NVAC NATIONAL VACCINE ADVISORY COMMITTEE

June 9, 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
Larry Pickering, M.D., FAAP, FIDSA
Robert Schecter, M.D.
Geeta Swamy, M.D.
Robert Swanson, M.P.H.

NVAC Ex Officio Members

Limone Collins, M.D. (for COL Tonya Rans, M.D.), Department of Defense (DoD)
Jeffrey Kelman, M.D., M.M.Sc., Centers for Medicare and Medicaid Services (CMS)
Troy Knighton, M.Ed., Ed.S., LPC, Department of Veterans Affairs
Linda Lambert, Ph.D., Biomedical Advanced Research and Development Authority (BARDA)
LTC Valerie Marshall, M.P.H. (for Marion Gruber, Ph.D.), Food and Drug Administration (FDA)
Nancy Messonnier, M.D., Centers for Disease Control and Prevention (CDC)
Justin A. Mills, M.D., M.P.H., Agency for Healthcare Research and Quality (AHRQ)
Anthony Marks, M.D. U.S. Agency for International Development
Barbara Mulach, Ph.D., National Institutes of Health (NIH)
Mary Rubin, M.D., Division of Injury Compensation Programs, Health Resources and Services Administration (HRSA)

NVAC Liaison Representatives

Tara Beitel (for Gina Charos), Public Health Agency of Canada (PHAC)
James S. Blumenstock, Association of State and Territorial Health Officials (ASTHO)
Rebecca Coyle, M.S.Ed., American Immunization Registry Association (AIRA)
John Douglas, M.D., National Association of County and City Health Officials (NACCHO)
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

Acting Designated Federal Officer

Ann Aikin, M.A., Communications Director, National Vaccine Program

Office (NVPO), Department of Health
and Human Services (HHS)

Proceedings

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

Ms. Aikin called the meeting to order at 2:02 p.m. 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 NVPO staff for their support in organizing the meeting and called the roll.

Opening Remarks and Office of Infectious Disease and HIV/AIDS Policy (OIDP) Update—RADM Sylvia Trent-Adams, Ph.D., RN, FAAN, Acting Director, OIDP; Principal Deputy Assistant Secretary for Health, HHS

RADM Trent-Adams thanked those who have been on the front lines of the response to COVID-19 (the disease caused by severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2]) for their dedication and sacrifices. She said HHS is leveraging every tool it has to respond to the pandemic, including technology innovation, policy change, and strategic partnership.

Among HHS' top priorities is developing a safe and effective vaccine. Operation Warp Speed, announced in May, is a public-private partnership that seeks to develop, manufacture, and distribute a COVID-19 vaccine by January 2021 and to make therapeutic and diagnostic products available as soon as possible. Through this effort, 14 promising vaccine candidates were selected from more than 100 in development, and some are already in clinical trials. Eventually, three to five candidates will go on to randomized trials of safety and efficacy. Other steps, such as nonclinical trials and animal models, will be conducted in parallel when possible. Manufacturing capacity will be implemented for the most promising candidates while they are still in development rather than after approval. RADM Trent-Adams said Operation Warp Speed pushes the boundaries of vaccine innovation, but every effort will be taken to ensure vaccine safety.

Recent data indicate that routine immunization has been disrupted significantly around the world during the COVID-19 pandemic. As a result, nearly 80 million children under 1 year of age are at increased risk for vaccine-preventable diseases such as diphtheria, measles, and polio. CDC data show steep declines in pediatric immunizations in the United States.

HHS is working to mitigate the impact of COVID-19 on children's immunization rates to reduce the threat of future disease outbreaks. CDC released guidance to help health care providers continue to offer well-child visits and routine immunizations during the pandemic. HHS is raising awareness and encouraging immediate action to ensure that children stay up to date on recommended vaccines. RADM Trent-Adams noted that providers have started to resume patient visits, and orders for childhood vaccines have increased in recent weeks. She appreciated NVAC's attention to the matter.

The COVID-19 pandemic has intensified challenges to the U.S. immunization system, including challenges related to immunization equity and vaccine confidence. Minority, rural, and vulnerable populations have been hit hard by the pandemic, which has underscored difficulties that many Americans face every day in accessing health care, including immunizations, RADM Trent-Adams observed. In addition, misinformation is already spreading about a COVID-19 vaccine,

with the potential to threaten future vaccine confidence and uptake. RADM Trent-Adams was pleased that NVAC will work on the issues of equity and vaccine confidence.

RADM Trent-Adams welcomed three new NVAC members: Kristen R. Ehresmann, RN, M.P.H.; Daniel F. Hoft, M.D., Ph.D.; and Robert Swanson, M.P.H. She thanked all of the NVAC members for their service. RADM Trent-Adams also expressed appreciation to outgoing member Larry Pickering, M.D., FAAP, FIDSA, for his tremendous contributions.

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 February 13–14, 2020, meeting were approved unanimously by NVAC members. Dr. Hopkins introduced the new NVAC members and recognized Dr. Pickering for his work with the Committee.

Written comments can be sent to NVAC for consideration by e-mail (nvac@hhs.gov). The agenda, minutes, and presentations of past meetings are available online. NVAC is scheduled to meet on September 23–24, 2020, and February 4–5, 2021. (See the appendix for a list of abbreviations used in this report.)

Front-Runners, Hurdles, and Insider Perspectives: The Race to Develop and Implement a Safe and Effective COVID-19 Vaccine

Coalition for Epidemic Preparedness Innovations (CEPI) and COVID-19 Vaccines—Nicole Lurie, M.D., M.S.P.H., CEPI

In partnership with the U.S. Government and others, CEPI has invested in products to address priority pathogens and as-yet-unspecified threats. The H1N1 influenza pandemic revealed the need to develop manufacturing capacity around the world. Because of the contracts in place and relationships established, CEPI was prepared to move quickly to address COVID-19. CEPI supported novel approaches, such as encouraging vaccine developers and regulators to work in parallel, anticipating the reproductive health implications of a potential vaccine, and scaling up manufacturing capacity to meet global demand. CEPI is supporting nine vaccine candidates so far.

Unlike smaller, less wealthy nations, the United States has Federal financing and incentives for pandemic vaccine development, legislation to protect vaccine makers from liability, and strong safety monitoring systems. Balancing fair allocation and equitable access to vaccine is a global challenge. Dr. Lurie said the first vaccine doses will likely be used in high-income countries, but many countries hope to make vaccine available to low- and middle-income countries (LMICs) around the same time. The early experience in high-income countries, especially around safety monitoring, will be key to uptake.

The Access to COVID-19 Tools Accelerator is an international collaboration of organizations working cooperatively to develop vaccines, diagnostics, and therapeutics. As part of the effort, CEPI and GAVI, The Vaccine Alliance, are overseeing the COVAX facility approach, which creates a purchasing pool so any country can buy in to a portfolio of up to 15 COVID-19 vaccines. The COVAX mechanism allows countries to support domestic vaccine development without limiting their access to only domestically produced vaccines.

Modeling suggests that vaccinating priority populations, such as health care and public safety workers around the world, rather than vaccinating all people in any one country is probably the

fastest route to global economic recovery. That approach, coupled with public health needs, is informing the evolving strategy. Dr. Lurie concluded that every month without a vaccine against COVID-19 costs about $165 billion in gross domestic product.

Biotechnology Innovation Organization (BIO) COVID-19 Vaccines Pipeline—Amy Walker, BIO

BIO's COVID-19 pipeline tracker, developed from industry databases and public announcements, contains information about the products in development and is updated weekly. As of early June, 550 programs for COVID-19 vaccines and therapeutics had been announced publicly. The speed with which products are progressing toward clinical trials is notable, said Ms. Walker.

Of the products in the pipeline, 142 (25 percent) are vaccines, and 16 of those have reached the clinical trial stage. A few trials are assessing the efficacy of existing vaccines for other diseases against COVID-19. Vaccines made in China are more likely to be in the later stages of development. No U.S. companies have yet advanced beyond Phase II. Most of the vaccines are being created through public-private partnerships. In general, about 10 percent of vaccine candidates progress to FDA approval, so many candidates and platforms are being put forth to increase the likelihood of success. Multiple vaccines will be needed to meet the global demand. Investments are being made in manufacturing infrastructure to speed the development pipeline.

Ms. Walker outlined some broad challenges to COVID-19 vaccine development:

- Incomplete knowledge of the epidemiology of COVID-19
- Shifting understanding of populations at highest risk
- Unpredictable spread of disease, making it hard to identify where to conduct trials
- Need for rapid manufacturing scale-up to meet unprecedented demand
- Need for rapid manufacture of ancillary products to support vaccination
- Maintenance of existing capacity to produce routine vaccines
- Public confidence concerns

Development of a Coronavirus Vaccine for Global Access—Peter Hotez, M.D., Ph.D., Baylor College of Medicine, Texas Children's Center for Vaccine Development

Dr. Hotez pointed out that COVID-19 disproportionately affects poor people, even in higher-income countries, so a low-cost vaccine is a priority. His laboratory has been working with coronavirus for a decade, with emphasis on transferring technology to and increasing vaccine development capacity in LMICs. For about 10 years, the Center for Vaccine Development has partnered with the New York Blood Center, which developed early candidates for severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS) vaccines. All of the current efforts to develop a COVID-19 vaccine build on principles facilitated by the New York Blood Center's research to induce immune response to the spike protein.

Studies from the past decade indicate that a vaccine that induces high levels of neutralizing antibodies against the spike protein would be especially effective. Achieving low titers of virus-neutralizing antibodies would provide some protection but not necessarily prevent infection or transmission.

The Center for Vaccine Development is part of a consortium, with support from NIH's National Institute of Allergy and Infectious Diseases (NIAID), advancing a promising COVID-19 vaccine candidate that can be easily produced in LMICs at low cost. Working with PATH, the Center for Vaccine Development is developing a second vaccine, which it believes will increase the

effectiveness of the first vaccine. The first vaccine is expected to begin Phase I clinical trials in September, with the second following shortly thereafter.

Dr. Hotez pointed out that the antivaccine movement is coalescing with groups on the far right that claim that restrictions intended to prevent the spread of COVID-19 violate their civil liberties. He believes that the current approach to rapid vaccine development has been tone-deaf to the antivaccine movement's fears that vaccines are rushed into production without sufficient concern for safety and accusations that developers are motivated by profit rather than public health. He cited the name "Operation Warp Speed" and various instances of profit-motivated behavior as examples that strengthen the antivaccine movement. As a result, polls are already finding that half of Americans say they will not get a COVID-19 vaccination when it becomes available. Dr. Hotez called for a concerted effort to avoid such an outcome.

Herd Immunity and COVID-19 Vaccines: Five Key Principles—David Dowdy, M.D., Ph.D., Department of Epidemiology, Johns Hopkins University Bloomberg School of Public Health

Dr. Dowdy presented five principles of herd immunity, the condition in which a sufficient portion of a population is immune to an infectious disease to make its spread from person to person unlikely:

1. Using traditional calculations, the threshold for herd immunity for COVID-19 is 60–70 percent. That is, if about 60 percent of the population had immunity, the transmission of disease would be stable over time.
2. Given that susceptibility to COVID-19 is not uniform across all populations, the herd immunity threshold may be lower—possibly about 30 percent.
3. Even when a designated threshold for herd immunity is met, outbreaks can still occur. (Such outbreaks tend to occur in pockets of a population, such as measles outbreaks in areas where vaccination rates are low.)
4. Herd immunity depends on the efficacy and durability of vaccines. The more effective the vaccine, the fewer people need to be vaccinated to achieve herd immunity (assuming that natural immunity works independently of vaccine-induced immunity). Given reported rates of infection and death, Dr. Dowdy estimated that about 8 percent of the U.S. population has some immunity to COVID-19. That rate is increasing too slowly (about 1.5 percent per month) to achieve the herd immunity needed.
5. Herd immunity is a continuum, not a threshold. Even a vaccine that does not help to achieve the target threshold will save lives. A vaccine that exceeds the target will save many more.

The Fight Against COVID-19: Bedside & Beyond —Melody Anne Butler, B.S.N., RN, CIC

Ms. Butler offered her perspectives as a nurse and infection preventionist who works on Long Island, NY. Her county has had more than 40,000 confirmed cases of COVID-19. New York State is investigating 204 suspected cases of pediatric multisystem inflammatory syndrome, and three children in the State have died from conditions similar to Kawasaki disease and toxic shock-like syndrome, possibly resulting from COVID-19.

Among the challenges Ms. Butler's hospital faced were finding space to accommodate the number of COVID-19 patients admitted, reassigning nurses from other units to partner with intensive care unit nurses to meet patient needs, and obtaining sufficient personal protective equipment and supplies.

Educating staff about frequently changing guidelines was difficult, but transparency proved to be key to building trust, said Ms. Butler. Staff understood that the evidence was evolving. Ms. Butler hoped lessons learned so far would help staff prepare for a potential second wave of COVID-19. She noted that health care systems in New York are struggling to deal with the number of employees who are sick and the emotional toll of colleagues dying from the disease.

Misinformation online about COVID-19 has become a significant challenge, especially that which comes from well-organized, well-funded sources. Even health care providers can be taken in by false claims. Ms. Butler said that debunking myths offers an opportunity to educate about proper infection prevention and control techniques. She stated that social media platforms must be active in removing dangerous misinformation. Facebook relies on users reporting misinformation, and its fact-checking approaches can take weeks to determine that a post should be removed. Hackers have found ways to get around content restrictions, especially content originally posted in languages other than English.

Ms. Butler said medical providers should be encouraging their professional organizations and institutions to actively debunk misinformation about COVID-19. Providers should model exemplary behavior by wearing facemasks, sharing credible information, and staying on top of routine vaccinations (including influenza vaccine). Ms. Butler suggested starting now to work with those in other sectors—such as religious leaders, politicians, influencers, and celebrities—to lay the groundwork for vaccine acceptance when a COVID-19 vaccine becomes available.

Discussion

Some members asked about the mechanics of the vaccine candidates in development by the Center for Vaccine Development. Dr. Hotez clarified the findings so far and the questions to be addressed in Phase II clinical trials.

Robert Schecter, M.D., asked how superspreader events can provide insight into questions about the heterogeneity of risk and the thresholds for herd immunity. Dr. Dowdy said such events provide a sense of the heterogeneity, but there are also other broader questions of heterogeneity that are important to consider.

Leonard Friedland, M.D., sought opinions on the potential impact of a multidose vaccine. Dr. Lurie thought it likely that a two-dose vaccine would be needed. Ms. Walker anticipated that delivering a multidose vaccine during a pandemic will increase the logistical complexity. Guidelines for providers will have to take into account the need for social distancing, adequate personal protective equipment, and reminder/recall systems to ensure patients complete the vaccine series, said Ms. Walker.

Cody Meissner, M.D., FAAP, observed that once a vaccine is licensed, there is less incentive for other vaccine developers to continue their work, even if it might produce a more effective vaccine. Dr. Dowdy said that several vaccines are being evaluated in parallel. Once a vaccine is deemed effective and approved, it is likely that attention will turn to the durability of immunity. He believed that developers would continue to improve vaccines over time.

Dr. Hotez noted several examples in which developers refined and improved vaccines. He believed there would be multiple COVID-19 vaccines for multiple uses. Also, Dr. Hotez observed, early vaccines might offer only partial protection, so public health authorities will have to communicate effectively with the public about the need for continued safety precautions. Dr.

Lurie added that a single vaccine will probably not be sufficient to meet global needs; more than one vaccine will be needed, and some vaccines may be better suited for certain populations.

Dr. Meissner questioned whether institutional review boards would approve new vaccine trials once an effective vaccine was available. Dr. Hotez noted that the early *Haemophilus influenza* type B and rotavirus vaccines were replaced by better vaccines for the target populations. He thought that further trials would be approved, especially if the first COVID-19 vaccine only provides partial protection.

Dr. Meissner requested that Dr. Hotez elaborate on the idea that lower titers of neutralizing antibody may modify the disease but not prevent it. Dr. Hotez referred to a Chinese study using nonhuman primates that found that a single dose of vaccine that yielded low titers of neutralizing antibodies was partially protective. Whether high titers of a virus-neutralizing antibody correlates with disease protection in humans remains to be seen in clinical trials, but it is an important trend to watch closely, he said.

Molly Howell, M.P.H., asked whether new distribution mechanisms would be needed to disseminate a COVID-19 vaccine. Ms. Walker said conversations are ongoing within the industry, but she felt it was likely that initial procurement and distribution would follow the same model as H1N1 influenza vaccine. If COVID-19 becomes endemic, the vaccine might become part of routine immunization protocols. Ms. Walker said the lack of clarity is leading to confusion around access, and more discussion and guidance are needed to determine the systems required to ensure adequate distribution. Ms. Howell observed that NVAC should consider the topic in more depth. Timothy Cooke, Ph.D., pointed out that the industry is aware that the success of any vaccine will be judged on whether it can be successfully distributed globally.

Dr. Hopkins added that correlates of immunity are an important aspect to consider in vaccine research. In addition, vaccine trials must include people from traditionally underrepresented groups.

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 2014 recommendation for hepatitis B screening in nonpregnant adolescents and adults at high risk. The draft recommendation was posted in May. USPSTF recommends screening in adolescents and adults at increased risk for hepatitis B infection. USPSTF based this recommendation on adequate evidence that the screening is accurate for identifying persons with chronic hepatitis B infection, that the hepatitis B vaccination is effective at decreasing acquisition in those who are negative for hepatitis B, and that there is antiviral treatment for chronic hepatitis B infection that is effective for improving intermediate and health outcomes. The public comment period for the recommendation ended June 1, and USPSTF is currently finalizing its recommendation.

On April 6, AHRQ posted a protocol for an in-progress systematic review on the safety of vaccines used for routine immunization in the United States. The review was commissioned by HHS' OIDP to evaluate adverse events reported in the literature.

BARDA—Linda Lambert, Ph.D.

BARDA recently announced two new partnerships to further development of COVID-19 vaccine candidates. Merck will develop a recombinant vesicular stomatitis virus vaccine based on its

Ebola virus vaccine, which was approved by the FDA in late 2019. AstraZeneca will advance efforts on AZD1222, a vaccine candidate that uses a replication-deficient chimpanzee adenovirus viral vector that contains the genetic material of the SARS-CoV-2 spike protein. BARDA is now supporting five vaccine candidates.

BARDA continues to support work on Ebola virus vaccines, including Merck's single-dose vaccine and Janssen's prime-boost vaccine. Other efforts are progressing toward smallpox and universal influenza vaccines.

CDC—Nancy Messonnier, M.D.

CDC is determining how a COVID-19 vaccine would be distributed and administered to the public. The agency is concerned about the decline in uptake of childhood immunizations, although vaccine ordering and uptake has increased in the past few weeks. Dr. Messonnier believed that strong messaging and support from immunization advocates contributed substantially to the recent increases. CDC is also concerned about the potential for influenza to coexist with COVID-19 in the fall, which would put additional stress on the health care system. Anything that prevents illness would help reduce that stress, so CDC has launched new initiatives to promote influenza vaccination and increase the number of doses of influenza vaccine available. It is working with health departments to target those who are at higher risk for both influenza and COVID-19, such as staff and residents of long-term care facilities, adults with underlying illness, and African Americans.

To improve influenza vaccination coverage for the 2020–2021 season, CDC is working with pharmaceutical companies to make sure the maximum number of influenza vaccine doses are available. The ability to deliver the vaccine will be affected by the need to maintain social distance at health care providers' offices and pharmacies.

CMS— Jeffrey Kelman, M.D., M.M.Sc.

Under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Section 3713, Medicare fee-for-service plans must cover all approved COVID-19 vaccines. This coverage will fall under the Part B medical benefit, similar to influenza and pneumococcal vaccines, rather than the Part D pharmacy benefit. The coverage extends to Medicare Advantage, a private insurance system that provides, at a minimum, the same services as Medicare fee-for-service plans.

Regarding Medicaid, which is a collaboration between CMS and the States, Section 6008 of the Families First Coronavirus Response Act makes available to States an enhanced Medicaid Federal medical assistance percentage if they meet certain requirements. To qualify for this temporary 6.2-percent increase, States must waive copays for testing services and treatments for COVID-19, including vaccines. In terms of private health insurance, Section 3203 of the CARES Act requires that group or individual health plans, employer-based group health plans, and non-Federal-government plans impose no cost sharing for immunizations that would hinder or mitigate the effects of COVID-19.

FDA—Valerie Marshall, M.P.H.

FDA is working on multiple fronts to address the COVID-19 pandemic, such as engaging in international and domestic collaborations aimed at expediting clinical trials for preventive vaccines and providing timely regulatory guidance to sponsors who seek to develop vaccines for COVID-19. In April 2020, FDA approved the meningococcal conjugate vaccine MenQuadfi, manufactured by Sanofi Pasteur, for active immunization for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W, and Y in

individuals 2 years of age and older. In January 2020, FDA approved an adjuvanted influenza A (H5N1) monovalent vaccine, Audenz, manufactured by Seqirus Inc. In February 2020, FDA approved a supplement to the biologics license application for the adjuvanted influenza vaccine Fluad Quadrivalent, manufactured by Seqirus.

HRSA—Mary Rubin, M.D.

Dr. Rubin said 2019 data from HRSA's Bureau of Primary Health Care's Uniform Data System will be publicly available in August 2020. The National Vaccine Injury Compensation Program (VICP) continues to process an increased number of claims. In fiscal year 2019, 1,282 claims were filed, $196.2 million was awarded to petitioners, and $29.2 million was awarded in attorneys' fees and costs. As of May 1, 2020, 682 claims had been filed with the program, and $160.2 million had been awarded for petitioners and attorneys' fees and costs. The VICP has a backlog of 936 claims alleging vaccine injury awaiting review. As of May 1, 2020, the Countermeasures Injury Compensation Program had compensated 40 claims totaling $5.7 million. The HHS Secretary issued a COVID-19 declaration, effective February 4, 2020, that provides liability immunity for the manufacture, testing, development, distribution, administration, and use of COVID-19 countermeasures. In addition, the declaration permits individuals seriously injured by COVID-19 countermeasures to file a claim with the Countermeasures Injury Compensation Program. The countermeasures include any vaccine that will prevent or mitigate COVID-19 or transmission of SARS-CoV-2.

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

At its March 6, 2020, meeting ACCV members received routine program updates and updates from ex-officio members and discussed the VICP's draft notice of proposed rulemaking (NPRM), which proposed to amend the Vaccine Injury Table. ACCV members requested a separate meeting on the topic to obtain more information. They did not vote on any policy issues or recommendations related to the VICP. On May 18, 2020, ACCV met again to discuss the draft VICP NPRM, which would remove shoulder injury related to vaccine administration and vasovagal syncope from the Vaccine Injury Table on the basis that these injuries generally result from administration of a vaccine, not the vaccine antigen.

The draft NPRM also proposes to remove the new vaccine category Item 17 from the table, because HHS has serious concerns that Item 17 is contrary to applicable law. ACCV members heard 16 public comments about the draft NPRM and reviewed three written public comments. All commenters opposed implementation of the draft NPRM, except for one individual with an unknown affiliation and one person from the Department of Justice. After the discussion, the members unanimously voted to oppose the draft NPRM and to send a recommendation to the Secretary. They also intended to reiterate their support for a recommendation previously sent to the Secretary to increase staffing and funding resources for the VICP.

AIM— Claire Hannan

Program managers are focusing efforts on restoring high levels of routine vaccination and catching children up on routine vaccines, preparing for influenza season and increasing the uptake of influenza vaccines, and preparing for COVID-19 vaccination campaigns. AIM is targeting most of its activities on preparing for COVID-19. It is holding Peer Connect meetings to allow program managers to work with each other virtually to talk through challenges. One meeting focused on routine vaccination, one focused on influenza, and several have focused on preparing for COVID-19 vaccinations.

AIM is also holding planning calls with CDC. It is continuing to offer orientation for new program managers, also in partnership with CDC. The orientation is now held virtually, instead of via a 3-day, in-person meeting. Four new program managers will be participating this June, and another orientation is expected later this year. AIM continues to provide leadership and skill training and mentoring for new program managers. The turnover is still considerably high for people in State immunization director positions, Ms. Hannan noted.

AIM held its annual leadership training conference in December, where it celebrated its 20th anniversary. AIM partnered with the University of Michigan to publish an article on improving fourth-dose diphtheria-tetanus-pertussis vaccine completion rates in the February 4, 2020, issue of the online journal, *Human Vaccines and Immunotherapeutics*. The information came from a roundtable conducted in June 2018 with nine city and State public health programs. AIM is working on two toolkits, one around lessons learned from engaging in policy work and another on improving vaccine confidence and reducing vaccine hesitancy.

AIRA—Rebecca Coyle, M.S.Ed.

AIRA created a fact sheet describing efforts that State and local health departments can take in preparation for a COVID-19 vaccine, such as onboarding immunization providers, including those who have not traditionally administered a lot of vaccines in the past. AIRA is strongly encouraging efforts to fine-tune immunization information systems and electronic health records to align with standards, which will greatly increase the ability to onboard providers quickly and efficiently. AIRA is looking at policies that limit some data exchange and working with a variety of partners to identify and mitigate those challenges. The organization is also working with partners to expand consumer access, so that when a vaccine becomes available, people can keep track of their immunizations. If there is a multidose vaccine, AIRA wants to make sure that people get all the doses recommended, said Ms. Coyle.

AIRA has shifted some of its education efforts to pandemic preparedness. Lessons learned from the H1N1 influenza pandemic are being reviewed and updated. AIRA is working closely with CDC to develop digital tools to support a vaccine rollout. It is standing up a working group to provide quick and timely feedback on some of CDC's fast-moving efforts.

The pandemic is taking a toll on routine immunizations. AIRA started a webinar series (available on the AIRA website) on the use of reminder/recall systems to bring in patients who are due for immunizations. AIRA has offered an address cleansing service for several years. Ms. Coyle said there has been some national attention about the value of having clean address lists that align with U.S. Postal Service standards, which can improve data mapping. As contact tracing ramps up, and in anticipation of future immunization campaigns, having good data is critical. Some States have already adopted the SmartyStreet license that AIRA offers, and the organization hopes to add more. AIRA rolled out a workshop in early March to help the Pacific Island Territories and Freely Associated States develop business continuity plans for their immunization information systems, which they implemented immediately. That information is available on the AIRA website.

DoD—Limone Collins, M.D.

DoD is participating in Operation Warp Speed. It is working with the AstraZeneca vaccine candidate and is identifying the specific immunologic treatment facilities that will be implementing clinical trials. DoD's influenza vaccination program will be implemented soon. The Department is in the third year of its influenza vaccine effectiveness study; Dr. Collins said COVID-19 may pose challenges to the ongoing study. In addition, DoD is looking at new candidates for smallpox vaccination. It has organized two postsurveillance studies that it hopes to

implement at the end of the year, based on the availability of the vaccine. For the first time, starting in May 2020, DoD began giving a Southern Hemisphere influenza vaccine to service members, reserves, and beneficiaries who are going to the Southern Hemisphere.

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

APhA continues to focus on training, education, and information around immunization. Its continuing education webinar series, "15 on COVID-19," is available to all pharmacists and pharmacy technicians, as well as a weekly seminar. APhA provides education about vaccines, including updates after every meeting of the Advisory Committee on Immunization Practices (ACIP), an annual immunization update, and strategies to address vaccine hesitancy. It seeks to ensure that pharmacists are geared up to help with COVID-19 vaccination when a vaccine becomes available. APhA is working with CDC to revise guidance for pharmacies on administering routine vaccines during the COVID-19 pandemic. At its annual meeting, held virtually in March, APhA announced its Immunization Champion awards. Dr. Goode said the APhA website describes what awardees are doing around immunization.

ASTHO—James S. Blumenstock

ASTHO is continuing its work on several initiatives to address vaccine hesitancy and ensuring that States are in line with CDC's strategic framework, "Vaccinate with Confidence." To that end, ASTHO is developing tools and resources to assist State and Territory health officials in communicating with legislators and the public to strengthen vaccine confidence. ASTHO's chief executive officer sent RADM Trent-Adams a strong recommendation and commitment to collaborate in exploring the development of an aggressive, robust national campaign around the strategic framework to increase its visibility and impact in communities across the country.

ASTHO is planning a forum with health equity directors in the States and Territories to address vaccine disparities. The forum will allow participants to learn about successful efforts that could inform future vaccination efforts, strategies, and tactics. Regarding COVID-19, ASTHO has prepared a risk communication guide, training programs and materials around contact tracing, and a roadmap to recovery, written in partnership with the National Governors Association.

ASTHO hopes to increase visibility and attention to the topic of administering a COVID-19 vaccine, drawing on the H1N1 experience. As vaccine development progresses, there is tremendous pressure on the public health system to allocate, distribute, and administer the vaccine. ASTHO is working with members to ensure that partnerships among State health directors, preparedness directors, immunization managers, and others are as strong and collaborative as possible as they prepare for the anticipated vaccine campaign. In addition, ASTHO is working closely with other national organizations, including the National Governors Association's Homeland Security Advisors Council and the National Emergency Management Association, to ensure that public safety and homeland security colleagues are familiar with the ongoing development of plans or procedures for a national vaccination campaign.

NACCHO—John Douglas, M.D.

NACCHO has been facilitating discussions about preparation for a COVID-19 vaccine and more immediate issues, such as contact tracing, social distancing, and wearing face masks. (As an aside, Dr. Douglas said he believes the army of contact tracers currently being recruited might be able to provide vaccine information and potentially even act as nontraditional vaccine providers.) NACCHO activated its emergency response structure in February to stay in touch with members and Federal partners around the needs of local public health departments. Its Immunization Advisory Work Group has been involved in addressing the lag in childhood immunization uptake.

Finally, NACCHO has been working on implementing preparedness and better vaccination efforts. NACCHO is a founding member of the new Coalition to Stop the Flu, a multisector advocacy group launched to help curb influenza deaths in this country. Given concerns about a possible second wave of COVID-19 in the fall, Dr. Douglas said NACCHO is pondering whether the Coalition to Stop the Flu could position influenza immunization as a way of maintaining a more open economy.

PAHO—Nathalie El Omeiri, Ph.D.

Three million cases of COVID-19 and over 180,000 deaths have been reported in the Americas as of June 8, 2020. All countries and territories have confirmed cases, and a growing number of countries have ongoing community transmission. PAHO continues to work closely with the member states to bring them COVID-19 data. Vaccine Week in the Americas was intended to promote and celebrate vaccines. This year, there is a sense of urgency that, until a vaccine for COVID-19 is available, health services must deliver routine immunization alongside the response to COVID-19. PAHO issued guidance for immunization during the pandemic to help countries consider both potential outbreak risk and the burden on health systems as part of their decision-making.

Vaccination to prevent severe influenza is more critical than ever, particularly for high-risk groups, which are also at high risk for COVID-19 infection and complications. Numerous countries in the region have begun to immunize against seasonal influenza, with more than 71 million of the target population already being vaccinated—a true testament to the preparation and commitment of the member countries. Many countries have taken creative approaches to influenza vaccination in the Southern Hemisphere. For example, Brazil is vaccinating older adults at pharmacies and at home. Chile is offering drive-through vaccinations. Bolivia is sending out immunization brigades to nursing homes and prisons. El Salvador has set up vaccination stations at banks. Vaccination against seasonal influenza will allow countries to be better prepared to vaccinate high-risk groups against COVID-19.

At least three countries are working to contain measles outbreaks in Latin America, and those efforts should continue alongside the COVID-19 pandemic to sustain the elimination of measles in the rest of the Americas. PAHO is developing guidance for countries resuming and intensifying routine vaccination as COVID-19 slows down. It is drawing on lessons learned from the H1N1 influenza pandemic to build the readiness necessary to deliver COVID-19 vaccines.

PHAC—Tara Beitel

PHAC is working to ensure that Canada's preparedness and response measures are appropriate, adaptable, and based on the latest science and the evolving situation. The country's Chief Public Health Officer has been in close contact with provincial and territorial chief medical officers of health to ensure that any cases of COVID-19 occurring in Canada are readily identified and managed. Canada's National Microbiology Laboratory is performing COVID-19 diagnostic testing and working with provincial and territorial public health laboratories, which are now able to test for COVID-19.

On April 23, 2020, the Prime Minister announced more than $1 billion for the National Medical Research Strategy to fight COVID-19 to fund vaccine development, the production of treatment, and tracking of the virus. The government of Canada is also supporting multiple organizations to develop candidate vaccines. One vaccine has been authorized to start clinical testing. At least 30

other organizations are at earlier stages of vaccine development, and several are anticipated to advance to human clinical trials in the coming months.

On May 13, 2020, PHAC's National Advisory Committee on Immunization introduced interim guidance on continuity of immunization programs during the COVID-19 pandemic, recommending the following:

- Routine immunizations for children under the age of 2 years should be considered a priority.
- Immunizations in symptomatic individuals or vulnerable populations should be deferred.
- Workers exposed to vaccine-preventable diseases should continue to receive routine immunizations.
- Maintaining seasonal influenza vaccine programs is important.

The Committee also launched a working group to focus on COVID-19 vaccine planning and is preparing vaccine prioritization guidance.

Regarding vaccine hesitancy and COVID-19, PHAC is reminding Canadians, through social media and other modes of communication, to keep their routine vaccines up to date. Research is underway to better understand the perceptions and intentions of Canadians about a future COVID-19 vaccine to inform strategies and messaging to promote vaccine acceptance.

In anticipation of an increased demand for this year's seasonal influenza vaccine, PHAC staff is increasing the volume of orders on behalf of provinces and territories in Canada. This coming season, for the first time, all provinces and territories are expected to offer Fluzone high-dose vaccine for all eligible residents of long-term care facilities across the country. Planning is underway for PHAC's 2020 influenza campaign, which will use a number of approaches to promote vaccination, including social media, resources for health care providers, and a national webinar that will cover seasonal influenza, vaccination, treatment and infection prevention and control measures for influenza clinics in the context of COVID-19. To help minimize challenges that the COVID-19 pandemic may cause to the health care system, the 2020 campaign will focus on at-risk populations.

VRBPAC—Hana El Sahly, M.D.

On March 4, VRBPAC met and made recommendations about the influenza strain composition for the Northern Hemisphere's 2020–2021 influenza vaccines. It also reviewed and approved the results of the Laboratory of Respiratory and Special Pathogens site visit.

NIH provided a written report to NVAC.

Coverage for Future COVID-19 Vaccination: The CARES Act—Katie Keith, J.D., M.P.H., Georgetown University

Ms. Keith explained that the CARES Act builds on the structures put in place by the Patient Protection and Affordable Care Act (ACA), which requires insurance providers to cover a range of preventive services without cost sharing, such as immunizations recommended by ACIP and certain recommendations of the USPSTF. Once a COVID-19 vaccine becomes available, insurers will have 15 days from the time that ACIP recommends its use to begin covering the vaccine. The CARES Act explicitly applies other ACA coverage rules to a COVID-19 vaccine.

Insurers have some discretion in imposing cost sharing for vaccines. They may apply "reasonable medical management" to define the scope of coverage if it is not specified by the ACIP recommendation—such as the setting in which the vaccine may be administered to qualify for full coverage. Sometimes, cost sharing is imposed as a result of the way that services are billed and who provided the service. In recent years, the availability of new vaccines has generated confusion about what is covered; such issues have already arisen around COVID-19 testing.

The CARES Act extends to Medicare fee-for-service and Advantage plans; Ms. Keith interpreted the legislation as covering COVID-19 vaccine upon FDA approval. Congress created a $27 billion fund to develop and purchase vaccines and authorized HHS to ensure that vaccines developed with Federal funds are affordable in the commercial market (although HHS is not obligated to do so). The Families First Coronavirus Response Act provided State Medicaid programs with funding for COVID-19 treatment and vaccination, but those dollars are only available for the duration of a declared public health emergency. There is no plan or funding source in place to pay for vaccine for the uninsured.

A number of questions remain:

- How will the cost of a vaccine be determined? Insurers usually negotiate with manufacturers and suppliers on the price, and they normally have 1 year before they must begin covering a new, ACIP-recommended vaccine.
- How will insurers pay for a vaccine if it becomes available midyear? Insurance premiums may rise dramatically to offset immediate costs. Ms. Keith said a high-cost vaccine would have an impact on health equity.
- How specific will ACIP recommendations be for the new vaccine?
- Will ACIP make recommendations that apply to the whole population or just those at high risk? How insurers translate ACIP recommendations will affect whether costs are passed on to beneficiaries.
- How will vaccines be covered by insurance plans not addressed by the CARES Act, such as those that are exempt from ACA requirements? If individuals must bear the cost of vaccination, uptake may be affected, especially if media headlines highlight the high cost of vaccination, Ms. Keith.
- Will Congress or States legislate further vaccine coverage? Nine States have already required that a vaccine be covered when it becomes available. The Health and Economic Recovery Omnibus Emergency Solutions Act would require ACIP to make a recommendation within 15 days of FDA approval of a new vaccine, and it would extend coverage to include the Vaccines for Children (VFC) program and Medicaid's Children's Health Insurance Program.

Discussion

Ms. Howell asked whether any legislation would allow local public health departments to be treated as in-network providers for the purpose of COVID-19 vaccine, regardless of the insurer. Ms. Keith said there was no guidance, but it might be possible for the Federal government to make regulatory changes to support such an approach.

Melissa Martinez, M.D., FAAFP, pointed to the financial challenges that clinics face in stocking, monitoring, and administering vaccines. Medicaid vaccine reimbursement varies by State and tends to be low. Dr. Martinez asked whether any legislation provides incentives to stock or administer vaccines. Ms. Keith did not know of any such legislation.

In response to Dr. Schechter, Ms. Keith said COVID-19 vaccine will be covered by Medicare under Part B. There have been several congressional proposals related to coverage of COVID-19 treatment, but it appears that Medicare will cover all services related to COVID-19.

COVID-19 Vaccine Intentions: Findings from Two Surveys

Expectations for a COVID-19 Vaccine— Jennifer Benz and Missy Nachbar, The Associated Press(AP)-NORC Center for Public Affairs Research

Ms. Benz said her organization's survey found that about four in 10 people are very or extremely worried that they or a relative will contract COVID-19. The availability of a vaccine is seen by many as important for reopening, but not essential. The public generally has realistic expectations about the timing of a vaccine; only 21 percent believe a vaccine will be available this year. About half of respondents said they would accept a vaccine, and about 30 percent were unsure. The intention to be vaccinated varies according to partisanship, age, race/ethnicity, and level of concern about infection. Older White males who identify as Democrats are most likely to get vaccinated. Ms. Benz pointed out that 32 percent of Black Americans were unsure about vaccination, and that represents a large group of people who could potentially be persuaded.

The topmost reasons for accepting vaccination are protecting oneself and one's family, followed by a desire to protect the community and get back to normal. Of the 20 percent of people who said they would not be vaccinated, concern about side effects was by far the top reason, followed by the belief that the vaccine could cause COVID-19.

Ms. Benz noted that, given the realistic expectations for vaccine development timeframes, acceptance that other measures can suffice to reopen the country in the meantime, and concerns about safety, messaging that focuses on the speed of vaccine development may be counterproductive. She added that communities of color, young people, and women currently express significantly less intention to vaccinate, so public health messaging could target those groups.

Where the Public Stands on a COVID-19 Vaccine—Chris Jackson, Ipsos U.S. Public Affairs

Mr. Jackson said his organization's survey found similar results as the AP-NORC survey, although his asked about interest in a vaccine rather than intent to be vaccinated. Similar to the AP-NORC, the Ipsos poll found men were more likely than women to express interest, although Mr. Jackson said women tend to be more honest about uncertainty. In terms of race/ethnicity, the Ipsos survey found about 32 percent of African American respondents expressed no or little interest in a vaccine, and 20 percent expressed uncertainty.

In contrast to the AP-NORC survey, the Ipsos survey found older people were more likely to say they were unsure about a vaccine, while younger people expressed more interest. Mr. Jackson believed that the findings indicate young people could be persuaded to accept the vaccine. The Ipsos survey found that lower-income earners had less interest than high-income earners.

Of those who were not interested in the vaccine, 48 percent said they were nervous about a vaccine being developed so quickly, and 42 percent felt the risks of taking a new vaccine outweighed the benefits. About one third said they did not trust those developing the vaccines. The survey found that interest varied depending on how a vaccine might come to market, based on scenarios proposed to respondents. A vaccine developed in China would not increase interest, nor would President Trump vouching for the safety of the vaccine. Recommendations or support from doctors and U.S. public health authorities, FDA approval, and safety data from large

scientific studies would increase interest. Mr. Jackson said people want real scientific evidence; politics will not drive them to accept a vaccine.

A vaccine was seen as necessary for a return to high-risk events such as concerts and sporting events. Mr. Jackson said interest in influenza vaccination for the coming season is higher than usual. He concluded that there are heightened concerns about the safety of vaccines in general, probably coinciding with a lot of misinformation as well as anxiety and uncertainty about the current health marketplace.

Discussion

Dr. Schecter asked whether gender differences around vaccine acceptance had been noted in other surveys. Ms. Benz said previous surveys about influenza vaccine uptake did not reveal the same gender gaps.

Dr. Hoft questioned whether race/ethnicity affected the reasons for not accepting a vaccine. Ms. Benz said safety concerns were the dominant reason by far, so much so that demographic or political differences did not show up in the AP-NORC survey. Mr. Jackson said sample sizes of African American and Hispanic respondents were relatively small in the Ipsos survey, which may explain why no such differences reached statistical significance.

Two NVAC members wondered whether the novel scientific approaches being used for the vaccines in development and the potential use of adjuvants would affect perceptions of safety. Mr. Jackson said he had no such data but believed that people are reluctant to accept products they do not understand. Therefore, trusted messengers must communicate about the safety of new products. If there is a lot of dissent about safety, the public response is likely to be mixed.

Ms. Benz agreed, adding that the NORC's work also confirms that people tend to trust the messages that come from scientific and medical authorities. She cautioned that even those who trust such authorities say they get most of their information from media, including social media, so the potential for discordant messaging should be addressed.

John Dunn, M.D., M.P.H., asked whether reluctance to accept a COVID-19 vaccine overlaps with vaccine hesitancy in general. Ms. Nachbar responded that the number of people who said they would not get a COVID-19 vaccine is similar to the number who said in previous surveys that they would not get an influenza vaccine, but the rationale for avoiding the latter is often based more on inconvenience than safety concerns. Mr. Jackson said Ipsos sees a lot of overlap between people who are not interested in a COVID-19 vaccine and people who would not get an influenza vaccine.

Dr. Schecter queried whether people were more likely to accept a vaccine that received traditional FDA approval rather than emergency use authorization. Mr. Jackson said the Ipsos survey found that FDA approval might have a positive influence on uptake, but he was not sure whether respondents would distinguish between the two types of pathways.

Dr. Douglas asked what factors increased vaccine confidence across demographic variables. Mr. Jackson said that a stamp of approval from official scientific agencies increased acceptance across all groups and had the biggest effect on older people and women. Approval from a trusted source can persuade those who are uncertain, he added.

Sounding the Alarm: Routine Immunization During Unprecedented Times

American Academy of Pediatrics (AAP)—Sally Goza, M.D., FAAP, AAP President

Dr. Goza outlined AAP's response to the decline in childhood immunizations since the onset of the COVID-19 pandemic. AAP launched a virtual media tour to spread the message that vaccines are important and describe steps that providers are taking to alleviate parents' concerns about the safety of office visits, such as virtual visits and designating blocks of time for well-care visits. The #CallYourPediatrician campaign offers relatable and humorous content tailored for social media platforms, so that messages can go beyond traditional media approaches.

AAP supports the proposed Vaccine Awareness Campaign to Champion Immunization Nationally and Enhance Safety Act to combat vaccine hesitancy. It is calling on HHS to ease the financial burden on pediatric practices by increasing Medicaid payment rates for immunization administration, revising vaccine reporting codes to reflect the value of vaccines, and collaborating with State Medicaid programs to create a prospective payment system for vaccines. AAP also recommends strengthening the VFC program by providing financial bonuses for provider participation, increasing administration fees, and paying providers for vaccinating uninsured children in the VFC program, among other steps.

Vaccine Myths—Patricia N. Whitley-Williams, M.D., Rutgers University Robert Wood Johnson Medical School

Dr. Williams summarized a litany of myths about vaccine effectiveness, safety, and utility, many of which persist despite solid evidence to the contrary. She offered tips for providers to communicate with parents about vaccinating their children. For example, the presumptive approach normalizes vaccines as part of routine care. Motivational interviewing enables parents who are hesitant about vaccines to share their concerns. In both approaches, providers are encouraged to provide information in a conversational manner, without lecturing parents or dismissing their concerns.

Notably, attempting to debunk myths with detailed information can strengthen the myth in the listener's mind, as a result of disconfirmation bias. Providers should call out the myth as false and state the facts simply. Rather than refuting false information, providers should seek to replace it in the listener's mind with new, correct information. Dr. Williams further suggested refocusing the conversation on the diseases that vaccines can prevent and using storytelling techniques to communicate effectively. Dispelling myths around vaccines requires trust, especially among communities of color, said Dr. Williams. Parents continue to see their child's health care provider as the most trustworthy source of vaccine information.

Specific strategies to address communication challenges and dispel myths about COVID-19 include using mobile technology (e.g., text messaging) to answer questions, respond to concerns, and enhance the provider-patient relationship. More research is needed on effective communication strategies. Health care providers should take part in unconscious bias training to better understand the roots of vaccine hesitancy, especially among African Americans. Communities should be engaged in the communication strategy. For example, community health workers could be trained to talk about the safety and effectiveness of vaccines. An AAP survey found that educating health care providers increased their confidence in communicating successfully about vaccination.

Pediatric Mobile Unit—Mona Doss, D.O., Boston Medical Center Pediatrics, Boston University School of Medicine

In response to the significant drops in the number of children receiving immunization during the pandemic, Dr. Doss and colleagues created a mobile vaccination unit following brainstorming

with clinic leadership and patients' families. A local ambulance company donated a vehicle and driver. Staff reviewed the appointments missed during the early weeks of the pandemic and identified missed opportunities for vaccination. The planning effort involved stakeholders from the hospital administration, local public health and safety entities, the nurses' union, and laboratory and pharmacy services.

Providers categorized patients by the type of visit and then by ZIP code. The first visits started in geographic areas with the highest volume of patients. Providers reached out to families to screen for symptoms of infection and ask about other family needs. (The Center had a supply of donated diapers, food, and other items.) In preparation for the visit, staff reviewed the travel plan, stocked the mobile units, and contacted families with the estimated time of the mobile unit's arrival.

Staff received approval from the State to create vaccine travel packs, which included data loggers, and followed CDC guidance on transporting vaccines during an emergency. Dr. Doss said the mobile unit was cramped but had everything needed to support a routine health care visit. (The Center also set up a pediatric clinic in a large tent in the facility's parking lot, with strict precautions to prevent disease transmission.)

The mobile unit completed 149 pediatric examinations, including vaccinations, and 27 visits in which partial services were provided. Seven patients did not show up for their appointments. Dr. Doss said areas for improvement include decreasing the no-show rate, addressing the high cost of the mobile unit (even with a donated vehicle), evaluating the impact of reassigning staff, and ensuring that health screening is conducted (e.g., using telehealth services) before the visit. The mobile unit made a small dent in the vaccination rate, and it improved morale of the staff. Families appreciated the access, and providers learned more about the families they serve and the communities where they live.

A Community Pediatrician's Perspective: Routine Immunizations, Equity Issues, and Safe Outreach During the Time of COVID-19— Medhine Anusha Wijetilleke, M.D., M.S., FAAP

Dr. Wijetilleke gave an overview of barriers to vaccine acceptance and compliance with vaccine schedules, including access challenges, perceptions about vaccine safety, and lack of provider recommendations and counseling about vaccines. Her pediatric practice in Northern Virginia is part of a Federally qualified health center that provides affordable, accessible care to a low-income population of predominately Spanish-speaking recent immigrants. Already, the practice has seen a 34-percent drop in patient visits compared with last year.

Dr. Wijetilleke said the COVID-19 pandemic has limited access to health care, especially for low-income people. Undocumented parents cannot afford not to work, and they have no access to emergency benefits. Many lack sufficient knowledge about COVID-19. The safety net systems that contributed to vaccine compliance are gone. Public transportation poses an increased risk of infection, so some families have no transportation. Parents are reluctant to bring their children in for well-child visits.

To reassure patients and their families, providers must lead by example, said Dr. Wijetilleke. Her practice has reconfigured public areas to support social distancing. When possible, staff checks patients' vital signs in the parking lot, while patients are in their cars. The practice is communicating with families constantly about the availability of well-child visits and vaccines and explaining all the precautions that staff are taking to keep people safe. Visitors are limited; one parent can bring one child to the office (which is difficult for some families). Children more

than 2 years old must wear a face mask. All staff and visitors are screened for signs or symptoms of COVID-19 in a consistent manner when they enter the building. The practice is also trying to maintain some normalcy—for example, by continuing the Reach Out and Read program.

Dr. Wijetilleke wondered what would happen in the fall and winter, when influenza and other viruses routinely spread. Her practice is encouraging parents to schedule well-child visits this summer in anticipation of another shutdown in the fall or winter.

Discussion

Dr. Hopkins appreciated the presenters' descriptions of the challenges to providing care during the pandemic. He said his pediatric clinic offered drive-through vaccinations for older children, as well as virtual visits. Dr. Meissner asked whether AAP has recommendations on recall notices for those who missed vaccines. Dr. Goza felt that pediatric providers should reach out to families who missed checkups, and she thought AAP should consider making a formal recommendation.

Public Comment

Catharine Krebs of the Physicians Committee for Responsible Medicine expressed concern that NIAID, NIH's Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership, and other bodies are prioritizing animal models of COVID-19. NIAID has acknowledged that previous experience with MERS and SARS suggests that replicating human disease in an animal model may be challenging. As with SARS and MERS, COVID-19 animal model research is failing to reproduce the susceptibility, clinical features, and immunologic responses better observed in humans. These findings come after decades of failures of animal research to replicate human disease features and produce safe and effective therapeutics. Animal research is also time- and resource-intensive, which cannot be overlooked when responding swiftly to a devastating global pandemic. Meanwhile, researchers at NIH's National Center for Advancing Translational Sciences, the Wyss Institute, and elsewhere are leading the way in developing and using innovative, human-based, in vitro techniques, gene editing techniques, patient-derived tissue analysis, and passive immunization using convalescent plasma to study COVID-19 pathogenesis, develop vaccines and therapeutics, and perform preclinical testing.

The Physicians Committee for Responsible Medicine urges NVAC and HHS to develop and use nonanimal experimental systems, making this a cross-agency priority in basic research and in the development and testing of COVID-19 vaccines. Specifically, NVAC should direct NIAID to update its strategic plan for COVID-19 research, remove the development of animal models as an objective, and instead prioritize the use of human biospecimens, human-based in vitro models, and computational models. NVAC should also direct ACTIV to update its framework to remove the focus on developing animal models for preclinical evaluation of COVID-19 interventions and instead prioritize human-based preclinical effort. Finally, the Physicians Committee for Responsible Medicine supports the work of NVAC and HHS to increase access to immunization in underserved communities. COVID-19 affects socially disadvantaged groups, such as people of color and those of low socioeconomic status, more severely and at higher rates. The Physicians Committee for Responsible Medicine remains committed to health care equity and the elimination of racial and other demographic health disparities. Such work must be a central tenet of any public health response, including COVID-19 immunization efforts.

Debra Ann Kosko of the North Carolina Immunization Coalition said her organization partners with the State health department and county health departments, which are planning now in anticipation of a COVID-19 vaccine. A vaccine will only be effective if people are willing to receive it. Ms. Kosko said the data presented today that found groups least likely to receive the

vaccine or most hesitant are women, people of color, and young people are valuable. Advocating for a COVID-19 vaccine will take all hands on deck. Ms. Kosko emphasized the need for advocacy at the local level, through groups like the North Carolina Immunization Coalition, which is an all-volunteer coalition. Therefore, Ms. Kosko encouraged funding of smaller grants to local, community-based organizations that can provide the community-centric advocacy that will be needed to increase the COVID-19 vaccine uptake, especially among vaccine-hesitant communities. Such coalitions can reach the hard-to-reach communities if provided the financial support to do the work.

Rita K. Kuwahara, M.D., M.I.H., a physician at a Connecticut Federally qualified health center, said she has been working on the front lines to care for patients with COVID-19 and recognizes how vital a COVID-19 vaccine is to end the global pandemic. She emphasized that HHS must commit to ensuring that any vaccines developed to prevent against COVID-19 be provided to all individuals in the United States without cost sharing for the patient, regardless of health insurance or immigration status. Widespread and timely access to a COVID-19 vaccine without placing financial burden on patients is a fundamental public health strategy to prevent the ongoing spread of COVID-19 and prevent unnecessary deaths.

Dr. Kuwahara also emphasized the need to support vaccination programs working to provide adults and children with vaccines to protect against hepatitis B and other vaccine-preventable diseases to prevent against other infectious disease outbreaks in the midst of the current COVID-19 pandemic. The United States has already recently experienced alarming regional rises in vaccine-preventable acute hepatitis B infection, largely driven by the opioid crisis. Among States most affected by the opioid crisis, Maine had a 729-percent increase in adults with acute hepatitis B from 2015 to 2017. Kentucky, West Virginia, and Tennessee had a 114-percent increase in acute hepatitis B from 2009 to 2013. While universal childhood hepatitis B vaccination has been in place since the mid-1990s, only 25 percent of adults are vaccinated against hepatitis B. Many adults over the age of 25 were not vaccinated as children and are currently in the age group most at risk for acquiring hepatitis B in the setting of the opioid crisis. Dr. Kuwahara said the tools exist to curb the recent rises in hepatitis B and prevent liver cancer, liver failure, and cirrhosis, which occur in up to one in four people with unmanaged chronic hepatitis B. There is an urgent need to increase awareness of the availability of the adult hepatitis B vaccine to increase adult vaccination rates and the fact that the adult hepatitis B vaccine is available with no cost sharing for patients with private insurance, Medicare Part B, and most of Medicaid.

Dr. Kuwahara appreciated that Congress recognized the need to increase adult hepatitis B vaccination awareness in the setting of the opioid crisis by designating April 30 as National Adult Hepatitis B Vaccination Awareness Day, a move that was endorsed by more than 75 organizations, including the American Medical Association, the American College of Physicians, and the American Public Health Association. With the alarming regional rises in acute hepatitis B infection in the setting of the opioid crisis, Dr. Kuwahara hoped that NVAC and HHS would commit to developing a coordinated, public health response to protect the health of communities during the COVID-19 pandemic by instituting public health measures now that will maintain and expand adult and childhood vaccination programs to prevent further outbreaks of vaccine-preventable diseases such as hepatitis B, increase adult hepatitis B vaccination rates, and reconsider the public health benefits of recommending universal adult hepatitis B vaccination.

Kamrynn Saylor of the California Immunization Coalition appreciated NVAC's work to keep the American people safe and healthy. She encouraged NVAC to recommend that each State develop a task force to review the unique needs of their State in preparation for a COVID-19 vaccine and ensure health plans and systems are ready to cover the vaccine and its administration

with no cost sharing. Ms. Saylor also hoped NVAC would encourage ACIP to make the recommendation for a COVID-19 vaccine broad enough so that health plans have the opportunity to cover it with no cost sharing. She appreciated NVAC's strong emphasis on the need for safety and surveillance of all vaccines, particularly the COVID-19 vaccine, which will be essential in the effort to protect communities. Ms. Saylor hoped organizations like hers could help get that message across as public health advocates.

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 5:30 p.m.

APPENDIX: Abbreviations

AAP	American Academy of Pediatrics
ACA	Patient Protection and Affordable Care Act
ACCV	Advisory Commission on Childhood Vaccines
ACIP	Advisory Committee on Immunization Practices
ACTIV	Accelerating COVID-19 Therapeutic Interventions and Vaccines
AHRQ	Agency for Healthcare Research and Quality
AIM	Association of Immunization Managers
AIRA	American Immunization Registry Association
AP	Associated Press
APhA	American Pharmacists Association
ASTHO	Association of State and Territorial Health Officials
BARDA	Biomedical Advanced Research and Development Authority
BIO	Biotechnology Innovation Organization
CARES Act	Coronavirus Aid, Relief, and Economic Security Act
CDC	Centers for Disease Control and Prevention
CEPI	Coalition for Epidemic Preparedness Innovations
CMS	Centers for Medicare and Medicaid Services
COVID-19	coronavirus disease (2019)
DoD	Department of Defense
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
LMICs	low- and middle-income countries
MERS	Middle East respiratory syndrome
NACCHO	National Association of County and City Health Officials
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NVAC	National Vaccine Advisory Committee
NVPO	National Vaccine Program Office
OIDP	Office of Infectious Disease and HIV/AIDS Policy
PAHO	Pan American Health Organization
PHAC	Public Health Agency of Canada
SARS	severe acute respiratory syndrome
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
USPSTF	U.S. Preventive Services Task Force
VFC	Vaccines for Children
VICP	Vaccine Injury Compensation Program
VRBPAC	Vaccine and Related Biological Products Advisory Committee