

# June 4-5, 2019, Meeting Minutes

### **Committee Members in Attendance**

Robert H. Hopkins Jr., M.D., MACP, FAAP; Chair
Melody Anne Butler, B.Sc.N., RN
Timothy Cooke, Ph.D., by phone
John Dunn, M.D., M.P.H.
David Fleming, M.D.
Leonard Friedland, M.D.
Ann Ginsberg, M.D., Ph.D.
Mary Anne Jackson, M.D., FAAP, FPIDS, FIDSA
Melissa Martinez, M.D., FAAP
Cody Meissner, M.D., FAAP
Larry Pickering, M.D., FAAP, FIDSA

### **NVAC Ex Officio Members**

- LT COL Chris Ellison (for Tonya Rans, M.D.), Department of Defense (DoD)
- Andrew Ford, Ph.D. (for Barbara Mulach, Ph.D., National Institutes of Health (NIH)
- Mary Beth Hance (for 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 (VA)
- Linda Lambert, Ph.D. (for Rick Bright, Ph.D.), Biomedical Advanced Research and Development Authority (BARDA), day two only
- 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)
- Mary Rubin, M.D. (for Narayan Nair, M.D., CAPT), Division of Injury Compensation Programs (DICP),

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

# **NVAC Liaison Representatives**

- 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)
- Kristen R. Ehresmann, RN, M.P.H., Association of Immunization Managers (AIM)
- Hana El Sahly, M.D., Vaccine and Related Biological Products Advisory Committee (VRBPAC)
- Jean-Venable "Kelly" Goode, Pharm.D., BCPS, FAPhA, FCCP, American Pharmacists Association (APhA)
- Kim Martin (for James S. Blumenstock), Association of State and Territorial Health Officials (ASTHO)
- Christopher Regal, M.S., America's Health Insurance Plans (AHIP)

### **Acting Designated Federal Officer**

Ann Aikin, M.A., Communications
Director, National Vaccine Program
Office (NVPO), Department of Health
and Human Services (HHS)

# Proceedings Day One—June 4, 2019

# 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 9:07 a.m. and welcomed the participants. She announced two retirements: ex officio member CAPT Narayan Nair, M.D., of HRSA, and liaison James David Nordin, M.D., M.P.H., of AHIP. Ms. Aikin 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—ADM Brett P. Giroir, M.D., Assistant Secretary for Health (ASH), HHS

Dr. Giroir thanked NVAC members for their time. He emphasized the importance of providing evidence-based guidance on fighting infectious disease. The current measles outbreak, the recent influenza season, and the Ebola virus outbreak in the Democratic Republic of Congo underscore the relevance and importance of vaccines as well as the need for collaboration to ensure health systems remain resilient.

Dr. Giroir announced that NVPO and the Office of HIV/AIDS and Infectious Disease Policy will merge to become the Office of Infectious Disease and HIV/AIDS Policy, led by Tammy R. Beckham, D.V.M., Ph.D. The move aims to increase alignment, efficiency, and capacity.

Since the National Vaccine Plan was published in 2010, the immunization landscape has changed, said Dr. Giroir. The emergence and deliberate spread of misinformation online is just one example. At the March 2019 NVAC meeting, Dr. Giroir charged NVAC with making recommendations to modernize and strengthen the Plan. He looked forward to the recommendations, to be presented at this meeting.

Dr. Giroir described efforts by HHS' senior leaders to improve vaccine confidence by combating misinformation. He charged NVAC with updating its June 2015 report on the state of vaccine confidence in the United States, assessing its impact on the vaccination rates of all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP).

Specifically, the report should address the determinants of vaccine confidence across the life span and make recommendations for actions HHS can take to help improve confidence in ACIP-recommended vaccines and the vaccine schedule. It should draw on evidence-informed best practices and best-practice models from scientific research fields such as anthropology, psychology, and economics to describe how to foster vaccine confidence through public, provider, and policy interventions. Dr. Giroir recommended NVAC establish a working group (WG) of NVAC members, other Federal representatives, and subject matter experts to summarize recent evidence. He asked that the WG finalize its recommendations and present them to the full NVAC for approval at the September 2020 NVAC meeting. He concluded by expressing his commitment to and gratitude for NVAC.

# Chair's Welcome—Robert H. Hopkins Jr., M.D., MACP, FAAP, NVAC Chair

Dr. Hopkins welcomed the participants to the public meeting, which was accessible by webcast and telephone. He described the meeting proceedings and the agenda for this meeting. The minutes of the March 25, 2019, meeting were unanimously approved by NVAC members.

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 at http://www.hhs.gov/nvpo/nvac/index.html. Later this year, NVAC is scheduled to meet on September 17–18. (See the appendix for a list of abbreviations used in this report.)

# NVPO Update—Tammy R. Beckham, D.V.M., Ph.D., Acting Director, NVPO

Dr. Beckham welcomed the members and thanked them for their efforts. She explained that the Office of HIV/AIDS and Infectious Disease Policy's broad portfolio includes HIV/AIDS, viral hepatitis, tick-borne diseases, blood-borne pathogens, and sexually transmitted diseases. Combining it with the NVPO allows HHS to take advantage of the talent and expertise in both.

NVPO efforts to improve vaccine confidence include working with CDC and other operational divisions to develop an HHS-wide strategy to address the barriers, increase access to credible information, and better understand the drivers of vaccine hesitancy. NVPO will work closely with partners to support their efforts and identify best practices in specific communities.

The ASH identified human papillomavirus (HPV) vaccination as a priority, and NVAC provided recommendations to improve HPV vaccination rates. NVPO is now working to develop an evidence-informed innovative initiative and collaborating with a broad array of partners—such as retail pharmacies, faith-based institutions, universities, and health systems—to expand reach and impact.

For example, NVPO, CDC, the American Cancer Society, and the American Medical Group Association are discussing how to work with integrated delivery networks using a learning collaborative process that will help identify evidenced-informed and best practice models within their health systems. NVPO is piloting a faith-based initiative to increase HPV awareness and vaccination rates in Region IV, where HPV vaccination rates are among the lowest in the country. It is also working closely with CDC on projects targeting rural health care providers, particularly in Kentucky, Mississippi, Missouri, and Wyoming. In addition, NVPO is using social media and conventional approaches to disseminate messaging on HPV prevention and vaccination.

To advance the goals of the National Adult Immunization Plan, NVPO continues to host stakeholder meetings across the nation. The meetings have proven to be a unique opportunity for State and local organizations to build partnerships, spark new projects, and prioritize adult immunization as a central component of their portfolios. Dr. Beckham thanked RADM Sylvia Trent Adams, the principal deputy ASH, for giving the keynote address at the annual National Adult and Influenza Immunization Summit (NAIIS) in May, where RADM Adams asked summit members to prioritize reducing disparities in immunization.

Once NVPO receives NVAC's recommendations for the next National Vaccine Plan, it will convene stakeholder meetings, conduct individual interviews, and coordinate with agencies across the Federal government to draft the next iteration of the National Vaccine Plan.

# National Vaccine Plan WG Update and Vote—Robert H. Hopkins Jr., M.D., MACP, FAAP, NVAC Chair

Dr. Hopkins described the charge to NVAC, summarized the 2010 National Vaccine Plan, and outlined the WG's process. The WG proposed five new goals and identified priorities for each:

- Goal 1: Foster innovation in vaccine development and related technologies.
  - 1. Prioritize the development of innovative vaccines to prevent infectious diseases of population health significance.
  - 2. Enhance systems for vaccine production, storage, and delivery.
  - 3. Improve the quality and efficacy of current vaccines.
- Goal 2: Continue to leverage the vaccine safety system.
  - 1. Sustain and enhance current tools, standards, and approaches used to assess vaccine safety.
  - 2. Develop new methods to rapidly and accurately assess the safety of all recommended vaccines.
  - 3. Disseminate lessons learned from the vaccine safety system.
- Goal 3: Enhance knowledge of and confidence in routine vaccines and the immunization system.
  - 1. Research effective communication strategies to reach underimmunized populations, including messaging, outreach strategies, and cultural and linguistic approaches.
  - 2. Unify and promote vaccination standards across the life span.
  - 3. Enhance the delivery of vaccine safety and effectiveness messages to providers and the public.
- Goal 4: Optimize access to and utilization of all routinely recommended vaccines across the life span.
  - 1. Eliminate geographic, racial/ethnic, and socioeconomic barriers to vaccine access across the life span and improve care through quality improvement initiatives.
  - 2. Increase the use of, and data exchange within, electronic health records (EHRs) and immunization information systems (IIS') to collect and track immunization data, support clinical decision-making, assist with vaccine forecasting, and identify areas of need.
  - 3. Strengthen public, private, and community-based partnerships and the public health infrastructure to increase delivery of immunizations for routine use and for protection during outbreaks.
- Goal 5: Promote global immunization.
  - 1. Improve global surveillance for vaccine-preventable diseases and track progress against goals.
  - 2. Support international vaccine research and development and delivery programs to ensure vaccines are available to address global disease prevention.
  - 3. Sustain partnerships to prepare for emerging diseases and ongoing vaccine-preventable challenges.

### Discussion

Dr. Hopkins said NVPO will consider the NVAC recommendations as it revises the Plan and will determine the priorities. Throughout the new goals, NVAC recommends engaging partners, which should help NVPO identify resources it can use to implement the goals. The WG focused its recommendations on areas for which progress can be tracked, and NVPO will flesh out the metrics to do so. Timothy Cooke, Ph.D., appreciated that Goal 1 highlights innovation in vaccine development but expressed concern that no industry representatives took part in the WG.

### Vote: NVAC members unanimously approved the recommendations as written.

Ms. Aikin said NVPO will engage stakeholders as it develops the Plan; the WG's charge includes identifying new stakeholders to include. The WG will craft a brief report encompassing the recommendations for consideration by NVAC at the September 2019 NVAC public meeting.

#### Public Comment

Theresa Wrangham of the National Vaccine Information Center (NVIC) noted the focus on vaccine hesitancy and lack of confidence in the system overall. She said her organization for 37 years has been a voice for those concerns and has participated on various Federal advisory committees that shape vaccine laws and policy. NVIC has asked to be a participant in the stakeholder engagement, and it was included in 2011. Yet there has been no participation in this round of review of the National Vaccine Plan by NVIC or similar groups. To truly understand the concern, those who are hesitant and those who lack confidence must be at the table, and safety concerns must be addressed. Ms. Wrangham said it is of great concern that those types of stakeholders have not been called to the table.

# Experiences in the Field: Success Combating Misinformation in the Somali Community in Hennipen, MN—Kris Ehresmann, RN, M.P.H., Minnesota Department of Health

From 2004 to 2010, rates of measles-mumps-rubella (MMR) vaccination dropped from 91 percent to 54 percent among Somali children in Minnesota. Rates have started improving thanks to concerted efforts by Minnesota health officials, community leaders, and others. Ms. Ehresmann said that in 2017, Minnesota experience the largest measles outbreak in the country, predominantly in the Somali community. That same community had among the highest vaccination rates in the state until 2008, when a local news story focused on the disproportionate number of Somali children in special education courses, and the community linked the finding to MMR vaccination.

During the 2017 measles outbreak in Minnesota, 61 of 75 cases occurred in people of Somali descent, primarily young children. Of the 75 cases, 68 were not vaccinated. The Department of Health issued health alerts to providers which, along with media attention to the outbreak, resulted in increased vaccine uptake. Exposure mainly occurred in childcare settings. The Department of Health educated schools and childcare centers that unvaccinated children who were exposed to measles should stay home for 21 days (according to the CDC recommendations). It also applied a blanket exclusion approach in some cases, suggesting all children stay home, when it was difficult to determine which children had been vaccinated.

For one childcare center, by comparing the center's records with the State IIS, the Department of Health was able to identify unvaccinated children and recommend exclusion. Another childcare center was forced to close while staff worked to provide a full roster of attendees; before it shut down, it experienced multiple cases of measles. The Department of Health identified 8,000 exposures overall and excluded more than 600 people from group settings—all of whom complied voluntarily. The ability to identify susceptible people and recommend exclusion helped limit exposure and tamp down the outbreak relatively quickly.

Beginning several years ago, the Department of Health started taking a new approach to encourage vaccination in the Somali community. Instead of focusing on vaccines, staff aimed to provide parents with information about normal, healthy child development; the early signs of

autism; and vaccine-preventable diseases, drawing on staff from across the Department with expertise on immunization, child development, and autism. It hired Somali staff to conduct outreach; convened a group of influential Somali community members as public health advisors; and worked with childcare providers, mothers' groups, and faith organizations to provide information and education. As a result, vaccination coverage among the Somali community increased from a low of 42 percent in 2014 to a peak of 59 percent in 2015, tapering down to 55 percent in 2016. The relationships that developed through the efforts were integral to addressing the 2017 outbreak.

After the outbreak, the Department of Health surveyed the community so that members of the Somali community would know that they still had a voice. The survey revealed that most parents did seek vaccination for their children, mostly out of fear of the disease, and 95 percent of them felt good about their decision. A few reported side effects; on follow up, the Department of Health determined that the symptoms had either resolved or were unrelated to vaccination. Most reported positive experiences at the clinic, but a few (8 percent) said they felt judged by clinicians for not having their children vaccinated sooner. Ms. Ehresmann suggested clinicians focus on the positive decision rather than spend time talking with parents about why they waited to vaccinate.

### Discussion

Ms. Ehresmann pointed out that the alternative to voluntary exclusion from group settings was mandatory in-home quarantine, so parents were willing to work with the Department of Health to find a feasible option. Melissa Martinez, M.D., FAAFP, asked whether efforts have been made to educate more people about recommended adult vaccinations as an inroad to increasing child vaccinations. Ms. Ehresmann said the Department of Health has been emphasizing a culture of vaccination as a norm.

Leonard Friedland, M.D., wondered why parents were more motivated to vaccinate primarily by fear of disease rather than a provider's recommendation. Ms. Ehresmann believed that providers do make recommendations, but the Department of Health is educating providers about understanding and fostering better relationships with the Somali community.

John Dunn, M.D., M.P.H., asked for more detail on the broader educational approach used. Ms. Ehresmann reiterated that in 2008, the message that vaccines are safe and effective did not resonate with parents who were concerned about autism. Educating them about the full range of child health development proved more effective. One challenge, however, is that community influencers and parents are tired of talking about MMR vaccine and want to move on to other health priorities. Ms. Ehresmann added that the Somali community has good uptake of other childhood vaccines, so messaging strives not to lump them all together.

Melinda Wharton, M.D., M.P.H., noted that controlling the outbreak in such a timely way is a tribute to the heroic efforts of the state and local public health community. The work highlights the role of public health in response, as well as prevention and vaccination. Large outbreaks can overtax state and local public health resources, she added.

Asked why the vaccination rate is not higher in the affected community, Ms. Ehresmann said not all parents found the outbreak a sufficient reason to vaccinate. Also, when media attention declined, so did public interest. Ms. Ehresmann said a later case resulted in another bump in vaccinations, which speaks to the role that media plays in public health.

In response to Larry Pickering, M.D., FAAP, FIDSA, Ms. Ehresmann said vaccination rates increased because more childcare centers began to require vaccination. The state provided

funding to ensure that childcare centers did not suffer economically because of the outbreak but made it clear that it would not do so in the future.

# **Measuring Vaccine Confidence**

# Development and Validation of the Emory Vaccine Confidence Index (VCI)—Robert Bednarczyk, Ph.D., Emory University

Dr. Bednarczyk outlined various efforts to assess and address vaccine confidence and hesitance, which can range from outright refusal to selective refusal to intentional delays to delays caused by unavoidable or complicated circumstances. He said the proportion of susceptible children increases when early vaccination is delayed and catch-up vaccination programs are not sufficient.

To develop a broad, holistic VCI, investigators looked at sociocultural factors and trust dynamics, among other issues. They validated the VCI through two surveys of parents (relying on self-reported data) and a survey conducted through pediatricians' offices that allowed for verification of vaccination records. The VCI contains eight items that assess confidence in the vaccines and the health care provider as a source of information about them; trust in scientists, CDC, and other federal agencies; and attitudes about the importance of getting recommended vaccinations. Dr. Bednarczyk said the scale performed well and consistently across three rounds of validation among three distinct populations. He concluded that the Emory VCI is easy to administer and provides a reliable snapshot of vaccine confidence.

# Measuring Vaccination Confidence and Hesitancy: The Challenges and Value of Two Popular Concepts—Glen Nowak, Ph.D., University of Georgia

Dr. Nowak said there is no consensus about how to define vaccine "confidence" or "hesitancy," the relationship between the two, or how to measure either. Hesitancy can be *addressed* with communication rooted in behavioral and social science; alternatively, it can be *overcome* through incentives to increase uptake (but not necessarily change beliefs). Confidence is associated with one's beliefs about the benefits of vaccination or the likelihood of adverse reactions (or both). Hesitancy is associated with reluctance to take a recommended action. It is commonly assumed that greater confidence will lead to less hesitancy.

A survey conducted during and immediately after a 2014–2015 measles outbreak found that just over half of those surveyed were aware of the outbreak, and only half of those followed news of the event closely, so overall awareness was lower than investigators expected. Those aware of the outbreak tended to be white, older and more educated than those who were not aware of it. Following media reports that some of those affected had been vaccinated, concerns about the protection provided by MMR vaccine increased, especially among the highly aware population. The survey also confirmed that trust (in providers, systems, scientists, etc.) influences decisions; for example, trust in experts who make decisions about vaccine recommendations corresponds with the likelihood of getting vaccinated.

Dr. Nowak concluded that most parents and adults have relatively high confidence levels—but that may not equate to reduced concern or fewer questions regarding recommendations. The value of assessing vaccination confidence and hesitancy should be linked to a specific goal, such as increasing uptake, increasing public trust, or influencing decision-making processes.

# Insights into Flu-Hesitant African American and Hispanic Adults—David Chavis, Ph.D., Community Science

Through a web-based survey, Dr. Chavis and colleagues determined that African American and Hispanic adults are more likely than White adults to say they do not know enough about influenza

vaccine to make an informed decision about getting vaccinated, but they also report receiving more information about the vaccine than Whites. A major barrier to vaccination among African Americans and Hispanics stems from past experiences with pain from vaccination; however, Dr. Chavis noted, focus groups revealed that the reluctance is more associated with historical trauma around needles than with the pain of vaccination. He recommended more research to better understand the nature of these beliefs.

African Americans and Hispanics were more likely than Whites to believe that vaccines can overload the immune system and are not needed by healthy adults. Both were more likely to cite religious or cultural perspectives as a barrier. Again, focus group interviews revealed that cultural perspectives were informed by traumatic events such as the syphilis experiments in Tuskegee.

Whites were more likely than Hispanics to report that a health care provider reminded them about getting an influenza vaccination. In terms of motivating factors, all groups said that protecting others from disease is important (but they had differing views on how to do so). More African Americans and Hispanics than Whites said social media posts motivated them to get vaccinated. Dr. Chavis said the volume of information available does not appear to be a problem; rather the content and source are most important to address perceived cultural conflicts.

More Hispanics said a family member's recommendation was influential; more African Americans said the availability of vaccination in one's workplace made a difference. Notably, the survey found no significant differences in access to or availability of vaccines by race/ethnicity. All groups said a provider's recommendation was influential. Dr. Chavis suggested interventions that involve providers and family members may help increase uptake.

# Cluster Anxiety-Related Adverse Events Following Immunization (AEFI): Assessment of Reports Detected in Social Media and an Online Search Engine—Tiffany Suragh, M.P.H., CDC

Ms. Suragh and colleagues sought to identify clusters of AEFIs that stemmed from anxiety about immunization and that were reported in social media but not captured in peer-reviewed publications. They found 39 reports referring to 18 cluster events—mostly in children, and mostly related to HPV vaccination, in clusters ranging from two to 360 individuals. All occurred in school settings or as part of national vaccine campaigns. The most common AEFI was syncope (fainting), reported in 50 percent of cases. In each case, investigations found no links to vaccination; however, in five cases, the vaccination campaign was halted.

While some reports reflected a belief that vaccines are safe, widely used, and well studied, others suggested that vaccines are harmful and there is distrust in public health investigators and pharmaceutical companies. Some reports expressed genuine uncertainty about the cause of the cluster AEFIs.

Despite the study's limitations, Ms. Suragh said it indicates that social media and the web can be a useful resource for identifying reports of cluster anxiety-related AEFIs not found in traditional peer-reviewed journals. In fact, relying only on the published literature may seriously underestimate the occurrence of such events. The findings may be useful in developing guidance for immunization programs on preventing these events and mitigating their potential negative impact on vaccination campaigns, vaccine schedules, and national vaccine strategies. Furthermore, public health agencies should be alert to the sentiment and tone of discussions in online forums. They should be prepared to respond effectively and rapidly to prevent or mitigate the spread of misinformation that might damage public trust and confidence in vaccines.

#### Discussion

Dr. Nowak said research has been showing a decline in trust in scientists and other experts over the years. Some mistrust may stem from lack of understanding about how vaccines are created, licensed, evaluated for safety, and recommended for use. He concurred with Ms. Ehresmann's observation that it is important to understand what people want to know and then work with them to build trust in public health and other systems.

David Fleming, M.D., asked whether vaccine hesitancy can be addressed by focusing on vaccines or whether bigger issues (e.g., distrust of the government) must be tackled. Dr. Bednarczyk said that people's values may be more resistant to change then attitudes. Dr. Nowak said it is important to invest in building trust in science, scientists, and public health agencies. Dr. Chavis pointed out that human decision-making is not entirely rational; his data suggest a link between beliefs, self-care, and health that should be considered. Ms. Suragh added that her study revealed that all the anxiety-induced AEFIs occurred in the context of mass vaccination campaigns, possibly reflecting underlying mistrust of the government. She reminded the group that context is important, and narrow guidance will not be sufficient for every situation.

Following some discussion about how to narrow down and interpret the findings of the VCI, Dr. Bednarczyk said there is some interest among health care providers in using a rapid VCI but many concerns about the logistics and feasibility of doing so. Dr. Nowak noted that those who have pioneered similar tools found they were used less for assessing confidence than for identifying areas of concern to address during the patient's visit.

Hana El Sahly, M.D., asked whether vaccination mandates affect confidence, hesitance, or trust. Dr. Nowak said mandates have typically met with some resistance. Building trust would probably increase compliance, he noted.

Dr. Friedland pointed out that in addressing the new charge from the ASH to update NVAC recommendations on vaccine confidence, better understanding is needed of different perspectives, because the current approaches are not working.

Dr. Chavis said his survey found that economic status and education were related to vaccine confidence and uptake. Dr. Nowak said that, for mothers of low socioeconomic status (SES), confidence that the vaccine itself would not cause problems was enough to overcome hesitancy, because they were concerned about missing work; high-SES mothers did not voice such concerns.

## **State Legislation to Increase Vaccination Coverage**

# Vaccine Mandates: An Overview of Evidence—Saad Omer, M.B.B.S., M.P.H., Ph.D., Emory University

States variously allow exemptions for medical, religious, or personal belief (or philosophical) reasons, Dr. Omer noted. California, Mississippi, and West Virginia are the only States that do not allow any nonmedical exemptions (as of June 4, 2019). In 2008, Dr. Omer and colleagues observed clustering of pertussis cases clustered in areas with high rates of nonmedical vaccine exemptions in Washington State. Consequently, the state began requiring those seeking nonmedical exemption to document that they received educational counseling from a licensed health care provider, and vaccine refusal rates dropped 40 percent. Some clusters of exemptions persist, and pertussis outbreaks are occurring there; Dr. Omer recommended monitoring the heterogeneity of exemption clusters.

Looking at California, where legislators passed three laws restricting nonmedical exemptions over a few years, Dr. Omer observed that parents sought medical exemptions more frequently in response. When all nonmedical exemptions were prohibited, assessment revealed clusters of children in Northern California who were not up to date on vaccinations, but no such clusters in Southern California.

Dr. Omer said states have many options around nonmedical exemptions, pointing to data on how the ease of obtaining an exemption corresponds with the number of nonmedical exemptions in any given state. States can require parents to discuss vaccination with a health care provider, review requests individually, require a letter describing the rationale for the request, or require annual renewal of exemptions. In some states, to get an exemption, parents need only download a form from a state website, print it, check a box, and hand it to the school administrator. Getting fully vaccinated in preparation for the first year of school should be at least as easy as getting an exemption, Dr. Omer said.

# Vaccines, Autism, and Vaccine Exemptions—Peter Hotez, M.D., Ph.D., Texas Children's Hospital and Baylor School of Medicine

Dr. Hotez said the large number of unvaccinated children in Texas led him to begin speaking out publicly about the dangers of vaccine-preventable diseases, especially measles. Notably, Texas has an aggressive, well-funded anti-vaccine group that has lobbied successfully to make it easy for parents to get exemptions and to prevent access to data on the percentage of unvaccinated children in a school. Dr. Hotez believes the number of unvaccinated children in some schools is so high that the schools are unsafe.

Data from 14 of 18 States that allow nonmedical exemptions confirm that the number of nonmedical exemptions is rising, and the problem is bigger in the West than the East. Dr. Hotez identified 15 urban counties with large numbers of unvaccinated children, resulting in a predictive map for measles. Not surprisingly, high numbers of nonmedical exemptions correlated with low MMR vaccination rates. Others expanded on the map, adding data on airline hubs to predict the introduction of new measles cases into the United States.

Dr. Hotez and his colleagues are struggling to combat the anti-vaccine movement in Texas, and they feel "outgunned." They seek to communicate the evidence showing there is no link between autism and vaccine ingredients or the timing of vaccines. Dr. Hotez said that the anti-vaccine lobby promotes new theories whenever one is proven wrong, and it is currently claiming aluminum in vaccines causes autism. He is in a unique position to speak out, because one of his children has autism and severe developmental disabilities. His book, *Vaccines Did Not Cause Rachel's Autism*, lays out the evidence showing there is no link between vaccines and autism and also summarizes what autism is and its roots in early fetal brain development.

# Mississippi Immunization Requirements—Becky Shipp, RN, B.S.N., Mississippi State Department of Health

Ms. Shipp explained that Mississippi law allows only medical exemptions for vaccinations; a physician licensed by the State must apply for a medical exemption on behalf of the child. Public and private schools are required to report immunization compliance status for all students twice a year to the State Department of Health. Schools and childcare facilities are required to have documentation of immunization compliance onsite at all times. The state reviews medical exemption requests filed by physicians from outside the state on a case-by-case basis. The state then determines whether the exemption is granted permanently or temporarily; if temporarily, the state's form includes an expiration date.

The requesting physician must state the reason for medical exemption and give his or her contact information. The requesting physician must also include a signed declarative statement validating the decision for the vaccine exemption request and indicating that appropriate education has been provided to the parent or guardian. The State Epidemiologist or Deputy validates that the documentation is complete. The original documentation is filed with the Department of Health for use in case an outbreak requires exclusion of a child from school or licensed childcare facility.

Ms. Shipp said 99.7 percent of Mississippi children from kindergarten through grade 12 have a complete certification of immunization compliance. For kindergarten children alone, the rate is 99.2 percent. The number of medical exemptions granted is increasing every year, Ms. Shipp noted. Vaccination rates are somewhat lower for rotavirus and hepatitis A, which are recommended but not required. Similarly, in teenagers, uptake of required vaccines is high, but HPV and meningococcal vaccine coverage is low. Ms. Shipp attributed the high compliance rates to the dedicated efforts of Department of Health to ensure access to vaccines and validate compliance; to state medical professionals for administering vaccines and documenting exemptions; to collaboration between the State Department of Education and the Department of Health to ensure compliance; and to the state chapter of the American Academy of Pediatrics and the Mississippi Public Health Association for their advocacy.

# California Legislation—Richard Pan, M.D., M.P.H., FAAN, California Senate

Dr. Pan described his firsthand experience treating measles during an outbreak in 1991 in Philadelphia. Later, he ran for the state legislature in California to address public health issues—particularly the growing number of personal belief exemptions from vaccination. At that time (2010), such exemptions were easy to get in California. Since then, Dr. Pan has authored two bills eliminating personal belief exemptions and one, still in the legislature, that would give the state more authority to refuse medical exemption requests that do not demonstrate a clear need.

It is not enough to bring doctors and scientists forward to make the case for vaccination, said Dr. Pan. He called for organizing pro-science, pro-vaccination parents, who make up the majority. Anti-vaccine groups spent \$500,000 to lobby against the California bill eliminating the personal belief exemption. Success has come when parents of children who cannot be vaccinated testify at the state and local level, including before school districts, about the unavoidable risks their children face when vaccination coverage slips. Broad coalitions should include medical and public health providers alongside advocates for children, school groups, and business groups, among others. Dr. Pan emphasized that vaccination protects public safety and individuals' right to live without the threat of preventable, communicable diseases. Moreover, vaccine hesitancy leads to very long discussions between parents and physicians about vaccination that take time away from other health discussions.

Dr. Pan said social media has enabled the anti-vaccine community to create forums that exclude credible scientific information, spread misinformation, and catalyze action against physicians who provide vaccines. Dr. Pan took issue with the conventional media's role in messaging, pointing out that many pro-science stories are illustrated with pictures of crying children and big, scary needles. While the majority of people support vaccination, media stories often depict the vocal minority. Photos, graphics, and headlines should be appropriate to the content of the story, said Dr. Pan.

Efforts to Enhance Vaccine Coverage: Colorado, 2019—John Douglas, M.D. Colorado has allowed nonmedical exemptions since 1978 and has only required schools and childcare facilities to report immunization and exemption rates annually since 2014, Dr. Douglas

stated. He observed that it might be easier to file an exemption than to get a child vaccinated. Data from Colorado illustrate some points made by previous speakers. Even in areas that appear to have good vaccine coverage, there are clusters with low immunization rates. Some parents might choose exemptions out of convenience, to avoid time away from work. While 92 percent of Coloradans say they believe vaccines should be required for school entry, only the anti-vaccine residents have organized and showed up to make their voices heard.

It is now clear that Colorado has the lowest rates of MMR vaccination among kindergartners in the country and is experiencing its worst measles outbreak in 30 years. A recent legislative proposal would have required the following:

- A state-level standardized form and submission process for exemptions
- Adoption of ACIP's recommendations defining qualified medical exemptions
- Mandatory hepatitis A, rotavirus, and meningococcal vaccination for school entry (mandatory HPV and influenza vaccinations were considered but withdrawn.)
- Personal belief exemption forms, delivered by hand to the local or state health department
- Entry of exemptions into the state immunization registry

One major line of attack on the legislation was the contention that the state was colluding with pharmaceutical companies to boost their profits. There was a claim that the mumps vaccine was derived from aborted fetal tissue, which became a prominent talking point in some religious communities. Some took issue with perceived problems of confidentiality with the immunization registry. Most surprising was the contention that immunization requirements would violate parents' rights. And while the 2018 elections led to a democratic majority in both state houses, the new democratic governor threatened to veto the legislation because it limited parents' ability to refuse vaccines for their children. Ultimately, the bill failed.

### Discussion

Dr. Pan believed that some proportion of personal belief exemptions are claimed out of convenience by busy parents, which seems to be supported by the immediate 20-percent drop in personal belief exemptions in Washington and California once the process was tightened. He added that homeschooled children are explicitly exempt from school-entry vaccination requirements in California, but their parents show up in support of anti-vaccine groups when legislation is proposed. Dr. Douglas believed that convenience plays a big role in exemptions in Colorado, especially among rural residents, but he had only anecdotal evidence. Dr. Omer said the issues point to the need for more high-quality science on vaccine hesitancy and confidence.

Dr. Pan said that California constituents called their legislators when the Disney measles outbreak occurred. His office used the opportunity to connect community members who were pro-science and identified a funding source they could use to organize themselves. His office also identified people who could educate parents about how to lobby successfully and how to raise issues with local politicians. Dr. Hotez added that the anti-vaccine movement has successfully leveraged social media, and pro-science groups should learn to mobilize as well.

Dr. Douglas agreed that testimony from more pro-vaccine parents would have helped Colorado's legislation pass. He pointed out that the parents who homeschooled their children were able to show up and testify at times when pro-vaccine parents, who worked, could not. Dr. Douglas suggested recruiting grandparents to advocate for vaccination when parents cannot. Dr. Pan said the goal is not to "out-scream" the opposition but rather to cultivate effective, pro-science parent

advocates to campaign in person, in the media, and on social media. He added that the anti-vaccine movement is willing to bully and suppress pro-science voices.

# **Combating Misinformation About Vaccines**

# Vaccine Misinformation—Paul A. Offit, M.D., Children's Hospital of Pennsylvania, Perelman School of Medicine, University of Pennsylvania

Dr. Offit pointed out that current concerns about vaccines are not related to any of the documented negative effects or safety issues around vaccines, which can occur with any medical product. The most prominent concern is a purported link to autism—based on minimal and fraudulent research—despite numerous studies demonstrating that vaccines do not cause autism. Dr. Offit summarized reasons why disproven theories persist and misinformation spreads.

#### MEDIA FACTORS

Dr. Offit faulted media outlets for giving equal time and consideration to credible, knowledgeable experts as to others putting forth conspiracy theories with no scientific evidence. The media is seen as defending the weak against the strong—in this case, parents and children against doctors, lawyers, public health officials, mainstream scientists, and pharmaceutical companies that are portrayed as uncaring and motivated by greed. Moreover, the media loves a maverick. Some apparently outrageous scientific claims have turned out to be true breakthroughs, so those on the fringes can be seen as daring, despite putting forth false claims. The media often gives too much attention to interesting results from a single study that have not been replicated or validated.

#### MEDIA AND PUBLIC UNDERSTANDING OF SCIENCE

Dr. Offit gave several examples demonstrating the lack of scientific literacy that leads to the spread of misinformation and mistrust of science. Epidemiologic studies do not detect rare events, but reports of such events are very powerful. Furthermore, epidemiologic findings do not prove a negative—for example, that vaccines do not cause autism. Emotionally moving anecdotes can generate strong emotions that are not easy to counter with statistics and data.

Science is an approach to thinking about a problem by testing hypotheses. Results thought to be reliable can later be disproven (and often are), leading to a fluidity that some people find upsetting, said Dr. Offit. As such, many are drawn to those who express no doubt in their conclusions, even if they are wrong. In addition, explaining cause and effect is difficult. As a result, many people believe in unfounded notions, such as astrology and the existence of ghosts. Many people are concerned about environmental toxins but do not understand basic chemistry.

#### OTHER FACTORS

Dr. Offit outlined other approaches used to sow fear and spread misinformation. For example, without evidence, some seek to discredit the messenger, claiming that those in favor of vaccines benefit directly from the vaccine enterprise. It is easy to scare people and hard to "un-scare" them, said Dr. Offit. He cited the persistent fear that children might be harmed by trick-or-treating on Halloween, which stems from a debunked story that a child found a razor blade in an apple. The best way to remove the unfounded fear is to provide an alternative, said Dr. Offit, such as a clear explanation of the real causes of autism or, better yet, a cure.

# Communicating Vaccine Safety—Dan Salmon, Johns Hopkins Institute for Vaccine Safety

Dr. Salmon emphasized the need to help people distinguish correlation from causation and fact from fiction, which is very challenging. He called on health care providers to take time to explain

to parents how the licensure process evaluates safety and rigorously assesses benefits and risks. Providers need to reach parents before they have come to conclusions about vaccines. More rigorous science is needed to determine what kinds of communication interventions work. Some research indicates that a health care provider's presumptive approach, identifying vaccines as the standard of care, is more effective than a participatory approach in which parents drive the conversation. A motivational interviewing method has also proven effective.

Observational studies, after products are licensed, allow for identification of issues that could not be seen in smaller, limited, prelicensure studies—but they are challenging. Dr. Salmon noted that NVAC's 2009 report on vaccine safety science acknowledged the need to address public concerns, such as the rapid expansion of the vaccine schedule for children.

Dr. Salmon argued for the need to find commonality rather than polarization. About 1 percent of the population is ideologically opposed to vaccines, but three or four of every 10 people have concerns. Beginning with the common understanding that everyone wants to protect children paves the way for constructive conversation. Applying the concepts of audience segmentation and targeted messaging, health care providers can identify those parents who are hesitant, learn why, and direct the appropriate time and resources to addressing their concerns.

The federal government demonstrated an effective approach to vaccine safety in its response to the H1N1 influenza outbreak and vaccine. Following recommendations by NVAC, the federal government rapidly put out information on background levels of disease and developed and distributed its plans for managing the outbreak. It set up a new surveillance system that remains in use today. It formed an independent risk assessment group that publicly reported findings frequently. The federal government worked with the media to explain the science.

Finally, Dr. Salmon said NVAC and others have laid out clear recommendations for high-quality vaccine safety science and good communication of knowledge and findings—but they all require more funding. He encouraged NVAC members to work with other stakeholders to secure the resources needed.

#### Discussion

Asked how to combat the effects of social media, Dr. Salmon suggested more attention to leveraging the opportunities that social media offers, such as promoting reliable, credible websites. Dr. Offit said it is impossible to eliminate bad information, but many are getting better at confronting it with good information. He added that a lot of people using social media are open to and appreciate well-reasoned arguments and explanations, so efforts should be made to provide answers rather than try to regulate misinformation away.

Gina Charos sought advice on how to communicate that recommendations change as new evidence comes to light. Dr. Offit responded that experts must do a better job of explaining how science works in ways that people can understand. He was confident that even the recent findings about the genes involved in autism could be expressed in a compelling, compassionate way, despite the complexity.

Asked how to find common ground, Dr. Salmon said stakeholder engagement is key. NVPO and NVAC have modeled the effectiveness of going into communities, gathering insights, and incorporating public opinion into policy. In addition, the scientific agenda should respond to public concerns, so that health care providers and public health officials have good data with which to answer parents' questions. Dr. Salmon stressed the importance of communicating with respect by understanding that all parents are trying to do the best thing for their children.

Dr. Offit said that concerns raised about mercury in vaccines gave rise to at least three antivaccine groups. He felt that experts and scientists did not trust that they could explain the safety of mercury, so their message got lost in a pile of data. He called for more communication by people who understand the science and can explain it well.

Melody Anne Butler, B.Sc.N., RN, noted that targeting science to address specific concerns, such as thimerosal in vaccines, does not seem to be effective. As Dr. Hotez noted, when one theory is disproven, anti-vaccine groups quickly move on to another. She wondered whether more focus should be given to improving communication of existing data.

Dr. Salmon pointed out that the need still remains for a good study of variability in the vaccine schedule. Research should address concerns in a smart, deliberate way, which requires adequate funding. Better communication is also needed, said Dr. Salmon, and it is remarkable how little is known about how to measure trust. More behavioral science research is needed to understand, for example, risk perception, so that providers can answer questions in a way that engenders trust.

## Remarks from the Secretary—Alex Azar II, Secretary, HHS

Secretary Azar thanked NVAC members for their service to the American people and to public health. He appreciated the HHS staff who support NVAC and the general public and stakeholders for their interest in this meeting. For more than 30 years, NVAC has helped inform the work of America's public health professionals and health care practitioners in spreading the benefits of vaccines, said Secretary Azar. He encouraged the members to keep up that important work, because there is a long way to go.

Vaccines are safe and effective, said Secretary Azar. Vaccines are some of the most tested medical products available and one of the most important public health tools ever developed. Yet the United States is now seeing the largest outbreak of measles since the disease was declared eliminated from the country. There are also challenges to promoting other vaccines, such as those for hepatitis, HPV, and influenza.

One of the most pressing public health challenges the country faces is vaccine hesitancy driven in part by misinformation—in the United States and around the world. The World Health Organization (WHO) named vaccine hesitancy one of the top 10 global health challenges for 2019. NVAC is in a position to help HHS understand the challenges and how to address them. Secretary Azar thanked NVAC for the work it has already done and for the recommendations voted on today to help lay the foundation for the next National Vaccine Plan.

Secretary Azar said the charge to NVAC to update its 2015 report on vaccine confidence will broaden understanding of this issue and give a more granular sense of the challenges around vaccine hesitancy on particular vaccines and across different ages. In the meantime, this administration has an all-hands-on-deck strategy for tackling vaccine hesitancy and promoting vaccination.

Last month, during National Infant Immunization Week, HHS leaders undertook a media campaign across the country, reaching tens of millions of Americans with messages about the safety and effectiveness of vaccines. Dr. Giroir, the CDC director, the Surgeon General, and many other HHS leaders have been working tirelessly to promote this message, traveling the country to affected communities, said Secretary Azar.

In addition, CDC has been on the ground, working with public health departments to increase vaccination rates, prevent outbreaks, and respond to infections. All of this work is going to continue as part of a steadily increasing drumbeat of action until today's troubling situation is turned around, said Secretary Azar. NVAC's leadership as advisors to HHS will continue to guide the work. In return, Secretary Azar committed to continuing to make vaccination one of the top public health priorities of HHS and of the entire Trump administration. He again thanked NVAC members for their work their commitment to the public health of the United States.

### Measles Outbreaks: Where Do We Go From Here?

### Measles: 2019—Melinda Wharton, M.D., M.P.H., CDC

Dr. Wharton summarized current measles outbreaks around the world. The United States is facing the largest outbreak in the Americas and the most cases since the disease was eradicated in 2000, especially in two areas of New York. The outbreaks were fueled by imported disease from various countries, mainly the Philippines, Ukraine, and Israel.

CDC implemented an incident management structure within the National Center for Immunization and Respiratory Diseases and continues to invest in state and local health departments for public health infrastructure and laboratory support to enable the frontline response and confirm measles cases. CDC also provides assistance on the ground through data gathering and analysis. Communication has been challenging in tight-knit communities that do not rely on traditional information sources. To assist public health officials, CDC identified specific resources to help physicians answer questions about measles and vaccines. It is also reaching out to rabbinical camps and medical associations to help spread clear, consistent, and credible vaccine information through trusted sources.

Finally, CDC is working with state and local partners, through existing cooperative agreements and funding, to identify and address issues of access to vaccination through a variety of activities. To combat misinformation, it is also making sure health departments and other partners have accurate information that is easy for people to find.

# State Responses to the Current Measles Outbreak—Kim Martin, ASTHO

Among many other activities, ASTHO is working closely with the media to explain what state health agencies are doing to address measles outbreaks, Ms. Martin said. She noted that Washington State's top public health official testified before a U.S. Senate committee on the importance of federal funding for vaccine programs. Outbreak response is expensive; for example, Washington's state and local health departments have already spent \$1.6 million; the costs incurred by schools, health care providers, families, and private businesses; loss of productivity; and lost income have not been calculated. The response to an outbreak also diverts resources from other public health services.

To increase vaccine coverage, most states now allow pharmacists, among others, to administer vaccines, although restrictions persist. States are providing education to combat misinformation. In some areas, public health authorities are struggling to counter misinformation that has persisted for years in close-knit communities. Some states are limiting or eliminating nonmedical exemptions from vaccination. States are looking for a national approach to track vaccination among homeschooled children that could be customized and implemented at the local level.

ASTHO coordinates with NACCHO and AIM to offer feedback on CDC and other HHS strategies. ASTHO is also developing a measles podcast and an infographic to demonstrate the cost of an outbreak. It is considering updating its 2012 toolkit, *Communicating Effectively About* 

*Vaccines*, participating in next month's National Press Foundation Fellowship Program on current measles issues, and supporting the passage of the Federal Vaccine Awareness Campaign to Champion Immunization Nationally and Enhance Safety (VACCINES) Act of 2019.

Measles Outbreaks: Where Do We Go From Here?—Michelle Cantu, NACCHO Ms. Cantu said a 2017 assessment of local health department immunization programs found vaccine hesitancy was one of the most commonly reported challenges, closely followed by the lack of education and confidence in vaccines. Even more concerning, said Ms. Cantu, is vaccine hesitancy among health care providers.

NACCHO provides its members with media talking points and platforms to disseminate CDC updates, guidance, and tools. It convenes advisory groups to discuss, for example, the costs and legal implications of outbreaks in areas with low vaccination rates. NACCHO is looking closely at social media messages, particularly those by corporations promoting vaccine confidence as part of corporate social responsibility efforts. It is ensuring its own messaging clearly conveys the importance of protecting children through vaccination.

NACCHO testified before congress and encouraged local health department staff to educate representatives about the need for vaccine funding. In April, the senate passed a resolution on the importance of vaccines in saving lives. In May, NACCHO endorsed the bipartisan VACCINES Act, which aims to identify communities at risk for vaccine-preventable disease outbreaks, educate the public, and combat misinformation about the safety of vaccines.

NACCHO's next steps align with NVAC recommendations for the updated National Vaccine Plan. For example, it aims to increase support for immunization programs and look closely at workforce development. NACCHO plans to further explore evidence-based strategies to understand hesitancy and identify vaccine-confidence messaging, leveraging work underway and learning from experiences in Minnesota and Mississippi. It will continue to support improved data collection mechanisms and work toward interoperability and data sharing. NACCHO will strive to coordinate efforts among federal agencies that deliver services to improve access to vaccines. Finally, NACCHO hopes the National Vaccine Plan update will be an opportunity to address immunization across the life span, bringing the message to a broader audience.

#### Discussion

Dr. Dunn said providers must have the information and tools they need to discuss vaccines with their patients. Most providers, particularly those who do not provide vaccinations frequently, lack basic information. Materials are available but are not always easy to find. Dr. Dunn suggested state and local health agencies begin gathering information in a well-organized, single repository.

Ms. Ehresmann asked what would change if the United States lost its measles elimination status. Dr. Wharton said only the two areas in New York have had sustained transmission; no other areas have seen repeated introductions of disease in large, undervaccinated populations. In most situations, it has been possible to identify the cases and implement interventions to stem the spread of disease, as in Minnesota. Dr. Wharton did not think any dramatic changes would occur if the current outbreak reaches the 12-month mark.

Dr. El Sahly asked whether vaccination rates are increasing among the affected populations in New York, particularly the Orthodox Jews in New York City. Dr. Wharton said uptake has increased, but data were not yet available to show how much the coverage gap has narrowed.

Dr. Hopkins felt more health care facilities should require health care providers to be up to date on their MMR vaccinations. Ms. Ehresmann said Minnesota saw very few transmissions of measles in health care facilities, in part because of good vaccination coverage among providers and also because providers quickly and fully implemented prevention measures, such as masking.

Dr. Wharton noted that the public health workforce at the local level has been declining over the past decade, so local health agencies are quickly overwhelmed in the face of an outbreak. The current measles outbreaks provides a very strong example of the need to maintain strong public health infrastructure. Ms. Cantu said NACCHO's data confirm the workforce decline, but local health departments frequently collaborate with other community providers to meet the community's needs.

Dr. Dunn asked whether local health departments are moving away from childhood vaccination in response to the Affordable Care Act, which covers vaccines in private clinical settings. Ms. Cantu said that some local agencies in large cities have indicated they plan to offer less childhood vaccination, but small and medium-sized local health departments continue to provide such services in their communities. Sometimes, they collaborate with primary care providers, federally qualified health centers, and community health centers; often, they act as a kind of umbrella organization that also helps to provide vaccines.

Ms. Charos said Canada has had two measles outbreaks so far. She noted that the imported cases are occurring in adults 22–49 years old. Dr. Wharton said the larger outbreaks in the United States have primarily affected young children, often those younger than school age. Some efforts to control the outbreak have involved working with religious schools in the areas affected.

### **Public Comment**

Rita Kuwahara of the Association of Asian-Pacific Community Health Organizations (AAPCHO) said it is vital to determine strategies to increase vaccination against measles, but it is also important to address another vaccine-preventable disease that has had recent alarming local rises. Rates of acute hepatitis B have risen sharply in states most affected by the opioid epidemic. Maine had a 729-percent increase in 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. Southeastern Massachusetts had a 78-percent increase in 2017, and North Carolina had a 62-percent increase from 2012 to 2016.

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 of those over the ages of 20 to 25 were not vaccinated as children and are currently in the age group most at risk of acquiring hepatitis B in the setting of the opioid epidemic.

Ms. Kuwahara said we currently have the tools to prevent hepatitis B and curb the regional hepatitis B rise by increasing adult hepatitis B vaccination to prevent liver cancer, liver failure, and cirrhosis that occurs in up to one in four people with unmanaged chronic hepatitis B. But there is an urgent need to increase provider and community awareness of the availability of both the two- and three-dose adult hepatitis B vaccine to increase vaccination rates among adults.

It is also important to increase awareness that the adult hepatitis B vaccine requires no costsharing for patients with private insurance or Medicare Part B and in most Medicaid programs. The AAPCHO was pleased that congress has recognized the need to increase adult hepatitis B vaccination awareness in the setting of the opioid epidemic through the introduction of the bipartisan Health Resolution 331 and Senate Resolution 177 designating April 30 as National Adult Hepatitis B Vaccination Awareness Day, which was endorsed by over 75 organizations, including the American Medical Association , the American College of Physicians, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American Public Health Association. It also appreciated the inclusion of language in the House Subcommittee on Labor, Health and Human Services, Education, and Related Agencies' appropriations bill to urge CDC to partner with state, local, and tribal health departments to develop a plan that takes into account best practices and model strategies to increase hepatitis B immunization coverage among adults to reach vaccination levels necessary to eliminate new infections of hepatitis B in the United States.

With the alarming regional rises in acute hepatitis B in the setting of the opioid epidemic, the AAPCHO hopes that NVAC and HHS will also examine this issue and determine strategies to increase provider and community awareness of the adult hepatitis B vaccine—particularly within the opioid epidemic—to increase adult hepatitis B vaccination rates from its current level of only 25 percent.

**Dr. Chime Nnadi, M.D., Director for Vaccine Confidence at Merck**, said it is important to continue this conversation, and he thanked the presenters from the different states for sharing perspectives that often are not heard, especially at the national level. As the presenters demonstrated, we have disparate experiences in different states. Dr. Nnadi asked whether there is an opportunity to have a conversation around hesitancy from the position of the vaccine environment. He said it seems like different states have different vaccine environments, which, to a large extent, affects the decisions of individuals and communities within those states to either accept vaccines or to be hesitant towards vaccines. So, the idea of looking at the entire vaccine ecosystem that includes the political system, the individuals, and communities as well as health care providers and immunization systems in a particular State or region becomes important.

Dr. Nnadi also addressed learning increasingly from other fields of public health, especially the idea of resilient immunization systems. In other areas of public health, such as emergency response, outbreak response, and Ebola containment, the conversation has moved quite substantially from just waiting for the event to happen to actually preparing to head off the event, to prevent the event, to prepare for the event in case it happens, and to rapidly contain the event were it to happen. He asked whether the same principle of resilience can be applied to prepare to head off hesitancy no matter the characteristic or approach that it comes in as, to prepare to contain hesitancy when it does occur in different settings, and, more importantly, to learn lessons to help shape the future response.

The current outbreak in the United States and other parts of the world is important. It has opened our eyes. Dr. Nnadi asked what lessons could be learned to help shape our immunization systems such that they become more resilient to hesitancy and vaccine confidence issues moving forward. He hoped NVAC and the scientific community would consider the question.

Ms. Wrangham of the NVIC said she appreciated Dr. Salmon acknowledging in his comments the role of NVIC's consumer member of the Vaccine Safety and Risk Assessment WG, reminding NVAC of NVIC's past stakeholder participation in light of her comment earlier in the day. Ms. Wrangham quoted federal law stating, "The Secretary shall establish in the Department of Health and Human Services a national vaccine program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reaction to vaccines." Today, there was much discussion on what creates or leads to

vaccine hesitancy and distrust in government and how to communicate susceptibility to "convince" people to vaccinate, said Ms. Wrangham.

Notably, there was little conversation on closing the gaps in vaccine safety research that were documented by the Institute of Medicine with the lack of epidemiologic studies and quality mechanistic studies. Informed consent protections also need to be integrated into activities within NVAC, acknowledging the risk for vaccine injury and death. Dr. Salmon's thoughtful comments about mischaracterization and labeling of people as anti-vaccine are appreciated, in contrast to the political views expressed today, as well as the acknowledgment of the role of NVIC's cofounders in crafting and assisting in the passing of the federal law that created this committee.

Over the course of NVIC's 37-year existence, the many people expressing concerns about vaccine mandates, vaccine safety, and informed consent protection are not necessarily antivaccine. Many vaccinate their children. Questioning or being critical of vaccine laws and policies does not equate to being anti-vaccine, and there are legitimate vaccine safety concerns.

From NVIC's perspective, Ms. Wrangham continued, distrust is in part due to the lack of transparency by federal agencies to communicate the frequency and severity of disease complication, existing conflicts of interest, and the lack of independent vaccine safety monitoring. For example, in 1962 measles was characterized as a self-limiting infection of short duration, moderate severity, and low fatality that has maintained a remarkably stable biologic balance over the centuries that the population has learned to live with.

Today current communication efforts are focused on the worst-case scenarios of what will happen if one does not vaccinate. Though community immunity is both a result of vaccination and recovery from mild infection, that fact is seldom communicated. However many who delay or decline vaccines understand that for many childhood diseases, the most severe outcomes rarely happen and so the risk perception is different, as may be their choice.

When government and health care providers do not communicate these types of facts, it plants the seed of distrust. Censorship of concerns, criticism, and legitimate facts also erode trust. Politics and bills that strip a minority of students of their federal privacy rights have health departments signing off on personal and religious beliefs, interfere with doctor-patient relationships, track medical information in registries without consent, and narrow medical exemptions in a manner that ignores individual, genetic, and environmental susceptibility as well. Education programs that make vaccination appear risk-free will not change minds.

Legislative mandates and coercion tactics playing out across America erode trust. Being from Colorado, Ms. Wrangham said, she added that the health department data in her state showed that exemptions declined over the kindergarten-through-12<sup>th</sup>-grade timeline as schools closed gaps on collecting vaccine information, as noted by the CDC. All that data was gathered by maintaining trust and also not asking people to give up their federal privacy rights.

Access issues should be resolved; however, it cannot be at the expense of rights. "Convincing" parents cannot be at the expense of transparency. The parents and doctors testifying and advocating against the Colorado bill understood that the overarching issues were human and civil rights and the exercise of informed consent. The continued ethical practice of medicine relies on the upholding of the informed consent ethic. Part of the role of government is to assure that the minority is able to exercise their rights and have equal protection under the law. As pointed out several times today, exemptors represent a minority that may delay or decline one or more vaccines.

Finally, NVIC has long supported access to vaccines as well as the critical need for an independent federal agency to monitor vaccine safety and safety research. NVIC has a long history of working with federal agencies to assist in informing policy-making and representing those with safety and informed consent concerns. Ms. Wrangham questioned NVIC's exclusion from recent undertakings and expressed concern about the lack of representation that exclusion represents.

# Adjournment

Dr. Hopkins adjourned the meeting for the day at 5:11 p.m.

# **Day Two—June 5, 2019**

# Chair's Welcome—Robert H. Hopkins Jr., M.D., MACP, FAAP, NVAC Chair

Dr. Hopkins recapped the first day of the meeting. Among the takeaways from day one were the need to engage the pro-science public in advocating for vaccination, to "diagnose" the reasons behind vaccine hesitancy among individuals before addressing their concerns, and to engage in social media but be prepared for pushback. Dr. Hopkins outlined the agenda for the day.

# Refueling the Vaccines Innovation Engine—Jennifer Heller and Tara Azimi, McKinsey & Company

Ms. Heller and Ms. Azimi summarized key points of their report, published in May, outlining data and ideas from experts in the field about innovation in vaccine development. Ms. Heller described the challenges to vaccine development, compared with other product development, which include the increased costs of research and development for preventive treatments; lower revenues for vaccines than other biologics; higher technical complexity; and increased uncertainty about commercial potential. McKinsey created profiles, or archetypes, to summarize areas of unmet need, their technical feasibility, and commercial potential:

		Description
1	High income + nosocomial	Target high burden diseases with large potential patient pools
2	Potential blockbusters	Target high burden diseases with large potential patient pools
3	Treatment vaccines	Used to fight an existing disease/condition, rather than a preventative measure
4	Incremental improvements	Improve existing vaccines to address unmeneeds (e.g., efficacy, duration, ease of use)
5	Emerging threats	Target emerging epidemiology threats and future priorities for innovation
6	Low income	Target diseases with higher burden in low income markets

Technical feasibility	Commercial potential
Moderate	Moderate
Low Moderate	High
Low Moderate	High
Moderate High	Low
Moderate	Low
Low Moderate	Moderate
	McKinsey & Company

Ms. Azimi outlined four potential approaches to address barriers:

- Demand clarity around priorities and commercial potential for products (e.g., target product profiles and public health priorities).
- Better communicate value by highlighting areas of common interest to the public and private sector.
- Create economic incentives, particularly for products with low commercial potential.
- Increase collaboration, data sharing, and transparency to overcome technical barriers.

Ms. Azimi said FDA is becoming more flexible in its guidance and is offering advice in the early stages of product development. Continued engagement is needed to ensure that development aligns with public health priorities.

#### Discussion

Ann Ginsberg, M.D., Ph.D., noted that the business model for product development partnerships (PDPs) to address urgent global health needs in low-income countries is not sustainable. Ms. Azimi said such partnerships have led to breakthroughs, such as MenAfriVac for meningitis A in sub-Saharan Africa, and it is critical to sustain them. She acknowledged that excitement around PDPs has tapered off. Ms. Azimi suggested a thorough assessment to identify the areas of highest return on investment as a good exercise to reignite interest. The next generation of PDPs might want to address vaccines across the lifecycle and focus on maximizing value, for example. Dr. Ginsberg said PDPs initially had strong support from regulators but product approval was more difficult than anticipated. She described work on a tuberculosis product that was forced to shut down because of lack of continued funding. Dr. Ginsberg stressed that funders must be willing to support the long development process (10–15 years) needed for products to reach approval.

Dr. Pickering asked how ACIP should take economics into consideration in its decision-making. Ms. Azimi said there are criteria and definitions around economic value, and ACIP considers products on a case-by-case basis. However, she called for better communication of the value of vaccines and their cost-effectiveness and a clearer understanding of the thresholds for making recommendations. Ms. Heller said the field recognizes that advanced recommendations are not feasible, but continuous dialogue could help minimize surprises that could derail development. Dr. Pickering pointed out that cost-effectiveness of vaccines is always a difficult calculation, as exemplified by the meningitis B vaccine.

Cody Meissner, M.D., FAAP, added that companies are reluctant to invest in products for emerging infectious diseases because the diseases can come and go suddenly, and large predicted outbreaks might never materialize. In general, he said, he did not think the goal is to have governments developing vaccines, but in some cases, that approach might be necessary.

Dr. Meissner floated the notion of limiting the duration of patents on vaccines to allow for manufacturing of generic equivalents, making the vaccines cheaper and more widely available. He acknowledged the concept might not be realistic but said many vaccines in development will not be fully justified by cost-effectiveness. Ms. Heller said biosimilar products have been slow to penetrate the U.S. market, and the clinical studies required to demonstrate effectiveness of a generic vaccine are too costly for many manufacturers to pursue. Ms. Azimi added that reducing prices over time is attractive to those in public health but not to business leaders for whom vaccines bring in a much lower return on investment than other biopharmaceutical products.

Dr. Meissner noted that NIH funds research that it hands off to product developers, who then profit from the product. He said there should be some mechanism for compensating taxpayers for their share of the risk. Ms. Heller said that continuing dialogue among stakeholders about the interplay of public health priorities, private investment, shared risks, and return will help advance the industry.

Dr. Friedland said vaccines are undervalued; he asked whether assessments of value take into account current knowledge and the impacts of related concerns, such as antimicrobial resistance. As vaccine development begins to focus on diseases that affect smaller, targeted populations, communication about value will play a crucial role in ensuring that vaccines reach the people who need them. Ms. Azimi responded that many assessments are based on past experience with vaccines; more discussion is needed about value, particularly for products for unmet needs.

Dr. Cooke pointed out that for biotechnology companies, the risk of failure is increasing; without clear market potential, investment dollars will go elsewhere. He noted that generic vaccines (which are available elsewhere) make the risk-benefit assessment less attractive for investors, who can turn their attention to more lucrative areas. Dr. Cooke added that the research investments made by NIH benefits taxpayers "tremendously" in the long run, and most of the costs of development are borne in phase II clinical trials, after NIH support has ended.

Dr. Fleming said that if one goal is to increase development and manufacturing of vaccines in low-income countries, there must be capacity to support that, such as regulatory pathways to commercialization, technology transfer, and postmarket surveillance. Dr. Fleming also pointed out that for emerging infectious diseases, the current economic model, based on sales per dose, is not viable, especially if the goal is to stem the disease before it spreads widely. Instead, a financing model is needed that looks more like an insurance policy, in which investment is made upfront to pay for a vaccine so that it is ready when needed, rather than paying for the vaccine per dose. Ms. Azimi and Ms. Heller both noted that BARDA has applied such a model for smaller biotechnology firms and in emerging markets overseas. BARDA is also partnering with CDC on creating and reserving vaccine for outbreaks, but the approach is economically challenging.

Ms. Azimi noted that Gavi, the Vaccine Alliance, is working to help countries become more self-sufficient in financing vaccines for their populations. As these countries graduate from Gavi support, many questions must be answered about how these countries will maintain access to vaccines at the scale needed. At the same time, in the past 5 years, international organizations such as UNICEF, WHO, and Gavi have invested considerably in vaccine market access in developing countries to improve supply chains and support manufacturing capacity, for example.

Dr. El Sahly reiterated the point that advanced recommendations are not tenable, and ACIP and FDA cannot fully assess a product until they have the results of efficacy studies. She added that the global pharmaceutical enterprise receives support from governments and nongovernmental organizations and, as such, has a role in public health, beyond the economic perspective. Ms. Heller responded that the industry is advocating for increased dialogue to better understand ACIP perspectives around cost-effectiveness, not advanced recommendations. Dr. El Sahly believed such dialogue is underway in the United States and Canada, at least around the design of phase III clinical trials.

Ms. Charos recommended mapping out the governance and decision pathways for the various vaccine innovation archetypes described by McKinsey, because different types of products appeal to the interests of different funders.

Ms. Butler questioned whether the country is adequately prepared for potential emerging infectious diseases, particularly those such as Ebola virus, which have existed elsewhere for years. She proposed a tax to support vaccine innovation as well as communication to ensure that vaccines reach the people who need them. It is important to explain, for example, that polio remains a concern even though it has been eradicated in the United States.

# **NVAC Liaison and Ex Officio Updates**

# AHRQ AND THE U.S. PREVENTIVE SERVICES TASK FORCE (USPSTF)—JUSTIN A. MILLS, M.D., M.P.H.

The USPSTF makes evidence-based recommendations on primary care services, although most recommendations on vaccination go through ACIP. USPSTF is updating its 2014 recommendation on hepatitis B virus (HBV) screening for nonpregnant adolescents and adults. The 2014 evidence review found that HBV vaccination can reduce the risk of acquiring HBV among high-risk populations, but it could not determine the impact of vaccination on long-term health care outcomes. A preliminary literature scan showed no new evidence addressing HBV vaccination; the ongoing evidence review will not be revisited because the efficacy of HBV vaccination is well established.

The updated analytic framework for the updated screening and recommendation notes that HBV vaccination is recommended for patients with positive isolated anti-HBV test results who are from countries with a low prevalence of HBV infections and who are moving to the United States or are immunocompromised. The research plan was posted in March 2019, and a systematic review is in progress.

The USPSTF is also updating its 2009 recommendation on HBV screening in pregnancy. The USPSTF found convincing evidence that universal prenatal screening for HBV infection reduces perinatal transmission of HBV and subsequent development of chronic HBV infection. The Task Force found adequate evidence that vaccinating all infants against HBV infection and providing postexposure prophylaxis at birth to newborns of mothers infected with HBV substantially reduce the risk of acquisition of HBV infection among infants. This recommendation was posted for public comment as a level-A recommendation, and the final recommendation is upcoming.

## BARDA—LINDA LAMBERT, PH.D.

On the vaccine preparedness front, BARDA is currently supporting three phase II clinical trials, one on H7 influenza and one on H5. BARDA is also supporting the development of seasonal and pandemic influenza vaccines that yield broader and more durable immune responses. BARDA continues to support late-stage development of products to address anthrax and smallpox, specifically expanding the use of vaccines for those threats to selected, at-risk populations (in particular, the pediatric population). In March 2019, BARDA awarded a development contract for a vaccine against Marburg virus.

In 2016, BARDA launched the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) with a number of collaborators. It recently gave an award to a company developing a vaccine to prevent methicillin-resistant *Staphylococcus aureus* (MRSA) based on toxoids that collectively provide protection against toxoids secreted by staphylococci.

BARDA continues to develop targeted vaccines for a number of areas. Vaccine development and manufacturing platforms that are rapid, integrated, and may be amendable to shifting to different infectious diseases or different applications is a very high priority. BARDA reaches out to developers and hosts tech watches, where companies at various stages of product development

meet with BARDA subject matter experts to describe their candidates and programs. BARDA assesses the product and offers guidance on how BARDA, NIH, or others can help, depending on the stage of effort. Companies are always welcome to avail themselves of BARDA's expertise and to take advantage of free clinical services for early development. BARDA works closely with federal partners, including other HHS agencies and DoD.

### CDC—MELINDA WHARTON, M.D., M.P.H.

At its February meeting, ACIP voted to recommend Japanese encephalitis (JE) vaccine for people who are relocating to JE-endemic countries and to longer-term or frequent travelers to JE endemic areas. The vaccine also should be considered for shorter-term travelers with an increased risk based on a variety of factors. The ACIP also voted to recommend a booster dose of anthrax vaccine to be given every 3 years to people who are not currently at high risk of exposure who have been previously vaccinated and wish to maintain protection.

The ACIP will meet next on June 26–27, 2019, and is scheduled to votes on expanding the age recommendation for HPV vaccine and reconsidering routine administration of pneumococcal vaccine to immune-competent adults aged 65 and older. It will also vote on influenza, meningococcal, hepatitis, and combination vaccines.

From January 1 through May 31 of 2019, 981 cases of measles have been confirmed in 26 States. This total is the greatest number of cases reported in the United States since 1992 and since measles was declared eliminated in 2000. Outbreaks are currently ongoing in a number of geographic areas. They are linked to importation from other countries where large measles outbreaks are occurring. CDC teams have deployed in Washington and New York to assist with outbreaks, including providing epidemiologic and communication support. CDC has created a measles outbreak toolkit to provide health care professionals and health departments with more vaccine resources to use in their communities. The toolkit for health care professionals includes tips for making strong recommendations and answering parents' questions about MMR vaccines and a video on diagnosing measles. CDC's website for health departments has graphics for public health use as well as a letter template that can be customized for outbreak situations.

The 2018–2019 influenza season finally ended after 21 weeks, breaking the previous record of 20 weeks during the 2014–2015 influenza season. The influenza A H1N1 virus predominated during the first part of the season. Later in the season, H3N2 predominated nationally; it is typically associated with more severe illnesses in older adults. Indicators are consistent with a season of moderate severity. CDC estimates that more than 500,000 people were hospitalized with influenza this season. To date, 109 influenza-related pediatric deaths have been reported to CDC. The total for last season (2017–2018) was 186.

At the NAIIS in May, manufacturers reported their estimates for influenza vaccine production for the upcoming season. The estimates were similar to those projected last year—in the range of 160 million to 165 million doses.

Dr. El Sahly asked whether data exist yet on the effectiveness of the influenza vaccine for this year. Dr. Wharton believed it was in the same range as recent years, with slightly higher effectiveness among children than older people. This year's vaccine strain did not match the H3N2 circulating strain, which impacted effectiveness.

### DOD-LT COL CHRIS ELLISON

Significant ongoing organizational changes throughout the military health system have had minimal impact on DoD's immunization approach and delivery program. For example, the Immunization Health Care Branch, working closely with the product manufacturer for yellow fever vaccine, has maintained product availability to support worldwide DoD operations despite product supply constraints. Major lines of effort supporting this success included restricted administration criteria, site ordering limitations, and active product redistribution. The Yellow Fever Vaccine Redistribution Program inside the DoD during the national shortage from April 16 through March of 2019 had 6,574 doses worth \$400,000.

The DoD met all of its immunization targets during the 2018 influenza season, including mandatory vaccination of uniformed personnel and health care providers in the DoD system. Preparations for the 2019–2020 influenza season are underway, with final publication of the seasonal influenza vaccine policy guidance pending.

The Pragmatic Assessment of Influenza Vaccine Effectiveness study, co-chaired by the Immunization Health Care Branch and the Infectious Disease Clinical Research Program at the Uniformed Services University, completed its first year of enrollment, with the aim of assessing the clinical effectiveness of licensed influenza vaccines used by the DoD. The study group has enrolled 1,623 participants into the main study at five different sites so far; it aims to enroll 13,500 subjects from 11 sites. Two hundred of those participants were also enrolled in an immunogenicity substudy developed in partnership with the Armed Forces Health Surveillance Branch, the Naval Research Center, the U.S. Air Force School of Aerospace Medicine, and FDA.

### FDA—VALERIE MARSHALL, M.P.H.

Dengue disease is a major global public health concern and is endemic in the U.S. territories of American Samoa, Guam, Puerto Rico, and the U.S. Virgin Islands. On May 1, 2019, FDA approved Dengvaxia, a dengue virus vaccine manufactured by Sanofi Pasteur. Dengvaxia was approved for the prevention of dengue disease cause by all dengue viral types (1, 2, 3, and 4) in people ages 9 through 16 years of age who have laboratory-confirmed previous dengue infection and who live in endemic areas. Dengvaxia is not approved for use in individuals not previously infected by any dengue virus strain type or for whom this information is unknown. Health care professionals should evaluate individuals for prior dengue infections to avoid vaccinating individuals who have not been previously infected by dengue. The safety and effectiveness of this vaccine was determined by three randomized, controlled studies involving approximately 35,000 individuals in dengue-endemic areas, including Puerto Rico, Latin America, and the Asian Pacific region.

## HRSA BPHC—JUDITH STEINBERG, M.D., M.P.H.

The BPHC funds and administers the Health Center Program, the country's safety net for primary care, with nearly 1,400 health center organizations that operate over 12,000 sites serving 27 million people. In September, the BPHC will have annual health center data on a clinical quality measure of the percentage of children fully immunized by age 2 years.

HRSA is supporting health centers around the measles outbreak through several forms of technical assistance and training. A weekly e-newsletter is the main form of communication in delivering that training. In May, the newsletter addressed what health centers can do to promote measles vaccination. It was a very quick snapshot for busy practitioners that included links to resources from CDC, the Surgeon General, and the American Academy of Family Practice. Approximately 34,000 people receive the newsletter, and the measles links were among the top

five items most read. A follow-up feature is planned on what health centers can do to protect their staff and contribute to infection control during the measles outbreak. Dr. Wharton added that the Health Center in Rockingham County, NY, has been "heroic" in its response to the measles outbreak there.

### HRSA DICP—MARY RUBIN, M.D.

The National Vaccine Injury Compensation Program (VICP) has continued to process an increased number of claims. In fiscal year (FY) 2018, 1,248 claims were filed with the VICP, \$226.6 million was awarded to petitioners, and \$26.9 million was awarded in attorneys' fees and costs (including fees for compensated, dismissed, and interim cases). In FY 2019, as of May, 709 claims have been filed with the program, and \$154.7 million has been awarded for petitioners and for attorney's fees and costs. HRSA has a backlog of 726 claims alleging vaccine injury awaiting review. More data about the program can be obtained at <a href="http://www.hrsa.gov/vaccinecompensation/data.html">http://www.hrsa.gov/vaccinecompensation/data.html</a>. As of February 1, 2019, the Countermeasures Injury Compensation Program has compensated 39 claims totaling \$5.5 million. VICP outreach efforts continue to focus on making providers and the public aware of this safety net program.

In response to Dr. Pickering, Dr. Rubin said the most common claims involve shoulder injury related to vaccine administration (SIRVA) and Guillain-Barré syndrome. Dr. El Sahly said reports of SIRVA appear to be increasing consistently, which may represent an opportunity for NVAC or others to provide education.

### NIH—ANDREW FORD, PH.D.

The National Institute of Allergy and Infectious Diseases (NIAID) issued two awards to establish longitudinal cohorts of infants to determine how initial and repeated infections or vaccinations change infant and childhood immunity to future influenza exposures. By studying children's immune responses to early influenza infection and subsequent exposures, the investigators seek to understand the factors underlying immune memory and a person's ability to amount an immune response to different influenza subtypes. The research could inform the design of more effective influenza vaccines or address the knowledge gap identified in the NIAID strategic plan for developing a universal influenza vaccine.

Additionally a phase I clinical trial is being conducted at the NIH Clinical Center examining the safety and tolerability of an innovative universal influenza vaccine candidate developed by NIAID. This candidate vaccine is design to teach the body to make protective immune responses against diverse influenza subtypes by focusing the immune system on a portion of the virus that varies little from strain to strain. The trial will enroll adults ages 18 to 70 years; investigators hope to understand how participant immune response to the experimental vaccine may vary based on age and likelihood of previous exposure to different influenza variants.

Lastly, NIAID published a funding opportunity announcement to establish a coordinated network of emerging infectious disease research centers in regions around the globe where emerging and reemerging infectious diseases are likely to occur. This program is designed to improve knowledge of emerging and reemerging infectious diseases, including their natural history, incidence, and prevalence; complement and leverage existing NIAID international research efforts; and allow NIAID to develop the flexibility and capacity to respond rapidly and effectively to outbreaks where they occur.

#### USDA—GEETHA SRINIVAS, D.V.M.

The latest foreign animal disease threat to the U.S. agricultural economy is African swine fever, a viral disease. The virus has existed for thousands of years, but in the early 1900s it was identified in domestic pigs. (It also exists but causes no disease in wild pigs.) The mortality rate is very high. African swine fever stayed within the sub-Saharan regions where it was identified until the late 1900s. In the 1980s it was identified in Europe; by the 1990s, through strict slaughter measures, it was eradicated in couple of European countries, such as Prague and Spain.

Until the early 2000s, the disease did not spread beyond Europe. In August of 2018, China reported its first case. By September, it had crossed borders and affected several Southeast Asian countries. China has taken strict measures to control any movement of pigs, alive or dead, and pork products. No vaccine exists for this disease, and it has a very complex host immune mechanism. Several research organizations in the European Union, the United States, and Canada have been working together to find an effective recombinant or modified live vaccine.

In the absence of any vaccine, the best strategy is surveillance and slaughter. Currently, the United States has put several measures in place, including surveillance similar to that used for classical swine fever virus. USDA is partnering with federal and state organizations to ensure that diagnostic measures and surveillance are in place. Investigations will begin that include evaluating incidents involving sick and dead feral pigs. USDA's is working with officials in Canada and Mexico on coordinated activities to prevent the spread of disease. USDA is also working with U.S. Customs and Border Control at ports of entry to prevent importation of pork products from affected countries. Affected or contaminated meat has been confiscated at the borders from several countries, such as Japan and Australia. Finally, USDA is also working closely with stakeholders on a response plan should infections occur.

# VA—TROY KNIGHTON, M.Ed., Ed.S., LPC

To date, no cases of measles have been reported within the Veterans Health Administration. The VA has communicated guidance and recommendations for screening, vaccination, and testing for measles, including a national call with the VA's director of infectious diseases, which about 300 providers attended. The VA completed its clinical guidance on hepatitis A and has almost completed guidance for hepatitis B. It released educational resources to the field on both.

About 2.1 million veterans received influenza vaccination this past influenza season, and about 111,000 of those were vaccinated through a partnership with Walgreens pharmacy. The VA continues to hope to expand the pharmacy program to other retailers across the country; so far, only Walgreens has met the program's contractual requirement.

The 2018–2019 influenza season was the second season for which FLUAD trivalent vaccine was available. About 22 percent of those within the VA system received FLUAD. There were no identified adverse reactions for any influenza vaccine this year. Just over 130 deaths related to influenza occurred.

Dr. Meissner asked whether the VA has data on the infection rate among those who received the adjuvanted vaccine compared with those who received the standard vaccine. Mr. Knighton replied that such information might be in the database but the question has not been posed. He added that individual sites choose the types of vaccine they order.

## AHIP—CHRISTOPHER REGAL, M.S.

Mr. Regal said AHIP would be naming a full-time NVAC liaison in the near future.

#### AIM—KRISTEN R. EHRESMANN, RN, M.P.H.

AIM is supporting immunization programs as they work to contain measles and hepatitis A outbreaks. It has provided webinars with presentations from the affected states that allowed everyone to learn from best practices. AIM is hosting regional meetings for program managers so that they can share successes and challenges with neighboring programs. It took part in the NAIIS in May. AIM continues to release chapters of the Adolescent Resource Guide featuring programmatic strategies to increase adolescent vaccination rates. Chapters 5, 6, and 7 have been released in the past 6 months. The guide also includes a toolkit with short videos and an adolescent resource library, which can be accessed on the AIM website. The AIM Leadership Institute provides training for new and experienced program managers.

### APHA—JEAN-VENABLE "KELLY" GOODE, PHARM.D.

APhA has trained over 300,000 pharmacists who provide vaccine education and access to communities across the country. In March, APhA held its annual meeting and gave its 12 Immunization Champions awards to notable individual pharmacists, friends of pharmacy, and corporations. As part of training and education, APhA holds a webinar after every ACIP meeting. It has also partnered with CDC on an HPV webinar to help pharmacists make recommendations and referrals around adolescent vaccines. Dr. Goode described APhA's online quizzes, which address topics such as immunization administration, vaccine storage and handling, adult immunizations, and HPV vaccine. The immunization administration quiz helps pharmacists make sure they know how to give injections and understand the SIRVA problem. APhA continues to publish about immunization topics in the *Journal of the American Pharmacy Association*.

### PHAC—GINA CHAROS

As of May 31, 2019, 63 confirmed cases of measles were reported to PHAC. Cases have been reported in six of 13 provinces and territories: British Columbia, Alberta, Ontario, Quebec, New Brunswick and the northern territory of Inuvik. Of all cases reported to date, most have been acquired outside of Canada. Most are among unvaccinated or undervaccinated people. To date, Canada has had two outbreaks, one small outbreak in British Columbia that ended in early March and a second outbreak, which is ongoing, in the province of New Brunswick. The latter is affecting at least one high school, so the number of measles cases is expected to rise. By comparison, 29 cases of measles were reported in 2018 and 45 in 2017.

In response, Canada's chief public health officer issued a statement to the public and health care providers expressing concern about vaccine hesitancy and in particular the proliferation of misinformation online. As in the United States, Canadian authorities have been working with social media organizations such as Facebook and Twitter to advance strategies that promote credible information about vaccination and reduce the spread of misinformation.

Results of PHAC's 2017 Childhood National Immunization Coverage Survey were released in March. (Canada does not have an interoperable national vaccine registry.) The survey found national coverage by age 2 was estimated to be 90 percent for MMR vaccines and 76 percent for diphtheria, tetanus and pertussis vaccines. The vast majority of Canadian parents reporting that they are vaccinating their children. Only 2.3 percent of parents of 2-year-old children report that they had not given their children any vaccines. However, the country has not met any of it childhood vaccination coverage goals of 95 percent in any age groups. In terms of knowledge, attitudes, and beliefs most parents agree that childhood vaccines are safe (94 percent) and effective (96 percent). However, about 13 percent of parents also report that they believe that alternative practices such as homeopathy and chiropractic can replace vaccines.

Like the United States, Canada experienced a longer than usual influenza season. In 2018–2019, H1N1 influenza was the predominate subtype overall, and it reached peak levels in the last week of December. However, a subset of a smaller spring wave of influenza H3N2 began in mid-February. Canada had very little influenza B circulating this year as compared with previous years, so it was a strange season. Mid-season vaccine effective assessments were published in January for H1N1, which was the predominate circulating strain at that time, and estimated at 72 percent overall, with substantial protection observed in all age groups but even higher for children.

Given the atypical late-season wave of influenza H3N2, the Canadian Central Practitioners Surveillance Network assessed vaccine effectiveness against the H3N2 strain and determined it was poor, 23 percent overall. Among adults ages 20 to 64 years, effectiveness was very low, suggesting the vaccine provided little or no protection at all for the H3N2 strain.

The National Advisory Committee on Immunization (NACI, the equivalent to the ACIP) is working on developing methods for vaccine-specific economic assessments as well as approaches to integrate other programmatic factors into guidance, such as ethics, equity, feasibility, and acceptability. One federal policy objective is to provide as much information as possible to decision-makers at the provincial and territorial level so that they can make timely decisions about vaccine introduction. In Canada, recommendations are made at the national level but the decision to list or not list is made by the provinces and territories. The NACI initiative seeks to develop cost-effectiveness guidelines specific to vaccines in Canada. In addition, NACI has recently committed to providing advice on vaccine stockpiles for high-consequence pathogens. The first project underway is interim guidance for the Ebola virus vaccine, which NACI hopes to complete by this fall.

Dr. Meissner asked whether Canada had data on the effectiveness of live-attenuated influenza vaccine (LAIV) compared with the killed vaccine, both of which were available in Canada last year. Ms. Charos said that when the ACIP issued its recommendation to not use the LAIV, Canada and other countries had a preferential recommendation for children. There was no evidence to suggest that it should not be recommended, but the evidence could have been stronger, so Canada removed the preferential recommendation. This recommendation as it stands for children is that any quadrivalent influenza vaccine should be used, whether inactivated or live, and if the quadrivalent is not available, trivalent vaccine should be used. However, comparative data are not available. Ms. Charos said the product is rarely used in Canada now, and use has been dwindling over the years.

# Update on the U.S. National Action Plan on Combating Antibiotic-Resistant Bacteria (CARB)—Amanda Cash, Office of the Assistant Secretary for Planning and Evaluation, HHS

Ms. Cash outlined the five goals of the current National Action Plan on CARB for 2015 to 2020 and HHS activities underway to achieve them. A federal interagency Task Force is charged with updating the Plan for 2020 to 2025. It is working closely with the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) to get input from stakeholders and the public. Ms. Cash said the updated plan will strive to be more streamlined, incorporate PACCARB input, and ensure that mechanisms are in place to measure progress toward the goals. It is hoped that the Government Accountability Office will complete its assessment of antibiotic resistance in time for inclusion in the updated Plan. In addition, CDC is updating its report, Antibiotic Resistance Threats in the United States, 2013.

The 2020–2025 Plan will retain the five goals of the current Plan and use the same framework. Annual progress reports on the 2015–2020 Plan are available online. PACCARB will recommend new priorities within the five goals. Ms. Cash said HHS aims to publish the updated plan by the summer of 2020.

#### Discussion

In response to Dr. Fleming, Ms. Cash said attention to the role of vaccines in addressing antibiotic resistance remains high. Dr. Friedland said NVAC's 2015 report on antimicrobial resistance recommended a PACCARB member take part in NVAC meetings. (Dr. Cooke later noted that there have been good links between NVAC and PACCARB through NVPO leadership and that he has participated in PACCARB WGs.) Dr. Friedland also recommended more economic modeling demonstrating the value of vaccines in preventing antimicrobial resistance.

Dr. Pickering asked about the status of resistance. Ms. Cash said trends in the United States are improving, but there is much work to do. Dr. El Sahly pointed out that the contributions of vaccines to reducing antimicrobial resistance (e.g., by preventing pneumonia) will be threatened if vaccine coverage declines. Dr. Cooke noted that the pipeline for vaccines against antimicrobial-resistant pathogens is not robust. He also said the CDC's 2013 report was very helpful and praised CDC for updating it.

# Update: A Vaccine Candidate against *Clostridium Difficile*—Shon Anthony Remich, M.D., Pfizer

Dr. Remich outlined the burden of *C. difficile*. The risk increases with age, and *C. difficile* is most fatal in those 65 years and older. Many efforts are underway to address hospital-acquired *C. difficile*, but community-acquired cases are rising. Dr. Remich described the development of Pfizer's vaccine candidate, which uses polyclonal antibodies to neutralize toxins.

The vaccine is in phase III clinical trials in 23 countries. Adverse effects detected so far appear to be mild. Participants in the phase III trial needed a lot of training, because they were required to digitally record any symptoms after vaccination and to collect and submit stool samples.

### Discussion

Discussion centered around specifics of the product and plans for upcoming clinical trials. Dr. Cooke said the presentation underscores the cost, effort, and challenges involved with vaccine development. Successful development would elevate the whole field, he added.

## **Promising Approaches in Adult Immunization**

# Update on NAIIS Activities—Carolyn B. Bridges, M.D., Co-Chair, NAIIS Access and Provider WG

Dr. Bridges described the origins and organization of the summit, outlining the agenda of the May 2019 summit. The bulk of the effort among summit members occurs within its WGs. Accomplishments of the Access and Provider WG include collaborating around adult immunization in health care systems, developing business cases to support adult immunization, and funding an effort to identify policy barriers to vaccine access in federally qualified health centers. The WG plans to revisit the concept of a reporting code for vaccine counseling of adults when vaccine is not administered; monitor the impact of new adult immunization quality measures; and identify how the summit can improve use of IIS' to support vaccination.

The Influenza WG developed and published "Guidance for Leaders/Administrators in Post-Acute and Long-Term Care Facilities Who Plan to Improve Staff Influenza Vaccination Compliance through Vaccination Requirement Policies" with a corresponding checklist, honor roll, and pledge to support employee vaccination. It is developing slide sets for speakers and working on partnerships to promote influenza vaccination modeled after successful public health campaigns. The WG aims to expand partnerships to promote vaccination coverage in non-health-care workplaces. The Quality Measures WG supported development of two new measures of adult vaccination that became effective on a voluntary basis in 2019. It will monitor the progress of these and other related measures.

Dr. Bridges said the Influenza Vaccine Availability Tracking System will be available for the 2019–2020 influenza season to help providers find vaccine for purchase if needed. It can be found at the summit's website, along with summit presentations, awards, and other information.

Healthcare Effectiveness Data Information Set (HEDIS) Immunization Quality Measures—Sepheen Byron, National Committee for Quality Assurance (NCQA)

Ms. Byron described the process of developing and implementing HEDIS measures, emphasizing that HEDIS measures are particularly helpful for tracking services obtained outside of a provider's office, as is common with influenza vaccine. Data are primarily gathered from claims, but new standardized, electronic data formats offer the opportunity to collect better data which, it

is hoped, will facilitate harmonization and increase accountability across the health care system.

All of the data sources and reporting mechanisms are now being captured through HEDIS' Electronic Clinical Data Systems method, which will provide a structured, standardized repository of data that clinical care providers can access. Collecting and sharing electronic data require strong collaborations between plans, providers, and others, as well as incentives, said Ms. Byron.

Two new HEDIS vaccination measures took effect in 2018: adult immunization status and prenatal immunization status. Both are in voluntary reporting status now as HEDIS ensures that the specifications are appropriate and consistent with information provided during field testing. After at least 1 year of voluntary reporting, NCQA assesses the feasibility and utility of new measures, with input from its multistakeholder approval panel. HEDIS measures are also used by programs such as Medicare's star ratings program and Medicaid's Adult and Child Core Sets.

Accomplishments and Promising Approaches in IIS—Rebecca Coyle, M.S.Ed., AIRA Ms. Coyle noted that 95 percent of all children less than 6 year old are captured within an IIS, as are 79 percent of adolescents (ages 11–17) and 51 percent of adults. She focused on efforts behind the scenes to build the infrastructure that will allow information to flow from IIS' to EHRs. For example, AIRA is measuring how IIS' adhere to existing standards and advising state and local health departments on how they can improve adherence and functionality. This initiative assesses how well systems can exchange data; AIRA is now determining how to evaluate the quality of the data exchanged. State and local health departments are participating voluntarily; they benefit by receiving concrete information that their information technology departments can use to improve their systems. AIRA is already seeing improvement among IIS' compared with baseline performance on various measures.

Ms. Coyle explained that not all IIS' and EHRs can communicate effectively, but the capacity is increasing rapidly. AIRA recently mapped out the process of onboarding—linking an IIS with an EHR to exchange data—and published consensus-based recommendations for the field. For

providers, AIRA is working on instructions and information on what to anticipate throughout the onboarding process.

Some jurisdictions are finding novel ways to take advantage of their IIS'. For example, Ms. Coyle noted, IIS can monitor the immunization status of transient individuals during an outbreak. Some departments of corrections are tracking inmates' hepatitis A vaccination status using their jurisdiction's IIS, thus ensuring that resources are not wasted on duplicate vaccinations. During the measles outbreak, Minnesota used its IIS to verify vaccination status of children who were exposed. Minnesota also quantified the hours and dollars saved thanks to the existence of an IIS. AIRA has developed several brief fact sheets that help communicate the role and value of IIS.

#### Discussion

Responding to Dr. El Sahly, Ms. Coyle said the ultimate goal is for health care providers to be able to quickly determine what vaccinations a patient needs. Dr. Hopkins pointed out that tracking quality measures is challenging and time-consuming for providers, who might not see the benefits of their individual efforts. Ms. Coyle appreciated the difficulty of rallying individual providers around a common goal of tracking immunizations with very limited resources. Ms. Byron added that NCQA hopes effective exchange of electronic data will decrease the burden on providers and that quality measures incentivize the use and flow of information.

Dr. Hopkins pointed to several gaps that must be filled before there is a seamless system of communication among IIS' and EHRs. He noted Canada's app, which serves as a personal vaccination record. Ms. Coyle said AIRA is working with HHS and others on IZ Gateway, which aims to connect the VA and DoD EHR systems. Ideally, IZ Gateway will provide a single entry point that allows multiple jurisdictions to exchange data.

Dr. Dunn asked about legal restrictions that limit uses of IIS' more broadly—for example, in managing outbreaks. Ms. Coyle said state laws dictate the use and utility of IIS'. She emphasized that linking IIS' across States faces policy challenges, not technical barriers. In a federated system, individual jurisdictions must craft agreements with neighbors on how to exchange data.

Dr. Hopkins posited that mandated interstate information exchange around opioid prescribing might be a model for improving immunization information exchange across states. Dr. Wharton reiterated that the technical capacity is not a problem; rather, policies are needed that compel jurisdictions to exchange such data. Dr. Hopkins hoped NVAC members would talk to their colleagues about the importance of data exchange. Ms. Coyle said AIRA has been trying to disseminate lessons learned from IIS' to ensure that States developing systems for tracking opioid prescribing do not focus their efforts too narrowly.

Jim Daniel of the Office of the Chief Technology Officer at HHS said the technology exists at the federal level to enable state IIS' to communicate with one other. HHS envisions the system supporting exchange of data for people when they move or seek care out of state or are suddenly displaced from their homes, for example. The barriers to joining stem from individual state policies, primarily the state's desire to enforce barriers on how data can be used.

### Remarks from the Surgeon General—VADM Jerome Adams, M.D., M.P.H.

Dr. Adams thanked NVAC members for their commitment to promoting vaccines. He stressed that most parents have gotten the MMR vaccine for their children; reaching those who have not requires going into communities and understanding that every outbreak is different. Dr. Adams cautioned against overcharacterizing all those who have not vaccinated their children as resistant.

Rather, more attention is needed to how to better deliver the information parents need in a compassionate way so they can make an informed decision for their children.

For example, some providers in Washington State offer after-hours grand rounds, where parents can talk to doctors outside of the 15-minute well-child visit. Other options are needed to increase access to vaccination for parents who cannot take time off to visit the doctor's office during regular working hours.

Further efforts are needed to communicate the risk to the broader community of not being vaccinated. In Washington, 800 children stayed home from school because of a single case of measles. Colleges have shut down, and pregnant mothers are afraid to go out in public for fear of exposing their fetuses to measles, Dr. Adams said. The economic and social impact goes beyond the individual impact.

In addition to an editorial, "The Truth About Vaccines," in the New York Times that he coauthored with Dr. Giroir and Dr. Redfield, the Surgeon General inaugurated a video series on Twitter, The Doctor Is In, with an episode on vaccines. He traveled to Arizona to talk with the governor, emphasizing the potential economic impact that an outbreak of vaccine-preventable disease could have. He visited Oregon and Washington to see firsthand the measles outbreak. Dr. Adams and other HHS leaders have promoted vaccination through high-profile, mainstream media and through more targeted efforts, such as meeting with "mommy bloggers." Dr. Adams emphasized the importance of finding and talking to new and different audiences.

#### Discussion

In response to Dr. Pickering, Dr. Adams said he is attending a meeting of the American Medical Association and working with medical societies such as the American Academy of Pediatrics and the American Hospital Association on immunization priorities. He welcomed suggestions of other potential partners.

# Usability Testing of CDC Adult Immunization Schedule—Candice Robinson, M.D., M.P.H., CDC

Dr. Robinson explained that CDC conducted a formal evaluation of usability of its adult immunization schedule to determine how providers use the schedule to guide their practice. The goal was to gather input through in-depth interviews with users on how CDC could improve the appearance and utility of the printed schedule.

The interviews revealed that although providers recommended vaccines, they were not confident that their EHRs were updated and comprehensive, and they had difficulty using the generic and trade names for vaccines. Most referred to the recommendations based on age only. Few referred to the recommendations by medical and other indications, and even fewer ever looked at the footnotes. Almost no one acknowledged using the table of contraindications and precautions. Many felt confident in their use of the schedule—even though they used it incorrectly when asked to respond to questions based on scenarios. The interviewees offered almost no suggestions for improving the schedule.

With little direction from users, CDC embarked on a redesign to address the potential for misuse and confusion. It also redesigned the schedules for children and adolescents to ensure a consistent approach and appearance. CDC reduced the amount of information on the cover page and used graphics to compartmentalize information. CDC added a table of generic and trade names and their abbreviations; the footnotes were renamed "notes" to convey the idea that they are meant to

be used in concert with the text. Contraindications and precautions were indicated with a link to the website but deleted from the printed schedule. The revised schedule added boxed text on how to use the schedule. A survey found that most users preferred the new format.

#### Discussion

Several participants discussed the potential for developing a calculator or app to simplify use of the schedule. Dr. Wharton said CDC's clinical decision support is updated whenever ACIP recommendations are updated, and IIS' use those tools. Any practitioner with a connection to an IIS can use the IIS to determine what vaccines are needed. Many EHRs incorporate CDC's forecasting algorithms. Dr. Wharton emphasized that the more practitioners use CDC's decision support tools, the more consistent vaccination recommendations will be. In addition, CDC has an online tool that individual adults can use to determine what vaccines are indicated for them depending on their medical status, as well as an app specific to pneumococcal vaccine.

In response to Justin A. Mills, M.D., M.P.H., Dr. Robinson said there has been discussion of adding information about catch-up vaccination schedules for children, but the childhood vaccine schedule has limited space for new text. For complicated catch-up schedules, CDC offers job aids online, which are easier to use than the catch-up table in the schedule. Dr. Mills suggested translating the catch-up job aids into an app.

Dr. Dunn appreciated the redesign; he particularly liked the decision to move the contraindications and precautions to the website, because people are likely to misuse information that is condensed and abbreviated. He suggested CDC survey the same users from the initial interviews to determine whether they are using the redesigned schedule correctly.

# Pan American Health Organization (PAHO): Towards Cervical Cancer Elimination in the Americas—Silvana Luciani, PAHO

Significant disparities exist in cervical cancer rates between poor and wealthy countries around the world, said Ms. Luciani. Mortality rates are declining but persist in countries with poor access to health services and technologies. Disparities also exist within countries, and different strategies are needed that prioritize populations with the highest rates of cervical cancer. In the Americas, because of the growing number of older people, cervical cancer mortality is projected to increase 34 percent by 2030. Ms. Luciani said the problem can and must be addressed now with prevention, early detection, and treatment.

Of the 44 countries that make up the Americas, 34 have introduced HPV vaccine. However, coverage rates range around 50 percent to 60 percent in most countries, and monitoring of coverage needs improvement. These countries generally have well-organized, well-funded vaccine programs, and overall acceptance of HPV vaccine for girls has been good. However, antivaccine messages have proliferated, and vaccine hesitancy has been fueled by some incidents in Columbia, Brazil, and Peru that made global news.

To address barriers to treatment, consideration is being given to various alternatives, such as screen-and-treat protocols that do not require referral to another provider. Ms. Luciani said PAHO is advocating that more countries integrate HPV testing to improve the quality and coverage of cervical cancer screening. The goal is to promote a "package" of vaccinating girls and testing their mothers. Challenges to scaling up the strategy are limited funding, competing public health priorities, lack of awareness, resistance to changing clinical practice, and costs of new technologies.

In recognition of challenges around the world, WHO initiated a global strategy for eliminating cervical cancer, with a commitment from 70 countries to rally their public and private institutions. Among the key questions to answer is what threshold must be reached to consider cervical cancer eliminated. The strategy of vaccinating adolescent girls (the current global recommendation) and screening all women will not result in elimination, according to modeling. PAHO is recommending a focused strategy of HPV vaccination, screening, and precancer treatment to speed up the timeline toward elimination.

PAHO has developed a plan of action with the goal of reducing the incidence and mortality rates of cervical cancer by one third by 2030 through the following steps:

- Improve cervical cancer program organization and governance, information systems, and cancer registries.
- Strengthen primary prevention through information, education, and HPV vaccination.
- Improve cervical cancer screening and precancer treatment through innovative strategies.
- Improve access to services for cancer diagnosis, treatment, rehabilitation, and palliative care.

PAHO has developed tools, training opportunities, and a communication campaign to support the goal. Ms. Luciani called on NVAC members and their networks to increase advocacy and communication around HPV vaccination and cervical cancer prevention. She also called for more investment in strengthening health systems and ongoing dissemination of evidence.

#### Discussion

Dr. Hopkins felt that getting rid of cervical cancer will require eliminating HPV. To do so, it is important to vaccinate men as well as women. Messaging should emphasize the benefits that vaccinating men will have on women (although some will benefit directly from reduction in other cancers related to HPV that affect men). Ms. Luciani said current efforts are focused on vaccinating girls because of cost and feasibility. Some modeling has determined that vaccinating boys will speed up progress toward the goal but not very much.

Ms. Butler asked what lessons can be learned from successful HPV vaccination campaigns in Australia and Rwanda. Ms. Luciani said both countries exemplify the impact of strong political will that trickles down as well as leadership from those in the community delivering services. Both countries have given a lot of attention to effective organization of services for vaccination, screening, and treatment. Both have also invested in monitoring, evaluation, and quality improvement. Ms. Luciani added that a need remains to link vaccine registries with cancer registries to improve monitoring.

## **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 NVPO staff and adjourned the meeting at 3:00 p.m.

#### **APPENDIX: Abbreviations**

AAPCHO Association of Asian-Pacific Community Health Organizations

ACIP Advisory Committee on Immunization Practices

AEFI adverse events following immunization
AHIP America's Health Insurance Plans

AHRQ Agency for Healthcare Research and Quality
AIM Association of Immunization Managers
AIRA American Immunization Registry Association

APhA American Pharmacists Association ASH Assistant Secretary for Health

ASTHO Association of State and Territorial Health Officials BARDA Biomedical Advanced Research and Development

BPHC Bureau of Primary Health Care

CARB Combating Antibiotic-Resistant Bacteria

CARB-X Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator

CMS Centers for Medicare and Medicaid Services
CDC Centers for Disease Control and Prevention
DICP Division of Injury Compensation Programs

DoD Department of Defense EHR electronic health record FDA Food and Drug Administration

FY fiscal year HBV hepatitis B virus

HEDIS Healthcare Effectiveness Data Information Set HHS Department of Health and Human Services

HPV human papillomavirus

HRSA Health Resources and Services Administration

IIS immunization information systems

JE Japanese encephalitis

LAIV live-attenuated influenza vaccine MMR measles-mumps-rubella [vaccine]

MRSA methicillin-resistant Staphylococcus aureus

NACCHO National Association of County and City Health Officials
NACI National Advisory Committee on Immunization (Canada)
NAIIS National Adult and Influenza Immunization Summit

NCQA National Committee for Quality Assurance

NIAID National Institute of Allergy and Infectious Diseases

NIH National Institutes of Health

NVAC National Vaccine Advisory Committee NVIC National Vaccine Information Center NVPO National Vaccine Program Office

PACCARB Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

PAHO Pan American Health Organization PDP product development partnership PHAC Public Health Agency of Canada

SIRVA shoulder injury related to vaccine administration

USDA U.S. Department of Agriculture VA Department of Veterans Affairs

VACCINES Vaccine Awareness Campaign to Champion Immunization Nationally and

Enhance Safety (Act)

VCI

VICP

Vaccine Confidence Index Vaccine Injury Compensation Program Vaccines and Related Biological Products Advisory Committee VRBPAC

World Health Organization WHO

