NVAC NATIONAL VACCINE ADVISORY COMMITTEE

February 4–5, 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.
Mary Anne Jackson, M.D., FAAP, FPIDS, FIDSA
Melissa Martinez, M.D., FAAFP
Cody Meissner, M.D., FAAP
Robert Schecter, M.D.
Geeta Swamy, M.D.
Robert Swanson, M.P.H.

NVAC Ex Officio Members

Uzo Chukwuma, Indian Health Service (IHS)
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)
Kristin Pope (for Nancy Messonnier, M.D., CAPT), Centers for Disease Control and Prevention (CDC)
Mary Rubin, M.D., Division of Injury Compensation Programs, Health Resources and Services Administration (HRSA)
Margaret Ryan, M.D., Department of Defense (DoD)
Geetha Srinivas, D.V.M., M.S., U.S. Department of Agriculture (USDA)

NVAC Liaison Representatives

Kimberly Martin (for 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)
Claire Hannan, Association of Immunization Managers (AIM)
Jean-Venable “Kelly” Goode, Pharm.D., BCPS, FAPhA, FCCP, American Pharmacists Association (APhA)
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—RADM Felicia Collins, M.D., M.P.H., FAAP, U.S. Public Health Service, Acting Assistant Secretary for Health (ASH), HHS

RADM Collins said that as a pediatrician, she particularly appreciates the importance of NVAC's work to ensure that the entire immunization system remains strong. In her long career in public health, she has focused on vulnerable and underserved populations in the pursuit of optimal health for all. RADM Collins said she was honored to be the Acting ASH amidst a worldwide, unprecedented vaccine effort. She offered gratitude for those on the front lines and behind the scenes of the COVID-19 pandemic response.

The pandemic has affected millions, and people of color have been hit disproportionately hard. In her work as director of the HHS Office of Minority Health, RADM Collins daily considered what could be done to support COVID-19 vaccination and decrease disparities faced by vulnerable and underserved populations. She praised NVAC's December 2020 recommendations, which offered suggestions on how to enhance informed decision-making about vaccines, increase confidence in the COVID-19 vaccine, enhance vaccination of diverse populations, and apply the lessons learned from the rapid COVID-19 vaccine development process to increase availability of new vaccines to the American public. Thanks to the tireless efforts of experts across the immunization system, there is momentum around COVID-19 vaccination.

HHS and its partners are working toward the goal of providing 100 million COVID-19 vaccinations within the first 100 days of the new Biden administration, following the announcement of the National Strategy for the COVID-19 Response and Pandemic Preparedness. The Strategy outlines ways to convert vaccines into vaccination, improving allocation, distribution, administration, tracking, and support to State, local, Tribal, and Territorial governments. The Strategy supports a large-scale, targeted, data-driven campaign to build trust and vaccine confidence, capitalizing on CDC's Vaccinate with Confidence framework and delivering culturally competent materials. The Strategy also calls for additional work to ensure that science-based information about vaccines and COVID-19 is communicated effectively and equitably, so everyone has accurate, up-to-date information on which to base decisions.

The Strategy outlines ways to focus on high-risk and hard-to-reach populations, recognizing that community-driven approaches are critical to making vaccine acceptable and equitable. NVAC has supported many of the components of the Strategy, and HHS will continue to rely on NVAC for its input, said RADM Collins.

RADM Collins called on NVAC members to spread the word that volunteers are still needed for vaccine clinical trials. More information is available at the Combat COVID website. NIH's Community Engagement Alliance Against COVID-19 Disparities offers tools for encouraging

diversity so that clinical trials adequately represent all of America, including people of various races and ethnicities and people with disabilities.

Finally, RADM Collins thanked two NVAC members who are completing their terms as of this meeting for providing their valuable time and expertise: Mary Anne Jackson, M.D., FAAP, FPIDS, FIDSA, and Melissa Martinez, M.D., FAAFP. She also welcomed Uzo Chukwuma, who took over as IHS's representative to NVAC.

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 three previous meetings (September 23–24, October 16, and December 4, 2020) 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 June 16–17 and September 15–16, 2021. (See the appendix for a list of abbreviations used in this report.)

Fear of Needles and Vaccine Compliance

Barriers to Getting the COVID-19 Vaccine—Jeanine P. D. Guidry, Ph.D., Virginia Commonwealth University

Dr. Guidry outlined the rate of vaccine hesitancy globally and particularly among people of color in the United States, who have a disproportionately higher risk of infection with COVID-19 and face more severe consequences. Vaccine misinformation and disinformation have contributed to people's concerns, as has the rapid pace of development and approval of the vaccine. Dr. Guidry and colleagues surveyed people in July 2020 about what would affect their acceptance of a theoretical COVID-19 vaccine. They identified the following:

- More people and more people of color in particular, said they were less likely to accept a vaccine approved through emergency use authorization (EUA) than through the conventional approval process.
- Fear of needles was a significant predictor of refusal to accept vaccine.
- Other specific barriers to being vaccinated were concerns about side effects and a possible vaccine shortage.

Dr. Guidry called out the unnecessary use of "fear visuals," such as pictures of very large needles, which amplify people's fears. Messages involving fear visuals tend to grab attention and are often unrealistic. Online, fear visuals are often associated with misinformation. Dr. Guidry advised communicators to pay more attention to how the graphics they use can affect fears around needles and vaccination. Her research demonstrates that many of the barriers to COVID-19 vaccine uptake predate the arrival of the vaccine.

In addition to portraying vaccination in a more positive light, Dr. Guidry recommended that providers discuss potential side effects honestly and that communication plans lean on trusted messengers, including health care providers, community leaders, and social media influencers, to reach diverse populations and address barriers to vaccine uptake.

Fear of Needles: A Common Barrier to Vaccine Compliance—Jennifer McLenon, M.P.H., University of Michigan

Ms. McLenon said the fear of needles can range from being afraid yet able to tolerate needle procedures to more severe conditions (e.g., phobia) that can cause someone to avoid medical care. Fear of needles is more prevalent in children and decreases with age. It is more common among women, and prevalence varies by country. Research studies often target people who have a lot of health care procedures involving needles. Notably, fear of needles has been documented among as much as 41 percent of people with diabetes, and higher levels of fear are associated with lower levels of control of diabetes.

The percentage of adults who avoid the influenza vaccine because of fear of needles ranges from 6 percent in the general population to 27 percent of hospital employees. About 20 percent of adults have not received pneumococcal or tetanus vaccines because of their discomfort with needles. Alternatives to injections are in development and have the added benefit of requiring less training for administration. Techniques to reduce fear include pain reduction, especially in children; distraction; and hypnosis. Cognitive behavioral interventions (e.g., desensitization through gradually increasing exposure) are also effective and merit more research. Ms. McLenon concluded that, because needle fear and phobia are more prevalent among children and women, efforts should target those populations.

Overcoming Needle Dread—Amy Baxter, M.D., FAAP, FACEP, Augusta University

Dr. Baxter emphasized that 38 million people in the United States might not get the COVID-19 vaccine because of their fear of needles, and 64 million people might not get the second dose in the regimen because of a combination of fear of needles, side effects, and pain. She pointed to research suggesting that the fear of needles has increased in adults as a result of an increase in the number of vaccines administered when they were young children. Some parents choose to space out injections; children who got one or two vaccinations on the same day had lower levels of needle fear later on than those who got four or five vaccinations on the same day.

The pain of vaccination can be reduced by neuromodulation (through topical anesthetics, ice, or devices). In children, combining pain relief with interventions to address fear through distraction is effective. Dr. Baxter noted that Buzzy®, a mechanical stimulation device, is used by children and adults to block stimulus and distract, and it can block the vasovagal response that causes fainting. Other distraction techniques are easy to teach. Addressing pain, fear, and other factors that contribute to needle dread (including shame and fear of fainting) in adults and children can chip away at vaccine resistance, said Dr. Baxter. She proposed that a major pharmacy chain invest in training staff on techniques to minimize fear and creating a comfortable space. Addressing needle fear could restore faith in health care systems among some populations.

Treatment of High Levels of Needle Fear—C. Meghan McMurtry, Ph.D., C. Psych, University of Guelph

Dr. McMurtry pointed out that pain and fear exacerbate each other. When pain is not properly managed, an individual may experience anxiety and fear around the next procedure, which leads to avoidance. Phobias are a combination of fear, anxiety, and avoidance that is out of proportion to the danger posed. Needle phobia can cause increased blood pressure, increased heart rate, dizziness, shakiness, sweating, tunnel vision, nausea, and fainting.

Dr. McMurtry and colleagues published companion evidence-based guidelines for those with low to moderate fear of needles and those who experience high needle fear or phobia. The latter

recommends screening for fainting and related conditions (e.g., dizziness, nausea) as well as screening for needle fear, recognizing that the two can be distinct or overlap.

A substantial body of evidence supports exposure-based therapy for overcoming phobias. The process involves facing one's fears in a gradual, controlled manner. The guidelines put forth by Dr. McMurtry recommend that individuals—rather than their health care providers—generate their own list of steps toward overcoming their fear and organize the steps from least to most difficult. Working methodically through each step, an individual comes to belief that the worst possible outcome is unlikely or, if it does happen, survivable. Dr. McMurtry added that individuals often escape a fearful situation before it reaches a peak and therefore never experience any resolution of the fear, which perpetuates the instinct to avoid the feared situation.

Ideally, exposure-based therapy is conducted in person with a mental health care provider, but alternatives include using a computer program or self-directed imagery. For those who experience fainting and related conditions, exposure-based therapy combined with muscle contraction-and-release exercises is effective. Access to exposure-based therapy is limited by cost, lack of insurance coverage, lack of trained providers, and stigma. Dr. McMurtry seeks to develop self-guided materials, tailored by age groups, to expand access to the treatment.

Patient Story—Armand Davila

Mr. Davila described his own extreme fear of needles, particularly the fear of being invaded by a foreign object. He did not know when his fear emerged, but he recalled that as a young man, the fear meant he was unable to donate blood for a cousin who needed a life-saving transfusion. Later, he was diagnosed with diabetes but could not administer his own insulin on a reliable basis. His fear of needles motivated him to manage his diabetes primarily through lifestyle changes, but he still requires some injections, which necessitate a raft of coping mechanisms.

Mr. Davila acknowledged that he is embarrassed by his fear and the tactics he must employ to tolerate needle procedures, and he recognizes the fear as irrational. The body remembers the fear, he said, and it cannot be rationalized away. Mr. Davila said he will push down the fear and do his best to get the COVID-19 vaccine because not being vaccinated could affect the whole planet. His philosophy is to consider the needs of the greater good.

Mr. Davila urged NVAC and others to think about the messaging around science, medical cures, and even failures (e.g., the Tuskegee syphilis experiment). The messages must be more digestible for the general public and for marginalized populations in particular. Mr. Davila appreciated the opportunity to tell his story and hoped it would help guide treatment of people like him and marginalized groups who have issues with getting vaccinated.

Discussion

Dr. Hopkins asked the panelists whether any common themes around needle fears have emerged. Dr. Baxter noted that people with needle fear need mechanisms for controlling and managing the experience, but they have different concerns about what aspect of the experience is distressing. She suggested giving people lots of management options from which to choose. In keeping with Dr. Guidry's observation, Dr. Baxter noted that even materials about dealing with needle fear feature pictures of big needles.

Dr. Guidry stressed that recognizing that images of needles can trigger a fear can help. She also noted that the past year has resulted in tremendous uncertainty for so many, some of whom have lost loved ones, lost their livelihoods, and had their lives upended. Dr. Guidry urged empathy for people experiencing so much disruption.

Via chat, John Douglas, M.D., asked how providers could better communicate about vaccines. Mr. Davila echoed that the pictures of needles are unhelpful, and media outlets seem to use them without thinking. He suggested thinking more thoroughly about all the possible angles of a message and recognizing that without information, the brain fills the gaps with the worst possible scenario as a protective mechanism. Mr. Davila called for improving access to reliable information, perhaps through an online portal. The previous administration muffled science, and the lack of a cohesive message left room for doubt and fear to take hold, he stated.

Dr. Baxter said some research indicates that among Black people, the word "immunization" is far preferable to "vaccination," and images of needles in the media are conflated with needle injection. Underscoring the need for an individualized approach to needle fear, Dr. Baxter said that at the time of injection, some will need to control their fear by watching the process, while others will need to look away. The promise that the jet injector (which does not use a needle) will be faster helps some but not all those with needle fears. Mr. Davila said the length of the intervention—a few seconds for an influenza vaccine compared with a few minutes for a blood draw—makes a big difference to him.

Dr. Guidry added that COVID-19 vaccination campaigns will likely try to handle a lot of people in a very short time, which affects what providers can do. Those organizing mass vaccination events should consider what can be done to minimize trauma. Dr. Baxter said mass vaccination events are likely to be very frightening for people with needle fear, so having an option such as a pharmacy that promotes a comfort-based approach would be ideal for them. If one such site was adequately prepared to address people with fear of needles, other, larger sites would not have to alter their approach.

Dr. McMurtry pointed to practice guidelines from the World Health Organization (WHO) on stress responses to immunization. She noted that mass campaigns should consider privacy, recognizing that seeing something go wrong could evoke a response in someone waiting to be vaccinated. Long wait times also contribute to fearfulness.

Robert Swanson, M.P.H., asked why the intranasal influenza vaccine and other alternatives have not been more widely adapted. Dr. McMurtry said that for some, like Mr. Davila, non-needle-based delivery systems do not address fears of invasive foreign materials, for example. Dr. Baxter added that the first intranasal influenza vaccine was not very effective and was taken off the market. However, she said, people do use alternatives when available. She also pointed to research showing that some people who were concerned about the damage that vaccines can cause were willing to accept the oral polio vaccine, indicating that fears about injection of foreign bodies do not necessarily translate to oral and intranasal vaccines.

Reducing Vaccination Pain: Interventions and Guidelines

Interventions to Reduce Vaccination Pain in Adults—Vibhuti Shah, M.D., Mount Sinai Hospital

Dr. Shah provided the conclusions of two systematic reviews of pharmacological and simple psychological interventions to minimize injection pain for adults. Topical anesthetics such as lidocaine are effective and should be considered, but it can take 30–60 minutes for the anesthetic to take effect. Vapocoolant sprays prevent pain transmission but can cause minor pain for some. Oral analgesics are not effective.

No studies addressed psychological interventions for vaccination injection pain, but research on other common needle procedures indicates that letting the individual know when the procedure will begin may reduce pain. Various methods of distraction work better in children than adults. Neither audio nor visual distractions had any impact on adults' pain, but breathing exercises were effective. The quality of evidence for all of the psychological interventions was low. Dr. Shah concluded that the literature on preventing or reducing injection pain among adults is limited. It might be helpful to allow individuals to choose the intervention they think might work.

Vaccination Pain: Clinical Practice Guideline and Outcomes—Anna Taddio, Ph.D., University of Toronto

Dr. Taddio pointed out that pain following vaccination is common and mostly ignored, but it is an iatrogenic harm that the field is obligated to address. Pain can diminish vaccine confidence, and the lack of attention to a patient's comfort can be a barrier; both factors can contribute to vaccine hesitancy. Addressing vaccine pain improves the quality of care. It might increase patient satisfaction and trust. Patients have a right to pain relief, Dr. Taddio emphasized. The combination of pain and fear may cause individuals to avoid getting health care, leading to poor outcomes.

An evidence-based clinical guideline for those with low to moderate fear of needles (mentioned earlier by Dr. McMurtry) addresses pain management through the "Five P's." The first four address procedures (e.g., give injections quickly), physical considerations (e.g., positioning), pharmacological interventions (e.g., topical anesthetic), psychological interventions (e.g., distraction). The fifth P, process, refers to educating providers, parents, patients, and consumers about the interventions available. The guideline offers other practice recommendations to minimize fear and anxiety, such as limiting fear-inducing stimuli and patient waiting time.

Dr. Taddio presented some of the educational materials used for providers and parents. The guidelines for addressing pain have been implemented in various health care settings. The most complicated set of materials describes the Comfort, Ask, Relax, Distract (CARD) System, which encourages individuals to select and apply the types of interventions that work for them.

Dr. Taddio emphasized that in a mass vaccination setting, discomfort and dissatisfaction can be addressed through some simple steps, such as offering more basic education (e.g., about the vaccine and the concept of community immunity), acknowledging and addressing pain, demonstrating care for vaccinees, and taking a patient-centered approach when setting up the clinical space. Providers and individuals should know what tools are available to minimize pain, and evaluation mechanisms should be implemented to assess the impact of such tools. Addressing pain more consistently across the life span could improve people's experiences and increase vaccine uptake. Dr. Taddio said taking steps to minimize vaccination pain and displaying more positive images of vaccination procedures could make a big difference.

Discussion

Robert Schecter, M.D., asked whether pain and anxiety affect the immune response and whether nonsteroidal anti-inflammatory drugs (NSAIDs) affect immunogenicity. Dr. Taddio said most providers recognize that NSAIDs do not work well for vaccine pain and are not recommended for preemptive use. However, because of concerns about the painful side effects of the COVID-19 vaccine, some providers may be reverting to preventive drugs. Dr. Shah said the effects of NSAIDs on immunogenicity vary and should be studied for each vaccine. There is little research about their effect on newer vaccines.

Cody Meissner, M.D., FAAP, invited the panelists to comment on reports of shoulder injury related to vaccine administration (SIRVA) with the COVID-19 vaccine. Dr. Taddio said SIRVA can be avoided with proper injection technique, and individuals can assist by wearing clothing that allows the provider to access the upper arm easily. She said there have been few reports of SIRVA related to COVID-19 vaccine in Canada. Pharmacists have only recently been authorized to deliver vaccines in Canada, and some people vaccinated by pharmacists have reported SIRVA. Dr. Hopkins noted that advising individuals about what to wear is one of the steps systems can take to prevent vaccination problems.

Dr. Taddio asked whether the United States is considering eliminating the step of swabbing the injection site with alcohol, which is unnecessary, time-consuming, and has been abandoned by other countries. Providers in Canada are reluctant to change, but doing so could save time and money and decrease waste, she noted, and the smell of the alcohol might also increase anxiety. Dr. Taddio hoped the need for efficiency in mass vaccination would be the impetus for getting rid of alcohol swabbing in the United States and Canada.

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, what HHS can do to increase vaccine confidence, and how to foster confidence based on evidence. The Subcommittee will present a full report for review at the June 2021 NVAC meeting.

Dr. Dunn summarized some notable themes from recent presentations to the Subcommittee. While CDC and others have launched vaccine confidence efforts, misinformation and disinformation campaigns are broad, pervasive, and difficult to counter. A literature review offered insight on how vaccine hesitancy and confidence vary by type of vaccine and population. Rather than propose a single approach to improve overall vaccine confidence, the Subcommittee intends to recommend strategies, informed by evidence, that can be tailored as needed depending on the vaccine and the target population.

The report will define vaccine acceptance as receiving a vaccination. It will highlight the subtle distinction between vaccine confidence and hesitancy and explore these issues across the life span. The report is not intended to describe the state of vaccine acceptance or how to increase uptake but rather how confidence and hesitancy contribute to acceptance, recognizing that they might not be primary drivers of acceptance, delay, or low coverage. The Subcommittee acknowledges that attitudes about vaccination exist on a continuum that spans from rejection to acceptance, with a lot of overlap in the perceptions that affect individuals' decision-making. Dr. Dunn said it will be challenging for the Subcommittee's report to put forward recommendations that speak to these complexities while also being easy to read and to use. He welcomed input from NVAC members.

Discussion

Dr. Hopkins observed that WHO, HHS, and CDC are working to address vaccine confidence but many issues still require attention. He also noted that the Vaccine Confidence Subcommittee's work is closely tied with that of the Immunization Equity Subcommittee. Dr. Dunn said the topic is complex, nuanced, and challenging. At the very least, he added, the report will identify and categorize the issues, while calling out areas where more evidence is needed. Dr. Dunn also indicated that much of the Subcommittee's report should be broadly applicable to most vaccines.

Dr. Douglas asked about the implications of links between vaccine misinformation and disinformation and other types of misinformation and disinformation. Dr. Dunn said one presenter laid out how easily misinformation and disinformation are spread through cross-promotion on social media with unrelated topics. Dr. Meissner added that according to several presenters, foreign actors, particularly from Russia and China, may deliberately spread disinformation to support an anti-vaccine movement.

Vaccine Confidence Consults—Neetu Abad, Ph.D., CDC

Dr. Abad said that although some populations are reliably fixed on one end of the vaccine acceptance/rejection spectrum, many people fall into the "movable middle," and efforts can focus on how to build confidence in vaccines among them. CDC's Vaccine Confidence Team aligns expertise in behavioral science, health communication, community engagement, and clinical care with its goal of promoting uptake of COVID-19 vaccine by conducting research and implementing activities in line with CDC's Vaccinate with Confidence framework. The framework rests on three pillars:

- **Build trust** by delivering clear, complete, accurate messages; taking visible steps to promote vaccination; and communicating transparently about processes for vaccine authorization and recommendations.
- **Empower health care providers** by increasing vaccine acceptance among providers and building their capacity for counseling patients about vaccination, engaging national professional associations to help disseminate good information.
- **Engage communities and individuals** in sustainable, equitable, inclusive ways to increase trust and build collaboration, acknowledging the role of peers and trusted messengers.

Dr. Abad outlined several Vaccine Confidence Team initiatives, including development of community partnerships, creation of communication toolkits, new data collection and assessment approaches, and efforts to provide targeted support on demand to States and jurisdictions. The team is developing a new rapid community assessment guide to assist State and local immunization program managers with better understanding community needs, such as which populations are disproportionately affected by COVID-19 vaccine and who is at risk for low uptake of COVID-19 vaccine. The guide will help users translate their findings into strategies for increasing vaccine confidence and uptake.

The Vaccine Confidence Team is also launching one-on-one consultations between vaccine experts and State and Territory immunization programs on how to address COVID-19 vaccine confidence. Through consultations, experts will diagnose barriers, provide guidance, share resources and tools, and link States and Territories to individuals and organizations with specialized expertise. Dr. Abad anticipated covering topics such as communicating effectively about COVID-19 vaccine, addressing misinformation, increasing health care providers' confidence in the vaccine and their capacity to counsel patients, and engaging community partners and trusted messengers. He noted that CDC welcomes experts to join the team of consultants. States and Territories are encouraged to contact CDC to talk about their needs.

Discussion

Dr. Meissner pointed out that it is difficult to assess vaccine hesitancy while the COVID-19 vaccine supply is inadequate, and Dr. Abad agreed. Dr. Abad said CDC surveys include questions about access to vaccine as a way to determine where individuals fall on the vaccine rejection/acceptance spectrum. CDC is considering using geomapping to identify whether hot

spots are related to low access or hesitancy, on the basis of other data. Dr. Abad noted that triangulating data from multiple sources is important.

Experiences in the Field: Increasing Acceptance of COVID-19 Vaccination in Nursing Home Settings—Lee Fleisher, M.D., Centers for Medicare & Medicaid Services (CMS)

Dr. Fleisher reminded participants that nursing homes were on the leading edge of the COVID-19 pandemic. Declines in infections represented the effects of infection control interventions and the rollout of the vaccines. Vaccine uptake is critical to restoring normalcy in nursing homes and revising the current guidance that restricts visitors to nursing homes. Uptake varies, and CMS relies on data from pharmacies to assess the situation. Among residents, about 80 percent accepted the first vaccine dose. However, only about 38 percent of staff received the first dose, which is a cause for great concern, Dr. Fleisher noted.

CMS is engaged in a 3-month partnership to ensure that nursing home staff and residents have access to vaccine through specialty pharmacies. Once the partnership ends, nursing homes will have to seek vaccination through whatever mechanisms are available to the general community.

CMS hosts weekly virtual meetings with the long-term care community to provide information and respond to questions. Participants have expressed concerns about the safety of the vaccine given the rapid development. Nursing homes are often staffed by hourly workers, most of whom are people of color. In the weekly meetings, some indicated that they lacked personal protective equipment early in the pandemic and that they felt abandoned. As a result, now that they are prioritized for vaccination, some say they feel like guinea pigs. Others have raised questions that stem from misinformation about the vaccine. A number have asked whether the vaccine was studied in people who look like them. Another common question is how soon one can be vaccinated after COVID-19 infection.

Dr. Fleisher emphasized that many people are worried about becoming sick—either from the virus or the vaccine. Those who are concerned want to hear from people like them, not celebrities. In response, Dr. Fleisher said, his office has identified about 15 people who initially refused the vaccine but changed their minds. He hopes these “converters” will be help communicate about the vaccine. CMS has also engaged a group of behavioral psychologists on how to encourage people to teach each other about the benefits of COVID-19 vaccination.

Discussion

Dr. Hopkins noted that vaccine acceptance in nursing homes seems to be related to whether the local medical director advocates vaccination. Dr. Fleisher said some efforts have been made to communicate with medical directors, but their level of engagement and their influence vary widely across the country.

Dr. Douglas asked whether CMS is considering expanding the partnership to promote vaccination. Dr. Fleisher replied that CDC is working on numerous approaches, but it is up to the COVID-19 Task Force to determine whether to expand the partnership.

Molly Howell, M.P.H., suggested that CMS provide incentives and reimbursement to increase staff uptake. Dr. Fleisher responded by referring to CDC’s visitation guidelines. Once more people are protected and rates of infection go down, the visitation guidelines will be revised accordingly.

Exploring Incentives and Disincentives for COVID-19 Vaccination—Daniel Polsky, Ph.D., Johns Hopkins University

In the context of COVID-19, Dr. Polsky explained, young, healthy people have the least to gain from vaccination, because they are least susceptible to severe disease. Yet they are also the most likely to interact with others and spread the virus, so vaccinating them has the most "positive externality"—or benefit to others. Such a situation provides a natural justification for incentivizing individuals to get the vaccine.

One incentive, already endorsed by the Federal government, is subsidizing the cost of vaccine by ensuring that individuals pay no out-of-pocket costs. However, Dr. Polsky noted, it is not clear how long that subsidy will remain in place. Another approach is addressing nonmonetary costs—such as the time and effort involved in determining eligibility, ensuring access, and counseling individuals. Some have proposed paying people to get vaccinated, including partial payment at the time of vaccination and the rest when the community reaches an immunity threshold. Mandating vaccination is another mechanism, but it is difficult to implement.

Dr. Polsky said paying people to get vaccinated addresses one barrier but, from an economic perspective, the most effective use of resources is to invest only as much money as needed to reach a certain threshold. That raises questions about when to start offering a cash incentive. Furthermore, those who have already been vaccinated would not receive payment, creating tensions between fairness and efficiency.

Since the approval of the first COVID-19 vaccines in December 2020, the number of people who say they will get the vaccine as soon as it is available has increased. A number of people remain unsure, and that "wait-and-see" group should be the target of incentives, said Dr. Polsky. Black and Hispanic people are more likely than people of other races and ethnicities to remain uncertain, which underscores concerns about equity.

Reducing disincentives by tackling nonmonetary costs could be a more efficient and more equitable approach, Dr. Polsky stated. Those facing the greatest costs—such as barriers to access—are also the most likely to benefit from vaccination, and fixing systematic barriers could fix some of the ingrained inequities. However, Dr. Polsky added, the Patient Protection and Affordable Care Act reduced out-of-pocket costs for preventive services, but that did not result in increased uptake.

Discussion

Dr. Hopkins questioned whether paying people to get vaccinated poses a moral issue. Dr. Polsky noted that payment could have the unintended effect of signaling that something is wrong with the vaccine.

Dr. Meissner noted that mandates could also have the unintended effect of reducing uptake, because people dislike being told what to do. On the other hand, health insurers require smokers to pay higher premiums than nonsmokers, which could be a model for incentivizing vaccination. Dr. Polsky said vaccine mandates are difficult to impose, although they have been used in schools and some workplaces. He also noted that the Affordable Care Act prohibited insurers from basing premiums on preexisting conditions with the exception of tobacco use, so that model is worth observation.

In response to Timothy Cooke, Ph.D., Dr. Polsky did not think that any jurisdiction in the world had implemented cash incentives for vaccination. Melody Anne Butler, B.S.N., RN, CIC, pointed

out that Australia offers financial incentives to families who have their children vaccinated according to the approved schedule. She believed the United States could consider tax credits or insurance incentives. Ms. Butler asked how an incentive could be implemented without alienating those who cannot be vaccinated. Dr. Polsky said vaccine messaging has traditionally emphasized the benefits to others as well as the individual who is vaccinated, and the fact that such a message has not been at the forefront of perceptions about COVID-19 vaccine indicates that the campaign is already behind.

Dr. Polsky noted that the Federal investment in vaccine is time-limited. Eventually, the cost of vaccination will fall on insurance companies. He urged NVAC to think about incentives now, anticipating that the issue will become more prominent when the immediate crisis is past.

Public Comment

Virginia Bader, M.B.A., of Students Assist America said that the United States now has two authorized vaccines being administered and other viable candidates on the way. A number of governors are using trained students to help administer vaccines with supervision in their States. These are both positive steps, but they are not consistently applied across the country. The pandemic is revealing that a fragmented, patchwork approach to vaccination is creating inconsistent, inequitable, and unpredictable access to vaccines. Equally troubling, vaccine doses are going to waste because of a lack of planning and workforce. Ms. Bader said 11 associations and Students Assist America submitted to HHS a letter asking for a declaration under the Public Readiness and Emergency Preparedness Act to permit all students in the health professions who are trained to give intramuscular injections with supervision to do so. Students Assist America has access to more than 830,000 students who are already trained to give intramuscular injections or who can easily translate their method of injection to the deltoid muscle of the arm.

Students Assist America also has access to almost 150,000 additional students who stand ready to help with other, nonclinical aspects of the mass vaccination effort that are essential to an efficient roll-out. NVAC has discussed the need for consistent communication strategies about the importance and safety of COVID vaccines, and students can be essential to this effort, among others. The United States has implemented this approach for influenza vaccination efforts for decades and deployed students during the H1N1 influenza pandemic. The country needs a national, unified protocol for students to help during this unprecedented time. The nation is at war and needs to allow this group of students who are willing to volunteer to help their country, said Ms. Bader.

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 at 5:26 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. Dr. Hopkins summarized the proceedings of day one and gave an overview of the agenda for day two. He noted that as of Monday, February 8, more than 26 million people in the United States had received a first COVID-19 vaccine dose and about 6 million had received a second dose.

COVID-19 Vaccine Safety Monitoring

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 VaST, described the group's role in evaluating and interpreting COVID-19 vaccine data safety. In addition to NVAC and ACIP members, the group includes representatives and liaisons from various HHS agencies and other Federal departments. VaST considers active surveillance data from V-safe after-vaccination health checker, passive surveillance from the Vaccine Adverse Event Reporting System (VAERS) and VA's Adverse Drug Event Reporting System, and individual cases identified by CDC's Clinical Immunization Safety Assessment (CISA) project. As more data become available from larger databases, VaST will dig deeper into potential links between COVID-19 vaccine and adverse events.

VaST discussions have confirmed that well-established vaccine safety surveillance systems remain the cornerstone of COVID-19 vaccine safety monitoring in the United States, and novel approaches to surveillance have enriched understanding in the early phases of vaccine deployment.

Consistent with clinical trial data, local and systemic reactions are commonly reported following vaccination. Anaphylaxis following COVID-19 vaccination is being closely monitored; it is currently estimated to occur 2.8 to 5 times per million doses. In response, CDC has recommended screening for anaphylaxis risk, monitoring for symptoms after vaccination, and preparing for early recognition and management of anaphylaxis on site. Data from the United States and Europe suggest that reports of serious adverse events after vaccination are consistent with all-cause mortality rates, particularly in frail, elderly people.

COVID-19 Vaccine Safety Update—Tom Shimabukuro, M.D., M.P.H., M.B.A., CDC

Dr. Shimabukuro described surveillance systems that are capturing data on adverse events following immunization (AEFIs). V-safe is a smartphone app that links vaccinees to web-based surveys to monitor for adverse events for up to a year. It also helps identify women who were pregnant at the time of vaccination or became pregnant shortly after, some of whom have been enrolled in a pregnancy registry. Symptoms of vaccine reactogenicity are similar for Moderna and Pfizer vaccines. As observed during clinical trials, the second dose elicits substantially more reactions, which is a sign that the vaccine has induced a vigorous immune response.

VAERS is co-managed by CDC and FDA and rapidly detects potential safety signals and rare events. VAERS is best viewed as a mechanism for generating hypotheses for further investigation. Among the first 9,000 reports about COVID-19 vaccine, the median age of the individual vaccinated is 43 years, and 70 percent of events occurred among females, which might reflect the demographics of the U.S. health care workforce. About 45 serious events have been reported per one million doses, which is consistent with other adult vaccines. The types of events reported are consistent with those of clinical trial observations. FDA uses data mining techniques to identify disproportional adverse event reporting and has not yet detected adverse event–vaccine pairs reported at least twice as frequently as expected for a COVID-19 vaccine.

CISA's Project COVIDvax is a collaboration with seven medical research centers to address safety questions that are not otherwise addressed by guidelines. It has responded to 143 requests for consultation to date to evaluate complex medical issues and convened a working group to discuss cases of anaphylaxis, their mechanisms, and recommendations for management.

Dr. Shimabukuro described reports to VAERS of anaphylaxis following COVID-19 vaccination, noting that more than 80 percent of cases occurred in people with a history of allergies or allergic reactions. Most cases occurred after the first dose of the vaccine, which may be a function of timing, as relatively few people have had the second dose. Most incidents occurred within 25 minutes of vaccination, so CDC recommended a 30-minute observation period after vaccination for people with a history of allergies or allergic reactions. The rate of cases per million has decreased over time for the Pfizer vaccine (from 11 per million to 5 per million) and stayed relatively constant for the Moderna vaccine (at about 2.5 per million).

VAERS received 196 reports of deaths following vaccination, about one fifth in people under age 65 years and about two thirds among people living in long-term care facilities. Dr. Shimabukuro described the methodology for calculating the background mortality rate to put the reports in context and the processes for evaluating the potential cause of death. Most of the deaths among those living in long-term care facilities occurred in elderly people, one third of whom were in hospice care or had do-not-resuscitate or do-not-intubate orders. Data from a large database of 25,000 nursing home residents found that mortality rates were lower among those residents who were vaccinated.

Dr. Shimabukuro said analysis of all the available data suggests COVID-19 vaccination does not lead to excess deaths among long-term care residents. Similar evaluations are underway for deaths in people under age 65 who were not in long-term care. So far, most of those deaths have been attributed to cardiac issues, and one was related to COVID-19 infection. Dr. Shimabukuro concluded that the United States has implemented the most intense, comprehensive safety monitoring ever and the findings so far are consistent with clinical trial observations. Anaphylaxis is rare, and it does not appear that the vaccine is more harmful to older long-term care residents.

Rapid Cycle Analysis to Monitor the Safety of COVID-19 Vaccines in Near Real-Time within the Vaccine Safety Datalink (VSD)—Nicola Klein, M.D., Ph.D., Kaiser Permanente Vaccine Study Center

Dr. Klein said the VSD incorporates data from electronic health records (EHRs) of about 12.4 million people, and rapid cycle analysis of VSD information enhances the ability to detect rare AEFIs. She gave a detailed overview of a 3-year project to monitor the safety of COVID-19 vaccines in relation to predetermined outcomes. Investigators will compare the number of adverse events among vaccinees with the number of expected events in other groups of vaccinated and unvaccinated people. Various analytical approaches will be used to determine whether adverse events appear to be related to vaccination and will consider factors such as age, sex, race or ethnicity, geographic location, and prior COVID-19 infection.

Discussion

Dr. Jackson said people of color in her community have raised questions about the death of baseball legend Hank Aaron just weeks after he had received the COVID-19 vaccine. She asked for advice on better communicating about temporally related deaths. Dr. Hopkins agreed that messaging must take into account the concerns of the population targeted. Dr. Jackson said it is helpful to spell out the risks versus the benefits, reminding people that the virus is deadly, but more communication is needed.

Dr. Martinez noted that four cases of Bell's palsy during the vaccine clinical trials were reported in the lay press. Dr. Klein said another four cases were identified after the vaccines were authorized for use in the public. Dr. Klein said the surveillance systems are monitoring for cases of Bell's palsy, and no alarming signals have arisen yet.

In response to Dr. Douglas, Dr. Shimabukuro detailed the procedure for analyzing deaths reported to VAERS, indicating that clinicians review medical charts, death certificates, autopsy reports, and automated data. They also rely on data mining to reveal unusual findings or patterns. He reiterated that there is no evidence of excess deaths that would raise concerns about the safety of the COVID-19 vaccine.

Dr. Meissner pointed out that among the general population, the rate of anaphylaxis is similar to that with influenza vaccine. He proposed eliminating the post-vaccination observation period for people whose history does not appear to increase the risk of anaphylaxis. Dr. Shimabukuro replied that the recommendations are based on VAERS reports, which are not sufficient to assess the impact of risk factors. He added that anaphylaxis can occur after any vaccination. Dr. Hopkins said he encourages recipients of any kind of vaccine to stay in the clinic afterward out of an abundance of caution.

Dr. Schecter wondered how often the VSD rapid cycle analysis would identify signals that could be expected to occur by chance. Dr. Klein said the threshold for detecting signals was set at a relatively stringent level.

Immunization Equity Subcommittee Update—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. The Subcommittee presented draft recommendations for NVAC input on the following topics:

> **Access:** Recommendations focus on expanding the capacity of pharmacists to deliver vaccines, highlighting best practices to improve vaccination rates in rural areas, and addressing barriers related to disability, language, and immigration status.
> **Affordability:** Recommendations propose creating a Vaccines for All program to provide routine vaccines at no cost, exploring other mechanisms to remove financial barriers, addressing current roadblocks, and studying the impact of financial coverage on vaccine uptake.
> **Knowledge and Awareness:** Recommendations advocate for improving vaccine education, communication, and health literacy among trainees and health care providers and working with professional and community organizations to expand education.
> **Attitudes, Beliefs, and Vaccine Acceptance:** Recommendations call for increased investment and research in 1) understanding vaccine attitudes and beliefs, 2) effective communication approaches for various audiences, and 3) evidence-based practice interventions.
> **Data Tracking and Reporting Infrastructure:** Recommendations call for funding to facilitate the use of immunization information systems (IIS) data for research and exploration of creating a national IIS identifier to enhance data sharing.

Discussion

Dr. Dunn appreciated that the Immunization Equity Subcommittee addressed a number of topics that were related to but beyond the scope of the Vaccine Confidence Subcommittee. He was pleased that the recommendations apply broadly and that they suggest the Federal government take a more assertive position. Ms. Butler said the Subcommittee members agreed that the piecemeal approach is not working, and it took a pandemic to illustrate why a strong

immunization system is needed. Subcommittee members agreed that now is the right time to ask for these steps.

NVAC Liaison Updates

Vaccine and Related Biological Products Advisory Committee (VRBPAC)—Marion Gruber, Ph.D.

Dr. Gruber summarized VRBPAC's recent efforts on behalf of VRBPAC Chair Hana El Sahly, M.D., who recused herself from the NVAC meeting. At its October 2020 meeting, VRBPAC endorsed FDA's approach to evaluation of the safety and efficacy data for COVID-19 vaccines in development, expressing some concerns about the duration of follow-up monitoring of safety and efficacy. VRBPAC also discussed the underrepresentation of certain racial and ethnic groups in the studies underway and how to address pediatric populations. VRBPAC members debated how to preserve blinded follow-up of phase III trial participants and, if that is not possible, how the lack of blinding would affect the safety and efficacy data used to support vaccine approval.

At its December 10, 2020, meeting, VRBPAC discussed the data presented to FDA by Pfizer in support of its vaccine candidate. The overwhelming majority of members agreed that the benefits of the vaccine outweighed the risks, and FDA issued an EUA 24 hours later. VRBPAC again discussed the implications of the loss of blinding during follow-up, for which Pfizer had a plan. Members discussed how to get data on the impact of the vaccine on asymptomatic infection and viral shedding, potentially through studies to be conducted after EUA.

At the December 17, 2020, meeting, VRBPAC reviewed the data presented to FDA by Moderna in support of its vaccine candidate. It voted unanimously (with one abstention) in favor of the vaccine, and FDA issued an EUA. Members again raised questions about ongoing research design, expressing concerns that people would drop out of phase III trials and seek vaccination instead. VRBPAC proposed alternative designs and suggested that the company offer the vaccine to study participants who received a placebo (as they become eligible under CDC's guidelines for prioritization). Members also suggested other studies be conducted after EUA, such as dose-ranging studies in the elderly, how to help immunocompromised people, the effectiveness of a single dose (for two-dose regimens), and the potential for interchangeability of COVID-19 vaccines.

Advisory Commission on Childhood Vaccines (ACCV)—Mary Rubin, M.D.

At its December 3, 2020, meeting ACCV members received routine program updates from the HRSA Division of Injury Compensation Programs and the Department of Justice. An ACCV workgroup presented proposed language from the Vaccine Injury Compensation Program (VICP) statute of limitations to be added to vaccine information statements. Members voted three to one to approve adding the language, which describes the minimal timeframe for filing VICP claims. Invited stakeholders gave their input on the VICP's draft notice of proposed rulemaking, which proposes to amend the Vaccine Injury Table. ACCV received program updates from CDC, FDA, the National Institute of Allergy and Infectious Diseases, and OIDP. An ACCV member proposed that HHS initiate a study comparing health outcomes among vaccinated and unvaccinated populations, and CDC provided some background data on the issue. ACCV is seeking more input on the proposal in advance of its March 2020 meeting as it considers making a recommendation.

AIM— Claire Hannan

AIM is helping members roll out their COVID-19 vaccination programs by providing opportunities to learn from each other through weekly updates, peer connections, meetups, and general membership calls. AIM is also offering webinars featuring vaccine manufacturers and

vaccine hesitancy researchers, among others. It is participating with other COVID-19 efforts organized by the National Association Leadership Council on COVID-19 Vaccination, the Trust for America's Health, and the Ad Council, to name a few. AIM manages the Health Equity and Immunization Learning Hub for CDC's Racial and Ethnic Approaches to Community Health (REACH) project, which includes engaging specialists and subject matter experts to increase influenza vaccine uptake, and that effort will expand to include COVID-19 vaccine.

Through its partnership with the National Association of Community Health Centers, AIM wrote letters urging community health centers to use the influenza vaccine allotted to them and to prepare for COVID-19 vaccination. A collaboration among AIM, NACCHO, and the Johns Hopkins University Research Collaboration on increasing vaccine confidence will conduct focus groups to learn more about vaccine attitudes and beliefs and inform efforts to build trust. The information gathered will be shared with the Ad Council's initiative to increase confidence in the COVID-19 vaccine.

AIRA—Rebecca Coyle, M.S.Ed.

AIRA released two guidance documents on reporting priority populations and serologic testing. It is working on developing standards to record the information gathered. AIRA's measurement and improvement initiative was expanded to assess information needed for COVID-19 vaccines, and the organization created reports to show jurisdictions where they need to expand their reporting. In September, AIRA's cooperative agreement with CDC was extended to include the Immunization Integration Program, which brings together key stakeholders with expertise in IIS, public health, and EHRs. The goal is to work together to solve interoperability issues, beginning with the transport of information from the EHR to an IIS. Ms. Coyle said States have expressed a lot of interest in how AIRA can help them analyze and visualize their data.

APhA—Jean-Venable "Kelly" Goode, Pharm.D.

Dr. Goode said APhA continues to focus on providing training, education, information, and resources on vaccines, and COVID-19 vaccine in particular. It is partnering with ASTHO and CDC on immunization guidance for pharmacies and their staff. In early January 2020, an APhA survey indicated that most pharmacists plan to get the COVID-19 vaccine, and 50 percent had already received the first dose. Also, 98 percent said they were comfortable addressing patients' concerns, and 79 percent felt they were adequately staffed to administer the vaccine.

ASTHO—Kimberly Martin

ASTHO continues to support its members through situational awareness, technical assistance, information sharing, and resource development. It holds calls twice a week and publishes a daily newsletter with updated information from briefings. ASTHO regularly coordinates with Federal, State, and Territorial partners. It is developing materials to help increase vaccine confidence. The organization hopes to convene State health equity leaders, public health immunization program managers, and community stakeholders to identify best practices for increasing immunization uptake within diverse communities. ASTHO is working with HHS' Office of the National Coordinator for Health Information Technology, AIM, and AIRA to expand health information sharing to help public health agencies identify people who need a second vaccine dose and those at high risk who still need to be vaccinated.

NACCHO—John Douglas, M.D.

NACCHO accepted nominations for its 2021 Model Practices Awards for excellence among local health departments, and one award this year focuses specifically on work around the COVID-19 pandemic. Winners will be announced at the organization's annual conference, to be held

virtually from June 29 to July 1, 2021. NACCHO's Immunization Workgroup named new co-chairs and launched an initiative to increase vaccine confidence. NACCHO selected three local health departments to participate in intensive technical assistance to address vaccine hesitancy. On the advocacy front, NACHHO sent letters to Congress and the administration about several immunization and vaccine issues, including equitable access to COVID-19 vaccine. It is educating members about the vaccine through a host of webinars; two webinars addressed vaccine equity, and one discussed vaccine confidence.

Federal Agency Updates

BARDA—Linda Lambert, Ph.D.

BARDA continues to work closely with interagency partners to develop safe and effective vaccines for COVID-19, including advanced development and manufacturing of six vaccine candidates. BARDA's dedicated CoronaWatch portal on its website allows developers to request a meeting with BARDA and its partners. BARDA supported late-stage development of Merck's single-dose Ebola vaccine, which was approved by FDA in December 2019. Efforts are underway to gather data to support its use in pediatric populations and among people living with HIV. BARDA is supporting a phase I clinical study of Takeda's purified, inactivated, adjuvanted Zika vaccine.

DoD—Margaret Ryan, M.D.

DoD's COVID-19 vaccine implementation plan encompasses Active Duty, U.S. Coast Guard, Reserve, and National Guard personnel, in addition to retirees, beneficiaries, and others authorized to receive COVID-19 vaccine from DoD. This population of approximately 11.1 million people will be offered the COVID-19 vaccine in a phased approach that closely aligns with CDC recommendations. Vaccinations within DoD began December 14, 2020, and were rolled out in phases. If COVID-19 vaccines receive full licensure, DoD may consider making the COVID-19 vaccine a requirement, similar to influenza vaccine.

As of January 30, 2020, DoD has administered more than 500,000 COVID-19 vaccines at more than 300 immunization sites globally. The vast majority of immunization sites are well into phase 1B, which includes critical national capabilities, those preparing to deploy, and people who are 75 years of age or older. The Defense Health Agency engages with its beneficiary population through articles, videos, social media updates, graphic packages, communications tool kits, briefings, websites, town halls, community calls, and various social media platforms both inside and outside the military health system.

The vast majority of AEFIs reported have been expected side effects. DoD is monitoring VAERS reports and participating in CDC's VaST. The Defense Health Agency offers its own clinical call center for vaccine-related issues, which identifies some adverse events. Vaccine loss through reported temperature excursions or deviation from procedure has been exceedingly low to date: less than 0.03 percent. DoD eagerly anticipates additional COVID-19 vaccine candidates to be added to the portfolio to increase availability and access to vaccine worldwide.

FDA—Valerie Marshall, M.P.H.

Ms. Marshall reiterated that FDA gave EUAs for the Pfizer and Moderna COVID-19 vaccines in December 2020. On February 26, 2020, VRBPAC will meet to discuss Janssen Biotech's request for approval of its vaccine candidate. FDA is working on multiple fronts to address the COVID-19 pandemic.

HRSA—Mary Rubin, M.D.

Dr. Rubin said HRSA's Bureau of Primary Health Care awarded more than $2 billion to health centers for COVID-19 testing, contact tracing, vaccine development and distribution, and treatment. As of January 15, 2020, HRSA health centers had conducted more than 8 million tests and administered nearly 88,000 vaccines. The pandemic led to alarming declines in well-child visits and routine immunizations. In August 2020, HRSA urged health centers and health care providers to increase childhood immunization rates and improve access to immunization.

As of January 1, 2021, petitioners had filed 526 claims with the VICP, and $78 million was awarded to petitioners, including attorneys' fees and costs. As of January 11, 2021, HRSA had a backlog of 1,067 VICP claims alleging vaccine injury awaiting review. As of December 1, 2020, the Countermeasures Injury Compensation Program (CICP) determined that 39 claims were eligible for compensation totaling $6 million.

The HHS Secretary issued a Marburgvirus and Marburg disease declaration effective November 25, 2020, which provides liability immunity for the manufacture, testing, development, distribution, administration, and use of the covered countermeasures. The declaration permits individuals seriously injured by covered countermeasures to file a claim with the CICP.

IHS—Uzo Chukwuma

Ms. Chukwuma reported that IHS partners with various stakeholders to increase the vaccination rate among IHS populations. Data from the IHS influenza surveillance system for the 2020–2021 influenza season indicate more than 207,000 doses of influenza vaccine have been administered to date, with overall population coverage at 28.9 percent. Vaccination uptake was highest among the most vulnerable populations, specifically young children and elderly people.

During the COVID-19 pandemic, American Indian/Alaska Native early childhood immunization coverage has slightly decreased, but adolescent immunization coverage has remained stable. Specifically, immunization coverage among 2-year-olds slightly decreased from 64.7 percent after December 2019 to 60.6 percent at the end of March 2020. Immunization coverage rebounded to 63.6 percent by the end of September 2020. IHS has engaged in various initiatives to promote routine and catch-up immunizations during the COVID-19 pandemic, including hosting various webinars, sharing CDC and HHS communication and education materials, and disseminating provider resources and toolkits on childhood immunizations. IHS also promoted the HHS Catch Up to Get Ahead childhood immunization campaign's materials and toolkits, and it conducted a survey to assess childhood and adolescent immunization coverage before and during the campaign. Analysis of survey results is currently being performed.

IHS established a COVID Vaccine Task Force in September 2020 to finalize development of agency-wide planning for COVID-19 vaccine allocation, distribution, and administration within IHS, Tribal, and Urban Indian Health Facilities receiving vaccine from the IHS. IHS continues to work with CDC and other HHS agencies to track COVID-19 vaccine distribution and administration data.

Written updates only were provided by AHIP, AHRQ, CDC, the Public Health Agency of Canada, and VA.

Building Trust in and Access to a COVID-19 Vaccine Among People of Color and Tribal Nations: A Framework for Action—J. Nadine Gracia, M.D., M.S.C.E., Trust for America's Health

Dr. Gracia outlined the framework being spearheaded by the Trust in partnership with the National Medical Association and UnidosUS. The framework emerged from a convening of 40 organizations to craft policies to ensure access to COVID-19 vaccines in communities at high risk of disease because of racism and inequities. The underlying principles of the framework wemphasize agency, transparency, relevancy, and accountability. Dr. Gracia summarized policy recommendations under each of the following six areas:

1. **Ensure scientific fidelity of vaccine development process** through diversity among trial participants and transparency of clinical trial data released.
2. **Equip and fund trusted community organizations**, acknowledging that these organizations often lack the resources needed to do the work.
3. **Communicate needed information through trusted messengers** at local, State, and national levels, with materials that are culturally and linguistically appropriate, and through mechanisms tailored to the community.
4. **Make it easy for people to be vaccinated** by placing vaccine sites in communities disproportionately affected by the disease and allowing flexibility in funding to address barriers such as transportation and fears of immigration enforcement.
5. **Ensure complete coverage of costs associated with the vaccine**, including administrative costs.
6. **Fund and require disaggregated data collection and reporting**, so that data are available to inform decision-making.

Critical actions to achieve these goals include overcoming the challenges to collecting disaggregated data by race and ethnicity. Fewer than half of States report these and other key demographic data that would help tailor resource targeting. The lack of data can exacerbate inequities. It is also necessary to ensure that people of color and Tribal nations have resources to address the pandemic and that public agencies at all levels are held accountable for equity.

Discussion

David Fleming, M.D., wondered how systems could be incentivized to ensure vaccine is available to all who need it. Dr. Hopkins said incentives might be helpful, as would filling the gaps that lead to inequities.

Dr. Douglas asked for more detail on the barriers to data disaggregation. Dr. Gracia said State and local health departments receive data from various sources, not all of which report race and ethnicity. Some health departments use archaic data systems, making it difficult to communicate data across systems. These problems reflect the broader issue of underfunding of public health. During the pandemic, some localities have required data collection, resulting in some improvement. Modernizing data collection methods and gathering more demographic information are important to address a number of outcomes, not just those related to public health emergencies, Dr. Gracia concluded.

A New National Strategy for Vaccination—David Kim, M.D., Division of Vaccines, OIDP, HHS

Dr. Kim explained that the new 5-year strategic plan builds on the 2010 National Vaccine Plan and its corresponding midcourse reviews as well as the 2016 National Adult Immunization Plan. Development was guided by an interagency working group informed by vaccine experts representing numerous perspectives as well as public input. The plan addresses vaccination across the life span. It was limited to 5 years in recognition of how rapidly the field is moving forward.

OIDP released the National Strategy for Vaccination around the same time as it released new national strategic plans for HIV, sexually transmitted infections, and viral hepatitis.

Dr. Kim described the five overarching goals of the plan and summarized the objectives for each:

1. Foster innovation in vaccine development and related technologies.
2. Maintain the highest levels of vaccine safety.
3. Increase confidence in vaccines.
4. Increase access to vaccines.
5. Support global immunization efforts.

The strategy outlines 10 national indicators for assessing progress toward the goals and objectives, drawing on data routinely collected already. Five of the indicators focus on children (including one for adolescents), four address adults (including one for pregnant women and one for older people), and one—for influenza immunization—looks at all ages. Dr. Kim noted that OIDP is developing an implementation plan to advance the strategy.

Discussion

Dr. Cooke asked whether HHS had enough capacity to implement the strategy now that the National Vaccine Program Office has been folded into OIDP. Dr. Kim responded that the OIDP Division of Vaccines took on the work of the National Vaccine Program Office. He added that the strategy aligns with OIDP's approach to addressing infectious diseases.

Public Comment

Glen Hazlewood, M.D., Ph.D., of the Canadian Rheumatology Association noted that patients who have autoimmune diseases were excluded from the major clinical trials of COVID-19 vaccine. He asked when efficacy and safety data would be available for patients with autoimmune diseases. Specifically, he and his colleagues are interested in serious adverse events, autoimmune adverse events, and, in particular, the controlled data from the VaST analyses.

Theresa Wrangham, executive director of the National Vaccine Information Center, said her organization supports every individual's right to make voluntary, informed vaccine decisions, without sanction, and the public's access to vaccines, but it is against vaccine mandates that do not provide flexible exemptions. NVAC's discussion of incentives to promote vaccination raises many concerns. She voiced a concern about privacy and security associated with EHRs and IIS, which house sensitive medical information belonging to individuals, and think that written permission should be sought before their use. She also expressed concern for mandates and expressed the need for informed consent.

The National Vaccine Information Center also has concern about a lack of funding for high-quality research, and noted that this was echoed by Dr. Dan Salmon in his November 2019 remarks to NVAC. He also noted the importance of including those with safety concerns into stakeholder efforts and policy-making to address these concerns. Ms. Wrangham would like to see more NVAC activities include these voices, as well as those who opt out of one or more vaccines and to address the public's concerns to increase trust and decrease hesitancy. She asked NVAC to consider how vaccine hesitancy and uptake have been affected by informed consent.

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 4:11 p.m.

APPENDIX: Abbreviations

ACCV	Advisory Commission on Childhood Vaccines
ACIP	Advisory Committee on Immunization Practices
AEFIs	adverse events following immunization
AHIP	America's Health Insurance Plans
AHRQ	Agency for Healthcare Research and Quality
AIM	Association of Immunization Managers
AIRA	American Immunization Registry Association
AMR	antimicrobial resistance
APhA	American Pharmacists Association
ASH	Assistant Secretary for Health
ASTHO	Association of State and Territorial Health Officials
BARDA	Biomedical Advanced Research and Development Authority
CDC	Centers for Disease Control and Prevention
CICP	Countermeasures Injury Compensation Program
CISA	Clinical Immunization Safety Assessment
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
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IIS	immunization information systems
NACCHO	National Association of County and City Health Officials
NIH	National Institutes of Health
NSAIDs	nonsteroidal anti-inflammatory drugs
NVAC	National Vaccine Advisory Committee
OIDP	Office of Infectious Disease and HIV/AIDS Policy
SIRVA	shoulder injury related to vaccine administration
USDA	U.S. Department of Agriculture
VA	U.S. Department of Veterans Affairs
VAERS	Vaccine Adverse Event Reporting System
VaST	Vaccine Safety Technical Subgroup
VICP	Vaccine Injury Compensation Program
VRBPAC	Vaccine and Related Biological Products Advisory Committee
VSD	Vaccine Safety Datalink
WHO	World Health Organization