference for anecdotes and stories over facts. Vaccine hesitancy manifests across a spectrum, from refusal to acceptance, for health care workers (HCWs), just as it does for the general public. Dr. MacDonald put forth a new framework for addressing vaccine hesitancy that integrates education, communication, community systems, and infection control.

Addressing vaccine hesitancy requires a combination of strategies, such as education that covers specific concerns, pain control for those averse to needles, and improved access (e.g., time off from work and easy-to-reach vaccine centers). Other techniques include bringing forth champions within the community (ideally, people who reflect the target population, including the type of health care provider targeted). Dr. MacDonald pointed out that HCWs quickly attribute any adverse effects following immunization (AEFIs) to the vaccine and do not revise their understanding even if informed later that the vaccine was not the cause. Like everyone else, HCWs need up-to-date, accurate information about vaccines. "Data tells, but stories sell," said Dr. MacDonald, underscoring the importance of compelling and personal narratives.

Motivational interviewing and similar techniques used to encourage parents and patients to accept vaccines are also effective for HCWs. Understanding the difference between disinformation and misinformation—and how and why they are spread—can help HCWs prepare to combat both. Highlighting the consensus around science promotes more trust in science. Some websites offer gamified lessons in spotting fake news that reveal common disinformation tactics.

COVID-19 Vaccine Acceptance and Barriers to Uptake Amongst the U.S. Public and HCWs—Liz Hamel, Henry J. Kaiser Family Foundation

The number of people willing to consider COVID-19 vaccination has increased steadily as the vaccines rolled out and people better understood their safety and effectiveness. However, the proportion of people who say they will not be vaccinated or will only do so if required has changed little. Although data highlight the demographic divisions between those who accept and those who are skeptical of vaccines, Ms. Hamel said that none of demographic groups are monolithic. Within each, there are people who are confident, people who are hesitant, and people who have been vaccinated despite their misgivings.

Concerns range from side effects and safety of the vaccine to worries about missing work and lack of access to the vaccine. No single message or intervention will address all the barriers. Notably, among HCWs, doctors, nurses, and others who treat patients have higher vaccination rates than administrators and those who assist with care. Hospital HCWs are most likely and home HCWs least likely to have been offered vaccination by their employer. Not surprisingly, hospital HCWs have the highest uptake and home HCWs the lowest. Demographic differences in uptake among HCWs mirror those of the general public, as do the reasons for vaccine hesitancy.

Ms. Hamel said the public still trusts HCWs for information. Therefore, improving access and vaccine confidence around COVID-19 vaccines among HCWs remains a priority.

Engaging Health Care Professionals in Vaccination—Graham McMahon, M.D., M.M.Sc., Accreditation Council for Continuing Medical Education

Health care professionals are a sophisticated audience of learners, motivated to master the material and highly capable of absorbing information. At the same time, they mistake listening for learning and express confidence that they have acquired new skills when they have not. Changing long-held practices is difficult. Many providers are unwilling to risk sacrificing the patient-provider relationship by challenging patients' beliefs, thus reinforcing complacency. Provider burnout and fatigue contribute to a lack of engagement in learning.

The following concepts effectively promote learning and behavior change among HCWs:

- Education delivered by a trusted source, such as the HCW's professional society, alma mater, or employer
- Material that employs narratives to engage hearts and minds, which can undermine competing disinformation from peers and social media
- Setting interesting and meaningful goals that encourage the HCW to develop skills
- Presentation of data comparing performance with peers, which activates the motivation to improve and master skills
- Education that feels goal-oriented, relevant, active and efficient, collaborative and safe, fun, positive, and rewarding

Moving a HCW across the spectrum from vaccine hesitance to acceptance requires identifying where the HCW is on the spectrum and addressing concerns accordingly. For example, HCWs may express reservations about the adequacy of COVID-19 clinical studies and vaccine makers' potential conflicts of interest. HCWs need a comfortable way to evaluate where they stand so that they can discuss their specific concerns. Creating a "safe space" for reflection and discussion means establishing an atmosphere free of judgment that allows for sharing and growth. Because compelling stories are being used to sow disinformation, it is particularly important to promote a culture of learning that insulates HCWs against unscientific information and behaviors driven by ulterior motives. Learning is transformative when it creates relationships, self-awareness, and improvement that leads HCWs to provide better care.

Improving Vaccine Uptake Among Health Care Staff: Applying Evidence from Implementation Science—Lila Finney Rutten, Ph.D., M.P.H., Mayo Clinic

Dr. Rutten described a framework for implementation research similar to that described by Dr. MacDonald for addressing vaccine hesitancy. Dr. Rutten focused on strategies that organizations can employ internally to boost vaccine uptake among HCWs:

- Evaluative and iterative strategies
 - Assess for readiness and identify local barriers and facilitators
 - Audit and provide feedback specific to clinics, care teams, and staff
- Adapt and tailor to context
 - Tailor strategies to address barriers and leverage facilitators
 - Promote adaptability
- Develop stakeholder interrelationships
 - Inform opinion leaders about vaccine initiatives
 - Conduct consensus discussions
- Engage health care staff
 - Involve staff in the planning and execution of interventions

- Identify and prepare vaccine champions
- Train and educate
 - Conduct ongoing training and consultation
 - Use train-the-trainer strategies
- Change infrastructure
 - Mandate change or require active declination
 - Change service sites
- Support staff
 - Develop and distribute educational materials to support staff in addressing questions from employees and patients
 - Remind staff to vaccinate

Dr. Rutten concluded that vaccine acceptance is determined by multiple factors, so it is necessary to address barriers at multiple levels. Evidence-based approaches can provide a roadmap for increasing acceptance.

The COVID-19 Pandemic: Impact on U.S. Adolescent and Adult Vaccine Utilization Across Markets—Sandra Lindsay, D.H.Sc., M.S., M.B.A., R.N., Long Island Jewish Medical Center

Dr. Lindsay, a nurse in the intensive care unit at a New York hospital hard hit by COVID-19, was the first person to receive a COVID-19 vaccine outside of a clinical trial. She said she was devastated by her daily experiences treating patients and decided that she would be vaccinated as soon as a vaccine was deemed safe and effective. She saw it as her professional responsibility to be a role model for her staff and to protect her patients, community, and family as well as herself.

The concerns Dr. Lindsay heard from others about the vaccine were the same as those described by other presenters. Her hospital system is taking a multipronged approach to increasing vaccine uptake among staff that includes town halls and other steps for providing information, offering vaccine on site, giving staff time off for vaccination, and offering incentives. Staff are encouraged to be role models for community members, who trust the medical judgment of HCWs. The hospital system recently began requiring new hires to be vaccinated or actively decline, and it is considering requiring regular testing for those who cannot or choose not to be vaccinated.

Dr. Lindsay emphasized that telling the story of COVID-19—that is, describing the experiences of staff caring for patients, even within the organization—rather than relying on statistics can help make the case for vaccination. She emphasized the importance of taking time to get to the root of an individual's hesitance. For example, she described a staff member who was extremely fearful of needles, but who eventually received the vaccine following personal encouragement.

Discussion

John Douglas, M.D., asked whether the Kaiser Family Foundation's serial surveys provide insights on whether attitudes are changing about mandatory vaccination. Ms. Hamel reiterated that data from the general public indicate that the number who say they would only be vaccinated if required to do so has not changed. However, among vaccinated people, a number say they felt unfairly pressured to be vaccinated, so Ms. Hamel believed there could be a backlash against mandates. Dr. Lindsay added that there is some anxiety among employees at her organization about requirements for regular testing of unvaccinated staff. Her hospital requires that staff who do not get annual influenza vaccination wear masks throughout influenza season, and it has seen good compliance with that policy.

Dr. McMahon distinguished mandates for optional activities, such as travel, from required activities, such as employment. When mandates are imposed on people who are resistant and who need their jobs, backlash is likely.

Cody Meissner, M.D., FAAP, reminded participants that overall vaccine uptake has been remarkable given the short time since the new vaccines became available. He questioned the impact of cost as a barrier, as the vaccine is free, and noted that it is widely available now. Dr. Meissner said he found it hard to understand why so many HCWs who saw people die from COVID-19 were not motivated to be vaccinated.

Dr. MacDonald pointed out that uptake is lower among HCWs who work in community settings than among higher-paid HCWs in institutions. Furthermore, at least in California, many community HCWs represent racial and ethnic minorities who have been disrespected by the health care system and society in general and, as a result, lack respect and trust for systems. Dr. MacDonald continued that it is important to understand an individual's reasons for hesitance and to have champions who reflect the communities they serve. Personal experience with the pandemic cannot be the only motivation, she stated.

Dr. McMahon said that from a psychological perspective, it is important to reframe vaccination to drive behavior change. A fear-based message focuses on the potential harm, even if it is rare. Vaccination could be better portrayed as a step toward protection and freedom. Dr. MacDonald added that negative messages are louder and more likely to stick than positive messages.

Dr. Lindsay noted that leaders in her organization were also perplexed by vaccine hesitancy among staff. She stressed that HCWs are human beings with the same fears as people outside of health care. Like other humans, some HCWs listen to false information, rely on untrustworthy news sources, and trust their own beliefs over evidence. On the other hand, Dr. Lindsay noted, the barriers are not always big issues of mistrust. As with the staff member who was afraid of needles, some HCWs would benefit from a respectful dialogue about their personal concerns.

Dr. MacDonald added that although the vaccine is free, individuals pay other costs, such as childcare, transportation, and taking time off from work. Dr. Meissner acknowledged those costs and noted also that some may require a health care visit if they experience side effects. Dr. MacDonald said early media reports about AEFIs had a broad impact. Dr. Rutten said data indicate that focusing on positive behavior is helpful for changing negative behavior (e.g., binge drinking or tobacco use), while focusing on negative behavior has a negative impact.

Immunization Equity Subcommittee Report and Recommendations—Melody Anne Butler, B.S.N., RN, CIC, Co-Chair

Ms. Butler described the charge and membership of the Subcommittee, which recognizes that immunization equity is vital to the success of vaccination efforts, yet disparities, inequities, and inequality persist. She summarized the Subcommittee's recommendations, organized according to the following topics:

Access: Expand the capacity of pharmacists to deliver vaccines, highlight best practices to improve vaccination rates in rural areas, and address barriers related to disability, language, and immigration status.

Affordability: Create a Vaccines for All program to provide routine vaccines at no cost and call on CMS and CDC to meet with providers and State policymakers to learn about barriers and ways to address them.

Knowledge and Awareness: Improve vaccine education, communication, and health literacy among trainees and HCWs and work with professional and community organizations to expand education.

Attitudes, Beliefs, and Vaccine Acceptance: Increase investment and research in 1) understanding vaccine attitudes and beliefs, 2) effective communication approaches for various audiences, and 3) evidence-based practice interventions; build on progress made around COVID-19 vaccination; and reach out to underserved groups.

Data Tracking and Reporting Infrastructure: Provide funding to explore the creation of a national immunization registry system; facilitate the use of immunization information systems (IIS) data for research, including sharing data across States, and advocate for improving IIS.

Discussion

Rebecca Coyle, M.S.Ed., observed that IIS are limited to the racial and ethnic categories determined by the Office of Management and Budget agencies. Those categories should be expanded so that the data can be disaggregated. Racial and ethnic information is often captured by an administrative staff person, not a HCW, for the electronic health record (EHR), which is used to send information to the IIS. More education is needed about how to capture racial and ethnic data correctly, why it is important to do so, and how the data are used. Ms. Butler acknowledged the need for more detailed categories and said that having a national database that poses questions in a uniform way would improve data collection.

Ms. Coyle asked whether the Subcommittee intended to recommend a national immunization registry system or a national IIS identifier. Ms. Butler said the Subcommittee made the ambitious proposal to create a national IIS. The pandemic revealed the capacity to capture patient information using a national standard, she noted.

Ms. Coyle suggested clarifying the text and correlating recommendation to indicate the intention to encourage providers to report immunization data across the life span.

Timothy Cooke, Ph.D., said that reducing out-of-pocket costs for adult vaccines is an important issue for the biomedical technology sector. He noted that legislation has been proposed in Congress to eliminate such costs in Medicare and Medicaid programs.

Dr. Douglas suggested that HHS and CDC encourage State and local health departments to enhance their community engagement to increase vaccine uptake and improve overall preparedness. Melinda Wharton, M.D., M.P.H., pointed out that CDC is funding such work already through COVID-19 resources, but maintaining those efforts beyond the pandemic would require additional funding.

Ms. Butler suggested that the Subcommittee summarize the lessons learned from COVID-19 vaccination in a separate report and make recommendations on what to retain to prepare for future pandemics. Dr. Douglas hoped the current recommendations would call for sustaining the investments in local community engagement.

Molly Howell, M.P.H., noted that data sharing between State IIS and various Federal systems and across States remains difficult. The recommendations should encourage development of policies for sharing data.

Ms. Howell observed that States are required to visit 50 percent of their VFC providers each year, which can limit a State's capacity for adding new providers. She proposed that the Subcommittee

recommend additional support for VFC providers or streamline the regulatory requirements around VFC to break down the barriers to enrolling more pharmacists in in VFC, and Kristen R. Ehresmann, RN, M.P.H., agreed. Ms. Butler concluded that the comments would be incorporated into the recommendations and presented to NVAC for a vote on the second day of this meeting.

Catching Up Adults and Adolescents After COVID-19 Vaccination Disruptions
The COVID-19 Pandemic: Impact on U.S. Adolescent and Adult Vaccine Utilization Across Markets—Christine Liow, Avalere Health

In February 2021, Avalere published data gathered from insurance claims showing the decline in routine vaccinations among children and adults during the pandemic. Ms. Liow presented updated and additional findings from further analysis. Routine vaccination rates dropped substantially in April 2020 and remained low despite a rebound, particularly among children and adolescents in the fall, when in-person school started for some students. A similar pattern occurred among adults, but vaccination claims remain below 2019 levels in all markets.

Influenza vaccination rates were higher in August and September of 2020 than for the same months in 2019, possibly because of increased awareness. However, the rates fell off later in the fall, and the overall influenza vaccination rates were lower than for 2019.

Avalere sought to estimate missed doses using extrapolation of the data. Compared with 2019, children missed approximately 8.8 million recommended vaccine doses in 2020, and adults missed about 17.2 million doses. These figures do not take into account the impact of events that might have created barriers to vaccination, such as holidays and facility shutdowns.

Keep Up the Rates—William Schaffner, M.D., National Foundation for Infectious Diseases (NFID)

NFID launched the Keep Up the Rates national campaign to remind health care providers to encourage all patients to catch up on missed vaccines and to educate consumers about the importance of keeping up to date with recommended vaccines. The campaign involves 120 partner organizations that provide resources, expertise, and platforms to reach health care providers and consumers.

Educating providers about the rapidly evolving information and guidance around COVID-19 and vaccines is a key component of the campaign. NFID hosted two webinars on COVID-19 vaccination, and they are available on demand on NFID's website.

To reach consumers, NFID worked with media to spread its message, garnering millions of impressions through social and traditional media outlets. All of the campaign materials are available online at no cost, and many are available in Spanish. As the pandemic continues, NFID will continue its campaign, highlighting three themes:

- Co-administration and education about other vaccines with COVID-19 vaccination
- Expanding the focus on childhood, adolescent, and adult vaccines
- Addressing health disparities and promoting equity

Experience of a Federally Qualified Health Center (FQHC)—Marisa Rowen, Pharm.D., CDE, El Rio Health Center

As El Rio, a large FQHC in Arizona, geared up for COVID-19 vaccinations, it was faced with determining how to calculate the amount of vaccine needed and how to refresh and maintain

inventory as demand shifted. To save money, El Rio partnered with a supplier so that it could order multiple types of vaccines from one company. Space was a concern, because the new COVID-19 vaccines required new freezers, limiting the health center's storage capacity for routine vaccines.

El Rio uses specialized software and EHRs to identify patients who have missed care and reaches out to them through automated text, phone, and mail reminders. The FQHC has standing orders so that nurses and medical assistants can administer vaccines without waiting for physician approval. El Rio promotes its message, Care Can't Wait, via public service announcements on radio, at bus stops, and on billboards, for example. HCWs use motivational interviewing techniques to encourage vaccination during any health encounter and commit to restarting the conversation at the next encounter if necessary. Providers aim to offer as many services as possible during one visit, recognizing that patients might not return. El Rio strives to have sufficient vaccine supplies on hand to respond to any patient seeking service at any time, even those without an appointment.

Throughout the pandemic, El Rio has worked closely with local health departments. Local data revealed two community pertussis outbreaks, prompting El Rio to identify and reach out to patients overdue for pertussis vaccination. Since the pandemic began, providers approach every visit as an opportunity for preventive care. El Rio has an increased appreciation for the role of new partners in vaccination, such as pharmacists. They also recognize the need to encourage in-person visits for services that cannot be provided through telehealth.

Vaccination Policies—Abby Bownas, Adult Vaccine Access Coalition

COVID-19 renewed interest in the value of vaccination across the life span, opening the door for strengthening the vaccine infrastructure, ensuring equity in access, reducing financial barriers, and promoting high immunization rates. Investment in infrastructure includes funding for IIS and State and local surveillance that continues beyond the pandemic. The Immunization Information Modernization Act would support such improvements.

The American Rescue Plan includes money for increasing vaccine confidence and improving COVID-19 vaccination rates. The Adult Vaccine Access Coalition advocates for expanding funding to include other vaccines. Legislation under consideration includes the Community Immunity Under COVID-19 Act, which would support health departments, and the Protecting Seniors Through Immunization Act to help older, low-income adults overcome barriers to vaccination. Other efforts aim to enhance Medicaid coverage of routine vaccinations and address maternal immunizations. Ms. Bownas emphasized that these are just some steps among many needed to improve health and save money through preventive care.

Public Comment

Susan Olsen Corrigan said she has attended local vaccine advisory committee meetings and others, and the common thread among them has been how to combat vaccine hesitancy. There have been countless public relations campaigns launched this year and billions of dollars spent to combat this issue. Yet no one is going to the vaccine hesitant and asking why they have concerns or reservations about getting vaccinations, including the COVID-19 vaccine. Ms. Corrigan said that for the COVID-19 vaccine, there is no compensation for people who have an adverse reaction or die after receiving the vaccine, under the Public Readiness and Emergency Preparedness Act. There is very little care or direction from physicians on how to address adverse events that may occur. There are no long-term safety studies, as the pandemic was considered a public health emergency. There are no safety studies on giving the mRNA vaccines along with

regularly recommended adolescent and adult vaccines. Although experts are encouraging people to get caught up on scheduled vaccines, there is no information about the interaction between mRNA vaccines and other vaccines.

Ms. Corrigan went on to say that the total amount of damage caused is unknown, but damage is happening. In addition to individual experiences, the Vaccine Adverse Event Reporting System (VAERS) is doing what it is designed to do: catch signals. Myocarditis is one of them. The CDC called an emergency meeting for Friday, June 18, to further explore the signal and potential steps to take. Among the adverse reactions reported regarding COVID-19 vaccine are 5,988 deaths, 19,000 hospitalizations, 43,891 urgent care visits, 1,737 cases of Bell's palsy, 1,459 cases of anaphylaxis, 58,000 office visits, 2,190 heart attacks, 1,087 cases of myocarditis, 1,564 cases of thrombocytopenia, 652 miscarriages, and 1,552 severe allergic reactions. These are just a few of the issues being reported after COVID-19 vaccination. VAERS is a passive reporting system and does not identify a definitive direct cause between the vaccine and the injuries, but the numbers are startling and it is clear there are issues. A Harvard Pilgrim Health Care study found that less than 1 percent of injuries are reported. If these numbers were multiplied by 100, the data would be staggering.

Sarah Barry, an independent advocate, stated that although she is a member of the public with no formal training in vaccine science, her research on the anti-vaccine (anti-vax) movement has accomplished several things. In 2019, *Wired UK* magazine reported that Amazon sold anti-vax books in which the writer claimed to teach parents how to cure autism. Ms. Barry raised alarms about the close ties between anti-vax lobbyists and legislators in the Ohio House of Representatives, which resulted in articles getting written. She attempted to give testimony criticizing the lobbyists' growing influence, but learned that the same anti-vax lobbyists made significant efforts to block her from testifying and, in their own words, "worked behind the scenes to make sure that didn't see the light of day." Ms. Barry contacted a reporter at Al-Jazeera about the incident, and viewers can see the lobbyists say the words themselves in a video on YouTube.

Ms. Barry said she believed that lobbyists blocked her testimony because they were so scared of the statement she has repeated many times: anti-vaxxers abuse autistic children. If solutions do not include discussions about the abuse of autistic children at the hands of the anti-vax community, then the solutions are incomplete. Ms. Barry pointed to the researcher Andrew Wakefield, who lost his medical license [when it was revealed that his research claiming a link between vaccines and autism was fraudulent], but also to Jack Piper, a child in the Wakefield study who suffered needlessly from the incredibly invasive medical tests conducted on him during that study. The book that used to be available on Amazon taught patients to use bleach as an alleged autism cure. Others have proposed extreme and dangerous treatments.

Anti-vax lobbyists are trying to kill a bill that would allow employers to require vaccination. Dr. Sherri Tenpenny created an anti-vax group that claims that COVID-19 vaccine makes people magnetic. The anti-vax community must be held accountable for the damage it causes.

Theresa Wrangham of the National Vaccine Information Center said the co-founders of her organization are parents of vaccine-injured children who worked with Congress to draft and pass the National Childhood Vaccine Injury Act of 1986, which created NVAC. The roots of that law are bound in hesitancy and vaccine injury, and the primary goals of the co-founders in participating in the 1986 act creation was that risk informing would be required for those deciding to vaccinate, ongoing research on vaccine injury would be required and would inform the vaccine

injury table and expedite no-fault vaccine injury awards, and Americans would be assured that when they chose to vaccinate, they would be choosing from the safest vaccines.

The National Vaccine Information Center supports the effort to ensure access to vaccines and vaccinations through the lens of the informed consent ethic, which has guided the practice of modern medicine since World War II, as every individual and parent has a right to make informed decisions without threat or coercion. No one should be treated differently in their community, schools, or workplaces because of their vaccination status. Doing so fosters inequity and discrimination and throws those who will be injured under the bus as collateral damage and creates a second class of citizens.

The National Vaccine Information Center's board members, founders, and supporters have a history and continue to serve on Federal advisory committees such as CDC's Advisory Committee on Immunization Practices (ACIP), yet the concept widely known in the disability community as "nothing about us without us" is not currently integrated in the current efforts to address hesitance. The continued strategizing and incentivizing coercion and mandate tactics being put into place to increase vaccine uptake, particularly relating to COVID-19 vaccines, are unlikely to be successful with a vaccine-hesitant population given the lack of representation from the community that these efforts seek to convince. NVAC is well aware that there are legitimate privacy, safety, and informed consent concerns held by the vaccine hesitant. It is unethical to impose mandates and not engage with the community and work to resolve these legitimate concerns while respecting informed consent rights. The hesitant and injured that NVAC respected for almost 40 years are increasing. Ms. Wrangham strongly encouraged NVAC to address inequity and informed consent protection and inclusion of the vaccine hesitant in policy and recommendation efforts undertaken. She said she appreciates the opportunity to provide public comment, but it is not a substitute for engagement to address these concerns.

Wrap Up—Robert H. Hopkins Jr., M.D., MACP, FAAP, NVAC Chair

Dr. Hopkins thanked the participants and the OI DP staff and recessed the meeting for the day at 5:58 p.m.

Day Two

Call to Order and Chair's Welcome—Robert H. Hopkins Jr., M.D., MACP, FAAP, NVAC Chair

The meeting resumed at 1:01 p.m. on June 17. Dr. Hopkins summarized the proceedings of day one and gave an overview of the agenda for day two. He noted that time has been allotted for NVAC to review changes made to the Immunization Equity Subcommittee's report and vote on its approval.

COVID-19 Vaccine Safety Monitoring Update

CDC ACIP COVID-19 Vaccine Safety Technical Subgroup (VaST)—Robert H. Hopkins Jr., M.D., MACP, FAAP

Dr. Hopkins, who co-chairs VaST, described the group's role in evaluating and interpreting COVID-19 vaccine data safety. VaST considers active surveillance data from V-safe after-vaccination health checker, passive surveillance from VAERS and VA's Adverse Drug Event Reporting System, and individual cases identified by CDC's Clinical Immunization Safety Assessment project. It also assesses data from larger linked databases, including FDA's Vaccine Surveillance Program, CDC's Vaccine Safety Datalink (VSD), and a number of other DoD and VA systems. VaST meets almost every week to coordinate information gathered across systems.

The most common issues reported following COVID-19 vaccination are local and systemic reactions. Anaphylaxis following COVID-19 vaccination is being closely monitored, and findings are reported on CDC's website. VaST is also evaluating vaccine effects in pregnant women (notably, V-safe established a registry for pregnant women) and the risks of thrombosis, thrombocytopenia, myocarditis, and pericarditis. VaST will present its findings to ACIP at its June 18 meeting. The group will continue to meet and review data, updating ACIP regularly.

Myocarditis and Myopericarditis After COVID-19 Vaccination—Judy Guzman-Cottrill, D.O., The Ohio State University

Dr. Guzman-Cottrill summarized a case series describing seven adolescents who developed myocarditis or myopericarditis after mRNA COVID-19 vaccination. The cases occurred at five sites and involved healthy male adolescents who had no known exposure to COVID-19 and developed symptoms within 4 days of vaccination. All presented with chest pain but otherwise had a range of signs and symptoms. All had elevated levels of troponin on admission, a sign of myocardial infarction among adults, which none of the subjects had. All had abnormal cardiac test results but normal blood pressure throughout hospitalization. Each of the hospitals took different approaches to treatment, and the optimal therapy remains unclear.

Dr. Guzman-Cottrill posited that myocarditis might be a rare adverse event related to increased systemic reactogenicity and immunogenicity and that younger people might have more frequent and more severe reactogenicity than older people. She emphasized that the cases were identified through personal communication, not systemic surveillance. Alternative etiologies have not been thoroughly excluded. The subjects were too healthy to justify cardiac biopsy.

The case series raised awareness about a potential early safety signal. Early recognition of symptoms of myocarditis following COVID-19 vaccination may prevent providers from conducting unnecessary invasive procedures (e.g., cardiac catheterization). At present, a comprehensive workup is recommended to exclude infectious and noninfectious causes. Providers are encouraged to report events to VAERS. Dr. Guzman-Cottrill and her coauthors concluded that the benefits of COVID-19 vaccination significantly exceed the possible risks. She called for education on evaluation and management of adverse events, including how to conduct a thorough workup, and more frequently updated safety surveillance data. Dr. Guzman-Cottrill noted that there is no mechanism for monitoring these patients following discharge in a systematic way that facilitates sharing of data.

FDA Update on COVID-19 Vaccine Safety Data—Hui-Lee Wong, Ph.D., FDA

FDA's Center for Biologics Evaluation and Research (CBER) relies on a combination of active surveillance programs to monitor COVID-19 vaccine safety across a broad range of the U.S. population, including the Biologics Effectiveness Safety (BEST) Initiative. For vaccinations, CBER evaluates data from CMS, VA, VSD, and BEST, which together cover all age ranges. The BEST Initiative also incorporates large commercial databases and EHRs.

Dr. Wong outlined the methods to identify safety signals rapidly, assess them through epidemiologic studies, and compare observed safety outcomes with expected outcomes to confirm or refute the relationship to vaccination. The design of epidemiologic studies depends on the signal and can include, for example, historical comparators. Study signals are often identified through passive surveillance techniques.

Discussion

Dr. Meissner asked whether informed consent for COVID-19 vaccination should address the potential for myocarditis. Dr. Guzman-Cottrill said that although occurrences are rare, CDC has indicated that the number reported is higher than expected, so it should be covered as part of informed consent. She added that the content of informed consent should be updated as the science unfolds. Dr. Guzman-Cottrill further noted that the number of adolescents receiving COVID-19 vaccination is growing, but she is not seeing a lot of reports of chest pain, so myocarditis appears to be rare given the growing denominator.

Dr. Meissner asked what advice the seven patients in the case series were given about exercise following discharge. Dr. Guzman-Cottrill said cardiologists followed the American Heart Association's guidelines, which recommend close follow-up and no strenuous activity for at least 3 months. She anticipated publishing follow-up data about the seven patients.

Monitoring Mutations: Virus Variants and COVID-19 Vaccination

Allison Greaney, Fred Hutchinson Cancer Research Center and the University of Washington

The spike protein of the severe acute respiratory syndrome (SARS)-coronavirus (CoV)-2 virus has a receptor binding domain (RBD) that binds to angiotensin converting enzyme 2 to allow the virus to enter cells. The RBD is a target of neutralizing antibodies that can protect against infection. Some emerging variants have mutations that can reduce or escape antibody binding, and investigators want to characterize them as quickly as possible. Ms. Greaney described work underway to prospectively characterize antibody binding of thousands of virus mutations using high-throughput technology.

While a single monoclonal antibody may be escaped by a single mutation, the RBD may be less affected by any one mutation if polyclonal serum antibodies bind evenly across the RBD. On the other hand, if serum is highly focused on one immunodominant site, then even polyclonal serum may be easily escaped by single mutations. Ms. Greaney's laboratory characterized 28 convalescent plasmas and found that some are substantially affected by single mutations. However, mRNA-1273 vaccine sera have broad binding distributed across the RBD surface such that a single mutation does not have a disproportionately large effect.

Data to Support Use of Modified COVID-19 Vaccines Against SARS-CoV-2 Variants—Doran Fink, M.D., Ph.D., FDA

In February, FDA published its regulatory approach to evaluating and authorizing modifications to COVID-19 vaccines in response to emerging virus variants. The guidance lays out definitions and assumptions—among them, that the modified vaccine would be made by the same manufacturer and same process as the prototype vaccine that was deemed safe and effective in clinical trials.

Clinical trials of the modified vaccine would have to support effectiveness through immunobridging studies comparing immune responses induced by the modified COVID-19 vaccine against the variant of concern with immune responses induced by the prototype vaccine against the originally targeted virus strain. Similarly, evaluation of booster doses would have to demonstrate that the effect of the modified vaccine against the variant is not inferior to that of the prototype vaccine against the original strain. Primary safety and immunobridging studies would have to be conducted in unvaccinated subjects, preferably people who have not had COVID-19. Within certain parameters, findings could be extrapolated from narrow demographic groups to broader populations. Various requirements for safety data are spelled out in the guidance.

FDA's guidance does not cover the following:

- Criteria for determining the need for modified COVID-19 vaccines or selection of antigen for inclusion, which would likely require an international effort involving public health and regulatory authorities
- Post-authorization studies to ensure that modified COVID-19 vaccines have expected effectiveness and to address potential future needs for additionally modified COVID-19 vaccines
- Approach to evaluation of multivalent COVID-19 vaccines
- Data or experience that would be needed to support authorization of “strain change” modifications based on manufacturing information alone (as with the current approach for annual updates to seasonal influenza vaccines)

Strategies for Utilizing Vaccines to Address SARS-CoV-2 Variants—Richard Kuhn, Ph.D., Purdue University

The key to preventing or slowing the emergence of SARS-CoV-2 variants is to limit the number of virus replication cycles to reduce the probability of vaccine escape, which can be achieved through increased worldwide vaccination. Current vaccines target the spike protein, which represents only 10 percent of the genome. Dr. Kuhn proposed that the next generation of COVID vaccine target T-cell response, which could enhance vaccine potency and durability.

Current vaccines do not create sterilizing immunity, so some virus replication occurs, and because the vaccines are not 100-percent effective, some vaccinated people will harbor some virus. The United States is behind the United Kingdom in terms of the percentage of people with COVID-19 for whom the virus has been sequenced. Increasing sequencing is necessary to identify where variants come through and what breakthrough infections occur. Breakthrough infections could be worse, because the variants are evolving and mutations are building on each other.

Great progress has been made on vaccines largely because of basic science research conducted in recent years and technological advances that allow for prediction of the next set of variants likely to emerge, as Ms. Greaney described. Continued focus is needed on how to protect people who cannot take the vaccine or do not respond to it, because they could become a reservoir of infection. Furthermore, as long as countries around the world lag in vaccination rates, more variants will emerge. Dr. Kuhn urged continued assessment of ways to improve vaccine durability and broad immune response as well as development of medical countermeasures for the immunocompromised.

Impact of SARS-CoV-2 Variants on Vaccines: Mutations, Efficacy, and Pipeline—Kaitlyn Morabito, Ph.D., National Institute of Allergy and Infectious Diseases (NIAID), NIH

Comparisons of current vaccines' effectiveness against the most widespread variants of concern differ depending on the variant, although it appears that the available vaccines provide good protection against severe disease from any type and that two doses of vaccine are more protective against the most prominent variants than a single dose.

In the absence of data about emerging variants, investigators look at levels of neutralizing antibodies, which appear to correlate with vaccine effectiveness and, with better models, could be useful for predicting vaccine effectiveness against a variant. Declining levels could also signal

waning immunity, which might predict the need for booster vaccinations. Neutralizing activity tends to wane at the same level, regardless of the variant.

Continued surveillance of vaccine effectiveness and the potential impact of variants remains a high priority. A Federal interagency working group formed to consider the impact of variants on vaccines and inform decision making. The next generation of coronavirus vaccines will include variant vaccines; broad activity, or pan-coronavirus, vaccines; and less expensive, less onerous vaccines that are more easily deployed around the world. The pipeline of vaccine candidates is robust; of nearly 300 candidates, more than 100 have reached clinical trials. NIAID is supporting research on pan-coronavirus vaccine, with particular focus on durable immunity and coronaviruses with pandemic potential.

Discussion

Daniel F. Hoft, M.D., Ph.D., questioned the feasibility of conducting immunobridging studies that could demonstrate noninferiority of novel vaccines that swap out the spike protein. He noted that correlative immunity has not yet been defined, and although neutralizing antibody levels are informative, no thresholds have been determined for assessing effectiveness. Dr. Hoft added that some developers are creating vaccines targeting T cells, but there is no precedent for defining how much protection they offer without an efficacy study. He asked how these challenges could be overcome.

Dr. Fink agreed that all of these factors pose challenges to authorizing or licensing the next generation of vaccines. It is critical to identify a biomarker of immunity, such as a threshold titer of neutralizing antibodies, that reliably predicts protection. Without a biomarker, it is difficult to use the immunobridging approach across vaccine platforms, including vaccines intended to elicit cellular immunity.

Dr. Morabito noted that studies are seeking correlates of protection, including some animal studies, and there is ongoing discussion among manufacturers. Some work is also underway toward an international standard, she noted. Dr. Kuhn cautioned that dengue virus researchers thought they understood correlates of protection but eventually found that neutralizing antibodies were not sufficiently predictive.

Dr. Meissner noted that mutating to increase virulence could be a disadvantage to the virus if it kills its human host. He asked whether the seasonal coronaviruses commonly seen in the fall and winter could have been more virulent forms on first appearance that became milder over time. Dr. Kuhn said experts believe that viruses are likely to be most virulent when they jump to a human host, but as they spread, they become less fatal so that they can continue to spread. However, viruses might adapt to attack new tissue, which raises other concerns.

Dr. Meissner asked whether there are similarities between SARS, Middle Eastern respiratory syndrome, and SARS-CoV-2 that could inform development of a pan-coronavirus vaccine. Ms. Greaney said the two SARS viruses have similar RBDs, and early in the pandemic, a lot of antibodies for research were isolated from people with SARS. There may be targets or other epitopes on the spike protein that could be susceptible to a pan-coronavirus vaccine.

Experiences in the Field: COVID-19 Vaccine Authorization and Beyond

Continued Challenges of Vaccine Development and Dissemination—Julie Gerberding, M.D., M.P.H., Merck

The unprecedented, multisector, global collaboration to develop COVID-19 vaccines and countermeasures has demonstrated that challenges such as varying regulatory requirements, intellectual property protection, and competition concerns can be overcome. Merck is now manufacturing the Johnson & Johnson vaccine because of problems with the original contractor, illustrating the capacity for cooperation as well as the difficulty of vaccine manufacturing.

Despite global efforts to produce COVID-19 vaccines, the supply has never been quite stable, and billions of needed doses are missing. In addition, the ability to distribute vaccines is hampered by insufficient infrastructure, shortfalls in public health, and lack of data management systems.

Dr. Gerberding proposed thinking further upstream by looking at ways to predict hotspots for outbreaks, prevent the spread of infectious disease, develop more countermeasures and position them for rapid deployment, and push new ways of manufacturing countermeasures. Collaborations should be sustained not just across sectors but across countries to ensure more robust networks of distribution, more manufacturing capacity, and a global supply perspective. Plans for equitable distribution should be developed before a crisis, acknowledging that countermeasures are a global good and not just a national commodity. The pandemic underscores the need to strengthen the vaccine ecosystem and use it to fight vaccine-preventable diseases and improve health around the world.

Pfizer-BioNTech COVID-19 Vaccine—Alejandro Cané, M.D., Pfizer Medical

Dr. Cané described the process from receiving the genomic sequence of the coronavirus spike protein to developing a safe, effective vaccine in less than 1 year. In February 2021, Pfizer began testing the vaccine in pregnant women and assessing the need for a third dose to provide continued protection and to address variants. It has since confirmed that its vaccine can be stored at temperatures used in standard freezers for up to 1 month and longer in specialized freezers.

The vaccine effectiveness determined in clinical trials has been borne out by real-world data. The company is now ramping up production and developing new dosage formulations so that vaccine is easier to use and store. It aims to expand vaccine for use among younger children and immunocompromised people. The vaccine platform allows for rapid changes, which will support preparations for tackling emerging virus strains.

Pfizer adapted its infrastructure at plants in the United States and Germany to accelerate vaccine production. It is engaged in an unprecedented and transparent collaboration with the public health community to monitor safety and build vaccine confidence among the public and HCWs.

Moderna Vaccine—Randall N. Hyer, M.D., Ph.D., M.P.H.

Dr. Hyer summarized the trials supporting the authorization of Moderna's COVID-19 vaccine, noting that real-world evidence is consistent with the trial findings. Moderna appears to maintain its efficacy against variants even as neutralizing antibodies decrease. The virus is expected to persist, so it is anticipated that boosters will be needed (even in the absence of variants of concern). Dr. Hyer noted that with the emergence of variants, a higher proportion of the population will need to be vaccinated to achieve and maintain herd immunity. Low rates of vaccination in other countries are contributing to virus transmission and emergence of variants.

Moderna is well positioned to address future coronavirus waves as it has capacity for rapid development and manufacturing. Also, its vaccine platform offers potential for multivalent boosters and for a primary series of heterologous boosters. Moderna envisions a variant vaccine that can be administered to anyone, regardless of whether they were previously infected or

vaccinated. Such a vaccine could help close gaps, such as geographic barriers to access. It could also be a good step toward a primary, multivalent vaccine.

There is an opportunity to get ahead of the virus through a combination of high vaccination rates, monitoring for emerging variants and waning immunity, and updated vaccines to combat variants of concern. Manufacturers must partner with public health entities to ensure that people have access to up-to-date boosters, Dr. Hyer concluded.

Lessons Learned from the COVID-19 Pandemic—Richard Nettles, M.D., Janssen/Johnson & Johnson

Dr. Nettles reflected on the remarkable progress made in vaccinating 170 million people in the United States to date, standing up extensive safety surveillance capable of identifying and diagnosing adverse events earlier than ever, and initiating a robust public health education effort that aims to address health inequities and build vaccine confidence. This progress was made possible through collaboration at every stage. Dr. Nettles noted that the work to ensure diversity in the vaccine clinical trials will lay the groundwork for more inclusive studies in the future.

Rigorous safety surveillance remains a priority. Following identification of a safety signal, the use of Johnson & Johnson vaccine was suspended for 10 days out of an abundance of caution, although use resumed when the data demonstrated an overall positive risk profile. Johnson & Johnson strongly supports raising awareness about thrombosis with thrombocytopenia syndrome to ensure early diagnosis and treatment as well as expedited reporting by health care providers.

Future public health emergencies will require that all facets of society are represented in the response. Government agencies such as BARDA are needed to support research and development in collaboration with manufacturers to create products for research use and eventual dissemination to the public. Public health, professional, and industry organizations play a leading role in vaccine education. Among the challenges ahead are ensuring that more people are vaccinated in the United States and around the world and that the global community is better prepared to deal with the next pandemic.

Novavax Vaccine—Greg Glenn, M.D., Novavax

Novavax just completed phase III clinical trials of its COVID-19 vaccine, demonstrating 90-percent overall efficacy, 100-percent efficacy against severe disease, and a good safety profile. Among the 14 breakthrough cases among vaccinated subjects, 82 percent were caused by variants of concern or interest, and all were mild. The results of sequencing of variants mirror findings in the United Kingdom.

Novavax is working to establish a global supply chain. It has eight manufacturing sites (two in the United States) with the projected capacity to produce 150 million doses per month by the end of 2021. Assuming that the vaccine receives regulatory approval, Novavax will provide vaccine to the Gavi/COVID-19 Vaccines Global Access effort to ensure fair, equitable access to vaccine. It has purchasing agreements in place with the United States and other countries. The vaccine is built on a highly adaptable platform that has potential for use as a booster, a variant vaccine, and as part of combination that includes seasonal influenza vaccine.

Discussion

Leonard Friedland, M.D., asked what steps can be taken to bolster vaccination rates while not disturbing routine care, especially for children returning to in-person school. Dr. Gerberding acknowledged the bottleneck that occurred when the pandemic shut down routine vaccination

programs for 80 million children, resulting in “a disaster waiting to happen.” The bottleneck must be confronted and attention paid to maximizing the immunization infrastructure. Adolescents receiving COVID-19 vaccines should be offered other routine vaccines at the same time. People should be reminded of the importance of resuming primary care services, especially routine vaccinations. Steps should be taken to decrease the burden on the public health system, such as empowering pharmacists to vaccinate. Dr. Gerberding said efforts might need to go beyond communicating about catching up on vaccinations and acknowledge the need to do better to ensure people are protected against vaccine-preventable diseases.

Dr. Douglas expressed interest in biologic approaches and studies underway to assess vaccine efficacy in immunocompromised persons. Dr. Cané said Pfizer is starting a clinical trial in September for immunocompromised people, who were excluded from early vaccine studies, and hopes to have data by the end of the year. Current real-world data indicate that immunocompromised people have less immunologic response to vaccine than immunocompetent people. Pfizer hopes that real-world information on vaccine effectiveness garnered through large databases will inform understanding about the need for a third vaccine dose. Dr. Nettles said Janssen is studying immunocompromised people in clinical trials starting this year and is working with U.S. Investigators and others to collect real-world data. Dr. Glenn said Novavax has some data from South Africa and is planning more research. Dr. Hyer observed that Moderna’s phase III clinical trial include people with well-controlled HIV. He noted the importance of expanding vaccination to include people at high risk.

Dr. Cooke expressed pride in the industry’s accomplishments during such difficult times. He noted that Operation Warp Speed spent about \$18 billion to develop the vaccines that are saving lives and preventing disease. By contrast, governments spent about \$16 trillion on programs to support the economy and health care systems during the pandemic. Dr. Cooke hoped policymakers would recognize that investing in vaccines is much less costly than combating a pandemic.

Dr. Gerberding suggested NVAC or CDC assemble a task force to identify creative ways to promote vaccine catch-up and getting routine vaccinations us back on track, domestically and globally. She noted that measles vaccination rates were not ideal in 2019. Via chat, Ms. Ehresmann stated that Minnesota is hoping to apply lessons learned about immunization equity to routine childhood vaccine catch-up. It also aims to combine adolescent COVID-19 vaccination with routine vaccine catch-up.

Immunization Equity Subcommittee Report and Recommendations: Revised— Melody Anne Butler, B.S.N., RN, CIC, Co-Chair

Ms. Butler described how the NVAC members’ feedback was incorporated into the revised recommendations and report. The revision included a new recommendation that the ASH work with the Office of Management and Budget to develop standardized racial and ethnic categories as well as other data collection categories for sex, disability status, and institutionalized, incarcerated, or homelessness people to facilitate the use of IIS data and immunization equity. Ms. Butler noted that the new recommendation should also refer to the LGBTQ community (using HHS’ preferred terminology).

Discussion

Dr. Meissner pointed out that the report introduction sets up a false comparison between “institutionalized, homeless, and incarcerated people” and white people as if no white people fall

into those categories. Ms. Ehresmann proposed changing “white people” to “the general public,” and NVAC members agreed with the suggestion.

In response to Troy Knighton, M.Ed., Ed.S., LPC, who requested clarification of “administrative burden,” Ms. Butler suggested that the new language added to recommendation 1.1 specify “regulatory burden” instead, and NVAC members agreed. For recommendation 3.3, Mr. Knighton proposed rewording to indicate that the lessons learned from COVID-19 vaccination should be applied to all future immunization programs, and members agreed. He and Uzo Chukwuma, M.P.H., requested that IHS be added to recommendation 5.2, and other members agreed. Discussion ensued about the intention behind new language in recommendation 5.5 that the ASH work with various partners “to facilitate a clinical decision support system for immunization applicable to IIS and EHRs to support routinization and standard immunization practices across all ACIP-recommended vaccines.” Dr. Hopkins said it would be more accurate to say “facilitate use of clinical decision support systems,” and NVAC members agreed.

Vote: NVAC members unanimously approved the Immunization Equity Subcommittee’s report recommendations with the changes discussed.

Federal Agency Updates

AHRQ—Justin A. Mills, M.D., M.P.H.

AHRQ’s Effective Care Program finalized a systematic review on safety of vaccines used for routine immunization in the United States. Since the 2014 report on vaccine safety, no new evidence was found of increased risk for key adverse events following administration of vaccines that are routinely recommended for adults, children, and pregnant women. The signals remain unchanged for adverse events, and there continues to be no evidence of increased risk of adverse events for vaccines currently recommended in pregnant women. There remains insufficient evidence to draw conclusions about some rare potential adverse events.

BARDA—Linda Lambert, Ph.D.

BARDA continues close coordination and collaboration with its private sector and interagency partners to support the Federal COVID-19 response for vaccines, which includes supporting the advanced development and ongoing manufacture of six vaccine candidates. BARDA also supports advanced development and manufacturing of vaccines against Ebola virus, anthrax, and other diseases, as well as advancements to improve vaccines, such as work on products that do not require needles or constant refrigeration. Dr. Lambert noted that BARDA initiated a phase III clinical trial of the safety, efficacy, and immunogenicity of Sanofi and GSK’s adjuvanted vaccine candidate in people age 18 and over. The trial is being conducted in two phases. The first phase will evaluate two doses of monovalent vaccine using the 614 strain, and the second phase will compare the bivalent formulation, the B614 and B5315 strain, against placebo.

CDC—Melinda Wharton, M.D., M.P.H.

As of June 15, CDC monitoring indicates that ordering for routine childhood vaccines for 2020–2021 remains below 2019 rates by about 12 million doses. Dr. Wharton said that things have looked okay for months from a weekly perspective, but spring 2020 was very disruptive. Preliminary results of CDC’s VFC provider survey suggest that local public health providers and FQHCs may have been particularly impacted by the interruption in vaccinations. The June 11 issue of *Morbidity and Mortality Weekly Report* includes IIS data from selected States for March through September 2020. CDC has made large investments in addressing racial and ethnic disparities in COVID-19 vaccination that it hopes will carry over to influenza vaccination programs this fall. An effort to engage with community-based organizations (CBOs) kicks off

with a large CBO-funded effort on June 30. Through several mechanisms, CDC will fund over 400 CBOs working to address disparities in COVID-19 vaccinations.

CMS—Mary Beth Hance

On June 9, CMS announced that Medicare would provide additional payment of \$35 per dose for administering in-home COVID-19 vaccine for certain beneficiaries as an incentive to providers. The American Rescue Plan included several provisions for Medicaid, including the Children’s Health Insurance Program (CHIP). CMS has been monitoring decreases in pediatric immunization through Medicaid and CHIP programs during the pandemic and making the information available. CMS encourages States to catch up on missed vaccinations and focus on back-to-school vaccine efforts. Ms. Hance appreciated the willingness of CDC staff to speak to CMS groups about vaccine catch-up efforts, as evidenced by presentations to the State CHIP programs via the Children’s Coverage Technical Advisory Group and to stakeholders via CMS’ Connecting Kids to Coverage national campaign.

DoD—David Hrcir, M.D.

The DoD’s COVID-19 implementation plan encompasses active duty, U.S. Coast Guard, Reserve, and National Guard personnel, in addition to retirees, beneficiaries, and others. The COVID-19 vaccine remains a voluntary option for uniformed personnel while it is under Emergency Use Authorization (EUA). As of June 2, 2021, DoD had administered over 3.6 million COVID-19 vaccines at over 360 immunization sites globally. The DoD’ written report describes its vaccine advocacy efforts among its covered populations. DoD systems for evaluating AEFIs have identified more cases of myocarditis, which Dr. Hrcir hoped would be published soon. The DoD population includes a lot of young adult males, he noted. For the second year, DoD has secured Southern Hemisphere influenza vaccine for people permanently or temporarily assigned to the region. DoD also has a back-to-school vaccination campaign, demonstrating its reach beyond the active duty population.

FDA—LTC Valerie Marshall, M.P.H.

On May 25, 2021, FDA updated its guidance, Emergency Use Authorization for Vaccines to Prevent COVID-19, to include a new section that clarifies how the agency intends to prioritize review of EUA requests for the remainder of the COVID-19 public health emergency. The document can be found [online](#). On June 8, 2021, FDA approved a product for active immunization to prevent pneumonia and invasive disease caused by 20 *Streptococcus pneumoniae* serotypes. In March 2021, FDA approved a supplement to the Biological License Application for Flucelvax Quadrivalent to extend its use to those 2 years of age and older.

HRSA—Mary Rubin, M.D.

To date, HRSA has awarded or announced funding opportunities for \$7.3 billion to support health centers in responding to the pandemic, increasing testing and vaccinations, conducting contact tracing, and participating in vaccine development and distribution. In August, in support of National Immunization Awareness Month, HRSA urged health centers and health care providers to increase childhood immunization rates and improve access to essential immunization services by extending hours (e.g., on nights and weekends) specifically for the administration of catch-up vaccines, informing parents about the COVID-19 safety precautions and practices that health centers have in place and encouraging them to bring in their children for vaccinations, and using social media messages and graphics from the Catch-Up to Get Ahead toolkit in digital communication efforts. According to data collected between August 1, 2020, and January 29, 2021, through weekly surveys, health centers administered 4,166,433 influenza vaccines, with 73.44 percent of those going to racial and ethnic minority patients.

The National Vaccine Injury Compensation Program continues to process an increased number of claims. In FY 2021, as of April 1, petitioners filed 1,599 claims, and over \$126 million was awarded to petitioners, including attorneys' fees and costs. As of May 3, 2021, HRSA had a backlog of 1,385 claims alleging vaccine injury awaiting review.

The National Vaccine Injury Compensation Program: Rescission of Revisions to the Vaccine Injury Table Final Rule was published in the *Federal Register* on April 22, 2021, and it rescinds in its entirety the rule entitled National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, published in the *Federal Register* on January 21, 2021. As of April 22, 2021, the January 21, 2021 Final Rule was withdrawn.

As of April 26, 2021, 445 COVID-19 claims had been filed with the Countermeasures Injury Compensation Program. About 152 of those claims allege injuries from COVID-19 vaccines. Alleged injuries range from allergic reactions to death. The program has not yet made eligibility determinations for these claims. About 90 percent of these claims cannot be reviewed because medical records have not been submitted yet.

IHS—Uzo Chukwuma, M.P.H.

IHS routinely tracks pediatric immunization coverage. In the past 5 years, IHS observed a slight decrease in the immunization coverage rate for 2-year-olds, and with the COVID pandemic, a further decrease in coverage has been observed. Before the onset of COVID-19, the IHS national immunization coverage for current age-appropriate ACIP-recommended vaccines for 2-year-olds was 64.7 percent. Coverage fell to 56.9 percent in the quarter ending March 31, 2021. Contrary to the trends observed among 2-year-olds, the coverage trend among adolescents (13–17-year-olds) for human papillomavirus, meningococcal, tetanus, diphtheria, and pertussis vaccines has remained relatively stable. The IHS continues working with Tribes, States, and CDC to promote routine childhood and adolescent immunizations.

In response to declining pediatric immunization coverage, IHS has engaged in various initiatives to promote routine and catch-up immunizations. IHS planned and implemented a pediatric immunization improvement initiative that kicked off May 13, 2021. Strategies implemented as part of this initiative included clinical activities, provider engagement, and community outreach and messaging. IHS will host a number of webinars, share CDC and HHS communication and education materials, provide training to immunization champions on how to use available tools to identify patients who are not up to date, increase immunization opportunities, and disseminate provider resources toolkits emphasizing childhood immunizations.

NIH—Barbara Mulach, Ph.D.

Dr. Mulach referred to work already described by Dr. Morabito of NIAID. In addition, NIH's Community Engagement Alliance Against COVID-19 Disparities is providing grant support for communities disproportionately affected by COVID-19. NIH also has several funding awards focusing on vaccine hesitancy, uptake, and implementation in areas experiencing disparities.

VA—Troy Knighton, M.Ed., Ed.S., LPC

Congress passed the Save Lives Act, which allowed VA to deliver COVID-19 vaccine to more than 65,000 caregivers, spouses, and not-otherwise-eligible veterans. VA has prepared guidance to open vaccination to adolescents 12–17 years of age. It has fully vaccinated more than 28,000 Federal employees from the Department of Homeland Security, HHS, FDA, the General Services Administration, the National Archives and Records Administration, and the Federal Judiciary.

NVAC Liaison Updates

AIM—Aleah Jensen

AIM continues to support its members by providing opportunities to share information and resources as immunization programs conduct COVID-19 vaccination campaigns. AIM is also focusing support on implementation of supplemental funding for health equity and community engagement activities, as well as back-to-school and catch-up routine vaccination. Each week, AIM provides an opportunity for members to share ideas and ask questions. To help program managers manage their inboxes and stay abreast of critical information, AIM provides a COVID update with critical information, resources, and updated talking points each week. AIM takes part in weekly White House calls to gather up-to-date, real-time information from the Federal level to share with members.

In anticipation of the upcoming influenza season, AIM held a back-to-school webinar on April 28, at which the National Association of School Nurses and Immunize Nevada presented strategies for getting adolescents and school-age children caught up on routine vaccinations. The webinar had 277 participants, including 143 CDC awardee immunization program staff. AIM is also focusing on health equity and vaccine confidence. Its Equity Committee began meeting in March 2021 to provide immunization program managers an opportunity to brainstorm, capture lessons learned from COVID-19 vaccine inequities, share knowledge about best practices, and discuss equity-focused work plans. AIM will continue to update its vaccine confidence toolkit, including lessons learned for vaccine opposition and engaging with communities at risk for preventing diseases. Notable AIM resources include a Medicaid checklist for program managers, a handout for leaders, and a tip sheet for businesses.

AIRA—Rebecca Coyle, M.S.Ed.

Ms. Coyle announced that all States now have an IIS. AIRA is trying to field questions about the role of vaccine credentials (e.g., vaccine passports or other proof of vaccination) and to distinguish the policy issues from the technology concerns. AIRA is focusing on what kind of technology needs to be developed and why it is important to have a standardized way of approaching vaccine credentialing systems, so it is developing a document describing the context and working definitions relevant to IIS. AIRA's written report addresses the need to capture race and ethnicity data, which ties in with NVAC's conversation around the Immunization Equity Subcommittee report. Ms. Coyle noted that all States now have the capacity to capture race and ethnicity data, which was not the case a couple of months ago.

In terms of being able to share data across State lines, AIRA continues to work with CDC and others on the Immunization Gateway, a secure router that supports the exchange of IIS data between jurisdictions and, eventually, will support data exchange among larger providers that operate in multiple jurisdictions. Over the past year, 54 jurisdictions have signed the data use agreement that provides legal clearance for sharing data, which represents a major step forward. With the increased number of staff being hired by jurisdictions, there is a need to educate everyone on the basics around IIS. AIRA piloted an interoperability course, which involved multiple sessions over 3 months in which participants got into the weeds of how jurisdictions can approach interoperability as well as some of the resources available. In an effort to increase data quality, between January and April of this year, AIRA cleansed more than 25 million addresses, which highlights how many vaccinations are being processed by IIS.

APhA—Jean-Venable “Kelly” Goode, Pharm.D.

Dr. Goode said APhA continues to focus on providing training, education, information, and resources on vaccines. It has been highly engaged with CDC around vaccine confidence. APhA surveyed its members and found that 92 percent of pharmacists had received the COVID-19 vaccine or planned to get it. Also, 98 percent said they were comfortable addressing vaccine confidence and hesitance, which helps highlight the role that pharmacists can play in COVID-19 vaccination.

ASTHO—Kimberly Martin

ASTHO continues to play a critical role in assisting members in their COVID-19 response efforts. It provided members with situational awareness and technical assistance and developed a number of issue briefs, available on its website, including recent briefs on travel during the pandemic and strategies to increase access to and confidence in vaccine. ASTHO developed several podcasts, such as a recent podcast on vaccine hesitance and vaccine credentials, and has conducted a number of media briefings. ASTHO is conducting virtual meetings in 10 States aimed at convening health equity leaders, public health immunization program managers, and community stakeholders to identify best practices to increase immunization uptake within diverse communities. It is holding a meeting June 28–29 to bring together partners from various backgrounds to better understand emerging best practices to address vaccine hesitance and generate ideas for applying those practices beyond COVID-19.

NACCHO—John Douglas, M.D.

NACCHO continues to support an incident management structure in response to the COVID-19 pandemic. Its primary work is carried out by the Immunization Working Group, which is currently focused on COVID-19 vaccinations as well as delayed childhood immunizations. Through that group, NACCHO offers broad support in four primary areas: COVID-19 vaccination, catch-up of other routine vaccinations, equity, and vaccine competence. The organization has been quite active in advocacy, particularly around the recent COVID-19 relief bill that was passed in the spring. It has also been providing training and resources for local public health agencies' immunization activities.

VRBPAC—Hana El Sahly, M.D.

Dr. El Sahly highlighted VRBPAC activities that were not related to COVID-19. VRBPAC convened on March 5 and reviewed influenza surveillance data from the United States and globally, which reflected very little influenza activity compared with previous years. It reviewed vaccine effectiveness data and data on the candidate strain. The committee voted to include the following strains for the egg-based 2021-2022 Northern Hemisphere influenza vaccine:

- A/Victoria/2570/2019 (H1N1)pdm09-like virus (EPI_ISL_417210)
- A/Cambodia/e0826360/2020 (H3N2)-like virus (EPI_ISL_806547)
- B/Washington/02/2019 (B/Victoria lineage)-like virus (EPI_ISL_352076)
- B/Phuket/3073/2013 (B/Yamagata lineage)-like virus (EPI_ISL_168822)

The cell- or recombinant-based vaccines would include the following strains:

- A/Wisconsin/588/2019 (H1N1) pdm09-like virus (EPI_ISL_404460)
- A/Cambodia/e0826360/2020 (H3N2)-like virus (EPI_ISL_944639)
- B/Washington/02/2019 (B/Victoria lineage)-like virus (EPI_ISL_347829)
- B/Phuket/3073/2013 (B/Yamagata lineage)-like virus (EPI_ISL_161843)

In both cases, for the trivalent vaccines, the B component would be a B/Washington/02/2019 (B/Victoria lineage)-like virus.

PHAC—Gina Charos

Canada’s COVID-19 vaccination campaign is well underway. The most recent statistics indicate that more than 70 percent of Canadians ages 12 years and older have now received at least one dose, representing about 65 percent of the country’s total population. At present, 53 percent of the population is considered to be partially vaccinated, and 12.5 percent has been fully vaccinated. The Federal government deployed 33 million doses to Canadian Provinces and Territories, which have administered about 30 million doses. Overall, vaccine confidence remains high in Canada. Almost 90 percent of those surveyed indicated they have either already been vaccinated or intend to be. However, there are gaps among some priority populations, including Black and Indigenous people, newcomers, and younger cohorts, and the country is doing some targeted outreach and communication to close those gaps.

Canada’s National Advisory Committee on Immunizations (the equivalent of the ACIP) has been very busy. It issued a number of guidance statements on COVID-19 vaccines, including advice on specific products, priority populations for sequencing early vaccine supply, intervals between vaccine doses, and vaccine use in special populations, such as pregnant women and immunosuppressed individuals. PHAC recently updated guidance on mixed vaccine schedules and co-administration of COVID-19 vaccine with other vaccines.

Canada did not have a proper influenza season this past year. Despite more intensive testing for influenza-like illnesses, there was no evidence of community circulation of influenza. Influenza vaccine coverage was fairly typical. About 40 percent of adults were vaccinated, which was higher than usual, and about 70 percent of seniors did so. PHAC is planning ahead with increased influenza vaccine supply for the upcoming influenza season and planning aggressive promotion of influenza vaccination this year. The most up-to-date data and reports are available [online](#).

Discussion

Dr. Douglas asked what is working in Canada to achieve high vaccination rates. Ms. Charos cautioned that the highest statistics represent only the first dose of COVID-19 vaccines, but the country is working hard to make sure people get their second dose. It is also focusing on reaching hard-to-reach and priority populations. Ms. Charos said that because of the limited vaccine supply, Canada offered a first dose of vaccine to as many people as possible before following up with the second dose, for which efforts are ramping up now. The vast majority of vaccines come from Pfizer and Moderna, although the AstraZeneca vaccine is also being used now, and the Janssen vaccine is available.

Written updates only were provided by the Advisory Commission on Childhood Vaccines and America’s Health Insurance Plans.

Public Comment

No public comments were given.

Wrap Up and Adjournment—Robert H. Hopkins Jr., M.D., MACP, FAAP, NVAC Chair

Dr. Hopkins thanked the participants and the NVPO staff and adjourned the meeting at 5:24 p.m.

APPENDIX: Abbreviations

ACIP	Advisory Committee on Immunization Practices
AEFIs	adverse events following immunization
AHRQ	Agency for Healthcare Research and Quality
AIM	Association of Immunization Managers
AIRA	American Immunization Registry Association
APhA	American Pharmacists Association
ASH	Assistant Secretary for Health
ASTHO	Association of State and Territorial Health Officials
BARDA	Biomedical Advanced Research and Development Authority
BEST	Biologics Effectiveness Safety (Initiative)
CBER	Center for Biologics Evaluation and Research
CBO	community-based organizations
CDC	Centers for Disease Control and Prevention
CHIP	Children’s Health Insurance Program
CMS	Centers for Medicare & Medicaid Services
COVID-19	coronavirus disease (2019)
DoD	Department of Defense
EHR	electronic health record
EUA	emergency use authorization
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
FQHC	Federally Qualified Health Center
HCW	health care worker
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IIS	immunization information systems
LGBTQ	lesbian, gay, bisexual, transgender, or queer
NACCHO	National Association of County and City Health Officials
NASEM	National Academies of Sciences, Engineering, and Medicine
NFID	National Foundation for Infectious Diseases
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NVAC	National Vaccine Advisory Committee
OIDP	Office of Infectious Disease and HIV/AIDS Policy
PHAC	Public Health Agency of Canada
POC	people of color
RBD	receptor binding domain
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
VA	U.S. Department of Veterans Affairs
VAERS	Vaccine Adverse Event Reporting System
VaST	Vaccine Safety Technical Subgroup
VFC	Vaccines for Children
VRBPAC	Vaccine and Related Biological Products Advisory Committee
VSD	Vaccine Safety Datalink