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## National Vaccine Advisory Committee (NVAC) September 11–12, 2012, Meeting Minutes

### **Committee Members in Attendance**

Walter A. Orenstein, M.D., Chair  
Richard H. Beigi, M.D., M.Sc.  
Sarah Despres, J.D.  
Seth Hetherington, M.D.  
Philip S. LaRussa, M.D.  
Clement Lewin, Ph.D., M.B.A.  
Ruth Lynfield, M.D.  
Yvonne Maldonado, M.D.  
Julie Morita, M.D.  
Charles Mouton, M.D., M.S.  
Amy Pisani, M.S.  
Mitchel C. Rothholz, R.Ph., M.B.A.  
Thomas E. Stenvig, R.N., Ph.D., M.S.  
Litjen Tan, Ph.D., M.S.  
Catherine Torres, M.D.  
Vish Viswanath, Ph.D.

### **NVAC Ex Officio Members**

Geoffrey Evans, M.D., HRSA, Vaccine Injury Compensation Program (VICP)  
Amy Groom, M.P.H. (for Richard Church, Pharm.D.), Indian Health Service (IHS)  
Phil Krause, M.D. (for Marion Gruber, Ph.D.), U.S. Food and Drug Administration (FDA)  
Iris Mabry-Hernandez, M.D., M.P.H., Agency for Healthcare Research and Quality (AHRQ)  
Rick Hill, D.V.M., M.S., Department of Agriculture (USDA)  
Richard Martinello, M.D., Department of Veterans Affairs (VA)  
Justin Mills, M.D., M.P.H., Health Resources and Services Administration (HRSA), Bureau of Primary Health Care (BPHC)  
Barbara Mulach, Ph.D., National Institutes of Health (NIH)

RADM Anne Schuchat, M.D., U.S. Public Health Service (USPHS), Centers for Disease Control and Prevention (CDC)  
COL Scott A. Stanek, D.O., M.P.H., Department of Defense (DoD)  
Murray Trostle, Dr.P.H., (for Margaret McCluskey, R.N., M.P.H.), U.S. Agency for International Development (USAID)

### **NVAC Liaison Representatives**

Anne Bailowitz, M.D., M.P.H., National Association of County and City Health Officials (NACCHO)  
Anu Bhatt, Association of Immunization Managers (AIM)  
Robert S. Daum, M.D., C.M., Vaccines and Related Biological Products Advisory Committee (VRBPAC)  
Charlene Douglas, Ph.D., M.P.H., R.N., Advisory Commission on Childhood Vaccines (ACCV)  
Renée R. Jenkins, M.D., Advisory Committee on Immunization Practice (ACIP)  
Wayne Rawlins, M.D., M.B.A., America's Health Insurance Plans (AHIP)

### **Executive Secretary**

Bruce G. Gellin, M.D., M.P.H., Deputy Assistant Secretary for Health and Director, National Vaccine Program Office (NVPO)

## Day 1—September 11, 2012

### **Welcome—Howard K. Koh M.D., M.P.H., Assistant Secretary for Health (ASH), U.S. Department of Health and Human Services (HHS)**

Dr. Koh welcomed all the participants and thanked the NVAC members for their efforts. Noting that the events of September 11, 2001, affected him both personally and professionally, he called for a moment of silence in remembrance of that tragedy. Dr. Koh summarized some of the public health accomplishments of HHS during the Obama Administration. He welcomed five new members of NVAC: Richard H. Beigi, M.D., M.Sc., an obstetrician–gynecologist who specializes in reproductive infectious diseases; Sarah Despres, J.D., a government relations strategist with expertise in immunization and vaccine supply, safety, and financing policies; Ruth Lynfield, M.D., a State medical director and epidemiologist; Yvonne Maldonado, M.D., a pediatrician and researcher who specializes in pediatric infectious diseases (and served as an NVAC member in the 1990s); and Mitchel C. Rothholz, R.Ph., M.B.A., a pharmacist and association executive. Dr. Koh recognized and thanked outgoing NVAC members Tawny Buck and Clement Lewin, Ph.D., M.B.A.

Dr. Koh gave a brief overview of the agenda for the meeting. In particular, he was excited about the promise of health information technology (HIT) and said that vaccination is the first priority of the Office of the National Coordinator (ONC) of HIT. Dr. Koh expressed enthusiastic support for the leadership and contributions of NVAC Chair Walter A. Orenstein, M.D., and NVPO Director Bruce G. Gellin, M.D., M.P.H.

### **Chair’s Report—Walter A. Orenstein, M.D., NVAC Chair**

Following introductions of Committee members, Dr. Orenstein gave an overview of the meeting process. He noted that public comment is important; while the public comment period is not a question-and-answer session, NVAC does listen to the comments and factor them into its deliberations. He emphasized that time for public comment is limited, but written comments can be sent to the NVAC for consideration by e-mail (nvpo@hhs.gov). Dr. Orenstein recognized the new and outgoing NVAC members. He then called for review of the June 2012 NVAC meeting minutes.

#### ***Action Item***

NVAC members unanimously approved the June 2012 minutes with no changes.

Dr. Orenstein briefly reviewed the status of NVAC action items and recommendations. He summarized the meeting agenda. The proposed NVAC meeting dates for 2013 are February 5–6, June 11–12, and September 10–11.

### **National Vaccine Program Topics**

#### ***National Vaccine Plan Implementation Plan & Stakeholder Engagement—Lauren Wu, NVPO***

Ms. Wu emphasized that the National Vaccine Plan, published in 2010, and the corresponding [Implementation Plan](#), released this week, reflect input from multiple stakeholders and require cooperation from partners outside the Federal sphere. To address the top 10 priorities for implementation identified in the National Vaccine Plan, the HHS Assistant Secretary for Planning and Evaluation (ASPE) recommended the Implementation Plan focus on the near future (2010–2015) and measurable outcomes.

The Implementation Plan identifies a timeframe and lead agency for each of its 62 action items. For example, in response to Priority C, enhance timely detection and verification of vaccine safety signals and develop a vaccine safety scientific agenda, CDC will redesign the online reporting form for the Vaccine

Adverse Events Reporting System (VAERS) by the end of 2013 to include new fields that capture additional demographic information and will implement web-based features to expedite complete and accurate online reporting. The Implementation Plan stipulates an annual progress review and a mid-course review in 2015, with guidance from NVAC. A second Implementation Plan will be developed for 2015–2020.

In creating the Implementation Plan, NVPO gathered input from stakeholders on achieving the priorities, and the findings of those efforts are described in a document published by the [\*Association of State and Territorial Health Officials\*](#) (ASTHO). The stakeholder engagement sessions brought to light strong concerns about the special needs of certain populations. In some areas, efforts have already moved forward. For example, discussions about access to care in border States led HHS to develop an initiative to engage promotoras (community health workers) to increase influenza vaccination rates. Ms. Wu pointed out that the National Vaccine Plan laid out numerous objectives in a table format alongside the government and external stakeholders who could play a role in achieving them. While Federal agencies are accountable for implementing the National Vaccine Plan, many efforts require public-private partnerships to succeed.

### ***Discussion***

Ms. Wu said the ASPE is developing a tool for tracking progress of HHS action plans; in addition, there is a plan to report progress regularly. NVAC members said they would have appreciated an opportunity to give input on a draft version of the implementation plan. Several pointed out that the Implementation Plan lacks specific outcomes and indicators by which success can be measured. In some areas, there are no baseline measures against which progress can be tracked. Creating a public-private partnership to enhance third-party billing (i.e., enabling public health providers to bill private payers when services are delivered to privately insured patients) was suggested.

### ***Action Items***

The Global Immunization Working Group (GIWG) should ensure that its recommendations are consistent with strategies identified in the Implementation Plan.

NVAC members will review the Implementation Plan and identify areas for further discussion at a future NVAC meeting in preparation for a mid-course review in 2015. NVPO should develop key target indicators to assess progress toward meeting the objectives outlined in the National Vaccine Plan as well as a strategy for revising the indicators if they do not yield sufficient data.

### ***Follow-Up on NVAC Vaccine Financing Recommendations—CAPT Angela Shen, Ph.D, MPH on behalf of NVPO***

CAPT Shen summarized the process and recommendations of NVAC, published in *Pediatrics* in 2009. She described progress on several fronts:

- HHS provided guidance to the 61 Vaccines for Children (VFC) programs to work with Federally-qualified health centers, rural health clinics, and public health departments to serve VFC-eligible underinsured children.
- The CMS website now includes an annual update of Medicaid vaccine administration reimbursement rates by State.
- CMS has proposed to update the fee schedule for the VFC program.
- The Patient Protection and Affordable Care Act (ACA) will increase vaccine administration payments to Medicaid providers.

- The American Medical Association, manufacturers, and medical societies are stepping up to address the recommendations regarding business practices in private provider offices. Similarly, efforts are underway to support employer health education efforts and develop model contract language and resources to support health insurance plan coverage of all ACIP-recommended vaccines.
- The ACA provides first-dollar coverage for all ACIP-recommended vaccines and their administration for children and adolescents.
- The CDC, the 317 Coalition, and NVAC's Immunization Infrastructure Working Group (IIWG) are all providing insight and professional judgment on the Section 317 program.
- Numerous published papers present data on the costs of and reimbursement for vaccine administration in public and private settings.
- CDC has improved the timeliness of publication of ACIP recommendations.
- CDC has invested in improving the public health infrastructure to provide vaccines for children and adolescents.
- CDC updated its cost-benefit analysis of the routine childhood immunization schedule and is conducting a similar analysis for the adolescent schedule.
- The H1N1 influenza pandemic spurred outreach efforts to providers who serve VFC-eligible children and adolescents.
- CDC is helping grantees develop third-party billing mechanisms, and AHIP is providing technical assistance.
- States are taking into account the costs to schools and others of ensuring compliance with childhood and adolescent immunization requirements for school attendance.
- Pilot programs are underway to promote immunization efforts in complementary venues.

### ***Discussion***

It was pointed out that some States create barriers to provider participation in VFC programs by tying it to Medicaid program participation. Provisions governing private provider reimbursement rates sunset in 2013; the expiration of other laws may also affect vaccine financing. Phil Hosbach of Sanofi expressed concerns about delays in insurance company reimbursement to providers for vaccines. Wayne Rawlins, M.D., M.B.A., pointed out that "clean" (i.e., 100-percent correct) claims are processed in 30–60 days, but CAPT Shen noted that in a review of claims, 80 percent were not clean, often due to minor discrepancies. It was noted that the clean claims issue is large enough to cause doctors to avoid administering vaccines. Dr. Rawlins agreed that timely payment is critical for all practitioners; moreover, adequate payment rates should be based on evidence-based research, which is lacking.

CAPT Shen described some efforts underway to increase adult immunization rates and improve financing for adult vaccines and administration. It was noted that payment rates are a significant barrier to adult immunization efforts.

### ***Action Items***

For a future NVAC meeting, NVPO will gather information on how long it takes the Center for Medicare and Medicaid Services (CMS) to process providers' vaccine claims.

At a future NVAC meeting, NVPO should present on 1) efforts underway to identify vaccine purchase costs as well as actual payment rates to providers for vaccine administration in various clinical settings by both private and public providers and 2) pressing or emerging issues related to vaccination financing, such as the planned changes to provider reimbursement rates.

NVPO will create a list of published resources and web links to data on vaccine administration costs.

### **Updates on Healthy People 2020 Immunization Goals**

#### **OVERVIEW—DON WRIGHT, M.D., M.P.H., DIRECTOR, OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION**

Dr. Wright gave a high-level overview of the Healthy People framework, its evolution, and the criteria for setting Healthy People objectives. He noted that Healthy People 2020 reflects a strong focus on social determinants of health—that is, the complex interplay of factors such as genetic disposition, behavior, environment, and access to care that affect an individual’s health. Dr. Wright said the target rates promoted by Healthy People objectives are considered too timid by some, too lofty by others. HHS strives to find the middle ground, using existing targets when available and mathematical models to determine others. The default target rate is 10-percent improvement over the previous decade.

Out of more than 900 objectives outlined in Healthy People 2010, CDC had tracking data for more than 700 of them. For about three quarters of the objectives, targets were either met, exceeded, or moved in the right direction. About one quarter moved in the wrong direction, such as measures of childhood obesity. Of 87 objectives related to immunization and infectious diseases in Healthy People 2010, targets for 65 were either met, exceeded, or moved in the right direction. Dr. Wright listed some of the surveillance systems and data sources used to track progress on immunization and infectious disease objectives.

#### **IMMUNIZATION UPDATE—RADM ANNE SCHUCHAT, M.D., CDC**

Dr. Schuchat emphasized that rates of most vaccine-preventable diseases are at record low levels. Healthy People 2020 sets targets that reflect the coverage needed to maintain disease control. Dr. Schuchat summarized trends in vaccine coverage. She noted, for example, that the switch to a 13-valent pneumococcal conjugate vaccine (PCV 13) resulted in a rapid, significant decline in cases caused by the additional serotypes not covered in PCV7 among both children and adults.

The Healthy People 2020 target for Tdap vaccination of adolescents has already been achieved, demonstrating that vaccine providers can reach teens, noted Dr. Schuchat. Coverage rates for adolescents reveal some surprising disparities: adolescents below the poverty line have lower coverage rates with tetanus, diphtheria, and acellular pertussis (Tdap); for human papillomavirus (HPV) vaccine, those below the poverty line have higher coverage rates. Dr. Schuchat said the HPV coverage rates could be attributed to many factors, but she noted that the HPV vaccine is the most expensive vaccine for adolescents. Another look indicates that both Black and Hispanic adolescents received the first dose of HPV vaccine at higher rates than White adolescents in 2011, but all three groups dropped off significantly in rates of completion of the three-dose course.

CDC is developing more evidence-based communication mechanisms about vaccines. According to analyses, Dr. Schuchat said, winning “the hearts and minds” of clinicians so that they can better communicate with parents and patients is key to improving vaccine coverage rates.

In response to the ACIP universal recommendation for influenza vaccination, CDC proposes to consolidate the 10 Healthy People 2020 influenza vaccine subobjectives into two targets for reporting purposes, one for people ages 6 months to 18 years, and one for those over 18 years. However, Dr. Schuchat said that CDC will continue to track vaccine uptake among various populations, with particular attention to health care personnel and pregnant women. She added that CDC has been speeding up its survey processes so that information learned can be applied to the following year’s influenza season.

## **DISCUSSION**

Dr. Schuchat said that CDC data available online can provide more detail on geographic variations across States in vaccine coverage. NVAC members pointed out the need to look even more closely, down to the level of neighborhoods, to better understand the interaction of factors that contribute to health disparities. Dr. Schuchat said CDC is supporting some States in developing and validating tools for small-area analysis; she acknowledged the frustration of getting local data but said that linking immunization information systems (IIS') to electronic health records (EHRs) should help. Amy Groom, M.P.H., agreed that registries can help identify gaps in coverage, as was the case in North Dakota for American Indians/Alaska Natives (AI/AN), who are not represented in CDC's data. She encouraged continued attention to gathering and evaluating local data to uncover disparities and target efforts.

Dr. Schuchat said materials are available online for providers and others to use and incorporate into their own communication efforts. She reiterated the belief that efforts should focus first on clinicians, so that they can better communicate with patients; she added that clinicians should understand that the HPV vaccine has a strong safety record and plays a significant role in preventing cancer. A Presidential panel on cancer has taken up the issue of HPV vaccination. It is not clear why Hispanic adolescents have higher uptake rates for HPV vaccine than other ethnicities, but they also have higher uptake rates for a number of vaccines. Dr. Schuchat pointed out that CDC reached out to Hispanics in a concerted manner under the leadership of Dr. Orenstein.

Where vaccine exemption rates are high, disease rates are also high, said Dr. Schuchat. However, State regulations on exemptions vary, as does data collection. CDC is working to get comparable exemption data from multiple States.

Dr. Wright recognized that the number of Healthy People objectives keeps increasing. While some feel the number is unmanageable, experts from an advisory committee to the HHS Secretary and the Institute of Medicine (IOM) keep recommending more Healthy People objectives. To compensate, CDC now publishes a list of leading health indicators in 12 topic areas.

### ***Action Items***

At future NVAC meetings, the CDC should provide a report card spelling out progress toward all the Healthy People 2020 immunization targets.

At future meetings, NVAC will consider the need for more granular data on progress toward Healthy People 2020 (e.g., by neighborhood or geographical subregions) to inform deliberations around infrastructure.

### **Update on Pertussis—RADM Anne Schuchat, M.D., CDC**

Dr. Schuchat reported that the United States is on track to see more cases of pertussis in 2012 than in any year since 1959. She provided data on incidence by State and cases by age. CDC published the lessons learned from the pertussis outbreak in Washington State and is reaching out through various media to promote maximum vaccine coverage. The goals are to sustain high vaccine coverage in early childhood, increase coverage among teenagers, and increase vaccination of pregnant women and contacts of newborns and infants (a.k.a. cocooning).

Updated ACIP recommendations for reducing the burden of Tdap:

- removed the minimal interval between boosters containing tetanus toxoid which eliminates one barrier;

- expanded vaccine use among undervaccinated children ages 7–10 years;
- updated recommendations for all health care personnel (HCP);
- expanded the upper age limit for vaccination
- recommended vaccination for pregnant women and infant caretakers/contacts (cocooning).

CDC activities include an investigation of vaccine effectiveness in Washington State and enhanced surveillance of pertussis. Dr. Schuchat hoped that in the future, registries would contain more broad information about vaccinations to improve understanding of the big picture.

The pertussis outbreak and response exemplify the role of Section 317 funding in addressing vaccine-preventable diseases. Dr. Schuchat said Section 317 supports a number of critical functions of immunization programs:

- Development of evidence-based policies
- Communication efforts
- Improved vaccine access
- Quality assurance
- Assessment of vaccine safety and effectiveness
- Program monitoring
- Public health emergency response

Dr. Schuchat mapped the efforts to address the pertussis outbreak to each of these critical functions.

### ***Discussion***

Dr. Schuchat explained the challenges to translating data into a more direct depiction of the burden of disease: estimates are based only on reported cases, current diagnostic tests are not ideal, and recordkeeping for a multidose vaccine poses a problem. CDC is undertaking more economic modeling of infectious diseases and seeks more data to flesh out those models. Dr. Schuchat said there is strong interest in better understanding the effectiveness of the vaccine. Regarding cocooning, Dr. Schuchat said efforts are underway to ensure that insured adults are vaccinated by in-network providers, which can be complicated from a logistic perspective. CDC is awaiting more data from Washington State to assess the effects of geographic clustering and ethnicity on disease.

The relationship of vaccine hesitancy—which is high in Washington State—with pertussis outbreaks there is unclear. Dr. Schuchat said concerns have been raised by some that the vaccine is not effective, and that perception may cement deeply held beliefs. However, Dr. Schuchat said some mothers who have lost children in previous outbreaks are speaking out; in California, the pertussis outbreak raised awareness among clinicians about the need for vaccination. Dr. Schuchat pointed out that most infants and teenagers in Washington State have been vaccinated, so she does not believe that the outbreak can be blamed on those who refuse vaccine. Dr. Schuchat said CDC is working to get more specific data on vaccines, such as brand and lot numbers, to determine whether any trends can be identified.

### ***Action Items***

Dr. Schuchat will write a brief case study that demonstrates how Section 317 provided critical funding to support the response to the pertussis outbreak and submit it to NVAC for inclusion in the IIWG report, *Protecting the Public's Health: Critical Functions of the Section 317 Immunization Program*.

At a future meeting, CDC should report on efforts to collect vaccine-specific information (e.g., vaccine brand and lot numbers among vaccinated individuals who develop pertussis).

At the February 2013 NVAC meeting, CDC will provide additional updates on pertussis.

### **Health Information Technologies (HIT)**

#### ***Overview—Lauren Wu, NVPO***

Ms. Wu briefly described how HIT tracks the flow of vaccine from the manufacturer to the provider's office to the patient. Vaccinations are tracked through State-run IIS' and also individual EHRs; ideally, the two systems communicate with each other, and much work is being done on that front. The CDC manages the Vaccine Tracking System (VTrckS) to facilitate ordering and distribution of publicly funded vaccine. Bar code readers can facilitate data entry into systems. All of these mechanisms inform decision-support tools, which are used to address individual patient need, supply chain issues, accountability, safety, etc. Ms. Wu noted that the final rule on Stage 2 Meaningful Use of EHRs was released in August and is especially important to IIS management.

#### ***Electronic Immunization Records and Stage 2 Meaningful Use of EHRs—Michelle Nelson, ONC***

Ms. Nelson explained that ONC writes the standards for EHRs, while CMS writes policies about what EHRs should do. The Meaningful Use policies are a collaboration of the two entities; they are being implemented in three stages. In Stage 1, providers attested that they had built basic functionality into their systems and were beginning to enter and use data in a meaningful way. In Stage 2, providers will start to use EHRs for patient engagement. In Stage 3, they will begin using EHRs to assess outcomes and improve performance by tracking clinical quality measures.

Meaningful Use health outcomes policy priorities are to:

- Improve quality, safety, efficiency, and reducing health disparities
- Engage patients and families
- Improve care coordination
- Improve population and public health
- Privacy and security

Stage 2 aims to leverage EHRs for better health experiences, better health outcomes, and reduced costs. Ms. Nelson said Meaningful Use depends on public health agencies that do not necessarily have the money from EHR incentives that providers do. Therefore, HHS is mindful of the limits that public health agencies face.

Ms. Nelson explained how objectives have changed from Stage 1 to Stage 2. For immunization, in Stage 1, providers simply demonstrated that they were able to submit information to State registries. In Stage 2, they must demonstrate that they are submitting data on an ongoing basis and doing so in accordance with Health Level 7 (HL7) interoperability standards. Ms. Nelson said EHRs should better align with public health agency reporting. She added that some providers will be grandfathered into the process so that the flow of information continues.

#### ***Discussion***

Ms. Nelson noted that ONC and CMS clarified the final rule to better define ongoing submission but did not specify how much information must be provided or how often to meet requirements for meaningful use. Because public health agencies are already strapped for funds and received no incentives to implement EHR systems, the Stage 2 policy is focused on ensuring that information is exchanged on a regular basis. There is no specific measure of success in relation to the number of vaccinations a provider

gives; it is expected that if the provider can send data successfully, the provider will do so on a regular basis.

***Electronic Immunization Records at the VA—Rick Martinello, M.D., VA***

Dr. Martinello explained that under the Stafford Act, when a national emergency is declared, VA can provide medical countermeasures and treatment to non-VA beneficiaries, but VA must track everything it does and bill each individual served. Under the National Response Framework's Emergency Support Function 8, the VA can provide vaccines and other services to non-VA beneficiaries. The directors of individual VA medical centers can authorize medical care to non-VA beneficiaries should the local situation warrant it.

To track such efforts, the VA developed the Occupational Health Recordkeeping System (OHRS) about 5 years ago (a companion to its main record system for tracking patient information). Providers can enter data into the web-based system from any location, and reports can be created rapidly, such as vaccine records. Dr. Martinello described the focus, features, and capabilities of the OHRS. Efforts are underway to capture and report more individual details, such as occupational health needs and potential exposures. The OHRS minimizes the labor of tracking data during a mass immunization effort.

***Discussion***

For privacy reasons, the OHRS does not link to IIS' or pharmacies, said Dr. Martinello. The system is affiliated with more than 100 U.S. medical schools. Ms. Groom noted that IHS does a lot of work to facilitate immunization record exchange.

***Immunization Registries—Gary Urquhart, M.P.H., Chief, IIS Support Branch, NCIRD, CDC, and Dan Martin, CDC***

Dr. Urquhart described what IIS' do, noting that IIS' gather population data, while EHRs document clinical encounters at the provider level. Most CDC grantees use an IIS, and only one State (New Hampshire) does not have a State registry. Dr. Urquhart summarized how NVAC spurred the creation of registries with three reports that emphasized the need, assessed the barriers, and offered recommendations for development of registries. Healthy People 2010 set a goal of increasing the proportion of children represented in immunization registries. Dr. Urquhart summarized the factors contributing to the need for IIS' to improve coverage, avoid costly excess vaccination, and promote efficient use of resources.

Dr. Urquhart described progress toward increased participation in IIS'. In 2009, the year of the H1N1 influenza pandemic, public and private provider enrollment spiked. He noted that CDC provides about \$37 million to support IIS', which amounts to more than half of the overall funding for IIS'. With decreasing funds at the state and local level, grantees are trying to sustain their IIS participation.

A number of CDC initiatives are underway to improve IIS', including national HIT initiatives to support interoperability with EHRs. Toward this end, CDC has proposed updated IIS functional standards to identify the operational, programmatic, and technical capacities that all IIS' should achieve by the end of 2017. Mr. Martin said the standards focus on two major issues: quality of care and support of public health programs. He noted that it may be necessary to revise some laws and policies to meet the standards for full implementation. He added that CDC will work with immunization programs to define metrics that measure progress toward achieving the standards.

Mr. Martin summarized six programmatic goals and the proposed functional standards that correspond with each goal (the complete draft proposal was also provided). He emphasized the importance of such issues as two-way information exchange, accessibility of record systems at the point of care, and avoiding duplicate paperwork. Mr. Martin said the definition of "timely" reporting depends on the context and is

likely to change as technological capacity changes. He summarized the core data elements that IIS' are required to store. Dr. Urquhart and Mr. Martin asked for NVAC's input on the proposed IIS functional standards for the 2013-2017 funding cycle, as NVAC has done in the past, potentially at the February 2013 NVAC meeting.

### ***Discussion***

Dr. Urquhart pointed out that the IIS' are rich data sources that allow for comparisons down to zip-code and county levels. He said IIS coverage assessments sometimes compare favorably with those of the NIS but not always. About 85 percent of registries cover the whole lifespan, and Dr. Urquhart hoped that all the registries are moving that way, although the functional standards do not require it. He said that that in light of Meaningful Use policies, CDC and ONC are working together to identify what core data elements will be useful. He hoped NVAC would provide input on how IIS can support utilization of IIS.

In response to suggestions that more stakeholders provide financial support for IIS', Dr. Urquhart said some change their minds about HIT when they see how complicated the issues are. However, he said, anyone who wants to use the CDC business logic proposed is welcome to do so. Ultimately, CDC aims to support local immunization practices by providing local data.

The reliability and completeness of private payer data was questioned, because, outside of the VFC program, private providers do not have incentive to report data thoroughly. It is also difficult to exchange data across State systems. Dr. Urquhart agreed that exchanging any kind of public health data across States is challenging. The ACA may make such exchanges easier. In the meantime, States are responsible for establishing their own formal agreements among each other.

The utility of IIS' for providers varies widely. The more effort that goes into building an IIS that adds value, the more providers will want to use it. Dr. Urquhart added that academic settings in particular like large databases, such as the Healthcare Effectiveness Data and Information Set (HEDIS).

### ***Bar Coding—Geoffrey Glauser, Biomedical Advanced Research and Development Authority (BARDA), and Warren Williams, CDC***

Mr. Glauser said that changes to the current requirements for bar code labeling of drugs are being driven by efforts in California (with support from the U.S. Food and Drug Administration [FDA]) to enhance tracking of a product "from cradle to grave." He described how U.S. law defines counterfeit drugs and the growing threat they pose. California's ePedigree law to support more sophisticated tracking and tracing of products will go into effect in a few years. The keys to the success of electronic pedigrees are standards that facilitate correct identification of a product, enable the capture of information, and support sharing of information through interoperability. Mr. Glauser said applying bar codes early in the process is relatively easy, and, at least in the first phase, California (and the FDA) only requires that a product bear a global trade identification number (GTIN) or universal product code (UPC) and a 20-digit serialization code that is unique to the package (not lot numbers or expiration dates). GS1 is the global standards organization that assigns the GTIN.

Mr. Glauser explained that the Datamatrix symbol, or two-dimensional (2D) bar code, can convey a lot more information than a one-dimensional, alphanumeric bar code in less space. FDA regulates some package elements, such as the primary container, but not all, such as the pallet. Monitoring the various elements of packaging is critical to maintaining the integrity of the supply chain, said Mr. Glauser. He also noted that new bar code readers can read 300–600 codes per minute, which is much faster than just 10 years ago.

Mr. Williams said CDC funded a feasibility study of the use of 2D barcode for vaccines. Barcoding of vaccine products (vials and syringes) can save money for providers by reducing the time it takes to manually read and record the data from products. Instead of having to manually record key fields (lot number, expiration date, product ID) into separate systems such as EHR, IIS, billing or practice management systems, this information with a new 2-D barcode can either be scanned in with the barcode reader or electronically shared with other systems. Economic modeling results from the feasibility study will be published soon; they reveal that the 2D barcodes save time per dose and would yield \$2.70 or more in benefits for every \$1 spent. CDC is now in the midst of a pilot study to assess the real-world implications of 2D barcodes for vaccine vials and syringes. It is working with manufacturers to add the barcode to the unit of use. As an incentive to participate, providers receive a scanner that is programmed to transfer data into EHRs, IIS', and custom applications.

Mr. Williams noted that the evaluation phase will be broad in scope. Some preliminary observations indicate that most practices require enhancements to EHR functionality to make the 2D barcode system work. There is some reluctance to adopt a new system. Participants' feedback so far has been positive; some say it improves accuracy but will only save time in very high-volume practices.

Recently, CDC added the 2D barcode to vaccine information statements (VIS') given to parents and patients. This approach allows providers to document the type and publication date of the VIS that a patient received.

### ***Discussion***

Mr. Williams said the California ePedigree law focuses on tracking and tracing a product, which differs from the intent of the use of 2D barcodes in clinical practice. He believes that the technology and regulations will be compatible. He acknowledged that some EHR manufacturers have configured their systems to work well with scanners, but some programs must be updated so that one scan captures information for all the relevant fields and translates it as needed.

Mr. Glauser said Brazil and Turkey have fully implemented GTINs and serialization codes, and pilot projects are in process in Germany, Sweden, and India. Where the government pays for vaccines through socialized medicine, he said, there are strong efforts to track products closely to avoid wastage. Other countries are further along in their use of 2D barcodes.

### ***Overall HIT Discussion***

Dr. Urquhart said there are good arguments favoring State-based registries over a national registry, but the environment is changing. Mr. Martin noted that with strong functional standards in place, it does not matter who captures the data. Some members felt that States should take on the larger responsibilities of capturing high-level data through registries. Dr. Urquhart said there are continuing calls to expand public health registries to address conditions such as lead exposure and hearing screening tests, but limited resources require CDC to focus on supporting vaccines. It was hoped that as the CDC pilot study progresses, CDC will gather lessons from the workflow analysis to develop guidance for providers to avoid misuse of barcoding technology.

Dr. Urquhart said CDC is investing a lot of money to enhance the relationships between EHRs and IIS'. He added that CDC is committed to providing useful data. Michigan has promoted its IIS to providers, and Dr. Urquhart said that Michigan listens closely to users to ensure the system has the functionality that the providers want.

Mr. Hosbach said serialization is "a heavy lift" and wondered how far the vaccine distributors have progressed on this front. Mr. Glauser said manufacturers are responsible for the alignment of serialization

codes as packages move through their system, and distributors will have to determine how to handle those codes. Some of the largest distributors are pilot testing and have concerns about the alignment of serialization codes as the scale of packaging increases and decreases. Mr. Glauser acknowledged that the use of serialization codes could take many years to iron out.

Dr. Schuchat said that vaccines are one part of an enormous system of medical products, and concerns about counterfeit products are driving many changes. The whole system is trying to take advantage of HIT, she said. Registries have been leading the way, but systems are changing, and CDC must determine when to focus on standards and when to give States flexibility. Dr. Schuchat hoped NVAC would provide advice on high-level strategies to help CDC target its big investments appropriately. An enormous amount of money has been invested in HIT in recent years, she said. By February, Dr. Schuchat continued, CDC should have more of its planning effort ready for review by the NVAC. She reiterated the stance that if the functional standards are well written, it does not matter whether IIS' or EHRs prevail, and clinical decision supports will improve. Dr. Schuchat concluded that she hoped NVAC would again turn its attention to the HIT aspects of immunization.

Some members pointed out that private companies such as Amazon and Federal Express ship and track products routinely, but it was noted that they are not responsible for ensuring refrigeration of products, nor must they meet the rigorous standards required for pharmaceuticals. In addition, pharmaceuticals are shipped to wholesalers who divide the products into smaller packages but must still maintain integrity of the product and track its progress forward.

Deborah Wexler of the Immunization Action Coalition said her organization has a cooperative agreement in place with the CDC to translate VIS' into other languages. Those VIS' will also have 2D barcodes, she said.

***Action Item***

NVAC members will review the proposed CDC IIS functional standards and send comments to NVPO staff by October 15.

At the February 2013 NVAC meeting, members will consider whether to revisit the issue of IIS in another NVAC white paper.

***Update: NVAC Maternal Immunization Working Group (MIWG)—Catherine Torres, M.D., Chair***

Dr. Torres announced that Dr. Beigi will join her as co-chair of the MIWG. Dr. Beigi is an OB/GYN who has played a major role in ACOG's work to improve the immunization of pregnant women. The purpose of the MIWG is to bring prenatal care into the culture of immunization and prevention in order to achieve goals outlined in the National Vaccine Plan and Healthy People 2020. Dr. Torres summarized the charge of the MIWG and its membership. The MIWG will address the following:

- Vaccines currently recommended for pregnant women (influenza and pertussis)
- Patient and provider barriers and Federal opportunities to overcome barriers to implementing current vaccination recommendations
- Vaccines under development

Dr. Torres said MIWG hopes to produce a draft document for consideration by NVAC and the public in the spring, followed by a final draft for NVAC approval in September 2013. She invited NVAC members to suggest others who should be included in the MIWG either as temporary or permanent members.

**Discussion**

Dr. Orenstein noted that the ACCV also has a Maternal Immunization Workgroup. It was suggested that a consumer representative or parent be invited to join the MIWG.

**Action Item**

The MIWG will consider inviting a member of the ACCV Maternal Immunization Workgroup to join or establishing some means of communication across the two groups. It will also consider adding a member(s) who represents parents or consumers.

**Public Comments**

No public comments were made, and the meeting adjourned for the day at approximately 5:10 p.m.

**Day 2—September 12, 2012**

**Old Business**

Dr. Lynfield said that the Infectious Diseases Society of America, the National Foundation for Infectious Diseases, and others are planning a meeting on pertussis this spring to discuss the burden of disease, health care utilization, estimates of the number of cases, vaccine effectiveness, alternative vaccines, (including adjuvants), the role of monovalent vaccine while alternatives are researched, and regulatory issues.

**Action Item**

Dr. Lynfield will provide an update on plans for a 2013 meeting on pertussis (organized by the Infectious Diseases Society of America, the National Foundation for Infectious Diseases, and others) at the February 2013 NVAC meeting and a summary of the meeting itself at the June 2013 NVAC meeting.

**Draft Report of the IIWG—Litjen Tan, Ph.D., M.S., Co-Chair**

Dr. Tan pointed out that the current draft represents a significant revision from the version reviewed by NVAC in June. Titled *Protecting the Public's Health: Critical Functions of the Section 317 Immunization Program*, it focuses on the contributions of Section 317 to establishing and maintaining the public health infrastructure. Questions were raised about why the report mentions Tribal programs sporadically; Dr. Tan said Section 317 does not support Tribal programs directly, but they are an extremely important part of the immunization infrastructure. Ms. Groom added that Section 317 funds do affect Tribal programs, and the report calls out areas for which there are unique issues related to jurisdiction. Dr. Tan described the overall rationale for the report, and then summarized the conclusions of the IIWG that are spelled out in the report and the corresponding recommendations.

**Discussion**

Dr. Orenstein requested that Dr. Schuchat write an appendix demonstrating how Section 317 supported critical functions in the response to the pertussis outbreak. It was noted that the report may be very helpful in educating Congress and its staff about what Section 317 funds and what the immunization infrastructure comprises. Dr. Tan said the journal *Public Health Reports* has already agreed to publish the final report, and he hoped ASTHO and other partners would use the published version in their advocacy efforts.

Dr. Schuchat noted that in crafting professional judgment estimates, CDC calls on subject matter experts to estimate 1) the personnel and systems needed on a daily basis to ensure that public health providers can provide a safety net and respond to public health emergencies and 2) the number of doses of a given vaccine that would be needed for emergency response. Dr. Orenstein said NVAC would like the opportunity to weigh in on such professional judgments.

Dr. Schuchat further explained that the Strategic National Stockpile was developed to provide medical countermeasures during emergencies, and the VFC also has its own stockpile. During an outbreak, however, the situation is complicated, and Section 317 funding helps public health agencies address the gaps that may arise during an emergency. NVAC members agreed to revise Recommendation 2 to include the concept of a timely response to public health emergencies.

Dr. Schuchat asked that communication be included in Recommendation 4 as an example of an area in which innovation is ripe. NVAC members agreed to revise Recommendation 4 to include the concept of innovative communication strategies.

NVAC relies on liaisons and partners to disseminate reports more broadly and use them as tools for discussion. The 317 Coalition is one organization focused on the issue of infrastructure funding, and it welcomes new members. Mr. Hosbach suggested that NVAC work with the IOM's Forum on Microbial Threats.

NVAC members agreed to delete the reference to a nonexistent graph on vaccine coverage rates demonstrating how the VFC program has reduced disparities. Instead, at the same point in the document, a reference will be added to a 2007 *Morbidity and Mortality Weekly Report* describing the elimination of disparities in vaccine coverage for children. Finally, NVAC members agreed that Figure 4 should contain a footnote indicating that the overall figures include PCV 7.

#### ***Action Items***

NVAC members unanimously approved the report of the IIWG, *Protecting the Public's Health: Critical Functions of the Section 317 Immunization Program*. NVAC members will submit any additional editorial comments (e.g., corrections, clarifications) to NVPO by September 19. NVPO will make final changes and corrections, add the appendix from the CDC on how the 317 grant program is helping address the resurgence of pertussis, and circulate it to NVAC members for review before finalizing the report and submitting it for publication.

NVAC members unanimously approved the following recommendations, as presented in the IIWG final report:

- **Recommendation 1:** NVAC recommends that the Section 317 Immunization Program be sustained to assure a strong public health infrastructure necessary to achieve and sustain high vaccination coverage and low disease burden among the civilian population in the United States.
- **Recommendation 2:** CDC should present its professional judgment regarding the size and scope of the Section 317 Program necessary to support a comprehensive immunization program. This should include program operations at the Federal, State, Tribal and local levels, and vaccine purchase to provide a safety net and a timely response to public health emergencies. CDC should present its professional judgment to NVAC annually at its June meeting for deliberation and discussion.

- **Recommendation 3:** HHS should consider CDC’s professional judgment for the Section 317 Program as an important input to its decision-making during the budget formulation process.
- **Recommendation 4:** NVAC recommends Federal, State, Tribal and local public health should seek efficiency, and innovation to achieve Healthy People 2020 targets and ensure high immunization levels across all age spans. Examples of such efficiencies include, but are not limited to improved vaccine ordering, supply management, and storage and handling such as through the use of vaccine barcodes. Examples of innovation include, but are not limited to implementation and use of immunization information systems and electronic health records; innovative communication strategies; providing vaccines as an in-network provider for the receipt of vaccine in public health clinics; and expanding sites of vaccination such as schools, workplaces, and pharmacies.

NVAC supports current innovations in operations and encourages continued innovation. NVAC recommends HHS through NVPO hold a public meeting of experts to examine and explore contributions toward efficiency and innovation at State and local health departments.

Dr. Tan said that the leadership team of the IIWG will discuss the next steps. He noted that private payers have not been represented in the IIWG’s discussions because the focus has been on public health infrastructure.

***Action Items***

NVPO will reach out to the leadership of NACCHO and ASTHO for input on infrastructure issues outside of Section 317 funding that the IIWG should address as well as to help in dissemination of the report.

In future deliberations, the IIWG will consider the role of private payers in infrastructure issues.

NVAC will consider inviting a member of the IOM Forum on Microbial Threats to participate in future discussions when CDC presents its professional judgment to NVAC for review.

**Update: NVAC GIWG—Philip S. LaRussa, M.D., Chair**

Dr. LaRussa summarized the purpose, charge, and membership of the GIWG, which reviews the role of the U.S. government in global vaccination. While the GIWG focuses on efforts within HHS, the global immunization effort involves many agencies as well as entities outside the Federal government. Global immunization is a component of Healthy People 2020 and a priority in the National Vaccine Plan.

GIWG has heard presentations from subject matter experts representing various Federal agencies to better understand the current status of global immunization efforts, what efforts are needed, how much money would be required, and what the United States gains in return for its investment. Dr. LaRussa said the GIWG is discussing the format of its report, which will address the following topics:

- Financing global immunization
- Strengthening HHS policy leadership, coordination, and partnerships
- Research and development

- Global regulatory issues
- Health systems and vaccine delivery
- U.S. response efforts to vaccine-preventable diseases of global health importance
- Communications/risk communications on vaccine safety

A critical component of the report will be to explain why investments in global immunization not only provide humanitarian benefits but enhance our own domestic health security as well. The GIWG is seeking input from NVAC about the appropriate audience for the report; whether the report should focus on maintaining the status quo or advocate for additional funding; and which, if any, issues rank highly in priority. The report will contain detailed background information on the current landscape of HHS activities. Dr. LaRussa said the GIWG aims to present final recommendations to NVAC members for consideration at the February 2013 and a final draft report at the June 2013 NVAC meeting.

### ***Discussion***

Dr. LaRussa said that the report will emphasize the need to maintain funding for the positive work already being done while pointing out gaps and the vision for future efforts. Thus, he hoped the report would make the case for protecting existing funding while laying the groundwork for expansion when more funds are available. Given the current financial climate, it was suggested that NVAC focus on recommendations that can be implemented without new, additional funding, yet continue to make the case for increased funding.

Dr. Schuchat suggested the GIWG report highlight the unique investment of HHS in global immunization, which includes a wealth of scientific and public health expertise that goes beyond purchasing vaccine. Dr. LaRussa said the report will emphasize the need to maintain the tremendous amount of international collaboration that currently occurs, but it will refrain from dictating roles.

While increased funding is unlikely, it is appropriate to point out those interventions that are particularly cost-effective, such as childhood vaccination, which may spur policymakers to consider the proportion of its investments in various areas. NVAC members should think about how they can help policymakers make tough choices rationally.

A number of global immunization topics can be addressed immediately by GIWG recommendations. Members asked whether the expert presentations from Working Group meetings could be provided to NVAC members or posted online. Dr. Gellin noted that presentations to NVAC are sometimes posted online when they comply with Section 508 guidelines. However, NVPO staff will have to discuss among themselves the feasibility of disseminating presentations made to the NVAC working groups.

### ***Action Item***

NVPO will consider how presentations made to the working groups can be shared with NVAC while still respecting confidentiality and meeting Section 508 compliance regulations.

## **Agency, Department, Advisory Committee, and Liaison Reports**

### ***AHIP—Wayne Rawlins, M.D., M.B.A.***

AHIP has been working with the CDC on a series of webinars about how public health providers can bill private insurance plans for vaccinating insured patients (a.k.a., third-party billing). Topics include infrastructure, contracting with health care providers, credentialing, and vaccine coding. Dr. Rawlins referred to the effort as “Billing 101” for those not traditionally involved in billing and said it will help them get up to speed if Section 317 funds decline.

**ACCV—Charlene Douglas, Ph.D., M.P.H., R.N.**

Dr. Douglas said that the Future Science Workgroup recommended that the VICP consider removing barriers to access to petitioners' medical information so that it can be used by clinicians and investigators, because the information would be useful to increase vaccine safety. The Maternal Immunization Workgroup met to consider whether the program should include all live-born infants who received vaccine in utero. The Process Workgroup met to consider appointing an adult to the ACCV who was vaccine-injured as a representative of the general public and also whether to allow compensation for family counseling expenses and for establishing trust. The Attorney's Fees Workgroup met to consider whether the VICP was providing competitive and timely fees to attract quality representation for petitioners and whether government funds are disproportionately going to attorney's fees.

**VRBPAC—Robert S. Daum, M.D.**

Dr. Daum reported that VRBPAC had not met since June and will meet later in September.

**ACIP—Renée R. Jenkins, M.D.**

Dr. Jenkins reported that Jonathan L. Temte, M.D., Ph.D., is the new ACIP chair. ACIP will meet in October; its agenda includes votes related to vaccines for meningitis and *Haemophilus influenzae* type b (Hib); measles, mumps, and rubella (MMR); and pertussis (for pregnant women). It will also hear updates from the Japanese Encephalitis Work Group and reports on hepatitis C vaccine and HCP, HPV vaccine, rotavirus, and quadrivalent influenza vaccine.

**AIM—Anu Bhatt**

Ms. Bhatt reported that the American Immunization Registry Association is hosting an IIS conference that provides opportunities to learn about new IIS', EHRs, and VTrckS. AIM is hosting an additional meeting of IIS subject matter experts on current challenges to documenting VFC eligibility. AIM and CDC are planning their annual program managers meeting, tentatively scheduled to take place in Atlanta in November. It will focus on changes to Section 317 as more children are fully insured and more adults are at least partially insured. The meeting will also address best practices for vaccine storage and handling, HPV vaccination, pertussis vaccination, and progress in third-party billing.

**NACCHO—Anne Bailowitz, M.D., M.P.H.**

NACCHO is working diligently on collating tools for billing used by county and city health departments, said Dr. Bailowitz. A preliminary version of the collected billing tools is available online at <http://www.naccho.org/>. The final version will be released later in September in collaboration with CDC through multiple communication methods. Local health departments continue to offer influenza vaccination. NACCHO is surveying health departments about their current influenza vaccine activities and will provide the results to NVAC as soon as possible. NACCHO contributed examples of model practices to the IIWG report on Section 317 and looks forward to offering insight to the IIWG on other issues.

**CDC—RADM Anne Schuchat, M.D.**

Dr. Schuchat said CDC is wrapping up the process for its special awards under the Prevention and Public Health Fund, which provides more than \$60 million for various immunization-related projects such as HIT support, storage and handling, billing, hepatitis B, and school-based vaccination. Chesley Richards, M.D., M.P.H., who led the CDC's Office of Prevention through Healthcare, has taken on the role of director of the Immunization Services Division at CDC's National Center for Immunization and Respiratory Diseases (NCIRD). Dr. Schuchat announced that she had been temporarily detailed to serve as the acting director of CDC's Center for Global Health while CDC recruits a new, permanent director. In the meantime, Melinda Wharton, M.D., M.P.H., will be the acting director of NCIRD.

***FDA—LT Valerie Marshall, M.P.H.***

LT Marshall announced that the FDA approved the 2012–2013 influenza vaccine formulation for all six manufacturers licensed to produce and distribute the vaccines in the United States. In June, FDA approved MenHibrix, a vaccine for infants and children that combines meningococcal and Hib vaccine. Also in June, FDA, NIH, and CDC met jointly to discuss scientific questions around early development and translation of universal vaccine candidates and advanced vaccine development. In July, the FDA Safety and Innovation Act was signed into law. It authorizes FDA to collect user fees from industry to fund reviews of innovative drugs, medical devices, generic drugs, and biosimilar biologics. It also reauthorizes two programs that encourage pediatric drug development.

***NIH—Barbara Mulach, Ph.D.***

Dr. Mulach said the National Institute of Allergy and Infectious Diseases (NIAID) made awards under two initiatives focused on HIV vaccine development. The first supports new, innovative approaches around basic immunology for vaccine development, and it provided 14 awards. The other initiative awarded \$31 million in first-year funding for the new Centers for HIV/AIDS Vaccine Immunology & Immunogen Discovery, a consortium of researchers at universities and academic medical centers. NIAID also awarded two new preclinical service contracts, which are intended to help investigators with promising products in development overcome specific hurdles, such as assay development, with the help of contractors identified by NIAID.

***NVPO—Bruce G. Gellin, M.D., M.P.H.***

Dr. Gellin noted that the priorities of the ASH become the priorities of NVPO. Dr. Koh's effort to lead a department-wide discussion on seasonal influenza broadened into a focus on adult immunization, he noted. Along those lines, NVPO is working with the creators of Flu Finder to expand the program so that it locates all adult vaccines. Dr. Gellin said he would provide more details at the next NVAC meeting.

***HRSA BPHC—Justin Mills, M.D., M.P.H.***

Dr. Mills said that HRSA supports community health centers at 8,500 sites across the country and collects data on clinical measures from those sites. In 2010, about 74 percent of grantees met the immunization targets for pediatric populations. Since then, HRSA has added requirements for many other vaccines, including hepatitis A, rotavirus, and influenza, and its standards are now more rigorous than those of Healthy People 2020. As a result, only about 43 percent of grantees have met the new immunization targets, but Dr. Mills said he believes grantees are doing a good job.

BPHC is helping clinics achieve accreditation as patient-centered medical homes (PCMHs). BPHC's goal is that 13 percent of grantees will be designated as PCMHs this year. The target will increase over time. Dr. Mills emphasized that immunization is a priority for BPHC.

***VICP—Geoffrey Evans, M.D.,***

Dr. Orenstein noted that this was Dr. Evans' last meeting, and he thanked Dr. Evans for his leadership of VICP.

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

Dr. Mabry-Hernandez said that the 2011 *National Healthcare Quality Report* includes measures of meningococcal vaccination among adolescents. The *National Healthcare Disparities Report* also looks at vaccines in children. AHRQ's [Innovations Exchange](#) links users across the country to quality tools and research (e.g., the Long-Term Care and Other Residential Facilities Pandemic Influenza Planning Checklist). Dr. Mabry-Hernandez noted two AHRQ-sponsored research efforts that may be of interest to

NVAC: one found that Black nursing home residents are less likely than Whites to receive influenza vaccine; another explored vaccine refusal by parents of pediatric patients.

**VA—Richard Martinello, M.D.**

Dr. Martinello said VA stakeholders met to discuss influenza vaccination of HCP. VA will not implement a policy of mandatory vaccination but recognizes that vaccination is critical to mitigate the impact of influenza on patients and staff. This year, 2.1 million VA patients and staff have been vaccinated, and the agency continues to work on improving vaccine uptake among HCP. Dr. Martinello added that the VA has a mechanism for reporting all vaccine-related adverse events internally. Those reports are subject to rapid-cycle review (every 2 weeks), and VA routinely reports its findings to the FDA's Center for Biologics Evaluation and Research and HHS' Immunization Safety Task Force.

**IHS—Amy Groom, M.P.H.**

Ms. Groom reported that IHS kicked off its annual influenza vaccination campaign on September 4. Weekly reporting of rates of influenza-like illness and vaccination begins in October. A recent report on health disparities among AI/AN shows decreases in childhood immunization rates, and IHS is considering how to address the issue. The response is complicated by the fact that IHS has no way to distinguish AI/AN served by IHS providers from those served by other health care providers.

**USAID—Murray Trostle, Dr.P.H.**

Dr. Trostle announced that USAID recently made its annual contribution to GAVI of \$130 million for vaccine purchase, part of the administration's 3-year commitment. USAID concluded its agreement with CDC to develop surveillance activities for the introduction of new vaccines. Dr. Trostle noted that mechanisms were developed for laboratory surveillance of meningococcal vaccine in sub-Saharan Africa, but USAID had to pull operations out of Mali because of the revolution there. Also, USAID had hoped to support CDC in introducing HPV vaccine in West Africa, but Congressional restrictions on maternal and child health funding disallowed any HPV vaccine funding.

**DoD—COL Scott A. Stanek, D.O., M.P.H.**

COL Stanek said preliminary results from DoD's study of adenovirus vaccine in recruits was published in the March 2012 issue of *Medical Surveillance Monthly Report*. It found a dramatic drop in cases of adenovirus, from 1,400 in the first 6 months of 2011 to about 300 since the vaccine was introduced in mid-2011. The significant decrease in morbidity ensures that recruits can spend more time training for duty. The DoD expects to achieve its goal for annual influenza vaccination rates of 90 percent by December.

**USDA—Rick Hill, D.V.M., M.S.**

Dr. Hill said USDA has had a busy summer responding to animal disease outbreaks. Colorado and New Mexico have had outbreaks of equine vesicular stomatitis, for which there is no vaccine. The disease presents similarly to foot-and-mouth disease (FMD). USDA has licensed a vaccine for FMD disease. It is the first such product to be licensed for use in the mainland United States (because it is genetically modified and does not require FMD virus to produce). Epizootic hemorrhagic disease in deer and other ruminants has been seen in many States this summer; there are autogenous and autologous products that deer farmers can use to protect their herds. Cases of encephalitis and West Nile virus in horses have roughly doubled since last year, despite the presence of vaccines. There is a wide variety of licensed swine influenza vaccines, all of which involve killed virus, and USDA allows manufacturers to swap out strains in an expedited fashion, which some manufacturers are doing. However, the process does not allow changes as dramatic and rapid as for human products. Dr. Hill said USDA is reviewing new, novel swine influenza vaccines.

USDA has been collaborating with CDC and State and local public health agencies to address the increase in human cases of influenza A H3N2 variant virus associated with county fairs. The cases involved contact with pigs during agricultural fairs.

### ***Discussion***

Dr. Hill explained that the licensed swine influenza vaccines do not include new strains, and USDA is studying their pathogenesis and effectiveness. There is some level of cross-protection, he added. Manufacturers are interested in adding new strains to their vaccines but are awaiting research results. Dr. Hill noted that, looking back at the H1N1 influenza pandemic, there was concern about a lack of cross-protection among pigs, but now it appears that such cross-protection exists. The protection is not clear, though; USDA is monitoring vaccine and disease and is poised to swap strains if a more effective vaccine is identified. The swine vaccine is effective in reducing clinical disease within a herd but does not necessarily stop shedding of the virus.

Dr. Martinello clarified that VA does not mandate influenza vaccination for HCP because it has had success improving uptake by focusing on other aspects of disease prevention, such as respiratory control. In addition, the VA recognizes the role of individual autonomy in this matter. Dr. Martinello added that VA ensures that HCP are fully informed about influenza vaccination and also promotes the message that VA has an expectation that HCP get vaccinated. Dr. Schuchat added that CDC is collaborating with other HHS agencies to report vaccination rates for HCP and testing how well incentives (e.g., linking vaccination to pay) work to improve uptake. Dr. Martinello said that VA has reached a vaccination rate of nearly 80 percent without mandates. He said there are no data regarding other vaccines for VA HCP, but the agency is working on a policy that provides more direction. In the past, each facility director determined the vaccination policy for that facility.

In response to a question, Dr. Mills said there are no measures of adult immunization for HRSA-funded health centers at present. The recent change in immunization policy for HRSA-funded health centers complicates measurement. HRSA may look at 2010 measures and look for a better way to collect data. Regarding incentives to improve immunization rates, Dr. Mills pointed out that every community health center serves a different population, and some serve homeless people and migrant workers, who may not return for follow-up care. BPHC has improved its clinical knowledge by hiring more physicians, nurses, and physician assistants to better assess how well the centers are doing. BPHC hopes to disseminate successful strategies to other centers. Finally, HRSA provides grants and technical assistance but does not pose a lot of conditions related to clinical measures. That situation may change given the political environment and the need to demonstrate improvements in health outcomes.

Julie Morita, M.D., said VFC programs may be able to provide data to HRSA. Dr. Mills noted that about 60 percent of grantees now have EHRs, which may be affecting current data collection but which also may improve future data collection efforts. BPHC is working on improving HIT among the health centers.

### ***Action Items***

For the February 2013 NVAC meeting, Dr. Hill will provide an update on the vaccination status of clients of USDA's Women, Infants, and Children (WIC) nutritional support program.

For the February 2013 NVAC meeting, NVPO will organize a presentation describing the interaction and coordination of efforts by CDC and USDA in managing the outbreak of H3N2 influenza.

## **Vaccine Hesitancy**

### ***Introduction—Bruce G. Gellin, M.D., M.P.H.***

Dr. Gellin pointed out that the issue of vaccine hesitancy has been raised in the context of various other issues undertaken by NVAC. Healthy People 2020 includes some recommendations relating to vaccine hesitancy. Goal 3 of the National Vaccine Plan is to “support communication to enhance informed vaccine decision-making.” Dr. Gellin asked the NVAC members to think about how vaccine hesitancy is defined, what key issues are involved, and what NVPO, NVAC, or another entity should do to address vaccine hesitancy.

### ***Epidemiology of Vaccine Refusal and Evidence Base for Addressing Vaccine Hesitancy—Saad Omer, Ph.D., M.P.H., M.B.B.S., Emory University***

Dr. Omer pointed out that a lot of social, cultural, and political factors play into the decision to vaccinate, but it is important to consider that much communication about the need for vaccination takes place against the backdrop of decreased incidence of vaccine-preventable diseases (which is directly related to high coverage rates).

School immunization requirements play an important role in increasing and maintaining vaccine coverage rates, but States institute their own requirements and allow a variety of exemptions. Dr. Omer and colleagues found that the incidence of pertussis is two times higher in States that allow personal belief exemptions (including those that define religion so broadly that they essentially allow personal belief exemptions) and also two times higher in those States in which exemptions are easy to obtain. Personal belief exemptions increase the financial impact of pertussis by 50 percent.

The use of exemptions tends to cluster geographically. Evaluation of pertussis outbreaks in Michigan and California found a high likelihood that an exemption cluster overlapped with a pertussis disease cluster. Dr. Omer stressed that the findings do not imply that exemptions are driving the current pertussis outbreak, but he believes they are an important factor.

Dr. Omer emphasized that those who choose not to vaccinate their children are not a uniform group, either in philosophy or action. Concern about vaccine safety is the most prominent reason for seeking an exemption or using an alternative schedule, but parents also cited perceived lack of disease severity, vaccine efficacy, and trust issues. The choice not to vaccinate a child (zero dose children) usually stems from a deliberate decision to avoid vaccination, whereas undervaccination (children with some but not all doses) stems from a mixed bag of reasons, said Dr. Omer. All parents, regardless of whether they seek vaccine exemptions, rate health care providers as the most trusted source of information.

One approach to address vaccine hesitancy is the use of informed declination forms that clearly spell out the risk of vaccine exemption to the child, the family, and the community, said Dr. Omer. Research indicates that parents trust information delivered by physicians orally, and concerned parents respond to personalized information about risks and benefits. Professional organizations should ensure that health care providers are up to date on the nuances and specifics of the vaccines they offer. Although the evidence base for addressing vaccine hesitancy is thin, the AAP recommends that providers share honestly with their patients what is and is not known about the risks and benefits of vaccines, listen to patients’ concerns respectfully, and explain the risk of not vaccinating. Dr. Omer stressed that providers should not gloss over the risk of the disease itself. On the basis of current data, Dr. Omer recommended the following approaches to reduce exemption rates:

- Stringent administrative requirements for granting exemptions
- Informed declination statements
- Effective provider-parent communication tools

- Robust evidence base for effective interventions

***A Closer Look at Vaccine Acceptance and Efforts to Address It—Dr. Glen Nowak, Ph.D., CDC***

Dr. Nowak described the factors that contribute to vaccine acceptance. The perception that health recommendations carry high value drives behavior. Moreover, high vaccine acceptance rates are needed to ensure high coverage rates. Dr. Nowak said vaccine refusal and acceptance are the endpoints of a continuum that also includes hesitation, delay, and lack of awareness. Ideally, he said, the provider recognizes where on the continuum a patient stands and helps that patient move toward acceptance—for example, by identifying and addressing concerns about a specific vaccine.

Dr. Nowak said building acceptance requires consideration of four key concepts:

- The definition and components of acceptance are complex and vary. For example, lack of acceptance may be related to an individual vaccine; immunization in general; or the cost, availability, or accessibility of the vaccine.
- There are no uniformly accepted indicators or measures of acceptance. Indicators range from overall coverage rates to compliance with schedules to measures of confidence and public support.
- It is difficult to determine when or whether acceptance is a problem or a potential problem. Acceptance is strongest among parents of infants and toddlers and varies for older children and adolescents by vaccine type and by State. Adult vaccination rates have hit a plateau.
- Various approaches are needed to maintain, extend, and build acceptance. Questions remain about whether education campaigns should focus on specific vaccines, the schedule, or immunization overall and whether interventions should be targeted or broad. Efforts are needed to understand whether certain policies foster immunization or pose barriers.

CDC is taking a multifaceted approach to building acceptance by strengthening understanding of the concept, collaborating with NVPO on research, disseminating communication resources to providers, improving online communication, and recognizing champions of immunization. Dr. Nowak emphasized that health care providers are an important source of advice and information about vaccination.

***Vaccine Hesitancy: A Global Perspective—Heidi J. Larson, Ph.D., London School of Hygiene and Tropical Medicine (LSHTM)***

Dr. Larson noted that vaccine refusal increased significantly around the world from 2000 to 2005. The LSHTM is focusing on the dynamic factors that lead to vaccine refusal. The globalization of vaccine hesitancy can be partly attributed to the rapid flow of information around the world. Understanding hesitancy means recognizing that not only local but also external national and global factors play a role. Concerns arise about vaccine products, preservatives, and antigens, as well as trust in providers and policies. By way of example, Dr. Larson pointed out that U.S. fears about thimerosal translated into global concerns; however, removing thimerosal from vaccines has huge cost implications for poorer countries.

The Decade of Vaccines initiative demonstrates that vaccine hesitancy is not just a “fringe” issue. The increase in hesitancy stems from the increasing amount of vaccines and products, which has led to many more questions about how and when they are used. The lack of clear metrics makes it difficult to understand and address hesitancy. In a 2003 survey, 25 percent of countries identified some problem. The Decade of Vaccines’ Global Vaccine Action Plan and the World Health Organization’s Strategic Advisory Group of Experts are both working on global assessments of vaccine hesitancy.

Investigators at LSHTM are developing a model to analyze public trust and drivers of vaccine hesitancy. Their database facilitates a systemic approach to monitoring global research. Hesitancy does not just stem from concerns about safety, noted Dr. Larson; it also relates to schedules, policies, etc., and the LSHTM database seeks to capture more of those factors and assess their likelihood of influencing vaccine hesitancy. Through sophisticated coding, researchers can look more closely at research, identifying, for example, spikes in a country's media around particular vaccines. Dr. Larson noted that the Internet increases the impact of print news. She and her colleagues are trying to understand the tipping points that could move a person toward acceptance; they are also trying to develop a vaccine confidence index to assess individual hesitancy/acceptance.

***Vaccine Hesitancy: Building Solutions for Washington State and Beyond—Ginny Heller, M.S.W., WithinReach***

Ms. Heller explained that VAX Northwest is a unique public-private partnership to develop evidence-based strategies to address the underlying issues of vaccine hesitancy. It was developed in a Washington State community with high exemption rates where parents were surrounded by conflicting messages about vaccines. Ms. Heller cited data on trends in vaccine hesitancy that raise concerns about a community unprotected from disease. She noted, for example, that mistrust of pharmaceutical companies is beginning to extend to physicians.

Communities can influence vaccine hesitancy, said Ms. Heller—for instance, by focusing on the fact that most people do vaccinate but remain silent. Ultimately, parents want to do what is best for their children. VAX Northwest engages parents as volunteers to advocate in their communities and provides them with tools, data, and technical assistance to support their activities. Immunity Community is a 5-year campaign in its first phase, with trained parents working at four pilot sites. The initiative receives input from a community advisory board and has two intervention approaches.

1. **Community Intervention:** the parent-advocates have taken the initiative, addressing vaccine issues at parent-teacher association meetings, through coffee chats, and on Facebook postings. They have made efforts to gather data from their own sites so they could put a face on the issue. Because the initiative involves parents talking to parents, privacy concerns are minimized. One advocate's efforts led to a policy change at a co-op preschool to facilitate collecting and monitoring vaccination records. That translated to a State-level recommendation that all co-ops have a parent who monitors vaccination records. In year 2, Immunity Community expands to seven sites.
2. **Provider Intervention;** VAX Northwest is also evaluating the impact of its 6-month intervention to help health care providers better communicate with parents using the AAA Approach—ask, acknowledge, advise. A controlled trial will train providers and provide communication tools, then evaluate the effects on vaccine hesitancy, providers' sense of self-efficacy, and parental trust. VAX Northwest is also considering expanding the intervention to prenatal care providers.

***Discussion***

Dr. Orenstein invited audience participant Julie Leask, Ph.D., of the University of Sydney (Australia), to comment. She said her organization has researched the impact of vaccine scares on parents and what factors inform behavior. Dr. Leask said the contribution of vaccine hesitancy and refusal to disease outbreaks is absolute. She stressed the need to fund systems for recordkeeping, because more long-term data are needed. Good indicators are also needed, as is a better understanding of causation of vaccine hesitancy. Dr. Leask said Dr. Larson's point about finding the tipping point is astute. Providers are the secret ingredient in maintaining confidence in vaccines; when they lose confidence, parents are affected. As noted by VAX Northwest, strategies to address provider confidence are key. Dr. Leask and her

colleagues are preparing to publish a framework for peer engagement that can be tailored depending on parents' perspectives. She also noted that research on motivational interviewing is informing decision aids under development.

Dr. Orenstein invited Vish Viswanath, Ph.D., to comment, and he raised a number of questions he hoped would be addressed through research and discussion:

- Does clustering extend beyond perceptions about vaccines to attitudes about science and medicine?
- How can we raise scientific literacy among the general public to promote understanding that as science evolves, knowledge changes and recommendations and practices also change?
- What can be learned from other areas of communication research, such as the impact of constructing narratives and framing messages?
- Can we categorize clusters by factors other than geography, demography, and psychography to inform more tailored outreach?
- How do we translate what we already know into practice and policy in different contexts?
- Can we expand existing models to promote change at the local level?
- What other stakeholders (e.g., representatives from the private sector and the media) should be invited to participate in the discussion of vaccine hesitancy?

It was suggested that payers should be involved, because providers will not take the time needed to talk with patients if the payers don't pay for it. In the era of personalized medicine, providers should have mechanisms to identify through screening which patients are more likely to experience vaccine-related injuries. More research is needed to better predict the risk from vaccines. Members discussed the role that celebrities play, both in validating beliefs and invalidating negative perceptions.

While working directly with communities is very important, deeply held beliefs can be very hard, if not impossible, to change. Factors driving vaccine hesitancy vary, therefore the approaches must also be diverse. Closer analysis of data may reveal very different pockets of vaccine hesitancy, depending on individual and cultural factors.

There is a need for better understanding of the data and where individuals get their information. Communication should reach out to people who are on the fence, not those who are already anti-vaccine. There has been a lot of discussion about using social media to understand vaccine hesitancy and to get ahead of the curve. Dr. Leask noted that a May 2012 special issue of the journal *Vaccine* focused on the Internet and social media.

Dr. Torres said that, as a State health official, she would like some guidance on how to decrease the number of personal belief exemptions in her State. NVAC members discussed various approaches to developing a white paper on vaccine hesitancy. Such a paper could integrate what has been learned so far; it could also look at the issue of vaccine hesitancy in the context of the topics raised by the most recent NVAC white papers. The paper could include discussion of public-private partnerships such as VAX Northwest. NVAC should consider whether the issues of childhood and adult vaccination should be addressed separately, and Dr. Beigi said he would like to see immunization of pregnant women addressed more thoroughly, but that topic opens another can of worms.

#### ***Action Item***

By October 15, NVAC members will send NVPO staff their thoughts about what should be covered in an NVAC white paper on vaccine hesitancy. NVPO will collate the comments and

propose an outline for the white paper that will be circulated to NVAC members for further consideration.

### **Public Comment**

Dr. Omer said he and his colleagues analyzed physician attitudes about vaccines by year of graduation. All the physicians are supportive but have different perspectives. Notably, those physicians who have experience treating vaccine-preventable diseases (e.g., hepatitis), particularly in children, have a more visceral connection that underpins their attitude. He said the medical curriculum has huge gaps, and even specialties that should emphasize more physician education about vaccines, such as pediatrics and infectious disease, do not. Dr. Omer recommended more emphasis on vaccination in the medical education curriculum. In addition, he said research is underway about the effect of engaging consumers in more detailed discussion versus appealing to them on a more visceral level.

Theresa Wrangham of the National Vaccine Information Center (NVIC) thanked NVAC for steps taken to improve transparency but said her organization would still like NVAC to make audio recordings and transcripts of meeting available. She commended the VA for its comprehensive approach to influenza vaccine management and its focus on education and individual autonomy.

Ms. Wrangham said NVIC has been around for 30 years and worked with Congress to get NVAC created. She believes trust can be regained by closing the existing scientific gaps and by looking to investigators such as those identified by the IOM as being independent of conflicts of interest. Parents would like more information on, for example, the risk of adverse events and what is not known about vaccine risk. Ms. Wrangham emphasized the need for more dialogue with parents; in the context of dialogues, she noted, it is important to recognize that parents may be bringing in “outside information” from reputable sources such as the NIH’s PubMed database. Parents would like more respect for their informed consent when they decide not to vaccinate, said Ms. Wrangham, rather than being treated as an inconvenience or labeled “anti-vaccine” for making an educated decision. NVIC hears from parents all the time that they want to be valued as individual, to receive honest information, and to be free to make decisions without the threat of reprisals—e.g., being excluded from education, fired from a job, or kicked out of a medical practice. Until these issues are addressed, said Ms. Wrangham, the lack of parents’ trust will only increase. Finally, she said, many conversations are one-sided, focusing only on how to get parents to vaccinate their children. An individual who can represent concerns related to vaccine hesitancy should be at the table, she concluded.

### **Closing Remarks and Adjournment—Walter A. Orenstein, M.D.**

Dr. Orenstein reviewed some of the action items. He thanked the NVPO staff and all the NVAC voting members, liaisons, and ex officio members for their hard work. He adjourned the meeting at approximately 1:25 p.m.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

*Bruce Gellin, M.D., M.P.H.*  
*Executive Secretary*  
*National Vaccine Advisory Committee*

*Walter A. Orenstein, M.D.*  
*Chair, National Vaccine Advisory Committee*

These minutes will be formally considered by the Committee at its next meeting on February 5–6, 2013, and any corrections or notations will be incorporated in the minutes of that meeting.

## NVAC Meeting September 11–12, 2012

### ACTION ITEMS

#### **Administrative Items**

NVAC members unanimously approved the minutes of the June 2012 NVAC meeting with no changes.

The 2013 NVAC meeting dates are as follows: February 5–6, June 11–12, September 10–11.

#### **National Vaccine Plan Implementation Plan**

The Global Immunization Working Group should ensure that its recommendations are consistent with strategies identified in the Implementation Plan.

NVAC members will review the Implementation Plan and identify areas for further discussion at a future NVAC meeting. NVPO should develop key target indicators to assess progress toward meeting the objectives outlined in the National Vaccine Plan as well as a strategy for revising the indicators if they do not yield sufficient data.

#### **Vaccination Financing**

For a future NVAC meeting, NVPO will gather information on how long it takes CMS to process providers' vaccine claims.

At a future NVAC meeting, NVPO should present on 1) efforts underway to identify vaccine purchase costs as well as actual payment rates to providers for vaccine administration in various clinical settings by both private and public providers and 2) pressing or emerging issues related to vaccination financing, such as the planned changes to provider reimbursement rates.

NVPO will create a list of published resources and web links to data on vaccine administration costs in various settings.

#### **Healthy People 2020**

At future NVAC meetings, the CDC should provide a report card spelling out progress toward all the Healthy People 2020 immunization targets.

At future meetings, NVAC will consider the need for more granular data on progress toward Healthy People 2020 (e.g., by neighborhood or geographical sub-regions) to inform deliberations around infrastructure.

#### **Pertussis**

Dr. Schuchat will write a brief case study that demonstrates how Section 317 provided critical funding to support the response to the pertussis outbreak and submit it to NVAC for inclusion in the IIWG report, *Protecting the Public's Health: Critical Functions of the Section 317 Immunization Program*.

At a future meeting, CDC should report on efforts to collect vaccine-specific information (e.g., vaccine brand and lot numbers) among vaccinated individuals who develop pertussis.

At the February 2013 NVAC meeting, CDC will provide additional updates on pertussis.

Ruth Lynfield, M.D., will provide an update on plans for a 2013 meeting on pertussis (organized by the Infectious Diseases Society of America, the National Foundation for Infectious Diseases, and others) which will include deliberation on the potential need for new vaccines at the February 2013 NVAC meeting.

### **Health Information Technology**

NVAC members will review the proposed CDC immunization information systems Functional Standards and send comments to NVPO staff by October 15.

At the February 2013 NVAC meeting, members will consider whether to revisit the issue of IIS in another NVAC white paper.

### **NVAC Maternal Immunization Working Group**

The Maternal Immunization Working Group (MIWG) has a parent/consumer representative, and the chairs will consider adding additional representatives. The NVAC MIWG will establish a means of communication with the Advisory Commission on Childhood Vaccines (ACCV) Maternal Immunization Work Group.

### **NVAC Immunization Infrastructure Working Group**

NVAC members unanimously approved the report of the IIWG, *Protecting the Public's Health: Critical Functions of the Section 317 Immunization Program*. NVAC members will submit any additional editorial comments (e.g., corrections, clarifications) to NVPO. NVPO will make final changes and corrections, add the appendix from the CDC on how the 317 grant program is helping address the resurgence of pertussis, and circulate it to NVAC members the final report submitted for publication.

NVAC members unanimously approved the following recommendations, as presented in the IIWG final report:

- **Recommendation 1:** NVAC recommends that the Section 317 Immunization Program be sustained to assure a strong public health infrastructure necessary to achieve and sustain high vaccination coverage and low disease burden among the civilian population in the United States.
- **Recommendation 2:** CDC should present its professional judgment regarding the size and scope of the Section 317 Program necessary to support a comprehensive immunization program. This should include program operations at the federal, state, tribal and local levels, and vaccine purchase to provide a safety net and a timely response to public health emergencies. CDC should present its professional judgment to NVAC annually at its June meeting for deliberation and discussion.
- **Recommendation 3:** HHS should consider CDC's professional judgment for the Section 317 Program as an important input to its decision-making during the budget formulation process.
- **Recommendation 4:** NVAC recommends Federal, state, tribal and local public health should seek efficiency, and innovation to achieve Healthy People 2020 targets and ensure high immunization levels across all age spans. Examples of such efficiencies include, but are not limited to improved vaccine ordering, supply management, and storage and handling such as through the use of vaccine barcodes. Examples of innovation include, but are not limited to implementation and use of immunization information systems and electronic health records; innovative communication strategies; providing vaccines as an in-network provider for the receipt

of vaccine in public health clinics; and expanding sites of vaccination such as schools, workplaces, and pharmacies.

- NVAC supports current innovations in operations and encourages continued innovation. NVAC recommends HHS through NVPO hold a public meeting of experts to examine and explore contributions toward efficiency and innovation in state and local health departments' immunization programs.

NVPO will reach out to the leadership of NACCHO and ASTHO for input on infrastructure issues outside of Section 317 funding that the IIWG should address.

In future deliberations, the IIWG will consider the role of private payers in infrastructure issues.

NVAC will consider inviting a member of the IOM Forum on Microbial Threats to participate in future discussions when CDC presents its professional judgment to NVAC for review.

#### **NVAC Global Immunization Working Group**

NVPO will consider how presentations made to the working groups can be shared with NVAC while still respecting confidentiality and meeting Section 508 compliance regulations.

#### **NVAC Liaison Reports**

For the February 2013 NVAC meeting, Rick Hill, D.V. M., M.S., of USDA will provide an update on the vaccination status of clients of the Women, Infants, and Children (WIC) nutritional support program.

For the February 2013 NVAC meeting, NVPO will organize a presentation describing the interaction and coordination of efforts by CDC and USDA in managing the outbreak of H3N2 influenza.

#### **Vaccine Hesitancy**

By October 15, NVAC members will send NVPO staff their thoughts about what should be covered in an NVAC white paper on vaccine hesitancy. NVPO will collate the comments and propose an outline for the white paper that will be circulated to NVAC members for further consideration.