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## September 23–24, 2020, 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

David Hrcir, M.D. (for COL Tonya Rans,  
M.D.), Department of Defense (DoD)  
Troy Knighton, M.Ed., Ed.S., LPC,  
Department of Veterans Affairs (VA)  
Linda Lambert, Ph.D., Biomedical  
Advanced Research and Development  
Authority (BARDA)  
Anthony Marks, M.D., U.S. Agency for  
International Development  
LTC Valerie Marshall, M.P.H. (for Marion  
Gruber, Ph.D.), Food and Drug  
Administration (FDA)  
Justin A. Mills, M.D., M.P.H., Agency for  
Healthcare Research and Quality  
(AHRQ)  
Barbara Mulach, Ph.D., National Institutes  
of Health (NIH)  
Mary Rubin, M.D., Division of Injury  
Compensation Programs, Health

Resources and Services Administration  
(HRSA)  
Geetha Srinivas, D.V.M., M.S., U.S.  
Department of Agriculture (USDA)  
Melinda Wharton, M.D., M.P.H. (for Nancy  
Messonnier, M.D.), Centers for Disease  
Control and Prevention (CDC)

### NVAC Liaison Representatives

James S. Blumenstock, Association of State  
and Territorial Health Officials  
(ASTHO)  
Gina Charos, Public Health Agency of  
Canada (PHAC)  
Rebecca Coyle, M.S.Ed., American  
Immunization Registry Association  
(AIRA)  
John Douglas, M.D., National Association  
of County and City Health Officials  
(NACCHO)  
Nathalie El Omeiri, Ph.D., Pan American  
Health Organization (PAHO)  
Hana El Sahly, M.D., Vaccine and Related  
Biological Products Advisory  
Committee (VRBPAC)  
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)

### Acting Designated Federal Officer

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

## Proceedings

### Day One

#### **Call to Order and Rules of Engagement—Ann Aikin, M.A., Acting Designated Federal Officer, Communications Director, ODP, HHS**

Ms. Aikin called the meeting to order at noon 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 ODP staff for their support in organizing the meeting and called the roll.

#### **Opening Remarks—ADM Brett P. Giroir, M.D., Assistant Secretary for Health (ASH), HHS**

ADM Giroir welcomed the members, speakers, and others watching the NVAC meeting online. He stressed the importance of seasonal influenza vaccination, particularly given the potential that the influenza and COVID-19 viruses could circulate simultaneously this fall and winter. HHS is working with the private sector to ensure ample supply of influenza vaccines this year and to ensure that every American—especially people of color and those at highest risk for the consequences of influenza and COVID-19—can easily get vaccinated. The country cannot lose ground in the fight against influenza and other vaccine-preventable diseases, said ADM Giroir.

Because of the pandemic, children and adults have not received routine vaccinations, and the risk of potential outbreaks of diseases such as measles is deeply concerning. Working with State and local health officials, professional associations, and many others, HHS has made progress in reversing this trend, particularly for children, but there is much more work to do. In August, HHS and a number of partners came together to raise awareness of the importance of catching up on childhood immunizations and to let parent know that it is safe to bring their children in for recommended vaccines. By using provisions of the Public Readiness and Emergency Preparedness Act, HHS increased access to childhood vaccines by authorizing State-licensed pharmacists to administer vaccines to children ages 3 to 18 years old during the COVID-19 public health emergency. Every child and community is healthier and stronger when immunization rates are high. HHS will continue to closely monitor immunization rates and spread the catch-up message.

Building vaccine confidence is a significant challenge. NVAC has examined the root causes of the issue and identified effective public health tools for building vaccine confidence. HHS will build on this valuable expertise in preparation for a novel coronavirus vaccine and to try to increase vaccination rates for all recommended vaccines.

Developing a safe and effective vaccine is one of the top global priorities in the COVID-19 pandemic. Through Operation Warp Speed, the U.S. Government (USG) is preparing to make a COVID-19 vaccine available in substantial quantities in 2021. In this unprecedented effort, ensuring a vaccine is safe and effective is of the utmost importance. ADM Giroir assured that there will be no shortcuts when it comes to the safety of COVID-19 vaccines. The risks being taken are only financial; vaccines are being manufactured before safety and effectiveness are confirmed. If the data and evidence demonstrate they are safe and effective, the vaccines will be immediately available. If any vaccine is not safe or effective, the money spent on manufacturing will be lost, but that is a small price to pay, said ADM Giroir.

Like all vaccines in clinical trials, COVID-19 vaccine candidates are undergoing rigorous scientific testing and must meet FDA standards for safety and effectiveness. ADM Giroir emphasized that the process is not subject to political influence. Nine of the leading pharmaceutical and biotechnology companies, including all companies with vaccine candidates currently in Phase III clinical trials, pledged their commitment to the safety and effectiveness of COVID-19 vaccines.

Preparing for a COVID-19 vaccine extends beyond developing one or more safe and effective vaccines. The vaccines must also be distributed equitably, and they must be available for the people who need it most, according to the data provided by clinical trials. The USG is developing plans for COVID-19 vaccine distribution, allocation, and prioritization with expert guidance from the Advisory Committee on Immunization Practice (ACIP) and the National Academies of Sciences, Engineering, and Medicine (NASEM).

Reducing the health threat of COVID-19 requires successful implementation of the largest vaccination campaign in recent U.S. history—one that is expeditious and equitable and that strengthens the existing vaccination infrastructure. NVAC is uniquely suited to provide guidance around addressing inequities in vaccination rates and improving the public's confidence in vaccines. ADM Giroir charged NVAC to provide insight on the following questions:

- To support communications to enhance informed vaccine decision-making:  
What should HHS do before, during, and after the COVID-19 vaccination campaign to improve the confidence in these vaccines and our nation's immunization system, especially in underserved communities, including among racial and ethnic minorities?
- To enhance vaccination of diverse populations:  
The FDA standards for approval and licensure of vaccines for COVID-19 address safety and effectiveness and encourage inclusion of minorities, the elderly, pregnant women, and people with medical comorbidities in clinical trials. In particular, for the COVID-19 vaccine, what approach should the nation should take in regard to vaccination of children, given that there will be relatively little data on children from some of the early clinical trials? As context, the case fatality rate for children under age 18 is .02 percent. What is the appropriate approach and timing of generating the needed data and proceeding to potential childhood vaccination as we move forward?
- To develop new and improved vaccines:  
What lessons can we learn from COVID-19 vaccine development more broadly to promote innovation and shorten timelines to increase availability of new vaccines to the American public?

ADM Giroir thanked the NVAC members for their participation, dedication, and commitment to improving the vaccination system in the United States.

### **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. The minutes of the June 9, 2020, meeting were approved unanimously by NVAC members.

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](mailto:nvac@hhs.gov)). The agenda, minutes, and presentations of past meetings are available [online](#). NVAC is scheduled to meet on

October 16, 2020; February 4–5, 2021; and June 16–17, 2021. (See Appendix A for a list of abbreviations used in this report.)

### **Serving Up Equity: Health-In-All Approaches for COVID-19 Vaccination**

#### ***Lessons Learned—Kirsten Bibbins-Domingo, Ph.D., M.D., M.A.S., University of California, San Francisco (UCSF)***

Dr. Bibbins-Domingo said the impact of the global pandemic intertwines with where people live and work, so an equitable approach is critical. Past events, such as the measles outbreak of 1989–1991, demonstrated that universal strategies around vaccination with national campaigns and enforcement succeed when paired with targeted efforts to reach those at highest risk. The combination of universal and targeted strategies is important for the pandemic response and for immunization efforts in general.

In San Francisco, a disproportionate number of Latinos were affected by COVID-19 because of increased likelihood of exposure through work and dense living situations, plus preexisting diseases and low access to care and testing. UCSF launched mass neighborhood screening campaigns in predominately Latino communities to guide the public health response to the pandemic. The results helped public health providers align resources with the areas that needed them and aided contact tracing. Partnering with strong Latino community-based organizations (CBOs) paved the way for addressing cultural and language barriers, linking workers to financial support, and countering misinformation and mistrust. UCSF has expanded its model of partnership, outreach, and testing to other low-income and minority communities. Dr. Bibbins-Domingo emphasized that decreasing disparities and improving health equity require a combination of universal and targeted approaches, developed with the communities affected.

#### ***Equitable, Efficient, Effective Vaccine Delivery—Rebecca Weintraub, M.D., Harvard Medical School***

In anticipation of the approval of one or more COVID-19 vaccines, Dr. Weintraub recommended planning around four connected strategies:

- **Literacy:** Understand the roots of vaccine hesitancy, and engage communities over the long term to ensure there is demand for the vaccine.
- **Allocation:** Muster the political will to prioritize vaccine allocation, based on evidence.
- **Distribution:** Ensure the vaccine is delivered effectively and efficiently, drawing on the expertise of people across the spectrum, from manufacturing to the last mile.
- **Verification:** Develop tracking mechanisms that are portable, interoperable, and secure.

Dr. Weintraub stressed that all four strategies require investment in systems to monitor progress and inform next steps. Modeling of the probability of success at each step from research to manufacturing reveals potential lags. Dr. Weintraub and colleagues developed a vaccine allocation planner to help States identify vaccine goals and priority populations and determine how to allocate vaccine. Tracking and verification will be needed, especially for multidose vaccines, but individuals' privacy must be considered. Data standards must be developed to ensure that States are capable of tracking and capturing needed data in functional and interoperable ways. The planned pandemic vaccination effort requires an urgent investment in upstream delivery strategies and systems to generate vaccine demand, facilitate vaccine allocation and distribution, and verify coverage. The aims of the systems must be aligned to protect populations against the virus and leverage systems across borders, Dr. Weintraub concluded.

***The National COVID-19 Resiliency Network (NCRN)—Dominic Mack, M.D., M.B.A., Morehouse School of Medicine***

Dr. Mack pointed out that disparity is a multifactorial problem, and social determinants of health (SDH) must be addressed to achieve equity. The NCRN focuses on access to services and community-level education among those disproportionately affected by COVID-19. Created through a cooperative agreement with HHS' Office of Minority Health (OMH), the NCRN has the following objectives:

1. Identify and engage vulnerable communities through local, State, territory, Tribal, and national partners.
2. Nurture existing and develop new partnerships to ensure the NCRN is an active information dissemination network.
3. Partner with vulnerable communities and national, State, local, and other government organizations to provide and disseminate culturally and linguistically appropriate information throughout States, territories, and Tribes.
4. Use technology to link members of the priority vulnerable communities to community health workers, COVID-19 health care, and social services, including testing, vaccinations, behavioral health counseling, and primary care.
5. Monitor and evaluate the success of the services and measure outcomes using process improvement methods to improve the quality of the overall program.
6. Use broad and comprehensive dissemination methods as resources and strategies to add to the body of scientific knowledge and to increase awareness, participation, education, and training.

NCRN is partnering with a technology company to expand wi-fi access so that more people have access to telehealth options. The network will continuously scan electronically throughout the country to identify hot spots, and it will engage community health workers and CBOs to connect individuals to testing and feed information back to OMH, CDC, and other agencies. A number of national partners representing vulnerable populations are involved, and they have local affiliates on the ground. NCRN will be informed by a national advisory committee and will use community-based, participatory marketing to inform research, get feedback, and improve communications and materials.

***A COVID-19 Vaccine and Equity—Oliver Brooks, M.D., National Medical Association***

Dr. Brooks explained that “equality” means providing the same resources to all, regardless of need, while “equity” means giving individuals the supports they each need to reach the same outcome. Inequity represents a lack of fairness and justice with respect to the distribution of resources and thus is directly relevant to COVID-19 vaccine.

Disparities in COVID-19 outcomes are the product of underlying health conditions (most of which are more common among people of color), SDH, and racism (evident at the social and even the cellular level). CDC's *COVID-19 Vaccine Programs Interim Playbook for Jurisdiction Operations* describes a phased approach to vaccination that assumes limited availability of vaccine. Its COVID-19 Vaccine Work Group will take race/ethnicity into account as it evaluates frameworks for equitable allocation of vaccine. It has already identified some challenges in distributing vaccines equitably. Of the four groups targeted for early vaccination—people who are age 65 or older, those with high-risk medical conditions, essential workers, and health care personnel—African Americans are highly represented in all but the elderly cohort.

Dr. Brooks emphasized that messaging around the vaccine is more important than any other step, because a substantial number of people have already indicated they would not accept a vaccine. The principles of crisis and emergency risk communication must be applied to build trust and ensure vaccine uptake:

- Be first.
- Be right.
- Be credible
- Express empathy.
- Show respect.

### ***Discussion***

Ms. Aikin asked the presenters for new ideas to promote COVID-19 vaccination. Dr. Brooks said the Federal government should communicate clearly that work is underway to develop COVID-19 vaccines and to assess their safety and effectiveness. Dr. Mack agreed on the need for a national campaign paired with efforts at the community level to address vaccine hesitancy. Dr. Bibbins-Domingo called for improving the infrastructure for influenza vaccination at the local level and leveraging it for COVID-19 vaccination. Dr. Weintraub also felt it was important to educate the public about the vaccine portfolio and why the USG invested in a range of approaches, which will increase vaccine literacy overall.

Robert Schecter, M.D., invited presenters to share their thoughts on how to manage the logistics of mobilizing community partners to deliver vaccines. Dr. Brooks said efforts should be highly transparent and communicate why certain steps are needed (e.g., why individuals must get vaccinated at a central site that can maintain the vaccine at the proper temperature). Dr. Bibbins-Domingo said that talking with community leaders about strategies usually helps to identify and overcome challenges. Problem-solving together is an essential first step to addressing everything from vaccine hesitancy to cold-chain logistics, she noted. Dr. Mack said financial resources are needed to ensure equitable access to vaccines.

In response to Daniel F. Hoft, M.D., Ph.D., Dr. Mack said NCRN is working on surveys that can be used to identify the reasons for vaccine hesitancy at the local level, particularly among underserved populations. Regarding the biology of racism, Dr. Bibbins-Domingo said UCSF aims to clarify that racism—not race—is the risk factor behind many disparities. The chronic stress caused by racism becomes embedded at the biological level and predisposes to disease, which explains the disproportionate rates of disease among people of color, she stated.

Molly Howell, M.P.H., asked how to avoid the perception that underserved and vulnerable populations are being used as test subjects for the vaccine. Dr. Brooks said messaging at the local level must build trust by relying on local leaders who can communicate clearly and transparently. Dr. Bibbins-Domingo pointed out that underserved and minority communities feel they have been neglected by the pandemic response so far, so building trust will be difficult. Troy Knighton, M.Ed., Ed.S., LPC, suggested being specific about the populations being addressed and being careful about language, avoiding words like “targeting.” Dr. Bibbins-Domingo proposed working with local leaders to make decisions and establish processes that are supported by national-level data.

### **Allocation and Prioritization: Considerations and Recommendations for the Distribution of COVID-19 Vaccines**

***Ethical Considerations of Vaccine Distribution—Ezekiel Emanuel, M.D., Ph.D.,  
University of Pennsylvania***

Dr. Emanuel described key ethical principles in terms of COVID-19 vaccine allocation. *Maximizing benefit and limiting harm* is fundamental to all ethical theories. Under this principle, a COVID vaccine would be given to those for whom it would save lives, directly or indirectly, and prevent socioeconomic harms, such as unemployment, poverty, and loss of educational opportunities. *Prioritizing disadvantaged people* could apply to those who experience socioeconomic hardship and oppression, higher risk of premature death, or medical vulnerability, and COVID vaccine allocation should address all of these, directly or indirectly. Finally, *equal moral concern* addresses discrimination, but does not support treating differently situated people the same or ignoring relevant differences.

The NASEM framework for vaccine allocation incorporates three more principles that Dr. Emanuel said were either redundant or not unique to the issue of COVID vaccine. Moreover, the NASEM framework does not rank the principles by importance. Dr. Emanuel raised questions about the NASEM framework, which prioritizes health care workers (HCWs); essential, high-risk workers; and people with serious medical conditions that put them at increased risk of complications from COVID-19:

- Are HCWs in the United States who have good personal protective equipment (PPE) at high risk for acquiring or spreading COVID-19?
- Are there some essential jobs—such as firefighting—that do not pose a high risk of acquiring or spreading COVID-19?
- How would people with medical conditions be identified, especially outside of a medical setting?
- If herd immunity is a goal, should children and young adults be prioritized?

***Overview of ACIP’s Ethics/Equity Framework—Sara Oliver, M.D., M.S.P.H., CDC***

Dr. Oliver discussed ACIP’s application of five proposed ethical principles—maximize benefits and minimize harms, equity, justice, fairness, and transparency—to its framework for allocating COVID-19 vaccine. She emphasized that ACIP’s recommendations must be grounded in ethical principles, evidence-based, and feasible for implementation. Transparency, Dr. Oliver pointed out, refers to the process of creating the recommendations for allocation and is foundational to the framework.

ACIP reasoned that HCWs are essential to the pandemic response, and prioritizing them in Phase 1 of vaccine delivery (specifically Phase 1a) may decrease the spread of transmission. Phase 1b would target people age 65 or older, those with high-risk health conditions, and those who hold essential jobs. Dr. Oliver noted that many HCWs have some combination of these high-priority characteristics. She described ACIP’s approach of applying each of the ethical principles to each potential priority group.

ACIP will continue developing its ethics/equity framework, particularly with respect to the first phase of vaccine allocation. It will also consider how ethics and equity can be incorporated into ACIP’s Evidence to Recommendations Framework.

***Discussion***

David Fleming, M.D., asked how decision-makers should think about the timing and ethics of transitioning to a strategy of universal COVID vaccination when sufficient vaccine becomes available. Dr. Emanuel responded that as more vaccine is available and progress has been made

toward mitigating the medical and socioeconomic harms, it may be appropriate to prioritize within groups to achieve herd immunity. Dr. Oliver said ACIP's recommendations would be updated as more is learned about the vaccine's use and supply.

Dr. Hoft pointed out that two thirds of the people in the United States fall into one of the four priority populations identified by ACIP and NASEM, so further prioritization is needed. Dr. Emanuel observed that the NASEM categories are so broad that they do not constitute real priority groups. He proposed focusing on reducing premature mortality, and he reiterated that not all HCWs are at extremely high risk.

Dr. Oliver said further prioritization will rely on the characteristics of the vaccines approved, because each vaccine's characteristics and indications dictate for whom the product is recommended and in what circumstances. Dr. Emanuel stressed that modeling should be initiated now to predict which populations are likely to receive the most benefit from which vaccines. Dr. Oliver said CDC is conducting modeling, but it is still not known whether the candidate vaccines will reduce severe disease, prevent shedding, or slow transmission.

Dr. Schechter questioned whether HCWs had uniform access to PPE and whether the extent to which PPE mitigates their risk is known. He requested advice on how to compare the value of allocating a lot of vaccine to one group with that of providing less vaccine to more, smaller groups. Dr. Oliver responded that CDC data on HCWs concluded that PPE reduces COVID-19 transmission in health care settings. However, the HCWs who get COVID-19 tend to be those who work in settings where less PPE is used—such as nursing aides and security staff. Dr. Oliver added that people who work in long-term care facilities have been instrumental in disease spread. PPE does not completely remove risk, she noted.

Regarding distribution, Dr. Emanuel suggested using modeling to determine 1) how much vaccine is needed in a given group to achieve a desired result; 2) whether the vaccine affects transmission or reduces severity in a given group; and 3) which groups benefit under different scenarios. Prioritization should limit harm and avoid compounding disadvantages. Dr. Emanuel pointed out that HCWs who are not providing medical care are more likely than physicians and nurses to be in disadvantaged groups. He stressed the need to tailor strategies on the basis of modeling rather than identifying broad, undifferentiated groups.

Leonard Friedland, M.D., added that prioritization and planning will also be influenced by data about the durability of protection of the available vaccines. Dr. Oliver said ACIP is currently focused on the first available vaccine. Dr. Emanuel said any vaccine should be durable for at least 1 year to be considered a viable option.

### **Perspectives From the Field: Operation Warp Speed—Moncef Slaoui, Ph.D., M.B.A., HHS**

Dr. Slaoui said Operation Warp Speed is likely to meet its objective of making a COVID-19 vaccine available in 2021, and some immunization may start earlier. The initiative accelerates vaccine progress by enabling processes, harmonizing various components, advising on logistics, and providing financing. It aims to minimize the risks to companies so they can execute their plans. The vaccines are the private property of the companies, which will determine how they are used. Operation Warp Speed sought to advance a portfolio of six to eight candidate vaccines to mitigate the risk of attrition and to yield vaccines with different profiles for allocation in various populations.



Dr. Slaoui stressed that the initiative sought to accelerate all the aspects of vaccine development except the assessment of safety and effectiveness. FDA has been helpful in speeding up the review process but its analysis remains independent. Very large Phase III efficacy trials will be conducted to accrue a large body of data and generate a large database for assessing safety. Dr. Slaoui believed that the current vaccine candidates are at least equivalent and probably superior to other recently approved vaccines, at least in the short term. Trials of the COVID-19 vaccine candidates will have a shorter follow-up period than usual, a decision made on the basis of the considerable risk posed by the pandemic, which is killing as many as 2,000 people per day. FDA determined that most adverse events from vaccines occur within 2 months of completing a vaccine regimen, and it is planning to issue guidance on emergency use authorization (EUA) that reflects that finding.

Operation Warp Speed absorbed substantial financial risk by investing in manufacturing and stockpiling candidate vaccines before they are approved, so that vaccines are available as soon as they are approved. Dr. Slaoui said all vaccine makers are expected to file a biologics license application (BLA) for their candidates to gain FDA approval, but some may seek EUA approval through FDA. Dr. Slaoui emphasized that all of the risk of the accelerated process is financial and not related to safety or efficacy.

Dr. Slaoui outlined the selection criteria for candidate vaccines, described the vaccine platforms, and summarized the status of the candidates in the portfolio. Operation Warp Speed is working closely with FDA and CDC to ensure appropriate assessment of vaccine safety, quality, and manufacturing as well as tracking vaccine distribution and administration to ensure correct dosing. It is working on a pharmacovigilance surveillance system to further characterize the long-term safety of the vaccines as they are introduced. NASEM is establishing a framework for prioritizing allocation of vaccine doses while the supply is limited. Notably, all the vaccine makers supported by Operation Warp Speed are required to make all of their data available to ensure transparency, which Dr. Slaoui hoped would influence public opinion about the safety of the vaccine. He concluded that Operation Warp Speed is committed to making the vaccines available at no cost to individuals.

### ***Discussion***

In response to Debra Blog, M.D., Dr. Slaoui said the vaccine trials include people who may have been infected but do not have COVID-19. Investigators will evaluate their immune response following vaccination. At least 40 percent of trial participants are considered at high risk for COVID-19, and they represent diverse populations.

Timothy Cooke, Ph.D., said the coordination among manufacturers is unprecedented. The industry has coalesced around the goal, as demonstrated by the CEOs of each vaccine maker pledging to follow the science and not bow to political pressure. The companies have also been remarkably transparent, releasing details of clinical trial protocols like never before. Dr. Cooke asked what could be done to ensure the success of Operation Warp Speed. Dr. Slaoui praised the industry for its rapid response and commitment. He hoped the pandemic would shine a light on the role that the pharmaceutical industry has played in increasing the life span, in conjunction with public health measures such as clean water.

John Douglas, M.D., asked whether any of the candidate vaccines appear to be especially effective for older people or those with high-risk conditions. Dr. Slaoui said the mRNA vaccines seem to have impressive results in older people, while the other platforms are more immunogenic in younger people. Adjuvanted vaccines might also be very effective in older people, he added.

## **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 had planned a full report, but their deliberations were interrupted by the pandemic. It will present a full report for review at the February 2021 NVAC meeting, but it determined that concerns about a potential COVID-19 vaccine should be addressed immediately. The Subcommittee drafted a letter to the ASH with five recommendations for NVAC review and approval. Dr. Dunn summarized the recommendations and asked for NVAC members' input:

**Recommendation 1:** Vaccines should be approved through FDA's time-tested, rigorous BLA process. If vaccine sponsors use an expedited pathway to approval, they should be cautious and transparent and clearly communicate the safety and effectiveness of the vaccines.

**Recommendation 2:** A Federal immunization safety task force should be established to facilitate rapid deployment and coordination of assets for vaccine safety monitoring.

**Recommendation 3:** A unified, proactive, highly visible communication structure should be established to keep the public informed on all aspects of vaccine development, safety, approval, and recommendations.

**Recommendation 4:** An independent group of vaccine and public health experts should be established to conduct ongoing and rapid review of the available data from safety monitoring systems, and the group's findings should be made available to all at the same time. This group should also advise the ASH on investigating and interpreting adverse events around vaccination and how to publicize the Countermeasures Injury Compensation Program (CICP).

**Recommendation 5:** The ASH should strive to ensure engagement with communities and stakeholders, starting immediately to ensure that vulnerable populations can express their concerns, priorities, and beliefs as a way to inform policies and practices.

### ***Discussion***

Dr. Meissner noted that the BLA process usually takes 2 years or more, and there is little precedent for approving a vaccine through EUA. He added that the Subcommittee members ultimately decided that the benefits of a vaccine approved through EUA might justify the potential risks given the number of deaths caused by COVID-19, especially for people at high risk. Dr. Friedland added that the BLA process is complicated and time-consuming, and FDA reevaluates all of the data submitted. In the case of EUA, FDA determines what data it will accept, and the process is less transparent, but it is much faster.

Dr. Hoft proposed recommending that COVID-19 vaccines be free for all and that compensation be available for injuries related to vaccination. Dr. Hopkins said that the COVID-19 vaccines all fall under the CICP, but cost and compensation were beyond the Subcommittee's scope. Dr. Meissner added that the Subcommittee specifically recommended that HHS publicize the CICP.

**Vote:** NVAC members unanimously approved [the letter](#) to the ASH on improving public confidence around potential COVID-19 vaccines as written.

## **The Infodemic, COVID-19 Immunization, and the Public's Health**

***The Public's Role in COVID-19 Vaccination—Monica Schoch-Spana, Ph.D., Johns Hopkins Center for Health Security***

Dr. Schoch-Spana provided highlights from [\*The Public's Role in COVID-19 Vaccination: Planning Recommendations Informed by Design Thinking and the Social, Behavioral, and Communication Sciences\*](#). In it, the Johns Hopkins Center for Health Security recommends the following:

- Communicate in meaningful terms, crowding out misinformation. Federal agencies should conduct urgent and ongoing study of attitudes and beliefs about vaccine safety, benefits, and supply and use the findings to inform the nation's COVID-19 vaccine communication approach and to test messages. States should perform rapid community-based research and listen to residents—especially communities of color hit hard by the pandemic—to explain in their own words what affects their ability and willingness to be vaccinated.
- Earn the public's confidence that allocation and distribution are evenhanded. Federal entities should hold a national dialogue to deepen understanding of allocation-related dilemmas and to boost confidence in decision-making. States and localities should provide clear, timely, and ongoing explanations about vaccine delivery and allocation.
- Make vaccination available in safe, familiar, and convenient places. States and localities should broaden vaccine delivery strategy to include nontraditional locations; address legislative and policy barriers that may prevent use of nontraditional vaccination locations; and bundle vaccines with other services (e.g., nutrition support).
- Establish accountability systems to instill public ownership of vaccines. States and localities should establish inclusive public oversight committees to review and report on planning and progress for COVID-19 vaccination systems.

Dr. Schoch-Spana suggested that an effective vaccination program for COVID-19 should take a long-term perspective, preparing for the likelihood of the current pandemic continuing for years and for the prospect of future pandemics. Planning would be improved by more fully incorporating the perspectives and needs of the underserved and communities of color to address vaccine hesitance grounded in historical trauma and bias. A strategy for recovery should set appropriate public expectations, acknowledge suffering, recognize the need for other interventions, and tie vaccination to larger social and economic revitalization goals.

***COVID-19 Vaccine Confidence: Reflection, Education, and Toward Community Building—Julia Wu, Sc.D., Harvard University School of Public Health***

Dr. Wu stressed the importance of building a foundation of public trust in vaccines. If a COVID-19 vaccine is developed and approved at record speed, uptake relies on people's faith in the safety and efficacy of the vaccine. Studies of vaccine uptake for human papillomavirus (HPV) and Ebola virus highlighted the need to understand individuals' fears and take social norms into account. Bolstering vaccine confidence must draw on all the factors that influence decision-making, such as traditional and social media, public policy, and historic and social contexts.

The Harvard University School of Public Health established a diverse student focus group that aimed to create an inclusive classroom culture and lead discussions on COVID-19. The success of the effort led to development of a social media partnership to conduct surveys and generate evidence for strategies to communicate about a COVID-19 vaccine. Dr. Wu said plans are underway to expand the collaboration and work with more social media platforms. She encouraged building trust through research-driven approaches and taking the time to listen, accept, understand, and support dialogue.

***Online (Mis)Information and Its Potential Impact on the COVID-19 Vaccine—Claire Wardle, Ph.D., First Draft***

First Draft's research tracks public health misinformation by monitoring online conversations about vaccine, most of which are now focused on COVID-19 vaccine, said Dr. Wardle. The public health community underestimates the extent to which online exchanges shape the dialogue. Dr. Wardle outlined the key trends underlying misinformation and disinformation about vaccines:

- The debate is framed around individual freedom, aligning with other communities that promote individual freedom in other contexts.
- Content is professionally packaged and put forward by influencers.
- Messages tap into high levels of distrust among people of color.
- Conversations bridge partisan divides, with similar messages on the left and the right.

Misinformation is spread effectively through the use of emotionally charged rhetoric and visual tools, and first-person narratives are particularly effective. Public health and academic communication tends to be text-heavy, relying on facts. Dr. Wardle pointed out that people are emotional, not necessarily rational, and that providing more facts is not enough. It is necessary to understand and recognize people's fears about vaccines.

Communication should appeal to a population that is digitally connected and highly responsive to visuals. Dr. Wardle praised the diagram explaining what it means to flatten the curve as a brilliant example of effective communication. Monitoring social media and understanding how people share information and build trust in others through online media is critical to the success of communication efforts, she concluded.

***Discussion***

Dr. Hopkins appreciated the suggestion to better understand the role of emotional responses in conveying information. Melissa Martinez, M.D., FAAFP, said she feels conflicted between being fully transparent: so much is unknown, and the science and rationale behind a vaccine can be quite dense. Dr. Wardle said people in the anti-vaccine community believe they have and understand the relevant data. She said communication should be more honest about nuances and complexity; when complicated issues are avoided, someone always finds a way to exploit that complexity. Dr. Wardle called for testing messages for clarity, adding that misinformation flourishes in a vacuum.

Dr. Schoch-Spana agreed with the need to improve communication, adding that people can handle uncertainty if the dilemmas of the situation are clearly explained. Communication should stress that some learning about vaccines occurs along the way and should describe how information is collected, assessed, and disseminated. Dr. Schoch-Spana also recommended message testing, so communications can be revised if they are not working. National survey panels are needed to gather insights as a vaccine campaign unfolds over time.

Dr. Schechter asked how to communicate successfully about vaccines that rely on novel technology. Dr. Schoch-Spana noted that not everyone is convinced by science, and vaccine hesitance does not just come from mistrust of the science but also stems from world views and values. Some communication should stress the role of vaccines in people's lives. To counter the message that vaccines impinge on personal freedom, for example, Dr. Schoch-Spana suggested framing messages about the benefits of vaccination in allowing people to return to work, school, and places of worship. Dr. Wardle agreed that in addition to talking about science, messaging

should promote a sense of community, using storytelling and first-person narratives that emphasize the benefits of vaccines. Dr. Wu added that some journalists are doing a great job educating the public. She also recommended leveraging the trust that people have in public health officers and medical scientists.

Sean O’Leary, M.D., M.P.H., of the University of Colorado pointed out that despite all the concern about vaccine hesitancy, uptake of childhood vaccines remains higher than 90 percent. When dealing with misinformation and disinformation, he said, it is important to understand what is being done right.

### **Immunization Information Systems (IIS) to Support the COVID-19 Response**

#### ***IIS Evidence Review —Holly Groom, M.P.H., Center for Health Research, Kaiser Permanente Northwest***

Ms. Groom described a systematic review of evidence conducted in 2010 that confirmed that IIS effectively support reminder/recall systems, give feedback to providers for assessment, and remind providers about vaccines, all of which improve vaccine uptake. Moreover, the review found that IIS were able to identify those most in need of vaccination (e.g., most susceptible to disease) and identify coverage disparities, which can help with targeting and allocating resources. Following the evidence review, the Community Preventive Services Task Force recommended IIS on the basis of strong evidence of effectiveness in increasing vaccination rates.

Since the initial review, participation in IIS is higher, especially for adults. A 2009 survey found that IIS were instrumental in helping States coordinate their responses to several disease outbreaks, and provider participation increased notably after those outbreaks. Ms. Groom said that it is clear that IIS work well for reminder/recall systems, but questions remain about how effective they are and for which populations. IIS could be key for tracking two-dose COVID-19 vaccine regimens.

An assessment of IIS data on Kaiser Permanente Northwest members who got H1N1 influenza vaccine between 2009 and 2015 revealed that about 17 percent were vaccinated outside their medical home. The finding points to the need for more IIS participation, rather than relying on electronic medical records (EMRs).

#### ***Use of IIS to Support the COVID-19 Response—Rebecca Coyle, M.S.Ed., AIRA***

An AIRA survey in April 2020 found that 94 percent of respondents planned to use their IIS as a core component of mass vaccination, possibly with some augmentation. IIS-based mass vaccination tools can be categorized as either rapid entry or quick-add screens (e.g., to check people in and capture essential data); integrated mass vaccine modules; or interface mass vaccine modules (which can stand alone and function without internet access). Other tools for mass vaccination include emergency preparedness or response tools (e.g., in the form of mobile applications for registration and scheduling appointments), paper recordkeeping, spreadsheets, web-based surveys, and locally developed solutions.

Jurisdictions face various challenges and considerations in determining how to apply any tools or solutions. Once a new vaccine is introduced, all entities will need to update their coding, databases, and systems. Ms. Coyle said updating can be achieved quickly but requires thinking through the whole process. A number of survey respondents indicated that they were concerned that their mass vaccination modules had not been maintained or tested since the H1N1 influenza pandemic in 2009. Concerns were also raised about the ability to identify populations at high risk or to capture data on race/ethnicity. Guidance is needed on specifications, capacities, and

reporting requirements. Data sharing policies must be addressed. Ms. Coyle noted that IIS web-based user interfaces are still functional and can be leveraged if needed.

Ms. Coyle concluded that more pandemics are likely, so IIS should be recognized as a critical part of the vaccine infrastructure. A lot of work has been done to ensure that IIS data can be exchanged, but more thinking is needed around future capacity. IIS will need funding and resources to build on their existing capacity.

***Building Healthy Communities—Amy Pisani, Vaccinate Your Family***

Ms. Pisani said that Vaccinate Your Family (formerly known as Every Child by 2) seeks to translate evidence and recommendations from bodies like NVAC into policy proposals that can be enacted at the local, State, and Federal level. Before the COVID-19 pandemic, CDC estimated that more than \$1 billion is needed to support immunization programs, yet the budget allocated by Congress remains well below that. No additional funds have yet been allotted for COVID-19 immunization programs.

Vaccinate Your Family annually publishes recommendations for improving vaccine uptake. Its 2020 recommendations take COVID-19 into account and call for providing \$400 million for strengthening IIS; increasing CDC's annual appropriation for immunization programs to \$1 billion, plus a \$900 million one-time appropriation for immediate pandemic response; and allocating \$1 billion for influenza vaccine purchase and infrastructure in 2020 and 2021.

Ms. Pisani stressed that vaccines save lives, and funding for IIS now will prepare the country for future pandemics. An optimal IIS will encompass all vaccines received during a person's lifetime, contain immunization histories from children and adults, meet AIRA standards, include all vaccine providers, and be capable of sharing data across State lines. Vaccinate Your Family has contributed to Federal legislation under consideration and partnered with the Adult Vaccine Access Coalition to call on Congress to support IIS and other infrastructure. Ms. Pisani also pointed to the need to address barriers to access to vaccines that could affect COVID-19 vaccine uptake.

***The Primary Care Perspective—Sean O'Leary, M.D., M.P.H., University of Colorado***

Dr. O'Leary said a Colorado task force determined that the most important step toward increasing access to childhood vaccines was to shore up IIS. Primary care providers (PCPs) have the infrastructure in place to deliver vaccines. IIS are currently used more to track childhood than adult immunization. Dr. O'Leary summarized the results of a 2015 survey of PCPs' knowledge and use of IIS, which found some improvement but still not universal use of IIS.

Whether they used IIS or not, PCPs described the primary barriers to use as the lack of communication between the IIS and their practices' EMR and the fact that the IIS does not capture vaccines received outside the State or region. The time required for data entry and concerns about the accuracy of the data were moderate barriers. Among the less frequently cited barriers were the cost, need for staff training, slow internet interfaces, and privacy concerns. Those who use IIS said the lack of direct connection with the EMR and the time to enter data are the most significant barriers they face.

Dr. O'Leary concluded that although PCPs could play a large role in delivering COVID-19 vaccines, use of IIS by adult immunization providers may be a barrier. Accurate tracking of vaccinations will be crucial for two-dose vaccine regimens. Dr. O'Leary asked NVAC to consider whether IIS use should be required of those delivering COVID-19 vaccines and whether the

pandemic presents an opportunity to address the greatest longstanding barrier: the lack of a national IIS.

### ***Discussion***

Mr. Knighton said CDC will track vaccines for VA beneficiaries, and Ms. Coyle said it is likely that CDC will stand up its Immunization Gateway system to route information from the VA and others (e.g., the Bureau of Prisons) to existing IIS. CDC is also rolling out the Vaccine Administration Management System (VAMS), which has different capabilities than an IIS but might be particularly useful for States that do not have a mass vaccination module. Ms. Coyle said it is possible that States that are prohibited from sharing IIS data with CDC can use VAMS to communicate with CDC. Dr. Hopkins observed that the communication between IIS and EMRs has improved in the past decade, but the pandemic will test the existing systems.

### **Discussion of COVID-19 Charge to NVAC—Robert H. Hopkins Jr., M.D., MACP, FAAP, NVAC Chair**

#### ***Vaccine Confidence***

Dr. Hopkins agreed with Dr. Meissner that the letter to the ASH on COVID-19 and vaccine confidence approved earlier in the day by NVAC addresses some of the ASH's new charge to NVAC, specifically item 1, what HHS can do before, during, and after the COVID-19 vaccination campaign to improve confidence in these vaccines and the nation's immunization system especially within underserved communities, including racial and ethnic minorities. The letter partially addresses item 2, the appropriate approach and timing of generating needed data and proceeding to potential childhood vaccination.

Dr. Fleming pointed out that the Vaccine Confidence Subcommittee highlighted the critical importance of engaging trusted voices from within vulnerable communities. He emphasized that HHS must consider the financing needed to support and implement local coordination and collaboration, including research and community engagement that informs effective communication—and those efforts should start immediately.

Dr. Martinez said communication must make it clear that the first vaccines on the market might not be the best and might not be appropriate for all. Expressing that will be a challenge throughout the vaccine rollout. Ms. Coyle added that clear, timely information on vaccine safety, availability, and access should be released broadly, especially to the underserved. Immunization programs often have close relationships with underserved communities and should be brought in as partners as early as possible. Vaccine-related materials should be available in multiple languages and should target specific cultural competencies. IIS should review participation among provider sites and underserved communities and conduct outreach and onboarding efforts with any sites not yet participating. IIS should strongly encourage submission of race and ethnicity data from all partners to improve the surveillance of coverage rates and promote health equity.

#### ***Lessons for Vaccine Development***

Dr. Cooke noted that the COVID-19 vaccine effort could increase interest in other vaccines, such as influenza, and in particular vaccines that can directly or indirectly prevent antimicrobial resistance (AMR). Some of the vaccine platforms that have advanced as a result of pandemic vaccine research might be desirable for prepandemic preparedness or other uses. Dr. Cooke added that massive government funding has been a huge part of promoting rapid innovation.

Ms. Coyle said public health officials must balance privacy concerns against the need to gather broad demographic data. She proposed leveraging the data from IIS to build public confidence in data privacy. Dr. Dunn noted that other data mechanisms, such as geomapping, can sometimes approximate demographic data. It might be helpful to identify the areas in which gathering demographic data has been a struggle, he stated.

### ***Vaccination of Diverse Populations***

Regarding vaccination in children, Dr. Schecter suggested gathering more data on whether immunization reduces transmission and whether there is significant transmission via asymptomatic children. Dr. Hopkins agreed that that much more must be learned about whether the vaccine mitigates disease or reduces transmission or both, and whether it plays into shifts in vaccine strains.

More discussion of the new charge was scheduled for day two of this meeting and at another NVAC meeting in October, said Dr. Hopkins.

### **Public Comment**

No public comments were offered.

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

Dr. Hopkins thanked the participants and the OIDP staff and adjourned the meeting at 5:27 p.m.

## **Day Two**

### **Call to Order and Chair's Welcome—Ann Aikin, M.A., Acting Designated Federal Officer, Communications Director, OIDP, HHS, and Robert H. Hopkins Jr., M.D., MACP, FAAP, NVAC Chair**

Ms. Aikin called the meeting to order at 12:01 p.m. Dr. Hopkins summarized the proceedings of day one. Among the key messages he heard is that, as soon as possible, public health efforts must engage and collaborate with communities of color that have been neglected to maximize uptake of COVID-19 vaccines and minimize misinformation. Also, modeling is needed to support vaccine prioritization planning. More understanding is needed about how to better use social media and IIS in the context of COVID-19 vaccination.

### **Progress in Using Vaccines to Prevent Superbugs**

#### ***National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), 2020-2025—Amanda Cash, DrPH, MPH, Office of the Assistant Secretary for Planning and Evaluation, HHS***

Dr. Cash outlined the growing problem of AMR, the development of the first National Strategy and National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), and the One Health approach. The Federal CARB Task Force brings together agencies across the Federal government to promote collaboration and communication. The Presidential Advisory Council on CARB (PACCARB), an advisory body under the Office of the ASH, is primarily made up of external stakeholders. Among the major accomplishments since implementation of the first National Action Plan are the establishment of the Antibiotic Resistance Laboratory Network, the CARB-X research accelerator program, and the AMR Challenge prize; USDA support for agricultural research and development; and broad stakeholder commitment to global action.



While it is difficult to link activities with outcomes, Dr. Cash cautioned, from 2012 to 2017, U.S. deaths overall from resistant infections fell 18 percent, and such deaths in hospitals dropped 30 percent. More hospitals now have high-quality antibiotic stewardship programs, thanks in part to more Federal support. Still, there are too many infections and deaths from resistant organisms, Dr. Cash said, and new resistant pathogens are emerging all the time. Community-acquired resistant bacterial infections are increasing. Challenges persist with developing new antibiotics.

The National Action Plan for CARB 2020–2025 maintains the five goals of the original National Action Plan, adds some new objectives and targets, and identifies new challenges. Implementation of the new plan depends on the resources available and capacity. The updated plan continues to prioritize the One Health approach, infection prevention and control, appropriate use of antibiotics, and support for innovative products. It incorporates an updated measurement and reporting strategy, with quantitative targets when possible. Targets will be updated as needed and described in annual reports. The new plan will be published in October 2020, followed by annual progress reports. A final annual report and a summary of progress toward the goals of the original plan are also expected.

***AMR and Vaccines—Dennis M. Dixon, Ph.D., National Institute of Allergy and Infectious Diseases (NIAID), NIH***

Dr. Dixon said [\*NIAID's Antibiotic Resistance Research Framework: Current Status and Future Directions, 2019\*](#) details the NIAID approach, and he highlighted some work of particular interest. Vaccines can indirectly mitigate AMR by reducing respiratory infections and thus reducing antibiotic use, decreasing selective pressure and resistance. Some vaccines directly target antibiotic-resistant pathogens, such as pneumococcus. Researchers are evaluating experimental vaccine candidates for some of the most resistant pathogens: gonococcus, *Staphylococcus*, *Pseudomonas*, and *Candida auris*.

Notably, one study found that meningococcal vaccine appears to protect against gonorrhea, and the results will inform efforts to develop a gonorrhea vaccine. A European study found that a *Pseudomonas* vaccine was safe in hospitalized, ventilated patients but not effective in preventing infection. Dr. Dixon hoped a larger company would build on these findings. A *S. aureus* vaccine study was halted because of futility, but Dr. Dixon believes some of the challenges posed can be addressed.

Preclinical studies are underway on using a vaccine originally created for *S. aureus* and *C. albicans* to treat *C. auris*. The potential *C. auris* vaccine candidate illustrates NIAID's efforts at all stages of research—basic, translational, and clinical—as well as the potential for cross-protection, Dr. Dixon concluded.

***Industry Perspectives on the AMR Vaccine Pipeline—Greg Frank, Ph.D., Biotechnology Innovation Organization (BIO)***

Dr. Frank stressed that vaccine development for humans usually takes 10–20 years and costs \$1.5 billion. Vaccines are particularly complex products that must go through a daunting regulatory structure. Clinical uptake is driven by USG recommendations, adding further risk to the financial viability of the product after it is approved.

AMR vaccines have great potential but face significant challenges. They often target pathogens that are difficult to treat and may not be common, so they have a lower probability of success. The economic case for investment is difficult to make for vaccines that target a subset of the

general population or healthcare-associated infections (HAIs) in even smaller subpopulations. A review of AMR vaccines in development demonstrates that the pipeline is deteriorating.

PACCARB offered several recommendations for strengthening the AMR vaccine pipeline, including additional funding for AMR vaccine development; improving interactions among sponsors, regulatory agencies (e.g., FDA), and use policy committees (e.g., ACIP); and incentivizing vaccine uptake by ensuring “first-dollar” coverage. Dr. Frank noted that the CDC’s list of AMR threats should not be perceived as a list of vaccine targets, as some AMR targets might be better served by other approaches.

***Vaccines: Another Strategy to Reduce Antibiotic Resistance in Health Care Settings—Anthony Fiore, M.D., M.P.H.D., M.S., National Center for Emerging and Zoonotic Infectious Diseases, CDC***

In recent years, the National Action Plan for CARB and Gavi, the Vaccine Alliance, have been among those focusing attention and resources on using vaccines to stem AMR. Dr. Fiore noted that vaccines can be effective in conjunction with antibiotic stewardship efforts, as health care systems might be reaching the limits of what can be achieved with infection prevention and control. Progress in reducing infections from certain HAI-associated pathogens is stalling, said Dr. Fiore. In addition, rates of community-onset methicillin-resistant *S. aureus* among people with no recent health care exposure are stalled, with no clear approach to intervention.

Dr. Fiore summarized the status of some studies underway of vaccines against *Clostridioides difficile* and *Escherichia coli*. Among the programmatic challenges to vaccine development are the delivery models, which mostly support universal, age-based vaccination of children. New vaccines will have narrower indications and target smaller populations and will be used in settings where vaccines are not frequently administered. There is potential for vaccines to interact with other therapies. Economic analysis of new vaccines is needed.

CDC has mechanisms in place that assist with technical and programmatic challenges, including its Emerging Infections Program: Healthcare-Associated Infections/Community Interface, a population-based surveillance system; academic research partnerships (Modeling Infectious Diseases in Healthcare and the CDC Prevention Epicenters); and the Antibiotic Resistance Laboratory Network, which offers laboratory capacity and infrastructure for addressing antibiotic-resistant pathogens. Dr. Fiore concluded that progress is being made on new vaccines that could have significant public health impact, including decreasing antibiotic resistance.

***Impact of Pneumococcal Conjugative Vaccine (PCV) on Antibiotic-Resistant Invasive Pneumococcal Disease (IPD) in the United States—Tamara Pilishvili, Ph.D., M.P.H., National Center for Immunization and Respiratory Disease, CDC***

Dr. Pilishvili said more than 2 million pneumococcal infections occur each year in the United States, resulting in more than 6,000 deaths and \$4 billion in total costs. Penicillin-resistant isolates are more likely to be resistant to other antibiotics. In more than 30 percent of pneumococcal infections, bacteria are resistant to one or more clinically relevant antibiotics.

PCVs have reduced antibiotic-resistant IPD. Since the first PCV was introduced in 2000 in the United States, rates of penicillin-susceptible and antibiotic-resistant IPD caused by vaccine strains decreased by 97 percent among children younger than 5 years old and by more than 60 percent among adults. The vaccine reduces colonization, leading to herd immunity.

However, resistant nonvaccine serotype clones continue to expand and emerge. In the United States, there is no evidence of replacement disease so far, and the increases in nonvaccine serotypes have not eroded the benefits of PCVs to date. New PCVs targeting additional serotypes that cause resistant infections have the potential to decrease further AMR, Dr. Pilishvili said.

***Impact of Influenza Vaccination on Secondary Bacterial Infections—Amber Smith, Ph.D., University of Tennessee Health Science Center***

Dr. Smith presented data showing that bacterial infection following influenza—most frequently with *Streptococcus pneumoniae* or *S. aureus*—has been a significant cause of morbidity and mortality in previous pandemics and during seasonal influenza outbreaks. Vaccines targeting pneumococcus and *Haemophilus influenzae* have driven down those bacterial infections, and influenza vaccines have expanded to cover more strains.

Research in ferrets demonstrates that influenza infection allows pneumonia infection to transmit more easily. Further animal research reveals that a complex interaction of the order, timing, dose, and strain of influenza and pneumonia infection dictates the likelihood of survival. Mortality is highest among mice that had influenza followed by pneumonia, and the same is true for mice infected by influenza and then *S. aureus*. The synergy between pathogens peaks at 7 days after influenza infection.

Influenza depletes the alveolar macrophages that protect against bacterial invasion in the lung. Dr. Smith described a number of mechanisms at play that drive the synergy between pathogens. Reducing influenza infection through vaccination reduces the severity of secondary bacterial infection and also decreases the window of time that bacteria has to invade the host.

***Discussion***

Melody Anne Butler, B.S.N., RN, CIC, asked which pneumonia strains appear to be most common among patients with COVID-19. Dr. Pilishvili did not know which strains had been identified, noting that testing has not been systematic. CDC is seeking to link its COVID-19 and bacterial surveillance to better understand the incidence and prevalence of secondary infections.

Dr. Cooke observed that the pipeline for AMR vaccines has not changed significantly in the past 5 years and reveals that vaccines face two “valleys of death:” first in translation from preclinical studies to Phase I trials and again moving from Phase II to Phase III. Large USG funding efforts are supporting the translation to clinical trials, and it will take time for those efforts to come to fruition. Dr. Cooke said lots of worthy AMR vaccine candidates get stuck at the transition to Phase III trials, and they need the same kind of substantial Federal funding. Dr. Cooke said AMR vaccines might benefit from lessons learned from COVID-19 vaccine development and expansion of BARDA funding.

**Now More Than Ever: Influenza Vaccination During COVID-19**

***Vaccination Planning for the 2020–2021 Influenza Season—Ram Koppaka, M.D., Ph.D., CAPT, U.S. Public Health Service, Immunization Services Division, CDC***

Dr. Koppaka said the available supply of influenza vaccine is 12 percent higher than last year. Significant Federal resources have been invested in ordering more adult vaccine for the coming season and implementing vaccination programs, which are expected to continue through December and beyond. CDC provided \$141 million to States, territories, and cities for adult and mass vaccination programs. Many of those jurisdictions plan to use the supplemental funds to increase vaccination among minority populations and vulnerable communities. Despite the

overall rise in vaccine coverage over the past 10 years, whites consistently have significantly higher rates of vaccination than people of color.

On the basis of advice gathered from listening sessions on adult vaccine coverage, CDC gave supplemental funding to most of the grantees of its Racial and Ethnic Approaches to Community Health program to increase outreach around adult influenza vaccination. As it does every year, CDC is preparing a robust communications campaign to promote influenza vaccination. This year, it is working with the Ad Council and the American Medical Association to reach more African Americans and Hispanics, among other partnerships to amplify the message and reach new populations.

***Flu LEAD (Linkages to End Access Disparities)—Justin Mills, M.D., M.P.H., AHRQ***  
Dr. Mills explained that Flu LEAD is a pilot project of the interagency Healthcare Resilience Working Group that seeks to increase influenza vaccination among residents and communities that receive assistance from the Department of Housing and Urban Development (HUD). It will leverage public housing agencies, HRSA-funded health centers, and HUD partnership facilitators, resident advocates, and meeting spaces. Flu LEAD will connect housing and health centers interested in providing vaccinations, coordinate outreach, collect and provide communication materials (rather than create new ones), and facilitate discussion through webinars. The overall goal is to foster partnerships between health and housing services, acknowledging that programs on the ground will work out the details of their collaboration.

Following vaccination programs for this influenza season, Flu LEAD aims to provide ongoing services to support community health, including raising awareness about COVID-19 vaccines and treatment and connecting individuals to primary and preventive care. About 10 Flu LEAD sites have been established so far.

***Maintaining Influenza (and Adult) Immunizations During COVID-19—Litjen (L. J.) Tan, M.S., Ph.D., Immunization Action Coalition***

Dr. Tan presented data indicating that vaccination rates—which have declined dramatically since the pandemic began—are recovering somewhat among children but much more slowly among adolescents and adults. Localized planning is needed to bring adult immunization rates back up. All types of in-person health care visits dropped substantially because of the pandemic, underscoring the need for novel access points for vaccination.

The impact of the pandemic on the upcoming influenza season remains unclear. In the Southern Hemisphere, the influenza season has been mild, likely because of a combination of pandemic-related social distancing and an aggressive influenza vaccination campaign. However, the United States is not practicing social distancing to the same degree. The COVID and influenza viruses will cocirculate, likely causing coinfection, leading to increased rates of illness and death and placing a tremendous burden on the health care system.

Influenza vaccination can diminish what Dr. Tan called “the twindemic,” but people must feel that they will be safe from COVID-19 exposure while getting the vaccine. Providers must increase access to influenza vaccine in alternative settings, in cooperation with telehealth, and over a longer period than in the past. The Immunization Action Coalition offers resources for maintaining immunizations during the pandemic and guidance on mass vaccination clinics. Dr. Tan concluded providers must be compensated for the increased costs of innovation to expand access and improve infection prevention and control.

***State Roles in Vaccination— Lawrence Gostin, J.D., Georgetown University***

Mr. Gostin outlined the role that State laws might play around influenza and COVID-19 vaccination, noting that steps to ramp up influenza vaccine coverage could be a good model for COVID-19 vaccination. Pharmacists have been helpful in reaching many people who traditionally get their influenza vaccine at their schools and workplaces. Strong public health measures—such as disinfection, wearing masks, and social distancing—are needed to ensure the public that getting vaccinated is safe, and those protocols will be even more important when COVID-19 vaccines are available.

As several have pointed out, the best health education campaigns come from the bottom up. They are locally driven and clear. Lessons from influenza vaccination campaigns should inform the anticipated COVID-19 vaccination campaign. From a legal standpoint, mandating influenza or COVID vaccination for adults could create a backlash. However, States can mandate that certain health care settings require employees to at least offer vaccination, which can be effective in raising rates without raising concerns about impinging on civil liberties.

***Influenza Vaccination Disparities and COVID-19: An Urgent Need for Targeted Action—Laura Lee Hall, Ph.D., Center for Sustainable Health Care Quality and Equity***

Dr. Hall emphasized that patient advocates, clinicians, health care systems, academics, and policymakers have great reach into communities of color, but their good work will not matter if individuals do not know how to access care, and the importance of the work may be diminished if the people who need the resources have minimal input into the programs and messages developed. Dr. Hall said communities are starved for trustworthy information, and health care providers must build trust within communities. By mapping the data demonstrating persistent racial and ethnic disparities in vaccination, it is clear where more attention is needed.

Dr. Hall offered the following steps to improve vaccine coverage:

- Train all those involved in health care to make strong recommendations for vaccines (including PCPs and specialists, office staff, pharmacists, community health workers, and patient advocates).
- Expand the pool of clinicians who offer vaccines.
- Increase safe access to influenza vaccines (e.g., provide guidance to PCPs on protecting patient and worker safety during the pandemic).
- Implement high-volume mechanisms for vaccination, such as drive-through clinics, and address how to pay for vaccination in such settings (e.g., for the uninsured).
- Engage community leaders from all types of organizations to understand community needs and concerns, and empower them to educate their communities.
- Focus on communities of color, areas with historically low vaccination rates, and those hardest hit by COVID-19.

The National Minority Quality Forum’s new initiative, [Demonstrating Real Improvement Value in Equity \(DRIVE\)](#) offers resources to support these steps.

***The Effectiveness of Life-Preserving Investments in Times of COVID-19—Jules van Binsbergen, Ph.D., University of Pennsylvania***

Dr. Binsbergen and colleagues computed the costs of influenza mitigation efforts to save lives and compared them to the costs of COVID-19 mitigation. They concluded that, given the large investments in COVID-19, investing more heavily in influenza mitigation is warranted.

Moreover, the spillover effects of influenza on hospital capacity during the pandemic strengthens case for more influenza mitigation.

The calculation takes into account the U.S. population by age, life expectancy, typical death rate from influenza, and life years lost from influenza. Dr. Binsbergen determined the cost of influenza mitigation per life year saved. He concluded that providing influenza vaccine free of cost to those unvaccinated would cost about \$3.85 billion, or \$24,000 per unvaccinated person. The figure supports his contention that the same amount of money should be invested in preventing seasonal influenza as in preventing deaths from COVID-19, which is projected at \$1.3 trillion. Large, government-sponsored influenza vaccination campaigns are economically justifiable given the burden, said Dr. Binsbergen, and the unprecedented steps being taken to fight COVID-19 could be applied to influenza vaccination.

### ***Discussion***

Dr. Schechter asked whether the decline in health care visits is more influenced by lack of access to care or concerns about the safety of in-person visits. Dr. Tan said anecdotal evidence suggests decreased access is the greater concern, but people still need reassurance about the safety of in-person visits. Dr. Mills said fears about visits have subsided in his clinic, largely because the clinic moved to a bigger space where it could better ensure patient safety. He noted that not all facilities have the space for social distancing, and as the weather gets colder, outdoor options are limited.

### **Overdue Immunization: Getting Back on Track**

#### ***Routine Childhood Vaccination During the COVID-19 Pandemic— Melinda Wharton, M.D., M.P.H., Immunization Services Division, CDC***

Dr. Wharton echoed concerns about the decline in childhood vaccinations. A survey of Vaccines for Children (VFC) providers in mid-July found that most were open and accepting new patients; the immunization infrastructure appears to be adequate meet needs and ensure that patients can catch up on missed vaccines; and most had the capacity to immunize children in time for the start of the new school year. However, providers and parents need some support to get routine childhood immunization back on track. CDC monitors immunization and provides guidance, communication, and planning to support immunization programs.

Dr. Wharton emphasized that CDC messaging seeks to raise awareness about the VFC program, especially among those who may have lost health insurance as a result of the pandemic. Additionally, it strives to communicate that well-child visits are safe and necessary for maintaining health and staying up to date on vaccinations. The new school year is an important opportunity to catch up on vaccinations, but with virtual education, some States may have deferred their school vaccination requirements. To counter the disruptions of the pandemic, immunization programs, providers, and partners should collaborate to get routine childhood vaccinations back on track.

#### ***Increasing Access to Vaccinations During COVID-19: Pharmacy Perspective— Mitchel C. Rothholz, R.Ph., M.B.A., APhA***

Mr. Rothholz noted that new legislation authorized pharmacists to administer vaccines to children ages 3 years and older during a public health emergency, including COVID-19 vaccine when available, to increase access to vaccines. As part of the authorization, HHS also required pharmacists to inform parents and patients about the importance of well-child visits and make referrals as needed.

APhA is encouraging pharmacists to find innovative ways to expand access to vaccines and increase the public's comfort level with vaccination. It is also highlighting techniques for ensuring customers feel safe coming to a pharmacy, such as visible precautionary practices. Pharmacies and their customers have gotten used to the measures. CDC has guidance for pharmacies on giving vaccinations outside of the pharmacy (e.g., curbside). The [VaccineFinder](#) app is helping people find the most convenient locations for immunization.

Mr. Rothholz said some gaps must be addressed to ensure that pharmacists can play a role in increasing access to vaccinations for their community, such as the following:

- Medicaid reimbursement
- VFC provider enrollment
- IIS enrollment
- Availability of PPE and supplies

***Catch-Up to Get Ahead: A National Immunization Initiative for Children—David Kim, M.D., HHS (Presented by Ann Aikin, M.A., Acting Designated Federal Officer, Communications Director, OIDP, HHS)***

Speaking on behalf of Dr. Kim, Ms. Aikin explained that OIDP mounted the Catch Up to Get Ahead campaign with little funding to focus attention on getting childhood immunization rates back to prepandemic levels. The campaign piggybacked on National Immunization Awareness Month in August and aimed to coordinate communication, increase access to childhood vaccines, and seek policy options to reduce vaccination barriers. It worked through various HHS divisions, their partners, and HHS awardees while also teaming up with State and local health partners and programs, community health programs, and health professional advocacy organizations to promote readily available, proven strategies. A communications toolkit for providers is available at [Vaccines.gov](#).

The campaign promoted three key messages across all communications:

- Remind parents of the need to stay up to date on vaccines and of school requirements.
- Convey safety precautions and practices at provider settings.
- Vaccines prevent illnesses so people can avoid seeking care at a strained health care system.

Analysis of the campaign's efforts in late August indicated that some of its Twitter messages generated a great deal of traffic to the National Vaccine Program's website, and the Surgeon General's video was highly popular. The campaign's work is ongoing.

***Discussion***

Dr. Hopkins observed that even with assurances, patients continue to be reluctant to come in to the office, especially in his State, where transmission rates are high.

**Evidence and Equity: What Works to Decrease Disparities in Immunization**

***Vaccine Hesitancy in Migrant Populations: Some Evidence from the Literature—Akhenaten Benjamin Siankam Tankwanchi, Ph.D., University of Washington***

Dr. Tankwanchi is exploring vaccine hesitancy among immigrant populations. He presented comments gathered through interviews and focus groups that reveal immigrant parents' concerns.

For example, some Somalis in Scandinavia had heard that the measles vaccine causes children to “stop talking,” and they do not trust vaccine recommendations. Dr. Tankwanchi said they also stated that they felt ignored or stereotyped by HCWs who prejudged their stance on vaccines.

Numerous concerns have been expressed by migrants from various parts of the world about HPV vaccination. Some African immigrants believe it is a license for girls to be promiscuous, that it is experimental, and that it is intended to sterilize and control Black girls. Dr. Tankwanchi said another study demonstrates that similar views on HPV vaccine among Korean immigrants traveled with them from South Korea. He noted that it is difficult to find sufficient data on Latinx immigrants, but some expressed similar concerns about the HPV vaccine. Latinx immigrants may have confidence in vaccines but lack access to the health care system.

***Vaccine Hesitancy and Access in Missouri—Randall Williams, M.D., FACOG, Missouri Department of Health and Senior Services***

Dr. Williams noted that vaccination rates are low in Missouri, more because of a lack of access and systemic barriers than because of vaccine hesitance. His office has worked to change the culture around vaccination, despite criticism and pushback. Through systemic reform in the past 10 years, the State has increased HPV vaccination rates.

Specifically, Missouri implemented community-based interventions to expand access, especially in high-risk communities; used IIS to generate reminders and track data; offered home and school visits; reached out through Federal food programs and other systems; and assessed providers’ performance through the Statewide IIS. Among the strategies used in urban areas, the State has hired nurses to vaccinate high-risk people, conducted mass vaccination clinics, and expanded access to adult vaccines in Federally qualified health centers. This year, it increased investment in programs and supplies for adult influenza vaccine.

In anticipation of a COVID-19 vaccine, Dr. Williams said the State is focusing on minority populations, again targeting the systemic barriers of access, provider education, and insurance coverage. Messaging is key. Dr. Williams noted that COVID-19 vaccine hesitance is apparent among many, particularly those in minority populations, and there are great concerns about safety.

***Immunization Equity at a Practice Level—Melissa Martinez, M.D., FAAFP, University of New Mexico***

On the basis of a literature search and her own experience in practice, Dr. Martinez offered some solutions for improving immunization equity. She said providers should prioritize vaccination, which requires buy-in from the leadership to ensure that their EMRs include immunization reminders and that providers have sufficient resources. Including adult vaccination as a Healthcare Effectiveness Data and Information Set (HEDIS) measure and having a vaccine champion on the staff are helpful. Providers need more data to support quality improvement efforts around vaccination. IIS can identify where vaccination efforts are needed and also avoid duplication of effort.

A systematic approach in which vaccines are recommended for every patient at every visit would decrease missed opportunities and lower disparities for minority populations, said Dr. Martinez. Staff should be trained on all aspects of vaccination, including making strong recommendations. Any efforts by ACIP to make its recommendations less confusing would be helpful.



Patients are more likely to get vaccinated if their health care provider has the vaccine on hand than if they are referred to a pharmacy. Stocking vaccine involves a lot of upfront costs and logistical considerations, and those costs may not be fully recouped depending on the mix of insurance payers among the patients served. Practices can mitigate some expense by enrolling in the VFC program; using online, bulk, or pooled purchasing approaches; and learning what Medicare and Medicaid covers in their State.

Finally, providers must take steps to build trust with patients, identify and address implicit bias, and provide culturally appropriate care. They should also forge partnerships with pharmacies, local health departments, health care training programs, and community organizations. Measuring and rewarding the results of such efforts are effective incentives.

***What Works to Decrease Disparities in Immunization—Sheri Winsper, RN, M.S.N., M.S.H.A., National Quality Forum (NQF)***

NQF convened stakeholders in 2017 to develop a road map, which reached consensus around the 4 I's for improving health equity: identify, implement, invest, and incentivize. The road map offered 10 recommendations that ranged from collecting more data on social risk factors to redesigning payment models to support health equity.

Noting that measurement drives uptake, Ms. Winsper pointed to the increase in adult influenza vaccination since an NQF measure went into effect for Medicare beneficiaries in 2009. Medicaid has implemented NQF measures for adult influenza vaccination, childhood and adolescent vaccinations, and pneumococcal vaccination in older adults.

NQF convened a bipartisan congressional briefing in 2019 to share the results of its SDH Payment Summit recommendations for recognizing how SDH are influenced by payment policies, which affect the ability to improve care for all. The recommendations are similar to those of the 2017 road map but are more focused on policy approaches. Implementing them requires resources to create, validate, and put into place new measures and conversations about power dynamics, goals, and values. It also requires building trust and consensus and creating a shared national infrastructure and unified strategy.

***Discussion***

Dr. Hopkins asked Dr. Tankwanchi for insights on overcoming vaccine hesitance among immigrants. Dr. Tankwanchi replied that African immigrants tend to be socially conservative when they arrive. There is reluctance to talk about sexual health, so the resistance to HPV vaccination is understandable. He added that it has been difficult to get Somalis in Minnesota to cooperate with research because they feel stigmatized. Dr. Hopkins observed that it is necessary to develop allies within a community before trying to study it.

***NVAC Liaison Updates***

***AHRQ and the U.S. Preventive Services Task Force (USPSTF)—Justin A. Mills, M.D., M.P.H.***

USPSTF is updating its 2015 recommendation for hepatitis B screening in nonpregnant adolescents and adults at high risk. The final recommendation is in the development process.

AHRQ is conducting a systematic review on the safety of vaccines used for routine immunization in the United States. The review was commissioned by HHS' Office of the ASH and OIDP to evaluate adverse events reported in the literature. AHRQ anticipates posting the draft report for public comment in mid-October.

***BARDA—Linda Lambert, Ph.D.***

BARDA continues to work with interagency partners to develop safe and effective vaccines for COVID-19, including collaborating with DoD's JPL. (See the written report for other infectious disease initiatives.) BARDA-supported COVID vaccines from Sanofi Pasteur and Janssen are in clinical trials. More updates on vaccines are available on BARDA's website at [medicalcountermeasures.gov](https://www.fda.gov/oc/medicalcountermeasures). At the end of October, BARDA will host its annual Industry Day, this time virtually, to provide updates on BARDA's work and priorities for the future and an opportunity to showcase new technologies.

***DoD—David Hrnecir, M.D.***

Dr. Hrnecir said DoD has a system in place for evaluating adverse effects of vaccines, and he hoped it would accommodate COVID-19 vaccines.

***FDA—Valerie Marshall, M.P.H.***

On October 22, FDA will meet virtually in open session with VRBPAC to discuss the development, authorization and/or licensure of vaccines to prevent COVID-19. Additional FDA updates are available in the written report submitted to NVAC.

***HRSA—Mary Rubin, M.D.***

Dr. Rubin said 2019 data from HRSA's Bureau of Primary Health Care's Uniform Data System indicate improvement over 2018 on the number of children under 2 years old who received seasonal influenza vaccines and selected other vaccines. Updates on the national Vaccine Injury Compensation Program (VICP) and the CICP are available in the written report submitted.

***NIH—Barbara Mulach, Ph.D.***

This past summer, NIH announced the awards for its Centers for Research in Emerging Infectious Diseases, which seek to better understand and prepare for pathogens in wildlife and other sources that become infectious in humans. The awards went to 10 institutions and a coordinating center. Additional updates on NIH's COVID-19 efforts are available in the written report submitted.

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

At its September 4, 2020, meeting ACCV members received routine program updates from the HRSA Division of Injury Compensation Programs and the Department of Justice, as well as an update from the U.S. Court of Federal Claims. It discussed the VICP's draft notice of proposed rulemaking, which proposed to amend the Vaccine Injury Table. ACCV members voted unanimously to invite speakers to a meeting to discuss the scientific and legal implications of the notice of proposed rulemaking. It also received program updates from CDC, FDA, and OIDP and reviewed modified vaccine information statements.

***AHIP—Christopher Regal, M.S.***

AHIP is working with its member insurance providers to promote vaccines among their members. It has developed resources on vaccines recommended for children and adults, available on its website. AHIP submitted comments to NASEM on the proposed COVID-19 vaccine allocation framework, requesting additional guidance on how to prioritize populations within each proposed phase, suggesting that local trends be considered as a factor to help guide prioritization, and emphasizing the need to follow the science and the best available evidence in allocation, distribution, and administration. AHIP believes that health insurance providers have an important role to play in helping ensure that when a COVID-19 vaccine is available, members will receive it as efficiently and effectively as possible.

***AIRA—Rebecca Coyle, M.S.Ed.***

AIRA recognizes the urgent need to ensure that policies are in place to capture and exchange data about COVID vaccinations seamlessly and quickly, and its web page highlights some key resources around this topic. Ms. Coyle said *Nature* published an article describing electronic data as critical for a large-scale U.S. vaccination effort. AIRA’s Measurement Improvement initiative is designed to ensure that standards are adopted. It is now working on the topics of data quality, clinical decision support, and validation. Reports from the initiative are available in the AIRA repository online. In addition to its Measurement Improvement initiative webinars, AIRA presented a series of webinars in lieu of an in-person national meeting this year.

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

Dr. Goode thanked HHS for recognizing the role of pharmacists in vaccine access through expansion of the authority for administering childhood vaccines and COVID-19 vaccine when it becomes available. APhA has been focused on providing training, education, information, and resources to make sure pharmacists are well prepared to step into this role. Additional updates are available in the written report submitted.

***AIM— Claire Hannan***

AIM is helping members navigate the CDC Playbook and hosting peer-to-peer sessions among members. It set up a COVID-19 resource library and established an interactive community vaccinator map. Ms. Hannan invited all community vaccinators to register so that States know that they are available and have capacity. To support seasonal influenza vaccine uptake, AIM provided unbranded communication materials to members, who are developing their own messaging and outreach. AIM is collecting materials created by members, which it will share via its website. AIM is working with the National Association of Community Health Centers to coordinate collaboration between community health centers and programs. AIM is also hosting a webinar series on vaccine confidence.

***ASTHO—James S. Blumenstock***

ASTHO and AIM coauthored a checklist for COVID vaccine planning implementation. ASTHO members and staff have also written blogs and produced podcasts on planning efforts for vaccination. In response to congressional staffers, ASTHO created seven guiding principles on policy matters associated with a national vaccination campaign. The organization also shared with Operation Warp Speed its ideas, concerns, and perspectives about the early stages of strategic and tactical planning around a national vaccination campaign. In correspondence with congressional leaders, ASTHO highlighted the need for an enhanced public health and health care infrastructure to ensure the COVID vaccine is successfully and carefully administered once it becomes available.

ASTHO convened an informal leadership council of approximately 20 national associations representing public health, pharmacy, health care, and supply chain associations to share information and understand each other’s perspectives on a national vaccination campaign. ASTHO submitted substantive comments to NASEM on its preliminary framework for vaccine prioritization. It also issued a policy statement, [Safety, Not Politics, Must Drive COVID-19 Vaccine Timeline](#).

***NACCHO—John Douglas, M.D.***

NACCHO’s program assessment of the impact of COVID-19 on local health department immunization programs was eye-opening in terms of immunization capacity. As of May 2020, 88

percent of local immunization staff had been reassigned to focus on the pandemic response in their jurisdiction. In addition, 90 percent of local health departments' essential immunization programs and services had been impacted by the shift to the pandemic response, and 62 percent of health departments reported a notable decline in vaccination coverage rates. Dr. Douglas said there may have been some recovery since May. NACCHO also submitted comments on the NASEM prioritization report. Its white paper, published in June, on the Strategic National Stockpile made the point that given the growing cuts that State and local health departments have sustained over the past 10 years, the Stockpile is more than the stopgap that it was designed to be. Health departments at all levels depend on the Stockpile, creating a disconnect, which was manifest in the spring. Finally, NACCHO hosted a webinar on COVID-19 vaccination planning, highlighting lessons learned from pilot sites in North Dakota, Florida, California, Minnesota, and Philadelphia.

***PAHO—Nathalie El Omeiri, Ph.D.***

PAHO's Technical Advisory Group (TAG) on vaccine-preventable diseases met in August to review the epidemiology of the pandemic, the impact on national programs in the region, and progress made in facilitating equitable access to COVID-19 vaccines for countries in the region. The TAG urged countries to implement immunization catch-up and coverage recovery activities and emphasized that countries should focus on improving program monitoring, including at the subnational and local level, to direct their efforts, implement catch-up strategies, and strengthen all of the components of their immunization programs as a fundamental part of health services. The TAG also stressed the importance of sustaining surveillance resources and efforts that have been effective during the pandemic. It drew attention to the fact that all of the current challenges are arising in the context of a serious decline in immunization coverage in the region over the past decade. Rates of diphtheria, pertussis, and tetanus vaccine coverage declined from 94 percent in 2010 to 84 percent in 2019. The TAG commended the countries that conducted safe and effective influenza vaccination campaigns in the Southern Hemisphere in the past few months and recognized the efforts of PAHO's Revolving Fund for access to vaccines; its facilitation of discussions; and its approach to access to future COVID-19 vaccines.

Understanding that strong national immunization programs are the foundation for the introduction of COVID-19 vaccines, the TAG encouraged countries to strengthen their capacity, information systems, and safety surveillance and urged countries to develop national plans for the introduction of COVID-19 vaccines. PAHO is already supporting and engaging with member countries' national immunization TAGs in the process.

Representatives from CDC and VA referred NVAC members to their organizations' written reports.

**Discussion of COVID-19 Charge to NVAC—Robert H. Hopkins Jr., M.D., MACP, FAAP; NVAC Chair**

***Vaccine Confidence***

Mr. Knighton reiterated that NVAC is well positioned to respond to the ASH on vaccine confidence, on the basis of its deliberations around seasonal influenza. Many of the same communication strategies for influenza vaccine can be applied to COVID-19 vaccine. Dr. Martinez stressed that physicians and other providers need to feel confident in the COVID vaccines. Education programs and resources should be developed to answer providers' questions about the vaccines in development. Several members agreed that providers and other HCWs must be confident that a COVID-19 vaccine is safe and effective. Ms. Butler added that more providers

and HCWs from different areas of health care should be included in conversations to ensure a common understanding of the vaccines.

Dr. Dunn noted that the three questions posed by the ASH are interrelated, making it challenging to structure recommendations. Mary Anne Jackson, M.D., FAAP, FPIDS, FIDSA, said the priority is to complete the trials and share the results in a transparent way before licensing and implementing the vaccine. Without trust that vaccine makers have adhered to all the standards for vaccine development, vaccine uptake may be limited. Dr. Martinez pointed out that the first vaccine available might not be the best vaccine overall, and communication must be transparent about the fact that vaccines will be rolled out as they are approved, and recommendations may change as new vaccines become available.

Ms. Butler stressed that HHS agencies must be united in messaging, transparency, and recognition of the challenges posed by a COVID-19 vaccination campaign. Public confidence in the vaccine is vital to coordinating access, especially in underserved communities.

### ***Vaccination of Diverse Populations***

Dr. Meissner said he would be very uncomfortable with a vaccine approved under an EUA that is indicated for children, because the severity of disease is modest for children under 18. It is important to ensure that the vaccine does not have adverse effects before it is given to children. Some side effects might be considered acceptable in vaccines intended for elderly people who are at higher risk for complications from COVID-19. Dr. Jackson concurred with Dr. Meissner, adding that research must also demonstrate that the COVID-19 vaccine is compatible with other childhood vaccines. Dr. Hopkins said there should be significantly more data on elderly people than children, at least in the early phases of research.

Dr. Fleming called for careful thought about the overall communications strategy to ensure that it is coherent and lays out the likely transition from a vaccine shortage situation, in which prioritization is needed, to a strategy in which many or all are encouraged to be vaccinated. He also said the communication strategy should be coherent and disseminated internally across the USG and externally to other jurisdictions. Dr. Hopkins added that there is clearly a risk of being perceived as putting out conflicting or changing messages, and communication must be proactive rather than reactive. Ms. Hannan called for better coordination between the Federal government and the States on messaging.

Geetha Srinivas, D.V.M., M.S., suggested NVAC consider recommendations for individuals who are not included in the Phase III trials, as they likely represent many of those at highest risk of COVID-related morbidity and mortality, including pregnant women, the immunocompromised, and frail older persons. Mr. Knighton suggested seeking lessons from experiences with other multidose vaccines on how to ensure recipients get the correct second dose in the appropriate time frame.

### ***Lessons for Vaccine Development***

Dr. Cooke asked for clarification of the scope of the ASH's question on vaccine development.

**Action Item:** OIDP staff will determine whether the question refers broadly to all aspects of vaccine development, from the early basic science to administering vaccine to patients, or more narrowly to the process of creating and manufacturing new vaccines.

Dr. Hopkins said he would like more information on the manufacture of vaccines while they are still being tested and on the cold-chain requirements for some of the vaccines. Dr. Meissner said a

shortage of reagents and supplies has compromised some aspects of COVID-19 therapeutic research, which is worth noting for the ASH.

Dr. Friedland pointed out that the value of a COVID-19 vaccine was immediately recognized by many. NVAC can help highlight the value of vaccines for AMR and for conditions that affect much smaller patient populations. The technological innovations brought forth by the COVID vaccine research are truly disruptive and novel. Dr. Friedland said it is important to look critically at how future vaccines are valued by society and policymakers.

Dr. Friedland added that cold-chain storage requirements are typically simplified over the long course of vaccine development, but the speed of COVID vaccine manufacturing has not allowed for studies to test ways to minimize the burden of cold-chain storage. If the ultimate goal is to develop platform technologies that can support vaccines for various emerging infections, it is necessary to invest early in gathering the kind of manufacturing and control data needed to move forward fast. Dr. Schecter asked whether PATH, the Gates Foundation, or others could bring insights to the research agenda around cold-chain storage.

Ms. Aikin said ODP staff would compile the comments, circulate them for further consideration by NVAC members, and gather more input for the October NVAC meeting. She asked members to think about whom they would like to invite to the October meeting to enhance the conversation. Ms. Aikin pointed out that HHS's Vaccine Communicators Group assists with coordinating messaging across government.

### **Public Comment**

**Gretchen LaSalle, M.D., AAFP**, said she has a passion for preventive care and a personal mission to fight vaccine misinformation and overcome vaccine hesitancy. Vaccine hesitancy is a complex and growing concern, and it will take a coordinated approach from multiple stakeholders to successfully counter this issue. Dr. LaSalle encouraged NVAC to think about how to support PCPs in working with vaccine-hesitant patients. A strong recommendation from a PCP is the biggest contributor to a person's decision to vaccinate. For COVID and other vaccines, ensuring that providers have confidence in their vaccine message will be key. Dr. LaSalle said a big source of frustration among providers is feeling as though they lack the background or data to speak to patients' very specific anti-vaccine claims.

During medical training, providers receive the building blocks of vaccine science through classes in immunology, infectious disease statistics, pharmacology, and more, Dr. LaSalle continued. These allow providers to understand vaccine recommendations and evaluate vaccine research, but they do little to help providers develop communication strategies for working effectively with vaccine-hesitant patients. They do not give providers the tools to address the very specific and constantly shifting issues that patients bring up, such as concerns over aborted fetal tissue, toxins, or microchips in vaccines. Dr. LaSalle said she has been out of training for years, so the medical curriculum may have changed, but she sensed that it has not. Dr. LaSalle asked that NVAC consider looking at vaccine hesitancy education for current and future clinicians who will be on the front lines of these vaccine discussions. PCPs can be the greatest bullhorn for immunization efforts, but first they need to have confidence in what they are recommending and the knowledge to speak to their patients' particular concerns, she concluded.

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

Dr. Hopkins thanked the participants and the NVPO staff and adjourned the meeting at 5:27 p.m.

**APPENDIX A: Abbreviations**

ACCV	Advisory Commission on Childhood Vaccines
ACIP	Advisory Committee on Immunization Practices
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
BIO	Biotechnology Innovation Organization
BLA	biologics license application
CBO	community-based organization
CDC	Centers for Disease Control and Prevention
CICP	Countermeasures Injury Compensation Program
COVID-19	coronavirus disease (2019)
DoD	Department of Defense
EMR	electronic medical record
EUA	emergency use authorization
FDA	Food and Drug Administration
Flu LEAD	Influenza Linkages to End Access Disparities
HAI	health-care-associated infection
HCW	health care worker
HHS	Department of Health and Human Services
HPV	human papillomavirus
HRSA	Health Resources and Services Administration
HUD	Department of Housing and Urban Development
IIS	Immunization Information Systems
IPD	invasive pneumococcal disease
NACCHO	National Association of County and City Health Officials
NASEM	National Academies of Sciences, Engineering, and Medicine
NCRN	National COVID-19 Resiliency Network
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NQF	National Quality Forum
NVAC	National Vaccine Advisory Committee
OIDP	Office of Infectious Disease and HIV/AIDS Policy
OMH	Office of Minority Health
PACCARB	Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria
PAHO	Pan American Health Organization
PCP	primary care provider
PCV	pneumococcal conjugative vaccine
PHAC	Public Health Agency of Canada
PPE	personal protective equipment
SDH	social determinants of health
UCSF	University of California, San Francisco
USDA	U.S. Department of Agriculture
USG	U.S. Government

VA	U.S. Department of Veterans Affairs
VAMS	Vaccine Administration Management System
VFC	Vaccines for Children
VICP	Vaccine Injury Compensation Program
VRBPAC	Vaccine and Related Biological Products Advisory Committee