National Vaccine Advisory Committee (NVAC)
September 9-10, 2015, Meeting Minutes

Committee Members in Attendance

NVAC Members
Walter A. Orenstein, MD, **Chair**
Richard H. Beigi, MD, MS
Timothy Cooke, PhD
Sarah Despres, JD
Ann M. Ginsberg, MD, PhD (day 2 only)
Philip Hosbach
Ruth Lynfield, MD
Yvonne Maldonado, MD
Charles Mouton, MD, MS
Saad Omer, MBBS, MPH, PhD
Wayne Rawlins, MD, MBA
Nathaniel Smith, MD, MPH
Kimberly M. Thompson, ScD
Vish Viswanath, PhD

Executive Secretary
Bruce G. Gellin, MD, MPH Deputy Assistant Secretary for Health, Director, National Vaccine Program Office, U.S. Department of Health and Human Services, Washington, D.C.

NVAC Ex Officio Members
Iris Mabry-Hernandez, MD, MPH (AHRQ) (via phone)
Richard Hatchett, PhD representing Robin Robinson, PhD (ASPR)
Anne Schuchat, MD (CDC)
Mary Beth Hance, representing Jeffrey A. Kelman, MMSc, MD (CMS)
Col. Margaret Yacovone, MD, MSPH (DoD)
Marion Gruber, PhD (FDA)
Justin A. Mills, MD, MPH (HRSA/BPHC)
A. Melissa Houston, MD, MPH, (HRSA/VICP)
Jeffrey McCollum, DVM, MPH representing Michael Bartholomew, MD (IHS)
Barbara L. Mulach, PhD (NIH)
Donna L. Malloy, DVM, MPH (USDA)
Troy Knighton, MEd, EdS, LPC (VA)

NVAC Liaison Representatives
Nancy M. Bennett, MD, MS (ACIP/CDC)
Scott Breidbart, MD, MBA (AHIP)
Kristen R. Ehresmann, RN, MPH (AIM)
Rebecca Coyle, MsEd (AIRA)
Kimberly Martin, MPH representing Paul Jarris, MD, MBA (ASTHO)
Tiffany Tate, MSH (NACCHO)
Hannah Kurtis, representing Isabella Danel, MD, MS (PAHO)
John Spika, MD (PHAC)
Robert S. Daum, MD, CM (VRBPAC/FDA)

Day 1 – September 9, 2015

Welcome

Dr. Gellin welcomed everyone in attendance and stated he would provide a brief update about recent National Vaccine Program Office (NVPO) activities. He explained that NVPO has recently contracted with Booz Allen Hamilton to assist in conducting the National Vaccine Plan Midcourse Review and will engage the NVAC Mid-Course Working Group later this year. He announced that NVAC's report, "Assessing the State of Vaccine Confidence in the United States: Recommendations from the National Vaccine Advisory

Committee" was accepted, and will be published soon in the journal *Public Health Reports*. He also mentioned that the National Adult Immunization Plan is in final clearance, and may be launched soon. Finally, he noted that NVAC's recommendations on the role of vaccines in combating antibiotic resistant bacteria have been forwarded to the White House as part of their assessment towards ways to meet that goal. Dr. Gellin acknowledged Dr. Anne Schuchat's contributions to NVAC because she is moving into a new position at CDC and will not be attending NVAC meetings in the future.

NVAC Chair's Report

After introductions, Dr. Orenstein mentioned that the meeting was announced in the Federal Register on August 25th as a regularly scheduled NVAC meeting and the agenda was posted on the NVAC website. Dr. Orenstein explained the meeting was being broadcast as a webcast and there was a publicly available toll-free conference line to listen to this meeting. After noting that a public comment period was available both meeting days, Dr. Orenstein described the process for making public comments at the meeting. Dr. Orenstein explained that minutes were being taken and will later be published on the NVPO website. He also explained that both the meeting and conference line were being recorded.

- ACTION ITEM: The Committee voted in favor of adopting the minutes of the June 9-10, 2015 NVAC meeting (13 in favor, 0 opposed, 3 absent).

Dr. Orenstein announced three new NVAC members, with terms starting on September 9, 2015. Dr. Timothy Cooke, CEO of NovaDigm Therapeutics, is a new Representative voting member. Representative voting members represent the viewpoints or perspectives of the vaccine manufacturing industry and earlier-stage biotechnology companies involved in vaccine development. Dr. David Fleming, Vice President of Public Health Impact at PATH, is a new Public voting member. Dr. Ann Ginsberg, Chief Medical Officer at Aeras, is also a new Public voting member. Public voting members represent their individual viewpoints and expertise on the Committee. He mentioned that Dr. Cooke was attending this September meeting for both days and Dr. Ginsberg was expected for the second day of this September meeting. Dr. Orenstein noted that all three new NVAC members are expected to attend the next NVAC meeting in February 2016.

Dr. Orenstein explained that the NVAC Charter was renewed for 2015-17, and three new non-voting members were incorporated into the charter: the American Immunization Registry Association (AIRA), the HHS Assistant Secretary for Preparedness and Response (ASPR), and the President's Advisory Council on Combating Antibiotic Resistant Bacteria (PACCARB).

NVAC's resolution on the Immunization Registry Interstate Data Exchange was published in the July/August 2015 issue of *Public Health Reports*. The report from NVAC's Vaccine Confidence Working Group will be published in the November/December 2015 issue of *Public Health Reports*.

Finally, Dr. Orenstein reviewed highlights of the September meeting agenda. He reminded the NVAC members that the next two NVAC meetings are scheduled for February 2-3, 2016 and June 7-8, 2016.

Healthy People 2020 Update

Healthy People 2020 Update for the National Vaccine Advisory Committee, Ms. Angela McGowan, Office of Disease Prevention and Health Promotion (ODPHP)

Ms. McGowan noted that HP2020 is in the U.S. Department of Health and Human Services (HHS), Office of the Assistant Secretary for Health (OASH). Ms. McGowan pointed out that Title XVII of the Public Health Act served as the authorizing legislation for the Office of Disease Prevention and Health Promotion (ODPHP), specifically to "formulate national goals, and a strategy to achieve such goals, with respect to health information and health promotion, preventive health services, and education in the appropriate use of health care."

She summarized how HP2020 is a framework for improving the nation's health. HP2020 is a national agenda that communicates a vision for improving health and, more specifically, for achieving health equity. It creates a comprehensive strategic framework for the whole nation, uniting health promotion and disease prevention issues under a single umbrella. HP2020 is a set of science-based, measurable objectives with targets to be achieved by the year 2020. It requires tracking of data-driven outcomes to monitor progress and to motivate, guide, and focus public health action.

Ms. McGowan described how Healthy People has evolved from target year 1990 to 2020. She pointed out that in 1990 the overarching goals were: decrease mortality from infancy through adulthood, and increase independence among older adults. Ms. McGowan explained that HP2020 has a broader definition of health in the four overarching goals, 42 topic areas, and 1,200 objectives. She stated that the HP2020 overarching goals are:

- Attain high quality, longer lives free of preventable disease, disability, injury, and premature death;
- Achieve health equity, eliminate disparities, and improve the health of all groups;
- Create social and physical environments that promote good health for all; and
- Promote quality of life, healthy development and healthy behaviors across all life stages.

She also showed a diagram illustrating how under the HP2020 framework, health outcomes interact with related social determinants, which is a conceptual approach to understanding how it all fits together. Those social determinants also overlap and interact with each other. Those determinants include physical environment, social environment, individual behavior, biology and genetics, and health services.

In addition to ODPHP these include a Federal Interagency Workgroup (FIW), the National Center for Health Statistics (NCHS), and Workgroup coordinators. The FIW includes 20 HHS members and representatives from the U.S. Department of Agriculture, U.S. Department of Education, U.S. Department of Housing and Urban Development, U.S. Department of Interior, U.S. Department of Justice, U.S. Department of Transportation, U.S. Department of Veterans Affairs, and U.S. Environmental Protection Agency. She noted that NCHS is part of the Centers for Disease Control and Prevention (CDC) and helps them analyze and report HP2020 data.

Ms. McGowan presented a list of the 42 topic areas, which include 12 new topic areas added for HP2020. She explained that HP2020 developed 26 Leading Health Indicators (LHIs), which are a subset of the 1,200 HP2020 measurable objectives. She noted that the LHIs were intended to cover a wide range of issues related to what makes people healthy.

Ms. McGowan focused on the Immunization and Infectious Diseases (IID) topic area. The IID topic area goal is: "Increase immunization rates and reduce preventable infectious diseases." For the IID topic area, HP2020 has 67 measurable objectives that are focused both on infectious diseases and immunizations. She recommended that everyone look at the healthypeople.gov website, which includes a lot of information on the topic areas and objectives along with other information such as national snapshots, stories from the field, eLearning, and webinars. As an example, she showed the IID topic area page and explained the tabs for overview, objectives, interventions and resources, and national snapshots. She showed the Objectives tab for one of the immunization-related goals and noted the available information for each objective includes the baseline, the target, target-setting method, and data sources, as well as revision history to help track efforts.

Ms. McGowan reviewed the HP2020 timeline and explained they are currently working on their mid-course review with help from NCHS for data analysis. In addition to the mid-course review, other ways that HP2020 measures progress are the *Who's Leading the Leading Health Indicators?* series and progress review webinars. The mid-course review will be released in the fall of 2016 as a data report published by NCHS assessing the status of HP2020 topic area objectives mid-decade. It will have an in-depth focus on data trends and movement and will focus especially on assessing disparities that are critical to promoting health equity. The mid-course review will be a useful tool to benchmark progress and plan for rest of the decade, and will consider new science and data.

Ms. McGowan concluded by providing a brief overview of HP2030 planning efforts that will begin in FY2016.They will be considering what approach to take, what groups to involve, and ways of getting input from the public. HP2030 will be launched at the end of 2020.

CDC Update on Achieving Healthy People 2020 Objectives for Immunization and Vaccine-Preventable Diseases: Midcourse Review, Dr. Nancy Messonnier, CDC

Dr. Messonnier explained that she would discuss HP2020 objectives and presented updates on progress towards goals related to immunization and vaccine preventable diseases. Of 83 pertinent objectives, 67 are measurable: 26 have met or exceeded their target and 28 objectives are moving towards their targets (that's 81% of objectives that are on the right track). The remaining are stagnant (6), moving in the wrong direction (3), have only baseline data (3) and one is tracked for informational purposes only (children 19-35 months who have received zero doses of vaccines (i.e., these children were completely unvaccinated)).

She presented data on vaccination coverage with vaccines included in HP2020 among children 19-35 months from the National Immunization Survey (NIS) 2008-2014. Currently the proportion of children 19-35 months who have received zero doses of any vaccine remains below 1%. She presented other NIS 2008-2014 data for "IID-9 – children 19-35 months who received no vaccinations." Dr. Messonnier stated these data showed most children are getting some vaccines. She noted that IID-9 could be used as a measure of vaccine confidence.

She presented data on vaccination coverage with vaccines included in HP2020 among adolescents 13-15 years from NIS-Teen, 2008-2014. For adolescent vaccinations, coverage rates are close to HP2020 goals for Tdap and Meningococcal vaccines, improving for Varicella, but far behind for HPV where more work is needed to address barriers.

Dr. Messonnier presented data from the CDC's National Health Interview Survey (NHIS) on estimated zoster vaccination coverage for adults ≥60 years. By 2014, zoster vaccination had reached the HP2020 30% target. She mentioned that they might want to increase this target with HP2030. Finally, she presented data from NIS, NHIS, and the Behavioral Risk Factor Surveillance System on estimated influenza vaccination coverage for four influenza seasons. For all ages, and for healthcare personnel, the coverage goals for influenza have not been met.

Dr. Messonnier reviewed some preliminary ideas under consideration for HP2030, including combining the HPV objectives for girls and boys, making a data source decision for a pregnancy/influenza measure and putting a spotlight on vaccine safety. In addition, they will be looking at whether to add new objectives and whether to modify or archive any existing objectives.

Discussion

Mr. Hosbach asked Dr. Messonnier about the thinking behind collapsing the 18-years and older for influenza to a 70% annual coverage number when the 65 years and older was originally targeted at 90%. He noted that 90% was a hard goal to achieve. He was concerned about this because 65 years and over is the area where the most hospitalizations and deaths occur and the age group where we see the biggest burden of influenza illness and healthcare costs. Dr. Schuchat responded that she is thrilled with their HP2020 consolidated influenza objective, which tried to capitalize on the universal influenza vaccination recommendations. She noted that the universal recommendations for vaccinating everyone 6 months and over got massive support from providers, manufacturers, and the public as much simpler. After we finally had one recommendation for influenza vaccination, it seemed like great time to have one overall objective for HP2020 for total vaccination. To set a target for 70% for HP2020 reflected that we were at early stages for pediatric vaccination and had just recommended that healthy adults get vaccinated.

In addition, Dr. Schuchat commented that the HP2020 process uncovered concerns from people that they were not honing in on the elderly. She stated that CDC is committed to tracking subset coverage and reports it regularly. The HP2020 process also highlighted that the current vaccines are not as effective as we would like, particularly in the elderly. There are many benefits from the universal recommendation, so vaccinating the elderly is not the only goal. She concluded by explaining their thinking was that simplifying the target would be consistent with the simplified recommendations and would help to simplify communication efforts.

Dr. Orenstein commented that the amount of HP2020 data could be overwhelming. He asked if NVAC could be helpful to review any objectives or specific issues related to HP2020. Dr. Messonnier commented that it is a lot of data and suggested that NVAC could perhaps help with prioritizing HP2030 objectives. Ms. McGowan agreed with Dr. Messonnier. Ms. McGowan commented they could use evidence-based resources and stories from communities for the HP2020 website to share them more broadly with the nation.

Dr. Beigi commented that NVAC has looked at the issue of maternal immunization as a more global effort, instead of simply focused on one vaccine-preventable disease. He hoped that by 2020 there would be more vaccine candidates available and suggested that NVAC may be able to help look at a more global objective for pregnancy rather than the single focus on influenza vaccination.

Dr. Thompson asked about the zero dose objective for children 19-30 months. Dr. Thompson noted that because we want to minimize the number of children that have received zero doses of recommended vaccines, the ideal goal would be zero percent. Dr. Messonnier stated that if it was above 1% they would start to get more worried but lower would be inappropriate. She commented that zero is probably not right because some children cannot get vaccines due to medical contraindications.

Dr. Smith added that there can be significant geographic differences in uptake that can be masked by an overall national goal. He suggested the goal should articulate the number of states that are greater or less than 1%. He believed that might help eliminate some of those pockets of zero vaccines that might otherwise get overlooked. Dr. Messonnier emphasized that zero dose is really a blunt instrument, and they do not use it as an HP2020 indicator; rather they follow it for information on general levels nationally. She believed that even the state level might not be the right number. She noted that part of this issue is information, and having community-level information available to help state health departments and families understand what is going on locally.

Dr. Gellin stated this was a great discussion and he wanted thoughts on how NVAC could move forward to be thoughtful for the Healthy People processes. Dr. Orenstein suggested that NVAC could think about the HP2030 objectives and provide input. He also suggested that it may be worthwhile to have an NVAC working group to think about the HP2030 objective issues as well as progress. He commented that looking to the future may be the best role that NVAC could play. He asked if there were any objections to NVAC forming a working group, and there were none.

Dr. Omer commented that it was very logical to have a spotlight on vaccine safety. It would be helpful to know how HP2020 is thinking about vaccine safety. He asked what kind of indicators HP2020 is looking at for vaccine safety. He then noted that one of the things that many people like about HP2020 is that these are measureable objectives. For example, using zero dose is an appropriate indicator, but it is not the only indicator. Data from multiple sources from Oregon and other places has shown there has been an uptick of people who get only a few doses but do not complete the full series. Dr. Omer stated that those cases where children get only one dose of one vaccine will get out of the zero dose group. He commented that zero dose should not be the only indicator because it would miss many children who are not fully vaccinated against some important diseases.

Dr. Messonnier agreed with Dr. Omer and commented they are hindered by the limitations of the available data. A spotlight allows you to spotlight an issue without having a metric that you track year-by-year. Ms. McGowan added that spotlights sometimes do have objectives, but they are really another mechanism they use to have a national discussion on those types of topics. Ms. McGowan explained that spotlight webinars tend to get a very large audience and are helpful to get attention to a topic of interest. She mentioned that if NVAC wants to help think about spotlight webinars that would be great.

Dr. Omer suggested that HP2020 could perhaps think about the number of children under coverage for vaccine safety assessment. He suggested that increasing the denominator could allow them to get an idea of how rare events can be measured.

Dr. Schuchat had several comments. For HP2030, she suggested it would be great if NVAC could think about metrics that would be meaningful related to immunization information systems (IIS). There has

been a lot of progress in the past year on developing draft metrics for how we are trying to improve the system. She believed that 2030 would be good timing for IIS indicators. There is a whole family of potential IIS indicators that stakeholders have been working on. In terms of a family of issues, she noted that Dr. Messonnier presented primarily data on coverage and mentioned some objectives that are off track that deal with disease occurrence. Dr. Schuchat believed that a current strength of the HP2020 immunization and infectious disease objectives is that they include outcome as well as process and coverage. These outcomes address a number of diseases that are targeted for elimination or sustained elimination or where we are targeting reduction in incidence. She observed that it is unusual around the world to have both strong coverage and strong disease surveillance data. This is important because sometimes disease impact is greater than expected by vaccine coverage and sometimes disease impact is less than expected by coverage. She believed that it is important to measure both. Dr. Schuchat made a plea that surveillance or disease objectives are important, and recommended that the HP2030 process or the potential NVAC working group retain them for HP2030.

Dr. Schuchat commented about sustaining the less than 1% of children getting zero doses and stated CDC had given a good deal of thought about trying to track children being in the system as both an access issue and, at a very extreme level, the number of parents completely giving up on vaccines. Dr. Schuchat explained they did propose a target of maintaining the less than 1% of children with zero doses, but it was not accepted in HP2020 process. She noted that understanding what this metric really means is a complex issue and that tomorrow's session on vaccine confidence may get at the richness of these issues.

Dr. Viswanath built upon Dr. Schuchat's remarks by noting that these are national goals. He suggested it was not advisable from a communications perspective to get into the weeds for national goals. It will be very difficult to communicate and very difficult to get people to rally around these goals. He noted that NVAC could start proactively developing the HP2030 metrics and help with getting the measurement infrastructure in place. He believed that an NVAC working group would be very helpful. Dr. Orenstein added that NVAC should consider introducing the issue with a number of states to also bring it down to that level, and NVAC should work on how to do both national and state metrics. He suggested that NVAC would look to CDC to help staff this working group to help NVAC move forward.

Vaccine Market Analysis

Creating a Healthy Vaccines Market, Mr. Michael Conway and Ms. Tara Azimi, McKinsey & Company
Mr. Conway and Ms. Azimi from McKinsey & Company gave an overview of McKinsey's current vaccine research efforts. McKinsey is developing a perspective on the challenges and opportunities in the vaccine market, answering questions like "What are the unmet needs in infectious diseases?", "Where has vaccine innovation failed in the past 10 years?", "What are the key drivers of success?", and "What are potential solutions to address unmet needs and create sustainable business economics?" He emphasized McKinsey is also interested in how the marketplace rewards or does not reward innovation.

Ms. Azimi stated their report will emphasize the facts, anchor on the U.S. market, be very diagnostic in focus, and offer some initial solutions. She mentioned the report development process will include a desk analysis of root causes, interviews, and workshops. In addition to interviewing NVAC members, they hope to include industry representatives from BIO; and other vaccine experts from industry, policy,

and academic stakeholders. Ms. Azimi reviewed their schedule for this report, which McKinsey expects to publish in early 2016.

Ms. Azimi concluded by summarizing McKinsey's two practical asks of NVAC members. First, McKinsey would like to conduct 60-minute structured discussions with NVAC members. McKinsey would also like to invite NVAC members to one or two workshops to review findings and refine perspectives. Ms. Azimi welcomed any inputs or reactions during the discussion period.

Discussion

Dr. Orenstein thanked the speakers from McKinsey, and commented that he appreciated McKinsey's focus on getting a better idea of what the problems are. Dr. Orenstein asked Dr. Gellin if he saw any FACA-related issues with McKinsey talking with individual NVAC members for those structured discussions. Dr. Gellin stated that any NVAC member who chooses to participate in the McKinsey interviews must speak as an individual; they cannot speak as an NVAC member and cannot represent or speak on behalf of NVAC or HHS.

Dr. Thompson commented that the McKinsey research is a great effort and commented that McKinsey is in a position to look at the complexity of the marketspace and ask the questions that need to be asked. She noted that breakthrough technologies are seeing a lot of innovation in the context of vaccine delivery. Dr. Thompson asked whether new vaccine delivery technologies will be in scope or out of scope for McKinsey's effort. Ms. Azimi replied yes, that they would be relevant to the extent those innovations are addressing unmet needs and have relevance for the market.

Dr. Daum asked for information on the history of how McKinsey got interested in this topic, who is funding it, and who will pay attention to the outcomes in the McKinsey report. Mr. Conway explained that McKinsey has a significant number of people around the world working in the vaccine arena and that he is the co-leader of McKinsey's vaccine practice. He stated that "reach and relevance" is the McKinsey term for such efforts to work on topics where their firm wants to contribute with reach and relevance in a particular sector. McKinsey's vaccine practice thought innovation was a good topic to review based on their observations that innovation potentially may have declined. McKinsey will publish a paper and they hope it will attract interest and be a contribution to the vaccine arena they are working in as a firm. Mr. Hosbach pointed out that funding is not coming from industry, and also noted that industry representatives were briefed on McKinsey's effort at a recent BIO meeting.

Dr. Viswanath asked why McKinsey is limiting it to the U.S. only and whether there are there any plans for a more global scope. He also asked about their plans for dissemination and how the lessons learned would be shared with the broad range of stakeholders. Ms. Azimi explained that the U.S. and Western Europe markets are their entry point. She stated that currently their intent is not to cover the middle to lower income markets. She added that the report will be published solely under McKinsey's name, and be available on their website and hard copies will be distributed broadly. Mr. Conway provided an example of another paper that McKinsey published in 2000 on developing markets.

Dr. Maldonado reiterated the issue that the global market is important. She noted that the global utilization of vaccines will actually impact the U.S. market and create perceived needs. She also stated that another issue is who the audience would be and how aggressive to be in disseminating the findings to the appropriate people. Dr. Maldonado commented that the question of resources is important and

observed that it may or may not be that innovation has failed or is not as robust. She wondered whether there might be innovation but there are not sufficient resources for progress. She suggested that McKinsey add research on lack of resources, or sources of resources, to their section on economics.

Mr. Hosbach also reiterated that he thinks global is very important, given the influence that Gates and Gavi have on what happens with the research agenda and funding in the vaccine arena. He also stated that the value of incremental improvements in vaccines that occur with innovation should be accepted as a way to big improvements. He strongly encouraged acceptance of incremental improvements as a valuable step to improved vaccines and believed that it should be rewarded to foster innovation.

Dr. Hatchett, ASPR, commented that the barriers to innovation or to late stage development vary depending on the micro-segment of the vaccine market. He noted, for example, the barriers are very different for developing influenza vaccines versus the barriers for developing biodefense vaccines. Dr. Hatchett recommended looking at the specific market structure for specific sectors of the vaccine industry. He suggested a series of case studies that outline specific barriers for specific sectors of the vaccine market would be very helpful.

Dr. Thompson commented that academic or peer-reviewed journals are important to this audience. She strongly encouraged that McKinsey consider organizing their study to meet the standards for publishing their results in an academic journal to get an impact in reaching that audience.

COL Yacovone, DoD, asked whether McKinsey has considered DoD as a stakeholder in their analysis given that DoD has traditionally been involved in vaccine development, and has continued to be involved in vaccine development particularly for vaccines with a global impact. Ms. Azimi replied that McKinsey will look broadly at the stakeholder set. She added that the dynamics of middle-income markets and in the Gavi markets are very real and have an impact on the business economics.

Dr. Omer commented that he hoped McKinsey would define innovation in a way that includes academia. He believed that academia is important because they contribute to big picture, high risk-high reward innovation. He recommended that academia be considered separately from other nonprofits because the dynamics, barriers, and opportunities are different.

Dr. Orenstein noted that McKinsey got a lot of feedback from NVAC. He suggested NVAC might want McKinsey to come back in February to make another report on their preliminary phases.

Influenza Vaccination of Health Care Personnel – Remaining Challenges in Long-Term Care

Update on Healthcare Personnel Influenza Vaccination Reporting Via the National Healthcare Safety Network, Ms. Megan Lindley, CDC

Ms. Lindley reminded everyone that NVAC recommended standardizing HCP vaccination measurement as part of reaching the HP2020 annual target of 90% coverage of influenza vaccination among healthcare personnel. This measurement was based on an evidence-based measure piloted by CDC and endorsed by the National Quality Forum. She gave an update on the 2014 status of reporting influenza vaccination among healthcare personnel in acute care hospitals to the National Healthcare Safety Network (NHSN), facilities newly reporting to NHSN on this measure, and remaining data limitations. She noted she will also discuss the implications for long-term care reporting.

Ms. Lindley provided an overview of CDC performance measurement specifications. The three required denominator categories are: 1) employees; 2) licensed independent practitioners; and 3) adult students, trainees, and volunteers. She listed the five distinct numerator categories: 1) vaccinated at facility, 2) vaccinated elsewhere and provided documentation, 3) medically contraindicated, 4) declined vaccination, and 5) status unknown. Ms. Lindley explained the CDC performance measurement reporting includes all HCP who physically work in the facility for one day or more between October 1 and March 31, regardless of clinical duties or patient contact. This includes full- and part-time HCP. They include vaccination received any time between when the influenza vaccine becomes available through March 31.

The CDC measure for HCP influenza vaccination summary data was included in the Centers for Medicare and Medicaid Services (CMS) quality reporting programs beginning on January 1, 2013 for acute care hospitals. Beginning on October 1, 2014, this CDC measure was also included for long-term acute care hospitals, inpatient rehabilitation facilities, and ambulatory surgery centers. Ms. Lindley stated that data analysis includes all NHSN-enrolled facilities of the specified type. CDC uses data aggregated within facility types to calculate proportions of HCP reported vaccinated for each of the three required denominator categories and overall. Aggregation of the data mitigates the effect of wide ranges among states in the number of reporting facilities and the number of HCP working in those facilities. She emphasized that there are no denominator exclusions, so the proportion for each category will include those who are contraindicated.

Ms. Lindley presented data on the proportion of HCPs reported vaccinated for the 2014-15 influenza season from 4,120 acute care hospitals. At these sites, the majority (71%) of HCP were employees. Overall, 84.5% of all HCPs at hospitals were reported vaccinated. She explained that the data on HCPs reported vaccinated at hospitals was 88.6% for employees; 83.8% for students, trainees, and volunteers; and 65.1% for licensed independent practitioners. Overall, 10% of HCP had unknown vaccination status at hospitals. Ms. Lindley also compared data for hospitals from the 2014-15 season to the previous 2013-14 influenza season. She explained that the percentage vaccinated increased and the percentage unknown decreased in each of the required denominator categories.

She presented data on the proportion of HCPs reported vaccinated for the 2014-15 influenza season from 1,096 inpatient rehabilitation facilities (IRFs). She emphasized that the number of HCP working in IRFs is less than 400,000 for the whole nation. Overall, 81.6% of all HCPs at IRFs were reported vaccinated. Ms. Lindley pointed out that for employees at IRFs, 87.7% were reported vaccinated and 5.3% were unknown.

She also presented data on the proportion of HCPs reported vaccinated for the 2014-15 influenza season from 475 long-term acute care hospitals (LTACs). Ms. Lindley believed that the overall 77.1% of all HCPs reported vaccinated at LTACs was lower than the other two facility types because licensed independent practitioners are a much larger proportion (27%) of all HCPs at LTACs. She explained that the data on HCPs reported vaccinated at LTACs was 90.7% for students, trainees, and volunteers; 83.5% for employees; and 57.2% for licensed independent practitioners.

Ms. Lindley described the limitations of the NHSN data and compared NHSN data with data on HCP influenza vaccination from other sources. For example, NHSN reports data for HCPs in specific facility

types compared to HCP in all settings and reports estimates for broad groups versus the occupation-specific estimates used in the National Health Interview Survey (NHIS). NHSN reports facility-level summary data instead of individual-level data. While other data sources use a survey sample and are self-reported, NHSN is a near-census and has documentation for some data elements. Ms. Lindley noted that NHSN is tied to CMS payment incentives to report, which she believed are valuable.

Finally, Ms. Lindley discussed implications for long-term care reporting, emphasizing that influenza vaccination of HCP in long-term care facilities (LTCFs) is suboptimal. HCP in LTCFs are most likely to report their employer neither requires nor promotes influenza vaccination. The majority of HCP working in LTCFs are assistants/aides, who have the lowest reported vaccination coverage. Ms. Lindley noted there are a number of factors combining to keep influenza vaccination below target levels in LTCFs. NHSN already includes a long-term care component, and there are 254 active LTCFs in NHSN as of August 27, 2015. Ms. Lindley noted that the estimated number of LTCFs that would need to be enrolled in NHSN for CMS quality reporting is over 12,000. Because the current NHSN enrollment is 16,952 facilities, adding LTCFs would nearly double NHSN.

Discussion

Dr. Orenstein asked if there were any clarifying questions. Dr. Maldonado asked a question about the definition of a licensed independent practitioner versus an employee. Ms. Lindley stated that they are the physicians, advanced practice nurses, and physician assistants that are not employees of the hospitals. She explained the employee category comprises anyone who is on the payroll.

Dr. Mouton asked about the definition of employees versus contractors, such as the housekeeping and other contractors that some hospitals have. Ms. Lindley stated that contract personnel are not included. She explained this has been the source of significant discussion with the National Quality Forum. She did not present information about contract personnel because they are currently an optional reporting category. In their pilot of this measure, they found that around 10-20% of personnel in the pilot facilities were contract personnel so it potentially excludes many personnel not to require them. The reason it is not a required category now is that the data quality were so poor due to the difficulties of tracking them. Dr. Mouton commented that contract personnel may be a growing category as facilities consolidate. It is potentially a significant source of missing data, so it may be revisited in the future.

Dr. Beigi asked if CDC queries each facility during their data collection about what their policy is and, if so, can they stratify their data by different policy approaches for the facilities. Ms. Lindley stated there is an optional seasonal survey that asked the facility about their strategies for promoting influenza vaccination that she believed included information about declination policies. She does not know whether it has information about whether vaccination is required or promoted. The reason that it is optional is because reporting on specific policies is not part of the CMS reporting measure, so CDC cannot mandate facilities to report something that is not mandated by CMS.

Vaccination Initiative for Nursing Assistants and Aides Project: Overview and Key Findings, Dr. LJ Tan, Immunization Action Coalition (IAC)

Dr. Tan presented a summary of the Vaccination Initiative for Nursing Assistants and Aides (VINNA) study. He acknowledged that VINNA was supported by a partnership grant from Pfizer Inc. to the IAC. Dr. Tan stated that the rationale for the VINNA study was: respiratory outbreaks continue to occur in LTCFs despite high reported rates of resident vaccination for influenza and pneumococcal diseases, HCP

influenza vaccination prevents resident morbidity and mortality, and nursing staff influenza vaccination rates in LTCFs are low.

Dr. Tan reviewed the methods for the VINNA study. First, they conducted a baseline assessment in the spring and summer of 2014. To develop this baseline, they looked at site characteristics, history of respiratory infection outbreaks, resident vaccination rates for influenza and pneumococcal, employee vaccination programs, and nursing staff knowledge. For each LTCF, they created customized interventions, which were based on the assessment and were developed to meet local needs. They provided support for program implementation at the LTCFs. They conducted an interim evaluation of vaccine uptake and employee engagement with interventions. They also did a final evaluation after the influenza season. They hope the assessment and interventions can be applied elsewhere.

He reviewed some insights about the LTCF environment. Dr. Tan noted that LTCFs are seen as residences, not health care facilities, and there is a wide variation along the continuum of care. He stated that although skilled nursing facilities ("nursing homes") are regulated, assisted living is an unregulated environment. Dr. Tan explained that CMS regulation provides opportunities for intervention design. Nursing homes are rated by CMS as 1-5 stars (with one being a poor rating and five being a high rating) based on quality measures. He stated that around 65% of nursing homes are rated 1-3 stars by CMS. Because of the CMS ratings, he believed that nursing homes may be seeking ways to demonstrate quality to CMS and residents.

Dr. Tan described the institutional culture at the VINNA sites. LTCFs are struggling to stay in business. Their residents are vulnerable adults with high needs, which include limited or no financial resources, often a lack of family support, serious health problems, and personal issues (e.g., mental illness, addiction, homelessness). Because of lack of resources, the LTCFs have low technology capabilities, so the VINNA study had to rely on flip charts and fax instead of more modern digital methods.

He explained that nursing assistants/aides at LTCFs have low educational backgrounds (≤75 hours of training), and that 36% have total household income less than $20,000. Many LTCF staff are not eligible for benefits or cannot afford premiums. Turnover is high because the pay is low and the work is hard. Vaccination rates for CNAs or nursing assistants/aides are lowest among those who have shorter tenure, are dissatisfied with their job, do not feel respected for their work, are employed by for-profit facilities, or do not have employer-sponsored health insurance.

Dr. Tan described the four LTCFs that participated in their study. One LTCF had a CMS quality rating of 3-stars, one was rated 2-stars, and two were rated 1-star. He explained that VINNA did not look at 4-5 star LTCFs, which generally performed better. Dr. Tan presented a comparison of influenza and pneumococcal vaccination rates among residents in the four LTCFs based on data extracted from medical records for VINNA versus data reported to CMS. He noted that two LTCFs reported higher vaccination rates to CMS than were documented in medical records. Dr. Tan also presented data on staff turnover at the four LTCFs. He noted challenges with tracking vaccination coverage particularly in LTCFs where all or nearly all staff turned over within a year. Dr. Tan also summarized gaps identified in existing vaccination programs at the four study sites, which included lack of clear policies (e.g., corporate policies are not known or not implemented), absence of tracking mechanisms or documentation for who was vaccinated or supply of vaccine, resistance from both leadership and nursing staff who are often anti-vaccination or vaccine-reluctant, and sustainability issues associated with staff turnover.

Dr. Tan provided an overview of VINNA's intervention components: goal-setting, clear policies on staff vaccination and declination, improved documentation and tracking, educational programming, staff engagement and incentives, and ways to increase multiple vaccination opportunities at work. He presented examples of VINNA's Goal-setting and Policy Worksheet. He also presented an example of an employee vaccination roster, which is an Excel-based tool to track vaccination status in LTCFs with high staff turnover. He showed an example of another tracking tool consisting of a vaccination gauge poster and instructions for use, and mentioned this poster was put in a prominent place and was very popular.

Dr. Tan presented preliminary results from the evaluation along with other VINNA data. He emphasized that it is important to consider staff turnover when analyzing LTCF data. Vaccination rates increased at all four LTCFs after the interventions. They also saw an increase in the proportion of employees who encouraged others to get flu shots. There was also an increase in the vaccination of HCP's young children and older family members after the interventions. Dr. Tan explained that for all four LTCFs combined there was a statistically significant reduction in staff absenteeism due to respiratory illness. He noted that the reason was probably precautions taken to prevent the flu through education about infection control.

He provided summary data and examples of the types of education provided at the LTCFs including educational posters, kick-off events, and graphical representations to publicly report vaccination rates among staff members to help them track their incremental progress towards a pre-determined target goal. Dr. Tan presented VINNA data that showed giving flu shots onsite works to increase vaccination rates among LTCF nursing staff. Dr. Tan explained that for all four LTCFs combined there was a statistically significant increase in the LTCF nursing staff intent to receive flu shots in the future, but the increase to 75% was not as high as the 90% they wanted. Dr. Tan presented data on the main reasons for LTCF staff refusing flu shots. The top three reasons were: 1) concerned about side effects, 2) concerned about getting the flu from the shot, and 3) don't think that the flu shot works. He noted that the 2014 vaccine mismatch for the H3N2 strain also may have created some challenges in increasing concerns about whether the vaccine works.

Dr. Tan then summarized the key findings from the VINNA final evaluation and then reiterated the challenges such as high staff turnover, limited resources, competing priorities, and entrenched misperceptions that affect intent to vaccinate.

Discussion

Dr. Orenstein asked whether they had done any economic analysis about how much it costs to bring in an outside group, and how much time it took to work with the facilities to implement these interventions. Dr. Tan stated they had not done any formal economic analysis and that the in-service delivered at the Illinois site was by the Chicago Department of Health. In Minnesota, the in-service was delivered by a local immunization coalition. They tried to connect the facilities with local expertise to deliver the in-service educational programs instead of using IAC staff or IAC experts in order to improve sustainability of the program. The intervention toolkit developed for the study has information about ways to connect with local resources to give these in-service educational programs, etc. However, sustainability of success in these facilities was a concern.

Dr. Orenstein expressed concerns over whether we have an adequate infrastructure for adult immunization to do this. Dr. Tan commented that LTCFs provide a very different challenge from the overall adult infrastructure. Dr. Tan believed that the infrastructure to deliver influenza vaccination to healthcare workers was there in LTCFs, but the challenge was getting past barriers such as logistics, education, time, convenience, tracking employees, and policy-setting. Dr. Orenstein also expressed concerns about the adequacy of public health logistics.

Dr. Thompson noted, with respect to sustainability concerns, that the influenza vaccination is needed every year. She suggested there might be simple things they could do to keep the effective interventions going and also to keep the momentum going in those facilities for another year (e.g., revise existing posters). She mentioned that it would be interesting to continue this study for another year to determine if they got a "bigger bang for the buck" by going back to previous facilities and using the same interventions a little differently versus going into new facilities.

Dr. Tan explained they went back and followed up with all four sites, and found that all four LTCFs are going to implement the same interventions again. The LTCFs all decided to continue the interventions on their own, without any suggestions from IAC to continue for a second year. He believed that some of the motivation was from external pressure to get workers vaccinated.

Dr. Lynfield asked whether they will measure it again next year. Dr. Tan stated that no, the funding will run out. Dr. Lynfield commented that at some point it would be a good idea to get some resources to do that evaluation to see how sustainable it is. Dr. Tan agreed.

Dr. Maldonado asked about other venues given the population and the income and demographics of the LTCF staff. She asked whether they had tried Facebook or Twitter to reduce costs of contacting staff for participation versus visits to facilities. She suggested they consider a survey with an award for participating in the survey. She mentioned that the survey could be a brief teaching module. Dr. Tan believed they had looked at social media, but one of the LTCFs resisted because of concerns about computer and Internet access for their staff.

Dr. Mouton explained that from his experience, most of these LTCFs have very high turnover rates because it is a difficult work environment. He added that it was a highly regulated industry. Dr. Mouton stated that the toolkit was a great idea. He suggested that the staff orientation when hired would be a good intervention point. He also mentioned that through its Title VII programs, HHS sponsors education in geriatrics for the workforce that is supposed to be an opportunity to help educate those workers. Dr. Mouton suggested that NVAC could recommend that the current HHS geriatric workforce education program is an opportunity to pick up some of this to help educate workers in nursing homes in their regions as part of their requirement.

Dr. Rawlins commented that the LTC industry is very low margin and it may be helpful to support developing a robust business case around encouraging influenza vaccinations. He recommended looking at Dr. Tan's slide on reductions in absenteeism for information about a return on investment to encourage LTCFs to invest in vaccinating their workers. Dr. Tan agreed this was a good point. He mentioned that reduction in absenteeism is a different kind of a return on investment and could perhaps be quantified.

Dr. Daum asked whether there is any effort to conduct a similar study in day care centers, because they also have a high staff turnover and other similar issues. Dr. Tan stated they are not funded to do this now, and he is not aware of any such efforts, but he believed it was a good idea.

Dr. Orenstein asked Ms. Ehresmann and Ms. Tate whether their organizations would have the resources to do this or would they need additional resources. Ms. Ehresmann, AIM, stated they are putting a lot of emphasis now on healthcare-associated infections and working more directly with facilities. They have a flu-safe program in Minnesota that is encouraging more vaccination in hospitals and LTCFs. She observed that it could fit into what they are doing now, but she cannot say there is not a need for resources. Ms. Tate, NACCHO, explained they have been looking at these issues for years in Maryland. They have had a healthcare personnel immunization initiative for around eight years. They started with influenza, and expanded it and got good results with acute care hospitals. They started to direct attention to LTCFs but unfortunately the former secretary did not see that as a priority. She explained they have a new administration now that is very interested in immunization. She just met with them and there is definitely support. She cannot guarantee there are resources.

A Toolkit for Long-term Care Employers, Dr. Jennifer Gordon, NVPO

Dr. Gordon summarized NVPO efforts, in collaboration with CDC, to develop an online long-term care (LTC) toolkit: http://www.cdc.gov/flu/toolkit/long-term-care/. She explained that HHS met with stakeholders and found the LTC workforce is different, consisting primarily of nursing assistants/aides, and that HHS needs to pay more attention to developing tailored strategies for the LTC workforce. The toolkit was developed to help LTC employers and administrators promote influenza vaccination among their workforce. It will also help anyone working in LTC facilities to understand the importance of influenza vaccination for LTC workers. NVPO wants the online LTC toolkit to be a “living resource” that can be updated as new information becomes available. NVPO wants this LTC toolkit to reflect the most current data and submission of best practices.

Dr. Gordon presented a snapshot of the home page for the LTC toolkit including key features and resources and noted that the home page allows people to email feedback about the online toolkit to CDC. The LTC toolkit was launched on the CDC website on December 4, 2014. It was promoted through social media, especially Twitter. During the first week of its launch, the LTC toolkit was one of the top five pages for all traffic to CDC’s influenza site.

Dr. Gordon stated that NVPO and CDC wanted to know how useful the online LTC toolkit would be, so they are conducting LTC toolkit research. NVPO worked with four LTC organizations who are partners of CDC’s influenza vaccination awareness campaign to identify and recruit interview participants. Eight interviews were conducted with nine participants who make decisions about vaccination in LTC facilities, and they also got exercises to use the toolkit. This research gave ideas on how to make the toolkit more user-friendly.

Dr. Gordon mentioned that NVPO plans to get influential LTC-related organizations to sign a letter in support of the toolkit and engage partners early. In June 2015, they began promoting the LTC toolkit through CDC’s GovDelivery newsletters. She noted that a Spanish language version is available on the CDC website and emphasized this is very important because language is an important barrier in LTCFs.

Toolkit updates will include integrating recommendations from the first round of research, and adding vaccine coverage data once available (September 2015). Tracking resources are also important and she mentioned there is a current lack of tools available for tracking vaccinations within facilities, such as fillable forms to help track employees vaccinated and/or facility coverage rates. Dr. Gordon stated that NVPO and CDC will conduct ongoing evaluation throughout the 2015-16 influenza season and will be monitoring website metrics.

Discussion

Dr. Thompson stated it was a great toolkit. She believed it was a type of pull mechanism to help people find information, but it could also be a push mechanism. It could be an opportunity to get more information in and to create communication. Dr. Thompson suggested NVPO could do an annual poster that people can download every year to drive traffic to the website. They could have a contest to draw a poster and then a vote on the posters. Dr. Gordon explained they want to encourage people to provide highlights of successful interventions at their facilities, so people become vaccine champions, and also so it stays current and provides fresh information. They also provide links to other parts of the CDC website that provide information that gets updated regularly.

Dr. Viswanath commented that in his research he has found the elderly Spanish-speaking community in Massachusetts spends substantially more time in senior centers than in LTCFs. He suggested that those senior centers serve in almost an adult day care capacity. He suggested considering senior centers. Dr. Gordon agreed that senior centers as well as drug rehabilitation facilities may be an option. She emphasized that there is not a lot of evidence-based data for interventions in those types of facilities. NVPO and CDC currently focus the website on evidence-based information strategies and educational material.

Dr. Mouton suggested that NVPO consider developing something for home health aides. Home health care agencies are similar but they do not have facilities. A toolkit could go out from home health care agencies to the home health aides. Other options to consider could be child care centers, adult day care, and senior centers. He mentioned that CMS issues letters monthly to LCTFs that are received by their administrators.

Mr. Hosbach commented that there is a lot of great information available but being able to find the information and to know how to use it is very important.

Ms. Coyle, AIRA, suggested that the IISs be considered as a tool for tracking influenza vaccinations and noted that 47 IISs allow for lifespan adaptation. The IIS could also be used at a more advanced level to allow for an employer module to allow someone to be able to track an employee vaccination record.

Data Collection on State Exemptions – How to best use the available data

A Comprehensive Database of U.S. Immunization Information, Ms. Anu Bhatt, AIM

Ms. Bhatt began by explaining that vaccinefactsandpolicy.org (VFAP) was developed through collaboration between three project partners: the Association of Immunization Managers (AIM), George Washington University (GWU), and IAC. She stated that the purpose of VFAP is to collect and catalog information that characterizes the immunization environment and infrastructure of all 64 jurisdictions. The 64 jurisdictions include the 50 states, the District of Columbia, five immunization grantee cities (Chicago, Houston, New York City, Philadelphia, San Antonio) and eight U.S. territories (American

Samoa, Guam, Republic of Marshall Islands, Federated States of Micronesia, Northern Mariana Islands, Palau, Puerto Rico, Virgin Islands).

Ms. Bhatt noted that VFAP provides a large amount of information in five major topic areas related to immunization law and policy such as demographics and rates, fiscal environment, law and policy, strategies and initiatives, and the structure of immunization programs.

Ms. Bhatt emphasized that VFAP allows users to access information from a variety of sources in one place, including information from different partners. VFAP provides an opportunity for users to identify and learn about awardee characteristics or activities. In addition, users can view data in table or map form; view aggregate responses by state, city, or territory; and save and print reports. Ms. Bhatt stated that the major audience is awardees and health departments along with the public health community at large. However, their target audience also includes researchers, policymakers, and media outlets.

Ms. Bhatt outlined the data sources currently used for VFAP. She noted that VFAP allows users to dig deeper into the data and identify the data source. For example, the AIM Annual Survey is conducted in the spring each year, and covers the previous year and current policies and priorities. In the most recent survey, 63 of the 64 awardees responded. The survey had 60 questions covering program practice, program structure, program priorities, and fiscal and programmatic environment. She noted the survey data have some limitations, including that priorities and engagement are subjective, and the awardee environment is a rapidly changing environment.

Ms. Bhatt explained the exemption data in VFAP, which includes:

- School vaccination entry requirements, by jurisdiction;
- Types of exemptions (personal belief, religious, medical) allowed in each jurisdiction;
- Exemption rates, non-medical vs. medical, by jurisdiction;
- Text of exemption laws for each jurisdiction; and
- Documentation of exemption/parental refusal of vaccine using IIS.

Ms. Bhatt summarized the challenges with exemption and vaccine confidence data in VFAP. She explained that the completeness of exemption data varies because of variability in collection methods (sampling vs. IIS or school-specific data). She noted that enactment and enforcement of school requirements varies. These can be laws, regulations, or administrative rules, and authorities administer them differently in different jurisdictions. She mentioned that frequent changes to laws, regulations, and rules make it hard to keep information up-to-date. Ms. Bhatt stated that privacy laws can prevent gathering of exemption data. In particular, she noted the Family Educational Rights and Privacy Act (FERPA) and schools. She explained that vaccine hesitancy varies by region; it is a high priority in some areas, and low priority in others. Finally, she noted that awardees have different priorities, which can create challenges in comparing awardees, and make measuring change difficult.

Ms. Bhatt also summarized VFAP's strengths regarding exemptions and vaccine confidence. She emphasized that VFAP is a great resource to look up the language on exemption laws, regulations, and rules. She stated that VFAP was valuable last year when exemptions were a hot topic. During those recent public discussions on exemptions, VFAP gave the media and policymakers access to reliable data. VFAP also gave immunization programs access to information on what other immunization programs are

doing, and how others are wording their exemptions. She mentioned they heard from awardees that access to this information was valuable to them.

She presented a summary of VFAP's data wish list, and explained several of them. First, they would like current data from the awardee annual report and program assessment submitted to CDC. Second, they would like data on pharmacies because that is a popular topic for partnerships. Third, they would like more data on cities and counties. She explained there is an ongoing need to have the most current information in VFAP because statutes, regulations, and policy language are continuously reviewed and/or updated. She then concluded stating that the biggest challenge to updating and maintaining the website was funding resources. More funding would allow VFAP to update data, and expand the law review and data categories and topics. Website functionality could be improved with additional funding. VFAP could also expand partnerships and create custom reports on hot topics.

Discussion
Dr. Viswanath commented that he liked everything they had done except he believed that using "vaccine facts and policy" as the name sounded very academic and official. He believed that framing an effort with the name is a critical communication aspect. Ms. Bhatt mentioned that the first name they wanted to use was taken, and she commented it has been a bit of a struggle to find a name that was not already taken.

Dr. Thompson stated that legislation and regulations are often interpreted by the courts. Some court decisions can be significant. She asked whether there would be any benefit to looking at legal interpretations from case law for this website. Ms. Bhatt replied that this is a possible area if more funding is available.

Dr. Orenstein asked what types of resources AIM would need to fulfill their data wish list. Ms. Claire Hannan, AIM Executive Director, indicated that they have put together a budget and the website takes approximately $200,000 per year to maintain. They would like to do some expansions to the website and Ms. Hannan explained that all three partners have ongoing funding proposals out.

Dr. Orenstein asked whether they had data on the number of website visits. Ms. Bhatt stated that they have some analytics; however, she explained that because this is a large website, the number of hits is not a good indicator of how useful it has been to people. Instead they focus on the comments they are getting via email (info@vaccinefactsandpolicy.org) from people who are using the website.

Challenges and Opportunities to Improve Kindergarten Vaccination Coverage and Exemption Data, Dr. Amanda Cohn, CDC
Dr. Cohn began by noting that every state and local area has different challenges related to kindergarten vaccination coverage. Measuring vaccination coverage among kindergartners is important to ensure high coverage is maintained in school-aged children. Vaccination coverage and exemptions are defined by state and local school requirements. She emphasized that dose requirements and regulations vary and documentation varies across states and local areas, and both impact the data. Most awardees do a census of kindergarteners, and both public and private schools are included- however, home schooled children and, in some cases, private schools are not included.

Dr. Cohn provided an overview of the median estimated vaccination coverage and exemptions among kindergartners in the U.S. for 2014-15. Overall coverage remained high for childhood vaccines - median coverage among kindergarteners for MMR, DTaP and Varicella is >90% for all 3 vaccines but varied greatly by state. Exemptions remained low - the median for any exemption was 1.7%, the median for medical exemptions was 0.2%, and the median for non-medical exemptions was 1.5%.

A map of the U.S. showed variations in the estimated percentage of children enrolled in kindergarten exempted from receiving one or more vaccines in the 2014-15 school year. She noted that exemptions might not accurately reflect a child's vaccination status. Children with an exemption who did not receive any vaccines are indistinguishable from those who have an exemption but are up-to-date for one or more vaccines. Dr. Cohn mentioned that the states in the 2-4% category and the ≥4% category tend to stay the same each year. She also mentioned some states do not have data available because of the way those states report their data.

Dr. Cohn presented a graph showing the estimated MMR vaccination coverage among kindergartners in the 2014-15 school year, noting that some states are several percentage points below the 94% median target. Another graph showed the estimated percentage of children enrolled in kindergarten exempted from receiving one or more vaccines in the 2014-15 school year. Dr. Cohn noted that most states below the 1.7% median target are not much below that target. Another graph showed the estimated number of children without documented 2-dose vaccination for measles and the number of children exempt to one or more vaccines among kindergartners in 37 states reporting MMR coverage and exemptions for the 2014-15 school year.

Dr. Cohn explained that the estimated number of children with undocumented vaccination status for measles is high in many states. She noted it is difficult to tease apart unvaccinated children from children without documentation of vaccination. She explained that procedures to follow up on children with conditional approvals to enter school are very different by state and local jurisdiction. Resources at the school level are scarce, especially school nurses. Dr. Cohn stated they plan to add an additional category for the 2015-16 school year on conditional/provisional enrollment.

She also discussed methodology challenges between the census-based method and using a sample-based method. She stated that the census is resource intensive for schools, but the sample is resource intensive for health departments because they actually implement the sample. She explained that the census can identify clusters of low coverage or high exemptions, but the sample may miss those clusters. She noted that the census is a more collaborative effort between the school and health department, because they can review samples from the census to validate data collected by non-health staff. The sample approach limits opportunities to educate school staff.

Dr. Cohn summarized policy challenges related to FERPA that are impactful in limiting how much public health departments can work with schools. She explained that FERPA restricts individual school records, including health records, from being shared. The only exception is in a public health emergency or outbreak. In addition, schools can only report aggregate data, and are unable to report data on individual children to public health departments. Dr. Cohn noted that because only aggregate data are available, public health departments are unable to follow up on children that are missing vaccines. Finally, she mentioned that public health departments are unable to support data collection or validate

data, which continues to drain resources from schools and school nurses and noted that FERPA impacts each of these areas differently.

Dr. Cohn stated that using IIS data can provide an opportunity to streamline data collection and provide accurate vaccination coverage data at the community, child, and possibly school levels. She added that high functioning IISs with near complete participation can produce reports for schools, which can also streamline efforts. Dr. Cohn noted that schools may be able to report vaccination records to IIS, but FERPA is a barrier that may not allow schools to input them into IIS. Finally, she mentioned that IISs could produce a validated certificate, if they know that IIS data is complete and accurate.

CDC is encouraging awardees to move from a sample to the census methodology for measuring exemptions. In addition, CDC wants to increase the use of IIS to support school vaccination coverage assessments.

Dr. Cohn emphasized that school coverage assessment is an opportunity to identify unvaccinated children who were missed prior to school entry, noting that outreach to schools with low coverage or high rates of exemptions is an opportunity for action. Another is following up on children who are missing vaccines, but acknowledged that this is a lot of work for public health departments.

Discussion

Dr. Orenstein commented that one of the issues NVAC recommended in their Vaccine Confidence Report is the ability to provide parents the aggregate data by school about actual vaccination coverage level. He asked whether FERPA causes any problems for publishing local data and whether publishing aggregate data for a school is possible. Dr. Cohn stated that aggregate data can be reported locally. She noted that the number of jurisdictions that reported their local data online this year increased. She stated that 21 awardees put their local data online.

Dr. Viswanath asked whether there are other ways of sending that information to schools, in addition to putting it on the website. Dr. Cohn believed that awardees do have feedback mechanisms to the schools, but how that data is used and how it gets to the schools would vary significantly based on procedures by district. She believed that having schools have knowledge of their coverage is very important. She stated if they were able to use IISs, then school-specific reports could be produced.

Dr. Orenstein suggested that schools within a state could be ranked by the number of exemptions, from the lowest exemptions to the highest. He asked whether states use that information and whether states could provide this information to individual schools. Dr. Cohn believed that the process of validating the sample is an opportunity to discuss the coverage rates with individual schools. She does not know how formalized this process is with the awardees. This whole process takes a long time and the schools have many things going on, and although that would be ideal, she believed there are additional challenges to overcome.

Ms. Ehresmann, AIM, commented on the “one or more exemption” category and the CDC’s desire to collect that data. She stated that in Minnesota, it may appear that they do not collect this data on exemptions but they actually collect their exemption data differently. They collect data on exemptions to every individual vaccine and not in that aggregate way. She would like to know whether this is one of highest priorities for CDC to get complete data for the “one or more exemption” category. In Minnesota,

they have found it is very useful to look at each antigen and see what children are being exempted from. She asked whether CDC would be interested in looking at this more specific data or whether Minnesota should be looking at changing the way they are collecting exemption data.

Dr. Cohn stated that some awardees will collect data on different vaccine exemptions. Some children will have an exemption but the exemption data do not always show how many vaccines a child has been exempted from. It is important to consider that just because a child has an exemption, this does not mean that the child has not received that vaccine. Dr. Cohn believed that vaccine coverage data is more critical than vaccine exemption data. In particular, it is more critical to have stronger data to know whether or not a child has received a vaccine.

Ms. Coyle, AIRA, wanted to bring up the difference between what is reported and what is actually happening. It is important to look at the exemptions in states that do not have a strong policy that restricts children being admitted to school, because she has found that often those exemptions are just for convenience. She would argue that school nurses are not providing exemptions; instead it is administrative staff doing this. She believed the IIS will help with this and the reporting. She believed that the vaccination rate is probably higher than indicated by the exemption rate.

Ms. Claire Hannan, AIM, added that some states with high kindergarten vaccination rates cannot make this a priority because they do not have the manpower to dig deeper to look into their smaller number of exemptions. She indicated that often states do not have the resources to compile this type of data.

Dr. Orenstein stated that the obvious focus has been on kindergarten where most of the vaccines are given, but asked whether there are many states with adolescent vaccine requirements. He wondered whether there was any data collected on exemption rates for adolescent vaccines. Dr. Cohn noted there are states with adolescent vaccination requirements but the CDC does not systematically collect exemption data for adolescent vaccines because they have the NIS to look at coverage. She does not know whether awardees collect adolescent vaccination data. Dr. Orenstein mentioned he is primarily interested in enforcement issues, rather than just measurement.

Dr. Schuchat noted that CDC has discussed adding an adolescent question to the NIS-Teen survey. She mentioned that most states now have middle school vaccination requirements. The CDC strategy has been that exemption data is useful to parents and the community so they encourage the jurisdictions to post their data in whatever way they can. She believed this can be valuable information to help sustain social norms about vaccination. In terms of priorities, it makes sense to step back and think through what is the goal here, because IISs can automate much of this so some day they will be able to look at all this data, and it will be accurate, and they will be able to know what is going on at the local level.
Dr. Thompson asked how we are dealing with children that move to a different state, because the IISs are currently state-based. She believed it would be helpful to have clear guidance on how to get missing data for children that move to different states into the IISs and how to track children that move from state-to-state. She emphasized it is important to get IISs to realize that interstate cooperation is important for data quality. Ms. Coyle, AIRA, commented that most of the time schools probably have the data that IISs are missing, but FERPA is the barrier to populating the IISs with the best data that the schools have. Ms. Coyle stated that this is the overarching issue, but she is not sure how to resolve the unintended consequences of FERPA on sharing information.

Dr. Orenstein asked Dr. Cohn whether there was any particular area where NVAC could be helpful. Dr. Cohn stated that all of the work that NVAC has done to support interstate data sharing and IISs was helpful and encouraged NVAC to continue moving forward with work on those strategies. Secondly, she mentioned that the interpretation of FERPA and how it affects collecting this data and submitting school vaccination records to IISs is done at local level. She believed that guidance would potentially be helpful and that is potentially an area where NVAC could help as well.

Limitations and Utility of Exemption Data, Dr. Saad Omer, NVAC

Dr. Omer began by noting that he would discuss the limitations and utility of exemption data and some of the nuances. He presented several examples from other research illustrating the imperfect association between attitudes and actions, explaining that there is much research showing there will be a gap between attitude and action, and also explained that this gap should be expected. He pointed out some circumstances when attitudes are related to behavior: measurement issues, perceived behavioral control, attitude formation, cognitive processing, and situational factors.

With respect to vaccination, he showed an example from the 2010 HealthStyles Survey where the results for the action—intentions to vaccinate—were much different from results for attitude—specific vaccine concerns. While 77% of respondents had specific vaccine concerns, 82% had already vaccinated, 11% planned to vaccinate, 5% intended to partially vaccinate, and only 2% would not give any vaccine. Dr. Omer also presented summary data from his own research that showed an association between some parents' perceptions and non-medical exemptions for their child. Those parental perceptions were low disease susceptibility, low disease severity, low vaccine efficacy, low vaccine safety, low trust in HCP, and low trust in government.

Dr. Omer mentioned that 3% of the U.S. population is home schooled. He emphasized there is a nuance that arises from many of those homeschooled children being covered by school requirements if they use school gyms or labs. Homeschooled children have lower vaccination rates than public school children, one online survey of homeschoolers showed that 38% had full vaccination, 56% had partial vaccination, and 6% had no vaccination. This data indicates that we are probably underestimating the refusal rate for homeschooled children.

Regarding potential limitations related to vaccination coverage assessments, Dr. Omer explained that 74% of states are using a census methodology, and those states represent 86% of the U.S. population. He further explained that nine of those states had a census for public schools but used a voluntary response for private schools. Next, he presented annual data from 1994 through 2009 on school-level personal belief exemption rates for all schools, public schools, and private schools. Dr. Omer noted that the data are stable among the three categories and is useful for looking at trends.

Dr. Omer stated that potential limitations related to exemption status may not reflect vaccination status. He emphasized that these issues are quantifiable and can be incorporated into results and would be important to include in IISs. Dr. Omer stated that the CDC's research methodology for the NIS is the "gold standard," and uses the Council of American Survey Research Organization (CASRO) methodology for response rate. Dr. Omer presented a graph showing CASRO response rates for NIS from 2008-2014, for all households and for cellphone only households. 2014 response rates were 62.6% for landlines and 33.5% for cell phones. He noted that when only land-lines were used from 2008-2010 they had a good response rate, but after cellphone only households were included the response rate went down. As the

contribution of cellphone only households has increased, the overall response rate has decreased. He stated that adjustments for bias were needed, but could not be applied to the Childhood NIS response rate.

Dr. Omer noted it would be important to consider an active decision on vaccinating or filing for exemption. He mentioned that states are already collecting the exemption data, and he believed that such data should be used judiciously to capitalize on existing infrastructure. For example, exemption data can be used to identify clusters. Dr. Omer presented data from his own research that looked at clusters of exemptions and clusters of pertussis, and how those clusters overlapped. He also showed maps and statistics from other research that used exemption data to identify clusters.

Dr. Omer concluded by recommending that exemption data should be used with other sources of information and also emphasizing that exemption data are not a substitute for vaccine confidence.

Discussion

Dr. Orenstein asked Dr. Omer whether there are any recommendations that NVAC might make with regard to collection and analysis of this exemption data. Dr. Omer replied that he agreed with Dr. Cohn's recommendation that in the short term, states should move toward census data. In the longer term, the states should move to IIS. Dr. Omer noted that FERPA is a structural barrier to IISs and suggested that it would be helpful if FERPA could be interpreted more uniformly. He suggested that CDC's public health law programs could present an analysis of FERPA to help the states, or other groups present analyses of the interpretations of FERPA at the state level that could be actionable.

Dr. Thompson mentioned that some people get exempted overall because that is their only option. Some children have exemptions on record but actually have received many vaccines. In Florida, people have told her the only way to get exempt from one vaccine is to get an overall exemption. She asked whether anyone has looked at whether some people may get a reaction from their first vaccine and then go to get an exemption. She commented that is different from those who get an exemption but then they end up getting some vaccinations. Dr. Omer mentioned that some states had looked at related phenomena such as short limiting behaviors and different vaccine schedules.

Dr. Schuchat wanted to step back regarding the question on information needs, and introduce the element of time. CDC's program has made certain compromises based on resources and the urgency and feasibility of the information needs. CDC has an expensive national survey based on phones, and they have done bias comparisons after adding cell phones to the land-lines for this survey. She mentioned that CDC has looked at what a census-like effort would take to contact households using household addresses while still needing to get provider verification. Regarding exemptions and vaccine confidence, Dr. Schuchat explained that CDC wanted to understand how bad it was and what CDC needed to know, but she believed they need to be careful regarding the short-term changes versus the long-term trends. She noted that the recent measles outbreak caused a lot of short-term changes just this year.

Dr. Omer noted that the CDC's response rate had doubled for NIS. He believed that the cohort of parents is substantially younger than those households who have land-lines. We have more cell phone only households in the country, and he believed that people do not answer their cell phones when surveyors call. He suggested a variety of tools could improve the quality of the exemptions data.

Dr. Orenstein mentioned that the first NIS in 1994 made it possible to provide a relative ranking of states. In 1994, Michigan was at the bottom of this ranking but their state immunization person was able to use Michigan's lowest ranking to get resources to improve their state's efforts. With respect to the issue of NIS versus exemptions, he noted that exemptions are later in life than the NIS. The key issue with exemptions data is feeding it back to the right people who can take action. Making the exemption data public is important. People need to feel responsibility to take the actions needed to overcome these problems. Having at least comparable data allows comparison from area to area, which he believed is very important and played a major role in Michigan in 1994.

Dr. Omer agreed and stated that there was no substitute for something like NIS and it should be the information need priority. He suggested that an approach that NVAC could consider endorsing is a "feedback loop." Data are coming in from most of the states and providing them a perception of where they are in comparison to other states can endorse a social norm and serve as a "nudge" to action. Adding an information feedback loop to the census-based approach that most states now use will allow parents to look at that data to understand the milieu of their child's school. It will help communities see if they have any gaps to fill. He did not believe this would go to the level of shaming, but would be a "nudge" for communities to take action.

Dr. Maldonado mentioned that California just passed a bill eliminating all but medical exemptions. The vast majority of families that believe in vaccination do not advertise their fear of vaccines. She emphasized that it is important to get the positive message out to legislators. In California, she believed that in the recent past most of the demonstrations and most of the communication to the state legislators had come from vaccine refusers so they could mislead legislators. The information coming to state agencies and legislatures can become skewed because it tends to involve the population that is not supportive. Dr. Maldonado also commented that perhaps if states were at the bottom of the rankings then shaming might work on a statewide basis, but she noted that Dr. Omer's research has shown that shaming does not work on an individual basis.

Dr. Viswanath commented that one part is how do you ask questions and the other part is how do you make this data useful for people to organize, mobilize, and advocate. The question is how to organize and how to structure and communicate this data to influence the right group at the right time. Dr. Viswanath believed that shaming was not a technique for ranking. He provided the example of the Mothers Against Drunk Driving state rankings that were criticized by the states but then they all worked to improve their rankings. He provided another example of the universities that criticize the U.S. News and World Report for their university rankings, but then those same universities also are trying to game their system to get a higher ranking. Dr. Orenstein stated that he agreed completely. He suggested that Michigan and California used data in a way that was useful to move forward in making a major policy change.

Ebola Vaccine Update

Ebola Vaccines Update, Dr. Gary Disbrow, Assistant Secretary for Preparedness and Response (ASPR)
Dr. Disbrow acknowledged that development and evaluation of Ebola vaccines has been a coordinated effort among a large number of government, non-government, country, and industry partners led by the World Health Organization (WHO), CDC, and the National Institutes of Health (NIH). In the summer of 2014 there were Ebola vaccines under development in the discovery and preclinical development

phases. He explained that currently there are three Ebola vaccines in Phase I and two Ebola vaccines in Phase II/III of development, representing a dramatic shift in progress over one year.

Dr. Disbrow next summarized information about the Ebola vaccine trial in Guinea, noting results were recently published in *Lancet*. This trial evaluated the NewLink/Merck rVSVΔG vaccine as an open-label, cluster randomized, ring vaccination trial. This trial randomized adult contacts and contacts of contacts of a laboratory confirmed case of Ebola into two groups: immediate vaccination, or delayed vaccination (21 days). There was no placebo in this trial. He stated that individuals were assessed for Ebola virus disease with onset at least 10 days after randomization.

He reviewed the preliminary analysis conducted in the Guinea trial and explained it was based on clusters with 50-100 individuals in each cluster. These preliminary results suggest efficacy of the vaccine and data will be reviewed by regulatory authorities. Dr. Disbrow also explained there was an open-label Phase IIb trial in Guinean healthcare workers evaluating safety and immunogenicity. This currently includes over 800 vaccinated and the target is 1,200 individuals.

Dr. Disbrow asked Dr. Schuchat to summarize the STRIVE Ebola vaccine trial in Sierra Leone. Dr. Schuchat remarked that this trial was a partnership between CDC and Sierra Leone, and evaluated the NewLink/Merck rVSVΔG vaccine. She mentioned that Canada licensed the vaccine to NewLink, and then Merck entered into a partnership agreement with NewLink. Dr. Schuchat explained that the Sierra Leone trial is an unblinded, individually, randomized trial without a placebo arm. She noted that individuals were randomized into two groups: immediate vaccination, and delayed vaccination (6 months). The trial included healthcare and front-line Ebola response workers. Dr. Schuchat explained that over 8,700 individuals have been enrolled. For the immediate vaccination group, around 4,150 have been vaccinated. The delayed vaccination group will begin in September 2015. This trial was intended to assess laboratory confirmed Ebola virus disease, safety, and immunogenicity. She explained that because Sierra Leone did a good job of controlling the Ebola epidemic, they will not be able to measure efficacy because there were no new Ebola cases, but they can measure safety.

Dr. Disbrow summarized information about the PREVAIL Ebola vaccine trial in Liberia. He explained it was a randomized, double-blinded, placebo controlled trial. He also explained this trial evaluated both Ebola vaccine candidates: the NewLink/Merck rVSVΔG vaccine and the GSK ChAd3 vaccine. Dr. Disbrow stated that this trial was designed to evaluate the safety, efficacy, and immunogenicity of the vaccine candidates. The Liberia trial included healthy adults or individuals at risk for Ebola virus disease. There were 500 individuals in each of three arms. Dr. Disbrow noted that enrollment and vaccination is completed. Because of lack of Ebola disease, they have been unable to evaluate efficacy of the vaccines. However, they will have a large database on vaccine safety and immunogenicity.

The NewLink/Merck rVSVΔG candidate appears to be safe and well tolerated. This vaccine has been administered to around 14,000 individuals. In addition, this vaccine has been administered to 20 individuals 13-17 years of age and 20 individuals 6-12 years of age (Gabon) with no reported significant adverse effects. Dr. Disbrow commented that this vaccine appears to be well tolerated in pediatrics. He stated that the Phase I trial had to be paused as a result of reports of arthralgia/arthritis, but they were able to complete the trial. Immunogenicity results will be forthcoming. The GSK ChAd3 vaccine candidate also appears to be safe and well tolerated. Multiple doses have been evaluated (this bivalent

vaccine has both Ebola and Marburg viruses). There were no reports of administration to pediatric patients. Immunogenicity results for this candidate are also forthcoming.

Dr. Disbrow summarized the vaccine trial challenges, as listed below:

- Balancing, establishing, and running a clinical trial during an international response to an epidemic.
- Cold chain issues (these are frozen vaccines that must have cold storage at -80°C) and lack of infrastructure.
- A rapid decrease in the number of Ebola cases, which is a good thing, but it impacts ability to determine efficacy.
- Adapting to cultural, educational, and language differences (e.g., vial labels need to be in French).
- Lack of previous clinical trial experience in West Africa; however, healthcare workers and volunteers are/were enthusiastic to help conduct the trials.
- Follow-up and tracking of trial participants, even up to six months.

Dr. Schuchat added that they encountered some suspicion with the Ebola vaccine trials. She mentioned they found it was necessary to call it “Ebola prevention vaccine” instead of “Ebola vaccine.” There was distrust of international partners. Dr. Schuchat explained that the communication team on the ground worked very hard with all partners.

Dr. Disbrow explained that BARDA is currently supporting three vaccine candidates with a fourth under consideration. BARDA is working in collaboration with DoD and NIH. He mentioned that BARDA funding was provided under an Ebola Continuing Resolution and $215 million was provided in FY2015 as an Ebola Supplemental. He stated FY2016 funding is uncertain above base Advanced Research and Development (ARD) funding, and there will probably be no Ebola Supplemental. He also stated there is a potential for vaccines and therapeutics funding to transition to Project BioShield in FY16-17. Dr. Disbrow explained that Project BioShield would stockpile vaccines for an emergency. He noted BARDA is supporting manufacturing for clinical trials, scale-up manufacturing, and enhanced formulation.

Dr. Disbrow also explained that the current Ebola vaccine candidates are monovalent, but both DoD and HHS have an objective to develop trivalent vaccines. He asked who will support manufacturing if a mass vaccination campaign is implemented? How will regulatory authorities license vaccines in the absence of definitive or sufficient efficacy data? Dr. Disbrow commented that the three Ebola vaccine trials will provide some data if the Food and Drug Administration (FDA) licensing process uses the animal rule. He also commented that FDA’s Vaccines and Related Biological Products Advisory Committee (VRBPAC) will have a meeting soon to discuss the accelerated approval pathway.

Discussion

Dr. Cooke commented that having all the different players come together is basically how vaccines get developed. He was impressed with how quickly the Ebola vaccine moved through the vaccine development chain. He noted there were many other candidates that were in an earlier stage for Ebola. He asked about the lessons learned for other emerging diseases, such as Middle East respiratory syndrome (MERS) or severe acute respiratory syndrome (SARS), and how far society should go to have vaccines ready that may never be used.

Dr. Disbrow stated that for Ebola there were candidates under development and there were well-characterized animal models and reagents under development to evaluate candidate vaccines. He commented that was not the case for MERS because there are not well-characterized animal models. Dr. Disbrow stated that society has to address big questions about resources needed to stockpile such vaccines. He suggested stockpiling such vaccines at an intermediate stage, because they may have a longer shelf life, may be an option.

Dr. Hatchett commented that Ebola in this circumstance behaved like an emerging disease, but it had been on their biodefense list as a potential terrorist threat for decades. For biodefense reasons, they had already done a lot of work to study Ebola, which was an advantage. He commented that the recent Ebola situation was an "eye opener" with respect to emerging diseases, because they would not have the decade of research that Ebola had to facilitate the speed of the response. He believed that the coalescence of international collaboration would occur again, but there probably would not be products at the same stage of maturity as for Ebola.

Dr. Lynfield asked about how they were able to do tracking under those field conditions. Second, she asked for comments on what we can learn and apply to vaccination for children and pregnant women. She noted that only one Ebola trial included children, which had only 40 children. She believed that the vaccines should be used in children and pregnant women. Third, she asked for comments on stockpiling by WHO or elsewhere.

Dr. Disbrow referred these questions to Dr. Schuchat. She mentioned that each of the Ebola trials was carried out as a clinical trial, with oversight. There was urgency because of the epidemic and there was interest among participants. They had an unprecedented problem for CDC in that they were enrolling people faster than they could keep up with in terms of the oversight and safety, and all the paperwork for participants. She noted that people raised the question about whether this was a vaccine rollout or a clinical trial, where enrollments would typically go slower. CDC is pleased that their follow-up is at a very high level. She stated that the Guinea follow-up is at a very high level, and the Liberia follow-up is at a very high level. Dr. Schuchat stated they are not at the 6-month point to evaluate immunogenicity yet. They do not know yet whether the deferred group will have as high participation as the immediate group had, but she would not expect them to have similar participation given the dynamics.

Dr. Schuchat stated that the NewLink/Merck rVSVΔG is a live viral vaccine. In Sierra Leone they did pregnancy testing to make sure they could exclude pregnant women, and they counseled the participants to avoid pregnancy for two months as Merck recommended. Some participants did become pregnant soon thereafter, and they have a registry of those participants to monitor them through pregnancy and delivery of the baby. At the point of the Guinea trial interim results, they modified their protocol to go down to adolescence. She was not sure if that had been approved yet. Because many of their cases were in adolescents, the children were always intended for broader studies. Dr. Schuchat commented that she was impressed that they had so many adults participating in the three Ebola trials.

Dr. Schuchat indicated that WHO and Gavi have discussed developing a stockpile. Gavi has put some funding toward purchase and initial distribution of the Ebola vaccine including a stockpile. WHO's Strategic Advisory Group of Experts (SAGE) will be discussing this issue at their October meeting. Dr. Disbrow added that the BARDA's analytical decision support group is currently working with WHO's modeling group to evaluate multiple scenarios of stockpile issues for WHO.

Dr. Thompson stated she believed that the ring vaccination strategy that was reported in *Lancet* did show efficacy in the trial. She was not sure why the animal rule was needed if data was collected on efficacy. Second, with respect to stockpiling, she asked whether there was any cross protection for the three Ebola virus strains from the different monovalent Ebola vaccines and whether the trivalent vaccine was needed.

Dr. Disbrow explained that the U.S. government needs a material threat determination issued in order for BARDA to stockpile vaccines. They now have a material threat determination issued for three viruses: Ebola, Marburg, and Sudan. He is not aware of any cross protection between the viruses, which is another reason to pursue the trivalent vaccine. The monovalent vaccines are still relevant, because an outbreak may involve one virus and the additional antibodies produced for the other two viruses in the trivalent would not provide any additional protection. Dr. Disbrow stated that the *Lancet* publication reported on suggested efficacy but that data still needs to be reviewed by regulatory agencies. The question is whether the data will meet regulatory rigor, and if it does they might not have to go under the animal rule but could use the accelerated pathway.

Dr. Daum commented that the slowdown in Ebola cases has given everyone time to pause and think through options. He asked what would happen if an Ebola outbreak occurred tomorrow and there was a decision to implement a mass vaccination campaign somewhere in Africa.

Dr. Disbrow explained that part of the role of BARDA is to support the scale up of manufacturing. Both NewLink and Merck, and also GSK, were manufacturing their vaccine at a very small scale. BARDA is working with the manufacturers to support their scale up in manufacturing going to commercial scale so that the vaccine will be available. They are looking at various options, such as stopping at an intermediate stage, to prepare and stockpile. BARDA will continue to support the manufacturers even if the primary vaccine candidates have to go under animal rule. Dr. Disbrow stated that BARDA and DoD own 150,000 doses of the NewLink/Merck vaccine that are available for a future outbreak. BARDA is also working on how to provide doses to first responders and healthcare workers if an infected person comes to the U.S.

Dr. Schuchat added that the current WHO protocol for ring vaccination has been expanded for Ebola case contacts as well as contacts of case contacts in Sierra Leone. At the present time, this needs to be done under clinical trial. Dr. Schuchat commented that the opportunity cost for manufacturers and BARDA of Ebola vaccine development because of the recent outbreak should be considered. She mentioned that in contrast to international partners who have praised the recent rapid progress, Sierra Leone authorities have questioned why an Ebola vaccine was not developed yet since Africans have known about Ebola for many years. Dr. Schuchat also commented that for emerging infections we need to think about whether vaccines or therapeutics are the priority.

Dr. Spika stated that from the Canadian perspective, they believe that BARDA did incredible work to facilitate the recent Ebola vaccine development process. In terms of the Guinea trial, he stated that the randomized part was stopped in early August and now everyone gets the vaccine that is part of a ring. He stated that the other change in the trial is that the vaccine is now offered to children down to six years of age, when previously it was only offered to adults 18 years and older.

Maternal Immunization Working Group Update

Maternal Immunization Working Group Phase II, Dr. Saad Omer, NVAC

Dr. Omer noted that this was the second incarnation of this working group. He briefly reviewed the topics the working group had covered since the June NVAC meeting and presented a list of five MIWGII meetings scheduled from September 2015-January 2016.

Dr. Omer then summarized some of the initial impressions from MIWGII's work to date. These initial impressions are listed below:

- There are potential opportunities to clarify federal regulations and suggest Office for Human Research Protections (OHRP) guidance. As part of this potential OHRP guidance, there are also opportunities to develop special training for institutional review boards (IRBs). In addition, it will be interesting to define "minimal risk" in the context of maternal immunization, when you are asking a woman to think not only about herself but also about the infant. They may consider a smaller "working group" to define "minimal risk." They will look at data on IRBs interpreting regulations.
- Efforts are needed to increase availability of pregnant women to be enrolled in clinical trials. MIWGII has noted there were some successes already with vaccine trials for HIV-infected pregnant women.
- Researchers will need new methodologies, especially for observational studies, to address challenges in linking datasets of the mother and child.
- Researchers need to determine the appropriate length of follow-up for adverse effects in the mother and her child, including developmental assessment in the child.
- Reiteration in the importance of including maternal immunizations in the Vaccine Injury Compensation Program.
- There is potential that an independent ethics panel could support the maternal immunization community on ethical challenges and develop clear guidelines together with FDA. For example, maternal risk for infant benefit is an ethical issue that MIWGII has identified.

Discussion

Dr. Orenstein stated that in the interest of time, they will refrain from any comments or questions.

NVAC Liaison Updates

Advisory Commission on Childhood Vaccines – Dr. Charlene Douglas

On behalf of Dr. Douglas, Dr. Melissa Houston read the ACCV report. ACCV had a meeting on September 3, 2015. They welcomed three new members. ACCV had a brief update about the upcoming annual U.S. Court of Federal Claims judicial conference on September 24, 2015 in Washington, DC. The meeting included program updates from the Division of Injury Compensation Programs (DICP) and the Department of Justice. They discussed whether to make a recommendation on increasing DICP's Vaccine Injury Compensation Program administrative funding since the number of claims filed has been steadily increasing. The ACCV requested additional information about the workload impact of the increase in claims, before making a recommendation. They also discussed whether ACCV should submit a recommendation on the prevention of shoulder injury related to vaccine administration (SIRVA). ACCV decided to monitor the data on the incidence of SIRVA before considering a recommendation.

Advisory Committee on Immunization Practices – Dr. Nancy M. Bennett

Dr. Bennett, who recently assumed the Chair of ACIP for a 3-year term, reported on the ACIP's June 24-25, 2015 meeting. ACIP considered influenza vaccines, and voted to approve the new dosing

algorithm for children 6 months through 8 years of age. They considered new product approvals that will be reflected in the table of available vaccines in the ACIP influenza statement. They also discussed the influenza vaccine composition for 2015-16 that will be reflected in the ACIP influenza statement.

For pneumococcal vaccines, ACIP voted to approve a change in the recommendation regarding the interval between PCV13 and PPSV23 in adults ≥65 years of age. A dose of PPSV23 should be given at least one year following a dose of PCV13. For meningococcal vaccines, ACIP voted to approve a B category recommendation for MenB: A serogroup B meningococcal (MenB) vaccine series that may be administered to adolescents and young adults 16 through 23 years of age to provide short-term protection against most strains of serogroup B meningococcal disease.

For smallpox vaccine, ACIP voted to approve recommendations for the use of smallpox vaccine among laboratory workers and healthcare personnel.

ACIP voted to approve five chapters of the General Recommendations on Immunization document, which were altered immunocompetence, special situations, vaccination records, vaccination programs, and vaccine information source.

Dr. Bennett reported that ACIP's upcoming October meeting (October 21, 2015) will review the child and adolescent immunization schedule as well as the adult immunization schedule and vote on changes. They will discuss the HPV vaccine, and review HPV vaccine coverage and have a quick review of HPV vaccine safety. They will review influenza vaccines, Japanese Encephalitis vaccine, combination vaccine (DTaP-IPV-Hib-HepB), and Cholera vaccine.

America's Health Insurance Plans – Dr. Scott Breidbart
Dr. Breidbart reported that in late August, AHIP released its summary report of the National Adult Immunization Roundtable, which was convened by AHIP in February. The summary report includes recommended actions to improve adult vaccination rates resulting from the Roundtable discussion. Dr. Breidbart encouraged everyone to download and review this summary report, which is available on the AHIP website.

In July, AHIP disseminated highlights from the last ACIP meeting, including new and updated vaccine recommendations to its Chief Medical Officer Committee, Medical Policy Directors, Prevention and Population Health Working Group, and Immunization contacts. Also in July, AHIP disseminated its draft recommendations to increase adult immunization rates with its member plans to seek their input and convened a call with them to review and discuss. Dr. Breidbart mentioned that additional resources from the CDC and other stakeholders were also widely disseminated among member health plans in August during National Immunization Awareness Month.

Association of Immunization Managers – Ms. Kristen Ehresmann
Ms. Ehresmann reported that AIM held its 2015 Annual Business Meeting during the Immunization Awardee Meeting on July 15, 2015 at the CDC Global Communications Center. They presented the 2015 Natalie J. Smith Award, for outstanding immunization program management, to Dr. Jane Zucker from New York City. They presented the 2015 Bull's-Eye Awards, for outstanding and innovative immunization strategies, to the Illinois, Nevada, and New Jersey immunization programs.

Ms. Ehresmann mentioned that AIM had a conference call for new AIM members on August 20, 2015 to discuss strategies for preparing cooperative agreement and grant applications. AIM held its first Virtual Exhibit Hall webinar on July 22, 2015 to provide an opportunity for immunization program staff to learn about technology to improve vaccine storage and handling.

She stated that AIM sent a letter to the American Academy of Pediatrics (AAP) encouraging the addition of vaccination status to the Pre-participation Physical Evaluation (PPE) form that physicians fill out for adolescents participating in sports or other school activities. AIM believes this addition to the PPE form will reduce missed opportunities for vaccination in the adolescent age group and increase immunization coverage for the ACIP-recommended adolescent vaccines.

American Immunization Registry Association – Ms. Rebecca Coyle

Ms. Coyle reviewed AIRA activities on developing operational guidance for the 2013-2017 IIS Functional Standards. During the last week of July 2015, a broad set of representatives from across the IIS community gathered at the Public Health Informatics Institute (PHII) in Decatur, Georgia, to develop operational guidance for the 2013-2017 IIS Functional Standards. The 3-day meeting was sponsored by CDC, and facilitated by Bill Brand and Therese Hoyle of PHII. The effort brought together IIS Managers, Immunization Program Managers, IIS vendors, and partners from AIRA and the CDC IIS Support Branch who collaborated to develop guidance statements to assist IIS in better aligning with the IIS community's current functional standards. Participants addressed all six functional standards throughout the three days, drafting language to clarify how IIS can more directly meet the standards. Additional work is needed on this project, including a deeper exploration of the Core Data Elements and more clarity on industry standards for IIS security.

Ms. Coyle also reported on AIRA's activities in best practice development. The Modeling of Immunization Registry Operations Workgroup is one of the AIRA steering committees that identify and prioritize functional areas of IIS that can benefit from a collective approach and develop best practice recommendations for these areas using business modeling and facilitation techniques. Because Chapter 1 has just been revised, the new guidance on "Management of Patient Active/Inactive Status in IIS" is now available online and being mailed to immunization programs.

In August, AIRA completed its work on the "Operational and Technical Guidance for Implementing IIS-Based Coverage Assessment – Phase 1" document. AIRA's work supported the CDC's Assessment, Feedback, Incentives, eXchange (AFIX) Program. This document provides CDC's requirements and recommendations for incorporating AFIX assessment functionality in IIS. Ms. Coyle stated this document was issued to all AFIX awardees.

Ms. Coyle reported that AIRA just completed the *Analytic Guide for Assessing Vaccination Coverage Using an IIS* and it is now on the AIRA website. The purpose of this guide is to assist IIS staff and other interested parties in using IIS data to conduct population-based coverage assessments. This guide describes practical considerations and key decision points in designing a population-based assessment using an IIS.

Association of State and Territorial Health Officials – Ms. Kimberly Martin

Ms. Martin, representing Dr. Paul Jarris, reported on several current ASTHO immunization initiatives. ASTHO's IIS meeting in August 2014 brought together relevant state stakeholders from five key states to

discuss barriers and identify potential solutions for multi-state IIS interstate data exchange. As a result of the meeting, ASTHO, in coordination with The Network for Public Health Law, developed a template IIS interstate data sharing Memorandum of Understanding (MOU). This template MOU is now available on the ASTHO website. The MOU will initially be piloted with the states that attended the IIS meeting, but can be used by other interested states in the future.
Ms. Martin discussed the Vaccines for Children (VFC) Project. ASTHO conducted a survey of various stakeholders to assess the key considerations related to inclusion of pharmacies in the VFC program. The project explored opportunities and challenges surrounding pharmacy participation in VFC, current models of state-wide VFC programs with pharmacy participation, and current statutes and legislation related to pharmacy participation in VFC. Ms. Martin announced that this report will be available on the ASTHO website shortly.

Ms. Martin also provided an update on the Public Health/Pharmacy MOU. Since 2012, ASTHO and CDC have been assessing best practices for coordinating pandemic vaccination preparedness activities between public health programs and pharmacies. Successful strategies, tactics, and operational components, identified through stakeholder interviews and workshops, were incorporated into a template MOU. The MOU is intended to formalize responsibilities between state-level public health programs and pharmacies during pandemic vaccination planning and response. Ms. Martin announced this template MOU is now available on the ASTHO website.

National Association of County and City Health Officials – Ms. Tiffany Tate
In June 2015, NACCHO hosted representatives from the 10 local health departments (LHDs) and the HPV Project Advisory Board to discuss action plans and prepare for implementation. During Phase II of the HPV project, LHDs will implement the action plans developed during Phase I. Ms. Tate explained that NACCHO plans to release an additional funding opportunity this fall to a second cohort of LHDs to plan for increasing HPV vaccination rates in their communities. She noted that in May 2015, NACCHO released the *Guide to HPV Resources for LHDs* and announced it is on the NACCHO website. Ms. Tate mentioned that NACCHO created the HPV Learning Community, which is an online forum for LHDs to share resources, post updates, and discuss their action plans.

For the General Immunizations Project, the immunization workgroup met in June to discuss priorities for the upcoming project year and how NACCHO can best support LHD immunization programs. Ms. Tate believed that this workgroup is doing a great job. She noted that NACCHO hosted a workshop for LHD staff at NACCHO's Annual Conference on July 7, 2015 titled *Moving People off the Fence: Create a local communications campaign to increase vaccine confidence*. Ms. Tate mentioned that this workshop was well received. NACCHO collaborated with CDC and Oak Ridge Associated Universities to survey health departments about methods used to collect information about patients and vaccines administered during routine vaccination and pandemic vaccination exercises; the survey closed June 16, 2015. Finally, Ms. Tate explained that NACCHO is conducting a survey on how LHDs use IIS in programmatic or clinical functions and this survey will open in the fall of 2015.

Public Health Agency of Canada – Dr. John Spika
Dr. Spika explained that Canada is officially in election mode now, so officially he is not supposed to say anything as a government spokesperson and instead be an observer. However, Dr. Spika announced that this would be his last NVAC meeting because he has moved into a new position. Dr. Orenstein acknowledged Dr. Spika's contributions on behalf of NVAC and congratulated him on his new position.

Pan American Health Organization/WHO – Ms. Hannah Kurtis
Ms. Kurtis, representing Dr. Isabella Danel, described selected highlights of PAHO's recent work with Member States on immunization-related activities. She explained that the 23rd meeting of PAHO's TAG on Vaccine-preventable Diseases was held from July 1-3, 2015 in Varadero, Cuba, with participation from Ministries of Health from all countries in the Americas. The slogan for the TAG meeting was "Bye-bye rubella! Let's go for more!" in recognition of the recent certification of the regional elimination of rubella and congenital rubella syndrome. The objectives of the TAG meeting were multifold and included presenting the Regional Immunization Action Plan, which is the adaptation of the Global Action Plan for the Americas; reviewing progress on several disease elimination and control initiatives; and issuing recommendations to address the many challenges faced by national immunization programs. The final report of the meeting, including all recommendations, is available on the PAHO website.

She explained that from August 17-19 2015, PAHO held a regional meeting on the Polio Eradication and Endgame Plan in Bogotá, Colombia. In total, 122 participants attended the meeting representing 29 countries in the Region, the Regional Certification Commission for the Polio Endgame in the Region of the Americas, PAHO/WHO, WHO, UNICEF, CDC, the Task Force for Global Health, and the Bill & Melinda Gates Foundation. During the meeting, global and regional progress on the implementation of the *Polio Eradication and Endgame Strategic Plan 2013-2018* was discussed, with emphasis on the guidelines for the switch from trivalent oral polio vaccine (tOPV) to bivalent oral polio vaccine (bOPV), and poliovirus containment in laboratories.

Ms. Kurtis stated that both the TAG meeting and the Polio meeting counted on participants from the U.S. In addition, Ms. Kurtis reported that the Region of the Americas is well on its way to being able to also certify the elimination of measles. This process had been interrupted by the reintroduction of measles in one state of Brazil, but to date, three months have passed since the last case was reported. Finally, Ms. Kurtis announced that PAHO's 54th Directing Council meeting will take place from September 28-October 2, 2015.

Vaccines and Related Biological Products Advisory Committee – Dr. Robert Daum
Dr. Daum noted that VRBPAC has not met since the June NVAC meeting. The next VRBPAC meeting on the safety and immunogenicity of influenza vaccine will occur on September 15, 2015.

NVAC Ex Officio Updates

Agency for Healthcare Research and Quality – Dr. Iris Mabry-Hernandez
On behalf of Dr. Mabry-Hernandez, Dr. Orenstein read the AHRQ update. AHRQ funds investigator-initiated research grants and conferences on vaccine topics. One grant is Improving Immunization Rates in Young Children: A Comparative Effectiveness Trial. Another grant is Understanding and Addressing High Rates of Refusal of Pneumococcal Vaccination among African-Americans. The third grant is Disparities in HPV Vaccine Awareness among U.S. Parents of Preadolescents and Adolescents. AHRQ created the Health Care Innovations Exchange to speed the implementation of new and better ways of delivering health care. One example of service delivery innovations is a hospital program modeled on their emergency preparedness plan, which features in-unit vaccinations and morning "lockdown" for increasing employee influenza immunization rates. Morning lockdowns were a practice where employees must enter the hospital through a single entrance manned by vaccination teams. AHRQ is working in collaboration with NVPO to develop a data management tool, or dashboard, to depict

HP2020 immunization data in a clear, easy-to-view format. This dashboard highlights ongoing racial and ethnic disparities in adult immunization and brings more attention to key gaps in coverage.

Assistant Secretary for Preparedness and Response – Dr. Richard Hatchett
Dr. Hatchett, representing Dr. Robin Robinson, noted that ASPR is a new NVAC Ex Officio member. He mentioned that Dr. Disbrow had already explained much of what ASPR is doing with respect to biodefense programs in his presentation during the morning session. Another biodefense activity is related to the Smallpox vaccine manufactured by Bavarian Nordic. Dr. Hatchett reported that Bavarian Nordic has initiated a pivotal non-inferiority study of their vaccine, which is known as Imvamune, and that is an ongoing trial in South Korea with military recruits.

With respect to ASPR's influenza vaccine program, he had a number of things to mention. On June 26, 2015, Dr. Robinson chaired a tabletop with HHS partners and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) on the vaccine mismatch and potential steps to remedy mismatches in the future. There were a number of preliminary findings from that tabletop. First, it appeared the decision point that is the last opportunity to include a new strain in a multivalent vaccine would be in the May timeframe. After that, it would be necessary to consider going to a monovalent vaccine. Some steps that could potentially reduce the chance of having a vaccine mismatch include improved surveillance, improved predictive analytics, facilitating rapid availability of candidate vaccine viruses, and speeding up the production of potency reagents. Dr. Hatchett emphasized that these are only very preliminary findings. They will have a follow-up tabletop with HHS partners and IFPMA in November 2015 focusing on vaccine strain selection, and Dr. Hatchett noted that he will have more to report on their vaccine mismatch findings at the next NVAC meeting. Finally, BARDA will be focusing on negotiating with a number of partners to facilitate development a more effective influenza vaccine.

ASPR released an RFP in January 2015 to renew their stockpiling program for pre-pandemic vaccines, and they are currently in negotiation with a number of offerors. He noted that most of the vaccines in their pre-pandemic stockpile are stored as bulk product, and in-vitro assays show they appear to be retaining their potency. However, some of that bulk product is approaching 10 years in age. They will be conducting a clinical study to ensure that they have a pre-pandemic stockpile that is maintaining its immunogenicity.

Dr. Hatchett stated that because Novartis is getting out of the vaccine business, ASPR has decided to partner with bioCSL at their manufacturing facility in Holly Springs, North Carolina. ASPR is working closely with both partners to facilitate that transition.

Centers for Medicare and Medicaid Services – Mary Beth Hance
Dr. Orenstein stated that because Ms. Hance, who was representing Dr. Jeffrey A. Kelman, was not there, he had agreed to read the CMS update. CMS recently released an outreach toolkit, entitled Living Well, which is designed for state Medicaid programs and Children's Health Insurance Programs. It focuses on general, preventive services for adults that are covered by the Medicaid program and encourages adults to think about the importance of preventive health care. States can add their branding to the toolkit or amend it to address specific services available in their state. The toolkit is found in the Outreach Tools section of Medicaid.gov.

With respect to live-tracking influenza vaccinations for Medicare beneficiaries, CMS and NVPO will again track the prevalence of Medicare influenza vaccines this influenza season. The Interactive Mapping Tool, which is on NVPO's website, provides information on the number of fee-for-service Medicare beneficiaries who have obtained influenza vaccine using claims data. The data is updated weekly. Dr. Orenstein stated again that the map can be found at the NVPO website.

Centers for Disease Control and Prevention – Dr. Anne Schuchat

Dr. Schuchat, representing Dr. Nancy Messonnier, reported that on July 31, 2015, CDC released the adolescent vaccination coverage rates for 2014. She explained that some states had significantly greater increases in HPV vaccination first dose in girls and their strategies are being shared with other states. On August 5, 2015, CDC convened an IIS stakeholder meeting to discuss the challenges and opportunities related to sharing and using IIS data to advance immunization coverage nationally. The discussion focused on strategies and barriers for promoting the use of IIS data for both patient care and public health. Dr. Schuchat provided an update on polio containment. She noted that Africa has exceeded a year without wild poliovirus. Dr. Schuchat announced a leadership transition at CDC's National Center for Immunization and Respiratory Diseases (NCIRD). Beginning September 14, 2015, Dr. Schuchat will be serving in her new role as CDC's Principal Deputy Director. A search committee for a new NCIRD director is being formed. In the interim, Dr. Rima Khabbaz will serve as the Acting NCIRD Director as well as maintain her current role as Director of the Office of Infectious Diseases. Dr. Nancy Messonnier is the permanent NCIRD Deputy Director. Dr. Orenstein thanked Dr. Schuchat for her great legacy in working with NVAC over the past decade, and he noted that NVAC was looking forward to working with her successor.

Department of Defense – COL Margaret Yacovone

COL Margaret Yacovone highlighted the 2015-16 DoD Seasonal Influenza Vaccination Program. Influenza vaccination is mandatory for all uniformed personnel including Active Duty, Coast Guard, Reserve, and National Guard, with an immunization goal of 90% compliance by mid-December. Influenza vaccination is also mandatory for healthcare personnel who provide direct patient care in military treatment facilities, and is recommended for all other healthcare personnel in the military healthcare system. For the 2015-16 season, the DoD ordered more than 3.6 million doses of vaccine. The Defense Health Agency (DHA) Immunization Healthcare Branch (IHB) provides an extensive library of tools and resources for the influenza season, to include an online training program for personnel who will be administering the vaccine. COL Yacovone emphasized that this training program is used by 15,000 students annually. DoD is also partnering with the Office of Personnel Management (OPM) to help coordinate a Federal Employee Health Benefit (FEHB) program for providing no-cost influenza immunizations to government civilians at military facilities.

She also provided a summary of the DHA IHB Vaccine Hesitancy Working Group (VHWG), which held its first meeting on August 26, 2015. Topics considered important to effectively and efficiently address vaccine hesitancy within the DOD included: 1) methods of measuring vaccine hesitancy's nature, determinants, and scope; 2) communication strategies; 3) audience targeting; and 4) an examination of current civilian and military programs. Two major influences of both vaccine hesitancy and vaccine acceptance identified by VHWG were the impact of social norms influenced most by social networks, and the impact of a knowledgeable healthcare provider. Included in the review were two DHA IHB vaccine hesitancy pilot programs examining patient, provider, and on-site immunization counselor education, patient/parent counseling opportunities, increasing barriers to immunization exemption, and

a registry of under-immunized individuals. A subcommittee was formed to explore primary prevention strategies, such as targeting mothers-to-be and adolescents as prevention strategies; thus far, efforts have produced inconsistent results in bringing about vaccine acceptance.

COL Yacovone stated they are currently looking at meningococcal disease in the military. In the U.S. military overall, the incidence of meningococcal disease is currently about the same as that of the age-adjusted U.S. general population (less than 0.2 cases per 100,000 person-years). To investigate differences by Military Service and training level, the DHA IHB is working with the Naval Health Research Center to develop a study of *Neisseria meningitidis* carriage and immunity in military recruits at various training sites. They will correlate carriage rates, antibody levels, and protection from *N. meningitidis* serogroups associated with invasive disease. Data generated from this study will improve understanding of the incidence of meningococcal disease in U.S. military recruits and assist immunization policy makers.

Food and Drug Administration – Dr. Marion Gruber
Dr. Gruber reported that in May 2015 FDA approved an update to the package insert for Prevnar 13, based on a confirmatory efficacy study that showed this vaccine protects against community-acquired pneumonia in people 65 years of age or older. In June and July, the FDA approved the supplements for the seasonal influenza vaccines for the 2015-16 influenza season. FDA will consult with VRBPAC on the safety and immunogenicity of FLUAD. Dr. Gruber explained that FDA will continue collaboration with national and international partners in assessing Ebola vaccines and will continue discussions with manufacturers about clinical development and pathways to licensure.

Health Resources and Services Administration / Bureau of Primary Health Care – Dr. Justin Mills
Dr. Mills reported that the Bureau of Primary Health Care (BPHC) released CY 2014 Uniform Data System (UDS) data for the Community Health Center Program in June 2015. He explained that UDS collects data on childhood immunizations for 1,278 health centers. Dr. Mills discussed a table with the 7-year trend (data first collected for CY 2008). In CY 2014, 77.2% of health centers had immunization rates that matched the HP2020 goals. Dr. Mills stated that to date 43% of health centers are exceeding BPHC's goal for 75% of their health centers to meet the HP2020 target for childhood immunizations (up from 40% in CY 2013). Dr. Mills also discussed a graph with CY 2014 immunization rates by state. He noted that the U.S. territories have lower percentages, but they have slightly different standards than the mainland. BPHC continues to work with health centers to improve their immunization rates through a number of different efforts. These include continued funding for new access points as well as support for electronic health records adoption and Patient-Centered Medical Home recognition.

Health Resources and Services Administration / Division of Vaccine Injury Compensation – Dr. Melissa Houston
Dr. Houston reported that the National Vaccine Injury Compensation Program (VICP) continues to have a busy year processing claims. As of August 2015, 665 claims were filed in FY 2015. Dr. Houston reported that 484 claims were adjudicated, of which 407 were compensable and 77 were dismissed. To date in FY15, approximately $196 million in awards were paid to petitioners and approximately $18 million was paid in attorney's fees. She noted that more data about VICP can be obtained at their website.

Dr. Houston stated that VICP has also completed development of proposed regulations to make several changes to the Vaccine Injury Table. The Notice for Proposed Rulemaking was posted for public

comment on July 29, 2015 and will be available for 180 days (until January 29, 2016). The final rule proposing to add intussusception as an injury associated with rotavirus vaccine was published in the Federal Register on June 23, 2015. On August 7, 2015 the Pandemic Influenza Injury Table final rule was published in the Federal Register.

Dr. Houston reported that to date in FY 2015, the Countermeasures Injury Compensation Program (CICP) has compensated four claims totaling $2.3 million. The CICP continues to work with its contractor in developing outreach partnerships. VICP outreach efforts continue to focus on making providers and the public aware of this safety net program.

Indian Health Service – Dr. Jeffrey McCollum
Dr. McCollum, representing Dr. Michael Bartholomew, reported that much of their immunization activities since his last NVAC update have focused on influenza prevention. The IHS influenza plan for the upcoming season has been finalized and fielded earlier this summer and the goals are aligned with HP2020 influenza vaccination targets. He explained the IHS achievements from the last influenza season, which included around 37% coverage among patients and 71% coverage among IHS healthcare personnel at their facilities. Core components of the IHS influenza plan are the same. Some new elements of this year's influenza plan include the addition of a new requirement that each of 12 IHS administrative regions develop their own influenza plan that is tailored to the recognized barriers, strategies, and available resources specific to each region. Another milestone is the establishment of an agency-wide policy requiring influenza vaccination among civilian healthcare personnel working in IHS federal health care facilities. This new policy was just signed last week on September 3, 2015, and they anticipate full implementation of this policy in the upcoming influenza season.

Two new IHS performance measures have been adopted for influenza vaccination: 1) influenza vaccination coverage among children ages 6 months to 17 years, and 2) coverage for adults 18 years and older. Baseline data collection will occur from July 1, 2015 through June 30, 2016. The two new measures will replace the previous measure of influenza vaccination coverage only for adults 65 years and over. Beyond influenza, other new performance measures currently being developed include: 1) TdaP and influenza vaccination coverage among pregnant women, and 2) a composite immunization measure looking at age-appropriate routine immunization coverage for adults age 18 and over. In addition, the IIS electronic health care reminder for PCV 13 for adults 65 years and older was rolled out early this summer and is now in place.

National Institutes of Health – Dr. Barbara Mulach
Dr. Mulach stated that she had three brief updates. First, she mentioned the upcoming Global Vaccine and Immunization Research Forum 2016, which will be held under the umbrella of the Decade of Vaccines. This meeting will be held March 15-17, 2016 in Johannesburg, South Africa. More information is on the WHO website.

With respect to antibiotic resistance and the potential role of vaccines, she highlighted that Dr. Carole Heilman, Director of the Division of Microbiology and Infectious Diseases, has published an editorial in the July 2015 *Infectious Disease News*. This online editorial provides a perspective on vaccines and an innovative approach to combating antimicrobial resistance.

The National Institute of Allergy and Infectious Diseases (NIAID) will have three receipt dates annually over the next three years for researchers to make grant proposals for research to advance vaccine safety. This program announcement on research to advance vaccine safety has been a collaboration effort between CDC and NIH since 2008. She mentioned that NIAID is getting inquiries from new researchers, so they hope researchers with potential hypotheses will respond with proposals.

U.S. Agency for International Development – Dr. Angela Shen
Dr. Orenstein noted that no one was present from USAID.

U.S. Department of Agriculture – Dr. Donna Malloy
Dr. Malloy reported that the USDA's Animal and Plant Health Inspection Service (APHIS) has been preparing for the potential recurrence in the fall of highly pathogenic avian influenza (HPAI) that affected more than 48 million birds at over 200 poultry facilities earlier this year. As part of these preparations, APHIS and its state and industry partners are examining the potential use of vaccines to help prevent illness in birds and interrupt the spread of the disease. APHIS has taken two significant actions related to vaccine use: the issuance of a proposal request for vaccine that will be included in the National Veterinary Stockpile, and notification that APHIS will publish an environmental assessment evaluating the potential environmental impacts of using vaccine in the event of an HPAI outbreak this fall.

Dr. Malloy explained that APHIS is seeking to create a stockpile of vaccine for the Eurasian H5 virus strain that circulated in domestic poultry earlier this year. APHIS issued a request for proposals to vaccine manufacturers with the interest and capability to supply a variety of H5 vaccines in sufficient quantity to establish the emergency stockpile.

She explained that the Agricultural Research Service (ARS) has developed a highly specific H5 assay, which targets a specific Eurasian H5 gene. ARS has also developed a vaccine seed strain. Vaccines will be carefully evaluated on a number of factors including their efficacy against Eurasian H5 viruses, and products must meet all of APHIS' safety, potency, and purity standards. Vaccine manufacturers will be evaluated on their ability to produce such vaccines in a timely manner in adequate numbers to meet the needs of the response.

Finally, Dr. Malloy noted that within the coming weeks, APHIS will also publish an environmental assessment (EA) that examines the impacts of using HPAI vaccine in the field during an outbreak response. Once published, the EA will have a 30-day public comment period.

Department of Veterans Affairs – Troy Knighton
Mr. Knighton began his report by discussing the VA's influenza vaccination campaign for healthcare workers. The VA continues to face challenges with immunization rates among their paid staff. Last year the vaccination rate for VA staff was approximately 50% despite robust campaigns and access to free vaccination. He reported they vaccinated over 1.8 million enrolled veterans. Mr. Knighton reported on the VA Retail Pharmacy Pilot for influenza vaccinations. He stated that the VA had partnered with Walgreens. Approximately 10,000 veterans received vaccination against influenza through this partnership to date. He noted this program will continue in the 2015-16 influenza season. Mr. Knighton explained the VA is exploring expansion to other retail pharmacy outlets for 2016-17. They also continue efforts to improve bidirectional exchange of health information and data accuracy.

With respect to clinical decision support tools, Mr. Knighton reported the Veterans Health Administration (VHA) National Center for Health Promotion and Disease Prevention is developing clinical decision support tools for tetanus vaccination and herpes zoster vaccination. He also reported on an application developed by the VA for providers to use on tablets to assist them in evaluating the immunization status of enrolled veterans. VHA's Office of Connected Health will be field testing the immunization app at three VA medical facilities in September and October 2015. This app has been in development for over a year. It is designed to connect with patient medical records via tablet use. The influenza vaccine is the first to be tested, but the app will expand to other vaccines.

Public Comment

Dr. Orenstein then invited public comment, noting that the comments should be limited to three minutes. No commenters were present at the meeting or on the telephone.

Adjournment

Dr. Orenstein thanked everyone and noted there was a lot of interesting information to digest. He recapped issues discussed during the meeting where he believed that NVAC could play a role and then summarized the agenda for the next day. Dr. Orenstein declared the meeting in recess until the following morning at 9:00 a.m.

Day 2 – September 10, 2015

Welcome

Dr. Orenstein called the meeting to order, and introduced Dr. Karen DeSalvo, Acting Assistant Secretary for Health. Dr. DeSalvo thanked NVAC for their contributions to public health, and welcomed new NVAC members Dr. Ginsberg and Dr. Cooke. She thanked Dr. Schuchat for her contributions to NVAC and congratulated Dr. Schuchat on her new position as CDC's Principal Deputy Director.

Dr. DeSalvo mentioned that the influenza season is approaching soon, and stated that a kick-off news conference would be conducted the following week. She encouraged everyone to carry the influenza vaccination message across the nation to protect people in communities.

Dr. DeSalvo announced that she signed off on the National Adult Immunization Plan, and explained that it was working its way through clearance. Dr. DeSalvo stated that one strategy is to bring the success we have seen in pediatric immunization to adults.

With respect to vaccine confidence and vaccines to combat antibiotic resistance, she stated that NVAC was ahead of the curve and emphasized that NVAC has given HHS a lot of information to work from and get ahead of these challenges. She noted that vaccine hesitancy is an important issue, particularly in some communities, some geographic areas, and some populations. NVAC's work will help HHS do a more targeted job to address vaccine hesitancy at a community level. In particular, NVAC's work will help HHS work with their regional offices to send out broad campaigns and messages but especially to micro-target to help people understand the facts and science behind vaccination.

Update on Effort to Support Global Immunization Initiatives

Introduction on Efforts to Support Global Immunization Initiatives, Dr. Jennifer Gordon, NVPO
Dr. Gordon reviewed the NVAC Global Immunizations Working Group report published in September 2013. The OASH charge to NVAC in February 2012 was to review the role of HHS in global immunizations. This charge also asked NVAC to review the effects of global immunizations on global populations and the effects of global immunizations on U.S. populations. NVAC was also asked to recommend how HHS can best continue to contribute to these efforts, consistent with its newly established Global Health Strategy and Goal 5 of the National Vaccine Plan. Finally, NVAC was asked to recommend how to best communicate this information to decision makers and the general public to ensure continued sufficient resources for global vaccination efforts.

The Global Immunizations Working Group produced a comprehensive report entitled "Enhancing the Work of the HHS National Vaccine Program in Global Immunizations - Recommendations of the NVAC." It was unanimously approved by NVAC on September 12, 2013. The approved report was published in a Supplement of *Public Health Reports* *http://www.hhs.gov/nvpo/nvac/reports/nvac-global-report-supplement.pdf*. The report focused on 1) Tackling time-limited opportunities to complete polio eradication and to advance measles mortality reduction and regional measles/rubella elimination goals, 2) Strengthening global immunization systems, 3) Enhancing global capacity for vaccine safety monitoring and post-marketing surveillance, 4) Building global immunization research and development capacity, 5) Strengthening capacity for vaccine decision making, and 6) Unifying HHS global immunization efforts: leadership and coordination. Dr. Gordon explained the report's recommendations looked at highlighting how HHS is playing a role in global immunizations.

She stated the recommendations drew heavily on other strategic plans. Dr. Gordon noted at the same time there was also a global effort to develop the WHO Global Vaccine Action Plan (GVAP) http://www.who.int/immunization/global_vaccine_action_plan/GVAP_doc_2011_2020/en/. Although not specifically included in the NVAC goals, NVAC was aware of the five goals of the GVAP and the two documents are in harmony. She gave an overview of the GVAP goals: 1) achieve a world free of polio, 2) meet global and regional elimination targets, 3) meet vaccination coverage targets in every region, country and community, 4) develop and introduce new and improved vaccines and technologies and 5) exceed the millennium development goal 4 target for reducing child mortality.

Dr. Gordon also stated that the GVAP has six priority objectives, which the regions and nations were asked to incorporate into their strategic plans. She explained that this session was intended to provide an update on the current priorities and efforts (both within the U.S. government and with our Regional partners) for accomplishing our global immunization goals including revised strategic plans from other agencies: USAID, PAHO, and CDC.

USAID Strategic Blueprint, Dr. John Borrazzo, USAID
Dr. Borrazzo stated that USAID focuses on 24 countries that account for over 70% of the world's maternal, infant, and child deaths. He explained the U.S. government and USAID are committed to the goal of Ending Preventable Child and Maternal Deaths (EPCMD). He presented a graph that showed in 1990 under-five deaths were 643 million, but by 2030 they want to reduce under-five deaths to 2.5 million. Dr. Borrazzo commented that reaching this goal will require reaching hundreds of millions of people, and more effort from both domestic and international resources is needed to reach this goal.

He presented a map with data on program appropriations for the 24 priority countries. He noted that sixteen of those countries are in sub-Saharan Africa, six countries are in Asia, and one country is in the Middle East. Only one, Haiti, is in the Americas.

Dr. Borrazzo presented a graph that showed how USAID Global Health Programs funding for material and child health had grown from FY2002, FY2008, and FY2013, to FY2014. He noted that overall funding available from all sources has been growing, in part because results achieved are drawing more resources to be provided. Because the USAID funding for the 24 USAID priority countries has also grown, from 27% of $391.7 million in FY2002 to 59% of $813.3 million in FY2014, the resources are increasingly focused on a set of countries that are not all over the map. In addition, he pointed out that Gavi represents a larger and larger proportion of total funding, increasing from 14% of $391.7 million in FY2002 to 22% of $813.3 million in FY2014.

EPCMD requires a multi-pronged approach, drawing across USAID's health programs. Dr. Borrazzo emphasized that immunization is one of the most effective tools they have for maternal and child survival. Every year USAID produces a report, *Acting on the Call*, which can be found at www.usaid.gov/actingonthecall , that gives progress updates on their plans in different countries and what has happened in the 24 USAID priority countries. Overall, immunizations contributed 24% to cumulative under-5 lives saved from 2008. He mentioned that USAID can also provide estimates of total child and women's lives saved, and stated that family planning interventions are critical.

Dr. Borrazzo stated that USAID decided they needed to have a more strategic statement for the immunization efforts. USAID immunization-related focus areas are 1) facilitating availability of new and underutilized vaccines, 2) overcoming behavioral barriers to vaccination through community engagement and education, 3) helping countries overcome barriers to financial self-reliance for vaccines and their delivery, 4) promoting integration of routine immunization programs into broader health system development through leadership, and 5) finishing the job with respect to polio eradication and other disease elimination targets.

Dr. Borrazzo also explained that the immunization focus of USAID is a part of the USAID's cross-cutting issues. For example, service delivery is a core premise of USAID's immunization focus area. In addition, human resources are a ubiquitous issue in the 24 USAID priority countries. Healthcare workers often do not get paid and there are shortages of healthcare workers. Lack of Information is a critical issue, but he believed there has been a revolution in the amount of information available at the country level. With respect to logistics, the cold chain issues are critical.

Dr. Borrazzo presented information about USAID's *Immunization Blueprint for Action 2016-2020*, but emphasized that this document is still a draft. It will contribute to the USAID's priority goal for EPCMD. He explained that currently USAID is framing the blueprint into three major blocks: 1) Strengthen Routine Immunization Systems in USAID Priority Countries; 2) Increase and Sustain Demand and Engagement; and 3) Drive Accountability and Partnership. The plan focuses on equity, sustainability, accountability and integration, supports a continued role for USAID in global immunization, and aligns with EPCMD and the US National Vaccine Plan and the Global Vaccine Action plan. USAID will continue to work with global partners including national governments, and government and non-government organizations (e.g. UNICEF, WHO, and GAVI) to achieve plan objectives.

He commented that "strengthen managerial capacity for service delivery . . ." would cover all the management issues related to Service Delivery that he addressed previously under cross-cutting issues. He emphasized that USAID wants to ensure that "increase commitment to immunization . . ." encourages the trend that countries are increasingly willing to finance national vaccination programs with their own resources.

Dr. Borrazzo continued by noting that USAID works closely with partners around the world including national governments; CDC and other U.S. government agencies; UNICEF; WHO; Gavi, the Vaccine Alliance; and others to extend access to life-saving vaccines. He mentioned that USAID's limited funding resources require partnerships, but those partnerships also require USAID staff resources.

Dr. Borrazzo briefly addressed the U.S. government and Gavi. He noted there are still 73 Gavi-eligible countries, including all 24 USAID priority countries for EPCMD. The U.S. government has obligated over $1.3 billion since FY2001, and pledged an additional $1 billion through 2018. He commented that the pledge for an additional $1 billion was a substantial increase. He stated that the U.S. government is Gavi's third largest donor in this next strategic period. He also mentioned that USAID represents the U.S. government and serves as the Board member on Gavi as well as on a number of Gavi's key committees.

Discussion

Dr. Orenstein stated that USAID's work was very impressive and also very consistent with a number of NVAC's recommendations. He mentioned that there were a couple of issues for which he was not clear on whether USAID is playing a role. He asked Dr. Borrazzo to comment on whether USAID is working on enhancing global capacity for vaccine safety monitoring or post-marketing surveillance, or on building global immunization research and development capacity. With respect to vaccine safety, Dr. Borrazzo explained that USAID has a history of making investments in product development to help enhance vaccine safety and has contributed to products that enhance vaccine safety that are now part of routine systems in many places. With respect to vaccine safety monitoring, he stated that such monitoring is actually part of USAID's service delivery. Regarding research and development, USAID is still involved in developing a malaria vaccine and other vaccine development efforts. He added that USAID is struggling to decide how to incorporate research on vaccine development into their blueprint.

Dr. Thompson stated that USAID's efforts have been important, especially their role in Gavi and their role in successes with polio eradication. She asked about the draft blueprint's first major block: "Strengthen innovative approaches to reach all – equity and coverage." Dr. Thompson believed that we might have to redefine "routine immunization" based on what has been learned from polio eradication efforts. She commented that we need to start thinking more broadly about strategies for reaching the hard-to-reach areas for routine immunization and that the model of having children come to one center is not necessarily the most cost-effective strategy. Dr. Borrazzo mentioned that USAID is looking at what they can learn from what they have done with polio to work with community engagement and civil society organizations to get the reach out into the community as opposed to service delivery that requires coming to a fixed location.

Dr. Maldonado mentioned they are currently subcontracting through an NGO with USAID to do monitoring and evaluation for a demonstration project looking at under-5 mortality in the Democratic Republic of the Congo (DRC). There is often a question of diagnosis related to child mortality. She wondered whether there can be other methods of confirming diagnoses in some areas where it is hard

to know the actual cause of child mortality. Some children die at home and they do not have true autopsies so they are trying to do virtual autopsies.

Dr. Borrazzo stated this is related to implementation to help partners strengthen their ability to most effectively reach children on the ground with interventions. He explained that in the DRC, most children die from undernourishment contributing to complications of childhood diseases, specifically malaria, pneumonia, and diarrhea. Between the last two national demographic and health surveys for the DRC there was a 35% reduction in under-5 mortality over the past six years probably due to better diagnosis and treatment of childhood diseases in remote areas. He stated we need to do a much better job of making sure that children in the community get care as well as the children at health facilities. Dr. Borrazzo explained there has been more effort in Africa to develop formalized systems of community health workers to effectively conduct outreach which may be a model. He commented that a possible role for the community health workers in immunization is to help stimulate demand.

PAHO GVAP Regional Immunization Action Plan, Dr. Martha Velandia, PAHO

As an introductory overview, Dr. Valendia stated that PAHO has 35 Member States and four Associate Members in the Region of the Americas. The 2014 population was 981,373,000 and the annual birth average is 15,595,200. She explained that as of 2014, they now have 20 vaccines and will give 20 doses per child less than one year old. Because they have 15 million children less than one year old, she commented that this becomes expensive at an estimated US$70 for each of these vaccinated children. She also commented that they are moving to family vaccination instead of focusing on child vaccination.

Dr. Velandia presented selected data to describe vaccination coverage in the Americas. For global and regional diphtheria-tetanus-pertussis vaccine third dose (DTP3) coverage from 1980-2013, she noted that the Americas have always had good coverage in comparison to other regions. Dr. Valendia pointed out that the Americas had seen a decrease in DTP3 coverage in recent years, which is a new problem that PAHO needs to address. As a more in-depth example, she presented a map of the Americas with 2013 data on the percentage of municipalities with different coverage rates (≥95%, 80-94%, <80%) for DTP3 in children less than one year old. She pointed out that many countries have municipalities with <80% coverage, and a few countries have over half of municipalities with <80% coverage for DTP3 in children less than one year old.

She also presented data showing that the Americas are leading the world with respect to countries with pneumococcal conjugate vaccine in their National Immunization Program and planned introductions in 2015. The Americas are also leading the world regarding countries with rotavirus vaccine in their National Immunization Program and planned introductions in 2015. The Americas are still making progress in terms of the data on countries with HPV vaccine in their National Immunization Program in 2015. Dr. Valendia concluded her introductory overview by presenting graphs showing achievements in the Americas for polio eradication, rubella elimination, good progress to approach measles elimination, and progress on diphtheria and pertussis cases and vaccination coverage.

Dr. Valendia explained that the PAHO Regional Immunization Action Plan, 2016-2020 (RIAP) was developed with input from the Global Vaccine Action Plan (GVAP) and Global Polio Eradication Initiative (GPEI). In 2014, PAHO began work on the PAHO's Strategic Plan, 2014-2019 and PAHO's Biennial Work Plan, 2016-2017. She explained that they used those two PAHO plans to build the RIAP. Dr. Valendia presented a list encompassing their large umbrella of health services: political priority and legal

frameworks; planning and coordination; purchase of vaccines and supplies; maintenance of the cold chain; training, supervision and monitoring; epidemiological surveillance and laboratory; communication and social mobilization; and technical excellence.

She stated that a draft of RIAP was presented to PAHO's Executive Committee in June 2015, which was approved for presentation to PAHO's Directing Council. She next reviewed some key steps in the context for development of the RIAP. In 2007, they had the Regional Immunization Vision and Strategy, 2007-2015. Then from 2011-12, the GVAP was created through a global consultation process. PAHO started work on RIAP, and during 2012 and 2013 had presentations on the GVAP during PAHO Technical Advisory Group (TAG) meetings. From 2014-15, there was a consultative process to adapt the GVAP in the context of the Americas to develop RIAP. In 2015, during June and September/October, they will have presentations of the RIAP before PAHO's governing bodies.

Dr. Valendia next discussed the vision of the RIAP stating that the vision is based on the six GVAP principles: Equity, Shared responsibility, Solidarity, Universality, Sustainability, and Quality. In the RIAP, PAHO has four strategic areas: 1) sustain the achievements, 2) complete the unfinished agenda, 3) tackle new challenges, and 4) strengthen health services for effective vaccine administration. She noted that the general objectives for each of the RIAP's four strategic areas are also similar to the general objectives of the GVAP. PAHO's general objectives constitute disease eradication, elimination, and control goals. Dr. Valendia presented a list of indicators for each of RIAP's four strategic areas. She noted that each strategic area has indicators for each general objective and strategic objective. The baseline year is 2013 and the target year is 2020. PAHO is working to decide how frequently to measure those indicators. Dr. Valendia concluded stating that the RIAP would be presented to the PAHO Member States during the 54th Directing Council (September 28-October 2, 2015).

Discussion

Dr. Orenstein noted that the Americas led the effort for polio eradication and for measles elimination. All six WHO regions have measles elimination as a goal. One of the controversies about a global goal for measles is the vertical versus horizontal. He commented that in the U.S., the focus on measles elimination led to building our routine immunization delivery system. He asked about the experience in Latin America with regard to whether the focus initially on polio and then on measles helped or hindered the development of routine immunization systems.

Dr. Valendia explained that for measles, they have coverage for first dose of MMR around 92% and they are recommending the second dose at 18 months. In their region, they have large campaigns and they also have microplanning where the health services person is focused on small populations, such as households or small communities. They feel they have to work with health services to try to do integration and avoid huge campaigns of vertical activities.

Dr. Cooke asked about whether the PAHO region has issues with parental concerns about vaccination. Dr. Valendia stated that in the PAHO region parents are asking for the vaccines and they know the importance of immunization. She explained they are now facing problems that they have multiple injections of vaccines at same time. In Bolivia, PAHO survey results found that healthcare workers are recommending that parents do not give simultaneous vaccinations to their children. Dr. Valendia commented that they have to work first with the healthcare workers to empower them about the importance of the simultaneous vaccinations.

Dr. Maldonado wondered about their partnerships at the horizontal level, specifically about how involved the community healthcare providers (e.g., pediatricians) are in vaccinations. Dr. Valendia explained that each country has their own committee, which has healthcare providers and they are very involved in the committees and vaccination issues.

CDC Global Immunizations Strategic Framework, Dr. Eric Mast, CDC

Dr. Mast explained that his presentation would focus on three main areas: 1) successes and challenges in global immunizations from 2011-15, 2) evolution of the global immunization environment from CDC's perspective, and 3) overview of the draft "CDC Global Immunization Strategic Framework, 2016-2020." He noted he will highlight some of CDC's work related to NVAC global immunization priorities.

Dr. Mast stated the last polio case in India was in 2011. Four regions (Americas, Western Pacific, Europe, and Southeast Asia) are now certified polio-free. He explained that Wild Poliovirus (WPV) Type 1 is the only remaining type now circulating. Dr. Mast reviewed activation of emergency operations. National Emergency Operations Centers were established in Nigeria (2012), Pakistan (2014), and Afghanistan (2015). In Nigeria and Pakistan, CDC collaborations with the Ministry of Health and national Field Epidemiology Training Programs (FETPs) established National Stop Transmission of Polio (N-STOP) programs to strengthen operations in high-risk districts. He explained these N-STOP programs gave CDC a much greater footprint at the country level for reaching the underserved and chronically missed, supporting GPEI pillars, and providing an evidence-base for program management and program improvement.

Dr. Mast presented data on developments in WPV cases from 2013-14. Africa has been free of endemic polio for a year and the last two countries to "get over the finish line" that had WPV type 1 cases in the last six months are Pakistan (nine cases) and Afghanistan (seven cases)- although both countries reported lesser numbers of cases than in 2014. Progress in Pakistan is related to intensified government commitment, Emergency Operations Centers already established, improved access in insecure areas, improved coordination with Army and security agencies, innovations to reach missed children (including use of female community volunteers, health camps, transit posts), and focused efforts on 12 high-risk districts. Ensuring progress in Afghanistan is related to engagement of new leadership, the Emergency Operations Center, access through neutrality and dialogue with all sides, and more rigor and innovation to reduce missed children in an updated National Emergency Action Plan.

The goal is to complete polio eradication by the end of 2014 and certification in 2018.Dr. Mast briefly reviewed IPV introduction and the coordinated global switch of tOPV to bOPV by 2016, and how that is incorporated into the plan for OPV withdrawal by 2019-20. He presented a map that showed IPV introduction status for each country based on WHO data through March 2015.

In addition, Dr. Mast quickly reviewed poliovirus containment requirements from 2015-20. He noted that an estimated 500 facilities are holding WPV Type 2. He presented information on National Certification Committees (NCCs) related to poliovirus containment. NCCs are expected to oversee the process and documentation of: 1) the detection and interruption of all WPV transmission and the quality of the acute flaccid paralysis surveillance system, and 2) implementation of safe handling and containment measures to minimize risks of facility-associated reintroduction of poliovirus. By January

2016, NCCs are expected to submit WPV containment reports to the Regional Certification Commission (RCC).

For measles and rubella elimination, Dr. Mast presented data on the reduction in estimated measles deaths from 1985-2013. There was an 87% decrease in measles deaths during 1985-2013. For 2000-13, there was a 75% decrease in measles deaths. He pointed out, however, that in the last five years the reduction in measles deaths has plateaued. The problem areas are sub-Saharan African countries and the Indian subcontinent. He reviewed progress toward measles elimination by WHO region in 2014-15.

Dr. Mast summarized CDC's efforts on strengthening global immunization systems. He noted that CDC introduced the Meningococcal A conjugate vaccine rollout in sub-Saharan Africa countries from 2010-17. CDC has supported other vaccine introductions during 2011-15, including HPV, influenza, Japanese encephalitis, Meningococcal, pneumococcal, rabies, rotavirus, and typhoid. Another key area that CDC introduced involves the activities of the Global Vaccine Preventable Diseases (VPD) Laboratory Network, which he believed are crucial. CDC is building on the Polio Laboratory and Surveillance Network, which has over 700 labs. He noted that other VPD Laboratory Networks with CDC support are the Global Rotavirus Laboratory Network, Global Influenza Surveillance and Response System, and Global Invasive Bacterial-VPD Laboratory Network.

He presented 2013 data by vaccine for WHO regions on the number and percentage of member states with vaccination recommended in the immunization schedule during the second year of life. He noted that 82% of countries had ≥1 health care visit during the second year. Dr. Mast reviewed the benefits of strengthening the second year of life platform for vaccination: stronger platform for vaccine doses, opportunity to catch up on vaccines missed during the first year, and opportunity to integrate vaccination with other health interventions. Dr. Mast also explained that CDC has expanded the STOP Program from 2009-14.

Dr. Mast also summarized CDC's efforts on enhancing global capacity for vaccine safety monitoring and post-marketing surveillance. CDC provided support for the WHO report, *Global Vaccine Safety Blueprint*. He explained that the Blueprint is intended to assist low and middle income countries to develop capacity for vaccine safety assessment and response. The Blueprint was also created to establish a global vaccine safety support structure. CDC also provided support for two WHO guidance documents for adverse events following immunization. The WHO report, *Causality Assessment of an Adverse Event Following Immunization (AEFI): User Manual for the Revised WHO Classification*, was developed as a guide to a systematic, standardized causality assessment process for serious AEFI. The WHO report, *Global Manual on Surveillance of Adverse Events Following Immunization*, provides guidance on setting up AEFI surveillance systems with standardized methodologies and tools.

Dr. Mast explained that most of CDC's efforts have focused on strengthening National Immunization Technical Advisory Groups (NITAGs). He noted that only 63 out of 191 countries (33%) have a well-functioning NITAG based on 2012 data on NITAG indicators by WHO region. CDC support for NITAGs has included development of training materials and facilitation of workshops for NITAG members, and support for attendance of NITAG members at the WHO's Strategic Advisory Group of Experts (SAGE) meetings or regional TAGs. CDC has supported NITAG training activities in EURO and PAHO countries from 2011-15 in collaboration with WHO, the Supporting Independent Immunization and Vaccine Advisory Committee (SIVAC) Initiative, the Sabin Vaccine Institute, and ACIP.

Dr. Mast explained that CDC has supported strengthening national capacity for immunization advocacy and policy making in collaboration with AAP. They work with national pediatric societies to provide workshops to train in-country immunization champions to promote and support targeted immunization priorities (e.g.,, strengthening immunization systems, implementing the Polio Endgame, achieving measles and rubella elimination, vaccine introduction). He noted this work will also support efforts to develop appropriate immunization policies and recommendations by NITAGs.

Dr. Mast reviewed the evolution of the global immunization environment from CDC's perspective since 2011. He stated there are four key developments that CDC needed to take into consideration in developing a new framework: 1) the new Center for Global Health established in 2010; 2) launching of Global Health Security Agenda in 2014; 3) the transition from the *WHO/UNICEF Global Immunization Vision and Strategy, 2006-2015* to the *Global Vaccine Action Plan, 2011-2020*; and polio legacy planning.

He explained that these four developments were opportunities to link to the *CDC Global Health Strategy, 2012-2015*. The goals of that CDC strategy are: health impact, health security, health capacity, and organizational capacity. He elaborated that the last goal, organizational capacity, referred to maximizing CDC's organizational capacity to achieve impact with global programs. He noted that CDC's global presence includes a staff of over 1,600 located in over 50 countries, with a budget of over $2 billion.

With respect to the transition from the *WHO/UNICEF Global Immunization Vision and Strategy, 2006-2015* to the *Global Vaccine Action Plan, 2011-2020*, Dr. Mast noted this had occurred and presented a comparison of their goals. He noted that most of the goals are similar but GVAP has some differences. For example, GVAP focuses on polio and tetanus in addition to measles. GVAP has a more specific focus on equity in extending the benefits of immunization. In addition, GVAP goals and strategic objectives include that all countries commit to immunization as a priority, and include an emphasis that individuals/communities understand value of vaccines and demand immunization as their right and responsibility.

Dr. Mast discussed that the large GPEI workforce is currently focused on endemic and transitioning countries for polio eradication. He reviewed the key components of transition planning for the GPEI: 1) maintaining and mainstreaming polio functions, 2) sharing lessons learned to improve child health, and 3) transitioning polio functions to improve child health. He emphasized that other global health and development programs can benefit from GPEI's assets and capabilities. Dr. Mast specifically mentioned the following areas that GPEI could support: trained volunteers, social mobilizers, and health workers; unprecedented access to households untouched by health systems; maps and microplans to deliver health services to chronically neglected communities; and standardized, real-time global surveillance and response capability.

Dr. Mast presented information about the goals and targets in the draft "CDC Global Immunization Strategic Framework, 2016-2020," which he also provided in a handout. He explained that each of the supporting goals has targets that are related to strategic areas. The immunization strategic framework supports the overarching goals of 1) a polio free world, 2) continued measles and rubella elimination progress, 3) other vaccine preventable disease control goals, 4) new/underutilized vaccine introductions, and 5) vaccine development. The framework further supports targets regarding a)

strengthening country ownership and partnerships, b) ensuring equity and improved coverage through quality immunization systems, c) strengthening surveillance and immunization information systems and d) conducting and promoting research and implementation science in the realm of vaccines and vaccine preventable diseases. The plan is expected to be reviewed, cleared and disseminated by January 2016. Dr. Mast concluded by showing progress in global immunization at CDC from 1965 through 2015. He noted that CDC's global immunization work began in 1965 when former President Lyndon Johnson pledged support for global smallpox eradication. He also noted that in 1965 CDC began technical assistance to USAID-funded measles vaccination campaigns in West Africa. Dr. Mast expressed his gratitude and desire for NVAC's continued support particularly in the area of advocating for the importance of US government leadership in achieving global immunization goals.

Discussion

Dr. Orenstein noted that Dr. Mast's presentation addressed quite well all of NVAC's recommendations from their global immunization report.

Dr. Lynfield asked Dr. Mast about the global invasive bacterial and VPD laboratory network that he mentioned. She asked whether they were non-culture based or culture-based and what diseases they were tracking. Dr. Mast mentioned that this work is done through CDC's NCIRD, and he referred the question to Dr. Schuchat. Dr. Schuchat asked for clarification on whether the question was about just the bacterial or about the new VPD laboratory networks. Dr. Lynfield noted that diagnostics were challenging in many parts of the world, especially the ability to do culture-based diagnostics and that it was important to have the diagnostics capacity to make good evidence-based decisions. Dr. Schuchat explained that the efforts to get good national or regional data on rotavirus have been effective in dozens of countries to understand their burden and see the impact of vaccination. She noted that invasive bacterial disease is very difficult even in high resource environments and it easy to get poor data that is confusing and misinterpreted. In South Africa they have wonderful invasive bacterial disease surveillance, but in other countries the information can be misleading. The global invasive bacterial disease networks have been using traditional methods and are exploring other methods. Dr. Schuchat commented that although they are not where they wanted them to be, they are making progress.

Dr. Lynfield added that CDC is investing in advanced molecular detection. She wondered whether some of that effort can be used toward non-culture based diagnostics for invasive bacterial diseases in low resource areas. Dr. Schuchat stated that these issues are under exploration, but noted there were some challenges. She also commented that the Ebola epidemic has shown that we actually need to get diagnostic capacity out there in simple and safe ways that will take the newest technology and probably be independent of culture-based for technical and safety reasons. Upgrading CDC labs to advanced molecular detection as well as state and local labs will help us eventually to make similar progress internationally.

Mr. Hosbach asked Dr. Mast about his specific slide on poliovirus containment requirements from 2015-20. He is not sure that all stakeholders can meet the goal in the U.S. or even around the world by the end of 2015 for the designated polio containment requirements. He commented that this will be difficult whether you are a manufacturer using Salk wild poliovirus, down to laboratories, diagnostics, or universities with stool samples saved in numerous refrigerators. Mr. Hosbach asked how they are involving stakeholders and when was the last time that an assessment and inventory was done. He

pointed out that one background document (*Polio Eradication and Endgame Strategic Plan 2013-2018*) has a gap in that it missed Canada as a country that manufactures Salk IPV vaccine.

Dr. Schuchat offered to reply and acknowledged that Mr. Hosbach's questions and concerns were good points. She replied that CDC is sprinting for the end of 2015. The last time this level of assessment was done was in 2008. She commented that CDC may have 40% of the laboratory specimens that need to be addressed for polio containment. The CDC efforts this year on lab safety concerns involving clean sweeps and inventories have already helped to address the poliovirus inventory issue in the U.S. PAHO has convened a regional commission that will oversee this and is in the midst of surveying their countries. She acknowledged that even though there are a small number of manufacturers, they have a very complex set of issues. She commented that everything in polio eradication is interconnected, and they want to do their best to meet the incredibly ambitious timelines.

Mr. Hosbach commented that it is also important to consider companies that provide diagnostics. He pointed out that companies may decide to get out of the business of diagnostics if they have to upgrade their facilities and it costs too much. He stated we should be careful not to drive them out of business because they are low-margin businesses and those diagnostics are used by many organizations from all over the world, probably including CDC. He pointed out that these companies use small amounts of wild poliovirus for their diagnostics work. Dr. Schuchat stated that the diagnostic aspect is on CDC's radar as well as the manufacturing issues whether for diagnostics or vaccines. The interdependence between what the polio eradication plan is signaling and implications with respect to business impacts is something that CDC is aware of.

Mr. Hosbach commented that companies that work with wild poliovirus—whether serology, testing, or production—are probably working with all three types. Dr. Schuchat stated that the thinking was focusing on wild poliovirus Type 2 was the most urgent with respect to the 2015 requirements. She commented that the effort to do this well for Type 2 by the end of 2015 will later make Type 1 and 3 much easier. She commented that the last two times this was done, they did not take advantage of technology as well as they could in terms of inventory databases.

Dr. Lynfield followed up on the progress toward measles elimination for the WHO regions. Europe will not meet their 2015 goal. Dr. Mast commented that this illustrates the breadth and depth of the disease and vaccine-specific work at CDC. He noted that he is in CDC's global immunization division where they focus primarily on the programmatic aspects. Measles elimination will be a real challenge both in Europe, where the primary issue is vaccine hesitancy, as well as in the other regions. There have been efforts to outline the specific issues for each WHO region and what needs to be done. From his perspective, the main thing that needs to be done for measles elimination to succeed is a strategic focused effort to use measles elimination to drive routine immunization strengthening. There are other areas where a focused effort on measles elimination could be used to drive broader health system strengthening. The second year of life platform could drive getting the second dose of measles, but could also be used to increase coverage for other vaccines. After polio campaigns are gone, measles campaigns will be the broadest reach we have to identify unreached children. Surveillance is another key area that could provide opportunities for linking measles surveillance to the broader epidemic-prone VPD efforts. The occurrence of measles highlights areas where health system strengthening is needed. Dr. Valendia shared that for the PAHO region it was also very important to see a very high-level government leader commitment.

Vaccine Confidence

Vaccine Confidence Session Introduction, Ms. Judith Mendel, NVPO

Ms. Mendel provided an introduction and background to the vaccine confidence session. Overall, childhood vaccination rates in U.S. are high (e.g., recently released 2014 NIS data) and some have reached the HP2020 targets. Much work needs to be done because clusters exist where parents are delaying or declining some or many vaccines. She noted we also know there are many factors influencing vaccine confidence that vary across time, place, and vaccine. In addition, there are federal, state, and local efforts to better understand and address vaccine confidence in different populations. The NVAC Vaccine Confidence Working Group recommendations were approved on June 9, 2015; the report was accepted for publication in *Public Health Reports* November/December 2015 issue. The report focused on measuring and tracking vaccine confidence, developing strategies for effective communication and reaching communities as well as developing strategies to reach and aid providers in making strong recommendations, developing policy related strategies and ensuring continued and improved support and monitoring of vaccine confidence measures. The NVAC recommendation defined vaccine confidence as "the trust parents or healthcare providers have in a) the recommended immunizations b) the providers who administer vaccines, and c) the processes that lead to vaccine licensure and the recommended immunization schedule. Ms. Mendel asked NVAC as they listen to the upcoming panel of presentations on the latest in vaccine confidence to think about whether our current efforts are in line with what is needed, and whether there are specific areas that emerge as higher priority.

Measuring Vaccine Confidence Among U.S. Parents, Dr. Sarah Clark, University of Michigan

Dr. Clark noted that parental confidence in the safety and effectiveness of childhood vaccines is related to their willingness to seek and/or accept vaccination. National measures of vaccine confidence are helpful in tracking changes over time. She explained that the objective of her presentation was to share results of research to measure several aspects of vaccine confidence among U.S. parents over time.

Dr. Clark reviewed the methods of the C.S. Mott Children's Hospital National Poll on Children's Health (NPCH). NPCH is an online survey fielded three times per year, and is designed as a mechanism to solicit views of the U.S. adult population. NPCH also has different child health topics for each fielding. The primary purpose is to develop monthly reports targeted to lay media. She noted that participants are invited by an email that introduces NPCH as a survey from the University of Michigan on child health, which was an approach to avoid concerns that it was about vaccines or a survey coming from the government.

The NPCH method uses a KnowledgePanel® online research panel representative of the U.S. population including over 40,000 households. Recruitment is through address-based probability sampling. Dr. Clark noted it was important that households are provided with Internet access and hardware, if needed. They have the ability to do targeted sampling based on household demographics.

Dr. Clark explained that NPCH has asked vaccine confidence questions in NPCH over time, specifically January 2009, September 2011, January 2013, and May 2015. They have used standard wording of statements in order to compare results over time. Also they used the Likert scale of agreement.

For the statement "Getting vaccines is a good way to protect my child from disease," she stated they had a big increase in respondents with "Strongly Agree" for their most recent May 2015 data point. For the statement "Generally I do what my doctor recommends about vaccines for my child," they saw a similar pattern but the increase in "Strongly Agree" was not as high. She noted that the scale was the opposite for the statement "I am concerned about serious side effects of vaccines," with the level of "Disagree/Strongly Disagree" quite pronounced for the September 2011 data point. For the statement, "Parents should have the right to refuse vaccines required for school for any reason," the level of "Disagree/Strongly Disagree" was about the same for the first three data points, but jumped for the May 2015 data point. She also noted that the level of "Strongly Agree" dropped for the May 2015 data point.

Dr. Clark explained that for the May 2015 fielding, they spent more time probing vaccine confidence because of the measles outbreak. They included some statements to measure perceived change in May 2015. Based on their queried statements for the May 2015 fielding, they found parent confidence in vaccines was greater in May 2015, on several measures, compared to prior surveys. It is plausible that well-publicized vaccine outbreaks are associated with the increase in vaccine confidence. She stated that measurement of vaccine confidence should continue over time.

Dr. Clark stated that NPCH focused more on the preschool population in 2014. In particular, they wanted to examine attitudes toward vaccination in day care. The preschool population is important for this research because vaccine confidence among parents of young children has particular importance, due to the number and frequency of recommended vaccine doses. Furthermore, the extent to which parents support vaccine requirements for children in daycare settings is not well established. She explained the objective of NPCH research focusing on the preschool population was to examine attitudes toward vaccination requirements among parents of young children.

The NPCH data collection for the preschool population research was conducted in June 2014. It included 614 parents with a child 0-5 years old. Of these children, 35% were in a daycare center/preschool and 18% were in home childcare. She noted they used the Likert scale of agreement for the preschool population research. In general, parents felt children should be required to be up-to-date on vaccines. She noted that they saw some differences in results between daycare centers and home childcare, but less than they were expecting. In this study, parents also felt that childcare providers should be required to check the vaccine status of every child, every year, to make sure they are up to date.

Dr. Clark explained that they also asked parents about preferred daycare policies for children not up-to-date on vaccines. The results indicate 90% parents support enforcement of one of the three daycare policies such as "exclude from daycare until vaccinated," "give a grace period to get vaccinated", or "require a waiver from doctor".

Two-thirds of the parents surveyed also indicated that they would like to find out the number of kids not up-to-date in a specific facility. However, they were not supportive of being able to find out the names of kids not up-to-date. Dr. Clark commented that the NPCH results for those two scenarios indicate that parents are looking for information on how to assess risk instead of identifying individual children or families.

Dr. Clark continued by noting that NPCH asked parents about another statement that is a fairly realistic scenario. The results for the statement, "If you knew that 25% of children (1 in 4) were not up to date on

vaccines, would you consider taking your child out of that childcare center?" She noted that a total of 74% responded as "Definitely" or "Probably" would consider removing their children. Dr. Clark emphasized that those results show parents do not know that on average 1 in 4 children are not immunized, leaving their children at risk.

Finally, Dr. Clark reviewed a summary of the results and their implications. The NPCH results indicate strong parent support for childcare vaccination requirements, lack of appreciation about the extent of under-vaccination, and that strategies may be needed to support childcare providers in checking vaccination status. She added that their results would also support IIS efforts. Further reports and results are available on the organizations website: http://mottnpch.org/.

Childhood Immunizations: First-Time Expectant Mothers' Knowledge, Beliefs, Intentions, and Behaviors, Ms. Allison Fisher, CDC

Ms. Fisher described the first survey in a seven-part series for CDC's First-time Expectant Mothers Survey developed on the premise that talking with first-time pregnant women will help understand how they act or plan to act with respect to the recommended infant and childhood immunization schedule. The First-time Expectant Mothers Survey is a longitudinal study of U.S. women, with a goal of at least 100 women.

A commercial research firm used its national database of 70,000 panelists to identify first-time mothers with due dates between September and December 2014. She explained that Survey 1 sampled a panel of 200 women of which they retained 174 women in the panel. They excluded women on some factors, such as those women who were not going to vaccinate. Ms. Fisher provided some demographics on the women in their panel. The median age is 28 years. She noted that the majority were married or partnered, and had private health insurance. For the question, "Which of the following best describes your plans for vaccinating your baby?," they had the following results that were used to divide the panel into three groups: Acceptors (receive all as scheduled), Delayers/Decliners, and Undecided.

For the "Acceptors" category (n=150), overall participants were very confident in the safety, effectiveness, and value of vaccines. They were confident that immunization was important to their child's health and that their child should receive immunizations according to the recommended schedule. For the "Delayers/Decliners" group (n=29), they were much less confident, particularly in the safety of vaccines and the importance of following the recommended schedule. The "Undecideds" group (n=21), showed even less confidence in all areas of questioning.

Ms. Fisher explained in all groups, women expressed that they were not very satisfied with their current level of knowledge regarding childhood vaccines. She commented that pregnant women are high information seekers and a high number of women in the panel (63.5%) said by the second trimester they had not discussed any information with their obstetrician-gynecologist (ob-gyn) or midwife. Ms. Fisher explained they provided the following statement to the whole panel: "Parents should ask questions about the importance or value of their child's vaccinations." She noted that 80.9% said "strongly agree" and commented the panel felt that it was a parent's job to learn about vaccinations.

The top three sources of information for childhood vaccinations used by these women in the past month included Internet search engines, family, and the women's healthcare professional (e.g., primary care or ob-gyn). Ms Fisher commented that these sources are different from what they see in parents of young

children who already have a pediatrician and generally cite their child's pediatrician as a trusted source of information. For the Delayers/Decliners and Undecideds groups, internet search engines were the most important sources of information with family members ranking second and online pregnancy or parenting sites third. Unlike the Acceptor group, these groups did not consider healthcare professionals as a top source of information.

Ms. Fisher explained they also asked about a list of frequently provided vaccine messages through a 2-part question, what the women thought about the message itself and whether it influenced her decision to vaccinate her baby. Ms. Fisher presented examples of CDC's childhood immunization campaign materials and highlighted some messages including an information sheet for parents, a campaign print ad, and a sheet from CDC's vaccine information series.

In wrapping up her presentation, Ms. Fisher reviewed the limitations of the study. The database is not nationally representative, because they used an opt-in panel. Though they were satisfied with their sample size, it may be too small for some of the subgroup analyses they wanted to do. In addition, participants were allowed to skip questions. Finally, they excluded from the survey expectant mothers who said they did not plan to vaccinate their child.

Overall, their survey had found that first-time expectant mothers had positive beliefs and perceptions regarding childhood vaccines. They found differences in information sources for first-time expectant mothers compared to the sources CDC hears from parents. She commented that CDC will continue to ask about information sources as the children of the women in the surveys get older. They also found that satisfaction with vaccine information could be improved, in particular, expanding efforts to provide vaccine-related information to expectant mothers. CDC will continue to learn more as they follow these mothers and babies through the process of infant immunizations.

Protecting Infants by Vaccinating Pregnant Women: Development of an Educational Campaign on Tdap Vaccine during Pregnancy, Ms. Michelle Basket, CDC

Ms. Basket explained that the objectives of her presentation are to discuss findings and guiding principles from formative research with pregnant women and ob-gyns, and that she will conclude by discussing campaign materials for pregnant women and healthcare professionals. She stated that their research on pregnant women included a survey of pregnant women and also 28 focus groups with pregnant women. Their online survey included U.S. women 18-45 years of age. Ms. Basket explained that a total of 487 pregnant women were eligible respondents and completed the survey. Data were collected during June-July 2014 for the online survey.

Ms. Basket explained the 28 focus groups of pregnant women included a total of 214 participants. They chose locations for high pertussis incidence (San Diego) and low pertussis incidence (Atlanta). She noted these focus groups were segmented by parity and language (English and Spanish), and had a mix of trimester, race/ethnicity, and socioeconomic background. She explained the focus groups were conducted in two rounds (June and September-October 2014). From the focus groups, they identified the following "guiding principles" for pregnant women:

- Levels of awareness of pertussis and perceived susceptibility to the disease are low among pregnant women,
- Pregnant women are primarily concerned with the health and safety of their baby when making decisions about vaccines during pregnancy, and

- Pregnant women view their ob-gyn or midwife as the ultimate authority on pregnancy-related topics.

Ms. Basket commented that the ob-gyn has the ability to influence pregnant women, based on the focus group results. Knowledge and awareness of pertussis and Tdap vaccine recommendations was low in both the English and Spanish-speaking focus groups. She presented preliminary results from the online survey, which indicated that 60% of survey respondents said they had looked for information on Tdap vaccine. In addition, she stated that 71% had looked for information about vaccine safety, with online sources used most often for information.

Ms. Basket explained that concern over the baby's safety (50%) was the most common reason that survey respondents were unsure if they would get Tdap during their current pregnancy. She added that protecting the baby was the strongest motivator for vaccination among focus group participants. Ms. Basket mentioned that their research results showed that mothers understood the general concept of antibody transfer. They also understood that getting the Tdap vaccine during pregnancy did not preclude the need for Tdap later for the child. She explained that messages that included disease risks for the baby were generally more likely to encourage undecided survey participants to accept Tdap vaccination.

This research study also looked at the healthcare professional's influence. Among the survey participants, a healthcare professional's recommendation was the most common reason (69%) for accepting Tdap vaccination. The focus group participants preferred "talk to your doctor" as a call to action for Tdap vaccination versus "get the vaccine." Based on these results, she believed that educational materials should be used to supplement, but not replace, the conversation with the healthcare provider.

Ms. Basket next described an online survey of 32,056 members of the American College of Obstetricians and Gynecologists (ACOG). All ACOG respondents offer prenatal care. Data for this online survey were collected in February and March of 2014. She explained that 2,365 respondents completed the survey, which she noted is a small percentage of ACOG membership. Ms. Basked commented that the results that emerged from the ob-gyn survey helped guide the format and content of campaign materials. From this survey, they identified the following "guiding principles" for ob-gyns:

- Knowledge of the Tdap recommendation during pregnancy is high, but perception of individual risk for their patients (and their babies) is often low;
- Stocking Tdap is a barrier for some ob-gyns , often due to issues with reimbursement; and
- The most common channels for sharing vaccine information with patients are face-to-face during the office visit and in handouts at the first prenatal appointment.

Nearly all survey respondents reported recommending Tdap to their pregnant patients, with 77.1% administering the vaccine in their office. Another 20.7% reported recommending Tdap vaccine to their pregnant patients but refer them elsewhere to receive the vaccine.

With respect to the barriers to stocking Tdap, concerns over reimbursement were a barrier to stocking Tdap vaccine for the ob-gyns that participated during the in-depth interviews. Most physicians interviewed who recommended but did not stock Tdap did not follow-up with patients later to see if

they were vaccinated elsewhere. Despite the barriers, most interviewees felt that the obstetric provider was responsible for vaccinating pregnant women.

With respect to information channels, most respondents (88%) for the online survey use brochures or handouts to communicate with pregnant patients. She noted that most respondents reported these would be the most useful tools for them. Posters, patient websites, and training materials for staff were also listed as useful tools. Respondents turned to ACOG and CDC most often for vaccine information for themselves and their patients. Ms. Basket commented that these results reinforced the importance of partnering in the process of developing campaign materials.

Ms. Basket next discussed a new maternal Tdap campaign "Born with Protection Against Whooping Cough". She explained this new campaign was developed in collaboration with the American Academy of Family Physicians, AAP, the American College of Nurse-Midwives, and ACOG. It targets pregnant women and prenatal healthcare professionals. She mentioned that they tested draft campaign materials with and without cobranding and found that the cobranded materials worked better. She presented examples of campaign materials from the CDC website, posters, a fact sheet for pregnant women, and fact sheets for healthcare professionals. She commented that the CDC's pregnancy and whooping cough website saw 88,000 initial views since the October 2014 launch. Ms. Basket explained that the messages for the posters and fact sheet for pregnant women came from their focus group work and emphasized that safety information the most important information that women wanted. She added that the fact sheet for pregnant women promotes third trimester vaccination as the best choice.

She explained that all the campaign materials are available for free on the CDC website: cdc.gov/pertussis/pregnant. CDC is promoting awareness of the campaign among healthcare professionals, partners, immunization programs, and immunization coalitions. They are encouraging their partners to promote the campaign via social media messages. She explained the CDC is planning to target pregnant women during June-July 2015, with messages through Google, Facebook, Pandora, and BabyCenter.

Ms. Basket indicated that next steps include continuing to promote awareness of campaign materials and messages, including targeting of pregnant Spanish-speaking women. CDC will analyze findings from additional research that was already done for a survey with nurses, nurse practitioners, and nurse-midwives. They will publish research to practice efforts in the future. CDC also plans an evaluation of campaign reach through website metrics.

Moving People Off the Fence: NACCHO's Vaccine Confidence Workshop, Ms. Lisa McKeown, NACCHO
Ms. McKeown presented a summary of a vaccine confidence workshop held in July 2015 at NACCHO's annual meeting. She explained that there was a strong interest from Local Health Departments (LDHs) in sharing information and successes around community strategies to address vaccine confidence, and NACCHO is responding to that interest.

NACCHO first held a workshop pilot that included 30 people during an in-person meeting of NACCHO's immunization workgroup, HPV advisory group, and LHD HPV grantees in June 2015. They later held a 2-hour workshop at NACCHO's Annual Meeting in Kansas City, Missouri, with a larger group of 70 people. These 70 participants represented LHDs, nonprofits, hospitals, and the pharmaceutical industry and the

workshop agenda included presentations from LHDs/community organizations and brainstorming activity using facilitation methods.

Ms. McKeown explained that the workshop focused on the "fence sitter," which was defined as someone who held strong views but might make the right decision with more information. They discussed who the fence sitters were in the communities represented by workshop participants, and what characteristics described them. They discussed what messages would move their audience to action. She explained that the workshop participants were encouraged to work as a group and develop one message. She presented examples of messages developed at the workshop. Ms. McKeown noted that the audience for these messages ranged from homeschooler mothers, to new age or alternative health types, to healthcare providers who are vaccine hesitant.

She explained that after the workshop, they did an evaluation. With respect to what the workshop did really well, Ms. McKeown emphasized that the workshop invited participants to dive into an empathetic role to consider the driving forces, perspective, and commonalities inherent with fence sitters. With respect to how NACCHO could support their LHD in creating a vaccination communications campaign, they found NACCHO could help by: 1) sharing successful campaigns other health departments have launched, and 2) technical assistance and advice to identify target groups and methods to reach them.

Ms. McKeown concluded by explaining the workshop was the kick-off to a larger project. She reviewed the next steps. First, NACCHO plans to conduct regional focus groups of local health officials and immunization program staff to describe LHD perceptions, experiences, and concerns related to vaccine confidence within their communities. Secondly, NACCHO will convene a Vaccine Confidence Consortium to provide learning and peer engagement opportunities to support LHDs and their partners to address vaccine confidence. As the last step, NACCHO will plan to support five LHDs to develop a communications plan, test, disseminate, and evaluate messages to increase community-level vaccine confidence.

National Vaccine Program Office's (NVPO) Vaccine Confidence-Related Work, Dr. Glen Nowak, NVPO
Dr. Nowak reviewed NVPO's vaccine confidence objectives. NVPO wants to continue to provide leadership that advances efforts and activities in this domain. NVPO is seeking to foster collaborations and partnerships that further understanding, and help strengthen, vaccine confidence. NVPO wants to be involved in efforts to help strengthen vaccine and vaccination-related communication efforts and messages. Finally, NVPO wants to facilitate the visibility of research efforts and findings, interventions that have or show promise, and evidence-informed resources.

Using the NVAC's recommendations and report as a framework, core elements of NVPO's strategy include 1) lead, support and coordinate confidence related activities, 2) build partnerships to extend efforts, and 3) engage both domestically and internationally. Objectives include strengthening vaccine and vaccination related communication efforts/messages for parents and providers, facilitating visibility of evidence based resources, and identifying approaches to measure and track vaccine confidence.
For research and measurement, Dr. Nowak noted that NVPO wants to decide what vaccine confidence-related measures should be evaluated and how to evaluate them. NVPO is interested in furthering the visibility and reach of current studies. For the longitudinal study of first-time mothers, he mentioned that the fifth wave has been initiated. They are also aware of additional presentations and papers. NVPO

is working on identifying and cataloging vaccine confidence-related measures, studies, and findings. He explained they are looking at the published literature for vaccine confidence measurements.

NVPO is starting work on "vaccine confidence" measures, reviewing measures used to date and using NIS to look at the relationship between confidence and behavior. They are researching potentially available measures (e.g., HealthStyles, NIS, internet panels) and engaging in research, including pilot projects.

Dr. Nowak explained there have been efforts to use the HealthStyles surveys to ask about confidence in safety, effectiveness, and value/benefits of recommended vaccines. There is an association with vaccination-related behavior and intentions. He mentioned recent work by Gilkey et al. (2015) that used the 2010 NIS-Teen to assess associations between parents' mean scores on a 4- and 8-item Vaccination Confidence Scale and vaccine refusal, vaccine delay, and vaccination status. Having a lower level of vaccination confidence was associated with vaccine refusal and having a higher level of vaccine confidence was associated with higher levels of vaccination.

Dr. Nowak turned the podium over to Ms. Judith Mendel, NVPO, who discussed NVPO efforts currently underway on the repository. Ms. Mendel noted that NVAC recommended creation of a repository for communicating best practices related to vaccine confidence. She explained that NVPO is developing the Vaccine Confidence Resource Exchange (VCRE) to be housed on the NVPO website. She noted the VCRE will align with the third focus of the NVAC Vaccine Confidence Report. VCRE will be a central, online repository for healthcare researchers and practitioners to search for and submit materials that address vaccine confidence. She explained that VCRE will probably go under the Resources section of the NVPO website and presented some screen shots to illustrate the process as well as the form to submit a resource to VCRE and the information NVPO will request for indexing.

Dr. Nowak then reviewed NVPO's longer-term efforts, as listed below:

- NVPO will continue the many collaborative efforts that are underway, including interagency (especially with CDC); working domestically (e.g., with NACCHO, immunization programs); working with PAHO, Public Health Agency of Canada, and U.S. partners (i.e., NVPO and CDC); and also working globally (e.g., stakeholder and/or researcher network).
- NVPO will continue to identify ways to systematically compile and report on vaccine confidence-related measures and studies.
- NVPO will facilitate and participate in efforts to develop and assess the concept of a "Vaccine Confidence Index" related to recommended childhood immunizations.
- NVPO will be fostering and contributing to efforts, partnerships (e.g., with healthcare providers) and networks that seek to: 1) further understand the state and measurement of vaccine confidence, 2) increase vaccine confidence, or 3) develop vaccine confidence-related research agendas.
- NVPO will be participating in efforts related to healthcare provider training.
- NVPO will be considering whether and how to apply "vaccine" or "vaccination" confidence to adolescent and/or adult immunization, because most adults are not aware there is an immunization schedule for them.

Discussion

Dr. Orenstein asked the Vaccine Confidence Working Group co-chairs, Dr. Viswanath and Dr. Mouton, if they wanted to make any comments before opening it up for discussion. Dr. Viswanath began by thanking the panel for this session and commented that it was nice to see efforts underway to address vaccine confidence. He wanted to address several major issues for NVAC to think about. His first issue was regarding vaccine safety infrastructure, which he believed was fundamentally important. He commented that if the public had a better understanding of the tremendous amount of work involved and all the processes and hurdles that must be met in the vaccine approval process that confidence would be enhanced automatically. He suggested that the question is how to communicate this information to influence vaccine confidence and get that automatic response.

He also believed we should not be on the defensive—data show a very small percentage of people refuse vaccines. He believed that the majority of people comply with the recommendations and that vaccines are a social norm and we should emphasize why this is a social norm. There is a group of people who have questions or concerns, or who might be called hesitant, about vaccines but get their children vaccinated. He believed we must continue reinforcing that vaccination is the right thing to do, but noted that the media repeating and reinforcing the myths and falsehoods is part of the problem. It is extremely important to communicate aggressively why vaccines are a very safe medical procedure, and not be on the defensive.

Dr. Viswanath also suggested that measures should focus on specificity and time-bound action. He suggested talking about what a vaccine can do to protect from a specific disease. He used recommendations for physical activity as an example – recommendations should not be limited to "engage in physical activity" but rather be specific and state "walk every day for 30 minutes". It would be an empirical question to look at being that specific about what a vaccine can do to protect against a specific disease.

Dr. Mouton congratulated the panel and he was encouraged to see actions already being taken on the Vaccine Confidence Report. He would like to see more attention to and work with providers who have "a lack of enthusiasm" about vaccines. He commented that parents say strong recommendations from healthcare providers are crucial to getting them to make a decision about getting their children vaccinated in spite of parental concerns. He suggested having medical organizations emphasize this among healthcare providers. We should also put more focus on emphasizing that lack of vaccination is not the norm and has a public health threat that impacts not just the parent's child but the entire community.

Dr. Omer commented that the portal being developed by NVPO will be useful and needed to be done. First, parents are looking for information at the local level. Secondly, exemption rates have limitations. Dr. Omer suggested that one "low hanging fruit" is to make state-level exemption data available on a website. He believed that would also set a norm about sharing data on school exemptions at the state, local, and school level. He believed there should be minimal resource constraints.

Ms. Despres stated that when you look at school-level data, there are social norms not to vaccinate in some schools. She provided an example for Los Angeles where some schools have 60-70% exemption rates. Ms. Despres believed that targeting those micro-communities where the social norm is not to vaccinate is an important use of school-level data to target resources and develop strategies.

Dr. Smith suggested looking at the synergy between vaccine confidence as a driver and other factors such as access, policy, or enforcement. He provided the example of Arkansas that currently has one of the lowest childhood vaccination completion rates compared to Mississippi, which has no non-medical exemptions. Dr. Smith commented that the difference is probably not due to differences in vaccine confidence. He believed there are synergies between vaccine confidence and state policies, access, and enforcement of policies that need to be in place to make vaccination coverage increase. Getting a vaccination needs to be much easier than getting an exemption.

Dr. Orenstein asked whether the NVPO's vaccine exchange website could become the website for collecting and making available those exemptions data. Ms. Mendel stated that was not currently in the scope for the resource exchange. Ms. Ehresmann, AIM, stated that the data available on their Vaccine Policy and Facts Website (described on Day 1) is just what the states report.

Dr. Viswanath emphasized his view that resources repositories usually take a lot of effort but may not be well used. He emphasized there is a demand side to such repositories that needs strategic thinking. There needs to be some mobilization of people, but he believed this is not the government's job. NVPO should look at this demand side that is critical.

Dr. Orenstein asked Ms. Mendel a question about the website and the process for people to submit resources to be included. He wondered about the process for screening resources and deciding what resources to post on the website. He was concerned that some information submitted might encourage vaccine hesitancy. Ms. Mendel explained that nothing will be posted publicly until reviewed internally at NVPO. They want the resources to be evidence-informed and evidence-based. As they get through user testing, they will decide on the approach for selecting what is appropriate for posting. Dr. Orenstein emphasized that it will be important to develop a formal process for NVAC to review.

Dr. Orenstein asked Dr. Clark for more information about her data. He stated that those data were encouraging but with respect to looking further at the group that remained hesitant he wondered if there were any data such as demographics, socioeconomic status, education status, or geography. Dr. Clark stated they have a lot of different background data. She noted that the NVAC packets had two academic publications with more information and that included looking more closely at parental decisions about refusals or delays for specific vaccines. Dr. Clark added that some people do not see government as the most trusted source, so she believed that we need different sources asking questions about vaccine confidence to provide information for people. Her group is happy to be a partner with NVPO in helping to measure vaccine confidence over time.

Dr. Orenstein asked if anyone on the panel would like to make any comments. Ms. Basket emphasized the very critical relationship between the providers and the patients. She noted that CDC sees that throughout early childhood immunization, with teens, and throughout adult immunization. CDC has done a lot of work on that and they have some materials to help with that process. CDC is always open to working with partners to see what other needs are out there. The critical part is the partnership at the state and local levels as well as the partnerships with associations and other organizations.

Dr. Orenstein thanked everyone on the panel and commented he was pleased with the efforts underway related to vaccine confidence. He would like for NVAC to get further updates on these efforts

at future meetings. In addition, he would like for NVAC to get more information on the issues in the adult population regarding hesitancy for influenza vaccination.

Dr. Gellin added that WHO's SAGE and NVAC came out with similar work although the contexts were quite different. He noted that NVPO had spoken with WHO recently and he thought it was interesting that WHO was considering creating Centers of Excellence. Dr. Gellin acknowledged others were working in this area. Dr. Omer agreed and believed there was increasing recognition at the global level, and also at multiple regional levels. He stated that most of the research has come from the U.S. As more players get involved globally, he thought it was encouraging that the U.S. will be able to gain from them.

Public Comment

Two commenters provided written comments and spoke at the floor microphone during the public comment period. Another commenter provided written comments shortly after adjournment, because they had missed the opportunity to speak at the floor microphone. No commenters were present on the telephone.

Ms. Erin Fry-Sosne, PATH

Ms. Fry-Sosne provided comments from PATH on revitalizing global immunization in the National Vaccine Plan. PATH submitted their comments jointly with AAP, Aeras, American Red Cross, and Sabin Vaccine Institute. As organizations committed to improving the health and wellbeing of people around the world, they are pleased that NVAC has continued to pay attention to global immunization—specifically through the global immunization recommendations published in 2014 and for continuing to stay abreast of the U.S. role in global initiatives through the updates provided by PAHO, USAID, and CDC.

The mid-course review of the National Vaccine Plan comes at a pivotal moment. The goals of GVAP, which were adopted by all 194 member states of the World Health Organization—including the United States—at the 2012 World Health Assembly, are far off track. The world will fail to reach all but one of the GVAP targets set for 2015.

As one of, if not the largest funder of vaccine research and development and global immunization programming in the world, the U.S. government has a lot at stake in the progress of the world's global immunization strategy and a lot to contribute toward its success.

NVAC and NVPO must use the mid-course review to take stock of the U.S. government's collective role in global immunization and determine how its political leadership, bilateral and multilateral support, research funding, and technical expertise can maximize U.S. impact in global immunization. The U.S. government must recommit to the goals of the GVAP by prioritizing the globally agreed upon targets with associated activities in goals 1 (research and development) and 5 (global immunization) of the U.S. government's own plan. The National Vaccine Plan must call for increased political leadership to leverage the collective expertise of the U.S. government to inform global policy and activities and ensure that the goals of the GVAP remain at the forefront of the global agenda. To ensure ongoing interagency coordination, the plan must also establish and maintain a global immunization cross-agency working group.

The GVAP signatories committed to a new ambitious vision—a world where everyone lives free from vaccine-preventable deaths by 2020. Every day that the goals of the GVAP are off track, preventable

deaths occur. It is time to harness political, financial, and technical leadership across agencies to ensure that the second half of the decade of vaccines gets back on track.

Dr. Mychelle Farmer, American Academy of Pediatrics (AAP)
Dr. Farmer began by explaining that AAP is a nonprofit professional organization of 64,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health of all children. The AAP recognizes that vaccines are one of the most cost effective and successful public health solutions available.

The AAP has endorsed the NVAC report "Enhancing the Work of the Department of Health and Human Services National Vaccine Program in Global Immunization: Recommendations of the National Vaccine Advisory Committee." The AAP supports global immunization efforts through guidance in the Red Book® 2015, the annual report of the Academy's Committee on Infectious Diseases, as well as through additional policy documents and endorsements. Among these, the AAP has authored a clinical report on the Polio Endgame and endorsed the recommendation of the WHO's SAGE on immunization pertaining to the use of thimerosal in vaccines. The AAP appreciates the opportunity to partner with NVAC and looks forward to continuing to engage NVAC in these critical efforts.

With support from grants from the Bill & Melinda Gates Foundation and the United Nations Foundation, AAP's Global Immunization Advocacy Program supported polio and measles/rubella eradication, funding for Gavi, the Vaccine Alliance, and pneumococcal and rotavirus vaccine accessibility. The AAP has recruited more than 100 Global Immunization Champions as U.S. advocates.

This work has entered a new phase with a grant from CDC to support the strengthening of national immunization systems. The AAP will educate and strengthen capacity for pediatric leaders in partner countries to be immunization advocates by providing mentorship, technical assistance, and workshop trainings. Through mentored technical assistance, the AAP will also support identified pediatric societies in refining and implementing immunization advocacy plans, with focused priorities on strengthening routine immunization systems, implementing new vaccines, and readying their countries for Polio Endgame implementation activities.

This is a key moment for global immunization. Of the six targets in GVAP, only one is on track to being achieved (the introduction of underutilized vaccines). According to SAGE, "The targets each relate to different vaccines and diseases, but common threads run throughout: failure to extend vaccination services to people who cannot currently access them at all, and failure to strengthen the healthcare system so that all doses of vaccine are reliably provided."

The U.S. government has played a leading role in expanding access to immunizations around the world. In light of the need for the GVAP to be fully implemented, the AAP commends the NVAC report on global immunization. The AAP hoped that the U.S. government will follow these recommendations to achieve polio eradication and advance measles mortality reduction, strengthen global immunization systems, enhance global capacity for vaccine safety monitoring and post-marketing surveillance, build global immunization research and development capacity, strengthen the capacity for vaccine decision making, and strengthen HHS leadership and coordination for global immunization.

The AAP urged the U.S. government to recommit to the goals of the GVAP and align agency strategies accordingly.

Ms. Lissy Moskowitz, Gavi, the Vaccine Alliance
Since 2000, Gavi has driven unprecedented progress in global health by saving lives through vaccines—one of the most cost-effective public health interventions available. Through the efforts of the Vaccine Alliance, including the leadership of developing country partners, Gavi has helped immunize half a billion children, leading to seven million lives saved since its inception. It has played a pivotal role in ensuring continued introduction and rollout of new vaccines and improved equity in coverage.

The U.S. and Gavi have had a strong partnership since Gavi's inception. As discussed at this NVAC meeting, the U.S. has placed a significant emphasis on ending preventable child deaths by targeting funding for high-impact, low-cost interventions, and vaccines and immunization are an important component of this initiative. In 2014, USAID held a high-level forum to unveil *Acting on the Call*, a plan to save the lives of 15 million children in developing countries by 2020.

Expanding vaccine coverage through its support to Gavi is central to this plan, and the U.S.—both USAID and CDC—and Gavi continue to align programmatic interests in country to ensure greater efficiency and impact of these programs on the ground.

The evidence is clear: vaccines are a public health "best buy." They are one of the most efficient, successful, and cost-effective health and development investments we can make. Vaccines are a cost effective way to protect a child for life and avoid the tragedy of early death or a life-long disability. Moreover, as we are seeing more and more frequently, diseases—such as measles or polio—do not stay within country borders and can travel the globe quickly. This is another reason why global vaccination is critical. Yet more than 22 million children, mainly in the developing world, are still not vaccinated against common but deadly diseases. Improving equity in access to immunization both between and within countries in order to close the immunization gap is a priority for Gavi as it works to build upon the significant gains of the past 15 years. In fact, Gavi aims to help immunize more children in the next five years than it helped immunize in its first 10 years of operation.

Gavi thanked NVAC for continuing to ensure that global immunization remains a key goal of the National Vaccine Action Plan. Dedication to global vaccine efforts will continue to ensure strides in saving children's lives around the world.

Adjournment

Dr. Orenstein thanked Dr. Gellin and commended all the staff at NVPO for their efforts on organizing the meeting and developing the NVAC reports. In particular, he thanked Dr. Gordon who played a big role in making this NVAC meeting successful. Dr. Orenstein adjourned the meeting.