NVAC NATIONAL VACCINE ADVISORY COMMITTEE

September 14–15, 2021, Virtual Meeting Minutes

Committee Members in Attendance

Robert H. Hopkins Jr., M.D., MACP, FAAP; Chair
Melody Anne Butler, B.S.N., RN, CIC
Timothy Cooke, Ph.D.
John Dunn, M.D., M.P.H.
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.
Robert Schecter, M.D.
Robert Swanson, M.P.H.

NVAC Ex Officio Members

Uzo Chukwuma, M.P.H., Indian Health Service (IHS)
Troy Knighton, M.Ed., Ed.S., LPC, Department of Veterans Affairs
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
Barbara Mulach, Ph.D., National Institutes of Health (NIH)
Mary Rubin, M.D., Division of Injury Compensation Programs (DICP), Health Resources and Services Administration (HRSA)
Margaret Ryan (for COL Tonya Rans, M.D.) Department of Defense (DoD)
Melinda Wharton, M.D., M.P.H. (for Sam Posner, Ph.D.), Centers for Disease Control and Prevention (CDC)

NVAC Liaison Representatives

James S. Blumenstock, Association of State and Territorial Health Officials (ASTHO)
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
Jean-Venable "Kelly" Goode, Pharm.D., BCPS, FAPhA, FCCP, American Pharmacists Association
Claire Hannan, Association of Immunization Managers (AIM)
Christopher Regal, M.S., America's Health Insurance Plans (AHIP)

Designated Federal Officer

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

Proceedings
Day One

Call to Order and Rules of Engagement—Ann Aikin, M.A., NVAC Designated Federal Officer, Communications Director, OIDP, 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 OIDP 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 that, as ASH, she works every day 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. She thanked the public health professionals and health care providers (HCPs) who continue to respond to the crisis caused by the COVID-19 pandemic. The COVID-19 vaccines have a remarkable safety profile and are highly effective, but it is necessary that more people get vaccinated to protect themselves and others.

As of mid-September, 380 million COVID-19 vaccine doses had been administered in the United States; 178 million people were fully vaccinated, and 63 percent of the U.S. population had received at least one vaccine dose. Yet millions of Americans are not yet protected. Vaccination is more important than ever with the spread of the delta variant, which is more contagious and more dangerous than previous forms of COVID-19. Breakthrough infections are rare, with only one confirmed case of COVID-19 for every 5,000 vaccinated people. The administration released a science-based, comprehensive strategy to outline a path out of the pandemic, and vaccination is central. Additional steps will be announced to combat the pandemic globally.

Going forward, Dr. Levine planned to put equity at the center of all her work. She is a member of the newly created Health Equity Task Force, which will advise President Joseph Biden on the causes of inequity and how to prevent it. To increase access to vaccines, HHS is working to ensure there are vaccination sites across the nation. At present, 90 percent of people in the United States have a vaccination site within 5 miles of their home. HHS is also working with schools and local health clinics to provide more options. It established the COVID-19 Community Corps to identify local leaders who can speak to their communities about the effectiveness of the vaccine and answer questions about COVID-19.

Dr. Levine thanked NVAC for raising awareness about the need to augment efforts around routine vaccination for children and adults, which slowed during the pandemic. HHS is monitoring data and spreading the message about the importance of catching up with scheduled vaccines, especially as school resumes and influenza season begins. Dr. Levine noted that to improve overall public health, it is essential to overcome vaccine hesitancy and increase vaccine acceptance across the life span. She thanked NVAC's Vaccine Confidence Subcommittee for its ongoing work to synthesize the evidence related to vaccine confidence and to recommend new strategies and approaches to increase vaccination across the life span. Dr. Levine appreciated the dedication and commitment of NVAC members to optimizing the vaccine system, noting that their expertise is invaluable to the ASH and HHS to improve the health of all Americans.

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 June 16–17, 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 February 10–11, 2022. (See the appendix for a list of abbreviations used in this report.)

Experiences in the Field: Lessons from Operation Warp Speed—LT COL Nathan Packard, HHS

Operation Warp Speed is now known as the Countermeasures Acceleration Group (CAG). Its mission is to accelerate the development, manufacturing, and distribution of COVID-19 vaccines and therapeutics to the entire U.S. resident population by leveraging the expertise of government agencies, industry, and academia. Among the keys to the successful rapid development of COVID-19 vaccines were building vaccine manufacturing facilities while the vaccines were in development and investing in large clinical trials to assess vaccine efficacy. To deliver and administer the authorized vaccine, Federal authorities took advantage of existing capacity and partnerships, such as the U.S. military's expertise in logistics and the private sector's expertise in shipping. As a result, 5 years' worth of vaccinations were delivered to the American people in just 34 weeks; and 188 million vaccine doses were donated to 92 countries.

LT COL Packard explained that the CAG seeks to capture lessons learned for future reference. So far, it has identified a number of focus areas, including budget and financing, executive leadership, legal and contracting matters, information technology, and supply chain management, to name a few. It will provide input to the National Vaccine Program, create a library of primary documents and multimedia materials, and deliver a comprehensive report on its findings. As an example, LT COL Packard outlined some lessons learned regarding the rapid acquisition process required for the COVID-19 response:

- **Promotion of transparency:** A public virtual reading room was created to allow access to key documents, with government and industry working to minimize redactions so the documents would be readable.
- **Increased speed:** To speed up the acquisitions process, the Federal government exercised nontraditional contract options.
- **Enhanced collaboration:** An interagency headquarters was established to foster unity and communication across Federal agencies.
- **"Flattened" decision making:** Efforts were made to remove some of the bureaucracy that usually delays decision making. Decision makers demonstrated a higher tolerance for taking informed risk, given the nature of the emergency. Constant communication across all stakeholders contributed to situational awareness.

LT COL Packard requested NVAC input on other areas of focus, research questions to pursue, and additional people or organizations who should be involved in the CAG's effort to compile lessons learned.

Discussion

Timothy Cooke, Ph.D., suggested the CAG determine the full government investment in Operation Warp Speed and related work, such as basic research, and then create a model to assess the financial return on investment (e.g., in terms of lives saved and costs averted). He also noted

that Operation Warp Speed was overseen by a group located within HHS that had the ability to work across departments, which may have been the result of prepandemic planning.

Rebecca Coyle, M.S.Ed., pointed out that immunization registries have struggled with policies that limit data capture and sharing. Now is the time to focus on how to enable data collection and data sharing in anticipation of future public health emergencies.

Leonard Friedland, M.D., proposed that the CAG consider how lessons learned from COVID-19 could be applied to the increasing global problem of antimicrobial resistance, a looming threat with pandemic potential. Applying the same kind of comprehensive, urgent approach to antimicrobial resistance as COVID-19 could have a significant effect.

Robert Schecter, M.D., asked for more information about the role of the CAG in developing candidates for countermeasures and its role in determining how work will progress around emerging COVID-19 variants.

Dr. Hopkins encouraged NVAC members to submit suggestions and questions to the CAG via Ms. Aikin as soon as possible, but no later than November 30, 2021.

Data Review: New COVID-19 Vaccine Safety Findings

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

Dr. Hopkins, who co-chairs the VaST, described the group's role in evaluating and interpreting COVID-19 vaccine safety data from multiple surveillance sources. Its findings support informed decision making by CDC's ACIP and contribute to guidance for clinicians on prevention, early detection, and management of adverse events following immunization. The VaST is reviewing U.S. and global data on the risks of thrombosis with thrombocytopenia syndrome, myocarditis, pericarditis, and Guillain Barré syndrome (GBS).

Data suggest an association between myocarditis and mRNA vaccination in young adults, and work is underway to better understand risk management and long-term outcomes. FDA's approval of the Pfizer vaccine required the manufacturer to conduct postmarketing studies on the risks of myocarditis and pericarditis following vaccination. Data from Israel suggest that the risk of myocarditis is much lower after vaccination than after COVID-19 infection, and the number of adverse events is higher after infection than vaccination. These data demonstrate the protective benefits of vaccination. The VaST will continue to meet regularly and review domestic and international data, updating ACIP, NVAC, and others.

Update: COVID-19 Vaccination During Pregnancy—Sascha Ellington, Ph.D., M.S.P.H., CDC

Dr. Ellington explained that CDC updated its recommendation on COVID-19 vaccination during pregnancy in response to the risk posed by infection and emerging data on the safety of the vaccine among pregnant people. COVID-19 infection during pregnancy can cause pregnancy complications and result in severe adverse events for the pregnant person and the fetus. Perinatal transmission of infection (to the fetus or neonate) is rare. With the spread of the delta variant in July and August, COVID-19 infections rose. In August 2021, the United States saw an unprecedented number of deaths (19) among pregnant people, although the number may be higher when reporting delays are considered.

Before mid-August, CDC recommended that all pregnant people be offered vaccination, indicating that discussion with an HCP may be helpful but is not required. About one quarter of pregnant people have received at least one vaccine dose to date. With growing evidence of vaccine safety, CDC determined that the benefits of vaccination outweigh the known and potential risks and that vaccination is essential for pregnant people; vaccination during pregnancy might also protect the fetus or neonate from infection.

Two published studies using data from CDC's v-safe registry of vaccinated pregnant women and the Vaccine Safety Datalink, respectively, determined that the rate of spontaneous abortion following vaccination (with an mRNA vaccine) fell within the expected background rate. Two large studies in Israel that compared vaccinated and unvaccinated pregnant people concluded that vaccination reduces the risk of COVID-19 infection. Dr. Ellington noted that despite widely spread misinformation, no evidence indicates that the vaccine affects fertility.

On the basis of the cumulative data and the low vaccine uptake by pregnant women, CDC strengthened its recommendation, stating that "COVID-19 vaccination is recommended for all people aged 12 years and older, including people who are pregnant, breastfeeding, trying to get pregnant now, or who might become pregnant in the future." The recommendation aligns with advice from high-profile medical societies for women's health. CDC offers several tools to aid HCPs, pregnant people, and new parents in making decisions about COVID-19 vaccination.

FDA COVID-19 Vaccine Safety Update—Steven Anderson, Ph.D., M.P.P., FDA

Dr. Anderson outlined FDA's active surveillance program, which assesses for a set of possible vaccine adverse events—determined before the COVID-19 vaccine became available—using public and private insurance claims data. Anaphylaxis, which is a common adverse event following any type of vaccination, was noted among people of various ages. Data for people age 65 and older revealed four potential signals that have triggered more in-depth investigation: acute myocardial infarction, pulmonary embolism, immune thrombocytopenia, and disseminated intravascular coagulation—all among people who received the Pfizer mRNA vaccine. Dr. Anderson pointed out that the data did not identify myocarditis, pericarditis, thrombocytopenia syndrome, or GBS, but those conditions are among the additional outcomes of interest for which FDA is conducting further assessments.

Analysis of data from privately insured people under age 65 revealed an increased risk for myocarditis and pericarditis following Pfizer mRNA vaccination, particularly among males ages 12–25 years, but also among females in the same age range, although their risk is lower than that of males. Dr. Anderson drew attention to the fact that the Moderna mRNA vaccine is not used in people under age 18, so it is not yet possible to identify distinctions between the two vaccines. He added that the number of cases is very small, making it difficult to draw broad conclusions without more data and analysis.

The Vaccine Adverse Events Reporting System (VAERS) has received some reports of GBS, including 10 patients who were intubated or required mechanical ventilation and one death. These events occurred among people with a median age of 57. The VAERS data indicate an elevated risk of GBS among people age 30 and older who received the Janssen (Johnson & Johnson) vaccine. Among such people, the data revealed 8.1 cases of GBS per million vaccines administered. As a result, Janssen includes additional information about GBS in its fact sheets for HCPs and vaccine recipients.

What Americans Are Thinking About COVID-19 Vaccines—Mark Miller, de Beaumont Foundation

Mr. Miller said the de Beaumont foundation seeks to understand how to communicate public health data effectively to the public. Through polling and focus groups, the foundation revealed several common themes among unvaccinated people, regardless of demographics:

- Concerns about the safety and side effects of the COVID-19 vaccine overshadow concerns about infection.
- Vaccination is seen as a personal choice, and criticism or blame causes unvaccinated people to become more entrenched in their refusal.
- Information should be presented in the form of unbiased facts and data; marketing campaigns and messages from politicians or pundits are suspect. (Among vaccinated people, 72 percent trust the U.S. Government [USG], but only 24 percent of unvaccinated people do.)
- Most people trust their own HCPs for information.
- Unvaccinated people are against mandates, but mandates are the most successful mechanism for getting people vaccinated.

When administration of the Johnson & Johnson vaccine was paused, there were concerns that the move would strongly affect perceptions of vaccine safety. Instead, people saw the pause as evidence of an effective safety monitoring system. The overall perception of vaccine safety was higher in July 2021 than in April (when the pause occurred). According to the Kaiser Family Foundation, about 60 percent of vaccinated adults are very confident that the mRNA vaccines are safe. In contrast, about 65 percent of unvaccinated adults are not confident that any of the available vaccines are safe. Notably, among unvaccinated parents, 81 percent believe that other childhood vaccines are safe. Not surprisingly, more vaccinated than unvaccinated parents believe that COVID-19 vaccines are safe for children.

Finally, 66 percent of unvaccinated people believe that being required to get a COVID-19 vaccine is a greater threat to their individual health and safety than being exposed to COVID-19. At the same time, 25 percent of people indicate that an employer's mandate would prompt them to get vaccinated. Therefore, Mr. Miller said, recent moves toward vaccine mandates may improve vaccine uptake. Useful resources are available from the de Beaumont Foundation, the Public Health Communications Collaborative, and the Health Action Alliance.

Discussion

Daniel F. Hoft, M.D., Ph.D., said a simple mathematical calculation indicates that an individual is about one million times more likely to die from COVID-19 infection than from vaccination. He asked how to communicate clearly about the severe consequences of getting COVID-19. Mr. Miller responded that the source of information is key, as people choose their media and social groups, which can lead them to absorb and share a lot of misinformation. A basic tenet of health communication is that the audience must feel a personal connection to the message; even the most compelling statistics are not enough. Mr. Miller said one focus group revealed that some vaccine-hesitant people got vaccinated when they saw that their friends and family did not suffer from adverse events after vaccination.

Dr. Hopkins added that he has had the most success when he communicates one-on-one with people who know him. Mr. Miller pointed out that data support that people will listen to an HCP with whom they have a trusting relationship.

John Dunn, M.D., M.P.H., noted that the data are changing rapidly, and even HCPs do not feel they always have the most up-to-date information to help them have difficult conversations with people who are vaccine hesitant. He proposed that reliable data be better packaged into formats that HCPs can use and be more easily accessible to them, especially for HCPs who do not deal with vaccination daily. Mr. Miller added that it is important for HCPs to communicate honestly about what is not yet known and to share with patients the resources on which they rely.

Molly Howell, M.P.H., suggested creating a simple online calculator, table, or graphic for individuals to estimate their personal risk of COVID-19 compared with a vaccine-related adverse event. Ms. Coyle proposed communicating more information about the long-term effects of COVID-19 infection as a counterbalance to the concerns about long-term effects of vaccination.

Messaging About Vaccine Safety

Enhancing Vaccine-Specific Clinical Trial Communication, Decision Making, and Confidence—Aisha T. Langford, Ph.D., M.P.H., New York University

Dr. Langford focused her doctoral research on enhancing minority participation in clinical trials, and last year she participated in Pfizer's phase I COVID-19 vaccine trial. In recent months she took part in town hall events to promote vaccination, where participants had opportunities to ask questions and share concerns. Dr. Langford said it is essential to understand who influences community norms and, when possible, to capitalize on their influence—whether it is a celebrity, a local doctor, or a trusted organizational leader. Tailoring events to meet the needs of specific communities—for example, delivering a town hall in Spanish to reach the Spanish-speaking community—boosts the impact of messaging.

Dr. Langford's published model for health communication to increase clinical trial participation emphasizes the importance of considering a broad range of patient characteristics, such as health literacy. Investigators should consider upfront—as they are crafting their funding applications—how the study can be structured to enhance broad participation. Dr. Langford noted that when she took part in the vaccine trial, she had to block off 4 hours in the middle of the workday to account for the postinjection monitoring. The option to take part in studies on weekends or evenings would be helpful. Study organizers should consider the best sources for reaching the intended audience and how to convey messages with audiovisuals as well as words. In recent years, it has become clear that the social and political context of the communication source matters. The ASK approach to enhancing clinical trial participation is as follows:

- **Assume** that all patients want to know their options and offer them the opportunity to participate.
- **Seek** the counsel of stakeholders and think broadly about who they might be.
- **Know** your numbers; determine how many eligible candidates are within reach, whether they have been asked to participate in trials before, how many expressed an interest in participating, and how many enrolled. This information can be used to adapt the recruitment approach.

Finally, Dr. Langford shared several lessons learned, including the need to combat misinformation and acknowledge uncertainty.

Communicating and Normalizing Scientific Uncertainty—Paul K. J. Han, M.D., M.A., M.P.H., National Cancer Institute, NIH

A key component of managing a public health crisis is informing the public about what is and is not known, which is problematic when uncertainty persists about the nature of the threat and the

benefits and harms of protective actions, for example. Communicating scientific uncertainty demonstrates respect for autonomy and individuals' right to knowledge so they can make realistic and informed decisions. On the other hand, the uncertainty could dissuade them from taking action. "Ambiguity aversion" is the psychological theory that if information about risk is incomplete, imprecise, or unreliable, individuals make more pessimistic appraisals of their risk, experience fear and worry, and avoid making decisions.

Dr. Han and colleagues hypothesized that normalizing uncertainty in communications could mitigate the effects of ambiguity aversion. In two preliminary trials—one among adults in Spain in 2015 using a hypothetical novel influenza pandemic and one among U.S. adults in 2020 during the COVID-19 pandemic—researchers assessed participants' responses to messages that conveyed a lot of scientific uncertainty. One of the messages emphasized that uncertainty is normal, making comparisons to experience with other infectious diseases and treatments. In the Spanish study, participants responded negatively to the uncertain messages; they were less likely to believe that vaccines would be effective, for example. The uncertainty-normalizing language had no impact on their responses to the hypothetical situation. In contrast, in the U.S. study, the uncertainty-normalizing language neutralized participants' perceptions of an elevated risk of COVID-19 and their worries about the disease.

Dr. Han said the preliminary findings suggest it might be possible to inform and reassure the public without dissuading people from taking appropriate action. He acknowledged the limitations of the studies, noting that investigators asked about participants' intentions but did not assess their behaviors. Dr. Han concluded that the pandemic reveals the need to promote scientific literacy and help people accept and understand uncertainty in science. He proposed that normalizing uncertainty might help people develop more balanced responses to uncertainty.

Framing Messages with a Safety Perspective—Kathleen Hall Jamieson, Ph.D., University of Pennsylvania

Dr. Jamieson urged communicators to frame vaccine messages in such a way that emphasizes the safety of vaccines, an approach she referred to as communicating the gist. For example, much of the reporting about the pause of the Johnson & Johnson vaccine described the adverse events (blood clots), but only a few sources emphasized that such events are extremely rare. A safety gist framework would not only describe the rarity of the adverse events but also explain that the pause is an example of how vaccine safety monitoring works to identify even very rare events. Messaging around the pause—even from the mainstream media—contributed to the number of people who believe that the COVID-19 vaccines pose a significant danger to health.

Communicating in gists and through a safety framework rather than a risk framework should be incorporated into all messaging. Messages that emphasize facts and put misinformation in context are helpful. Where opportunities arise to communicate with the public, providing information in a safety framework gives people a baseline from which to build deeper knowledge. For example, a fact sheet that poses the question, "How do we know vaccines are safe?" frames the issue from the assumption of safety.

Dr. Jamieson presented a targeted video message in which prominent Black HCPs expressed their confidence in the research around the COVID-19 vaccine. It is an example of relying on trusted and influential voices to reach those who might be skeptical and speaking to their concerns. Dr. Jamieson also noted that countering inflammatory perspectives with specific information is effective. Critica, an organization that promotes rational health and security decision making, has taken such an approach on social media, pointing out, for example, that adverse events following vaccination are extremely rare among young people. Dr. Jamieson concluded that public health

messaging around vaccines has been effective, but media outlets should better convey that the benefits of COVID-19 vaccination far outweigh the risks.

Health Care Workers as Vaccine Advocates—Lauren Vulanovic, Pan American Health Organization (PAHO), World Health Organization (WHO)

HCPs are often the most trusted sources of information, but like everyone else, they can be exposed to misinformation that raises doubts about vaccine safety and efficacy. To help HCPs act as vaccine advocates, Ms. Vulanovic said PAHO uses various methods to learn from HCPs directly what questions they have, what questions patients and others are asking, and what rumors are circulating. These methods include monitoring social media; holding live, virtual, interactive sessions with experts; press conferences; and WHO's infodemic management techniques.

A survey of Caribbean HCPs about their intent to get vaccinated revealed their doubts about the vaccine's safety, low confidence about the processes for developing and testing the vaccines, and mistrust in health authorities—but it also demonstrated their faith in PAHO and WHO as trusted sources of information. PAHO and WHO used the findings to create practical materials for HCPs to learn more about vaccine safety and to help them communicate about vaccines with patients, parents, and caregivers.

The materials include specific guidance on how to respond to questions, some in the form of short fact sheets that address the most common concerns in ways that are easy for HCPs to use and share with patients and others. The PAHO website has a section for responding to questions and concerns that arise as situations change. Materials also incorporate links to references from well-known and trusted sources, such as the WHO and CDC. An annex covers more complicated questions. The materials are organized in ways to help HCPs find information quickly.

Helping Families Understand Vaccine Safety—Karen Ernst and Amy Callis, Voices for Vaccines

Ms. Callis summarized the results of a survey that highlighted that parents seek a broad range of information about vaccines and vaccine-preventable diseases, including the science around the vaccines, while HCPs tend to focus most on distinguishing facts from fiction. Parents trust information from their HCPs and the CDC, but the CDC website is not family-oriented, and HCPs do not always prioritize the kind of information parents want. Ms. Callis offered several recommendations to improve vaccine communication:

- Increase the amount of family-focused content online that addresses parents' priorities.
- Create tools to facilitate conversations between parents and HCPs and materials that respond to parents' concerns when there is no time for conversation.
- Build innovative tools to provide real-time information that addresses misinformation expressed in person or on social media.

In addition, efforts to promote understanding should:

- foreshadow change, reinforcing the message that changing guidance is a reflection that science is working;
- recognize families' need for additional information, including scientific information;
- engage community influencers and social networks, broadening the scope of credible voices;
- provide HCPs with support for talking with families;

- encourage questions but quickly address misinformation and disinformation; and
- acknowledge that most issues are grounded in concerns about safety.

The Voices for Vaccines website incorporates these ideas and relies on other health communication tenets, such as using visuals to explain some technical concepts. Ms. Ernst described tools available that prepare parents for what to expect during HCP visits, including normal reactions to vaccines. These tools also offer parents strategies for improving interactions with HCPs. Voices for Vaccines depicts the childhood vaccine schedule in a way that is less confusing for parents. The organization provides toolkits to help parents advocate for vaccination in their communities and beyond.

Voices for Vaccines is developing a mobile app that will help people start conversations about vaccination; it considers the setting, the audience, and the type of vaccine. It also provides a "debunking tool" for addressing misinformation quickly. The organization developed an online course for vaccine conversations that uses a storytelling framework and can be delivered by text messaging. Ms. Ernst pointed out that people have various levels of vaccine confidence, but good tools can help build confidence from any starting point.

Vaccine Confidence Subcommittee Update—John Dunn, M.D., M.P.H., Co-Chair

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. Dr. Dunn presented 34 preliminary recommendations under consideration, organized in five categories. He explained that the Subcommittee's report would provide the data and rationale behind each recommendation. Dr. Dunn emphasized that the current draft recommendations are broad in scope, and the Subcommittee seeks input from NVAC members on whether the recommendations adequately address the charge to the Subcommittee and whether significant gaps remain.

The five categories are as follows, and a few of the 34 recommendations are summarized to give a sense of the breadth and scope:

1. Investing in Vaccine Confidence Research and Data
   • Fund research on specific subpopulations.
   • Publish data on vaccine confidence at the State and county level.
   • Fund research on how to improve vaccine confidence.
   • Conduct a comprehensive review of recent data and use the findings to inform the research agenda.
2. Building Trust in Government
   • Invest in crisis communication training.
   • Develop culturally and linguistically appropriate materials to communicate with underresourced and low-literacy populations.
   • Identify all activities funded by the American Rescue Act related to vaccine confidence, their impact, and lessons learned.
3. Educating and Empowering HCPs
   • Evaluate the effectiveness of current efforts to improve vaccine confidence among HCPs.
   • Develop evidence-based curricula for training HCPs about vaccine science and how to talk with patients about vaccines.
   • Provide training to HCPs on reducing racism and discrimination and delivering appropriate and inclusive health care.

4. Fostering Community Engagement and Education
   • Evaluate the feasibility of responding to misinformation and disinformation in ways that are tailored to specific communities.
   • Develop a curricula for middle school students about understanding vaccines.
   • Evaluate and publish findings on community engagement around vaccine confidence.
5. Advancing Communication Strategies to Increase Vaccine Confidence
   • Consider how to mobilize expertise and information quickly to counter misinformation and disinformation.
   • Use emotive language in public health campaigns to increase vaccine confidence.
   • Train HCPs on using social media to deliver effective, accurate messages.

Discussion

Dr. Dunn said the rollout of the COVID-19 vaccine highlighted that some issues were more important than the Subcommittee realized when it began its deliberations. The pandemic drew attention to the need for consistency in communication and adequate, easy-to-access training for people at all levels of response.

Dr. Dunn clarified that the Subcommittee recommended that HHS identify the research on vaccine confidence that it has funded, as a step to improve transparency. It also recommended that CDC publish a systematic review of literature on vaccine confidence that includes international publications.

Ms. Howell asked whether the Subcommittee addressed the role of chiropractors in vaccine hesitancy or of any other groups that might contribute to misinformation. Dr. Dunn did not think the Subcommittee focused on any specific groups, but it recognized that HCPs of all types may lack confidence in vaccines. To that end, the Subcommittee suggested more education, training, and materials for HCPs, including allied health professionals, about the science behind vaccines.

Troy Knighton, M.Ed., Ed.S., LPC, asked whether the Subcommittee prioritized which subpopulations to target for research. Dr. Dunn said the Subcommittee recommended more research to identify which subpopulations would benefit from targeted communication, recognizing that much more data are needed.

Robert Swanson, M.P.H., suggested that language about educating HCPs should include education and training for medical assistants and nurses, who are playing an increasing role in vaccination. Dr. Dunn agreed, saying it is important for all those who communicate with patients to deliver a consistent message. Dr. Hopkins asked NVAC members to send additional comments to him, Dr. Dunn, and Ms. Aikin.

Public Comment

No public comments were offered.

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

Dr. Hopkins thanked the participants and the OIDP staff and recessed the meeting for the day at 5:33 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 1:00 p.m. on September 15. Dr. Hopkins summarized the proceedings of day one and gave an overview of the agenda for day two.

Correlates of Protection and Enduring Immunity

Correlates of Vaccine-Induced Immunity—Stanley Plotkin, M.D., University of Pennsylvania

Dr. Plotkin explained that vaccine correlates of protection can be absolute (i.e., a threshold of immune response at which everyone responds) or relative, mechanistic (a biological response) or nonmechanistic (a biomarker of response). Correlates of protection offer insight into the likely protective effects of vaccines in the absence of phase III clinical trials. Dr. Plotkin emphasized that the immune system involves built-in redundancies, so many immune responses could be correlates of protection.

Researchers have targeted the spike on the surface of the coronavirus protein, which induces protective responses. Less is known about other elements of SARS-CoV-2 that could be targets for vaccines or therapeutics. The COVID-19 mRNA vaccines and other vaccines produce varying levels of antibody response that correlate with protection against the virus. Even the vaccines with the lowest antibody responses are about 50 percent effective, suggesting that other factors may be involved in protection. For several vaccines, investigators determined that efficacy increases with a second dose; the optimal timing of the second dose varies by vaccine, but some time is needed for the initial dose to prime the system.

Dr. Plotkin said CD4 T cells respond to many SARS-CoV-2 antigens but added that CD8 T-cell responses might be more important, although the role of T cells in general remains controversial. Notably, CD8 T cells respond more to SARS-CoV-2 nucleid proteins than to its spike proteins. Researchers can now analyze which epitopes are important to induce specific immune responses, including epitopes other than those on the spike protein. Questions remain about the duration of antibody response, the role of mucosal or immunoglobulin A responses, and whether the virus will continue to mutate.

Protection Against Severe SARS-CoV-2—Taia T. Wang, M.D., Ph.D., Stanford University

Dr. Wang's work assesses the correlates of progression of the virus to severe COVID-19 infection, which has implications for the mechanisms involved in vaccine protection against severe disease. She described how antibodies binding to a target can increase the affinity for certain receptors, transforming a molecule into a powerful signaler, which in turn leads to recruitment of different effector functions. One modification that occurs as a result is afucosylation, or the absence of core fucose, which makes the molecule engage a specific receptor.

Dr. Wang's laboratory determined that people who develop severe COVID-19 disease have high levels of afucosylated antibodies and high levels of receptors for afucosylated antibodies. These antibodies trigger a number of responses that are associated with severe infection. The laboratory confirmed these findings in a mouse model. The level of afucosylation is lowest following mRNA vaccination and highest among those hospitalized with COVID-19.

On the basis of her findings, Dr. Wang proposed that severe COVID-19 infection results from two factors: 1) inadequate preexisting immunity and 2) a pathological immune response, which is less common but frequent enough to contribute to the significant morbidity seen with the virus. Furthermore, the data suggest that the mRNA vaccines might mitigate both factors by producing a robust neutralizing antibody response and ensuring that the immunoglobulin elicited is not inflammatory when it forms immune complexes in the lung.

Immune Correlates of Protection for COVID-19 Vaccines—Ruben Donis, Ph.D., BARDA

USG support for vaccine development required manufacturers to commit to clinical studies using harmonized endpoints so that data could be compared across companies. The goal was to identify correlates of protection that would support vaccine approval and potentially new vaccine indications, regimens, or compositions. Dr. Donis summarized the design of an analysis of the correlates of protection by assessing antibody thresholds according to four different biomarkers at two time points.

The analysis demonstrated that the higher the antibody level, the greater the vaccine protection. However, even when antibody levels were low or undetectable (e.g., 4 months after the second dose), the vaccines remained at least 51 percent effective, representing a limitation of the study. Dr. Donis noted that such protection is not unprecedented. A mediation analysis of the Moderna mRNA vaccine found that most but not all of the vaccine's effectiveness is related to the antibody response, which is also true of certain influenza vaccines.

A similar study was conducted for the AstraZeneca vaccine, which uses chimp adenovirus, and the findings were highly consistent with the U.S. analysis. For both, the predicted vaccine efficacy at a given level of antibody titer is very similar, which suggests significant strength and consistency of the correlates analyzed across the two studies.

Discussion

Dr. Schecter asked whether a third dose of mRNA vaccine should be considered a booster or a continuation of the primary series. Dr. Plotkin responded that with all inactivated vaccines, time is required for the immune response to develop fully. The data indicate that a third dose boosts the immune response and broadens the response against virus variants, which Dr. Plotkin believes aligns with the concept of a developing immune response.

Dr. Schecter asked panelists for their perspectives on correlates for severe disease versus those for infection overall. Dr. Wang indicated that the two factors she described—inadequate preexisting immunity and the aberrant inflammatory response involved in the progression to severe disease—are independent factors. Sufficient titers of neutralizing antibody are enough to prevent progression in most people; those who have the aberrant inflammatory response are at high risk for severe disease.

Dr. Schecter asked whether Moderna's ongoing studies are assessing correlates of protection for severe disease. Dr. Donis replied that the topic is of interest, but it is unlikely that there will be enough breakthrough cases involving severe infection to assess the issue. He said research is now looking at the single-dose Johnson & Johnson vaccine, and eventually more data will be published about the other vaccine platforms.

The Future of mRNA Vaccines for Widespread Use

mRNA Influenza Vaccines in Development: Duke CIVIC Vaccine Center (DCVC)— Tony Moody, M.D., Duke University

DCVC is one of three NIH-funded Collaborative Influenza Vaccine Innovation Centers (CIVICs) working toward better influenza vaccines using novel immunogens and platforms. Dr. Moody outlined two products currently in clinical trials. For one, DCVC is partnering with NIH to compare the NIH Vaccine Research Center's self-assembling nanoparticle that protects against influenza with the DCVC's mRNA version of the same. The second product in development involves administering mRNA lipid nanoparticles (LNPs) directly to humans. This approach has been shown in animals to protect against influenza.

Advantages to mRNA vaccines for influenza include the ease of manufacturing, the simplicity of changing antigens, the capacity for broad implementation (as demonstrated with the COVID-19 mRNA vaccines), and the relative ease of making multivalent vaccines. However, manufacturing is hampered by global supply chain limitations, concerns about reactogenicity, the need for cold-chain storage and transport, and the uncertain regulatory landscape around mRNA vaccines. Dr. Moody emphasized that the selection of antigens for the vaccine remains the key factor in a vaccine's success. Even mRNA vaccines cannot compensate for the selection of the wrong antigen. Dr. Moody concluded that mRNA technology enables advances in the field but does not eliminate the need to understand the target pathogens or the human response.

HIV Vaccine Development: Can mRNA Vaccine Technology Help Accelerate Progress Toward an Efficacious Vaccine?— Mark Feinberg, M.D., Ph.D., International AIDS Vaccine Initiative (IAVI)

HIV continues to pose a significant global threat, Dr. Feinberg noted. People with HIV require lifelong treatment, and the potential for development of resistance to therapy is a concern. The United Nations stated that sustaining global investment and commitment to equitable access to treatment will be a challenge for decades to come. HIV is similar in some ways to SARS-CoV-2, so there has been increasing attention to the possibility of adapting COVID-19 vaccine technology to create an HIV vaccine. However, with HIV, the epitope targets are hard to reach, unlike SARS-CoV-2, and it is very difficult to develop HIV neutralizing antibodies. Unlike coronavirus infection, HIV infection does not result in natural immunity, which limits researchers' ability to identify correlates of protection.

HIV vaccine researchers have adopted a rational design approach, in which they identify a target correlate of protection and design a vaccine accordingly. Advances in structural biology and immunology have allowed researchers to design immunogens based on the target epitopes. The Antibody Mediated Prevention study assessed a vaccine candidate that targets broadly neutralizing antibodies among people in the United States and South Africa who were at high risk for HIV. The vaccine reduced the incidence of HIV among people exposed to HIV and demonstrated high titers that corresponded with protection. IAVI built on this foundational work to create two vaccine candidates that use a germline-targeting approach, one of which has shown high efficacy in a phase I trial.

Dr. Feinberg explained that, at present, the rate-limiting step in HIV vaccine development is the time lag between generation of a promising immunogen concept and the ability to evaluate its promise in early-stage clinical trials. However, mRNA technology significantly shortens that lag time. The uncertain regulatory landscape around mRNA vaccines could affect the production time required. There is potential to simplify the formulation and delivery of complex combination vaccines. The COVID-19 pandemic validated the mRNA platform and increased manufacturing capacity, which also lowered the costs of production; for all these reasons, development of

mRNA vaccines could have a significant impact on global access. IAVI and others seek to build on the success of mRNA vaccines but, as Dr. Moody noted, the choice of antigen remains important.

mRNA-LNP Vaccines Against Flaviviruses—Justin M. Richner, Ph.D., University of Illinois

Flaviviruses, such as dengue and Zika viruses, are diverse and pose pandemic potential. Flavivirus infection can increase susceptibility to infection with other types of flavivirus, a phenomenon known as antibody-dependent enhancement (ADE). A successful flavivirus vaccine must elicit protective immunity with low ADE. Currently, researchers are embedding virus proteins in mRNA that is encapsulated in LNPs and testing them in animal models. A Zika mRNA vaccine candidate has been shown to be protective in a phase I trial. Dr. Richner and colleagues modified the vaccine to prevent ADE, and mice that received the modified vaccine did not experience severe infection when exposed to dengue virus.

Dr. Richner's laboratory developed a dengue vaccine that induces a neutralizing antibody response to four dengue serotypes and protects against a lethal challenge in mice. The vaccine also elicited lower ADE than dengue infection would.

Dr. Richner concluded that the mRNA-LNP vaccines elicit serotype-specific, protective immunity against Zika and dengue. The tetravalent dengue virus mRNA vaccine induces balanced, neutralizing response against all four dengue serotypes without ADE, which is important because the viruses cocirculate. The work represents promise for development of a panflavivirus vaccine. As previous speakers noted, mRNA vaccines facilitate the rapid modification and testing of novel antigens to enhance vaccine efficacy and safety.

Discussion

Dr. Cooke asked whether mRNA technology might be used for nonviral targets or whether they might replace live attenuated vaccines. Dr. Moody said there has been discussion about bacterial targets, and new screening approaches might identify a good bacterial target. Dr. Moody pointed out the economic challenges of switching from low-cost approaches (e.g., tetanus vaccine) to new technology. He predicted that in about 10 years, the field might see mRNA-based combined respiratory virus vaccines. Dr. Feinberg added that the success of the COVID-19 vaccines has been remarkable, but the technology cannot necessarily be extrapolated to work for other pathogens.

Dr. Richner said the success of COVID-19 vaccines has validated his laboratory's work, reinforcing that antigen selection matters. Making a vaccine against the spike protein is relatively easy with mRNA technology but harder to do for other targets.

Some discussion addressed the mechanics of mRNA technology, and Dr. Richner suggested more research on LNPs is needed. Dr. Moody noted that manufacturing antigens at scale is a substantial challenge. He added that much work is focusing on developing formulations that are easier to store and transport.

ACIP Influenza Vaccination Updates for the 2021–22 Season—Lisa Grohskopf, M.D., M.P.H., CDC

Dr. Grohskopf said CDC continues to recommend annual influenza vaccination for all those ages 6 months and older who do not have contraindications. She summarized the available vaccines approved for different age groups and described the strains targeted by the 2021–22 vaccine. The

timing of influenza season varies, with onset as early as October in some years, and peak activity ranging from December to March. The ideal timing of vaccination is influenced by the variations in onset and peak, waning effectiveness of the vaccine (especially in older adults), the desire to avoid missed opportunities, and programmatic constraints. Dr. Grohskopf outlined CDC's recommendations for offering influenza vaccination for the 2021–22 season.

Influenza vaccine can be administered at the same time as COVID-19 vaccine, and providers should check the CDC website for the most current guidance. CDC has updated its recommendations related to allergic reactions and contraindications and offers guidance on precautions when there is a high risk of severe allergic reaction.

Vaccine effectiveness varies by the season, circulating virus, and the age and immunity of the recipient. When the vaccine closely matches the circulating virus, overall effectiveness ranges from 40 percent to 60 percent and is generally better for children and young adults than older adults. However, even in a season of low effectiveness, vaccination provides benefits. For the 2019–20 season, the overall effectiveness was 39 percent, and it is estimated that vaccination averted:

- 7.5 million illnesses;
- 105,000 hospitalizations; and
- 6,300 deaths.

Discussion

Dr. Dunn asked whether there is consideration about developing vaccines for specific populations, such as older adults. Dr. Grohskopf responded that the high-dose and adjuvanted influenza vaccines were developed to target older adults, who are at highest risk for complications from influenza and for whom the current vaccines are less effective. Only limited data are available comparing the vaccines intended for older adults. More data are coming, including data from a large, retrospective study using CMS data, and the ACIP has discussed the need for a systematic review of influenza vaccines among older people. However, what works well in one season may not be as effective in another season. Ultimately, getting as many people vaccinated as possible remains the goal, Dr. Grohskopf stated.

In response to John Douglas, M.D., Dr. Grohskopf noted that there will likely not be enough cases of influenza from the 2020–21 season to assess the effectiveness of that season's vaccine. Relatively little influenza circulated last season.

Federal Agency Updates

BARDA—Linda Lambert, Ph.D.

BARDA continues to be highly engaged in the USG response to COVID-19 alongside its interagency and private-sector colleagues, including vaccine development, domestic vaccine supply, and international vaccine donation efforts. BARDA is supporting a collaborative study of coadministration of influenza vaccine and COVID-19 booster doses in people age 65 and older. The agency is working with the WHO to ensure that Ebola vaccine is available in case of an outbreak. It released a solicitation that will award contracts for it national prepandemic influenza vaccine stockpile program, which covers vaccines, supplies, and manufacturing and storage capacity. BARDA's Beyond the Needle program supports research on new vaccine administration methods; promising results have moved on to NIH for additional development and clinical trials. The annual BARDA Industry Day takes place November 3–4, 2021, and offers an

opportunity to share the USG's medical countermeasures priorities and to facilitate networking among public- and private-sector colleagues.

CDC—Melinda Wharton, M.D., M.P.H.

Dr. Wharton said CDC continues to be very engaged in the COVID-19 vaccine response, putting enormous effort into planning. It is anticipating COVID-19 booster shots, should they be authorized, approved, or recommended in the future. CDC also is planning for pediatric vaccination once it is recommended.

DoD—Margaret Ryan

DoD has vaccinated 5 million beneficiaries against COVID-19 so far. More than 70 percent of active-duty service members are fully vaccinated, and more than 80 percent have received at least one dose. Those numbers are going up daily since the President and DoD Secretary mandated vaccination for active-duty service members. Although vaccination is mandatory, it remains critical to promote vaccine confidence, which DoD achieves through social media partners, graphic packages, and communication tool kits. DoD also is monitoring carefully for adverse events following immunization. It is partnering with CDC and others to look at myocarditis and pericarditis following the mRNA COVID-19 vaccines, because DoD identified those effects early among its relatively young and predominantly male active-duty forces.

For the second year, DoD has secured Southern Hemisphere influenza vaccine for people permanently or temporarily assigned to the region during the Southern Hemisphere influenza season (as designated by the WHO). DoD is beginning its Northern Hemisphere influenza vaccination program now. The tick-borne encephalitis vaccine is of high interest to the military, and DoD is looking forward to recommendations of the ACIP regarding TICOVAC, which was approved by the FDA. Ms. Ryan noted that the military has had a key role in Operation Allies Welcome, which is relocating Afghanistan refugees. DoD is working with its Federal partners to address issues around infectious disease and immunization among refugees now housed at military bases inside and outside the United States.

FDA—LTC Valerie Marshall, M.P.H.

On August 23, 2021, FDA approved the first COVID vaccine, which was made by Pfizer-BioNTech and will be marketed as COMIRNATY, for individuals age 16 and older. The vaccine also continues to be available under Emergency Use Authorization for individuals ages 12 through 15 and as a third dose for certain immunocompromised individuals. On July 23, 2021, FDA approved a supplement to the Biologics License Application for zoster vaccine recombinant, adjuvanted (Shingrix), to include the prevention of herpes zoster (or shingles) in adults age 18 or older who are or will be at increased risk of shingles because of immunodeficiency or immunosuppression caused by known disease or therapy.

HRSA—Mary Rubin, M.D.

Via the Bureau of Primary Health Care, HRSA has awarded or announced funding opportunities for $7.3 billion through the American Rescue Plan Act to support health centers in responding to the pandemic, increasing testing and vaccinations, and providing critical health services. These awards helped health centers to prevent, mitigate, and respond to COVID-19 and to enhance health care services and infrastructure.

For the DICP, in fiscal year 2021, as of August 1, petitioners filed 1,870 claims with the National Vaccine Injury Compensation Program, and more than $171 million was awarded to petitioners, including their attorneys' fees and costs. As of August 2, 2021, HRSA had a backlog of 1,455

claims alleging vaccine injury awaiting review. More data about the program can be obtained at the National Vaccine Injury Compensation Program website. As of August 2, 2021, the Countermeasures Injury Compensation Program had received 1,692 claims alleging injuries and deaths from COVID countermeasures, including 686 claims alleging injuries from COVID-19 vaccines. Nearly 86 percent of claims are awaiting medical records for review. About 45 claims are in medical review.

IHS—Uzo Chukwuma, M.P.H.

IHS has maintained the COVID-19 vaccine task force it initiated in September 2020 to allocate, distribute, and administer COVID-19 vaccines within its Tribal and urban Indian health facilities. The task force's efforts have ensured efficient distribution and allocation of vaccine, administration, communication, data management, and safety monitoring. As of August 31, 2021, 1,961,585 COVID-19 vaccines were distributed within the IHS' jurisdiction, and 1,567,315 COVID-19 vaccine doses were administered by participating IHS direct Tribal health programs and urban Indian organizations that chose IHS for vaccine distribution. The CDC tracker also reports that 41.8 percent of the 22.1 million total population has received at least one dose, and about 34.4 percent are fully vaccinated. These estimates are based on vaccination rates among HCPs, beneficiaries, and nonbeneficiary community members who live and work in the Tribal communities. In early August, IHS implemented a policy requiring COVID-19 immunization for all personnel working in an IHS health care facility as an added strategy to minimize the risk of COVID-19 transmission to patients and among staff. The vaccine task force also collaborates with the CDC and engages the Tribal leaders and IHS area offices on strategies to improve vaccine confidence among American Indian/Alaska Native populations.

IHS routinely tracks pediatric immunization coverage. Long-term trends indicate a decline in immunization coverage for 2-year-old children, and a further decrease occurred with the COVID pandemic. Coverage rates fell from about 64.7 percent before the pandemic to 56.9 percent by mid-2021. Conversely, adolescent immunization coverage rates for HPV, meningitis, tetanus, diphtheria, and pertussis remained relatively stable through the pandemic. In response to declining childhood immunization coverage, in May 2021, IHS implemented a pediatric immunization improvement initiative, Safeguard our Future: Protect Tomorrow, Vaccinate Today. Strategies included communication that focused on supplying media content, providing parents with tool kits, and offering webinars to focus on the topic and share best practices. The health informatics arm of the initiative concentrated on educating the health care community about using data and information technology tools to identify and reach out to patients missing recommended vaccines. Implementation focused on executing a quality improvement initiative, targeting changes in immunization and workflow that resulted in improved and sustained pediatric vaccination coverage rates. IHS continues to work with Tribes, States, and CDC to promote routine childhood and adult immunization.

NVAC Liaison Updates

ACCV—Mary Rubin, M.D.

The ACCV conducted its 118th quarterly meeting by Zoom on September 2, 2021. The meeting began with program updates from the DICP and the Department of Justice. The ACCV also received program updates from the Immunization Safety Office and CDC, the National Institute of Allergy and Infectious Diseases, the Center of Biologics Evaluation and Research, and OIDP.

AHIP—Chris Regal

AHIP has been working on the Vaccine Community Connectors Program, which uses data and analytics to identify and vaccinate the highest-risk seniors in the highest-risk communities. At the

beginning of July, the program surpassed its goal of vaccinating 2 million seniors against COVID-19. At that point, AHIP shifted its program objectives to include Medicaid populations and other populations that have been more resistant. It is adapting its approach over time but is still working through public–private partnerships, such as a very successful partnership in Illinois. AHIP seeks to educate members about keeping people up to date on all vaccines, especially as school resumes and influenza season approaches. Health insurance providers are applying the lessons learned from the Vaccine Community Connectors Program to more effectively communicate with communities and connect them with the appropriate resources for preventive care. Insurance companies are taking the necessary steps to block appointments at clinics and work with pediatricians' offices to encourage families to keep up with visits and to make immunization as convenient as possible. AHIP continues to focus on getting vaccines to underserved seniors, especially with the upcoming influenza season. AHIP looks forward to collaborating with its nonprofit, government, and community-based partners to keep Americans healthy.

AIM—Claire Hannan

AIM recently held two special networking and educational events for new program managers, as turnover has been high among immunization program managers. New managers are starting jobs in the midst of a public health emergency as well. About half of immunization program managers are new since 2019. The networking events help them meet their peers and learn lessons from them. AIM is participating with AIRA and the Strategic Health Information Exchange Collaborative in an initiative organized by the HHS Office of the National Coordinator on Health Information Technology to assist States and jurisdictions with increasing data exchange between health information exchanges and immunization information systems (IIS').

AIM started a new partnership with the National Association of School Nurses, and it is also working with the Duke-Margolis Center for Health Policy and the Rockefeller Foundation to sponsor a symposium exploring successes and lessons learned for school-located vaccination. AIM is growing its partnerships with pharmacies, which has involved a number of meetings, a roundtable discussion exploring successful collaborations, and an engagement meeting with the National Association of State Pharmacy Associations to look at collaborations between immunization programs and pharmacy associations. In addition, AIM has been promoting diversity, equity, and inclusion within immunization programs, and it developed an educational webinar series exploring these topics.

AIRA—Rebecca Coyle, M.S.Ed.

AIRA is working with a coalition of private and public entities that seek to ensure there is a credible process for issuing digital vaccine credentials. In the absence of any Federal guidance, an emerging standard has been tested within the community and is rolling out across the United States now. Ms. Coyle emphasized that just because an IIS or pharmacy electronic health record system can generate a digital vaccine record does not indicate that any sort of policy exists for how those records may be used or any endorsement of such systems.

Notably, some COVID-19 vaccine clinical trials are still ongoing, yet participants may need proof of vaccination. AIRA has been working with manufacturers to determine how to transfer clinical trial data into IIS' once the clinical trial participant has been made aware of their vaccine status. Ms. Coyle pointed to the need to look beyond COVID to consider, for example, how to document pediatric clinical trial participation appropriately. Also, AIRA continues to move forward with its measurement and improvement update project.

ASTHO— James S. Blumenstock

ASTHO is identifying and sharing best practices for increasing vaccine uptake. It is improving partnerships to address vaccine hesitancy and will develop, among other elements, a document outlining practical strategies to improve trust, communicate effectively, and advance policies. As part of the COVID-19 Immunization Data Exchange, Advance, and Sharing program, ASTHO is developing a national landscape assessment of health information exchanges and IIS status and dynamics and a legal scan of policies that affect public health data sharing initiatives. ASTHO is reducing disparities in adult immunization programs through a coalition and advisory committee of partners who are working toward this common cause.

ASTHO's written report to NVAC summarizes its activities around COVID-19, specifically the national vaccination campaign, and provides links to services, resources, and products. The report describes desk-side briefings held with the press corps, featuring many ASTHO members who shared their stories. It describes areas of common ground around strategies, tactics, and approaches for increasing vaccine acceptance, confidence, and uptake; combating misinformation; and a host of the other topics. ASTHO products include an interim policy statement about vaccine verification systems and vaccination requirements that reflects members' common ground and their best thinking around principles and tenets to address these topics.

ASTHO produced a summary that compares the three COVID-19 vaccines side by side, and it is the most viewed and downloaded product on its website. Mr. Blumenstock said the popularity of the document underscores how much the practice community and the public needs and wants to know about the features of the three different vaccines. Finally, ASTHO partnered with the American Pharmacists Association to reconvene a community of practice among the leadership of the national associations. The community of practice is made up of 23 representatives of the public health, health care, pharmacy, and pharmacist communities and meets biweekly. It offers an opportunity for high-level strategic exchange of ideas and information as well as collaboration to improve COVID vaccination. The community of practice demonstrates the openness and candor among these 23 associations, illustrating the whole-of-community of approach.

NACCHO—John Douglas, M.D.

NACCHO members remain very active in the COVID vaccination effort, with particular focus on planning for possible booster vaccines, especially in long-term care facilities, where so much morbidity has occurred. NACCHO is meeting with CDC to gather insights and facilitate planning. Vaccine confidence remains a major focus area, so NACCHO has developed research guides for local health departments about how to address vaccine confidence, both in general as well as among adolescents. NACCHO has projects supporting various health departments in figuring out how to address vaccine confidence in their communities. The organization is also working to raise awareness about the need to catch up on routine immunizations and looking particularly at how the backlog has affected communities of color and communities experiencing health disparities.

Also, NACCHO is gearing up for the influenza season. It convened a national stakeholder consultation on influenza vaccination among older adults to try to come up with some emerging better strategies for reaching this group, as well as an updated version of a school-located influenza vaccination toolkit that can be used to promote influenza vaccination.

Written updates only were provided by the Centers for Medicare & Medicaid Services and the Public Health Agency of Canada.

Public Comment

Pam Dixon of the World Privacy Forum pointed to the need for transparency and policy around data-sharing practices. Very transparent policies are needed around protection of public health data, as are ways to make it transparent to vaccinees or those who would be vaccinated how their data are used in the public health context. Ms. Dixon said her organization is getting phone calls from ordinary people who are very concerned about how their data are being used. One complicating factor is the profound misunderstanding about how the Health Insurance Portability and Accountability Act (HIPAA) works and how public health data flows from the State level. Ms. Dixon said she responds to callers individually nearly every day to explain how data are used, but she noted that everyone involved could do a better job of making these issues clearer.

Secondly, Ms. Dixon said that in its May 2021 guidance, the ACIP prohibited the use of vaccinee data for commercial marketing purposes. She proposed extending this protection to vaccine credentialing or systems for proof of vaccination or testing. Vaccine mandates from employers are causing a lot of disruption in terms of public trust, as is the potential for the use of public health data for commercial marketing. In some situations, data might be covered under HIPAA, but in most cases, public health data will come from data released to an employer or to another entity. Therefore, data privacy protections should be extended.

Finally, to combat vaccine hesitancy, Ms. Dixon called for patients' feedback about their trust in public health systems, involving data governance and privacy experts and other stakeholders, facilitating dialogue, and supporting more data collection. For example, more data are needed about the correlation between vaccine hesitancy and data privacy and data governance concerns, as well as other sensitivities. Without such data, it is difficult to make decisions. Data privacy should become a priority as vaccine mandates spread.

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 4:22 p.m.

APPENDIX: Abbreviations

ACIP	Advisory Committee on Immunization Practices
ADE	antibody-dependent enhancement
AHIP	America's Health Insurance Plans
AIM	Association of Immunization Managers
AIRA	American Immunization Registry Association
ASH	Assistant Secretary for Health
ASTHO	Association of State and Territorial Health Officials
BARDA	Biomedical Advanced Research and Development Authority
CAG	Countermeasures Acceleration Group
CDC	Centers for Disease Control and Prevention
CIVICs	Collaborative Influenza Vaccine Innovation Centers
COVID-19	coronavirus disease (2019)
DCVC	Duke CIVIC Vaccine Center
DICP	Division of Injury Compensation Programs
DoD	Department of Defense
FDA	Food and Drug Administration
GBS	Guillain Barré syndrome
HCP	health care provider
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HRSA	Health Resources and Services Administration
IAVI	International AIDS Vaccine Initiative
IHS	Indian Health Service
IIS'	immunization information systems
LNP	lipid nanoparticle
NACCHO	National Association of County and City Health Officials
NIH	National Institutes of Health
NVAC	National Vaccine Advisory Committee
OIDP	Office of Infectious Disease and HIV/AIDS Policy
PAHO	Pan American Health Organization
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
USG	U.S. Government
VA	U.S. Department of Veterans Affairs
VAERS	Vaccine Adverse Event Reporting System
VaST	Vaccine Safety Technical Subgroup
WHO	World Health Organization