

March 25, 2019, Meeting Minutes

Committee Members in Attendance

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

NVAC Ex Officio Members

- Amanda Cohn, M.D. (for Nancy Messonnier, M.D.) Centers for Disease Control and Prevention (CDC)
- Hana El Sahly, M.D., Vaccine and Related Biological Products Advisory Committee (VRBPAC)
- 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)
- Valerie Marshall, M.P.H. (for Marion Gruber, Ph.D.), Food and Drug Administration (FDA)
- Jeffrey McCollum, D.V.M., M.P.H., Indian Health Service (IHS)
- Justin A. Mills, M.D., M.P.H., Agency for Healthcare Research and Quality (AHRQ)
- Barbara Mulach, Ph.D., National Institutes of Health (NIH)

- Narayan Nair, M.D., CAPT, Division of Injury Compensation Programs (DICP), Health Resources and Services Administration (HRSA)
- Tonya Rans, M.D., Department of Defense (DoD)
- Judith Steinberg, M.D., M.P.H., Bureau of Primary Health Care (BPHC), HRSA

NVAC Liaison Representatives

- James S. Blumenstock, Association of State and Territorial Health Officials (ASTHO)
- Nathalie El Omeiri, Pan American Health Organization (PAHO)/World Health Organization (WHO)
- Allison Chi (for Rebecca Coyle, M.S.Ed.), American Immunization Registry Association (AIRA)
- Kristen R. Ehresmann, RN, M.P.H., Association of Immunization Managers (AIM)
- Jean-Venable "Kelly" Goode, Pharm.D., BCPS, FAPhA, FCCP, American Pharmacists Association (APhA)
- Althea House (for Gina Charos), Public Health Agency of Canada
- James David Nordin, M.D., M.P.H., America's Health Insurance Plans (AHIP)
- John Douglas, M.D., National Association of County and City Health Officials (NACCHO)

Acting Designated Federal Officer

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

Proceedings

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

Ms. Aikin called the virtual meeting to order at 12:30 p.m. She welcomed new liaisons John Douglas, M.D., of NACCHO, and Hana El Sahly, M.D., of VRBPAC. 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.

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

Dr. Hopkins welcomed the participants to the virtual public meeting, which was accessible by webcast and telephone. He described the meeting proceedings and the agenda for this meeting. Written comments can be sent to NVAC for consideration by e-mail (nvac@hhs.gov). The 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 in person on June 4–5 and 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 emphasized that NVAC's recommendations have a large impact on vaccine policymaking. Following the release of the NVAC report on human papillomavirus (HPV) vaccination, Strengthening the Effectiveness of National, State, and Local Efforts to Improve HPV Vaccination Coverage in the United States: Recommendations of the National Vaccine Advisory Committee, NVPO convened several HHS entities to develop a plan to implement the report's recommendations. The implementation plan will focus on engagement and communication, integrated delivery networks, and rural and faith-based organizations. In March, NVPO participated in the National HPV Vaccine Roundtable's Southeastern Summit, which focused on catalyzing coalitions in the Southeast. In addition, HHS put out a request for information to gather input from retail pharmacies about their capacity to provide HPV vaccinations to customers in rural locations.

Offices across HHS kicked off an HPV vaccine communications campaign and introduced a new HPV vaccine toolkit on International HPV Awareness Day (March 4). Dr. Beckham said HHS will assess the needs of rural health care providers regarding HPV vaccination and will hold focus groups in four rural areas. A collaboration of rural health systems, organized by CDC, the American Cancer Society, and the American Medical Group Association, will encourage evidence-based practices to increase HPV vaccination.

Since NVPO published the *National Adult Immunization Plan* and a corresponding implementation plan, based on NVAC recommendations, it has collaborated with HHS' regional offices to host public meetings around the country on topics such as disparities in vaccine access. Through these meetings, NVPO is establishing or reinvigorating collaborations. This spring and summer, four more regional meetings will take place. In May 2019, NVPO and CDC will cohost the annual National Adult and Influenza Immunization Summit in Atlanta, GA.

Dr. Beckham said the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) held a panel at its January 2019 public meeting on the role of vaccines in combating antimicrobial resistance and another on infection prevention and control, during which NVAC

member Timothy Cooke, Ph.D., spoke about vaccines to prevent infection. On April 8, 2019, PACCARB will meet virtually to deliberate on a recommendation that CMS finalize the conditions of participation rule mandating antibiotic stewardship programs. In addition, HHS is updating the National Action Plan for Combating Antibiotic-Resistant Bacteria, and NVAC will have an opportunity to provide input on the role of vaccines to prevent antimicrobial resistance.

Over the next year-and-a-half, NVPO will begin updating the National Vaccine Plan, with a particular focus on addressing disparities, and will ramp up communication about vaccine confidence and the safety of the national immunization system. Dr. Beckham thanked the NVAC members for their time and expertise and the NVPO staff for their efforts.

Opening Remarks—ADM Brett P. Giroir, M.D., Assistant Secretary for Health, HHS

Dr. Giroir thanked NVAC members for their service. Despite having one of the strongest and safest immunization systems in the world, today the United States is facing an unprecedented outbreak of measles—a disease that had been eliminated nearly 20 years ago. Several factors contribute to vaccine hesitancy and lower vaccine rates in certain communities, said Dr. Giroir, but vaccines are highly effective, safe, and the foundation of a robust public health system. He urged public health officials to be loud, clear, vocal champions of the importance of vaccines for all Americans. To that end, Dr. Giroir, CDC Director Robert R. Redfield, M.D., and Surgeon General VADM Jerome M. Adams, M.D., M.P.H., jointly authored an editorial published in the *New York Times* on March 6, 2019, This Is the Truth about Vaccines, making it clear that vaccines are safe, lifesaving tools that protect the most vulnerable.

Dr. Giroir called on all stakeholders to take responsibility to counter misinformation that fuels anti-vaccine sentiment and ensure every American understands the importance of vaccines over the course of their lifetime. Dr. Giroir said his office recently collaborated with partners inside and outside of the government to help spread this message on Twitter. He hoped to have many more opportunities to engage stakeholders, providers, and public health officials to amplify the message around the safety of vaccines and their critical role in public health.

Thanks to NVAC's work and recommendations, HHS has developed a comprehensive strategy for addressing the low vaccination rates for HPV in the United States, as described by Dr. Beckham. HHS is working with diverse to improve HPV vaccination rates, reduce missed opportunities, and address disparities—especially in rural areas. This effort is driven by a simple vision: increase HPV vaccination in adolescents to 80 percent, which would prevent 30,000 new cases of HPV-related cancers in the United States every year.

National Vaccine Plan—Charge to NVAC

The National Vaccine Plan is mandated by statute and aims to provide a comprehensive strategy to enhance everything from vaccine development and innovation to ensuring access and use of recommended vaccines. The most recent National Vaccine Plan was published in 2010, and NVPO and NVAC conducted separate but parallel mid-course reviews of the Plan to identify changes and emerging opportunities across the immunization landscape.

In 2016, in response to a critical need to improve adult vaccination rates, the National Adult Immunization Plan was developed and released. Both plans have provided significant guidance, but the immunization system is constantly evolving. To remain responsive to the changing landscape, HHS will release an updated National Vaccine Plan in 2020 that will set a course for the next 3 to 5 years and incorporate the National Adult Immunization Plan, resulting in a

strategy that addresses vaccination across the lifespan.

To prepare for the updated National Vaccine Plan, Dr. Giroir charged NVAC with reviewing the goals and objectives of the current National Vaccine Plan, the mid-course reviews conducted by NVPO and NVAC, and the National Adult Immunization Plan as follows:

- Assess the relevance of the goals and updated requirements, both in terms of the topics each goal represents and the wording used to describe each goal and objective.
- Combine the goals from the National Vaccine Plan and National Adult Immunization Plan to generate a set of comprehensive, prioritized goals reflective of immunization priorities across the lifespan.
- Propose new goals, as determined necessary, for inclusion in the National Vaccine Plan and an appropriate rationale for each proposed goal.
- Prioritize the three top objectives within each National Vaccine Plan goal area, or proposed goal area, poised to make the greatest impact on the U.S. immunization system in the next few years.
- Identify new stakeholders to engage during plan development that reflect the expertise and priorities of all stakeholders working to optimize the vaccination system in the United States.
- Develop a report encompassing these recommendations, to be voted on during the September 2019 NVAC meeting, of less than 10 pages.

Immunization Disparities—Charge to NVAC

Dr. Giroir said he wants to ensure that the next decade of immunization is rooted in an approach that supports health in all, health by all, and health for all. Immunization disparities persist in the United States—including disparities in vaccination rates by age, socioeconomic status, race and ethnicity, and geographic areas. Dr. Giroir pointed to recent CDC data:

- Black, Hispanic, and Asian adults have lower vaccination rates than Whites for all recommended adult vaccines.
- Rural adolescents are less likely to receive their first dose of the HPV or meningococcal conjugate vaccines than those living in urban areas.
- People without health insurance have vaccination rates for influenza, shingles, HPV, and other diseases that are two to five times lower than people with health insurance.
- Black and Hispanic health care professionals had lower vaccination rates than White health care professionals for influenza, hepatitis B, and tetanus, diphtheria, and pertussis (whooping cough, combined tetanus, diphtheria, and pertussis [Tdap] vaccine).

Dr. Giroir charged NVAC with providing a comprehensive set of recommendations that will lay the foundation for an effective national strategy to end immunization disparities in the United States. To complete this charge, he recommended that NVAC establish a working group consisting of select NVAC members; a broad array of federal and non-federal stakeholders, including NVAC ex-officio and liaison members of the Committee; and other experts. The NVAC working group should achieve the following:

- Review and summarize the complex and interrelated factors that contribute to vaccination disparities, such as access, affordability, awareness, acceptance, and activation.
- Deliver a set of system-wide recommendations for overcoming drivers of immunization disparities and reducing gaps in coverage that will provide the foundation for development of a collaborative immunization equity strategy.

• Report findings for a vote during the September 2020 NVAC meeting.

Dr. Giroir said the country faces a pivotal time for vaccination, and he implored NVAC members to be engaged in this process. He looked forward to NVAC's recommendations addressing these two charges.

Panel 1: Addressing Rural Disparities in Immunization

Assessing Disparities in Pneumonia Vaccine Service Delivery in the Rural Fee-for-Service Medicare Population—Jeffery Talbert, Ph.D., and Patricia R. Freeman, Ph.D., University of Kentucky College of Pharmacy

Using Medicare data from 2012 to 2015, Drs. Talbert and Freeman assessed the uptake of pneumonia vaccine among people 65 years and older before and after the CDC's 2014 recommendations. They found disparities in uptake between rural and urban residents, consistent with findings of other studies, with significant variation across communities (ranging from 8 to 26 percent). They also found that in rural areas, pharmacies are providing an increasing number of pneumococcal vaccinations to Medicare fee-for-service beneficiaries, while the number remains steady in urban areas. The study indicated that older, White, non-Hispanic women were more likely to get vaccinated. Those less likely to be vaccinated lived in rural areas, had poorer overall health, and used outpatient more than inpatient services.

Other key findings from the study indicated that, among various provider types, primary care providers continue to deliver the most pneumococcal vaccine to Medicare beneficiaries. Pharmacy providers deliver about a quarter of such vaccines. Dr. Freeman concluded that community pharmacies are important access points for vaccinations. Because of the disparities between urban and rural services, continued support of rural service providers is needed to ensure older adults get recommended vaccines.

Strategies for Improving Rural Health Equity: Leveraging Strengths and Assets—Alana Knudson, Ph.D., The Walsh Center for Rural Health Analysis/NORC at the University of Chicago

Rural communities frequently cite their individual residents as their greatest assets, describing civic and community engagement, entrepreneurial spirit, resilience, and the deep connections across small populations. Organizational assets include educational institutions, small businesses, food production and distribution systems (e.g., farmers' markets), community-based organizations, and financial institutions with direct local investments. Local media, particularly newspapers, are important assets and key to communicating with rural residents, said Dr. Knudson, but rural citizens also use social media.

Every county has a cooperative extension office associated with a land-grant institution, said Dr. Knudson, but not every county has public health services. Cooperative extension services are increasing their focus on health services and might be potential partners for reaching more rural residents, she noted.

From a cultural perspective, rural communities are close-knit and support ties with neighbors. Religious faith plays a strong role. Social cohesion and collaboration, particularly in response to adversity, are important components of rural life. Dr. Knudson said the innovation and creativity that emerges in rural areas is often overlooked or underreported. She stressed the importance of considering the interconnectivity across sectors when reaching out to rural communities to address public health issues and fostering collaboration across sectors. The figure describes many rural community assets.

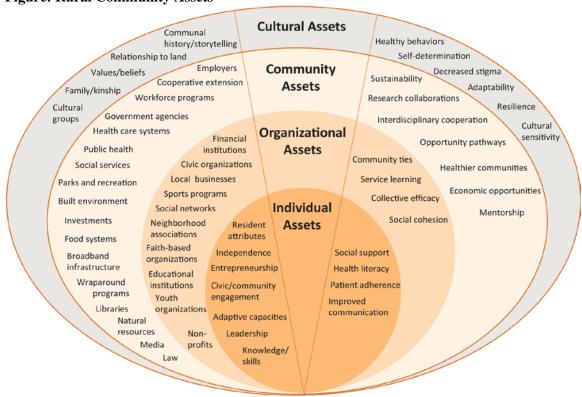


Figure: Rural Community Assets

Contextual Factors: Political environment, policies, history

Dr. Knudson pointed out that rural communities might lack the infrastructure to apply for funding opportunities; encouraging communities to collaborate could help them take advantage of available funding and resources. To build trust and increase the likelihood of success, outside organizations should ask communities what they need rather than impose a ready-made solution, said Dr. Knudson. Rural communities might be ideal locations for demonstrations and pilots, because there are fewer competing interventions. Dr. Knudson stressed the need to understand community priorities and tailor communication and messaging accordingly. She recommended visiting the Rural Health Information Hub for information, toolkits, and educational modules.

Disparities in HPV Vaccination—Elektra Paskett, Ph.D., The Ohio State University Comprehensive Cancer Center

Dr. Paskett described the burden of HPV disease and low HPV vaccine uptake in Appalachian states. An assessment of cervical cancer among Appalachian women found high rates of risk factors (e.g., abnormal Pap test results, smoking, poverty, HPV, risky sex behaviors, and depression), low access to health care services, and low levels of trust in health care providers. The following factors affected HPV vaccine uptake:

- Lack of health care providers' recommendation
- Lack of awareness (among providers and parents) of the need for HPV vaccine
- Confusion about when to start vaccination
- High cost of the vaccine

Negative attitudes toward HPV vaccination and vaccines in general (among parents and providers)

A multilevel intervention targeted parents of adolescent girls, health care providers in clinics, health departments, and providers' offices. On the basis of focus groups and community input, researchers developed outreach materials that used a narrative structure, emphasized family ties, addressed families' concerns, and featured a culturally representative family. They also offered providers and parents education and resources. The intervention was only moderately successful. Many providers still failed to offer vaccine to eligible candidates, apparently because they lacked understanding of the guidelines. When providers recommended the vaccine or parents discussed it with the provider, girls were 3.5 times more likely to receive vaccine.

A second intervention, limited to two clinics in a single county, focused on implementation. It took a similar multilevel approach, this time including boys and girls. Researchers tailored HPV vaccine education materials to include the name and logo of the local clinic. They identified clinic champions who vaccinated their own children and featured them in the outreach materials. They also offered initial and booster training for providers. One of the clinics reported increased vaccination among girls, especially older girls. (The second clinic was unable to provide data because of technological barriers.) Dr. Paskett said tailoring the strategy to the region appeared to be key to success. Future interventions will incorporate more education for providers, such as training on how to make recommendations for HPV vaccine, in the context of cervical cancer prevention.

Discussion

Dr. Paskett clarified that the first phase of her project included individuals who visited physicians who had not received education through the project about HPV vaccination. The second phase included clients and health care providers in the same clinics and systems. Dr. Hopkins observed that the presentations all underscored that effective communication requires a multifaceted approach, involving community thought leaders, providers, pharmacists, and others. Dr. Paskett noted that rural communities in particular see pharmacists as trustworthy and accessible.

Melissa Martinez, M.D., FAAFP, asked about the potential financial barriers to receiving services from retail pharmacists. Dr. Freeman said reimbursement depends on the payer. Under some Medicaid programs, pharmacies are not authorized to provide vaccinations to children under the Vaccines for Children (VFC) program; others allow pharmacies to participate in VFC but do not pay the associated costs around administering vaccine. For example, Kentucky pharmacists can give vaccines to children as young as 9 years old, but few provide HPV vaccination because Medicaid does not cover the fees for administering the vaccine.

Panel 2: Experiences from the Field: Responding to Vaccine-Preventable Outbreaks Hepatitis A Outbreak in Arkansas: 2018–2019—Nathaniel Smith, M.D., M.P.H., Director and State Health Officer, Arkansas Department of Health

Describing hepatitis A, Dr. Smith pointed out that the incubation period can last up to 30 days, which poses challenges to response and monitoring. Transmission through blood exposure has been uncommon historically, said Dr. Smith, but injection drug use has been identified as a risk factor for hepatitis A in the current outbreak and might contribute to the outbreak in Arkansas.

Hepatitis A cases began increasing in Arkansas and other states in 2017 and dramatically spiked in 2018. Most cases have occurred in the rural, northeastern corner of Arkansas. More than half of those infected use or inject drugs. A small percentage were food handlers. One third were coinfected with hepatitis B or C.

The State Department of Health used Section 317 funds to purchase vaccines, billed Medicaid and private insurance providers for immunization, and received supplementary funding for laboratory and epidemiology activities from CDC. In addition to mass vaccination clinics in 13 counties, the Department targeted high-risk groups by offering vaccinations in jails, shelters, and food pantries, for example. To reach more people in emergency settings, immunization nurses travel with emergency services personnel and provide vaccination in local emergency departments. To overcome stigma, the Department began offering free vaccination to all residents in the affected areas, targeting those ages 18–60 years old, which helped reach more high-risk people. The occurrence of hepatitis A among food handlers can have devastating effects on the restaurant industry, so many restaurants cooperated in Department efforts to vaccinate food handlers.

Among the challenges posed by the rural location of the outbreak are the lack of services for people who are homeless or use drugs, stigma (especially in small communities), and the difficulty of reaching people at risk before they are infected through their contacts. Given the State's limited resources, the risk of similarly transmitted pathogens—such as HIV and hepatitis B and C—is increased. Dr. Smith concluded that he anticipates a new normal in which hepatitis A is endemic in the country. He hoped the outbreak would lead to a renewed commitment to adult immunization.

Measles Outbreak: 2018–2019—Jane Zucker, M.D., M.S.C., FIDSA, New York City Department of Health and Mental Hygiene

Dr. Zucker described the outbreak of measles that began in late 2018, which has centered around two areas of Brooklyn populated predominantly by Orthodox Jews. The first identified case occurred in an unvaccinated child who had recently traveled to Israel. About 80 percent of the cases in this outbreak have occurred in unvaccinated people, mostly in children ages 1–4 years.

The city has taken a tremendous number of steps to contain the outbreak, said Dr. Zucker, using traditional public health approaches. Because of its robust citywide immunization registry, the city can rapidly identify unvaccinated people and the contacts of people who have been infected. Dr. Zucker noted that measles-mumps-rubella (MMR) vaccine uptake increased when children went back to school, when the first outbreak was declared, and following each round of letters to parents indicating that children could not attend school without MMR vaccination.

Controlling the outbreak has been challenging for many reasons, including vaccine hesitancy and the fact that many affected people do not seek care. To respond, the city has forged key partnerships within the Jewish community, most notably with the Orthodox Jewish Nurses Association and other health care providers, to educate, communicate, and vaccinate. However, the city is now seeing some transmissions outside of the Orthodox Jewish community and new importations that are affecting other neighborhoods in Brooklyn.

Dr. Zucker said the city plans to continue excluding unvaccinated children from daycare and school settings, and it is auditing every daycare and Orthodox Jewish school in the area to assess compliance. It has lowered the minimum age for MMR vaccination to 6 months and is increasing efforts to prevent exposure and ensure timely notification. Finally, the city seeks to mobilize religious leaders in the community who have not been vocal about the outbreak so far.

Discussion

Dr. Hopkins observed that community leadership, trust, vaccine hesitancy, and stigma are factors involved in both outbreaks and in vaccine uptake in rural areas. Cody Meissner, M.D., FAAP,

said he believes hepatitis A viremia is so short-lived that transmission by blood is unlikely; he asked whether there is evidence that needle-sharing has resulted in transmission. Dr. Smith responded that such transmission has been documented historically but remains an open question in the current outbreak. At the same time, injection drug use has been responsible for most of the hepatitis A cases in the Arkansas outbreak. Dr. Smith added that public health entities offered vaccine to people in jails but most inmates declined—until staff at the jails requested vaccination. He noted that coinfection has been observed, suggesting that there may be different modes of transmission.

Dr. Smith said Arkansas generally offers cotesting for HIV and hepatitis with the opportunity to opt out; people at high risk for these conditions are still reluctant to accept testing. In general, hepatitis B vaccination is offered as a means of long-term protection to those who have not been vaccinated, he added.

Dr. Cooke recommended tracking the direct and indirect costs of the outbreaks, including the administrative time required to track down contacts and the cost to public health departments when staff time is devoted to outbreaks rather than other activities. Such information could be useful in calculating the true cost-benefit ratio of vaccination and highlighting the need to invest in prevention. Dr. Zucker responded that a cost analysis of New York City's 2013 outbreak indicated that treating 58 cases cost the city \$400,000, and 84 percent of that cost was related to personnel. Her office is tracking the costs of the current outbreak; already, it has spent an estimated \$1 million related to personnel and \$400,000 in other expenses. The office had 10 staff members in place and has mobilized 50 others.

Dr. Smith said Arkansas estimated that the cost of the public health response to the outbreak ranges from \$3 million to \$6 million, and that does not include, for example, the losses faced by restaurants from closing. He noted that the outbreak requires an intensive staff response in rural areas. Dr. Cooke said the costs of parents staying home from work, the impact of outbreaks on the community, and the costs of hospitalization are other variables that could be calculated.

Melody Anne Butler, B.Sc.N., RN, asked whether Dr. Zucker had any contact with the antivaccination groups in her area. Dr. Zucker said her office has seen a booklet distributed by Parents Educating and Advocating for Children's Health (PEACH). She noted that PEACH is very secretive, and it is hard to identify who funds it. Her office has distributed materials that address myths around vaccination. The Orthodox Jewish Nurses Association has also been dispelling myths with culturally sensitive education. New York City uses print advertising to address misinformation around public health concerns and works closely with CBOs on the ground. It also offers inservice education to providers so that they can give accurate information and make strong recommendations for vaccination.

Panel 3: Improving Access by Reducing Financial Burden of Immunization Strategies and Practices for Identifying and Vaccinating Uninsured Adults—James S. Blumenstock, ASTHO

ASTHO's guide to <u>Identifying and Vaccinating Uninsured Adults</u>, published in 2017, compiles resources and strategies used by immunization programs. It was developed through interviews with program managers, adult immunization coordinators, and community partners who worked to increase vaccination rates among uninsured adults. Mr. Blumenstock said ASTHO is considering updating the guide. Although respondents represented 13 areas across the country, an updated version would likely seek to feature a more demographically and geographically diverse sample.

The guide features links to resources and materials, including contracts, protocols, and job descriptions. The content falls into four major themes:

- Identifying and reaching uninsured adults
- Tools and activities to incorporate adult immunization into state immunization programs
- Clinical practices to facilitate successful incorporation of adult vaccination activities
- Maximizing limited resources

For each theme, Mr. Blumenstock summarized some of the recommended strategies. For example, to maximize limited resources, the guide suggests advocating for state legislation that requires health plans to cover the costs of vaccines for adult beneficiaries and includes links to state legislation so that users can craft language for their legislators to consider. Mr. Blumenstock requested feedback on improving and modernizing the guide.

Adult Safety Net (ASN) Program—Denise Starkey, Texas Department of State Health Services

Ms. Starkey pointed out that Texas has a large adult population and a high percentage of people ages 18–64 years old who are uninsured (24 percent). From 2016 to 2017, Texas saw declines in adult immunization rates for influenza, tetanus, and hepatitis B. In the same period, uptake of HPV and pneumococcal vaccine increased, as did influenza vaccine in people age 65 years and older. The ASN works in every region of the State to set up adult vaccination programs, train clinicians, and follow up with the programs to address problems that may have arisen.

The ASN program began in 2003 as an initiative around hepatitis B vaccination for uninsured and underinsured adults. Now, it supplies vaccines to 534 sites in the State that vaccinate people 19 years old and older through Federally qualified health centers, rural health centers, local health departments, and public health regions. The program includes numerous vaccines but not influenza or meningococcal B vaccine.

Ms. Starkey said program challenges include inactive sites, missed opportunities, vaccine inventory management, consent procedures, and funding. She noted that the program faces funding cuts frequently and must constantly adjust to sustain itself. The ASN program has the capacity to provide vaccines in emergency settings, such as natural disasters and disease outbreaks. The program relies on collaborations and partnerships with key stakeholders, including pharmacies and vaccine manufacturers, Ms. Starkey concluded.

Influenza Vaccine Pop-Up Clinics—Priscilla Haynes and Ellen Niemitalo, Tulsa Health Department

Tulsa County seeks to become one of the healthiest counties in the country. Almost 21 percent of adults ages 19–64 years in the county are uninsured. Until 2010, the Tulsa Health Department provided free influenza vaccines at clinics and community events. Since then, funding has been cut and the cost of vaccines has increased, forcing the department to be creative.

At the peak of the particularly severe 2017–2018 influenza season, the department set up a popup clinic in a shopping mall storefront on a Saturday afternoon in February. The clinic had vaccine purchased by the Vaccines for Children program, the state, and the county so that it could provide vaccine for anyone who dropped in. The clinic administered 300 vaccine doses that day.

In preparation for the 2018–2019 influenza season, the department set up another pop-up clinic offering free influenza vaccinations, this time as part of a local emergency preparedness exercise.

The clinic provided more than 600 vaccinations, with a throughput of about 20 minutes per person. The department is working with other local partners to offer public health services and overcome barriers to seasonal influenza vaccination, including a mobile vaccination unit, a popup clinic for homeless people, an annual "community baby shower," and a brunch for seniors.

Discussion

Ms. Niemitalo said Tulsa normally distributed about 10,000 doses of influenza vaccine annually; through its more aggressive outreach efforts, it has distributed about 14,000 doses this influenza season. Ms. Starkey said the Texas ASN program does not offer influenza vaccine because so many local health departments already do and because it is not clear that the ASN program can obtain sustainable funding to support influenza vaccination.

John Douglas, M.D., asked for more information about state-funded universal vaccine coverage. Kimberly Martin of ASTHO said Vermont has agreements with enrolled providers to purchase vaccine for all children and adults. Since 2014, insurers in that State have been required to pay into a pool to support vaccine purchasing, based on the number of members in their plans.

NVAC Liaison and Ex Officio Updates

VRBPAC—HANA EL SAHLY, M.D.

VRBPAC met March 6–7, 2019, to make recommendations about the 2019–2020 seasonal influenza vaccine on the basis of data from surveillance, epidemiology, genetics, epigenetics, and the availability of candidate strains and reagents. A new strain was recommended for influenza A, H1N1, because of evidence of genetic and antigenic drift. Decision-making on influenza B, H3N2, was delayed until late March. There seems to be minimal genetic and antigenic drift associated with influenza B, so the same strains will be used in the next seasonal vaccine: B/Colorado and B/Phuket in the quadrivalent vaccine and B/Colorado only in the trivalent vaccine.

VRBPAC also reviewed evidence submitted to FDA by Sanofi Pasteur about its dengue virus tetravalent vaccine, Dengvaxia. The results of safety and efficacy data were mixed, and there was an increased risk of hospitalization for dengue virus among people who received Dengvaxia and were seronegative for dengue at baseline. VRBPAC voted not to recommend Dengvaxia for adults ages 17–45 years who are seropositive at baseline because there is no reliable test to determine seropositivity. However, it voted in favor of approving Dengvaxia for those in endemic areas ages 9–16 years who are seropositive at baseline on the basis of data supporting the safety and efficacy of vaccination among younger people.

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)—CODY MEISSNER, M.D., FAAP

At the 109th quarterly ACCV virtual meeting on March 8, 2019, the Commission heard updates from HRSA DICP and the Department of Justice. The Commission discussed a workgroup recommendation to develop an exit questionnaire to obtain information on petitioners' experiences with the program, which would help the program and the ACCV determine potential areas for improvement. The ACCV voted unanimously to recommend to the HHS Secretary the development of such an exit questionnaire. Finally, the Commission heard program updates from the CDC's Immunization Safety Office, NIH's National Institute of Allergy and Infectious Diseases (NIAID), FDA's Center for Biologics Evaluation and Research, and NVPO.

ASTHO—JAMES S. BLUMENSTOCK

ASTHO and its members have been responding to measles outbreaks around the country. ASTHO held a desk side briefing for media with Immediate Past President John Wiesman of Washington State, who also appeared before the Senate Health, Education, Labor, and Pensions Committee to share his experience. He described the urgent need for state-level resources, Section 317 funds, Public Health Emergency Preparedness Program funds, and a national campaign to address vaccine hesitancy. He also called for routine efforts to communicate the critical importance of immunizing children, the goals of herd immunity, and the effect of international travel on disease spread. ASTHO has been reaching out to major media to spread the message about vaccination.

ASTHO is launching a new learning community based on the education and collaboration model of Project ECHO (Extension for Community Healthcare Outcomes)[®]. This initiative aims to improve HPV vaccination rates by strengthening knowledge-sharing networks to promote HPV promising practices. ASTHO is adapting the Project ECHO clinical model to give it a public health face by incorporating public health practices and principles, such as reducing disparities. Project ECHO facilitates case-based learning and peer consultation.

NACCHO— JOHN DOUGLAS, M.D.

The NACCHO Annual 2019 Conference, themed "Improving the Nation's Health through Public and Private Partnerships," will be held July 9–11 in Orlando, FL; awardees of the Model Practices program will be announced. NACCHO continues to convene an immunization advisory group made up of local health officials, local health department program staff, and immunization coalition members. Among the priority topics identified by the advisory group is vaccine hesitancy. To this end, the advisory group organized a webinar featuring former NVAC member Saad Omer, M.B.B.S., M.P.H., Ph.D., who discussed effectively communicating about vaccines. It has developed a template for organizations to submit editorials to local media about the emerging problems posed by vaccine hesitancy.

NACCHO has also hosted some vaccine awareness and education events. It partnered with Hep B United to conduct a webinar series on local approaches to eliminate hepatitis B, among other topics. During National Influenza Awareness Week, NACCHO recorded a podcast with CDC immunization expert Melinda Wharton, M.D.. NACCHO recently updated its guide to HPV resources for local health departments.

PAHO/WHO—NATHALIE EL OMEIRI

Vaccination week in the Americas will take place April 20–27, 2019. The regional launch will take place in Brazil, with the participation of the PAHO Director, Brazil's Ministry of Health, and other key partners and United Nations agencies. There is a big push this year to use Vaccination Week to stop the current measles outbreaks in the region by vaccinating the most vulnerable populations. Other top priorities for this year's campaign are polio, influenza, and HPV. Notably, 33 member states in the Americas have maintained their measles elimination status. However, endemic transmission of the virus was reestablished in Venezuela in July 2018 and in Brazil in February 2019. PAHO has intensified its response, providing technical support for rapid outbreak control, increased vaccination, enhanced laboratory diagnostic capacity, epidemiologic surveillance, and communication. The response includes expanding vaccination teams and advocating at the highest political levels to implement the measures agreed upon by ministers of health in 2017 with the adoption of the *Plan of Action for the Sustainability of Measles, Rubella, and Congenital Rubella Syndrome Elimination in the Americas, 2018–2023*. PAHO also continues to provide technical assistance to priority countries with low vaccination coverage and ongoing vaccine-preventable disease outbreaks, such as Haiti and Venezuela.

Following the endorsement by PAHO member states in September 2018 of a *Regional Plan of Action for Cervical Cancer Prevention and Control, 2018–2030*, PAHO is working closely to increase HPV vaccine uptake and monitor program performance. PAHO is facilitating the update of countries' vaccine deployment plans for pandemic influenza preparedness and continues to support the generation of evidence for influenza vaccines and maternal immunization in collaboration with CDC and Emory University. It is also supporting evidence-based decision-making by working with national immunization advisory groups in Latin America and the Caribbean. Finally, the 25th meeting of PAHO's Regional Technical Advisory Group on vaccine-preventable diseases will take place in Cartagena, Colombia, in July 2019, with over 200 participants expected to attend from the Americas to discuss the regional immunization priorities and agenda.

AIRA—ALLISON CHI

AIRA will celebrate its 20th anniversary at its national meeting in Indianapolis, IN, August 13–15, 2019. Over the past six months, AIRA has published three new guidance documents for the immunization information systems (IIS) community. Its Onboarding Consensus-Based Recommendations provide guidance for improving and standardizing onboarding and includes examples from a variety of IIS throughout the country that are using their data to identify pockets of need through small area analysis. AIRA also released the publications *Identifying Immunization Pockets of Need Using Small Area Analysis* and *Data Quality Practices to Monitor and Evaluate Data at Rest*.

Clinical decision support (CDS) is the fourth content area of AIRA's Measurement and Improvement Initiative. Because CDS testing leverages hundreds of test cases, there has been significant discussion about the proportion needed to meet a given measure. The first CDS discovery and assessment reports will be available in March. (They were delayed because of the unavailability of National Institute of Standards and Technology tools during the Federal government shutdown.) In December 2018, AIRA and CDC, in partnership with HL7, completed the balloting process and published the balloted HL7 2.8.2 guide on the HL7 website. This next version is not anticipated to be broadly adopted immediately but will be available when the community supports moving beyond the current HL7 2.5.1 Release 1.5 guide.

In January 2019, AIRA collected, consolidated, and submitted two sets of community comments on Federal topics, representing views from across the membership. AIRA weighed in on the proposed Healthy People 2030 rules, voicing concern that there was a significantly decreased emphasis on public health measures. It also commented on the Office of the National Coordinator for Health Information Technology's report, *Strategy on Reducing Burden Relating to the Use of Health IT and EHRs*, emphasizing that electronic health record (EHR)–IIS interoperability brought value and lowered burden for providers.

AHIP—JAMES DAVID NORDIN, M.D., M.P.H.

AHIP reached out to member health plans and found that most are interested in improving HPV vaccine coverage. More member plans are doing active outreach to adolescents and their families than in the past in an effort to boost HPV vaccine rates.

Ex Officio Member Updates HRSA DICP—NARAYAN NAIR, M.D., CAPT

The National Vaccine Injury Compensation Program (VICP) has continued to process an increased number of claims. In fiscal year (FY) 2018, 1,243 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 February 1,411 claims have been filed with the program, and \$74.4 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 http://www.hrsa.gov/vaccinecompensation/data.html. 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.

BARDA—LINDA LAMBERT, PH.D.

Ebola virus reemerged in the Democratic Republic of the Congo last year. The first outbreak was quickly contained, but a second has spread to become the second largest (after the 2014–2016 outbreak in west Africa) since discovery of the Ebola virus. In 2014, BARDA began working with partners in industry to accelerate the development of vaccines, therapeutics, and diagnostics for Ebola virus. It is now supporting two vaccine candidates in the late stages of development, one of which is being used in the outbreak in the Congo.

BARDA has a long history of work on pandemic influenza. It recently published a study—the first of its kind—looking at the safety and effectiveness of vaccine stored in the Strategic National Stockpile for more than 10 years. The study found that two doses of monovalent pandemic influenza vaccine stored for more than 10 years was safe and demonstrated immunogenicity; adjuvants stored for 5 years were found to be safe as well.

CDC—AMANDA COHN, M.D.

The Advisory Committee on Immunization Practices (ACIP) met February 27–28, 2019, and voted to recommend a booster dose of anthrax vaccine absorbed, to be given every 3 years to persons not currently at high risk of exposure but who have been previously primed and wish to maintain protection. It also voted to recommend Japanese encephalitis (JE) vaccination for persons moving to a JE-endemic country, longer-term travelers to JE-endemic areas, and frequent travelers to JE-endemic areas. This recommendation reflects minor updates to the existing JE recommendations; major changes will be discussed at the June 2019 ACIP meeting.

Since January 1, 2019, 15 states have reported 268 confirmed cases of measles. So far in 2019, six measles outbreaks have been reported in the United States. These outbreaks are linked to travelers who brought measles back from other countries, such as Israel and Ukraine, where large measles outbreaks are occurring. For comparison, in 2018, the United States experienced 17 outbreaks, and 82 people brought measles to the United States from other countries. This figure represents the greatest number of imported cases since measles was eliminated from the United States in 2000.

The Notice of Funding Opportunity for the 2019–2023 Immunization and VFC cooperative agreement was released February 5, 2019. It is the primary CDC funding opportunity for eligible state, local, and territorial immunization programs and supports a range of immunization activities, including perinatal hepatitis B prevention, adult and adolescent immunization initiatives, IIS, and pandemic preparedness. To begin program planning, representatives from the 64 currently funded immunizations programs—representing all 50 states, the District of Columbia, 5 large cities, 5 U.S. territories, and 3 freely associates state entities—attended a kickoff meeting January 23–25, 2019.

CDC launched an animated video series for parents about how vaccines work. These short videos answer parents' common questions. They were launched on YouTube monthly in January, February, and March 2019. In February, the *Journal of Pediatrics* published the first assessment of state-specific HPV vaccination among male adolescents ages 13–17 years by provider recommendation. It found that HPV vaccination coverage among male adolescents significantly increased between 2011 and 2016, from 8.3 percent to 57.3 percent. Prevalence of provider recommendation increased from 14.2 percent in 2011 to 65.5 percent in 2016. In 2016, HPV coverage was significantly higher among male adolescents with a provider recommendation (68.8 percent) compared with those without a provider recommendation (35.4 percent). Finally, CDC is reevaluating its strategies for addressing vaccine hesitancy and improving vaccine coverage. It is currently seeking feedback from partners.

NIH—BARBARA MULACH, PH.D.

NIH is conducting several influenza vaccine trials; NIAID is supporting a Phase I trial of a tuberculosis vaccine. In September 2018, NIAID launched a strategic plan on tuberculosis research to build on current work and to develop and apply new tools. In December 2018, several NIH Institutes issued a Notice of Interest in Advancing Research on acute flaccid myelitis and Guillain-Barre syndrome. The goal is to encourage new applications and requests for supplements to existing grants to support basic, translational, and clinical research on the causes, diagnosis, prevention, or treatment of these and other acute neurologic conditions of muscle weakness and paralysis triggered by infectious agents or related immune responses. In December, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development issued a request for applications to investigate the effects of in utero opioid exposure on infant and child development. The initiative will provide support for conducting imaging scans and follow-up studies to assess social, behavioral, and brain development in 200 opioid-exposed children from birth through age 2.

DOD—TONYA RANS, M.D.

The Defense Health Agency officially assumed administrative and management responsibilities of a handful of hospitals and clinics as part of the Military Health System reforms mandated by Congress to create a more integrated, efficient, and effective system of readiness and health care that best supports patients and DoD.

The Pragmatic Assessment of Influenza Vaccine Effectiveness in the DoD study is a 2-year prospective study comparing different vaccine types, specifically egg-derived and cell-culture-derived or recombinant protein. The study began in the 2018–2019 influenza season across several U.S. sites.

Vaccine redistribution continues to be a widely successful program. Individual DoD immunization sites have the capability to communicate near-expiring vaccine surplus or a vaccine deficit through personnel at the Immunization Healthcare Branch at the Defense Health Agency. Branch staff then can reach out to other immunization sites to redistribute vaccine as needed. In FY 2018, \$740,000 worth of vaccine was successfully redistributed.

FDA—VALERIE MARSHALL, M.P.H.

In December 2018, FDA approved diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus, Haemophilus B conjugate (meningococcal protein conjugate) and hepatitis B (recombinant) vaccine (Vaxelis®). Vaxelis is indicated for active immunization to prevent diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, and invasive disease due to *Haemophilus influenzae* type b. It is approved for use as a three-dose series in children 6 weeks

through 4 years of age (prior to the 5th birthday). In October 2018, the FDA approved a supplement to the biologics license application for HPV 9-valent vaccine, recombinant (Gardasil®), to extend the age range for the use of the vaccine to include women and men from 27 to 45 years of age.

VA—Troy Knighton, M.Ed., Ed.S., LPC

As of March 16, 2019, over 1.82 million veterans received influenza vaccination in a VA facility, and about 400,000 of those received FLUAD, the trivalent vaccine indicated for people 65 years and older. About 111,000 veterans received vaccination through the VA's partnership with Walgreens. So far this season, the VA has recorded approximately 63 deaths related to influenza among veterans.

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

HRSA's Community Health Center (CHC) program aims to provide accessible, affordable quality health care, especially for underserved and vulnerable populations. As of 2017, HRSA is funding nearly 1,400 CHCs, operating at more than 12,000 sites in every U.S. state and territory. These sites serve more than 27 million people. Dr. Steinberg will provide the results of annual data collection of relevant HRSA clinical quality measures at the September 2019 NVAC meeting.

HRSA is increasing efforts to support the CHCs in addressing the measles outbreak, focusing particularly on vaccine hesitancy. For example, BPHC is developing a Clinician's Corner article on the recent measles outbreak that will be published in its weekly e-newsletter, which is distributed to health center leaders, staff, and other stakeholders. In addition to background information about the outbreak, BPHC will include links to vaccination resources for clinicians to use with their patients and health center promising practices. This article is scheduled to be published in April 2019.

OTHER ENTITIES

The APhA, IHS, and the U.S. Department of Agriculture submitted written reports only.

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 5:10 p.m.

APPENDIX: Abbreviations

ACCV Advisory Commission on Childhood Vaccines
ACIP Advisory Committee on Immunization Practices

AHIP America's Health Insurance Plans

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

APhA American Pharmacists Association ASN Adult Safety Net [program, Texas]

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

BPHC Bureau of Primary Health Care CHC community health center

CMS Centers for Medicare and Medicaid Services
CDC Centers for Disease Control and Prevention

CDS clinical decision support

DICP Division of Injury Compensation Programs

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

FY fiscal year

HHS Department of Health and Human Services

HPV human papillomavirus

HRSA Health Resources and Services Administration

IHS Indian Health Services

IIS immunization information systems

JE Japanese encephalitis

MMR measles-mumps-rubella [vaccine]

NACCHO National Association of County and City Health Officials NIAID National Institute of Allergy and Infectious Diseases

NIH National Institutes of Health

NVAC National Vaccine Advisory Committee NVPO National Vaccine Program Office

PACCARB Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

PAHO Pan American Health Organization

PEACH Parents Educating and Advocating for Children's Health

Project ECHO Extension for Community Healthcare Outcomes®

Tdap tetanus, diphtheria, and pertussis [vaccine]

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

VFC Vaccines for Children

VICP Vaccine Injury Compensation Program

VRBPAC Vaccines and Related Biological Products Advisory Committee

WHO World Health Organization