

National Vaccine Advisory Committee (NVAC)

February 16–17, 2011, Meeting Minutes

Committee Members in Attendance

Guthrie S. Birkhead, M.D., M.P.H., Chair
Richard D. Clover, M.D.
Seth Hetherington, M.D.
Lisa A. Jackson, M.D., M.P.H.
Philip S. LaRussa, M.D.
James O. Mason, M.D., Dr.P.H.
Marie McCormick, M.D., Sc.D.
Julie Morita, M.D.
Christine Nevin-Woods, D.O., M.P.H.
Amy Pisani, M.S.
Laura E. Riley, M.D.
Thomas E. Stenvig, Ph.D, MS, MHP, RN, CNAA
Litjen Tan, Ph.D., M.S.

NVAC Ex Officio Members

Norman Baylor, Ph.D., Food and Drug Administration (FDA)
COL Renata Engler, Department of Defense (DoD)
Geoffrey Evans, M.D., Health Resources and Services Administration (HRSA), Vaccine Injury Compensation Program (VICP)
Laura Herrera, Department of Veterans Affairs (VA)
Jeffrey Kelman, M.M.Sc., M.D., Centers for Medicare and Medicaid Services (CMS)
Margaret McCluskey, R.N., M.P.H., Agency for International Development (USAID)
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)

NVAC Liaison Representatives

Anne Bailowitz, M.D., M.P.H., National Association of County and City Health Officials (NACCHO)
Charlene Gallagher, Advisory Commission on Childhood Vaccines (ACCV)
Claire Hannan, M.P.H., Executive Director, Association of Immunization Managers (AIM)
Wayne Rawlins, M.D., M.B.A., America's Health Insurance Plans (AHIP)
Jose Romero, M.D., Vaccines and Related Biological Products Advisory Committee (VRBPAC, for Jack Stapleton, M.D.)
Kathy Talkington, M.P.Aff., Association of State and Territorial Health Officials (ASTHO, for Paul Jarris, M.D., M.B.A.)

Executive Secretary

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

Assistant Secretary for Health (ASH)

Howard Koh, M.D., M.P.H.

Day 1—February 16, 2011

Opening Remarks—Guthrie S. Birkhead, M.D., M.P.H.

Dr. Birkhead welcomed the participants and summarized the agenda for the meeting. (The agenda is available [online](#).) He emphasized that during the public comment period, NVAC members, liaisons, and presenters would not be taking questions from the general public or the media.

Chair’s Report—Guthrie S. Birkhead, M.D., M.P.H.

Dr. Birkhead summarized some NVPO and NVAC accomplishments and efforts since the last meeting, including publication of an [article](#) that highlighted NVAC’s role during the H1N1 pandemic. He reiterated the requests to NVAC of the ASH (evaluate and monitor the Healthy People 2020 goals for immunization, consider how to address health disparities in the context of adult immunization, and comment on materials from the Interagency Viral Hepatitis Working Group) and the NVPO (evaluate the 2010–2011 seasonal influenza vaccination campaign in light of the universal vaccination recommendation and examine issues around mandatory health care worker influenza vaccination).

Action Item

NVAC approved the September 2010 minutes.

Dr. Birkhead said the draft 2010 State of the National Vaccine Program Report describes a renewed focus on prevention. The report also makes the case for continued emphasis on coordination across the Federal vaccine enterprise and recommends that the Secretary of the Department of Health and Human Services (HHS) increase coordination among Federal agencies. It outlines National Vaccine Program goals for 2011.

Discussion

Members noted that the 2010 National Vaccine Plan, published in December, refers to “communication” and “cooperation” but does not specify coordination across the vaccine enterprise. Others pointed out that NVAC had discussed the need to maintain and improve the infrastructure for vaccination programs that was so helpful during the H1N1 pandemic, but concerns about the lack of funding to support that infrastructure were not reflected in the report. Evaluations of immunization infrastructure and funding were deferred to the NVAC evaluation of the current influenza vaccination season.

Action Item

NVAC approved the draft State of the Program Report as written.

Director’s Report—Howard Koh, M.D., M.P.H., ASH

Dr. Koh thanked the NVAC for their continued input and noted that five new members had been sworn in: Seth Hetherington, M.D.; Philip S. LaRussa, M.D.; Walter Orenstein, M.D.; Amy Pisani, M.S.; and Thomas E. Stenvig, PhD, MS, MHP, RN, CNAA. He thanked Dr. Birkhead for continuing to serve as NVAC chair. Dr. Koh commended NVPO staff for publishing the 2010 National Vaccine Plan, which had not been updated since 1994. He looked forward to implementing the plan to improve the U.S. vaccine system.

The improved coordination that resulted from the H1N1 pandemic response bore fruit, Dr. Koh pointed out, as the 2010–2011 seasonal influenza vaccination campaign distributed 160 million doses of vaccine, which represents the most doses ever, made available earlier than ever. Efforts across Federal departments and agencies (including CMS) combined with those of employers, retail pharmacies, faith-based organizations, and others to reach more people. Dr. Koh reminded participants that the Affordable Care Act (ACA) emphasizes prevention (including vaccines) and community outreach. The legislation

established the Prevention and Public Health Fund, which will provide \$750 million in 2011 and \$1 billion in 2012 for prevention, infrastructure, and research.

Discussion

Dr. Koh emphasized that the government is moving forward with health care reform efforts prescribed by the ACA, despite some ongoing court challenges to the law and potential budget issues. He believes the more the U.S. public learns about the ACA's preventive benefits, the more it will appreciate the law. The website HealthCare.gov gives substantial information on the preventive benefits and insurance options under the ACA. Dr. Koh said more communication about the benefits is needed.

2010 National Vaccine Plan—Bruce G. Gellin, M.D., M.P.H., DASH, Director, NVPO

Dr. Gellin underscored that the 2010 National Vaccine Plan was developed with extensive input from stakeholders and relies on entities beyond the Federal government. The document describes a comprehensive, 10-year strategic plan around five major goals (including a new one on global prevention of death and disease). As it develops a corresponding implementation plan in 2011, NVPO will seek to strike a balance between achievable and aspirational goals. The Institute of Medicine (IOM) has already engaged stakeholders across the country in crafting its [Priorities for the National Vaccine Plan](#) in 2009, which NVPO will use to guide its implementation plan and metrics.

Dr. Gellin noted that even before the National Vaccine Plan was finalized, Federal efforts to achieve the new goals were underway, including creation of the IOM Committee for Identifying and Prioritizing New Preventive Vaccines for Development, development of the Vaccines.gov website (to launch in spring 2011), and focus on the vaccine safety research agenda and immunization of pregnant women. The IOM Committee will develop an evidence-based approach to prioritizing the needs to develop new vaccines and improve existing vaccines, weighing, for example, emerging diseases, costs, scientific opportunities, and the potential for dual-use technology, and incorporating stakeholder perspectives.

Over the next year, NVPO will develop an implementation plan that incorporates stakeholder input and focuses on priorities. NVPO will evaluate national progress toward the National Vaccine Plan goals annually and conduct a mid-course review in 2015. Dr. Gellin asked for NVAC input specifically on how to measure progress toward the goals in a transparent, valid manner that includes the efforts of non-Federal entities. He hoped NVAC would review the annual progress reports and mid-course review.

Discussion

Dr. Gellin said NVPO has struggled to determine its role in global prevention of disease through vaccination, and more consideration is needed, with input from entities such as CDC, USAID, the Global Health Initiative, and the Global Alliance for Vaccines and Immunisation (GAVI). He also noted that the National Vaccine Plan assumes efforts will be made to meet the Healthy People 2020 goals; however, it is unclear whether the Healthy People 2020 measures could be used to assess progress toward the National Vaccine Plan's goals. Dr. Gellin hoped to provide metrics for NVAC's consideration soon, ideally before the June 2011 NVAC meeting. He added that coordination of efforts across agencies and departments is an ongoing assumption that underlies the entire plan.

Dr. Gellin asked NVAC to consider aligning its working groups with the goals of the National Vaccine Plan (except the global health goal, which is better addressed by others). Kathleen Stratton from the IOM emphasized that the new IOM Committee for Vaccine Prioritization will not set priorities but rather develop a framework for identifying priorities.

2010–2011 Influenza Season

Progress in Meeting Universal Recommendations—Cindy Weinbaum, M.D., M.P.H., CDC

Dr. Weinbaum described the evolution of the Advisory Committee on Immunization Practices' (ACIP's) recommendations for influenza vaccination toward the 2010 universal recommendation and the CDC's

communication and outreach plan for the 2010–2011 campaign. Evaluation of this season’s campaign indicates that more doses of influenza vaccine were distributed than ever and that seasonal influenza vaccine was produced and distributed more rapidly than ever. While the universal recommendation simplified the messaging for this year’s influenza vaccination campaign, CDC continued to provide materials to reach vulnerable and underserved populations.

Annual vaccine coverage is a good indicator of the success of CDC’s outreach, and Dr. Weinbaum provided survey results indicating that seasonal influenza vaccine uptake has increased among all populations. Coverage continues to be higher among Whites than Hispanics or Blacks. About 80 percent of children receive vaccinations in a doctor’s office; adults receive them in various places, primarily the workplace and retail sites. Dr. Weinbaum said 49 percent of pregnant women would likely be vaccinated by the end of this influenza season, which represents the largest increase seen among any subpopulation compared with vaccination rates in 2008–2009. Among health care workers, 62 percent would likely be vaccinated this season; coverage among those with direct patient contact (physicians, nurses, physician assistants) is higher than among health care technicians (78 percent vs. 47 percent).

Amy Groom, M.P.H., of the Indian Health Service (IHS) said her organization developed an influenza monitoring system in response to the H1N1 pandemic that allows it to track both illness and vaccine coverage among its population very rapidly. About 380,000 influenza vaccine doses were administered as of February 12, 2011. About 33 percent of pregnant women had been vaccinated. Of the IHS’ 28,000 health care workers, 71 percent had been vaccinated. Ms. Groom explained that the universal recommendation makes it easier to communicate about the importance of influenza vaccination, but because such a high proportion of American Indians and Alaskan Natives are considered to be at high risk and for whom vaccination would have been recommended in previous years, she did not anticipate a very large increase in overall uptake.

HHS Interagency Influenza Vaccine Task Force—Bruce G. Gellin, M.D., M.P.H., DASH, Director, NVPO

Recognition of the key role that everyday public health systems play in responding to emergencies led to development of the Interagency Influenza Vaccine Task Force, which has been monitoring vaccine coverage in an effort to determine how to use available monitoring systems to get more and better data over time, said Dr. Gellin. He said all the systems support the CDC’s findings that overall uptake has increased, and he felt optimistic, particularly about the increased uptake among pregnant women.

This season, retail pharmacies undertook a huge effort to increase influenza vaccination. While some were concerned that the effort would draw people away from doctors’ offices, Dr. Gellin said vaccination in both retail settings and doctors’ offices increased. In late 2010, Walgreen’s pharmacy provided free vouchers for 350,000 doses of vaccine across the country; evaluation of the impact is underway.

Discussion

In Chicago, the late start and the timing of Walgreen’s voucher program may have hindered the uptake. The increase in vaccination among pregnant women is a positive step forward and suggests that messaging about the safety of the influenza vaccine among pregnant women may finally be taking hold.

Dr. Weinbaum said the reasons most often cited for not getting vaccinated (among all populations, including health care workers) were a lack of concern about getting influenza and concern that the vaccine causes influenza. It was suggested that the Interagency Task Force invite a representative of the U.S. Department of Agriculture’s (USDA’s) Women, Infants, and Children program to participate. Phil Hosbach of Sanofi Pasteur reminded participants that communication encourages collaboration among stakeholders.

Vaccine coverage among health care workers is not increasing dramatically. In light of the finding that health care worker occupation influences uptake, an NVAC Adult Immunization Working Group (AIWG)

subgroup and HHS are both considering how to better define and measure vaccine uptake. The CDC and the National Quality Forum (NQF) are conducting a pilot study on the use of health care worker vaccine coverage as a hospital quality measure that is eligible for payment under CMS' quality reporting initiative. Determining the acceptable numerator and denominator for such a measure is challenging.

Members agreed that additional information is needed to assess the impact of the universal recommendation.

Action Items

NVAC will continue to provide input on systems issues related to how the Department is managing the universal recommendation. In addition NVAC will seek information to evaluate how the vaccine system infrastructure has changed since the H1N1 pandemic response, including, for example, whether State and local health departments were able to maintain the improved infrastructure they created in response to H1N1 and whether nontraditional vaccine providers and providers who enrolled for the first time in vaccination programs continued to participate in seasonal influenza vaccination programs after the pandemic. NVAC asks that AIM, ASTHO, and NACCHO gather and provide such information from their constituents, if feasible.

When the results of CDC's March 2011 snapshot survey on seasonal influenza vaccine coverage are available, NVPO staff will forward the data to NVAC members for consideration.

NVPO staff will provide NVAC with additional relevant data about seasonal influenza vaccine (uptake, barriers, messages, etc.) as they become available. NVPO staff will help collect and organize ideas from NVAC members for consideration.

Before the June 2011 meeting, NVAC will identify research that defines and quantifies the barriers to seasonal influenza vaccination in general and among specific subpopulations (e.g., pregnant women, health care workers). Information may be available from AIM, ASTHO, NACCHO, the National Influenza Vaccine Summit, and IHS, among others.

Stakeholder Perspectives

AMERICAN MEDICAL ASSOCIATION (AMA), NATIONAL INFLUENZA VACCINE SUMMIT—LITJEN TAN, M.S., PH.D.

Dr. Tan provided results from both an AMA member survey and a National Influenza Vaccine Summit survey of organizational members about the impact of the universal recommendation. The AMA found more physicians were administering more doses of vaccine and more patients were familiar with the recommendations for seasonal influenza vaccine, which may be related to the universal recommendation or to heightened awareness about influenza carried over from the H1N1 pandemic. Doctors identified the top challenge to providing influenza vaccine to all patients as patients' concern about vaccine safety; conversely, organizations responding to the Summit's survey said lack of demand/lack of concern about influenza was the biggest challenge. Dr. Tan said the universal recommendation spurred creation of programs to increase vaccine coverage, including new partnerships, new materials, new promotional efforts, and expansion of clinics and provider protocols. He concluded that increasing uptake for next season requires addressing public apathy, State laws that impose age limits, funding, and education about the universal recommendation.

AIM—CLAIRE HANNAN, M.P.H.

Ms. Hannan said the late delivery of vaccine to public providers was the primary challenge for managers of Vaccines for Children (VFC) programs this season. Public health clinics reported low demand and low uptake in their annual vaccine clinics, but the CDC data suggest people are taking advantage of other sites. The universal recommendation simplified messaging and helped VFC program managers better communicate with providers. Participation of pharmacies and other nontraditional providers helped

spread the word, but AIM is concerned about the impact of pharmacy administration, for example, on the public health system's emergency response capability. The recommendation about high-dose influenza vaccine is not definitive and led to some confusion. The lack of sustainable funding for school-located vaccine clinics remains a concern that could potentially be addressed by billing insured patients who get vaccinated at school clinics or charging an administration fee. Ms. Hannan emphasized that private providers received vaccine in September, while VFC programs did not receive vaccine until late October, which raised concerns about timely, equitable distribution.

ASTHO—KATHY TALKINGTON, M.P.AFF.

Ms. Talkington said the perception among her organization's members is that overall uptake is no higher this year despite adequate supply and widespread disease, but the universal recommendation was well received. Most members feel pharmacy participation is beneficial because it raises awareness among the public through advertising, but it does hamper the ability of public health departments to estimate the amount of vaccine needed. The media was not interested in State efforts to promote vaccination, and it's possible that the public did not take influenza seriously this year because of the lack of media attention, said Ms. Talkington. The lack of clarity about the indications for the high-dose vaccine posed a communication challenge. In general, States used Federal stimulus funding for vaccine purchases and infrastructure. The lack of sustainable funding reduces States' ability to capitalize on lessons learned from the H1N1 epidemic, such as the use of school clinics. Ms. Talkington concluded that she felt the 2011–2012 influenza season—when States have no Federal stimulus funding and the H1N1 pandemic has faded from public memory—will look more like the new normal in vaccination trends.

NACCHO—ANNE BAILOWITZ, M.D., M.P.H.

Dr. Bailowitz said several local health departments reported normal operations, and some reported communication challenges stemming from the combination of seasonal and H1N1 vaccine. In some areas, demand was low (a.k.a. “flu fatigue”), while in others, the public seemed to expect a large-scale response similar to that for H1N1 vaccination. Where demand was high, public health departments used Federal stimulus funds to purchase vaccine and hire staff. The vaccine supply was boosted by donations from Pharmacia, but the donation came after demand peaked in October and November. Positive, sustained media attention played a role in vaccine uptake early in the season. Public health departments had less access to supply and distribution data than they did in 2009–2010. Dr. Bailowitz reported incremental increases in vaccine uptake among health care workers. She said those local health departments that define all their employees as health care workers and apply rigorous vaccine qualifications have a high uptake among workers.

IHS—AMY GROOM, M.P.H.

Ms. Groom said the IHS had similar concerns as public health providers. Many IHS providers did not receive the influenza vaccine for distribution until late October.

BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)—PHYLLIS ARTHUR

Ms. Arthur said her organization worked hard to get the vaccine out early and to educate consumers and providers about the universal recommendation. To reach more people, especially young people and health care workers, BIO recommends increasing investment in influenza vaccine production capacity in the United States and globally, improving the speed and efficiency of vaccine production, and nurturing a vibrant vaccine market. She hoped NVAC would:

- encourage government investment in consumer and provider education;
- encourage vaccination for all health care workers;
- encourage States and health care insurers to allow vaccination at as many sites as possible and to address barriers to vaccination at alternative sites;
- promote the ACA provisions that provide more first-dollar coverage for vaccines;
- encourage employer vaccination programs; and

- continue to stress the links among seasonal vaccine uptake, public health infrastructure, and pandemic preparedness.

DOD—COL RENATA ENGLER

COL Engler reported that DoD got its vaccine supply earlier than usual and vaccinated 90 percent of its active duty military members around the world by January 1, 2011, which represents a huge accomplishment. The DoD enacted more stringent requirements for vaccination among health care workers and is moving toward mandatory vaccination of civilian workers (with some religious and medical exemptions). This season represented the first year that TRICARE allowed beneficiaries to be reimbursed for influenza vaccination wherever they chose, and some chose retail pharmacies, for example, for convenience.

Discussion

It was noted that, for primary care providers, determining how much vaccine to purchase and the cost of unused vaccine are significant barriers to increasing vaccination. NVAC members agreed that more information is needed to better identify all the barriers.

2010–2011 Influenza Vaccine Safety Update

Overview of Vaccine Safety Monitoring Systems—Dan Salmon, Ph.D., M.P.H., NVPO

Dr. Salmon briefly described current safety monitoring systems:

- The Vaccine Adverse Event Reporting System (VAERS) is a passive system that detects signals of unanticipated events and covers the entire U.S. population.
- The Real-Time Immunization Monitoring System (RTIMS) involves both active and passive data capture and facilitates evaluation of subpopulations. It can be useful for generating hypotheses.
- The Vaccine Safety Datalink (VSD) provides rapid, active surveillance and enables study of subpopulations.
- Rapid cycle analysis allows for ongoing rapid evaluation using the VSD to identify potential problems, usually by focusing on pre-specified outcomes.
- The IHS' Influenza Awareness System covers a moderate number of people in the American Indian and Alaskan Native communities. Because it draws on data from a unified, electronic records system, it enables chart review of cases.
- Medicare has a large database that mostly covers people over 65 years old, who may be underrepresented in other databases.
- The VA system primarily captures elderly people and those with comorbidities.

Post Marketing Safety Monitoring—David Martin, M.D., M.P.H.

Dr. Martin described the FDA's process for evaluating signals through data mining, emphasizing that the FDA conducts constant surveillance of the 71 vaccines currently licensed, among other products. Influenza vaccines fall under the purview of five medical officers, who review daily the serious adverse events (as defined by FDA guidelines) reported to VAERS and in the literature. Dr. Martin cautioned that all of the limitations that apply to findings from VAERS data in general apply to the FDA's findings for influenza vaccines. A finding does not constitute a signal, he noted, and requires further evaluation.

In the past year, the FDA's data mining identified a finding of 42 febrile seizure cases following administration of Fluzone, the only influenza vaccine licensed and recommended for those under age 2 years. The FDA is working with the manufacturer to further investigate the cases and posted a public communication about the finding in January. The finding will be analyzed further using the VSD, and preliminary results will be presented at the February ACIP meeting.

Discussion

Dr. Martin clarified that legislation dictates when an FDA finding for a non-vaccine product must be reported but no such law governs vaccines, and FDA does not report every data finding without further information. Findings of interest are posted online quarterly in a special section of the FDA's website. Dr. Hosbach of Sanofi Pasteur, which manufactures Fluzone, said his company would like to get VAERS reports and other notifications sooner. Sanofi Pasteur is working with FDA, he said, and has not yet identified any association between Fluzone and febrile seizures. Dr. Martin noted that FDA was primed to look for cases of febrile seizures following influenza vaccination because of similar occurrences in Australia. Dr. Salmon clarified that VAERS casts a broad net to detect signals, whereas VSD can help calculate relative or attributable risk. Dr. Martin noted that the FDA's approach identified a finding worth exploring further because the number of febrile seizure cases appears to be disproportionately high, although the FDA does not yet have a baseline figure for comparison. NVAC may wish to consider making recommendations on how CDC and FDA can improve their surveillance systems.

Dr. Salmon noted that multiple monitoring systems were evaluated for the three potential signals identified by NVAC's Vaccine Safety Risk Assessment Working Group (VSRAWG) in relation to H1N1 vaccine—Guillain-Barré syndrome (GBS), thrombocytopenia/idiopathic thrombocytopenic purpura (TP/ITP), and Bell's palsy—and no signals were found for this year's seasonal influenza vaccine.

H1N1 Vaccine Safety Monitoring: VSRAWG Interim Report—Marie McCormick, M.D., Sc.D.

Dr. McCormick described the VSRAWG's charge and the process it has used since it was formed. She presented the VSRAWG's interim report, noting that some end-of-season data are not yet available. The VSRAWG found no association between H1N1 vaccination and either Bell's palsy or TP/ITP; a conclusion about the association between H1N1 vaccine and GBS will be made when more data are finalized. Some databases have suggested that H1N1 vaccine may be associated with hypersensitivity reactions, which will be addressed in the final report once additional analyses are available. Other analyses are evaluating pregnancy outcomes related to H1N1 vaccination, and these findings will also be addressed in the final report.

The interim report suggests that the FDA's data mining approach be refined if it is to be used to conduct surveillance comparing adverse events associated with H1N1 vaccine to those associated with similar vaccines, because the results are unstable, difficult to interpret, and nonspecific. Dr. McCormick said the FDA's analysis of VAERS did reveal vaccine administration errors that could be reduced. She said the final VSRAWG report may be available by June 2011.

Discussion

Dr. McCormick and Dr. Salmon noted that signals regarding conditions of moderate severity arose relatively quickly, which should provide reassurance that the systems can gather data rapidly and that more serious, high-risk events would have been identified quickly if they had occurred. However, getting definitive data takes time. It was also noted that end-of-season analyses are needed to distinguish seasonal events from vaccine associations. RADM Anne Schuchat, M.D., noted that the VSRAWG sought to identify important issues as they arose, and she was pleased that no big problems were identified.

Vaccine Safety Working Group (VSWG) Update—Marie McCormick, M.D., Sc.D.

Dr. McCormick described the membership, charge, and process of the VSWG and summarized the group's work to date on a white paper recommending improvements to the Federal vaccine safety system. She said the group hopes to present a draft with conclusions and recommendations to NVAC in late February. A spring meeting is planned to gather public input on the draft, which will then be revised and presented to NVAC for consideration in June, with the goal of achieving final NVAC approval at the September 2011 meeting.

Agency, Department, Advisory Committee, and Liaison Reports

USAID—Margaret McCluskey, R.N., M.P.H.

Ms. McCluskey said USAID's Administrator, Rajiv Shah, has a strong commitment to science, technology, and innovation. The agency is emphasizing research to support a malaria vaccine initiative and an international AIDS vaccine initiative and probably will join the search for a tuberculosis vaccine. USAID continues to support GAVI, and a USAID senior technical advisor reports that more sophisticated approaches to supply and procurement under GAVI are underway. Also, USAID may help meet some GAVI funding commitments. President Obama has proposed substantially increasing funding for global health programs in his 2012 budget.

CDC—RADM Anne Schuchat, M.D.

In December, CDC launched its new Vaccine Tracking System (VTrckS) at its headquarters and four pilot sites, said RADM Schuchat. It replaces the legacy systems built around the 1994 National Vaccine Plan and should improve vaccine accountability, inventory management, and forecasting quality.

RADM Schuchat said 2010 was a bumper year for pertussis, especially in California, and CDC is conducting extensive analysis to understand why. One hypothesis CDC is evaluating in collaboration with researchers in California and Michigan is that the increased disease is related to waning vaccine immunity in kids immunized with the acellular pertussis vaccine. It does not appear that the rise in pertussis cases is a function of vaccine refusal.

The February 2011 ACIP meeting will be webcast. The National Immunization Conference takes place in Washington, DC, March 28–31 and offers a good opportunity to meet a range of people representing the broad immunization community.

RADM Schuchat added that in 1994, when the first National Vaccine Plan was published, she was in Niger testing a meningococcal vaccine. Now, 19.5 million people up to age 29 in Niger have received that vaccine, which costs about 40 cents per dose and is produced through a public-private partnership involving the World Health Organization, FDA, an Indian health agency, CDC, and the United Kingdom's national organization for biostandards. The vaccine was tested around Africa and India and rolled out with GAVI support. The progress and success of the vaccine are exciting, said RADM Schuchat.

FDA—Norman Baylor, Ph.D.

Dr. Baylor said the FDA's vaccine production advisory committee will meet soon to determine the influenza strain for the 2011–2012 season. He noted that there would be a discussion on the H5 and H9 antigens at that time.

VICP—Geoffrey Evans, M.D.

Dr. Evans said the VICP is seeing a lot of non-autism-related claims. Claims related to the influenza vaccine are increasing, probably because so many more doses of influenza vaccine are administered than any other vaccine in the United States.

The Omnibus Autism Proceeding involving six test cases have all been adjudicated and the appeals process completed, and all were decided in favor of the government. Thus, the court is now asking the petitioners of the 4,700 remaining claims to determine whether they wish to continue by presenting a theory of causation different from any of those in the test cases already decided. Dr. Evans believed some petitioners may pursue a theory of metabolic/mitochondrial causation. However, the bulk of the proceeding seems to be drawing to a close.

The U.S. Supreme Court has heard the case of *Brusewitz v. Wyeth Inc.*, which addresses whether the National Childhood Vaccine Injury Act limits design defect claims against a manufacturer after an individual has gone through the VICP process. The two sides differ over the meaning of "design defect"

and what Congress intended by the term “unavoidably unsafe.” Dr. Evans noted that Justice Elena Kagan recused herself because she was the U.S. Solicitor General when the case was presented to the Supreme Court, so the case will be decided by the remaining eight justices. It could be decided soon or as late as June. The ruling will be significant for the VICP but even more so for the private sector, because a number of claims could go to the private sector or civil courts in an attempt to obtain compensation.

The IOM will report to the ACCV soon on the status of its effort to evaluate adverse events following vaccination for 12 vaccines. The IOM findings will be sent to the HHS Secretary for consideration in revising the Vaccine Injury Table.

ACCV—Charlene Gallagher, R.Ph., J.D.

Ms. Gallagher described the ACCV’s communication and outreach project to inform the public about the VICP. A comprehensive report was published in November 2010 describing the results of research among key populations, multifaceted plans for communication, and key measures for successful implementation. It defines the goals of the project to raise awareness of the VICP among health care providers so that they can better communicate with patients and to provide easy and direct access to the public about the VICP. Messages about the VICP will be disseminated through venues that the target audience visits and trusts, e.g., health care providers, public partners, and media. The outreach efforts will not be a blanket approach but rather selective, phased, and responsible. The ACCV recognizes that the outreach approach must be cost-effective, sustainable, flexible, and scalable and that the information should be accessible and empowering. Implementation of the project is ongoing. The future of the project depends on financing, but many efforts underway do not require a lot of resources, so Ms. Gallagher was confident that the project will raise awareness. While the main purpose is to raise awareness about VICP, it is possible that some education about VAERS can also be included or that ACCV can partner with others to increase awareness about VAERS.

HRSA—LCDR Kent Forde

LCDR Forde said the HRSA Administrator created the Office of Special Health Affairs to raise awareness about HRSA programs. It is directed by Terry Adirim, who recently worked at the Department of Homeland Security. The Office of Special Health Affairs has the capacity to do a lot of cross-cutting work across bureaus, such as the Maternal & Child Health Bureau and the HIV/AIDS Bureau, said LCDR Forde. The office is trying to promote vaccines in general, and influenza specifically, among the divisions of HRSA.

DoD—COL Renata Engler

COL Engler said DoD is engaged with the Countermeasures Injury Compensation Program (CICP) to review cases and address those that involve smallpox or anthrax vaccine. Issues of causality remain a struggle, she said. Dr. Evans added that the CICP has received more than 420 letters of intent to file a claim; one is related to anthrax vaccine, and the rest relate to H1N1 vaccine.

NIH—Barbara Mulach, Ph.D.

Dr. Mulach described some papers of particular interest published in the past few months: [Influenza Vaccines for the Future](#), in the *New England Journal of Medicine*, was coauthored by Anthony Fauci, M.D., director of the National Institute of Allergy and Infectious Diseases, and Linda Lambert, Ph.D. Dr. Fauci also coauthored [Induction of Unnatural Immunity: Prospects for a Broadly Protective Universal Influenza Vaccine](#) with Gary Nabel, M.D., Ph.D. It was published in *Nature Medicine* and encourages researchers to think more broadly about influenza vaccine. Dr. Fauci has also raised the possibility of using the upcoming recompetition process for the HIV/AIDS Clinical Network as an opportunity to open that existing infrastructure to other infectious diseases. Dr. Mulach said NIH has asked the infectious disease community for feedback and is holding town hall meetings open to the public as well. The next town hall meeting is March 7.

Public Comment

Dr. Paul G. King said the information provided at the meeting was interesting, but no one was talking about the fact that most recommended vaccines are not medically cost-effective. He said there is not a lot of money in the health care system to waste on ineffective practices.

Additional Comments from NVAC Members

NVAC members praised the NVPO's document *Understanding the Vaccine Safety System: The Key to Informed Decision-Making About Vaccination*, which was distilled from a much longer document. Dr. Salmon noted that an upcoming supplement to the journal *Pediatrics* will include several articles that aim to help physicians address the concerns of patients and parents about vaccine safety. Dr. Gellin said his office will consider assembling in one place all of NVPO's information on vaccine safety, which are aimed at different audiences.

Day 2—February 17, 2011

Old Business—Guthrie S. Birkhead, M.D., M.P.H.

Dr. Birkhead said that, by the June 2011 meeting, NVAC should have completed its assessment of the impact of the universal recommendation on seasonal influenza vaccine uptake and have recommendations ready for the ASH. Members reiterated the need for additional information to inform their assessment and for a process to develop preliminary recommendations before the next in-person meeting. Participants further discussed the impact of the delayed distribution of vaccine to the VFC program and the CDC's recognition of the need to revamp the distribution process. It was noted that the delay does affect the likelihood that a child will receive the second dose of influenza vaccine.

Action Items

A small group of NVAC members (to be determined) will develop some preliminary assessments of the impact of the universal recommendation on seasonal influenza vaccine uptake (via e-mail exchange or teleconference) for discussion at the June 2011 NVAC meeting.

Dr. Tan will send the agenda for the National Influenza Vaccine Summit (May 9–11, 2010 in San Diego, CA) to NVAC members. It is hoped that some NVAC member(s) will attend and gather relevant input that will be helpful to NVAC's assessment.

Before the June 2011 meeting, NVPO staff will gather information or organize a presentation from CDC staff on CDC's proposal to improve the distribution timeline in the VFC program. AIM and NACCHO representatives are invited to work with NVAC to gather more information on the issue of delays in distribution to VFC beneficiaries.

In response to questions about the mechanism for billing Medicare for vaccination when a patient also has private insurance, Jeffrey Kelman, M.M.Sc., M.D., clarified that influenza vaccine is covered by Medicare and that Medicare is almost always the primary payer. When Medicare is the secondary payer, both payers should be billed.

AIWG—Julie Morita, M.D.

Dr. Morita summarized the AIWG's efforts to date and presented its draft recommendations for consideration. To overcome barriers to adult immunization, the AIWG recommends that HHS 1) establish national leadership in the form of an interagency working group to improve adult immunization rates, 2) allocate adequate resources to support adult immunization, and 3) develop and implement a strategic action plan (that references the National Vaccine Plan and Healthy People 2020 goals). In addition, the

AIWG made recommendations on five categories of operational components, which are detailed in the draft white paper:

- Bolster the general infrastructure:** Align adult immunization goals across agencies, include adult immunization in CDC grant guidance, and support the development of infrastructure and quality measures for adult immunization.
- Expand vaccine access:** Expand the CDC Immunization Grant Program (Section 317) to include more adults, foster partnerships with public health and other organizations, and update the maximum allowable reimbursement under CMS.
- Implement provider/system-based interventions:** Improve provider education about vaccine practices and ACA benefits, engage nontraditional providers, and expand registries to include adults.
- Increase community demand:** Use multiple media outlets to reach out to patients and providers to address disease prevention and vaccine safety.
- Address research needs.**

The AIWG will host stakeholder meetings in Denver in March and Chicago in April to gather more input on the draft white paper. Dr. Morita hoped the final paper would be submitted to NVAC for approval at the June 2011 meeting.

Discussion

More discussion is needed on the role NVAC might play in a national adult immunization leadership entity. The AIWG white paper should note that provider education should begin in training programs and that public health authorities already have numerous, inexpensive opportunities to educate providers about vaccination. It may be worth mentioning in the context of evaluating economic benefits that pediatric vaccines are more effective than adult vaccines. NVAC members noted that lack of vaccine supply for adults, as in the case of herpes zoster vaccine, dramatically diminishes providers' enthusiasm for adult vaccination. In addition, the lack of a large market for adult vaccine undermines the commitment to research and development.

Dr. Morita clarified that the recommendations targeted Section 317 because it represents an existing program that could be leveraged to expand adult immunization without a large amount of new funding. State liaisons expressed concern that Section 317 funding is already stretched to the limit and that future funding is uncertain.

Eddy Bresnitz, M.D., of Merck & Company stressed that progress is being made slowly toward increasing adult immunization. He acknowledged that concerns about vaccine supply are important but said they should not hold back efforts to increase adult immunization. He concluded that the United States is among the leaders in promoting adult immunization, which sets an example for the rest of the world.

Subgroup on Influenza Vaccination of Health Care Providers—Christine Nevin-Woods, D.O., M.P.H.

Dr. Nevin-Woods said the subgroup is charged with developing recommendations on strategies to achieve the Healthy People 2020 annual goal of 90-percent influenza vaccine coverage for health care personnel. The subgroup defined health care personnel as all paid and unpaid persons working in health care settings who have the potential for exposure to infectious materials. A number of settings were identified, and the subgroup noted that health care personnel include a range of those directly, indirectly, and not involved in patient care who have the potential for transmitting influenza to patients, other health care personnel, or others.

The subgroup is debating the pros and cons of various strategies and members have agreed that a comprehensive approach is needed to meet the goal. The subgroup has not determined what its final product will be, but Dr. Nevin-Woods hoped draft recommendations would be presented to the NVAC as

early as the June 2011 meeting so that they could be considered for the 2011–2012 influenza season. The subgroup plans to gather stakeholder input on its draft recommendations through meetings and a public comment period.

Discussion

It was noted that designating health care worker vaccination as a quality measure for hospitals (assuming NQF validation) would likely go a long way toward reaching the Healthy People 2020 goal. It was also noted that vaccine mandates are most successful when accompanied by comprehensive education. The subgroup should take into account the results of HHS’ evaluation of health care worker vaccination strategies (currently underway) and George Washington University’s model statute (under development). The National Influenza Vaccine Summit has information on its website about best practices in health care worker vaccination. Melanie Swift of the American College of Occupational and Environmental Medicine, a liaison to the subgroup, said efforts are also needed to measure progress, ensure appropriate infrastructure in occupational settings, and invest in research and development to create a vaccine of increased efficacy and longer duration.

Healthy People 2020

Presentation of Baseline Data—RADM Anne Schuchat, M.D., USPHS, CDC

RADM Schuchat said that 21 of the 32 objectives in the category of Immunization and Infectious Disease are related to vaccination. She described the data sources that CDC uses to track progress toward meeting the Healthy People objectives. Among toddlers, she noted, vaccination rates are high and efforts are underway to sustain them. RADM Schuchat said that in some cases important goals can be achieved with lower targets; for example, she pointed to a huge reduction in the incidence of hepatitis A and rotavirus coinciding with the introduction of the corresponding vaccines for toddlers, despite coverage rates of about 43 percent, or about half the target for 2020.

For adolescents, vaccine coverage appears to be increasing, although the coverage for human papillomavirus (HPV) is “pathetic.” RADM Schuchat said the vaccine system is not well organized to provide a series of vaccine injections to teenagers. While there do not appear to be disparities in terms of who gets a first dose of HPV vaccine, there are real disparities among those who get the third dose, and a 2020 goal may help improve uptake and series completion.

Strategies to achieve the 2020 targets include increasing communication with the public and providers and spreading the message about immunization across the lifespan. CDC is partnering with other organizations to create provider toolkits that address vaccine hesitancy. Vaccine reminder/recall messages are effective for the pediatric population and could be expanded to other age groups. Initiatives are focusing on improving interoperability among immunization information systems and electronic health records. The ACA should help reduce some financial barriers. CDC has seen that giving providers’ feedback about progress toward the targets helps improve coverage, and some State and local health departments already use immunization registries to target low performers. CDC seeks to leverage the increased participation of obstetrician–gynecologists for H1N1 vaccination to reach more pregnant women. It is also enhancing partnerships with nontraditional venues, such as workplaces, pharmacies, and schools. RADM Schuchat concluded that reaching the goals requires targeted, multiyear efforts to reduce disparities plus incentives for health care worker vaccination (such as a quality measure for hospitals).

NVAC Identification of Barriers to Achieving Healthy People 2020 Objectives—Guthrie S. Birkhead, M.D., M.P.H.

Dr. Birkhead said NVPO staff used NVAC reports and recommendations since 2000 to compile a list of barriers already identified that could prevent achieving the targets, which he summarized.

- Barriers to tracking and reporting disease burden:** Disease hard to diagnose or classify, rare, underreported (or nonreportable)

- Provider barriers:** Storage costs, vaccine insurance costs, staff time, cost-to-reimbursement ratio
- Patient barriers:** Lack of awareness or access, out-of-pocket costs, lack of insurance
- Supply barriers:** Limited number of manufacturers and market competition, removal of vaccine from market
- Manufacturing barriers:** Increasing complexity and cost, regulatory compliance, low revenues
- Market barriers:** Uncertainty, costs of large trials, unpredictable demand

The most common barrier to coverage for children is the cost. Other barriers specific to children include the following:

- Parent-/patient-related barriers:** Delays in scheduling appointments, insufficient reimbursement, lack of awareness of VFC, referral outside the medical home
- Provider-/system-related barriers:** Long office waiting times, lack of age- or culturally-appropriate educational materials, separate supplies of VFC and private patient vaccine, missed opportunities for vaccination because of lack of medical home
- Context-related barriers:** Perceived risk of disease, inaccurate or misleading information, complexity of vaccine schedule
- Systemic financial barriers:** Lack of health plan coverage/underinsurance, VFC limitations (e.g., does not cover new vaccines), insufficient State and local funding, State mandates that don't apply to self-insured plans

Dr. Birkhead concluded that the ACA may address some of these barriers. He said NVAC members should keep the barriers already identified in mind as they work to identify solutions to meeting the targets. He noted that NVAC must develop a process for monitoring progress annually and discuss with CDC how best to provide input.

Discussion

RADM Schuchat said some of the 2020 objectives correlate directly with strategies underway, such as those addressing adolescent immunization, information technology (IT), and hepatitis. She felt the benefits of the ACA and IT initiatives were promising in terms of meeting the goals, but she remained concerned about the ability to establish public-private partnerships that would meet the needs of kids who do not have regular medical providers. RADM Schuchat said CDC could report progress toward the Healthy People 2020 goals to NVAC annually in the fall, when it has the most complete vaccine coverage data for the previous year. She added that a new process was instituted to determine the 2020 targets, which limited the aspirational goals and in some cases eliminated goals for which maintaining current rates is acceptable.

Action Item

NVAC will develop a plan for annually evaluating progress toward the Healthy People 2020 goals for immunization. To gather data for evaluation, a progress update from CDC will be scheduled for the fall NVAC meeting, beginning this year (September 2011).

Dr. Bresnitz reiterated concerns that the public health system infrastructure at State and local levels is underresourced and asked how CDC has addressed these concerns in light of achieving the 2020 goals. RADM Schuchat responded that vaccine programs are in better shape than other areas of health care. CDC is working to help States in various ways, such as improving IT systems and expanding care provided by community health clinics.

Public Comment

No public comments were made.

Closing Remarks and Adjournment—Guthrie S. Birkhead, M.D., M.P.H.

Dr. Birkhead thanked all those who took part and adjourned the meeting at approximately 11:30 a.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

Guthrie S. Birkhead, M.D., M.P.H.
Chair, National Vaccine Advisory Committee

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

National Vaccine Advisory Committee (NVAC)

February 16–17, 2011, Meeting

Summary of Action Items

Administrative Issues

NVAC approved the September 2010 minutes.

NVAC approved the draft State of the Program Report as written.

2010–2011 Influenza Season: Impact of the Universal Recommendations

NVAC will seek information to evaluate how the vaccine system infrastructure has changed since the H1N1 pandemic response, including, for example, whether State and local health departments were able to maintain the improved infrastructure they created in response to H1N1 and whether nontraditional vaccine providers and providers who enrolled for the first time in vaccination programs continued to participate in seasonal influenza vaccination programs after the pandemic. NVAC asks that AIM, ASTHO, and NACCHO gather and provide such information from their constituents, if feasible.

When the results of CDC's March 2011 snapshot survey on seasonal influenza vaccine coverage are available, NVPO staff will forward the data to NVAC members for consideration.

NVPO staff will provide NVAC with additional relevant data about seasonal influenza vaccine (uptake, barriers, messages, etc.) as they become available. NVPO staff will help collect and organize ideas from NVAC members for consideration.

Before the June 2011 meeting, NVAC will identify research that defines and quantifies the barriers to seasonal influenza vaccination in general and among specific subpopulations (e.g., pregnant women, health care workers). Information may be available from AIM, ASTHO, NACCHO, the National Influenza Vaccine Summit, and IHS, among others.

A small group of NVAC members (to be determined) will develop some preliminary assessments of the impact of the universal recommendation on seasonal influenza vaccine uptake (via e-mail exchange or teleconference) for discussion at the June 2011 NVAC meeting.

Dr. Tan will send the agenda for the National Influenza Vaccine Summit (May 9–11, 2010 in San Diego, CA) to NVAC members. It is hoped that some NVAC member(s) will attend and gather relevant input that will be helpful to NVAC's assessment.

Before the June 2011 meeting, NVPO staff will gather information or organize a presentation from CDC staff on CDC's proposal to improve the distribution timeline in the VFC program. AIM and NACCHO representatives are invited to work with NVAC to gather more information on the issue of delays in distribution to VFC beneficiaries.

Evaluating Progress Toward Healthy People 2020 Goals

NVAC will develop a plan for annually evaluating progress toward the Healthy People 2020 goals for immunization. To gather data for evaluation, a progress update from CDC will be scheduled for the fall NVAC meeting, beginning this year (September 2011).