



National Vaccine Advisory Committee (NVAC)

September 20, 2016, Meeting Minutes

Committee Members in Attendance

Kimberly M. Thompson, Sc.D., Chair
Richard H. Beigi, M.D., M.Sc.
Timothy Cooke, Ph.D.
David Fleming, M.D., M.P.H.
Ann M. Ginsberg, M.D., Ph.D. (by phone)
Philip Hosbach
Ruth Lynfield, M.D.
Yvonne Maldonado, M.D.
Saad Omer, M.B.B.S., M.P.H., Ph.D.
Wayne Rawlins, M.D., M.B.A.
Mitchel C. Rothholz, R.Ph., M.B.A.

NVAC Ex Officio Members

Iris Mabry-Hernandez, M.D., M.P.H.,
Agency for Healthcare Research and
Quality (AHRQ, *by phone*)
Julie Schafer, MPH, MS (for Richard
Hatchett, M.D.), Biomedical Advanced
Research and Development Authority
(BARDA)
Nancy Messonnier, M.D., CAPT, Centers
for Disease Control and Prevention
(CDC)
Mary Beth Hance, Centers for Medicaid and
Medicare Services (CMS)
COL Margaret Yacovone, M.D., M.S.P.H.,
Department of Defense (DoD)
Karen Farizo, M.D. (for Marion Gruber,
Ph.D.), Food and Drug Administration
(FDA)
Justin A. Mills, M.D., M.P.H., Bureau of
Primary Health Care (BPHC), Health
Resources and Services Administration
(HRSA)
Ken Luna, D.O. (for CAPT Narayan Nair,

M.D.), Division of Injury Compensation
Programs (DICP), Health Resources and
Services Administration (HRSA) Jeffrey
McCollum, D.V.M., M.P.H. (for
Michael Bartholomew, M.D.), Indian
Health Service (IHS)
Barbara Mulach, Ph.D., National Institutes
of Health (NIH)
Donna Malloy, D.V.M., M.P.H.,
Department of Agriculture (USDA)
Troy Knighton, M.Ed., Ed.S., L.P.C.,
Department of Veterans Affairs (VA)

NVAC Liaison Representatives

Anuradha Bhatt, M.P.H. (for Kristen
Ehresmann, R.N., M.P.H.), Association
of Immunization Managers (AIM)
Rebecca Coyle, M.S.Ed., American
Immunization Registry Association
(AIRA)
Tiffany Tate, M.H.S. National Association
of County and City Health Officials
(NACCHO)
Cara Janusz, M.P.H., M.A., (for
Cuauhtémoc Ruiz Matus, M.D., M.P.H.)
Pan American Health Organization
(PAHO)
Kathryn Edwards, M.D., Vaccines and
Related Biological Products Advisory
Committee (VRBPAC)

Designated Federal Official

Bruce G. Gellin, M.D., M.P.H., Deputy
Assistant Secretary for Health (ASH)
and Director, National Vaccine Program
Office (NVPO), Department of Health
and Human Services (HHS)

Call to Order—Bruce G. Gellin, M.D., M.P.H., Deputy ASH and Director, NVPO, HHS

Bruce G. Gellin, M.D., M.P.H., called the meeting to order at 9:03 a.m. Dr. Gellin welcomed Kimberly M. Thompson, Sc.D., the new NVAC Chair, and thanked Walter A. Orenstein, M.D., for his contribution to NVAC as the former chair. He also thanked Jennifer Gordon, Ph.D., former NVAC Executive Secretary, for her excellent work and welcomed Alice Tsai, M.P.H., who recently joined NVPO and provided her support to NVAC. He outlined key parts of the Federal Advisory Committee Act, its conflict-of-interest rules, and standards of ethical conduct for NVAC members. The following NVPO staff was also acknowledged for their support to NVAC and associated working groups: LaForest Dupree, Viola Jacobs, Chrystian Frazier, Ilka Chavez, M.P.A., Roula Sweis, Ph.D., Michael Daley, M.P.P., Karin Bok, M.S., Ph.D., Cristina Messina, M.S., Ph.D., CAPT Angela Shen, Sc.D., M.P.H., Lauren Chambers, M.P.H., Anju Abraham, M.P.H., M.S., Jordan Broderick, M.A., Guthrie Birkhead, M.D., M.P.H. Dr. Gellin then called the roll.

Welcome—Jewell Mullen, M.D., M.P.H., M.A., Principal Deputy ASH, HHS

Dr. Mullen appreciated NVAC because there is always so much activity around vaccines. In summarizing the agenda for this meeting, she noted that much has happened since the National Vaccine Plan was update in 2010: the implementation of the Affordable Care Act (ACA), the expanding use of electronic health records (EHRs), and the emergence of Ebola and Zika outbreaks. She emphasized the mid-course review (MCR) of the National Vaccine Plan that will ensure the HHS has an up-to-date roadmap that will help to assess progress made on the goals and objectives outlined in the Plan and strengthen implementation efforts. Dr. Mullen emphasized that prioritization is important in the face of uncertain resources and a changing political environment, so she encouraged NVAC to identify areas in which HHS and its partners can make the most impact. She said the unique experience and expertise of NVAC members is critical, and HHS appreciates NVAC's recommendations.

Dr. Mullen observed that vaccine uptake for adults is well below Healthy People 2020 goals. As a result, morbidity and mortality continued for vaccine-preventable diseases among adults. Under the leadership of HHS ASH Karen DeSalvo, M.D., M.P.H., M.Sc. and NVPO Director Bruce Gellin, M.D., M.P.H., a wide range of stakeholders came together through the National Adult and Influenza Immunization Summit and championed the effort for adult immunization and the implementation of the National Adult Immunization Plan.

Dr. Mullen also highlighted the importance of utilizing quality measures in quantifying processes and outcomes to enhance immunization practices in the healthcare system. In addition, she stressed the importance of consideration by NVAC of the report by its Maternal Immunization Working Group and a vote to help ensure the availability of vaccines among pregnant women. Also, given the upcoming flu season, an understanding of lessons learned in the year when the flu vaccine was not matched well to circulating viruses is crucial for the HHS to continuously improve and optimize public health protection.

Dr. Mullen also noted the establishment of a new NVAC Innovation Working Group to support the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) Incentives Working Group from the development aspect of therapeutics, rapid diagnostic, and vaccines to counter antibiotic resistance. This collaborative workgroup will provide a response

to the Secretary by exploring incentives needed to produce vaccines while ensuring sufficient return on investment, encouraging stewardship, and maintaining access for both human and animal domains.

In closing, Dr. Mullen thanked retiring member Richard H. Beigi, M.D., M.Sc., for his dedication and leadership as an NVAC member, particularly for his contributions as Co-Chair of the Maternal Immunization Working Group (MIWG) and his service on the Human Papillomavirus (HPV) Working Group. In addition, Dr. Mullen thanked the six NVAC members who agreed to extend their terms for 180 days: Sarah Despres, J.D.; Philip Hosbach; Ruth Lynfield, M.D.; Yvonne Maldonado, M.D.; Wayne Rawlins, M.D., M.B.A.; and Mitchel C. Rothholz, R.Ph., M.B.A.

Chair's Report—Kimberly M. Thompson, Sc.D., NVAC Chair

Dr. Thompson expressed her gratitude to Dr. Beigi, the NVAC members who agreed to extend their terms, and Dr. Gordon. She also thanked the NVPO staff and welcomed Ms. Tsai. She outlined the agenda, indicating that NVAC may vote on the recommendations from the MIWG and the MCR Working Group (MCRWG).

Dr. Thompson gave an overview of the agenda and meeting proceedings. She noted that the public comment period is not a question-and-answer session; rather, it is an opportunity for the public to give comments that will appear in the public record. Time for public comment is limited; written comments can be sent to the NVAC for consideration by e-mail (nvpo@hhs.gov). Dr. Thompson noted that the minutes and presentations of past meetings are published online at <http://www.hhs.gov/nvpo/nvac/index.html>.

Dr. Thompson called for review of the June 2016 NVAC meeting minutes. NVAC members unanimously approved the minutes with no changes. The next two NVAC meetings are for February 7-8, 2017 and June 6-7, 2017.

NVPO Update—Bruce G. Gellin, M.D., M.P.H., Deputy ASH and Director, NVPO, HHS

Dr. Gellin gave some examples of NVAC's influence. The NVAC recommendations for adult immunization formed the basis for the National Adult Immunization Plan (NAIP), in which Federal agencies and non-Federal stakeholders will play a role. The joint effort with PACCARB came about as a result of prior NVAC comments on the role of vaccines in preventing antibiotic resistance. Finally, the NVPO used recommendations from NVAC on vaccine confidence to develop a strategy, and HHS awarded Emory University a cooperative agreement to support implementation.

2016–2020 CDC Global Immunization Strategic Framework—Eric Mast, M.D., M.P.H., Deputy Director for Science and Program, Global Immunization Division, CDC

Dr. Mast summarized the CDC 2016-2020 Global Immunization Strategic Framework, which aligns with the NVAC global immunization goals published in 2014 in *Public Health Reports*. Complete eradication of global polio remains a top priority. Nigeria recently reported three cases of polio after nearly 2 years with no cases. Dr. Mast noted the inaccessibility of the communities in the outbreak area limited vaccination and associated surveillance efforts, and discussed the outbreak response vaccination campaigns performed and planned in Nigeria and adjacent

countries, along with stronger surveillance and coordination of efforts with humanitarian response teams.

Currently, four World Health Organization (WHO) regions are polio-free, and substantial progress continues in Afghanistan, Pakistan, and Nigeria. By mid-2016, all 155 countries still using oral polio vaccine (OPV) switched from trivalent to bivalent formulations, and many are introducing inactivated polio vaccine (IPV). Challenges to eradication include inaccessible areas due to armed conflict; accountability and performance management issues; collaboration between countries, particularly in joint border areas; vaccine hesitancy due to cultural and religious restrictions; and the need for high-quality surveillance globally.

A WHO assessment of progress on the Global Vaccine Action Plan (GVAP) found achievement of only one of six of the 2015 goals (i.e., introducing or increasing use of vaccines in low- and middle-income countries). However, Dr. Mast noted that global coverage remains low, particularly for rotavirus and pneumococcal vaccines at 19% and 31% in 2014, respectively. Dr. Mast raised concerns about sustainability in countries eligible for GAVI support and the ability of middle-income countries to provide vaccines. With respect to the goals missed, Dr. Mast noted that we did not reach the 2015 elimination targets for measles, rubella and neonatal tetanus, and diphtheria-tetanus-pertussis vaccine coverage lags well behind targets in Southeast Asia, Africa, and the Eastern Mediterranean regions. Although the estimated annual measles mortality declined by 79% since 2000 (from around 550,000 to 114,000), progress toward elimination appears stagnated since 2007.

To address these unmet goals, the 2016–2020 CDC Global Immunization Strategic Framework aims to promote a global vaccine-preventable disease safety net (through improved detection, response, and policy), to enhance program capacity (including vaccine delivery, surveillance, and information systems), to protect Americans from imported disease, and to protect populations around the world. Dr. Mast summarized the following five interconnected goals of the framework and associated priorities:

- 1) Control, eliminate, or eradicate vaccine-preventable diseases to reduce death and disability globally
- 2) Strengthen country ownership, policy and practices, and partnerships
- 3) Ensure quality of vaccination delivery to achieve high and equitable coverage
- 4) Strengthen surveillance and immunization information to prevent, detect, and respond to vaccine-preventable diseases (VPDs)
- 5) Conduct and promote research, innovation, and evaluation

Dr. Mast suggested that implementation requires connecting vertical, or disease-specific, responses with horizontal, or programmatic and system-wide, activities to form a “diagonal” approach. He discussed linking efforts to strengthen immunization programs with steps toward eliminating measles and rubella from four aspects: 1) utilizing the introduction of the second dose of measles vaccine to create new opportunities to receive vaccines and other child health interventions in the second year of life; 2) using measles as an indicator of health systems strength to identify and target high-risk populations for improvement to routine immunization services; 3) conducting measles risk assessments to identify and target chronically unreached and underserved populations and geographies for the planning of measles campaigns; and 4)

advocating for measles elimination to strengthen institutional policies and practices for high quality immunization programs.

Building on the success of polio eradication efforts, the targets for the next 5 years include:

- a world free of measles and rubella,
- ending deaths from vaccine-preventable diseases among children under 5 years,
- reducing chronic disease and cancer deaths from vaccine-preventable diseases, and
- improved detection of and response to vaccine-preventable diseases.

Next steps of the implementation include possibly building a global immunization coalition, developing a roadmap to redirect polio resources to other diseases, and developing the evidence base for key strategies and interventions for the framework. Dr. Mast expressed concern that despite the existence of several major global immunization partnerships and initiatives (including the Global Polio Eradication Initiative, GEPI; the Gavi Alliance, GAVI, or formerly the Global Alliance for Vaccines and Immunization); the Measles & Rubella Initiative; the International Health Regulations; and the Global Health Security Agenda), no overarching or cohesive framework exists to comprehensively address the unmet needs of immunization program in all countries to achieve universal access to vaccines and to address the unfinished GVAP agenda. Dr. Mast also elaborated on the potential functions of such global immunization coalition in addressing unmet needs and reinvigorating global efforts to get the stalled GVAP agenda back on track.

Discussion

Dr. Maldonado supported a global immunization coalition as a good idea, because all of the potential partners face fluctuating resources. She asked how such a coalition would be funded and organized. Dr. Mast emphasized the early stages of the discussion of creating such a coalition and noted it would focus on building capacity and partnerships within countries, as well as bringing together the pieces of a global vaccine safety net.

David Fleming, M.D., M.P.H., pointed out that a streamlined approach would help to reduce the overlap across organizations and missions. He suggested Dr. Mast consider whether a coalition could incorporate efforts to finance vaccine development. Dr. Fleming added the need to establish mechanisms to ensure vaccines reach the target populations. Saad Omer, M.B.B.S., M.P.H., Ph.D., noted intrigue about the concept proposed, but suggested other entities may already play key roles and he recognized the importance of not overextending resources and manpower. Mr. Hosbach said vaccine procurement remains unpredictable and unreliable for manufacturers and suggested that CDC and the proposed coalition could contribute to the strengthening of the current procurement and delivery system. Dr. Gellin said vaccine development and vaccination programs exist in separate worlds and should come together.

Dr. Mast expressed concern at CDC about the fragmentation of the agendas of partners and how it affects country health departments. He believes a new streamlined, coordinated entity is needed to address the unfinished work of the GVAP. Dr. Mast noted that while existing entities play strong roles, the proposed coalition could fill critical gaps with its broader focus. He hoped that NVAC would continue to highlight the important role of the U.S. Government (USG) in

supporting global immunization efforts, and the need to transfer resources dedicated to polio eradication to meet unmet goals of the GVAP.

2010 National Vaccine Plan Mid-Course Review (MCR)

NVPO 2010 National Vaccine Plan MCR Report—Diane Epperson, Ph.D., Booz Allen Hamilton

The NVPO commissioned a federal MCR report, and Dr. Epperson presented the process and findings of the NVPO report. She explained that the purpose of the MCR: to guide future activities and incorporate areas ripe for progress, recognizing that the landscape has changed since 2010, and to provide a potential roadmap during the transition to the next Administration. The NVPO MCR focused on whether the 2010 National Vaccine Plan is meeting its objectives and still going in the right direction. It also assessed optimal efforts in the current landscape and how to measure progress. The NVPO MCR process included engaging Federal and non-Federal stakeholders in focus groups and interviews as well as other information-gathering efforts.

Two broad themes emerged in the NVPO MCR: 1) collaboration was essential to past achievements and will continue to be vital, and 2) capitalizing on technology is key to past and future success. The stakeholders helped to identify five opportunity areas (OAs) that fall into two categories:

Vaccination/Coverage

- Strengthen health information and surveillance systems to track, analyze, and visualize disease, immunization coverage, and safety data, both domestically and globally.
- Foster and facilitate efforts to strengthen confidence in vaccines in the immunization system to increase coverage rates across the lifespan.
- Eliminate financial and systems barriers for providers and consumers that facilitate access.

Vaccine Development

- Strengthen the science base for development and licensure of vaccines.
- Facilitate vaccine development.

Dr. Epperson summarized some of the key findings. For example, stakeholders emphasized the importance of improving surveillance and data systems, addressing vaccine confidence and communication, and breaking down systems barriers to access. They also suggested broad steps needed to improve vaccine development.

The NVPO MCR report identified 59 existing indicators, including global indicators, as potentially useful for tracking progress, and it linked these to corresponding OAs. Dr. Epperson mentioned the final stages of the approval process for the NVPO MCR and its expected later release following clearance.

NVAC MCRWG Update and Draft Report—Yvonne Maldonado, M.D.

Dr. Maldonado presented the draft report prepared by the MCRWG to NVAC for discussion. This NVAC discussed draft recommendations at its June 2016 meeting, and the MCRWG considered comments that it received from NVAC members while writing the draft report. The MCRWG focused a great deal on identifying existing proposed metrics to assess progress and conceptualizing metrics where none exist. Dr. Maldonado highlighted the need to develop some new metrics in the mid- and long-term. In some cases, available data could support the development and use of new metrics, but lack of access to these data makes their use impractical. Dr. Maldonado also pointed out that in addition to the five OAs, the stakeholder engagement process identified four other topics as high priorities to keep in mind:

- Increase coordination, collaboration, and knowledge-sharing among related parties and disciplines.
- Improve the transparency of the vaccine safety system and the entire vaccine enterprise to policy-makers, the public, and providers.
- Improve scientific knowledge about why and among whom vaccine adverse events occur.
- Support the strengthening of immunization systems globally through policies, practices, and partnerships.

As at the June 2016 NVAC meeting, Dr. Maldonado described the characteristics of success, challenges to progress by 2020, and existing and proposed metrics for each of the five OAs as discussed in the NVAC MCR draft report, which proposed the following recommendations:

- Overall, NVAC supports the NVPO MCR findings and its focus on the five priority OAs. With the availability of additional funding or other resources, NVAC recommends that stakeholders continue to support the 2010 National Vaccine Plan objectives not included in the five OAs described in the NVPO MCR report.
- The NVPO should highlight NVAC recommendations from previous NVAC reports in support of implementation of the priorities outlined in the NVPO MCR.
- Findings from the MCR should inform future development by NVPO of the 2020 National Vaccine Plan, recognizing that many of the activities described only lay the groundwork and real advances in these areas will take both near-term and long-term strategies to realize the full potential of these efforts on the vaccine and immunization enterprise.
- The ASH should take into account the additional considerations outlined in the NVAC MCRWG report in decisions regarding resources and activities to fulfill the goals and objectives in the National Vaccine Plan going forward and support the development of new metrics around OAs for which no appropriate metrics exist.
- The ASH should continue to support and integrate global immunization efforts into OAs to support the National Vaccine Plan.

Discussion

NVAC members offered numerous detailed and specific points for consideration before finalizing the NVAC MCRWG report. For example, for the challenges in OA 5, Dr. Lynfield noted that in addition to identifying emerging pathogen threats early enough to prepare vaccine candidates for response before the end of the outbreak, the language should recognize the challenges of developing vaccines to address populations at high risk for these emerging threats,

such as pregnant women. Nancy Messonnier, M.D., CAPT, suggested the document more explicitly distinguish efforts to develop vaccines for unexpected and emerging threats (e.g., Ebola and Zika virus) from efforts to create vaccines for known diseases for which no vaccine currently exists (i.e., the vaccine pipeline).

Kathryn Edwards, M.D. brought up data sharing and transparency and wondered if it could help speed up licensure and analysis. Dr. Maldonado said the MCRWG discussed the need to share data, and thought it would be helpful to encourage more transparency in the metrics. Mr. Hosbach noted renewed effort by the FDA in designing efficacy studies to identify correlates of protection to improve future vaccine development. Dr. Maldonado said the next iteration of the National Vaccine Plan could potentially include metrics that track correlates of protection.

Regarding a proposed metric for OA 2, Dr. Omer suggested that states will probably not eliminate personal belief exemptions (PBEs) and that a focus on PBEs would miss out on the progress made in many states that continue to make obtaining non-medical exemptions more difficult. Better measures of progress toward increased vaccine confidence should reflect less dramatic legislative and policy changes and he suggested that the NVAC propose a metric that tracks smaller nuances in legislation. Regarding a proposed metric for OA 5, Dr. Omer hoped that investments in basic research efforts would count as part of the total USG investment.

Dr. Fleming suggested more attention to measuring disparities and inequities in immunization by collecting more granular demographic data that could reveal immunization rates by neighborhood. Dr. Maldonado agreed about the need to parse the demographic data in more detail. CAPT Messonnier pointed out that recent National Immunization Survey data show continued discrepancies in childhood vaccines by poverty status at the State level. She said the MCR should call for decreasing disparities.

In relation to OA 3, Mr. Rothholz asked for a closer look at new compensation policies may negatively affect the immunization neighborhood and suggested that compensation policies are a big driver in the lack of progress. The absence of consensus around key measures for assessing performance of vaccine providers also poses a challenge, said Mr. Rothholz.

Mr. Hosbach suggested that the metrics on vaccine confidence should include periodic updates from the NVPO, which created an implementation plan for the NVAC vaccine confidence report recommendations. He also suggested establishing a metric for confidence in adult vaccines. Dr. Beigi suggested NVPO and NVAC reach out to the American College of Obstetricians and Gynecologists to address issues around vaccination in obstetric and infant populations.

CAPT Messonnier suggested the MCR more prominently address the importance of making data available and accessible to consumers, which contributes to vaccine confidence. She added that vaccine confidence would be improved by the availability of more effective vaccines for more populations, so vaccine development research should address special populations, such as pregnant women and the elderly. Furthermore, CAPT Messonnier said the MCR should emphasize that new laboratory diagnostics and whole genome sequencing continue to significantly improve our understanding of pathogens and disease.

Based on the discussion, Dr. Thompson noted that NVAC members need more time to review the draft NVAC report as well as the companion NVPO report, which the MCRWG reviewed but which was still in clearance for broad distribution at the time of the meeting. CAPT Messonnier pointed out that the new Administration will look for some quick wins. She suggested that the NVAC report highlight not just the most important areas but also those items that a new Administration could address promptly. Dr. Maldonado agreed and said some of those quick wins could come from adopting existing metrics.

Action Item

NVAC members will send additional comments and proposed changes to the MCRWG for further consideration within 2 weeks of this meeting. The MCRWG will present a final draft for approval at the February 2017 NVAC meeting.

NVAC MIWG: Findings and Recommendations—Saad Omer, M.B.B.S., M.P.H., Ph.D.

Dr. Omer reminded the NVAC of the MIWG charge to identify barriers and opportunities for developing vaccines for pregnant women and make recommendations to overcome the barriers. The MIWG presented its draft recommendations at the June 2016 NVAC meeting. Dr. Omer reiterated the recommendations in four categories: ethical issues, policy issues, preclinical and clinical research, and provider education and support and noted that the current draft reflects input from NVAC members and further deliberation by the MIWG.

Notably, the MIWG recommendations on ethical issues maintain that pregnant women should not be considered a “vulnerable population.” Unlike other such populations (e.g., children, prisoners), Dr. Omer said pregnant women have full autonomy and agency in their decision-making. The MIWG suggested the term “scientifically complex” to recognize that pregnant women make up a special category. The MIWG recommends that policy and regulatory guidelines promote the inclusion of pregnant women in clinical trials when scientifically appropriate.

The MIWG recommendations on policy encourage investment in developing new vaccines that focus on pregnant women and also in broadening indications for existing vaccines to include pregnant women. They also call for the HHS Secretary to resolve uncertainties around coverage under the Vaccine Injury Compensation Program (VICP) for vaccines administered to pregnant women and liability protections for infants born to women vaccinated during pregnancy.

Dr. Omer outlined numerous recommendations about preclinical and clinical research, particularly the need for more and better surveillance. He said that expanding pharmacovigilance by linking maternal data systems, infant data systems, and surveillance systems would require some effort but could represent an easy win for the next Administration. In addition, the MIWG called for more provider education, especially on how to interpret new labeling regulations concerning pregnant and lactating women.

The MIWG solicited public comments on its draft report. The group reviewed all the 20 public comments received from various stakeholders and explained why it did not revise the report recommendations or justifications in response to them. Most of the commenters supported the recommendations, and most strongly supported the recommendation to clarify VICP policies on

pregnant women. Many individual commenters advocated for creation of a group B Streptococcus vaccine. The manufacturer Novavax cautioned against requiring manufacturers to justify their exclusion of pregnant women in studies. The Biotechnology Industry Organization suggested identifying specific stakeholders in some of the recommendations. The National Vaccine Information Center opposed the recommendations and stated that maternal immunization should not be standard practice.

Discussion

Mr. Hosbach and Timothy Cooke, Ph.D., expressed concern about the reference to the Pediatric Research Equity Act in the report that will accompany the recommendations. Both felt that the current wording could lead to a requirement to include pregnant women in all studies. The NVAC discussed the level of effort involved, in the context of research funding applications and research approval, in justifying the exclusion of a particular population from a study. Mr. Hosbach said the effort goes beyond inconvenience and could have a chilling effect on research. Dr. Omer and Dr. Maldonado responded about the need to encourage researchers to include pregnant women in more studies. Mr. Hosbach and Dr. Cooke suggested changing the language in the report from “a similar effort directed to require” to “a focused effort to encourage,” and NVAC members agreed.

Dr. Thompson offered some minor editorial revisions and recommended deleting the text in the accompanying report referring to thalidomide as an example for which clinical testing of vaccines in pregnant women prior to FDA approval could have prevented adverse events, because thalidomide is a drug (not a vaccine) and the FDA did not approve its use in the US. The NVAC members agreed with the suggestion. Dr. Beigi confirmed the absence of examples for which the lack of pre-approval testing of vaccines in pregnant women prevented the discovery of adverse events until after FDA approval.

Recommendation

NVAC unanimously approved the MIWG report and recommendations pending incorporation of the changes suggested.

Response of HHS to the 2014–2015 Seasonal Influenza Vaccine Mismatch—Dr. Armen Donabedian, Scientific Technical Advisor and Vaccine Development Branch Chief, Influenza Division, BARDA

Dr. Donabedian described the background of the 2014-2015 seasonal influenza vaccine mismatch. The A(H3N2) component of the vaccine did not respond well to the circulating virus in the winter and spring of 2014, with mounting evidence of an antigenic drift and a vaccine mismatch. By January 2015, evidence suggested only 23% effectiveness of the vaccine and the number of hospitalized individuals 65 years and older attributed to influenza reached a record high, which prompted a Congressional hearing involving several HHS agencies. By March 2015, the HHS Secretary requested an action plan to address flu vaccine mismatches. That request set in motion numerous interagency meetings, discussions with industry stakeholders, and collaborations with the WHO, ultimately resulting in the Seasonal Influenza Vaccine Improvement (SIVI) Implementation Plan.

In providing a contextual understanding of the SIVI plan, Dr. Donabedian illustrated the complex influenza vaccine production process from development, production, and distribution aspects with integrated timeline. He emphasized more flexibility at the beginning of the process than the back end and highlighted reagent preparation as a critical step because it determines the potency of a vaccine and represents the most time-consuming aspect of the process.

To mitigate the risk of mismatch, the HHS plan aims to:

- Improve decision-making on vaccine composition;
- Optimize development of candidates and shorten production timelines to increase flexibility;
- Expedite distribution, administration, and tracking; and
- Develop a five year plan of interagency collaboration (BARDA, CDC, FDA, NIAID, industry, and academic partners) that would build on the technical success of previous collaborations.

Dr. Donabedian described several of the key components of the work plan to achieve these goals, such as expanding the Global Influenza Surveillance and Response System (GISRS). He went on to explain how these steps would influence vaccine matching, noting that the likelihood of mismatch decreases as the time taken to observe the evidence increases (i.e., the longer the selection of the vaccine strains is postponed). The overall impact of the new HHS approach would enable the delay of the decision about one component of the vaccine, so that the rest of the vaccine could be prepared and the final component added just in time for distribution. In the context of extreme uncertainty, the approach would allow production of a second vaccine (ideally an easier to produce monovalent vaccine). However, the use of a second vaccine would necessitate good tracking mechanisms to ensure everyone appropriately vaccination. All of the improvements proposed would bolster the response to a pandemic influenza, but they could add to some delay in the timing of distribution of vaccine and significantly complicate logistics in vaccine delivery and use.

Expanding the GISRS will help with candidate vaccine virus (CVV) characterization and development, as would a “sequencing first” approach. Current, powerful technology allows investigators to see more viruses than before. Sequencing potential viruses first would lead to earlier identification of potential drift variance, enabling advance preparation of reagents for less likely viruses should they become dominant. Using new technology to improve characterization of viruses will lead to the selection of better matches with the circulating virus. Improved risk assessments require more data collection and new tools for predicting emerging viruses and viruses not likely to change. With such tools, vaccine production could begin on three components of a quadrivalent vaccine, leaving time and space to add the fourth component that addresses mismatch issues. Additional capacity for vaccine preparation would also provide more flexibility in the process.

Improving reagent preparation would allow identification of several candidates. If manufacturers prepare the reagents for three of the four components in the influenza vaccine in advance and/or produce CVVs that grow better, then this could shorten the timeline for manufacturing. Improving potency assays could reduce the quantity of reagents needed for vaccine release.

Finally, vaccine distribution and administration improvements depend on enhancing immunization information systems (IIS) at state levels to improve tracking of flu vaccines, including receipt of a second (monovalent) vaccine if needed.

Dr. Donabedian gave an example in which combining all of the proposed improvements to compress the timeline allowed public health officials to make a new monovalent vaccine to address an unexpected virus strain as late as mid-June for the upcoming influenza season (as long as the system accepts later delivery of the vaccine). He concluded that these improvements represent only part of the answer to avoiding mismatches and emphasized that developing a more broadly cross-reactive influenza vaccine offers the ultimate solution.

Discussion

Dr. Gellin emphasized that the HHS engaged many stakeholders in developing the work plan to help identify areas of flexibility in the timeline. Manufacturing and delivery of influenza vaccine represent the areas of least flexibility. Even among other governments with fixed systems, minor delay often triggers a chain reaction due to the globally-interconnected nature of the vaccine manufacturing system.

Dr. Maldonado asked about the approach of using predictive modeling based on next generation sequencing, Dr. Donabedian explained the use of sequence or antigenic data in the model development process and emphasized the capacity of GISRS and provision of data to CDC and others who make models are key to understanding how viruses act in real time. He reiterated that even knowing which viruses remain stable represents valuable information and offers some flexibility in the timeline for manufacturers.

Mr. Hosbach asked CDC how it defines a mismatch, and CAPT Messonnier responded about the multiple factors in play. She said CDC always tries to identify emerging strains and works on developing CVVs for them. Drift occurs every year, but the drift variant usually does not become dominant. CDC hopes that sequencing by CDC and state health departments first will make better data more readily available and improve data quality for modelers.

Mr. Hosbach emphasized the difficulties that would likely arise in explaining the need for a second monovalent vaccine to the public, and CAPT Messonnier agreed. She said in such a case, CDC would look to the Advisory Committee for Immunization Practices (ACIP) for help and ask the vaccine community how best to get the message out. CAPT Messonnier agreed about the importance of messaging in the long term, because mismatches affect public confidence in vaccines. Dr. Donabedian said one of the many HHS projects underway focuses on communication although ultimately the WHO and the HHS Secretary make the decisions.

Dr. Edwards applauded efforts for the real-time determination of vaccine efficacy, including standardization of definitions and communication strategy with the global community. She hoped such efforts would receive continued funding. Dr. Thompson suggested the HHS should consider the system-wide impact of delaying decision-making, including the effects in other countries. She also suggested thinking about reimbursement policies in the case of a second

vaccine. Ms. Tate noted other logistical concerns that would come into play in case of a second monovalent vaccine, such as storage capacity, information systems, and staffing challenges.

The NAIP Implementation Guidance—CAPT Angela Shen, Sc.D., M.P.H., NVPO

Dr. Shen explained the NAIP seeks to address public health vaccines for adults and align with other HHS priorities representing the perspectives of numerous stakeholders and NVAC recommendations. The four goals of the NAIP aim to 1) strengthen the adult immunization infrastructure, 2) improve access to adult vaccines, 3) increase community demand for adult immunizations, and 4) foster innovation in adult vaccine development and vaccination-related technologies.

Dr. Shen presented a draft of the Pathway to Implementation, which facilitates action on the NAIP by narrowing down 78 strategies into the following eight targeted priorities developed through a stakeholder engagement process that included focus groups and calls for data:

1. Address technical, legal, administrative, and practical barriers to greater use of EHRs and immunization information systems (IIS) to collect and track adult immunization data.
2. Evaluate the impact of current adult vaccination quality measures and the feasibility of future quality measure development projects.
3. Evaluate the impact of financial barriers, such as copays, on adult vaccination uptake.
4. Research the total costs of providing vaccination services in a provider setting to improve understanding of costs associated with the range of activities that are needed to ensure efficient and effective immunization services (e.g., ordering, handling, storage, administration, patient recall/reminders, and counseling).
5. Identify legal, practical, and policy barriers that may impede expansion of the adult immunization provider network, and communicate challenges to policymakers.
6. Encourage all providers, including providers in complementary settings, to implement the NVAC Standards for Adult Immunization Practice, which includes assessing patients vaccination status at every clinical encounter, strongly recommending needed immunizations, and either administering vaccines (including documentation in an IIS) or referring patients to others who administer vaccinations.
7. Engage community leaders in reaching the public with information about the importance of adult vaccination.
8. Engage ongoing efforts to develop and license new and improved adult vaccines, including support for research, development, and licensure of vaccines; improved effectiveness; and longer duration of immunity.

The Pathway for Implementation suggests concrete actions for implementation, but it does not commit any specific agencies or partners to action. The Pathway may help to support budget requests, inform decision-making, and set agendas; NVPO seeks feedback from stakeholders on how they might use the implementation suggestions. The NVPO and the Federal Adult Immunization Task Force will track and report annually on progress toward the NAIP goals using progress indicators derived from Health People 2020 targets. Following finalization of the Pathway to Implementation, the NVPO will post it publicly and share it with NVAC for review.

Discussion

Regarding priority area 4, Mr. Rothholz commented on the time-consuming (and thus costly) nature of IIS reporting for providers. Regarding priority area 5, for which Dr. Shen gave an example related to physician billing of Medicare Part D, Mr. Rothholz emphasized Medicare Part B and IIS reporting also create barriers that should be addressed.

During the transition between sessions and speakers, Dr. Thompson asked CAPT Messonnier how CDC will get more information to reassess the effectiveness of the nasal (live attenuated) influenza vaccine if ACIP is recommending against its use in children this year. CAPT Messonnier said data showing substantially better effectiveness of the shot compared to the nasal vaccine prompted the recommendation against use of the nasal vaccine. She acknowledged the lack of data poses a problem but said CDC will consider information from other countries (e.g., Canada and the United Kingdom) and will work with manufacturers to gather data for reconsideration. CAPT Messonnier said public health officials, medical societies, and manufacturers worked well together to communicate the new recommendation, and she remained optimistic that the recommendation would not have a major impact on influenza vaccinations this flu season.

Quality Measures: Narrowing the Gap in Measurement and Reporting for Adult Immunizations

Introduction—CAPT Angela Shen, Sc.D., M.P.H., NVPO

Dr. Shen outlined the National Quality Strategy, a byproduct of the ACA that aims to promote better care and better health at lower costs. It identifies six priorities and describes levers for action, including quality measures, which may reflect improvements at the community level, within practice settings, and among individual providers.

Endorsed by the Institute of Medicine, composite measures describe a set of routine, recommended vaccines for a target group (e.g., people over 65 years, people with a specific condition). Dr. Shen described two proposals to fill gaps in adult immunization performance measurement by developing composite measures for adult immunization—specifically, tetanus, diphtheria, and pertussis (Tdap) and influenza vaccination for pregnant women, and influenza, pneumonia, and hepatitis B for people with end-stage renal disease. The National Quality Forum (NQF) proposed and based on the results of pilot testing by HIS the National Adult and Influenza Immunization Summit (NAIIS) Quality Performance Measure Working Group supported these metrics.

National Committee for Quality Assurance (NCQA) and Immunizations: The Lifecycle of a Measure—Sepheen Byron, Assistant Vice President, Performance Measurement, NCQA

Ms. Byron summarized the mission of NCQA and explained how it fits into the landscape of organizations concerned with health care quality. She said that organizations implement guidelines for care by assessing objective quality measures that support comparisons of entities and health plan accreditation, provider and physician recognition, and public reporting. NCQA health plan accreditation combines results of performance measures (from the Healthcare Effectiveness Data and Information Set [HEDIS]), patient experience (through the Consumer Assessment of Healthcare Providers and Systems [CAHPS]), and individual system measures of management and governance.

The most desirable elements of a quality measures include:

- **Relevance:** The measure should be meaningful to all users, important to improving health, controllable, and contain the potential for improvement.
- **Scientific soundness:** The measure should adhere to the evidence base. It should link process measures to outcomes and should be valid and reliable.
- **Feasibility:** The measure should be precisely specified and auditable. It should not be subject to wide interpretation.

Ms. Byron noted the challenges of balancing these elements. The measure development process aims to ensure balance through a consensus process, with stakeholder feedback throughout. NCQA identifies potential measures as a result of an environmental scan, then drafts and field tests proposed measures, and posts information about the metric and process for public comment. Advisory panels give input on the final specifications and independent stakeholder panel that include representatives of health plans, consumers, providers, and other groups review the measures, which when completed get incorporated into HEDIS.

Once incorporated into HEDIS, NCQA does not publish the results of the new measure for the first year to allow time to address flaws or unforeseen issues. After the first year, the measure is reviewed and approved for public reporting and use in other programs. NCQA retires measures when they no longer provide useful measures (e.g., retirement of the use of beta blockers following a heart attack as a measure when results showed all providers consistently scored very high, which was replaced with a measure of persistence of treatment). The example demonstrates how the quality measure effectively raised the bar for health care, said Ms. Byron.

Pharmacy Quality Alliance (PQA): Experience in measure development and the PQA Adult Task Force—Hannah Fish, Pharm.D., Associate Director of Education and Communications, PQA

Dr. Fish said PQA, established in 2006 with the launch of Medicare Part D, focuses on the quality of medication management across health settings. PQA develops measures based on consensus of its membership, which represents diverse stakeholders. Dr. Fish pointed out that PQA develops measures and works with others to encourage their use and it uses a development process similar to that of NCQA. Developing measures takes time—on average, 18 months from the initial concept to endorsement. Once the PQA membership approves a measure, it goes to the NQF for approval, which takes another year.

PQA launched its Adult Immunization Task Force in 2014. It aims to prioritize measures based on NVAC recommendations and NQF Adult Immunization Committee priorities. The Task Force put forth two measure concepts:

- **IIS registry reporting** (the percentage of administered adult vaccinations submitted to IIS via any claim), which allows assessment of provider reporting at the state level (i.e., variability in state IISs makes national measures infeasible). This measure is slated for review by the PQA Quality Metrics Expert Panel. If approved, it would move to a testing phase.

- **Immunization status assessment in medication therapy management** (the percentage of adults who met eligibility requirements for medication therapy management and received an immunization assessment), which would evaluate activities such as counseling, usually performed by pharmacists. This measure seeks to identify how to improve adherence to CMS Medicare requirements. This measure is in review as evaluators consider how the information gathered from the immunization assessment should be used. A related measure is in development that would evaluate efforts to ensure that a patient is up to date on all immunizations.

Dr. Fish hoped these measures would be ready for implementation by the end of 2017. The PQA Adult Immunization Task Force plans to reconvene and prioritize the next measures to be developed. Dr. Fish said prioritization would help identify the most meaningful measures that can fill gaps in knowledge while not increasing the burden of reporting.

Discussion

In response to a question from Dr. Maldonado, Dr. Shen explained that a composite measure requires that a provider give all the vaccinations specified in the measure. Including multiple vaccines prevents preferential selection of one over another. A composite measure encourages full vaccination.

Dr. Maldonado asked how proposed PQA measures would use pharmacy systems, medical claims, and IIS to validate against each other. Dr. Fish explained that any claim submitted to a health plan should be reported to an IIS, so the measures would compare the two to identify the gaps in reporting. The goal is to create accountability across systems, she added.

Mr. Rothholz asked what NCQA and PQA are doing to ensure that immunization measures are incorporated in efforts to consolidate measures. He noted that a composite measure should reduce the reporting burden on providers. Mr. Rothholz also said that implementing measures on IIS use will also drive reporting. Mary Barton, NCQA vice president, said America's Health Insurance Plans (AHIP) convened a group to recommend core sets of measures for accountable care organizations and medical homes to help streamline reporting. The process is just starting, but Ms. Barton believed the pediatric core set would have immunization measures. She said improving the utility of registries would make it easy for providers to identify which patients are up to date on immunizations. Dr. Fish said PQA met with the AHIP Core Quality Measures Collaborative to ensure the inclusion of adult immunization. PQA is looking at composite measures beyond the IHS version and ways to incorporate immunization into provider workflow.

Dr. Shen pointed out that the immunization schedule for adults is based on risk, while for infants and children, it is based on age. She also noted that IIS and EHRs come up in every discussion of adult immunization. Ms. Byron said NCQA hopes to incorporate electronic clinical data systems. Current measures use registry data, but there is a push for more standardization. Ms. Byron said consolidation should be balanced by efforts to ensure the filling of gaps where measures do not exist. Dr. Shen said NVPO can update NVAC on the progress of consolidation efforts at a future meeting.

Dr. Gellin raised concerns about an excess of measures and asked how to prioritize among them. Ms. Barton noted that AHRQ sponsors a National Quality Measures Clearinghouse. NCQA scans the environment to verify non-redundancy of its proposed measures. However, Ms. Barton said, priorities change over time and issues emerge. A targeted, concrete measure can help to promote a specific health practice and further garner support and buy-in. NCQA develops measures for practices it deems important but also works with CMS and other Federal agencies on useful measures for health plans, especially Medicare. Ms. Barton said NCQA thinks about building measures for the future and for systems in various settings, because it recognizes the value of a durable system.

In response to Dr. Gellin, Dr. Fish said PQA and NCQA develop consensus-based measures, so organizations cannot just “pay to play.” Federal government priorities help drive the selection of measures, but ultimately measures focus on areas of importance to multiple stakeholders and to the field.

NVAC Liaison and Ex Officio Updates

AIM—Anuradha Bhatt, M.P.H.

Ms. Bhatt said AIM released its Adult Immunization Resource Guide, which profiles various activities that programs can implement, ranging from low-hanging fruit to more involved means to increase adult immunization. Topics include IIS, engaging providers and the public, working with pharmacies, and reaching high-risk adults and pregnant women. AIM is completing its annual survey, and new data will be released in coming months along with new CDC data.

AIRA—Rebecca Coyle, M.S.Ed.

Ms. Coyle said AIRA completed the first stage of an IIS assessment launched last year, testing interoperability that assessed what States can do and how they connect with reporting systems. AIRA now sends monthly reports to all jurisdictions to update them on performance. The next stage assesses query-and-response, or bidirectional, capacity between IISs. The third stage will evaluate data quality. AIRA also took part in a joint development initiative to look at services and begin to harness economies of scale across communities. The pilot phase of that project involves an address cleansing service as well as geocoding. Regarding global interest in IIS, Ms. Coyle said she recently attended meetings with the European Counterpart of the CDC and PAHO about implementing IISs, which will likely have implications for the rest of the world.

NACCHO—Tiffany Tate, M.S.H.

Ms. Tate said NACCHO regularly convenes its immunization working group comprised made up of local health officers, NACCHO staff, and coalition members to discuss emerging issues, best practices, and initiatives. The working group last met in June, just before the NVAC meeting and the working group shared its priorities for the next year and opportunities for collaboration.

In response to announcement that the ACIP would not recommend nasal influenza vaccine this season, NACCHO convened a group to identify resulting challenges, especially for school-based programs. NACCHO continues to collect information from local health departments on the impact of the decision and how it can support them in light of the changes. NACCHO received funding from the CDC to support local health departments in partnering with community providers to promote HPV vaccination. In phase 1, 10 local health departments received funding

to forge a partnership and create action plans. In phase 2, funding supported implementation of the action plans plus participation of 10 more local health departments. The recipients presented the status of their programs at an annual meeting.

PAHO—Cara Janusz, M.P.H., M.A.

Ms. Janusz described an upcoming review of the measles-free status of the region. In August, an international expert committee met in Brazil to review verification reports from all the countries in the region. Six reports from French territories were pending but have been reviewed since. The findings will be reported to PAHO's Directing Council, which will have the final say on the matter.

VRBAC—Kathryn Edwards, M.D.

Dr. Edwards said VRBPAC met in March to make final recommendations on which influenza strains to target for the annual seasonal influenza vaccine for 2016–2017. In May, the group heard a presentation about the FDA Laboratory of Bacterial Polysaccharides.

BARDA—Julie Schafer

Ms. Schafer said BARDA is part of a USG-wide effort to build a diverse portfolio of Zika vaccine candidates with different platforms. No one knows which of the four vaccine candidates identified to date will be the best, so researchers are racing to get one to the finish line. BARDA focuses on pandemic influenza but remains interested in more effective seasonal influenza vaccinations. In the past, it supported the licensed recombinant influenza vaccine, which is now approved for use across a wider range of ages.

DoD—Margaret Yacovone, M.D., M.S.P.H.

Dr. Yacovone said that to improve tracking of vaccine losses caused by temperature compromise, DoD developed a worksheet to gather critical information about such events. By standardizing the worksheet and reporting process, DoD improved its tracking of vaccine compromises. The worksheet also enables quick identification of compromises so DoD can identify loss prevention strategies and share them with the immunization community.

To better understand adverse events following immunization (AEFIs), DoD used metabolomics—the study of metabolites—and identified some phenotypes of genetic and environmental factors to identify metabolic signs in patients that suggest predisposition to AEFIs by evaluating serum samples before and after smallpox vaccination. They found that patients who experienced severe AEFIs, such as myocarditis, differed from those who experienced mild AEFIs and those in the control group with respect to certain metabolites.

In response to the recent yellow fever vaccine shortage, the DoD's logistics agency, multiple military departments, and other Federal agencies implemented mitigation strategies to give yellow fever vaccination to all those deployed in or traveling to endemic areas, but not all recruits. DoD received clearance from FDA to use the French vaccine product, which proved necessary because a reduced dose of the U.S. vaccine did not appear sufficient for military personnel in endemic areas.

FDA—Karen Farizo, M.D.

FDA recently approved a new vaccine against cholera for adults ages 18-64 years traveling to affected areas. Other supplemental approvals include quadrivalent influenza vaccine for children ages 4 years and older and expansion of approval of the 13-valent pneumococcal vaccine to include adults ages 18-49 years. The FDA approved Afluria quadrivalent influenza vaccine in August 2016 for use in adults 18 years and older. Also, FDA approved the use of the H5N1 pandemic influenza vaccine in ages 6 months to 17 years, which expanded on its previous approval to those 18 years and older.

HRSA BPHC—Justin Mills, M.D., M.P.H.

In August, BPHC released the calendar year 2015 Uniform Data System (UDS) data. The UDS collects data from 1,375 individual grantees, which translates to about 10,000 sites for community health centers. Mr. Mills said BPHC uses a composite immunization measure for children. Recent data indicate an immunization rate of over 77% for children at or before 36 months of age. BPHC set a goal for 75% of health centers to meet the Healthy People 2020 target for childhood immunizations. To date, 42.5% of health centers meet or exceed this goal, which appears comparable with 2013 and 2014 rates. BPHC continues to work with health centers to improve performance through a number of efforts, including continued funding for new access points as well as support for EHR adoption and recognition of patient-centered medical homes. BPHC health centers received 1.5 million more patients in 2015 than 2014, a 6.5% increase. The number of sites also increased by 600, from 2014 to 2015.

IHS—Jeffrey McCollum, D.V.M., M.P.H.

Dr. McCollum said IHS is nearing the finish line on a policy requiring mandatory influenza vaccine for all of its health care personnel, including union employees. He described two education and outreach efforts underway. First, video public service announcements were developed in collaboration with HHS and the Northern Plains Tribal Epidemiology Center, which it fielded in August. Second, IHS developed and implemented a basic vaccine training program and curriculum for its community health representatives, who serve as important liaisons between clinical services and communities. Also, IHS is in phase 2 of a pilot study of composite measures for adult vaccines. It is moving toward replacing its existing measure of adult pneumococcal vaccine for those 65 and older with the composite measure starting in July 2017, pending final approval and further evaluation.

NIH—Barbara Mulach, Ph.D.

Dr. Mulach said NIH has four Zika virus vaccine candidates in development. A DNA-based vaccine entered an early-stage trial in August at three sites, and NIH hopes to have results starting in January 2017. Also, in collaboration with a Brazilian national research organization, NIH launched the Zika in Infants and Pregnancy Study in June. It aims to enroll as many as 10,000 pregnant women over multiple sites and countries in which Zika is circulating. Participants will be enrolled in their first trimester of pregnancy and will be followed throughout pregnancy and afterward for infection with Zika virus. Their infants will be monitored for at least a year after birth. NIH also launched an early-stage yellow fever vaccine trial. Finally, on September 22–23, NIH is hosting a conference, Bridging Knowledge Gaps to Understand How Zika Virus Exposure and Infection Affects Child Development.

USDA—Donna Malloy, D.V.M., M.P.H.

Dr. Malloy gave an update from the USDA Food and Nutrition Service's Special Supplemental Nutrition Program for Women, Infants, and Children, commonly known as the WIC program. Last July, USDA and Every Child by Two hosted an immunization webinar for WIC staff to provide information about recommended influenza vaccination schedules for infants, children, and pregnant women. The webinar also provided an overview on how to review records to determine the immunization status of WIC clients.

The WIC program plays a role in immunization promotion by ensuring that children covered by WIC are screened for up-to-date immunizations using a documented immunization history and then referred to providers within their state for immunization. Although WIC funds cannot be used for the purchase or administration of vaccines, qualified medical professionals can work with WIC local agencies within states to administer vaccines to WIC participants.

VA—Troy Knighton, M.Ed., Ed.S., L.P.C.

Mr. Knighton said influenza season is in full swing, and the VA started influenza vaccinations. For a second year, Walgreen's received an open contract to provide veterans with influenza vaccine to enrolled veterans as part of a program to expand access to vaccines and other medical care to enrolled veterans. Last year Walgreen's vaccinated over 48,000 veterans. Mr. Knighton said the VA hopes the number of providers will continue to grow, as well as the number of veterans vaccinated.

The VA is looking at its policies for vaccinating health care personnel. Mr. Knighton anticipated that the VA will address the same kinds of labor issues that IHS did with its policy. The VA is completing testing of a tablet application providers can use to record vaccinations in mobile settings, such as drive-through influenza clinics, and throughout the health care system. Influenza vaccine is the first vaccine being tested with the new application. If it proves successful, the VA expects to add other vaccines. Mr. Knighton expressed excitement about the new technology because it could allow providers to offer vaccinations without having to find a terminal or use paper to record the transaction.

AHRQ—Iris Mabry-Hernandez, M.D., M.P.H.

Dr. Mabry-Hernandez said AHRQ continues to spread knowledge about vaccine-related topics through funding of technical reports and investigator-initiated research grants. Topics have included geographic access to care, HPV vaccine uptake among at-risk girls, using health information technology to improve delivery of vaccines, and using a social media website for parents with concerns about vaccines.

Other Liaison Reports

The ACIP, CDC National Center for Immunization and Respiratory Diseases, HRSA Division of Injury Compensation Programs, and the Public Health Agency of Canada submitted written reports.

Public Comment

Abby Bownas said the Adult Vaccine Access Coalition (AVAC) strongly supports processes and outcome measures that enable providers to increase adult immunization rates. AVAC seeks to balance the burden on providers against the value of quality measurement reporting. Ms. Bownas said quality reporting measures represent an increasingly important tool to track progress and desired outcomes in terms of benchmarking, monitoring, and reporting and they help ensure that the immunizations for adults remains a priority and in the forefront of clinical care standards. In addition, reducing the number of missed opportunities for vaccination is imperative to improving health and reducing the burden of vaccine-preventable disease. Developing, testing, and recommending the adult immunization quality measures and incentive benchmarks under Medicare, Medicaid, and private insurance would help improve patient access to these low-cost preventive services.

Recently, AVAC partnered with vaccine experts on a white paper, “The Value and Imperative of Quality Measures for Adult Vaccines,” available on AVAC’s website. It highlights how vaccines can prevent illness and death, reduce caregiving demands, reduce unnecessary spending, and set the foundation for healthy aging. Ms. Bownas commended the amazing work done by IHS on composite measures, which allow providers to follow the complex adult immunization schedule without additional burden. AVAC hopes work by PQA and others to develop quality metrics on adult immunization and improve IIS reporting will continue and receive support from NVAC. Ms. Bownas concluded that immunization reduces morbidity and mortality and improves overall health in a cost-efficient manner.

Closing Remarks and Adjournment—Bruce G. Gellin, M.D., M.P.H., Deputy ASH and Director, NVPO, HHS, and Kimberly M. Thompson, Sc.D., NVAC Chair

Dr. Gellin noted that more work remains to complete the NVAC recommendations on the MCR. He also said consideration should be given to how NVAC can participate in quality measure development. Dr. Thompson thanked all the meeting participants and adjourned the meeting at 4:35 p.m.