



National Vaccine Advisory Committee (NVAC) September 13–14, 2011, Meeting Minutes

Committee Members in Attendance

Guthrie S. Birkhead, M.D., M.P.H., Chair
Tawny Buck (by phone)
Richard D. Clover, M.D.
Seth Hetherington, M.D.
Lisa Jackson, M.D., M.P.H.
Philip S. LaRussa, M.D.
Clement Lewin, Ph.D., M.B.A.
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.
Walter A. Orenstein, M.D., M.P.H.
Amy Pisani, M.S.
Laura E. Riley, M.D.
Thomas E. Stenvig, R.N.
Litjen Tan, Ph.D., M.S.

NVAC Ex Officio Members

Norman Baylor, Ph.D., U.S. Food and Drug Administration (FDA)
RADM Richard Church, Pharm.D., Indian Health Service (IHS)
Geoffrey Evans, M.D., Health Resources and Services Administration (HRSA), Vaccine Injury Compensation Program (VICP)
Rick Hill, D.V.M., M.S., Department of Agriculture (USDA)
Barbara Mulach, Ph.D., National Institutes of Health (NIH)
Richard Martinello, M.D., Department of Veterans Affairs (VA)
Valerie Marshall, M.P.H. (for Norman Baylor, Ph.D.), FDA
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)
Melinda Wharton, M.D., M.P.H. (for RADM Anne Schuchat, M.D.), CDC

NVAC Liaison Representatives

Anne Bailowitz, M.D., M.P.H., National Association of County and City Health Officials (NACCHO)
Claire Hannan, M.P.H., Executive Director, Association of Immunization Managers (AIM)
Iris Mabry-Hernandez, M.D., M.P.H., Agency for Healthcare Research and Quality (AHRQ)
Susan McKinney (for Margaret McCluskey, R.N., M.P.H.), U.S. Agency for International Development (USAID)
Kathy Talkington, M.P.A. (for Paul Jarris, M.D., M.B.A.), Association of State and Territorial Health Officials (ASTHO)
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)

Executive Secretary

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

Day 1—September 13, 2011

Welcome—Bruce G. Gellin, M.D., M.P.H., DASH, Director, National Vaccine Program Office (NVPO)

Dr. Gellin welcomed the Committee and other meeting participants on behalf of the Assistant Secretary for Health (ASH), Howard Koh, M.D., M.P.H. He noted that the agenda for the meeting is generally structured around the National Vaccine Plan.

Opening Remarks and Chair's Report—Guthrie S. Birkhead, M.D., M.P.H.

Dr. Birkhead welcomed the participants. Following introductions of Committee members, Dr. Birkhead asked for review and approval of the June 2011 National Vaccine Advisory Committee (NVAC) meeting minutes.

Action Item

NVAC unanimously approved the June 2011 minutes as written.

Dr. Birkhead announced that NVAC members Richard D. Clover, M.D., and Laura E. Riley, M.D., will complete their terms following this meeting, as will Dr. Birkhead. He expressed appreciation to the Committee and NVPO staff for several productive years with NVAC. Dr. Birkhead also said that this would be his last NVAC meeting and that Dr. Koh would come to the NVAC meeting on the second day to discuss the future leadership of the Committee.

The NVAC charter was renewed in July 2011 with minor changes, including the addition of ex officio representatives from Indian Health Services (IHS) and Agency for Healthcare Research and Quality (AHRQ). Dr. Birkhead reviewed NVAC's actions and recommendations since the beginning of 2010 and noted that most have been completed or are underway. He described NVAC's many significant accomplishments since he became the Chair in 2008, including its involvement in responding to vaccine safety concerns during the H1N1 influenza pandemic. Dr. Birkhead also highlighted NVAC's contributions to the National Vaccine Plan, which he said will likely be NVAC's guiding principle for the future. He summarized the current meeting [agenda](#) and reiterated the statutory charge of the Committee. The next NVAC meeting is scheduled for February 7–8, 2011.

National Prevention Strategy—RADM Boris Lushniak, M.D., M.P.H., Deputy Surgeon General

RADM Lushniak explained that the National Prevention Strategy was developed in response to the emphasis on prevention in the Affordable Care Act (ACA) by the National Prevention Council, a group headed by the Surgeon General and populated by representatives across the Federal government, including the departments of Education and Transportation. The National Prevention Strategy and the National Prevention Council are also informed by an advisory group, similar to NVAC. The National Prevention Strategy seeks to align existing prevention and health promotion efforts—such as Healthy People 2020—to improve health by “moving the nation from a focus on sickness and disease to one based on prevention and wellness,” said RADM Lushniak.

The National Prevention Strategy identifies four strategic directions for improving health across the lifespan: empowered people, healthy and safe community environments, elimination of health disparities, and clinical and community prevention services. Seven priorities are identified:

- ☐ Tobacco-free living
- ☐ Prevention of drug abuse and excessive alcohol use
- ☐ Healthy eating
- ☐ Active living

- ☐ Mental and emotional well-being
- ☐ Reproductive and sexual health
- ☐ Injury- and violence-free living

RADM Lushniak emphasized that achieving the goals may take generations, but the National Prevention Strategy is a first step toward framing preventive health as a necessary for the survival of our population. Implementing it poses challenges, so partnerships are essential. The strategy spells out what the Federal government will do, what partners can do, and key indicators (drawn from existing resources) to assess progress. RADM Lushniak said the next steps are to execute and coordinate recommended actions across agencies involved in the National Prevention Council, encourage partners to create and execute their own plans, monitor and track progress, and share successes.

Discussion

Mary Beth Bigley, Dr.P.H., M.S.N., A.N.P., who coordinates the National Prevention Council, noted that vaccines are mentioned throughout the National Prevention Strategy in the context of community services and tracking progress using Healthy People 2020 measures. In response to NVAC members' queries about addressing medical errors and tertiary prevention (i.e., improving functional status among those with chronic conditions), Dr. Bigley and RADM Lushniak said the current strategy focuses on primary prevention, health, and wellness. RADM Lushniak noted the strategy requires support from partners at all levels for implementation. Dr. Bigley added that the Council hopes to collect data, report progress annually to Congress, and share examples of successes.

Action Item

NVAC members should read the National Prevention Strategy and provide comment.

Vaccine Safety

Update on Safety Coordination and Health and Human Services (HHS) Immunization Task Force—Dan Salmon, Ph.D., M.P.H., NVPO

Introducing Dr. Salmon, Dr. Gellin noted that the NVPO heard consistently from NVAC and the Institute of Medicine (IOM) that the National Vaccine Plan should address leadership and coordination. He said Dr. Salmon's presentation speaks to that issue.

Dr. Salmon said the Immunization Safety Task Force, created in 2008, includes HHS agencies and divisions involved in vaccine safety, the Veterans Affairs (VA), and Department of Defense (DoD). It was instrumental in coordinating and integrating assets and opportunities during the H1N1 influenza pandemic—for example, by activating the Vaccines and Medications in Pregnancy Surveillance System. It has been vital in developing the National Vaccine Plan goal to enhance understanding of the safety of vaccines and vaccination practices. The Task Force demonstrated its commitment to strategic planning with its contributions to the National Vaccine Plan and support for the IOM's Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule (a response to an NVAC recommendation). The Task Force will develop, prioritize, and regularly update a scientific agenda around national vaccine safety (a recommendation of the IOM) and consider the final report of NVAC's Vaccine Safety Working Group (VSWG).

Finally, during the H1N1 influenza pandemic, the Task Force planned and implemented surveillance, developed a new surveillance system (the Post-Licensure Rapid Immunization Safety Monitoring, or PRISM, system), and reviewed surveillance data—which it shared with NVAC's Vaccine Safety Risk Assessment Working Group. The PRISM system became part of the infrastructure for routine vaccine

safety monitoring. The Task Force will also review and respond to the IOM's report on the adverse effects of vaccines.

Discussion

NVAC members pointed out that the work of the Immunization Safety Task Force is not visible to the public; Dr. Salmon responded that the Task Force can consider communicating more and informed the members that safety monitoring for H1N1 has been published on the internet (http://www.flu.gov/professional/federal/monitor_immunization_safety.html). Today's presentation was intended to raise awareness about the Task Force. Dr. Gellin wondered about the right level of transparency for such efforts. Melinda Wharton, M.D., M.P.H., said the Task Force accomplishes a lot through the normal work efforts of its members. Marie McCormick, M.D., Sc.D., emphasized that the lack of a public presence feeds the perception that there is no coordinated oversight of vaccine safety. Tawny Buck echoed the concern, suggesting that the Task Force create a website that spells out its membership, its projects and achievements, and how the public can participate. Dr. Birkhead pointed out that the draft VSWG report spells out who is doing what in the Federal vaccine safety system and where more detail is needed; it also proposes that NVAC be the mechanism for transparent communication about Federal vaccine safety efforts. He added that NVAC can be "the eyes and ears" for products as well as processes, such as the scientific research agenda on vaccine safety. Dr. Gellin said the desire to increase transparency around the Task Force would be taken into account.

IOM Committee to Review the Adverse Effects of Vaccines—Ellen Wright Clayton, J.D., M.D.

Dr. Clayton explained that the IOM Committee was charged with reviewing the epidemiologic, clinical, and biological evidence regarding the adverse health events associated with specific vaccines covered by the Vaccine Injury Compensation Program (VICP). (The report is available [online](#).) The Committee was not asked to evaluate the efficacy or benefits of vaccines to individuals or to the population at large. The members reviewed more than 1,000 scientific articles over two years (winnowed down from 13,000 potentially relevant publications) and reached a consensus of opinion for all conclusions. Dr. Clayton emphasized that the Committee spent a lot of time developing the framework for its assessments with the hope that it would be both transparent and useful to others in the future.

Dr. Clayton described how epidemiological, biological, and mechanistic data were evaluated, weighed, and categorized. The findings were separated into one of four causality conclusions:

- ☐ Evidence convincingly supports a causal relationship.
- ☐ Evidence favors acceptance of a causal relationship.
- ☐ Evidence is inadequate to accept or reject a causal relationship.
- ☐ Evidence favors rejection of a causal relationship.

Dr. Clayton noted that, in a number of cases, the evidence was inadequate to accept or reject a causal relationship but is suggestive and therefore may indicate a signal that should be pursued. She presented some of the findings, most notably that the evidence favors rejection of a causal relationship between measles/mumps/rubella vaccine (MMR) and autism or type I diabetes. She also pointed out that the evidence favors rejection of a causal relationship between influenza vaccine and Bell's palsy, asthma exacerbation, or reactive airway disease—and one study suggests that influenza vaccine decreases the risk of stroke, myocardial infarction, and all-cause mortality. Dr. Clayton concluded that further scientific evidence will sway the findings toward or away from causation for various vaccines.

Discussion

Dr. Clayton gave examples of the complex interplay of individual genetic makeup, past and present environmental exposures, and intercurrent illness, among other factors, that may result in a window of

susceptibility to adverse effects from vaccine. Better understanding the pathways of these factors may help clinicians develop a workup that identifies who should or should not receive a vaccine at a given time. Dr. Clayton advocated for more research on susceptibility, but such a recommendation is beyond the scope of the IOM Committee, she noted.

Dr. Clayton said the quality and nature of the evidence determines its comparative strength, but in many cases, there are not sufficient data to assess relative risk. She added that the take-home message of the Committee's findings is that "vaccines have amazingly few risks," and many of the risks can be addressed successfully. She noted that the risk posed by vaccine-preventable diseases is far worse than that of the vaccines, adding that she is "not neutral" on the topic. She noted that the IOM is evaluating the ethical feasibility of comparing health outcomes between vaccinated and non-vaccinated children.

Geoffrey Evans, M.D., said Health Resources and Services Administration (HRSA) will review the IOM's findings after they are reviewed by the Immunization Safety Task Force. The Advisory Commission on Childhood Vaccines (ACCV) will review the findings, make recommendations, and request public comment. The VICP will evaluate the findings and incorporate them into its policies. Dr. Evans said the IOM Committee's findings are already being circulated among courts, judges, and others, who can use the information as they see fit.

Vaccine Safety White Paper, Version 3.0—Guthrie S. Birkhead, M.D., M.P.H.

Dr. Birkhead summarized the development of the white paper through several iterations, including a lengthy discussion at the June 2011 NVAC meeting. He said NVAC reached a high degree of agreement on eight of the nine recommendations in the report. Many—but not all—NVAC members agreed that NVAC should continue to serve as the mechanism to provide external assurance of vaccine safety. Dr. Birkhead oversaw revision of the report over the course of the summer and used his judgment to ensure that the report reflects clear direction from NVAC as expressed at the June 2011 meeting. Eight of the nine recommendations were largely unchanged from the previous version. Dr. Birkhead added that the VSWG received the current version at the same time as the NVAC members.

The current version includes an executive summary, a new section on the strengths of the current vaccine safety system, and a new section on the relationship of the recommendations to the National Vaccine Plan. It has been reorganized to combine findings and opportunities for improvement with the correlating recommendations. The order of the sections was revised for clarity. References to the Immunization Safety Task Force now refer more generally to the Task Force "or a similar body" to provide HHS more flexibility. The recommendation regarding external assurance reflects "the strong plurality of opinion" voiced by NVAC members. That recommendation also includes a suggestion that the IOM or a similar body assess progress toward vaccine safety in 3–5 years.

Discussion

NVAC members reviewed and approved with one minor revision a number of editorial changes suggested by the VSWG and presented by Dr. Birkhead.

Recommendation

The Committee unanimously approved the suggested editorial changes described in a motion by the Chair in the written motion, with one revision. In the first suggested change (page 54 and the correlating appendix 13), replace the phrase "provided direction" with the phrase "provided strong support." [See appendix for motion with suggested change]

Dr. Orenstein pointed out that the text supporting Recommendation 9 describes the need to increase funding for vaccine safety, but the recommendation does not clearly state that, at the very least, current funding levels should be maintained. In addition, the report should call for an assessment of current spending. An argument was made that in highlighting the amount spent on clear, discrete vaccine safety efforts, one could dramatically undercount other efforts that are deeply entwined but cannot be assessed independently. NVAC members unanimously approved a motion by Dr. Orenstein adding the following language to Recommendation 9.1:

Recommendation

NVAC recognizes that substantial activities to promote vaccine safety are currently underway. To maintain and enhance the vaccine safety system, NVAC strongly recommends that, at a minimum, budgets for these activities not be reduced. As the Federal budget permits, resources, including fiscal support and staffing, provided to vaccine safety activities should be increased at levels commensurate with the needs and opportunities that exist.

Dr. McCormick proposed strengthening Recommendation 3.4 to specifically recommend that the IOM or similar body undertake a review of progress in implementing the NVAC safety recommendations in 3–5 years. The purpose of an external review is to avoid requiring NVAC to evaluate its own progress. Neither the current recommendation nor the proposed revision would amount to giving another entity oversight of NVAC; rather, the external review would provide an objective assessment of progress toward the established goals. Some discussion centered on a suggestion to establish an external review entity now that would begin planning for a progress review in 3–5 years. By a vote of 14 to 2, a majority of NVAC members approved the motion by Dr. McCormick adding the following language to Recommendation 3.4:

Recommendation

For Assurance and Accountability Recommendation 3.4, replace the sentence, “Consideration should be given to charging another entity, such as the Institute of Medicine (IOM), to undertake a review in 3 to 5 years to assess progress toward vaccine safety system assurance as defined in this report,” with the following:

In addition, another entity, such as the Institute of Medicine (IOM), should be charged to undertake a review in 3 to 5 years to assess progress toward vaccine safety system assurance as defined in this report.

Members agreed that the new executive summary is too long and does not add anything. An abstract identifying key recommendations may be more helpful. NVAC reports are published in the journal *Public Health Reports*, for which an executive summary would be unnecessary.

Action Item

By consensus, the executive summary will be deleted. An abstract in the style of a peer-reviewed journal, giving a general overview of the report, may be added if needed for publication.

Members of the VSWG expressed concern that the timeline for revising the report has been compressed, leaving little time for feedback and debate. Vicky Debold, Ph.D., R.N., noted that the current report does not include a goal related to improving clinical practice or increasing public involvement in vaccine safety activities. Dr. Birkhead acknowledged the accelerated revision process since June but said the

report and recommendations have been under review for many months, and concerns about gaps should have been raised earlier in the process. James O. Mason, M.D., Dr.P.H., noted that the report often identifies actions that “could” be taken; it would be more helpful to identify those actions that rise to the level of need.

Public Comment on the Vaccine Safety White Paper

Claire Dwoskin of the National Vaccine Information Center said she had hoped for the creation of a truly independent body to look at vaccine safety, similar to the Consumer Product Safety Commission or the National Transportation Safety Board (NTSB). She said the current system encourages scientists to arrive at findings that promote vaccines and discourages those who find fault with them. She said there is no mechanism for testing the safety, toxicity, or long-term effects of vaccines in children or other vulnerable populations. As many as 54 percent of children have some chronic condition, said Ms. Dwoskin. Only independent science can help. With the government and industry protecting their own interests, someone needs to protect the children, she said.

Theresa Wrangham of the National Vaccine Information Center said that anything less than establishing an independent group to oversee vaccine safety (proposed by the VSWG at the June 2011 meeting) will not enhance public trust. She felt the public engagement process around the evaluation of the Federal vaccine safety system was lacking. She noted that every member of her family has experienced an unexpected reaction to a vaccine, and because the reactions are unpredictable, her family no longer receives vaccinations. She said her family falls into a special category, and it’s a mistake not to explore that category, as every population merits concern. The law provides for research, said Ms. Wrangham, and no population should be considered collateral damage. She added that of the 185 adverse effects reviewed by the IOM Committee, there was inadequate research to make a recommendation for 85 percent of them. With the research in such a state, she said, the public can’t be asked to trust and acquiesce. Ms. Wrangham called for more open reporting of findings from the Vaccine Adverse Event Reporting System (VAERS). Instead of stating that adverse events are rare, it would be closer to the truth to say that the number of adverse events is still being quantified. She said we are in desperate need of a study comparing the benefits and risks of vaccines.

Angelique Higgins [*spelling uncertain*], a member of the public was concerned that NVAC members were parsing words like “could” and “should” at this stage. She said it seems as though the report is being watered down. She warned that the report could be “another drip of water in a giant tea of inaction.”

Jim Moody from Safe Minds, said he would have liked more time to compare documents. He said NVAC missed an opportunity to support an independent vaccine safety commission. Vaccines are a special category, because they are used to prevent, not treat, disease. It is stated that adverse events are “rare,” although it is not clear how many events equals “rare.” The burden of assessment falls on a small number of people. When you get to showing how vaccines work up front, said Mr. Moody, people will stop taking them. The metrics already tell you that vaccine acceptance is down. He added that the government has had a mandate to study vaccines since 1986. He said NVAC should take the bold step of creating an independent safety commission, because vaccines are important, and what we owe to those who are injured is a high obligation.

Recommendation

By a vote of 15 to 1, a majority of NVAC members approved version 3.0 of the white paper on the United States vaccine system, with the changes noted.

Influenza

HHS Interagency Influenza Task Force, 2011–2012 Influenza Season—LCDR Shary Jones

LCDR Jones explained that the Task Force was formed to promote coordinating efforts across HHS in response to the universal influenza vaccine recommendation. . It addresses short- and long-term policies and programs on seasonal influenza vaccine use. The Task Force aims to reduce barriers, improve access, provide outreach and education, and raise awareness.

The Task Force’s Financing and Billing Working Group is examining barriers and opportunities around vaccine payment. The members of the Working Group met with CDC grantees to discuss third-party billing in public health departments. With the Pharmacists Working Group, the Financing and Billing Working Group is addressing reimbursement issues (e.g., recognizing pharmacists as VFC providers). The Pharmacists Working Group is seeking to improve vaccination rates through partnerships, outreach, and training. They have been great supporters of existing efforts and members have attended several call to action stakeholder meetings with national pharmacy organizations to support increasing vaccination rates, not only with influenza, but all vaccines. The Working Group recently published and soon will disseminate a letter to serve as a resource to pharmacists wishing to work with the underserved/underinsured populations to provide influenza vaccination

Members of the Task Force’s Minority and Underserved Populations Working Group took part in an HHS meeting with stakeholders in Houston, TX. Participants shared best practices for vaccination and key community interventions. The Pregnancy Working Group is planning a conference to assess barriers to increasing vaccination rates among pregnant women. The Employers Working Group reviewed the employers’ toolkit, which helps businesses implement CDC recommendations for promoting healthy workplaces. The Communications Working Group is “the glue of all the working groups,” said LCDR Jones, raising awareness about partnerships and activities. Finally, the Health Care Personnel Working Group held a stakeholders meeting to discuss increasing vaccination rates among long-term care healthcare workers and plans a follow-up meeting to address barriers.

Discussion

NVAC members asked to hear the results of the Health Care Personnel Working Group’s stakeholder meeting, the CDC-HHS National Influenza Vaccination Partnership Stakeholder meeting and any initiatives suggested by the Pregnancy Working Group when available. Jennifer Reid, M.D., said the Pregnancy Working Group is seeking to identify existing interventions and develop new approaches.

Litjen Tan, Ph.D., M.S., noted that 70 million doses of seasonal influenza vaccine are available now, so he hoped communications efforts would promote the effectiveness and availability of the vaccine. He suggested tying outreach to the movie “Contagion” to promote public health efforts. RADM Anne Schuchat, M.D., said CDC will host a press briefing to highlight the availability of vaccine and promote National Influenza Vaccination Week in December to keep awareness about vaccination going. The *Morbidity and Mortality Weekly Report* has been running a series on influenza vaccine coverage among various populations, including health care providers (HCPs), pregnant women, and children. It also describes activities underway and offers a retrospective report on severe pregnancy outcomes. RADM Schuchat said the movie “Contagion” does illustrate the importance of public health infrastructure but also has both positive and negative messages about vaccines.

Adult Immunization Working Group Health Care Personnel Influenza Vaccination Subgroup (HCPIVS)—Christine Nevin-Woods, D.O., M.P.H.

Dr. Nevin-Woods described the Subgroup's charge to develop recommendations to achieve the Healthy People 2020 annual goal of 90-percent influenza vaccine coverage for HCPs, defined as all paid and unpaid persons working in health care settings who have the potential for exposure to infectious materials. The Subgroup conducted a straw poll of its members about potential recommendations [*straw poll results can be found in the slides presented at the meeting*]. There was a near consensus among HCPIVS members polled that health care settings should develop comprehensive influenza vaccination programs for their workers, while a few sought more clarification of terms and context. There was dissent around the use of declination forms and protective masks. While most agreed that workers and managers should be involved in evaluating their organizations' vaccine policy, the burden of additional paperwork was raised.

A number of HCPIVS members polled were not in favor of requiring education of HCPs before issuing a declination form but for differing reasons. Some favored education for all, one disagreed with allowing declination forms, and one questioned the need to provide education for a worker who decides against vaccination. Nearly all agreed that funding for new and improved influenza vaccines should be encouraged and that the Centers for Medicare and Medicaid Services (CMS) and CDC should standardize measurement of HCP influenza vaccine rates. Most agreed that occupational health programs should have more resources to measure and track vaccine rates, although the source of the funding was a concern.

About 70 percent of HCPIVS members polled agreed that, for health care settings that implement a comprehensive vaccination program as recommended but cannot achieve the Healthy People 2020 goal of at least 90-percent coverage, a mandatory vaccination policy should be considered. Others suggested that before mandating vaccination as a condition of employment or credentialing, health care facilities should provide HCPs with more intensive education, evaluate the results of educational efforts, determine and implement best practices, or evaluate program failures. It was also noted that a better vaccine should be available before mandating vaccination. Among those who supported mandatory vaccination, there was a range of opinions about the types of exemptions that should be granted and the use of declination statements. Dr. Nevin-Woods said the HCPIVS will further discuss options for recognizing and addressing the concerns of the minority in its report. It will also discuss when and whether to engage stakeholders.

Discussion

Dr. Nevin-Woods said the HCPIVS is discussing the notion of limiting contact with high-risk patients by those who decline vaccination, but she said it is difficult to determine with certainty which patients are truly at low risk. If a minority report of HCPIVS is issued, attention should be given to setting a date for revisiting the recommendations. Thomas E. Stenvig, R.N., hoped liaison representatives to the HCPIVS would go beyond commenting and begin creating coalitions and seeking resources to meet vaccination goals. He also called for more review of the consequences of mandatory vaccination policies as a condition of employment. Dr. Nevin-Woods said there are complex legal and liability issues on both sides of the mandatory vaccination debate. She said the Subgroup poll was anonymous but she would try to provide the results by sector without revealing the respondents' identity.

Action Item

The HCPIVS will determine whether the results of its member poll can be analyzed to be presented by sector (e.g. public health, academia, industry, etc.) without compromising the anonymity of the respondents.

Dr. Nevin-Woods agreed the HCPIVS would explore whether organizations that mandate vaccination but allow more exemptions have better uptake than those that limit exemptions. The HCPIVS has discussed positive incentives for vaccination.

Some members felt that a mandatory vaccination policy is appropriate if an organization has implemented a comprehensive program that ensures education, outreach, and accessibility (including free vaccine and time off during the work day for getting vaccinated). Others felt that instead of mandating vaccination, facilities should better explore the reasons for refusal. There was discussion about the ethical obligation to be vaccinated to protect patients. Wayne Rawlins, M.D., M.B.A., noted that the issue pits personal freedom against patient safety, and both are important. Clem Lewin, Ph.D., M.B.A., added that it is reasonable to recommend that HCPs err on the side of safety. Jose Romero, M.D., pointed out that some HCPs refuse vaccination because they simply do not like being told what to do. Dr. Tan said that when vaccination is framed as an ethical obligation to protect patients, uptake by HCPs is high. Several members noted that an organization should be able to require vaccination as a condition of employment in the name of patient safety, but others added that collective bargaining agreements can complicate the matter. Lisa Jackson, M.D., M.P.H., added that heavy-handed mandates may not be worth the marginal benefits; she pointed out that influenza vaccine does not always work and that HCPs are not required to wear masks in every case of potential exposure to pathogens. Several members hoped a recommendation would stress that influenza vaccination “is the right thing to do.”

Deborah Wexler, M.D., of the Immunization Action Coalition said her organization has compiled an “honor roll for patient safety” of more than 100 medical settings that mandate influenza vaccination (mostly hospitals). She also noted numerous professional societies that favor mandatory vaccination of HCPs. Mandatory vaccination is not novel, said Dr. Wexler, it’s happening now and it’s all about protecting patients from infection. Dr. Nevin-Woods added that the American Medical Association (AMA) supports mandatory HCP vaccination.

William Borwegen of the Service Employees International Union asked that NVAC think carefully about requiring comprehensive education; such education is not happening now where it is required. Instead, workers sometimes get wrong information or insufficient information, and there are numerous racial and cultural barriers. He said the influenza vaccine is among the least-effective vaccines, and no one has evaluated the evidence on the effectiveness of masks, which are usually used punitively for those who refuse vaccination. As the recent Republican presidential candidate debates demonstrated, mandating vaccination can cause a backlash, said Mr. Borwegen. A statement with a position from the Occupational Safety and Health Administration (OSHA) on mandatory influenza vaccination for HCPs offers a very articulate explanation of why influenza vaccine is different from other vaccines, he said (*see Minutes Appendix B*). The New York Civil Liberties Union also makes a good case for abeyance. Mr. Borwegen asked for more consideration of the legal and ethical issues involved, noting that many other issues should be more fully evaluated before rushing in to a recommendation for mandatory vaccination. He said that if education is mandated, it should be at least as effective as the current mandate by OSHA for education about hepatitis B vaccination. Finally, he noted that the list of professional organizations that do not support mandatory vaccination is at least as long as the Immunization Action Organization’s honor roll.

Dr. Tan clarified that AMA’s ethical position is that HCPs have an ethical obligation to be vaccinated and should have either a medical or philosophical reason for refusal. The AMA’s policy position supports universal, routine vaccination for HCPs and leaves it up to facilities to develop processes to achieve that goal. Katherine Brewer, a representative of the American Nurses Association clarified that her organization supports mandatory HCP vaccination to be required at the State, instead of health care facility, level. Amy Pisani, M.S., wondered whether patients have a right to decline care from an HCP that has not been vaccinated.

Dr. Birkhead asked whether the breadth of stakeholder representation on the HCPIVS is sufficient to gather stakeholder input. Dr. Nevin-Woods noted that the HCPIVS has had numerous presentations and discussions about ethical and legal issues. Dr. Gellin wondered how the ASH could assist in implementing the recommendations of the Subgroup and how they intersect with the work of groups such as the AMA's Health Care Professionals Advisory Committee. In developing its recommendations and report, the HCPIVS will consider identifying operational steps that the ASH can take to implement the recommendations, particularly those outside the traditional purview of HHS.

Agency, Department, Advisory Committee, and Liaison Reports

VRBPAC—Jose Romero, M.D.

Dr. Romero said VRBPAC will meet later in September to hear an overview of the research program in the Laboratory of Enteric and Sexually Transmitted Diseases of FDA's Center for Biologics Evaluation and Research (CBER).

AIM—Claire Hannan, M.P.H.

Ms. Hannan said immunization programs are receiving notice of awards under the Prevention and Public Health Fund for immunization cooperative agreements. The program areas funded include enhancing immunization information registries (by improving electronic health record [EHR] interoperability and use of the CDC's Vaccine Tracking System [VTrckS]) and enhancing billing (including creating an area for adult vaccination in school-located vaccine clinics). AIM will facilitate sharing information and best practices among grantees. Ms. Hannan said the awards are particularly good news in the face of tight budgets.

IHS—RADM Richard Church, Pharm.D.

Dr. Church said IHS is working with NVPO to coordinate stakeholder meetings, such as a meeting in Alaska with the National Indian Health Board and an upcoming listening conference in Kansas in November. Also, IHS is surveying Federal and Tribal programs to identify how adult immunization is provided in those settings. It is looking at barriers to adult vaccination and the role that pharmacists can play in adult vaccination.

DoD—COL Scott A. Stanek, D.O., M.P.H.

COL Stanek said DoD is starting influenza immunization efforts early for its forces and their beneficiaries. He noted that it is always hard to reach those in medical treatment facilities, but the process is working well so far.

NIH—Barbara Mulach, Ph.D.

Dr. Mulach said NIH has a vaccine safety program that offers an opportunity for investigators to propose research on biological mechanisms and other core activities to understand vaccine-related adverse events and key mechanisms of vaccines. The program was to expire in September 2011 but has been extended to January 2012 and may be further extended. Dr. Mulach said it has taken a while for the research community to become aware of this mechanism to fund research on adverse events following vaccination, but now that the word is out, more potential applicants are expressing interest. She added that the program came about from discussions of the Immunization Safety Task Force.

CDC—RADM Anne Schuchat, M.D.

RADM Schuchat said 2011 has been a record year in the United States for measles, with over 200 cases, more than any year since 1996 (including the 2008 outbreak). She said the disease seems to be a result of importation and not outbreaks or extended spreading. Europe is also having a record year for measles

(e.g., France has 4,000 cases). The United States is trying to prevent re-establishment of measles transmission.

The Pan American Health Organization is organizing an update of the certification of measles and rubella elimination. The United States will look critically at the work done 10 years ago to ensure that it maintains its elimination status and will submit a report at the end of December. RADM Schuchat said that CDC recently launched its second 10-year partnership with the Red Cross, the World Health Organization, and UNICEF on the Measles Initiative to reduce measles mortality around the world. The effort made enormous progress in its first 10 years, she said, with 4.3 million lives saved. Challenges remain with outbreaks in Africa and elsewhere, but the global community is tackling them, said RADM Schuchat.

FDA—Valerie Marshall, M.P.H.

Ms. Marshall noted that seasonal influenza vaccine lots were approved by FDA and are now available. In mid-September, FDA is cosponsoring an international seminar on allergenic products. Also in mid-September, CBER and the National Institute of Allergy and Infectious Diseases are cosponsoring a public workshop on the development and evaluation of next-generation smallpox vaccines, covering such topics as who responds to vaccine and animal models to demonstrate effectiveness. VRBPAC will meet on November 16 for an update on the evaluation of Guillain-Barré syndrome after influenza vaccination in the Medicare population and to discuss the safety and immunogenicity of pneumococcal 13-valent conjugate vaccine in adults 50 years and older using an accelerated approval regulatory pathway.

VICP—Geoffrey Evans, M.D.

Dr. Evans said HRSA published a final rule this summer to move four vaccines on the Vaccine Injury Table into their own boxes on the table to clarify that injuries related to those vaccines are covered under VICP. At the moment, the boxes indicating the associated adverse events and time intervals are blank for those four vaccines. The new Vaccine Injury Table went into effect July 22, 2011. The ACCV met in September and reviewed the report of the IOM Committee on adverse events.

Action Item

Dr. Evans will present an overview of the VICP at the June 2012 NVAC meeting along with any new proposals from ACCV.

VA—Richard Martinello, M.D.

Dr. Martinello reported that about 5-percent fewer women than men are getting the influenza vaccine, and the VA is trying to address that disparity. It is seeking to ensure that pregnant women get vaccinated; the Women Veterans Health Strategic Health Care Group is reaching out to minimize gaps. During the 2009 H1N1 pandemic, the VA was tasked with providing H1N1 vaccine to non-VA Federal staff, but it was limited by its inability to upload outside information into the VA EHR system. Dr. Martinello said the VA now has that ability, which will help in mass vaccination settings. The VA is also collaborating with DoD on an integrated EHR that would support a comprehensive vaccination system.

Action Item

At the February 2012 NVAC meeting, Dr. Martinello, Veterans Affairs, will provide an update on expanding the capacity of its EHR system.

NACCHO—Anne Bailowitz, M.D., M.P.H.

Dr. Bailowitz said NACCHO published a paper on the impact of the recession on local health departments, focusing specifically on job losses

(<http://naccho.org/topics/infrastructure/lhdbudget/index.cfm>). It draws on a survey of more than 2,500 local health departments, of which NACCHO looked closely at 440. From 2008 to 2010, there were 29,000 fewer jobs in local health departments (resulting from both job loss and attrition)—a reduction of about one fifth of the workforce. Dr. Bailowitz said that three quarters of the U.S. population lives in jurisdictions with local health departments that are losing workers. Health departments in the largest areas have been hit the hardest. Wage freezes, furloughs, and increased costs, among other factors, hamper the ability of health departments to recruit staff. Health departments now employ more licensed practical nurses than registered nurses and fewer registered dietitians. Recruitment of physicians is poor. The salaries offered by local health departments limit their ability to recruit staff.

In addition to staffing, Dr. Bailowitz continued, from 2008 to 2010, more than half of local health departments cut programs, most often maternal and child health programs. Only about 8 percent of local health departments cut immunization programs. The City of Baltimore, Dr. Bailowitz noted, has felt a significant impact from the recession on its immunization program. The city's health department staff has dropped by about 57 percent. The budget has been stable, but increasing costs, inflation, etc., have led to a loss of part-time workers. The immunization program in the city is holding, but Dr. Bailowitz was not sure how much longer it could maintain its current status.

ASTHO—Kathy Talkington, M.P.A

Ms. Talkington reported that ASTHO had about 30 new members, and the organization is bringing those members up to speed on immunization and other issues. ASTHO is involved in the CDC's third-party billing project with pharmacists and with NVPO on the rollout of the National Vaccine Plan.

Public Comment

Diane Matthew Brown of the American Federation of State, County, and Municipal Employees said, regarding mandatory influenza vaccination in health settings, that she works with HCPs at all levels and in home health care. She said there is a big gap in the education component that has to do with staffing and timing of education, and NVAC did not touch on that influence. Also, she noted that leave policies may not permit an employee who has a poor reaction to the vaccine to take time off without fear of being disciplined, fired, or suspended. No one wants to work a 12-hour shift when they are feeling poorly, said Ms. Brown, and that's a huge influence on people getting shots—they know they can't take a day off. She said such things do happen, especially among non-unionized workers. Also, many home health care workers are not paid well and do not get free vaccine. Ms. Brown said her organization surveyed home health care workers, and most said they do not have enough time to get vaccinated or couldn't afford it or both. Those who did get vaccinated received the vaccine at a pharmacy, not from a doctor. A mandate will not work with home health care workers at all, said Ms. Brown.

In addition, Ms. Brown said, infection control is multi-faceted. Employers who institute mandatory vaccination may fall down on other infection control efforts when money is tight. She said staff will be pushed to the edge as employers cut back on time for education programs and time to get vaccinated. Ms. Brown said she participated in a hearing in Iowa involving unions pushing back against mandatory vaccination policies. In that hearing, she said, her organization showed that mandatory programs are not necessary, because voluntary programs achieved high rates. Most people wanted to get vaccinated; only a few did not want to (and they distrusted vaccines in general). Ms. Brown noted that that people don't trust vaccines based either on experience or publicity.

Mr. Jim Moody, from Safe Minds called Dr. Clayton (who gave the IOM Committee report) "a cheerleader for vaccines." He said the work is not finished until every injured child and adult gets appropriate compensation. The IOM report was very helpful in discussing studies explicitly and being honest about the lack of evidence—that is, how little we know about human immune response to vaccine

and the relation to adverse events, as well as the growing importance of understanding susceptibility. However, the report could have been better. It could have endorsed research to gather baseline data, which Mr. Moody said was Congress' original intention. The report could have better discussed the importance of developing animal models; papers published so far show differences between vaccinated and unvaccinated primates, said Mr. Moody. It also could have discussed developments in the scientific literature on the relationship between mercury and autism. It could have included more discussion of autism cases. Mr. Moody said it is not enough to note the absence or weak quality of evidence. The government has an obligation to ensure safe vaccines. NVAC did a good thing by identifying a gap in the scientific literature, Mr. Moody said, and he hoped the IOM report would lead to research comparing vaccinated and unvaccinated children.

Day 2—September 14, 2011

National Vaccine Plan

National Vaccine Plan Implementation—Lauren Wu, NVPO

Ms. Wu reiterated the rationale for updating the National Vaccine Plan. In consultation with NVAC, the IOM, and others, NVPO developed a list of priorities for implementing the objectives and strategies described in the Plan. Many efforts are already underway toward implementation, such as the establishment of the IOM Committee on Identifying and Prioritizing New Preventive Vaccines for Development; the launch of Vaccines.gov, a consumer portal to Federal information; new public financing and reimbursement requirements; and recent initiatives to promote adult immunization and engage more pharmacists in immunization.

The NVPO Implementation Plan for the National Vaccine Plan is being developed around the 10 identified priorities with input from stakeholders and partners at the regional and national level. NVPO will develop indicators to measure progress. NVPO began stakeholder engagement efforts in late summer that continue through fall 2011 and target community- and faith-based organizations, regional and local public health entities, and topically oriented groups. The stakeholder meetings will take place around the country and revolve around themes, such as health information technology (HIT, Ann Arbor, MI), health in border States (San Diego, CA, and Brownsville, TX), and health care among American Indians/Alaskan Natives (Anchorage, AK). For each meeting, national and regional partners such as ASTHO, regional health administrators, area academic institutions, and State public health departments are working with NVPO to identify stakeholders and spread the word. Through the meetings, NVPO hopes to gather input on how to measure progress and share information, how partners can help achieve the National Vaccine Plan goals, and how to address barriers. A summary of the findings from all the stakeholder meetings will be compiled and made available to all partners.

Ms. Wu explained that the Implementation Plan will incorporate findings from stakeholder engagement and will be updated periodically. NVPO plans to provide an annual report on implementation and to conduct a mid-course review in 2015 with NVAC.

Discussion

Ms. Wu stressed that the IOM Committee is just one of several Federal entities focused on research and development of new and improved vaccines. CAPT Angela Shen of NVPO added that IOM has lots of stakeholder input that will feed into the Implementation Plan. Dr. Gellin noted that the Decade of Vaccines initiative coincides with the publication of the National Vaccine Plan. Susan McKinney applauded NVAC and NVPO for ensuring that international vaccine efforts are incorporated into the decision-making.

Action Items

A future NVAC meeting will include a presentation on the progress of the Gates Foundation's Decade of Vaccines initiative.

At a future NVAC meeting, NVPO staff will summarize the findings of the stakeholder engagement meetings around the National Vaccine Plan Implementation Plan.

Healthy People 2020 and Immunization Goals—RADM Anne Schuchat, CDC

RADM Schuchat gave an update on the impact of vaccines on disease, noting, for example, a 90-percent decline in hepatitis A and varicella since the 1990s and a 100-percent decline in the seven types of disease targeted by the pneumococcal conjugate vaccine. Hepatitis B rates (designated a priority by the ASH) continue to decline, and hepatitis A is close to elimination. In most cases, vaccine coverage has surpassed Healthy People 2020 goals, said RADM Schuchat. CDC is moving to a new tracking approach that uses Internet panels to gather data rapidly for selective populations receiving influenza vaccination. Internet panel data suggest that half of pregnant women received the influenza vaccine in the 2010–2011 season. The Internet panel data also suggests the rate of HCPs getting the influenza vaccine is increasing.

Adolescent vaccine coverage is increasing for some vaccines, but RADM Schuchat called the plateau in human papillomavirus (HPV) vaccine uptake “pathetic.” RADM Schuchat said providers are uncomfortable counseling about HPV vaccine, even when parents raise the issue, and data show that providers miss the opportunity to provide HPV vaccine when adolescents are getting other vaccines. About half the parents of unvaccinated girls have no intention of requesting HPV vaccine for their adolescent girls—not because of safety concerns but because they don't see it as necessary for girls who are not sexually active. Moreover, without a strong provider recommendation or a school mandate, parents do not see the need for the vaccine. To complicate matters, the three-dose series is difficult to complete among adolescents, who have fewer visits to health care providers than infants and small children.

Provider recommendation is critical in the decision to vaccinate, said RADM Schuchat. Despite the good track record of safety with the 35 million doses distributed, attitudes about HPV vaccine are not changing. Among unvaccinated females, higher-income parents are more likely to have intentions to vaccinate their daughter in the next 12 months, although CDC offers free vaccine for uninsured patients. RADM Schuchat emphasized the need to improve communication about the vaccine—particularly the importance of vaccinating before a girl is sexually active. More education of providers may lead to stronger provider recommendations; RADM Schuchat recommended resources to help providers talk with parents about vaccinating adolescent girls. She said techniques that work for younger children can be used for adolescents, such as standing orders, electronic reminders, and avoiding missed opportunities. In 2012, a new Healthcare Effectiveness Data and Information Set (HEDIS) measure will go into effect for adolescent vaccines that includes completion of the three-dose HPV regimen by age 13. Finally working with schools, Federally qualified health centers (FQHCs), and pharmacists to promote HPV vaccine may help. CDC has updated and published new information on HPV vaccine and is using trusted channels to spread the word; it also has some funding to address barriers. Coverage for HPV vaccine is off track to reach the Healthy People 2020 objective, RADM Schuchat concluded, and NVAC input is needed.

Discussion

Asked about data on the effectiveness of HPV vaccine over time, RADM Schuchat noted that current data from studies that followed women for about 9 years does not suggest waning protection, also vaccinating at ages 11–12 years elicits a higher antibody response than later vaccination, and susceptibility to HPV is higher among younger people. Providers should be aware that the vaccine is not effective after infection, and the longer one waits to vaccinate, the higher the chances of exposure to HPV. It was suggested that

CDC revisit the lessons learned from recommending hepatitis B vaccination for infants rather than adolescents. RADM Schuchat noted that assessing vaccination coverage levels at the provider level and sharing vaccination rates among other area health care providers often spurs a healthy competition. It was suggested that providers also be made aware of the average age of initiation of sexual activity in their communities to aid in counseling parents. School-based health centers represent a very good opportunity to improve vaccination rates in adolescents. An NVAC member suggested that offering HPV vaccine to both boys and girls should be helpful in increasing uptake. Education and information should emphasize cancer prevention and public health to minimize the focus on sexual issues.

In addition to the low rates of initiation of HPV vaccine, it was noted that completion of the three-dose regimen is also poor. RADM Schuchat noted that minorities are less likely to complete the regimen than whites. Because the Vaccines for Children (VFC) program covers HPV vaccine, cost should not be a reason for failing to complete the regimen, she added. Some coalitions are forming to advocate for HPV vaccine, and parents are aware of it from the direct marketing campaigns. It may be appropriate to target messages to kids, because young teens should be encouraged to start taking control of their own health. CDC has some money to fund social media outreach efforts to teens and has done so before (e.g., for meningitis). Text messaging and Facebook works well in some settings, as does facilitating vaccination in the emergency department. Local health departments are also a good resource for families seeking vaccination.

The FDA-approved indication for HPV vaccine allows for initiation as young as 9 years, however the Advisory Committee for Immunization Practices (ACIP) recommends vaccination at ages 11-12 years because of other vaccines are recommended at this age and children see their health care providers less after age 11-12 years. But experience with other vaccines indicates that adolescent immunization rates are getting better. RADM Schuchat said that HPV vaccination rates in the United Kingdom are very high, thanks in part to a lot of education and the backing of champions for vaccination.

Action Item

NVAC members are encouraged to view the materials about HPV vaccine at the CDC website, <http://www.cdc.gov/vaccines/who/teens>, particularly the video on counseling by the Society for Adolescent Health and Medicine. (available at <http://www.mycme.com/hpv-vaccine-visit-cases/section/2291/>)

Vaccine Financing Coordination

Overview—CAPT Angela Shen, NVPO

CAPT Shen summarized NVAC's history addressing vaccine financing, including the recommendations published in 2009. The following updates highlight efforts to implement those recommendations.

Third-Party Billing Project—Lance Rodewald, M.D., CDC

The vaccine finance recommendations suggested that States and localities should develop mechanisms for billing insured children and adolescents who receive vaccines from public health providers. Dr. Rodewald summarized the arguments in favor of third-party billing. He noted that the cost of vaccines has increased sharply, decreasing the purchasing power of Section 317 funding. The American Recovery and Reinvestment Act provided \$6.4 million to fund the billables project—an effort to help public health providers in 14 States determine how to bill private insurers and assess the effects.

The billables project revealed some barriers. Public health providers must be deemed in-network providers by the insurer to be reimbursed for care. Providers must be credentialed, and some may not be eligible. Public health providers can't use VFC funds to "prime the pump"—that is, to purchase vaccine

for private patients. Public health clinics find it challenging to determine a patient's health plan eligibility at the point of service. State and local laws and policies may help or hinder implementation of third-party billing.

In July 2011, representatives from NVPO, ASTHO, NACCHO, AIM, AHIP, CDC, CMS, and the American Pharmacists Association (APhA) met to discuss challenges. The meeting revealed broad support for deeming health department clinics as in-network providers and yielded creative ideas to achieve in-network status. Participants discussed current and future HIT solutions to determine patient eligibility. They recognized that pharmacists face similar challenges in third-party billing. Participants also committed to take advantage of AHIP and other communication networks to share effective billing practices.

Final plans for billing programs are due this year from the initial 14 grantees, and NACCHO is facilitating the creation of toolkits to aid with development, training, and technical assistance for billing programs. Funds from ACA and the Prevention and Public Health Fund will support additional grantees. Dr. Rodewald cited numerous successes already in several States. He hoped NVAC and others would urge those who fund public health programs to ensure that savings realized as a result of third-party billing be reinvested in public health, which was the intention of the NVAC recommendation.

Dr. Rawlins emphasized that insurers are committed to vaccination and recognize their obligation to pay for services delivered to their beneficiaries. He noted that the meeting in July was positive and focused on optimizing the system. Ms. Talkington said interest in the project is high, but implementation is not easy, because insurers and public health providers use different terminology and have different ways of thinking. At the July meeting, the suggestion was raised to develop model contract language that local health departments could adapt for negotiating with insurers. Paul Etkind of NACCHO said the project is exciting because it represents a change of culture and because it has already been successful in some areas. He noted that collaboration between insurers and others is important for maintaining the health care system.

Future of the Section 317 Program—Melinda Wharton, M.D., M.P.H., CDC

Dr. Wharton explained that Section 317 and the VFC program help the uninsured and the underinsured for whom out-of-pocket costs are a barrier. Section 317 money provides the critical infrastructure to support vaccine operations, including quality assurance, data gathering, surveillance, and vaccine safety efforts. While VFC funding has increased along with the number of recommended vaccines, Section 317 funding has remained flat, despite the growing needs of a more complex vaccine delivery enterprise. Dr. Wharton noted that a very small portion of Section 317 funding is intended to support adult immunization.

Dr. Wharton and others anticipate that ACA will address the cost of vaccines for the underinsured (if fully implemented). However, there is great pressure to decrease Federal spending and a perception that Section 317 funds will no longer be needed. Dr. Wharton pointed out that after ACA is implemented, Section 317 funding could be used to reach more uninsured adults, improve the ability of public health providers to respond to outbreaks, and maintain operations funding.

In the future, VFC will continue to provide vaccines for uninsured children, while Section 317 could help meet the immunization needs of uninsured adults. Continued partnerships with retail stores, pharmacists, employers, FQHCs, and hospitals will help provide access to recommended vaccines for adults. Public health venues could provide vaccines to other uninsured adults through sexually transmitted disease clinics and substance abuse programs. Meanwhile, the Prevention and Public Health Fund is intended to

strengthen the infrastructure and operations of public health providers by supporting mechanisms for third-party billing, improved HIT, more efficient vaccine ordering systems (VTrckS), better adult immunization programs, and more school-based immunization. Some funding will support evaluation to strengthen the evidence base. The success of vaccine efforts relies on the availability of in-network providers to serve insured patients, adequate reimbursement rates for providers, and the ability of public health providers to bill private insurers. Dr. Wharton said implementation of ACA remains uncertain, as do the reimbursement rates from private insurers.

HRSA's Community Health Centers and Immunization—Matt Burke, M.D., HRSA

Dr. Burke outlined how FQHCs work, noting that sites are not Federal operations but rather non-profit community health centers that meet eligibility requirements for Federal funding. They must be located in designated health professional shortage areas and medically underserved areas. They receive only about 17 percent of their funding from Federal grants; the rest comes from Medicaid or Medicare and philanthropic and private sources. In 2010, community health centers served 19.5 million unique patients, said Dr. Burke, 93 percent of whom earned less than 200 percent of the Federal poverty level, and one third of whom were under age 18. Mandatory annual reporting shows that community health centers are on par with the national average for vaccine coverage at 74 percent. HRSA is pushing FQHCs to adopt HIT and the patient-centered medical home model of care to improve the delivery and quality of care over time, said Dr. Burke.

The Federal government's meaningful use measures for immunization differ from National Quality Forum measures and Healthy People 2020 indicators; HRSA grantees use the Uniform Data System to gather information for evaluation. HRSA is considering the interaction of all these systems. HRSA also provides technical assistance and education through webinars, cooperative agreements with national associations, and State-level mechanisms. Dr. Burke said millions of dollars have been allocated to FQHCs to expand school-based health care. Other efforts focus on coordinating and exchanging data and improving interoperability of HIT across systems and jurisdictions. Better HIT will allow providers to follow patients over time so they avoid providing redundant services and can better meet patient needs.

Discussion

Dr. Wharton said no one has estimated how many people would not purchase insurance despite the ACA mandate, although many expect it to be a small number. The CDC billables project may provide some insight on the number of undocumented people who seek care, which may help identify the number of people who would not purchase health insurance once ACA is fully implemented. Dr. Wharton reiterated the concern about the assumption that Section 317 dollars will no longer be needed once ACA is fully implemented. It was noted that a proposed decrease in Section 317 funding for 2012 would be offset by the Prevention and Public Health Fund. Ms. Pisani pointed out that the 317 Coalition provides detailed budget information on its website.

Dr. Nevin-Woods said some families prefer public health departments for vaccination because the health departments are efficient and provide good care and documentation. Phil Hosbach of Sanofi-Pasteur said third-party billing has been shown to save money for public health providers, and he urged NVAC to recommend that money saved be reinvested in public health operations. Dr. Lewin added that the increasing number of new recommended vaccines is driving up the cost of operations. Dr. Tan strongly supported the need to maintain Section 317 funding to support the underinsured.

Action Item

NVAC members will draft a recommendation that Section 317 funds that are freed up as a result of the CDC's billables project should be repurposed for public health operations. A draft recommendation will be presented at the February 2012 meeting. Dr. Birkhead will incorporate the

sentiment into his letter to the ASH. Drs. Tan and Lewin may be able to provide draft language for the recommendation.

Dr. Lewin recommended further partnership with retail pharmacies to promote vaccination. Dr. Rodewald noted pharmacists face some of the same barriers as school-based and other clinics, such as the difficulty of distinguishing VFC-eligible from privately insured patients.

Responding to questions about the status of previous NVAC recommendations on the policy implications of ACA, Ms. Talkington said ASTHO has a working group that is addressing vaccine administration reimbursement rates under Medicare and Medicaid for 2013 and 2014, and CAPT Shen said NVPO is working on the reimbursement issue through interagency meetings. Dr. Birkhead added that there will be more discussion with the new NVAC chair about reconstituting the Vaccine Finance Working Group to address such issues. Dr. Mason emphasized the importance of better communicating the cost benefit of vaccines and preventive services in general.

Role of Pharmacists in Adult Vaccination: APhA—Mitch Rothholtz, R.Ph., M.B.A.

Mr. Rothholtz said that in 2010, 20 percent of adult vaccinations were administered by a pharmacist. Most of the 150,000 U.S. pharmacists who are trained to provide vaccination were educated through an APhA program, he said. Pharmacies offer convenient access and can target patients (e.g., those with chronic conditions) who would benefit from vaccines. APhA offers guidelines for pharmacy-based immunization programs. It supports coordinated, integrated care for patients. APhA also supports annual influenza vaccination as a condition of employment, training, or volunteering in an organization that provides pharmaceutical services. The H1N1 pandemic was an example of how pharmacists partnered with public health providers to build a framework for community vaccination.

Pharmacists have the authority to administer vaccines in all 50 States, but the scope of that authority varies in each State, and State laws change rapidly. Pharmacists follow the same standards as other clinicians working in the same community. Thirty-eight States allow pharmacists to administer any type of vaccine, and 14 States allow them to administer vaccine to people of all ages. Mr. Rothholtz hoped that pharmacists could collaborate with clinicians to ensure that girls complete the three-dose HPV vaccine regimen. He said such collaboration would require a compensation agreement and recognition from the physician community that pharmacists can complete the regimen.

APhA took part in the July 2011 meeting about the CDC billables project and determined that pharmacists and health departments face many similar challenges, such as the need to be designated as an in-network provider. Efforts are underway to improve access for pharmacists to immunization registries. The VFC program recently clarified that pharmacists can serve as VFC providers to adolescent patients (where allowed by States). Mr. Rothholtz concluded that pharmacists want to use their access, knowledge, and skills to help meet public health goals. Ultimately, pharmacists will have access to EHRs to support better documentation and improve patient care.

Discussion

Dr. Birkhead noted that New York was among the last States to grant pharmacists authority to immunize patients but found pharmacies very valuable during the H1N1 pandemic. He noted that New York pharmacists are required to have standing orders from a physician within the same county, which can be a barrier. In response to a question, Mr. Rothholtz said that even those patients who get medications for chronic conditions by mail (about 20 percent) still come to the pharmacy for over-the-counter or other prescription medications. Mr. Rothholtz said pharmacists offer immunizations in retail settings, hospitals,

clinics, and long-term care settings. In some areas, they lead employee immunization efforts or head vaccine clinics.

Mr. Rothholtz emphasized that pharmacists receive the same training as physicians and other clinicians in dealing with complications of vaccinations. It was noted that some retail settings project a casual attitude toward vaccines that does not comport with the serious nature of adverse events. Mr. Rothholtz responded that, as a result of public education, more people are getting vaccinated at pharmacies and clinicians' offices. While no surveys have addressed the issue, Mr. Rothholtz said, pharmacists have a good track record of reporting to patients' primary care providers.

Remarks of the ASH—Howard Koh, M.D., M.P.H., ASH

Dr. Koh thanked the NVAC members for their contributions and remarked on the extraordinary progress the Committee has made. He offered special thanks to Dr. Birkhead, calling him "a public health leader and hero in many ways" and a "tremendous public servant." Dr. Koh summarized some of the accomplishments supported by NVAC since he joined HHS. With Dr. Birkhead's oversight, he said, NVAC has enhanced public engagement and spurred forward efforts to improve vaccine safety and HCP vaccination rates. Dr. Koh presented Dr. Birkhead with a plaque thanking him for his many years of distinguished service as both a member and chair of NVAC. Dr. Koh also announced that Dr. Orenstein would take over as NVAC chair.

Dr. Birkhead said it had been his honor and privilege to serve as chair and recognized the hard work of the members of the Committee, Dr. Gellin, and the NVPO staff. He said he was pleased to see how NVAC recommendations have had real impact, such as the vaccine finance recommendations, and he hoped NVAC and NVPO would continue to ensure that stakeholders are represented. Finally, he thanked Dr. Koh for his engagement with NVAC. Dr. Orenstein remarked that he had very big shoes to fill, but he was honored to be returning to NVAC.

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 1:45 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*

*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)
September 13–14, 2011
Summary of Action Items and Recommendations**

Administrative Issues

Action Item

NVAC unanimously approved the June 2011 minutes as written.

National Prevention Strategy

Action Item

NVAC members should read the National Prevention Strategy and provide comment.

Vaccine Safety White Paper, Version 3.0

Recommendation

NVAC approved version 3.0 of the white paper on the United States vaccine system, with the following changes.

Incorporate the suggested editorial changes described by the Chair in the written motion, with one revision. In the first suggested change (page 54 and the correlating appendix 13), replace the phrase “provided direction” with the phrase “provided strong support.”

Add the following language to Recommendation 9.1:

NVAC recognizes that substantial activities to promote vaccine safety are currently underway. To maintain and enhance the vaccine safety system, NVAC strongly recommends that, at a minimum, budgets for these activities not be reduced. As the Federal budget permits, resources, including fiscal support and staffing, provided to vaccine safety activities should be increased at levels commensurate with the needs and opportunities that exist.

For Assurance and Accountability Recommendation 3.4, replace the sentence, “Consideration should be given to charging another entity, such as the Institute of Medicine (IOM), to undertake a review in 3 to 5 years to assess progress toward vaccine safety system assurance as defined in this report,” with the following:

In addition, another entity, such as the Institute of Medicine (IOM), should be charged to undertake a review in 3 to 5 years to assess progress toward vaccine safety system assurance as defined in this report.

Delete the executive summary. An abstract in the style of a peer-reviewed journal, giving a general overview of the report, may be added if needed for publication.

AIWG Health Care Providers Influenza Vaccination Subgroup (HCPIVS)

Action Items

The HCPIVS will determine whether the results of its member poll can be analyzed to be presented by sector (e.g. public health, academia, industry, etc.) without compromising the anonymity of the respondents.

Agency, Department, Advisory Committee, and Liaison Reports

Action Items

Dr. Evans will present an overview of the Vaccine Injury Compensation Program at the June 2012 NVAC meeting along with any new proposals from the Advisory Commission on Childhood Vaccines.

At the February 2012 NVAC meeting, Dr. Martinello, Veterans Affairs, will provide an update on expanding the capacity of its electronic health record system.

National Vaccine Plan Implementation

Action Items

A future NVAC meeting will include a presentation on the progress of the Gates Foundation's Decade of Vaccines initiative.

At a future NVAC meeting, National Vaccine Program Office staff will summarize the findings of the stakeholder engagement meetings around the National Vaccine Plan Implementation Plan.

Healthy People 2020 and Immunization Goals

Action Item

NVAC members are encouraged to view the materials about HPV vaccine at the CDC website, <http://www.cdc.gov/vaccines/who/teens>, particularly the video on counseling by the Society for Adolescent Health and Medicine. (available at: <http://www.mycme.com/hpv-vaccine-visit-cases/section/2291/>)

Vaccine Financing Coordination

Action Item

NVAC members will draft a recommendation that Section 317 funds that are freed up as a result of the CDC's billables project should be repurposed for public health operations. A draft recommendation will be presented at the February 2012 meeting. Dr. Birkhead will incorporate the sentiment into his letter to the ASH. Drs. Tan and Lewin may be able to provide draft language for the recommendation.

APPENDIX A: Editorial motion to append Vaccine Safety White Paper

A Motion:

Edits recommended by the Chair for the NVAC Vaccine Safety White Paper, version 3.0.

1. Clarify that NVAC chose Assurance Option 1 at its June 14 meeting.

Page 54, Lines 12-15

“...Despite extensive efforts by its members to debate and discuss the options over a period of many months, the VSWG was not able to come to a consensus on the preferred assurance option prior to the June 2011 NVAC meeting where the White Paper recommendations were discussed in detail. At this meeting, the NVAC reviewed the options developed by the VSWG and provided strong support for Option 1: NVAC should continue to be the advisory entity primarily responsible for evaluating the NVP programs.

Appendix 13 - Page 118, Lines 12-14

“Three options were developed by the VSWG ~~discussed~~ for external, independent assurance ~~related to~~ of the vaccine safety system, with the second of these options having three potential configurations. The NVAC reviewed the three options at the June 2011 meeting and provided direction for Option 1: NVAC should continue to be the advisory entity primarily responsible for evaluating the NVP programs. Below is a review of the two options not selected by the NVAC ~~for recommendation by the Committee.~~

2. Clarify that NVAC’s review of the safety system considered leadership, assurance and accountability in addition to coordination, corresponding to Recommendations 1, 2 and 3.

Page 4, Lines 11-14

The NVAC's review of the federal vaccine safety system concentrated on these aspects of the system to determine where opportunities for improvement exist:

- Leadership ~~Coordination of the system~~ – Direction, Coordination and integration of federal efforts relevant to immunization safety, including mechanisms to provide assurance and accountability.

3. Clarify Recommendation 1.2/correct inadvertent change from prior version.

Page 8, Lines 22-34 and Page 50, Lines 11-23

Include the IHS and the Agency for Healthcare Research and Quality (AHRQ) as

participants in the NVP. Also, the Secretary should direct HHS agencies coordinated under the NVP—accompanied by a request to the DoD, the VA, and the USAID—to do the following:

- Fully participate in NVPO vaccine-safety coordination efforts.

- Identify and pursue opportunities for collaborative projects relevant to NVP vaccine safety objectives with other NVP-coordinated agencies.

- Regularly obtain the advice of appropriate subject matter experts and consumers to guide initiatives related to vaccine safety.

- Provide other governmental agencies, vaccine manufacturers, appropriate stakeholder organizations, and representatives of the public the opportunity to provide feedback regularly during the planning and implementation of initiatives related to vaccine safety, and tell them about initiatives and outcomes related to vaccine safety

The Secretary should ~~define~~ performance expectations related to vaccine safety for NVP-coordinated agencies.

4. Other clarified wording, typographical errors and factual corrections.

Page 3, Lines 32-33: "...a meeting to obtain stakeholder input was held on June 13~~2~~, 2011..."

Page 23, Line 27-29: "One of the functions of the NVAC is to recommend research priorities and other measures the Director of the NVP should take to enhance the safety and efficacy of vaccines, hence the rationale for their undertaking the writing of this report ~~which is the subject matter of this White Paper.~~

Page 38, Lines 24-26: "...The most current ~~A review is currently underway~~ to address changes in the Table regarding more recently recommended vaccines and adverse events potentially associated with them has just been published.^[2] ..."

Page 42, Lines 7-11: "Federal Advisory committees (e.g., the NVAC, the ACIP, the VRBPAC, the MDRAC, the Advisory Committee on Childhood Vaccines [ACCV], the Defense Health Board (DHB), ~~Armed Forces Epidemiological Board (AFEB)~~ which hold public meetings and have public representatives play a role in decision making processes regarding vaccination policy and practices (i.e. licensure alone is not sufficient for incorporation into the recommended vaccine schedule).

Page 67, Lines 21-22: "Expanded efforts to obtain information on ~~Calculation of~~ background rates of potential AEFI in subpopulations would assist in vaccine safety risk assessment.

Page 97, Line 17-19: "...A review of the Options for Accountability and Assurance deliberated on by the VSWG and presented to the Committee is provided in Appendix 13~~2~~..."

Page 118, Lines 4-5: "...In completing their charge, the National Vaccine Safety Advisory Committee (NVAC) Vaccine Safety Working Group (VSWG) found that; in order to assure ..."

APPENDIX B: OSHA Position Statement, as submitted by Mr. Borwegen, representative of the Service Employees International Union

The Occupational Safety and Health Administration (OSHA) is strongly supportive of efforts to increase influenza vaccination rates among healthcare workers in accordance with the Healthy People 2020 goals. However, at this time, OSHA believes there is insufficient scientific evidence for the federal government to promote mandatory influenza vaccination programs that do not have an option for the HCP to decline for medical, religious and/or personal philosophical reasons.

While we are supportive of the Healthy People 2020 goal of a 90% vaccination rate, we have seen no evidence that demonstrates that such a high rate is in fact necessary. Furthermore, the current influenza vaccine is no magic bullet. The current state of influenza vaccine technology requires annual reformulation and revaccination and the efficacy is quite variable. Every year there are numerous circulating strains of influenza that are not included in the vaccine. In years where the antigenic match is good, the vaccine only provides protection against the 3 strains in the formulation. In years when the antigenic match is poor, the vaccine may provide no protection at all. The limits of current influenza vaccine technology are especially problematic in the context of a mandatory influenza vaccination program that results in job loss. Lastly, reliance on a mandatory influenza vaccination policy may provide healthcare workers, health care facility management and patients with an unwarranted sense of security and result in poor adherence to other infection control practices that prevent all types of infections, not just influenza. Influenza vaccination has always been just one part of a comprehensive multi-layered infection control program.

While OSHA does not believe that there is sufficient evidence to meet the bar necessary to support mandatory vaccination programs, we nonetheless are convinced that influenza vaccination is generally beneficial and are supportive of efforts to promote vaccination. Influenza vaccination exemptions should be for HCP with valid medical contraindications to vaccinations, or religious and/or personal objections and a signed declination statement that indicates the HCP has been educated regarding influenza, is aware of the risk and benefits of influenza vaccination, has been given the opportunity to be vaccinated with the influenza vaccine at no charge, and can receive the influenza vaccine in the future at no charge to the HCP.