



**National Vaccine Advisory Committee (NVAC)
February 7–8, 2012, Meeting Minutes**

Committee Members in Attendance

Walter A. Orenstein, M.D., Chair
Seth Hetherington, M.D.
Lisa A. 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. (by phone)
Charles Mouton, M.D., M.S.
Christine Nevin-Woods, D.O., M.P.H.
Amy Pisani, M.S.
Thomas E. Stenvig, R.N., Ph.D., M.S.
Litjen Tan, Ph.D., M.S.
Catherine Torres, M.D.

NVAC Ex Officio Members

Geoffrey Evans, M.D., Health Resources and Services Administration (HRSA), Vaccine Injury Compensation Program (VICP)
Cyril G. Gay, D.V.M., Ph.D., Department of Agriculture (USDA)
Amy Groom, M.P.H. (for Richard Church, Pharm.D.), Indian Health Service (IHS)
Marion Gruber, Ph.D., U.S. Food and Drug Administration (FDA)
Iris Mabry-Hernández, M.D., M.P.H., Agency for Healthcare Research and Quality (AHRQ)
Richard Martinello, M.D., Department of Veterans Affairs (VA)
Susan McKinney (for Margaret McCluskey, R.N., M.P.H.), U.S. 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)

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)
Robert S. Daum, M.D., C.M., Vaccines and Related Biological Products Advisory Committee (VRBPAC)
Charlene Douglas, Ph.D., M.P.H., R.N., Advisory Commission on Childhood Vaccines (ACCV)
Claire Hannan, M.P.H., Executive Director, Association of Immunization Managers (AIM)
Paul Jarris, M.D., M.B.A., Association of State and Territorial Health Officials (ASTHO)
John S. Parker, Major General (Retired), M.D., National Biodefense Science Board (by phone)
Wayne Rawlins, M.D., M.B.A., America's Health Insurance Plans (AHIP)
Kathy Talkington, M.P.A (for Paul Jarris, M.D., M.B.A.), ASTHO
Jonathan Temte, M.D., Ph.D. (for Carol Baker, M.D.), Advisory Committee on Immunization Practice (ACIP)

Executive Secretary

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

Day 1—February 7, 2012

Welcome and Swearing-In of New Members—Howard K. Koh M.D., M.P.H., Assistant Secretary for Health (ASH), U.S. Department of Health and Human Services (HHS)

Dr. Koh welcomed all the participants and thanked the NVAC members for their efforts. Vaccines are a cornerstone of preventive health care and are recognized in Healthy People 2020, the Affordable Care Act (ACA), the National Vaccine Plan, the new HHS Global Health Strategy, and the HHS Action Plan to Reduce Racial and Ethnic Health Disparities, among many other approaches. Dr. Koh thanked the NVPO, especially NVPO Director Bruce G. Gellin, M.D., M.P.H., and the Institute of Medicine (IOM) for updating the National Vaccine Plan to form a blueprint for vaccine efforts.

Dr. Koh summarized some of the highlights of the agenda and welcomed Walter A. Orenstein, M.D., as the new NVAC chair. He also welcomed three new NVAC members: Charles Mouton, M.D., M.S., Catherine Torres, M.D., and Vish Viswanath, Ph.D. To commemorate her outstanding service to NVAC, particularly her leadership as co-chair of the Adult Immunization Working Group (AIWG), Dr. Koh presented a plaque to outgoing member Christine Nevin-Woods, D.O., M.P.H.

NVAC's work has informed HHS' influenza vaccination programs, providing input and recommendations on vaccine financing, access, and safety for children and adults, Dr. Koh noted. Recently, HHS released its Global Health Strategy, which overlaps with Goal 5 of the National Vaccine Plan to increase global prevention of death and disease through safe and effective vaccination. Dr. Koh requested that NVAC review the role of HHS in global vaccine efforts and recommend how HHS can work with global partners to further vaccine efforts.

Dr. Koh swore in Drs. Mouton and Torres. (Dr. Viswanath was unable to attend.)

Dr. Gellin pointed out that, in response to recommendations on improving the effectiveness of the NVAC, the NVPO has sought more specific direction on issues of particular importance to the ASH, and Dr. Koh has been very clear and forthcoming about his priorities. In addition, the NVAC established a mechanism for tracking the status of its recommendations. In response to an NVAC recommendation, the IOM is establishing a committee to conduct an independent assessment of the feasibility of studying health outcomes in children who were vaccinated according to the CDC recommended schedule and those who were not (e.g., children who were unvaccinated or vaccinated with an alternate schedule).

Chair's Report—Walter A. Orenstein, M.D., NVAC Chair

Following introductions of Committee members, Dr. Orenstein thanked previous NVAC Chair Guthrie S. Birkhead, M.D., M.P.H., and his assistant Rachel Hart-Malloy, M.P.H., for their extensive efforts in preparing the materials for this meeting. Describing the NVAC meeting process, Dr. Orenstein noted that public comment is extremely important. He emphasized that time for public comment is limited, but written comments can be sent to the NVAC for consideration by e-mail (nvpo@hhs.gov).

Dr. Orenstein called for review of the September 2011 NVAC meeting minutes. By e-mail, NVAC member Tawny Buck said the minutes do not adequately reflect the diversity of opinion among the members of the AIWG's Health Care Personnel Influenza Vaccine Subgroup (HCPIVS) around the issue of exemptions to mandatory influenza vaccination in the workplace.

Action Item

NVAC approved the September 2011 minutes with the following revision:

Add as an appendix to the report slide 18 of the presentation titled "Health Care Personnel

Influenza Vaccine Subgroup (HCPIVS)” by subgroup co-chairs Julie Morita, M.D., and Christine Nevin-Woods, D.O., M.P.H., presented to the NVAC on September 13, 2011, describing the Subgroup members’ support for various exemption options.

Dr. Orenstein reported the results of a survey of NVAC members; it indicated that the committee’s orientation process and overall communication efforts are strong, and the meeting process and speakers are good. The technical quality of the teleconferences and webcasts raised concerns. There was general support for the process used by the working groups, although concerns were raised about the transparency of the selection of working group chairs and members. NVAC members surveyed suggested that meeting materials be provided earlier.

Action Item

NVAC will work with NVPO staff to provide meeting materials in advance when possible.

Dr. Orenstein described the status of recommendations made since the February 2011 NVAC meeting, several of which would be addressed at the current or future NVAC meetings. He summarized the [agenda](#) for this meeting and presented the 2011 State of the Program Report to the NVAC for review.

Action Item

NVAC unanimously approved the 2011 State of the Program Report.

Finally, Dr. Orenstein reiterated the charge to the NVAC and said the next NVAC meeting is scheduled for June 5–6, 2012.

National Vaccine Plan Implementation—Lauren Wu, NVPO

Ms. Wu explained that the National Vaccine Plan lays out a 10-year strategic vision. The NVPO is coordinating an interagency working group that is developing the corresponding implementation plan. It will be organized around the five goals described in the National Vaccine Plan and in accordance with the priorities identified with input from the NVAC, the IOM, and the interagency working group. The implementation plan will include short-term (i.e., years one through four) indicators of success. Ms. Wu said HHS cannot commit to indicators that might not be measurable in 10 years, as budgets and measurements systems may change. Therefore, longer-term goals and indicators will be developed following the NVAC mid-course review of the plan in 2015.

The NVPO organized 10 stakeholder engagement meetings around the country, targeting specific topics and audiences for each, to gather input. (Summaries of those meetings will be published by ASTHO as a companion document to the implementation plan.) Feedback from the meetings revealed, for example, that better mechanisms are needed to measure vaccine coverage among American Indians/Alaska Natives (AI/AN), as 40 percent live in urban areas or do not use IHS providers or both.

Ms. Wu anticipated that the implementation plan will be published this coming spring. Annual reports will describe progress toward the National Vaccine Plan goals. Dr. Gellin added that the feedback from stakeholders and the NVAC identify areas of improvement that will help the overall vaccine system.

Immunization Programs: More than Just Vaccines—Melinda Wharton, M.D., M.P.H., CDC

Dr. Wharton summarized the Vaccines for Children (VFC) program, which provides vaccine to uninsured served at any participating provider and underinsured children, who are covered only if they receive their vaccines at Federally Qualified Health Centers (FQHCs). The Section 317 Federal Immunization Grant Program has been used to purchase vaccines for underinsured children served at other facilities including public health department clinics. Under ACA, the number of underinsured children and adults is

expected to decrease, and new health insurance plans must cover ACIP-recommended vaccines. Thus, the vaccine purchase needs for Section 317 funding are likely to decrease. However, Section 317 funding also provides the critical infrastructure to support vaccine operations, including provider recruitment and education, quality assurance, data gathering, surveillance, immunization information systems (IIS), and vaccine safety monitoring. Dr. Wharton emphasized that Section 317 funding not only supports the VFC program but also provides surveillance and response services that are vital to the private sector.

Even if ACA is fully implemented and the need for public funds to purchase vaccines for underinsured children decreases, the goal of making vaccination available to all remains. More work is needed to ensure that children and adults can receive recommended vaccinations from various providers in numerous venues within and outside of health care settings (especially the workplace).

In addition to the extensive surveillance systems needed to monitor vaccine-preventable diseases, resources are needed to ensure that public health officials can conduct careful investigations and have access to laboratories. National and State surveillance efforts helped identify important epidemiological changes in pertussis, pneumococcal disease, and rotavirus in the United States. Thorough investigation of and response to outbreaks is costly and enormously time-consuming, said Dr. Wharton. The evidence and information gathered underpins the development of immunization policy for the whole country, she added. Resources are also needed to:

- conduct quality assurance activities,
- educate providers,
- offer guidance on managing potentially compromised vaccine,
- manage vaccine shortages,
- implement IIS and health information technology, and
- assess vaccination coverage.

Vaccine safety surveillance, research, and reporting are critical, said Dr. Wharton. The Vaccine Adverse Event Reporting System (VAERS) can help identify serious adverse events early but it does not capture all related events and rarely provides evidence to establish a causal relationship. Rapid cycle analysis using the Vaccine Safety Datalink offers a much faster approach to testing. In addition, State-level vaccine safety coordinators work closely with the CDC and others to enhance safety surveillance.

Additional resources support communication, partnerships, and outreach with health care professionals, stakeholders, and communities. In short, “Vaccines don’t give themselves,” said Dr. Wharton (paraphrasing Dr. Orenstein). The enterprise requires a lot of people to work together across public and private settings, and continued public support is needed to sustain the effort.

Discussion

Even when ACA is fully implemented, some adults will remain uninsured; for example, many AI/AN will continue to face funding and access problems. Dr. Wharton said that in previous years, the cost of supporting the vaccine infrastructure has ranged from \$500 million to \$600 million. Kathy Talkington, M.P.A., of ASTHO said State health departments are very concerned about decreases in both State and Federal funding; she offered to share her organization’s information on State-specific infrastructure.

Concerns were raised that legislators do not fully understand how Section 317 funds are used beyond purchasing vaccine. It was proposed that NVAC establish a working group to identify and describe critical functions of immunization programs at the national, State, and local level and make recommendations to maintain, develop, and improve the vaccine infrastructure in light of anticipated changes resulting from ACA. Claire Hannan, M.P.H., of AIM expressed strong support. Several members

agreed that while implementation of ACA is the trigger for the discussion of Section 317 support, NVAC's recommendations should avoid inflaming political sensitivities and thus should not mention ACA. Once ACA is implemented, more financial support will be needed to provide the critical services that are not available now.

Anne Bailowitz, M.D., M.P.H., suggested publishing the new group's recommendations in a public policy-related publication as well as a medical journal. The new group should describe specifically how the entire vaccine enterprise will be affected if we fail to sustain the infrastructure.

Action Items

NVAC unanimously approved the following resolution:

Background

The ACA provides for a significant expansion of insurance coverage for immunization services, which will—when fully implemented—improve payment for vaccines for children and adults and significantly reduce the substantial population of underinsured children in the United States. As a result, it is expected that the need for public-sector purchase of vaccine for underinsured children will be reduced. However, there will remain other critical functions for immunization programs that will need to be developed, maintained, or improved. In addition, Goal 4 of the National Vaccine Plan specifically is to “ensure a stable supply of, access to, and better use of recommended vaccines in the United States.” In order to accomplish this goal, and in particular, objectives 4.2, 4.4, 4.5, 4.6, and 4.7, and in consideration of the changing environment, it is fundamentally important that we improve understanding of the significant roles that these immunization programs play in ensuring continued success of the country's immunization effort.

Resolution

NVAC charges a working group with the task of identifying and describing critical functions of immunization programs at the national, State, and local level. The working group should complete its work and make its report to NVAC by the September 2012 meeting. This report should provide recommendations to the ASH on methods to develop, maintain, and improve the nation's immunization programs in light of environmental changes forthcoming.

Dr. Orenstein designated Litjen Tan, Ph.D., M.S., and Dr. Torres as co-chairs of the new working group. NVAC members who wish to serve on the working group should contact Dr. Wharton of CDC. Suggestions for potential non-NVAC members who should be represented on the working group should be sent to Dr. Wharton. The group will provide an interim report of its progress at the June 2012 NVAC meeting.

AIWG HCPIVS Recommendations

Overview—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 health care personnel (HCP), defined as all paid and unpaid persons working in health care settings who have the potential for exposure to patients and/or infectious materials. HCP may include persons not directly involved in patient care but who are potentially exposed to infectious agents that can be transmitted to and from HCP and patients. A health care employer (HCE) is defined as a person or entity that has control over the wages, hours, and working conditions of HCP in health care settings.

Dr. Nevin-Woods outlined the Subgroup's process, including frequent meetings by phone and in person, extensive literature review, and presentations from subject matter experts. The Subgroup provided updates to NVAC three times and received input and guidance from the committee. In August 2011, it conducted an informal poll of Subgroup members (who represent a wide range of stakeholders within and outside of government) to gauge support for a draft set of recommendations, followed by a final vote in November 2011. The final recommendations were posted online for public comment in December and presented via a webinar on January 9, 2012; as of this meeting, NVAC was still receiving public comments on the recommendations.

As a preface to presenting the Subgroup's report and recommendations, Dr. Nevin-Woods emphasized that the Subgroup was charged with making recommendations to achieve the 90-percent goal—not to evaluate the goal itself. The recommendations were crafted on the basis of discussion and review of evidence-based strategies for improving vaccine coverage, and they have been revised to reflect as broad a perspective as possible. Opinions from both ends of the spectrum were voiced and considered throughout deliberations. The recommendations reflect the opinion of the majority of Subgroup members. Dr. Nevin-Woods presented the results of the final vote on each recommendation. She stated each recommendation and gave definitions, key points, and other explanatory information for each, all of which was detailed in the publicly available draft report. Regarding the recommendation that HCEs consider an employer requirement for influenza vaccination (Recommendation 4), Dr. Nevin-Woods presented both the majority's rationale and the minority's opinions about employer requirements.

Dr. Nevin-Woods also summarized the public comments received as of Monday, February 6, 2012, which focused almost exclusively on Recommendation 4. Comments came from 145 individuals and 37 organizations. Among the general comments, it was noted that the definitions of HCP and HCEs do not match those of the National Quality Forum or the Centers for Medicare and Medicaid Services (CMS), which may hamper measurement efforts. Several commenters said that Recommendations 1 and 2 should state that HCP and their representatives should be directly involved in the development and implementation of influenza vaccination and prevention programs and that vaccination programs should include free vaccine available during multiple shifts, locations, and days. A few commenters offered input on Recommendation 3 to improve the methodology for measuring coverage.

Fifteen organizations that submitted comments supported Recommendation 4 on employer requirements, while 16 organizations opposed it. Numerous comments focused on the issues of personal autonomy, broader and more flexible exemptions, and the likelihood of punitive or discriminatory practices. Several commenters opposed employer requirements on the grounds that influenza vaccine is not sufficiently effective and that increased coverage has not been shown to improve patient safety. Several pointed out that employer requirements would be considered a unilateral change to the conditions and terms of employment and could be subject to collective bargaining negotiations. Others were concerned that overemphasis on vaccination as a preventive measure may lead to poor adherence to other infection control practices. Still others commented on the Healthy People 2020 90-percent target, the potential liability issues of an employer requirement, and the use of protective masks to prevent infection.

Public Comment

Elizabeth Brown said she had worked as a nurse at the Washington Hospital Center for 29 years but was terminated because she refused to be vaccinated. She said vaccination should not be mandatory because it is unfair, and she has been jobless for 2 years. If there are exemptions for religious or medical reasons, said Ms. Brown, there should also be exemptions for personal choice. She added that she has never been sick and never had influenza.

William Borwegen of the Service Employees International Union (SEIU), a member of the Subgroup, added that Ms. Brown received no education at all from the Washington Hospital Center about influenza vaccination. He alleged that the Subgroup had major conflicts and its processes represented serious violations of the Federal Advisory Committee Act (FACA). A concerted effort was made to stifle dissent, misrepresent members' votes, and hide information that supports the minority position. Mr. Borwegen said the draft report was never sent to the Subgroup, and the Subgroup had not met in person or by phone for 5 months. The draft report is a product of the AIWG co-chairs and the designated Federal official, who hijacked the process and formed a "leadership team" to control the content of the report. Mr. Borwegen said the report fails to include studies, including a Cochrane Database report, that describe the insufficient link between HCP vaccination and patient safety. It also leaves out ethical arguments against vaccination. As a result of these omissions, neither NVAC members nor the American people have heard the whole story, said Mr. Borwegen, and the draft report is neither fair nor balanced. He requested that NVAC table its vote on the report. He requested a meeting with the HHS Office of General Counsel (OGS) to discuss FACA violations.

Debra Bonn, RN, director of the Nurse Alliance of Pennsylvania, an affiliate of SEIU Healthcare Pennsylvania, said she has 30 years of hands-on, acute-care experience in nursing and speaks for 10,000 nurses and 85,000 health care workers. Given the potential impact of vaccines, individuals should have a choice about vaccination, she said. As nurses and as private citizens, we do not agree with the vague wording of the recommendation, which would give license to employers to mandate vaccination, said Ms. Bonn. The Subgroup failed to address initial prevention, and the nonchalant attitude toward education is unacceptable. Studies show that comprehensive programs that allow individuals to raise and address concerns are effective in helping people make decisions. Ms. Bonn said the draft report suggests that facilities provide education, but education is not included in any of the recommendations. She described a setting in which the education about vaccination consisted of a computer program, available in only one location, that the HCP must watch on her own time, with no opportunity to ask questions and no follow-up effort to determine why an employee chose to decline vaccination. Long-term care settings are even more pathetic, she said; workers get a simplistic influenza vaccination sheet. The vaccination may be provided at an inaccessible office location at inconvenient times, and HCP must get vaccinated either during work or on their own time.

Ms. Bonn continued that the recommendations fail to focus on environmental issues that contribute to the transmission of influenza, the need for a thorough housekeeping plan to prevent transmission, or the use of masks in preventing hand-to-mouth or hand-to-nose transmission. The recommendations fuel a false sense of security and should include a more comprehensive plan for evaluation. The effectiveness of the influenza vaccine ranges from 35–60 percent; vaccine producers should be held responsible for making a safer, more effective product. Ms. Bonn requested that Recommendation 4 include free, easily accessible vaccine and mandatory education programs.

Cathy Stoddart, R.N., said she had been in nursing for more than 30 years and advocates for nursing policy as part of SEIU. Recommendation 4 could take her life, said Ms. Stoddart. To comply, she would have to choose between her financial and physical well-being. She described the severe allergic reactions she has suffered and said the recommendation would force her to take a "death march." All of her patients are immunocompromised, so she takes extra steps to prevent the risk of infection. Ms. Stoddart asked whether any NVAC members would put their lives at risk and why NVAC has the authority to give employers the ability to put lives and jobs at risk. Time would be better spent on education about methods of influenza prevention. Ms. Stoddart urged NVAC to vote against Recommendation 4 and instead support a mandate for comprehensive influenza education. She added that punishing struggling institutions with a 2-percent reduction in payments in 2013 leaves those institutions with no alternative other than mandatory vaccination.

Sandra Starr Romano, R.N., a medical-surgical nurse who has practiced for 32 years, said that if she performed at a level of 59-percent efficacy, her patients would be in danger, and if she posed her patients a risk of paralysis or loss of limb or life, she would be prosecuted. But the influenza vaccine carries those qualities. Even if allergies and Guillain-Barré syndrome (GBS) are rare, they are devastating. Handwashing and sanitizers have higher efficacy in preventing the transmission of disease, said Ms. Romano. Simple techniques that are easily practiced by all HCP and the public do more to prevent transmission than the influenza vaccine, which varies each year. The proposed recommendation puts profits before people. Ms. Romano said she would refuse vaccination and encourage others to do so as well. She noted that patients have the right to refuse care but under mandatory vaccination, she would not have that right. She urged NVAC to vote against Recommendation 4, which she called a license for employers to force people to be vaccinated against their will.

Kimberly Khizer, R.N., said she witnessed the results of a mandatory vaccination policy. Her employer required her to get tetanus, diphtheria and acellular pertussis (Tdap) vaccine. She developed cellulitis at the injection site and had soreness for weeks. Employees who do not get influenza vaccination at her hospital are required to wear a mask, which is discriminatory, said Ms. Khizer. No one polices hospital visitors to determine whether they are vaccinated, she said. Why don't HCP have the right to be protected from them? she asked. Ms. Khizer said she knew of two nurses who died from GBS and another who is in intensive care as a result of a vaccine-related injury. The influenza vaccine is not as safe as we wish it were, and requiring vaccination is overreaching given what we know from a scientific, legal, and philosophical perspective, she concluded.

Len Novick of the National Foundation for Infectious Diseases (NFID) said his organization has long been committed to increasing influenza vaccination rates among HCP. The NFID supports recommendations to address the gaps in immunization rates among HCP. The Subgroup's recommendations offer a measured, tiered approach to the issue and outline a comprehensive program that includes ongoing education, better reporting and measurement, and, finally, accountability. HCP influenza immunization is a critical patient protection issue, said Mr. Novick, and the NFID supports NVAC's stepped approach to achieving the goal.

Rajini Raj, R.N., is a nurse at the Washington Hospital Center and commented on behalf of the National Nurses Organizing Committee and the California Nurses Association, which, together with other organizations, form National Nurses United, the country's largest nurses' union. Ms. Raj said 95 percent of the organization's members work in hospitals. The union seeks to provide safe, direct care to patients and to expand the voice of nurses in creating policy. The union objects to Recommendation 4, said Ms. Raj, on the basis that overreliance on vaccination to stem the transmission of influenza puts other nurses and patients at increased risk. Because of supply and efficacy issues, vaccine cannot be relied on exclusively to prevent transmission. Employer programs can be effective if they include comprehensive education and vaccine access, said Ms. Raj, but Recommendation 4 does not include education and instead encourages coercion, or workers risk punishment, retaliation, or firing. Mandatory vaccination programs increase distrust, offer disincentives, and raise ethical and legal questions about the protection of individual rights.

Requiring masks will not stem the transmission of influenza and only promotes a false sense of protection, Ms. Raj continued. An abundance of research shows that masks don't protect against airborne transmission. Policies that require unvaccinated employees to wear masks are not borne of science. Ms. Raj said her organization opposes any version of this standard. Rather than an employer requirement to vaccinate, it would be safer to offer accessible vaccination to employees with extensive education on vaccination and infection control practices. Ms. Raj called for NVAC member Seth Hetherington, M.D., to recuse himself from voting on the recommendations. She said for-profit pharmaceutical companies were consulted about the recommendations but nurses were not. She continued that nurses call for an

open process to support patients and HCP that is not driven by corporate profits. Ms. Raj said she agrees with the Occupational Safety and Health Administration (OSHA) that there is insufficient evidence to promote mandatory vaccination programs that might result in employee termination. She asked that NVAC not adopt Recommendation 4.

Bill Kojola of the American Federation of Labor and Congress of Industrial Organizations (AFL-CIO) Safety Department said his organization represents hundreds of thousands of health care workers. While health care worker unions all support vaccination and encourage comprehensive programs to increase the vaccination rate, no HCP should lose a job because of refusal to be vaccinated. Therefore, his organization does not support Recommendation 4. The Healthy People 2020 goals are a target, not a mandate. Recommendation 4 violates the spirit and intent of those goals. Furthermore, the influenza vaccine is not very effective, said Mr. Kojola, and in years when the vaccine does not offer a good match, vaccination gives the false impression of protecting patients. Vaccination alone is not an infection control program, he added. He urged the NVAC to step back and look at the broader issues. The mandatory vaccine controversy is a diversion from real threats to patients; it distracts from the fact that 99,000 patients die each year from hospital-acquired infections and 100,000 die from preventable medical errors. Those issues should be addressed rather than focusing on vaccination with an ineffective influenza vaccine. Two hundred thousand deaths per year is a failure, Mr. Kojola concluded; don't create a side issue to distract from that, he said. The AFL-CIO recommends that the NVAC reject Recommendation 4, he said.

Laura Scott, executive director of Families Fighting Flu, said her organization is dedicated to protecting children. Its members are primarily families of kids who have died from influenza, and Ms. Scott described several of them. There are real consequences of skipping the influenza vaccination. Families Fighting Flu believes it is unacceptable for HCP—the people we go to for treatment—to not protect themselves and their patients against influenza. It is a serious disease, and it kills, said Ms. Scott. HCP should be expected to take reasonable steps to protect against it. Unvaccinated HCP are a threat to themselves and to their most vulnerable patients, including children. Annual influenza vaccination is the best option, and the risk of disease is far higher than the risks of vaccination. Ms. Scott said it is incomprehensible to her why any HCP would take a chance on influenza. Choosing not to be vaccinated is a choice to do harm, she added, and it has no place in health care. She said Families Fighting Flu strongly supports all five Subgroup recommendations and looks forward to educating HCP on the seriousness of the disease and working to achieve the Healthy People goal.

Deidre Beckford, R.N., said she has worked at the Washington Hospital Center for 22 years in the departments of medicine and interventional cardiology and is a member of National Nurses United. She opposed Recommendation 4 on the basis of the limited effectiveness of the vaccine and would prefer comprehensive education. Currently, she said, there is animosity among employers and HCP. In her 22 years, Ms. Beckford said, she had never seen a single nurse give any patients the flu.

Deborah Wexler, M.D., of the Immunization Action Coalition said her organization established the “honor roll for patient safety” in 2009 to recognize institutions that mandate influenza vaccination. The honor roll now includes 159 hospitals, health care systems, and clinics and is growing every week. Many more organizations are mandating vaccination and are not yet on the honor roll, and Dr. Wexler applauded them. Among the professional societies that endorse mandatory vaccination of HCP are the following:

- American Academy of Family Physicians (AAFP)
- American Academy of Pediatrics (AAP)
- American College of Physicians

- American Hospital Association
- American Medical Directors Association
- American Pharmacists Association
- American Public Health Association
- Association for Professionals in Infection Control and Epidemiology
- Infectious Diseases Society of America
- NFID
- National Patient Safety Foundation
- Society for Healthcare Epidemiology of America

Discussion

Dr. Orenstein asked that the OGC consider the allegation of FACA violations. Mr. Borwegen asked whether Recommendation 3 to standardize the methodology used to measure vaccination coverage rates means that CMS should penalize hospitals that don't achieve the 90-percent target. Dr. Tan clarified that CMS may apply penalties for insufficient reporting of measures, not the success of coverage efforts. It was suggested that Recommendation 3 leave out wording about vaccine coverage levels. There was further discussion about the interpretation of Recommendation 3 as currently worded but general consensus among the NVAC members that the intention of Recommendation 3 is to standardize methodology to ensure consistent reporting.

Anna Jacobs, Esq., of the HHS OGS, said that neither FACA, Federal regulations, nor HHS policy prescribe the activities of a subcommittee. She believed that NVAC acted in accordance with FACA guidelines. Dr. Gellin pointed out that the Subgroup works for NVAC, and the Subgroup's report to NVAC during a public meeting is the mechanism for inviting the public into the discussion. Ms. Jacobs added that the Subgroup does the preparatory work to draft recommendations; once NVAC votes to accept them, they become the recommendations of NVAC. Several NVAC members volunteered to work together to revise the draft recommendations in response to public comments and present them for NVAC consideration on day two of the meeting. Dr. Hetherington clarified that his company, Genocea Biosciences, does not work on the influenza vaccine. Dr. Orenstein suggested revisiting the FACA question and the Subgroup recommendations on day two of the meeting.

H1N1 Vaccine Safety

Overview of H1N1 Vaccine Safety Monitoring—Dan Salmon, Ph.D., M.P.H., NVPO

Dr. Salmon noted the response to the H1N1 influenza pandemic was the largest mass vaccination program in U.S. history—and corresponded with the largest vaccine safety monitoring effort. Public concerns about vaccine safety in general were highlighted by the pandemic. Dr. Salmon described the five recommendations made by NVAC addressing H1N1 vaccine safety monitoring and steps taken to implement them:

- Assemble background rates of adverse events that occur in the general population.**
A report published in *The Lancet* in 2009 estimated the number of background adverse health events that occur daily (e.g., 2,500 miscarriages and 3,000 heart attacks per day in the United States). During a mass vaccination, they could be temporally but not necessarily causally associated with vaccine. Public health authorities face the challenge of identifying vaccine safety signals rapidly and following up on them, but robust scientific investigation takes time.
- Develop and disseminate a Federal plan.**
The Federal Immunization Safety Task Force published online its plan to monitor H1N1 vaccine safety.

- **Enhance active surveillance for signal detection, assessment, and confirmation of possible associations between vaccines and adverse events.**
Before the H1N1 pandemic, several surveillance efforts and clinical trials were underway, including VAERS, the Real-Time Immunization Monitoring System (RTIMS), and the Vaccine Safety Datalink. The VA, DoD, IHS, and CMS all have databases that provide additional safety information. The CDC supports vaccine safety research at academic centers. When H1N1 influenza surfaced, NIH and the Biomedical Advanced Research and Development Authority launched long-term monitoring studies of children and pregnant women, among others; the Post-Licensure Rapid Immunization Safety Monitoring (PRISM) system was launched; and the CDC established the GBS Surveillance program. Rapid cycle analysis allows for ongoing rapid evaluation to identify signals, usually by focusing on prespecified outcomes. The approach offers a high level of detection but also yields a lot of false-positive findings.
- **Establish a transparent and independent review of vaccine safety data as it accumulates.**
The Federal Immunization Safety Task Force coordinates vaccine safety efforts across HHS, DoD, and the VA. It convenes frequently to exchange information and share findings. To provide an independent perspective, HHS established the Vaccine Safety Risk Assessment Working Group (VSRAWG), which met frequently throughout the H1N1 pandemic and beyond to evaluate safety data and make recommendations.
- **Develop, and where possible test in advance, a strong and organized response to scientific and public concerns about vaccine safety.**

H1N1 VSRAWG Final Report—Marie McCormick, M.D., Sc.D.

Dr. McCormick described the VSRAWG’s makeup, charge, and process, noting that members came from multiple advisory committees and were subject to a higher level of conflict-of-interest screening than is required for NVAC membership. Federal representatives presented and discussed data with the VSRAWG members, but members made decisions about their interpretation of the data in closed sessions. It was determined that the VSRAWG could review data that were proprietary or preliminary but not share it during open NVAC meetings, so NVAC members did not see the background data on which VSRAWG assessments were made.

The VSRAWG *Final Report* summarizes the group’s key findings. The VSRAWG found no association between H1N1 vaccination and either Bell’s palsy or thrombocytopenia/idiopathic thrombocytopenic purpura, despite weak signals detected by some systems. The VSRAWG followed up on early detection of a signal for GBS. A meta-analysis across systems revealed an increased risk of one to three cases of GBS per one million doses of H1N1 vaccine. Therefore, the VSRAWG concluded that there is an increased risk of GBS following H1N1 vaccine, but the risk is very small.

The VSRAWG also found the following:

- Hypersensitivity reactions might be more common with H1N1 vaccine compared with seasonal influenza vaccines.
- Methods of surveillance of pregnant women are not optimal and should be enhanced. (For example, medical coding does not capture gestational age.)
- Continued methodological development of data mining approaches for signal detection is warranted.
- Reports of administration errors (not associated with adverse events) suggest the need to explore opportunities to reduce such errors.

Discussion

Dr. McCormick pointed out that detecting a safety signal does not require that findings reach statistical significance. Dr. Salmon added that a group looking at the results of multiple systems will not necessarily identify when the same data point arises in more than one system. Dr. McCormick said the VSRAWG called for controls that address such issues.

Action Item

NVAC unanimously approved the VSRAWG *Final Report*, dated January 31, 2012 should be transmitted to the Assistant Secretary for Health.

Health Care Provider Toolkit—Kris Sheedy, Ph.D., CDC

Dr. Sheedy said the CDC had conducted many interviews, focus groups, and other efforts to evaluate what kind of information parents want about vaccines. Health care providers are the number-one source of vaccine information for parents, and the interaction between providers and parents is key. The Health Care Provider Toolkit gives providers resources to help them talk with parents about vaccine-preventable diseases and the risks and benefits of vaccination. The Toolkit contains more than 50 single-paged fact sheets on individual diseases, vaccine safety, and other issues. Some of the materials are longer and aimed at “high-information-seeking parents,” said Dr. Sheedy. All of the materials can be downloaded from the [web](#). Online, users can sign up to receive notifications about changes and new products.

Last summer, the CDC purchased some advertising space in professional journals to promote the Toolkit. It printed a limited amount of the Toolkits and mailed them to AAP and AAFP leadership and to immunization program managers. However, Dr. Sheedy noted, CDC is relying on its partners to promote the Toolkit further. It will be updated annually in time for National Infant Immunization Week. The CDC is gearing up for National Infant Immunization Week in April, when it will target more vaccination messages directly to parents.

Discussion

Dr. Sheedy noted that about 30 providers have volunteered to field-test the Toolkit and provide feedback, but no formal evaluation is planned. She added that the CDC could work with its partners at AAP and AAFP to get input from their members, and the website includes a mechanism for feedback.

The CDC is making efforts to ensure that all of its materials are written in plain language. Spanish translations of the Toolkit materials are available, but the CDC may need help from partners to translate them into other languages. While the CDC recognizes that it needs to move toward providing content tailored for mobile devices, the demands are extraordinary, and the CDC is struggling to keep up with the needs of the website alone.

Dr. Sheedy said the CDC can consider reaching out to Federally qualified health centers to raise awareness about the Toolkit information. RADM Anne Schuchat, M.D., pointed out that the Federal government has new restrictions on printing that limit how many copies of the Toolkit the CDC can disseminate. However, Dr. Schuchat hoped the NVAC would help get the word out. It was noted that asking small practices to print out the materials or expecting families in rural areas to access information using their phones is burdensome and unrealistic. Dr. Sheedy said the CDC is seeking partners to help and appreciates any efforts the NVAC can make to raise awareness about the Toolkit.

National Adult Influenza Summit—CAPT Carolyn Bridges and CAPT Angela Shen, CDC

CAPT Bridges said the CDC is modeling its first National Adult Influenza Summit after the National Influenza Vaccine Summit, bringing stakeholders from across the enterprise together to talk about ways

to improve coverage. She outlined the substantial burden of vaccine-preventable disease on adult health; vaccine coverage rates for adults are below those of children and below the Healthy People 2020 goals. About 43 percent of adults overall, and 63 percent of HCP, received influenza vaccination in the 2010–2011 influenza season, compared with Healthy People 2020 goals of 80 percent and 90 percent, respectively.

CAPT Shen noted that numerous entities have made recommendations over the past two decades to improve adult immunization rates, including the NVAC recommendations recently published in [Public Health Reports](#). The inaugural National Adult Influenza Summit will take place in Atlanta on May 15–16, 2012, immediately before the National Influenza Vaccine Summit. The goal of the National Adult Influenza Summit is to establish sustainable working groups that will identify specific actions summit participants can take to increase adult coverage rates. Target audiences are current and potential vaccinators as well as “under-vaccinators.” For the initial summit, the following working groups have been proposed:

- Provider education
- Patient education
- Expanding access
- Quality/performance measures
- Informing policy-/decision-makers

Outreach efforts will help lay the groundwork before the summit. The annual meeting will focus on working groups while being guided by a steering committee. A broad range of providers will be among the invitees, representing medical, pharmacy, public health, and community settings. Participants will be asked to pledge to take part in a working group and be active in promoting a sustained effort. More information will be available [online](#).

Discussion

Dr. Schuchat said the Summit’s initial efforts will target the low-hanging fruit, and she hoped the steering committee would identify specific issues to target. She added that the CDC expects other partners to drive the effort, not the CDC.

In response to members’ questions, Dr. Schuchat noted that the AARP has been involved in planning and will represent consumers for some portions of the summit; also, the CDC is talking with AHIP about how large health plans address quality performance measures and set payment levels. Dr. Schuchat hoped that financial issues would be addressed by the working group on expanding access. The CDC will invite some State-level stakeholders and has engaged them in planning and participating in the summit.

Action Item

For the June 5–6, 2012, NVAC meeting, NVPO staff will schedule a report on the status of implementation of the NVAC’s June 2011 recommendations for adult immunization.

National Influenza Vaccine Summit—Litjen Tan, Ph.D., M.S.

Dr. Tan said the National Adult Influenza Summit was a natural addition to the National Influenza Vaccine Summit. With the publication of NVAC’s recommendations for adult immunization, it was necessary to harness the energies of many of the partners already involved in the Influenza Summit. At present, the two summits are separate events being held on consecutive days (one-and-a-half days each), but consideration will be given to merging them. The National Influenza Vaccine Summit brings together public and private stakeholders from across the vaccine enterprise who are committed to the goals described in Healthy People 2020.

The Summit is an annual meeting, but also an informal, action-oriented organization and a resource for facilitating communication among stakeholders and providing education about influenza. The Summit website, www.preventinfluenza.org, provides information for health care professionals and the public. Partners working together through the Summit have established some common goals around influenza vaccination:

- Improve transparency and communications among partners around supply and distribution (e.g., a voluntary code of conduct for distributors, the Influenza Vaccine Availability Tracking System).
- Increase awareness about the severity of influenza and the benefits of vaccination throughout the season (e.g., pocket information guides, media briefings, website).
- Acknowledge successful immunization programs via an awards program and invite winners to share best practices at the Summit.
- Stimulate advocacy to change national policy (e.g., the universal vaccine recommendation, increased CMS administration fees, extended vaccination season, and stabilization of the national vaccine supply).
- Achieve national/local media coverage (e.g., annual Summit awards, National Influenza Vaccination Week).
- Facilitate timely communication among Summit stakeholders (e.g., weekly e-mail updates and conference calls about breaking scientific news).

Dr. Tan outlined the administration of the Summit and the structure of the annual face-to-face meetings. The 2012 Summit will take place on May 16–17. Sessions will cover new influenza science, strategies for reaching high-risk groups, and leadership and improving immunization rates. Participation is by invitation only.

Public Comment

Theresa Wrangham of the National Vaccine Information Center said her organization represents those who have been injured by vaccines, families of people who have died from adverse events following immunization (AEFI), and consumers concerned about issues such as informed consent. She acknowledged the importance of patient safety but said that HCPIVS Recommendation 4 has limitations. The Healthy People 2020 goals are aspirational, and they should not be leveraged to prevent individuals from exercising their informed consent rights. The recommendation should allow exemptions for medical conditions, religious beliefs, or conscientious/personal beliefs. It is no surprise that many HCP oppose mandates, said Ms. Wrangham, as harassment charges have arisen from them. From the summary of public comments, it is clear that the public is concerned about mandates without adequate exemptions. The most frequent claims submitted to VICP are from adults injured by influenza vaccination, and they are compensated for conditions like GBS, which do occur. Ms. Wrangham said that injuries should be taken into consideration.

The science on which the recommendations were made is not sufficient to address those at high risk or the issues raised by the IOM in its report, *Adverse Effects of Vaccines: Evidence and Causality*, Ms. Wrangham continued. She said the medical literature is insufficient to determine causality in many cases because there are no studies or because existing studies are not sound. Systematic reviews of the research of influenza vaccination found that most studies were poorly designed and do not show that the vaccine is safe or effective. In addition, the impact of HCP vaccination on patients is not clear.

Recommendations without extensive exemptions and education unfairly punish HCP with the threat of job loss for noncompliance. Ms. Wrangham requested broad exemptions and recognition of the research deficits surrounding vaccination and acknowledged by the IOM. Also, Ms. Wrangham complained that the quality of the audio for the webinar was very poor, and she asked that NVPO make audio recordings

of the meeting available for purchase. She also stated that the *Federal Register* notice of the meeting indicated that public commenters would be allotted 5 minutes each to speak.

Diane Matthew Brown of the American Federation of State, County, and Municipal Employees asked whether the AIWG considered the possibility of punitive employer practices and abuse of the use of sick leave in making its recommendations. She said many adults, including HCP, such as home health workers, do not get immunized because they are punished for taking sick leave should they experience a reaction to the shot. The reality is that people are afraid to use their sick leave and instead take their chances with getting influenza. Ms. Brown said such issues must be considered, especially in the current economy.

Ms. Brown said there are rumors circulating that the H1N1 vaccine is made in China and is contaminated; in presentations to her organization's members, those rumors have come up repeatedly. It is hard to bust those fears once people get erroneous information, she said, and she hoped the AIWG and the CDC considered those fears and rumors in the recommendations and in the Health Care Providers Toolkit.

Day 2—February 8, 2012

Old Business

FACA and the HCPIVS Process—Anna Jacobs, Esq., HHS OGS

Ms. Jacobs gave the definition of a subcommittee according to the *Code of Federal Regulations* and presented the following excerpts regarding FACA (41 C.F.R. sec. 102-3):

- **What policies govern the use of subcommittees?**
 - (a) In general, the requirements of the Act and the policies of this Federal Advisory Committee Management part do not apply to subcommittees of advisory committees that report to a parent advisory committee and not directly to a Federal officer or agency. However, this section does not preclude an agency from applying any provision of the Act and this part to any subcommittee of an advisory committee in any particular instance.
 - (b) The creation and operation of subcommittees must be approved by the agency establishing the parent advisory committee.

- **What policies apply to subcommittee meetings?**

If a subcommittee makes recommendations directly to a Federal officer or agency, or if its recommendations will be adopted by the parent advisory committee without further deliberations by the parent advisory committee, then the subcommittee's meetings must be conducted in accordance with all openness requirements of this subpart.

In this case, the HCPIVS may be considered a subcommittee convened by the parent committee, NVAC, Ms. Jacobs noted. The HCPIVS is not subject to FACA requirements and therefore did not violate FACA. In addition, NVPO continually sought feedback from the public.

Timeline of HCPIVS Process—Christine Nevin-Woods, D.O., M.P.H.

Dr. Nevin-Woods reiterated that the draft report and recommendations represent the discussion and deliberations by the HCPIVS in its effort to achieve a balance of policies that bolster patient safety while protecting both the health and autonomy of HCP. Dr. Nevin-Woods described the timeline of the HCPIVS process since September 2011 in response to the allegation that the Subgroup had not met in 5 months.

The draft recommendations were initially presented to the NVAC for consideration at its September 2011 public meeting. The HCPIVS met in person immediately afterward to discuss the NVAC's input (September 12); 23 of the Subgroup's 27 members attended (some by phone). The HCPIVS held a teleconference in October 12, 2011, during which members reviewed the revised draft recommendations; 24 HCPIVS members took part. Written comments were solicited, and members were sent two e-mail reminders in advance of the deadline for written comments (October 19). The HCPIVS co-chairs adjudicated the comments and incorporated them into the recommendations; the revised recommendations were sent to the HCPIVS members in November. From November 10–17, all HCPIVS members were invited to vote on the revised recommendations, and reminder e-mails were sent to all members. Of the 27 members, 24 voted. During voting, members were encouraged to submit additional comments for consideration by the NVAC.

On November 18, an editing committee received the results of the HCPIVS voting and the comments submitted. The editing committee consisted of the following members:

- Dr. Nevin-Woods, HCPIVS co-chair
- Dr. Morita, HCPIVS co-chair
- Jon Almquist, M.D., American Academy of Pediatrics
- Hilary Babcock, Society for Healthcare Epidemiology of America, Infectious Diseases Society of America
- Guthrie S. Birkhead, M.D., M.P.H., NVAC Chair
- Melanie Swift, American College of Occupational and Environmental Medicine
- Litjen Tan, Ph.D., M.S., NVAC member
- Kathleen Harriman, PhD, MPH, California Department of Health

The editing committee revised the recommendations on the basis of the comments and sent them to the HCPIVS members on December 5. Eleven members returned further written comments that were adjudicated by the co-chairs. The final draft recommendations were published on the NVPO website on December 16 for public comment. The recommendations were also presented at a public, listen-only, informational webinar on January 9, 2012. On February 3, the public comments were forwarded to NVAC members in advance of this public NVAC meeting. The past 5 months have been a period of intensive, continuous work and open communication among the members of the HCPIVS, Dr. Nevin-Woods concluded.

Discussion

Mark Grabowsky, M.D., M.P.H., Deputy Director of NVPO and Designated Federal Official for HCPIVS, said that the SEIU representative has been a tireless advocate who has brought attention to important causes and helped clarify issues for the HCPIVS. However, he emphasized that the allegations that the HCPIVS process was flawed are unfounded, and no FACA guidelines were violated. The SEIU representative has raised vigorous challenges and advocated appropriately on areas that deserve attention. The minority opinion has been represented. Dr. Grabowsky said the challenge remaining is to determine when the process has run its course, and he believed that time has come. Mr. Borwegen maintained that the FACA-related charges were serious and that e-mail communication is not deliberation.

International Vaccine Issues

HHS Office of Global Affairs Global Policy Perspective—Nils Daulaire, M.D., M.P.H.

To better coordinate the country's international and domestic health efforts, the HHS Secretary recently released its first Global Health Strategy (available online at globalhealth.gov). It focuses on leveraging the

Department's key strengths and enhancing collaboration across agencies to accomplish critical goals. The strategy identifies three goals:

- Protect and promote the health and well-being of Americans through global health action.
- Provide leadership and technical expertise in science, policy, programs, and practice to improve global health.
- Advance U.S. interests in international diplomacy, development, and security through global health action.

Dr. Daulaire explained that the strategy's 10 objectives focus on key priorities and correlate with the National Vaccine Plan in areas such as research, surveillance, vaccine safety, regulatory considerations, supply stability, and access to vaccine. Both Goal 5 of the National Vaccine Plan and the Global Health Strategy support the Global Health Initiative to improve health systems and health outcomes.

The Global Health Strategy calls on international partners representing governments, the private sector, and key stakeholders in civil society to work together. HHS is taking part in a broad slate of global immunization activities, such as polio eradication. Following a high-level conference at the World Health Organization (WHO) on noncommunicable diseases in September 2011, the CDC is developing key targets and indicators to address noncommunicable diseases; the CDC's efforts may form the basis of plans in this country to improve access to hepatitis B and human papillomavirus (HPV) vaccine. Dr. Daulaire said HHS believes its work at the international level will contribute to better health around the world and for all Americans.

Discussion

Dr. Daulaire said his office places special emphasis on areas with rapidly emerging economies, such as Mexico, Brazil, China, and India. The United States–Mexico Border Health Commission is a model of cross-border collaboration, demonstrating how joint efforts can have a measurable impact on health status and equitable access to services on both sides, he noted.

The Decade of Vaccines—Orin Levine, Ph.D., Johns Hopkins University

Dr. Levine described the Decade of Vaccines initiative, which seeks to leverage the promise of vaccines to address the significant unmet global health needs. The initiative has received more resources from its partners but more countries need to step up to demonstrate national ownership.

All 193 WHO member states acknowledged the need for a Global Vaccine Action Plan to advance the Decade of Vaccines; the plan is in the draft stage. The guiding principles of the plan are equitable access, shared responsibility and partnership, integration, country ownership, and innovation. The target outcomes reflect those principles in the form of government commitment, individual education, equitable access, integrated health systems, sustainable and long-term financing, adequate vaccine supply, and continued research and development. The initiative could save \$231 billion over 10 years.

For each target outcome, the Global Vaccine Action Plan will identify actions to be taken, building on what works, as well as transformative or innovative steps to achieve the goals and improve effectiveness. Dr. Levine said more input is needed on potential transformative and innovative actions. The Decade of Vaccines is currently working to build support for the Global Vaccine Action Plan in the World Health Assembly, which will vote on the final version in May. If it is approved, efforts will shift to focus on implementation. Individuals and organizations can engage with the Decade of Vaccines by taking part in its civil society organization teleconferences in February and March 2012 or visiting the [website](#) to participate in online consultation, register for e-mail updates, or send feedback.

***Controlling Vaccine-Preventable Diseases in the United States and Global Immunization Efforts—
RADM Anne Schuchat, M.D., CDC***

Dr. Schuchat provided data showing the high levels of vaccine coverage in the United States and the subsequent decreases in vaccine-preventable diseases. However, vaccine coverage rates are still not high enough to ensure disease control, as evidenced by recent outbreaks of measles imported from other countries. Outbreaks tend to spread in communities that have broad exemption policies for vaccination; expanding vaccine acceptance will help address the challenge of outbreaks, said Dr. Schuchat. Investigating even a small outbreak is a massive undertaking but also necessary to improve and maintain disease control.

Maintaining measles elimination in the United States requires not only high vaccination coverage, good surveillance systems, rapid identification and response to cases, and all the other components of an effective vaccination strategy but also thinking beyond country borders. For example, Canada led the Americas in a recent resurgence in measles; transmission was traced to the current measles epidemic in France. The United States receives 17,000 refugees each year; almost 40 disease outbreaks over the past 5 years have been traced back to refugees, about one third of whom arrive with no documentation of vaccination. (HHS is working with the Department of State and international organizations to explore how to address vaccination of refugees.)

Global immunization efforts have had good results—e.g., 12.7 million deaths were averted thanks to measles vaccination programs from 2000 to 2008. However, resurgences in Africa and elsewhere since 2008 demonstrate that sustained programs are needed. In April, the CDC and international partners will launch a national immunization program in Haiti, which remains fragile since the 2010 earthquake. Maintaining disease control and ensuring that eliminated diseases do not resurface require substantial public health and clinician efforts. Global immunization is a good investment in U.S. health; supports the country's security, diplomacy, and humanitarian goals; and reflects our nation's values, Dr. Schuchat concluded.

Discussion

Framing the issue in the context of return on investment, Dr. Schuchat said aggressive response, investigation, and control of outbreaks is expensive, but the risk of going backward is worse. The human cost, especially in places like Africa, must be considered. Dr. Schuchat hoped the United States would continue to sustain its focus and invest in health while eliminating arbitrary distinctions between global and domestic health. It was noted that many State and local health departments no longer have sufficient workforce or resources to allow for adequate investigations of public health problems.

Polio Eradication and the New CDC Emergency Response—Rebecca Martin, Ph.D., CDC

Echoing Dr. Schuchat's point, Dr. Martin pointed out that no country is safe from polio until the disease is eradicated worldwide. Much progress has been made since the Global Polio Eradication Initiative began, but Afghanistan, Nigeria, and Pakistan have never interrupted transmission, and polio continues to spread to previously polio-free countries. Eradication is within reach, but the goal is off track, primarily because of lack of accountability and lack of country ownership. In January 2012, WHO declared polio a programmatic public health emergency, which enabled the CDC and others to mobilize resources to scale up operations with the goal of stopping transmission in infected areas.

Smallpox was eradicated globally in 1977; as a result, by 1985, the United States recouped its investments in worldwide eradication efforts many times over. Thanks to the polio vaccine introduced in the 1960s, polio transmission in the United States stopped in 1979, and only a few cases have occurred since. However, other countries have seen outbreaks, and sustained efforts are needed to continue the

success of eradication efforts in, for example, India, which recently completed its first year with no polio cases.

Many challenges remain to reach the goal of polio eradication, particularly ownership and political commitment. In addition, the Global Polio Eradication Initiative is facing a \$535-million gap in 2012, and another \$1.9 billion is needed to sustain efforts from 2013 to 2015. Dr. Martin emphasized the future savings that eradication of polio would yield.

Discussion

The United States provides about 2–3 percent of the total funding for the Global Polio Eradication Initiative, said Dr. Martin. The Gates Foundation is working to ensure that other countries keep the commitments they pledged to the initiative. Dr. Levine suggested that NVAC consider how global health efforts can inform domestic programs—e.g., how lessons learned by the Global Polio Eradication Initiative about vaccine delivery can shape domestic vaccine delivery.

Architecture of Global Immunization—Susan McKinney, USAID

Ms. McKinney noted that the U.S. public and private sector together play a tremendous role in global immunization, from vaccine manufacturing to foreign aid administration. Despite successful global vaccine initiatives, nearly two million children die annually from vaccine-preventable diseases. Numerous government, private sector, and nonprofit organizations have forged partnerships. Ms. McKinney outlined the vaccine-related efforts of WHO, UNICEF, the Bill & Melinda Gates Foundation, and the GAVI Alliance.

The GAVI Alliance demonstrates the success of building broad partnerships together around the goal of reaching the most children possible and decreasing mortality. Its strategic plan for 2011–2015 emphasizes accelerating uptake of new and underused vaccines and strengthening the capacity of health care systems. It supports these primary goals with efforts to improve the sustainability of national financing and shaping vaccine markets. The GAVI Alliance is forging innovative financing mechanisms, such as leveraging donor pledges to achieve lower, sustainable pricing for vaccine for developing countries. (Ms. McKinney pointed out that U.S. contributions to the GAVI Alliance are made on a strictly cash basis.)

USAID serves three functions:

- Provide funds to help reduce child mortality through immunization (at the country, regional, and global levels).
- Engage in policy dialogue and development (at the global and country level).
- Engage in technical dialogue and development and provide technical support (at the global and country level).

USAID is investing in malaria and HIV/AIDS vaccine development initiatives by U.S. Government (USG) and international organizations. It supports immunization efforts through the GAVI Alliance, the Global Polio Eradication Initiative, WHO, and the CDC, and through its own Maternal/Child Health Integrated Program. USAID also targets investments to specific countries, regions, or missions.

Discussion

There are many options for individuals to make donations to support global immunization, including the United Nations Foundation's Shot@Life campaign. United States purchasing power permits manufacturers to provide tiered pricing that helps poor countries get the vaccines they need; tiered pricing may also foster innovation and encourage manufacturers to make vaccine available to emerging markets for marginal costs. Vaccine manufacturing efforts in developing countries benefit from the research and

development that takes place in industrialized countries. Dr. McKinney noted that USAID has target product profiles that may provide some guidance for manufacturers. She also noted that research and development must focus on packaging, shipping, storage, and administration issues as well as vaccine development for developing countries.

Action Item

For an upcoming NVAC meeting, NVPO staff will schedule an overview of the United Nations Foundation's Shot@Life campaign.

***National Institute of Allergy and Infectious Diseases (NIAID) International Vaccine Research—
Barbara Mulach, Ph.D., NIH***

As part of the U.S. vaccine enterprise, NIH plays a large role in conducting and supporting research on the next generation of vaccines—for HIV, malaria, tuberculosis, etc., said Dr. Mulach. The bulk of vaccine research takes place within NIH's NIAID. Within NIAID, the Division of Microbiology and Infectious Diseases supports research in 93 countries through the International Collaborations in Infectious Disease Research program, the Tropical Medicine Research Centers, the International Research in Infectious Disease including AIDS program and the International Centers of Excellence for Malaria Research. Other global efforts include the Centers of Excellence for Influenza Research and Surveillance, the Indo-United States Vaccine Action Program, the Tuberculosis Research Unit, and the Tuberculosis Clinical Diagnostics Research Consortium.

NIAID is involved in several public-private partnerships, including the PATH Malaria Vaccine Initiative, Aeras Tuberculosis Vaccine Development, and the Pediatric Dengue Vaccine Initiative. Dr. Mulach presented a graphic illustrating the role of NIAID in efforts to develop a new malaria vaccine. NIAID partnered with the government of Gambia, USAID, WHO, and others to test pneumococcal vaccine in 17,000 infants in rural Africa, reducing childhood mortality by 16 percent and cases of pneumonia by 37 percent.

Dr. Mulach said NIH is active throughout the product development pathway, providing researchers with funding, research tools and technologies, and preclinical and clinical services to facilitate product development. But the process requires collaboration across government and with industry, academia, nonprofit organizations, and international organizations, she concluded.

Discussion

In addition to research on pathogens, NIH funds efforts to improve vaccine technology, such as delivery systems. Dr. Mulach said NIH appreciates insight from NVAC on its priorities for vaccine development. Dr. Gellin pointed out that the IOM is evaluating the research portfolio and initiatives at NIH, USAID, the Decade of Vaccines, and other sources to inform its evaluation of vaccine research priorities; the IOM's first report on the matter will be released in April.

Action Item

For the June 5–6, 2012, NVAC meeting, NVPO staff will provide an update on the IOM's committee tasked with evaluating priorities in vaccine research and development.

Dr. Mulach noted that researchers are working on the next generation of malaria vaccines and getting promising results. Investigators have had limited success developing an HIV vaccine; they have been frustrated by the difficulty of achieving high levels of immunogenicity and so are considering other strategies.

FDA International Engagement in Vaccines—Marion Gruber, Ph.D., FDA

Dr. Gruber said the Center for Biologics Evaluation and Research (CBER) at FDA recognizes the importance of international engagement and collaboration as well as the need for creative and flexible regulatory pathways to licensure. CBER has information-sharing agreements with regulatory authorities in other countries and participates in international advisory groups. Its numerous collaborations with WHO include the Global Advisory Committee on Vaccine Safety, the Strategic Advisory Group of Experts, the Expert Committee on Biologic Standardization, the African Vaccine Regulators Forum, and the Developing Countries' Vaccine Regulators Network.

For national regulatory authorities in developing countries, CBER contributes to WHO training workshops and advisory efforts. For example, in 2010, CBER and its Australian counterpart sent subject matter experts to Thailand to participate in an independent evaluation of a Japanese encephalitis vaccine, advising the Thai authorities on the process.

CBER developed a conjugate vaccine to prevent meningitis in Africa that was used by the Meningitis Vaccine Project (a collaboration between PATH and WHO) to vaccinate 20 million people so far. The effort demonstrates how CBER applies technologies developed in its own laboratories to address public health issues in the United States and around the world.

The development of a malaria transmission-blocking vaccine illustrates the challenges to creating flexible regulatory frameworks. The vaccine provides no direct benefit to the recipient but rather indirectly and over time may lower morbidity and mortality within a community. A group of regulators, scientists, and public health authorities evaluated the U.S. regulations and determined that a product is not required to benefit the recipient directly, allowing vaccine developers to move on to advanced clinical development.

In 2008, FDA issued new guidance on regulatory pathways for vaccine development. FDA encourages sponsors to develop vaccines for global infectious diseases and recently updated its guidance to reflect the shift in regulatory policy. Dr. Gruber clarified that FDA can license vaccine for an infectious disease not endemic to the United States and can accept data from outside the United States to support licensure applications.

Discussion

FDA continues to face resource constraints that can lead to bottlenecks in the regulatory process. Dr. Gruber noted that much work needs to be done to establish sound regulatory requirements around the world. It was noted that there has been discussion at the international level of “banking” evidence assessments as a means to ensure a standardized, evidence-based foundation for recommendations without the laborious and costly process of developing new evidence for every situation.

Charge from the ASH

Dr. Gellin reiterated the charge from the ASH to review the role of HHS in global vaccine efforts. A working group was proposed. Ms. McKinney hoped the NVAC would support continued and greater engagement of the USG in global immunization efforts; Dr. Orenstein said USAID should be represented on the working group. It was suggested that the charge to the working group clearly specify what the group should address, including raising the visibility of USG efforts and their value to the general population. The economic as well as public health benefits of global immunization initiatives should be highlighted. It was determined that the NVAC can establish a working group to address the ASH's charge, and the working group itself can consider in detail what to address and how.

Action Items

NVAC unanimously approved the following resolution:

Preamble

Goal 5 of the U.S. 2010 National Vaccine Plan specifies that the United States should increase efforts towards global prevention of death and disease through safe and effective vaccination. The role of the USG in global vaccination should be reviewed to ensure that we are on track to fulfill our responsibilities and meet these goals and objectives.

Resolution

NVAC charges a working group with the tasks of reviewing the role of HHS in global vaccination, the effects of global vaccination on global populations, and the effects of global vaccination on U.S. populations and recommending how HHS can best continue to contribute, consistent with its newly established Global Health Strategy and Goal 5 of the National Vaccine Plan. The working group should also make recommendations on how best to communicate this information to decision-makers and the general public to ensure continued sufficient resources for the global vaccination effort.

The working group should complete its work and make its report to NVAC by the February 2013 NVAC meeting. This report should provide recommendations to the ASH on how to implement the recommendations.

Dr. Orenstein designated Philip S. LaRussa, M.D., as chair of the new working group on global vaccination. NVAC members who wish to serve on the working group should contact Dr. LaRussa. NVPO staff will work with Dr. LaRussa to identify potential non-NVAC members of the working group.

Revised HCPIVS Recommendations

Dr. Nevin-Woods reiterated that the recommendations represent the majority opinion of the HCPIVS members. Dr. Orenstein designated a group of NVAC members to review the recommendations one more time and make changes if necessary based on the public comments received during the meeting on Tuesday, February 7. That group consisted of Dr. Nevin-Woods, Dr. Morita, Amy Pisani, M.S., Dr. Torres, and Dr. LaRussa as well as Dr. Grabowsky and Jennifer Gordon of the NVPO.

Dr. Orenstein read aloud the following statement submitted by NVAC member Ms. Buck, who was unable to attend the meeting but submitted her votes by proxy:

I am unconvinced that the root of the issue lies with individual health care workers and therefore will not, at any time, support financial penalties or a mandate that threatens one's employment if they exercise their right, as an American, to decline the flu vaccine. I would not support this type of mandate even if it allows for exemptions because I am aware of aggressive campaigns to end the use of exemptions and suspect that this would quickly follow any recommendation the NVAC makes.

The problem, as I see it, lies with the product itself. If the consumer has limited confidence in a product they have the right to choose whether or not they will use the product. In this case the product doesn't have a good efficacy rate and, as with all vaccines, carries a risk of adverse event following vaccination. I see the consumer demanding a better product and would suggest the solution to this issue lie with the manufacturers. I would argue that if they design an improved

product with a better efficacy rate and that has a much better safety profile, uptake rates will rise and perhaps the goals listed in Healthy People 2020 can be achieved.

For these reasons, I will vote no on the recommendations in the draft report, even if they are amended following NVAC discussion. Thank you.

Discussion of Recommendation 1

The recommendation was revised to emphasize that HCP education is a key component of a comprehensive influenza infection prevention plan. The definitions of HCP and HCE come from HHS and the CDC; they are broad and meant to apply to anyone who might be exposed to or transmit influenza. However, the recommendations do not specify that individual facilities must use those definitions. Because the Healthy People 2020 goal of 90-percent coverage of HCP was controversial and because goals may be revised over time, it was suggested that the report and recommendations refer to the Healthy People 2020 goal but not specify “90 percent.” There was a suggestion that the HCPIVS evaluate the goal itself, even though it was not part of the charge.

In response to concerns raised about coercive education efforts, Dr. Nevin-Woods pointed out that the HCPIVS report describes the many aspects of a comprehensive influenza prevention plan (including standard infection control practices, free and readily accessible influenza vaccination, interactive education on the benefits and risks, and education on prevention and the role of vaccine). Dr. Orenstein emphasized that education is just one component of a comprehensive infection control effort.

Recommendation

A majority of NVAC members present and on the phone approved Recommendation 1 by a vote of 14 in favor and 1 vote by proxy against:

NVAC recommends that health care employers (HCEs) and facilities establish comprehensive influenza infection prevention programs that include education of health care personnel (HCP) as a key component. Comprehensive influenza infection prevention plans are recommended by the CDC as an essential step for all HCEs and facilities to achieve the Healthy People 2020 influenza vaccine coverage goal.

NVAC recommends that the ASH strongly urge all HCEs and facilities to adopt these recommendations.

Discussion of Recommendation 2

No changes were made to Recommendation 2.

Recommendation

A majority of NVAC members present and on the phone approved Recommendation 2 by a vote of 14 in favor and 1 vote by proxy against:

NVAC recommends that HCEs and facilities integrate influenza vaccination programs into their existing infection prevention programs or occupational health programs.

NVAC also recommends that the ASH assure that this recommendation is implemented in HHS facilities and services (including the Public Health Service, HHS staff, and Federally qualified health centers) and strongly urges all HCEs and facilities to do the same.

Discussion of Recommendation 3

Recommendation 3 was revised so that it focuses exclusively on encouraging the CDC and CMS to develop standardized methodology for measuring vaccine coverage rates.

Recommendation

A majority of NVAC members present and on the phone approved Recommendation 3 by a vote of 14 in favor and 1 vote by proxy against:

NVAC recommends that the ASH encourage CDC and the Centers for Medicare and Medicaid Services to continue to standardize the methodology used to measure HCP influenza vaccination rates across settings.

Discussion of Recommendation 4

Recommendation 4 was revised to emphasize that the first three recommendations should be implemented before an employer requirement is considered. A sentence was added to make explicit that HCEs may consider exemptions other than medical exemptions in their policies. Dr. Hetherington said several aspects of the report and recommendations trouble him: 1) HCP vaccine coverage is used as a surrogate for the goal of reducing influenza infection; neither the intended results nor the definition of a successful intervention are quantified. The language is imprecise and does not describe measurable benefits. 2) The barriers to vaccine uptake are not sufficiently addressed; the need to impose an employer mandate may be a marker for the lack of availability of vaccination opportunities in the workplace. 3) The potential for unintended consequences of a mandate has not been thoroughly discussed. 4) The recommendations do not seem to be helpful for organizations that are trying to implement vaccination programs.

Dr. Nevin-Woods pointed out that the recommendations are intentionally broad, and the HCPIVS recognized that studies may be flawed or controversial and efficacy of the seasonal influenza vaccine changes annually. To make evidence-based recommendations, the HCPIVS evaluated studies from organizations that reached the goal of 90-percent HCP vaccination coverage—some of which have done so while allowing all three exemptions (medical, religious, and personal). It was suggested that the recommendation implies that organizations should do whatever it takes to reach the 90-percent goal. A recommendation similar to that for hepatitis B, which requires employers to offer vaccination and requires employees to sign a declination statement if they refuse, may be preferable. The HCPIVS report clarifies that facilities can determine exemptions in consultation with HCP. Dr. Grabowsky asked that the recommendations state “HHS staff who are HCP” to clarify that they do not apply to all HHS staff.

Recommendation

A majority of NVAC members present and on the phone approved Recommendation 4 by a vote of 12 in favor, 1 abstained, 1 against and 1 vote by proxy against:

For those HCEs and facilities that have implemented Recommendations 1, 2, and 3 above and still have not consistently achieved the Healthy People 2020 goal for influenza vaccination coverage of HCP in an efficient and timely manner, NVAC recommends that HCEs strongly consider an employer requirement for influenza immunization. In addition to medical exemptions, HCEs may consider other exemptions in their requirement policies.

NVAC also recommends that the ASH assure that this recommendation is implemented in HHS facilities and services (including the Public Health Service, HHS staff who are HCP, and Federally qualified health centers) and urge all other HCEs and facilities to do the same.

Discussion of Recommendation 5

The phrase “improved vaccine immunogenicity” was replaced by the phrase “improved vaccine effectiveness.” There was some discussion about whether effectiveness or immunogenicity was the ultimate goal.

Recommendation

A majority of NVAC members present and on the phone approved Recommendation 5 by a vote of 14 in favor and 1 vote by proxy against:

NVAC recommends that the ASH encourage ongoing efforts to develop new and improved influenza vaccines and vaccine technologies, including support for research, development, and licensure of influenza vaccines with improved effectiveness and duration of immunity, as well as steps that improve the immunogenicity and rapid production of existing influenza vaccines.

Discussion of the Executive Summary

The following statement was added to the first paragraph of the Executive Summary:

HCP who are committed to promoting the welfare of patients and the health of the public, and to safeguarding their own and their colleagues’ well-being, have an ethical responsibility to take appropriate measures including vaccination, to prevent the spread of influenza infections in health care settings.

Recommendation

A majority of NVAC members present and on the phone approved the change to the Executive Summary by a vote of 12 in favor, 2 against and 1 vote by proxy against:

NVAC approved the report, *Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccination Coverage for Health Care Personnel*, with two changes. First, the document will refer to the Healthy People 2020 goal for influenza vaccine coverage of HCP without the phrase “of 90 percent.” Second, the following sentence will be inserted into the first paragraph of the Executive Summary:

HCP who are committed to promoting the welfare of patients and the health of the public, and to safeguarding their own and their colleagues’ well-being, have an ethical responsibility to take appropriate measures, including vaccination, to prevent the spread of influenza infections in health care settings.

It was noted that NVAC takes public comments into consideration in its deliberations but is not required to demonstrate how or whether it responded to specific public comments.

Agency, Department, Advisory Committee, and Liaison Reports

ASTHO—Paul Jarris, M.D., M.B.A.

Since the most recent election, there has been a lot of turnover among State health officials. ASTHO is orienting new officials about the VFC, Section 317, and other programs. In March, ASTHO will meet with representatives on Capitol Hill; the availability of Section 317 funds to sustain vaccine infrastructure is among the organization’s top five priorities. Also, at the kickoff meeting of an advisory committee that brings together pharmacists and public health providers, there were a lot of questions about vaccination during a pandemic or public health emergency.

AHIP—Wayne Rawlins, M.D., M.B.A.

AHIP is working with Lance Rodewald, M.D., of the CDC on mechanisms that allow public health providers to bill private insurance plans when insured individuals receive vaccine from a public health provider (a.k.a., third-party billing).

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

The HHS Secretary proposed adding intussusception to the Vaccine Injury Table for rotavirus vaccines. At present, the two vaccines, Rotarix and RotaTeq, are covered by VICP but the Vaccine Injury Table does not list specific injuries or conditions covered for these vaccines. When conditions are listed on the Table, petitioners do not have to prove causation. Studies from South America and Australia reported a small risk of intussusception with both vaccines. ACCV approved the proposal and alternative causes that, if present, would render the vaccine unrelated to the condition. The proposal will be published for public comment. VICP has received 15 claims related to rotavirus vaccine since 2006. At its next meeting, ACCV will hear a report from the IOM. The notes from the December ACCV are now available here at the ACCV [website](#)

ACIP—Jonathan Temte, M.D., Ph.D.

At its October 2011 meeting, ACIP voted to approve the 2012 childhood, adolescent, and adult vaccine schedules, which are now being disseminated in multiple journals. ACIP recommended routine use of HPV vaccine in males ages 11–21 years and for males ages 22–26 years who are HIV-positive or who have sex with men. ACIP made a “permissive recommendation”—i.e., the vaccine may be considered—for all other men ages 22–26 years. ACIP also recommended that all previously unvaccinated adults ages 19–59 years with diabetes mellitus be vaccinated against hepatitis B as soon as possible after a diagnosis of diabetes is made. Adults age 60 years or more with diabetes may be vaccinated at the discretion of the treating clinician after assessing their risk and the likelihood of an adequate immune response to vaccination.

Dr. Temte noted that ACIP has been using an evidence-based framework for over a year that involves grading the available evidence. The recommendations for HPV and hepatitis B vaccine are the first two to result from the new system. While the new system is slow, ACIP work groups feel it improves their deliberations and helps them focus on the evidence. A description of ACIP’s methods was published in *Vaccine* in [November 2011](#). At its February 2012 meeting, ACIP will vote on Tdap vaccine recommendations for people age 65 years and over. It will also discuss influenza vaccine, 13-valent pneumococcal conjugate vaccine for people age 50 years and over, hepatitis B protection in HCP, meningococcal vaccine for infants ages 29–33 months, use of a third dose of measles-mumps-rubella (MMR) vaccine for mumps outbreaks, and measles and rubella elimination status.

AIM—Claire Hannan, M.P.H.

Ms. Hannan said her organization strongly supports mandatory influenza vaccination as a condition of employment for HCP. AIM recently held its annual immunization program managers meeting with the CDC, where the main focus was on the next 5-year grant cycle for Section 317 funding. Discussion centered on changes to the environment for insured children and using funds to support infrastructure and to modernize information technology. AIM is working with the CDC to ensure that the grant priorities align with those of the States. Money from the Prevention and Public Health Fund continues to support additional activities beyond those supported by Section 317, such as awards to States to modernize IIS and make them interoperable with electronic health records and to implement new vaccine ordering and management systems. The money also supports States in developing third-party billing systems and immunizing adults in school-based clinics. The organization is tracking how States use their Federal funding. Ms. Hannan emphasized that the Prevention and Public Health Fund is an important supplement

to Section 317, and AIM hopes it continues. She added that AIM strongly supports NVAC's resolution on continued funding for vaccine administration infrastructure.

NACCHO—Anne Bailowitz, M.D., M.P.H.

At its annual meeting in July, NACCHO agreed to support policies for adult and adolescent vaccine recommendations that synchronize with those of the CDC. Ms. Bailowitz noted that the 2011–2012 influenza season has been a mild one from the perspective of local health departments. Local health departments are seeing their clientele shift: 67 percent of their clients for seasonal influenza vaccination are people ages 25–64 years; more people age 65 and older are getting vaccinated by private providers. NACCHO is compiling a collection of the billing tools being used by public health departments that are beginning to implement billing procedures; the tools will be available online to anyone.

CDC—Melinda Wharton, M.D., M.P.H.

Dr. Wharton noted that Dr. Rodewald will be moving to the CDC's global immunization division and then to Beijing to assist the WHO epidemiology program. The first [National Immunization Conference Online](#) will be held March 26–28, 2012. It is a virtual professional education opportunity that will highlight high-priority immunization issues. Dr. Wharton hoped the new format would facilitate participation by a broader range of people, including those who could not attend the conference in person. Dr. Orenstein thanked Dr. Rodewald for his contributions to domestic programs.

VRBPAC/FDA—LT Valerie Marshall, M.P.H., FDA

LT Marshall announced that Norman Baylor, Ph.D., who had been the FDA's ex officio representative to NVAC, retired. Dr. Gruber is the Acting Director of the CBER Office of Vaccines Research and Review. Robert S. Daum, M.D., C.M., is the new VRBPAC chair. At its next meeting, VRBPAC will discuss influenza strains for 2012–2013 and licensure pathways for pandemic influenza vaccine.

NIH—Barbara Mulach, Ph.D.

Dr. Mulach said the NIH collaborative program with the CDC was extended for another 3 years; under this program, investigators are invited to submit their vaccine research ideas. The 2012 Jordan Report on accelerated development of vaccines will be available [online](#). It contains an article by Dr. Gellin on the National Vaccine Plan, another on immunization and pregnancy, and more. Dr. Mulach provided a handout to NVAC members listing vaccines for which trials are ongoing or in development; she offered to provide more details on request.

VICP—Geoffrey Evans, M.D.

In March, VICP will present proposals to ACCV for consultation. Dr. Evans said he would provide an update to NVAC on ACCV at the June 2012 NVAC meeting.

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

Dr. Mabry-Hernandez described the role of AHRQ. In terms of vaccines and quality measurement, AHRQ is responsible for the *National Healthcare Quality Report*, which tracks health care quality measures, and the *National Healthcare Disparities Report*, which looks specifically at vaccines in children. AHRQ also supports investigator-initiated vaccine research. More information is available [online](#).

VA—Richard Martinello, M.D.

In an effort to improve patient safety and staff health, the leadership of the Veterans Health Administration (VHA) met to discuss influenza vaccine effectiveness and safety, operational aspects, and ethical issues of vaccination programs and concluded that more work is needed to meet the Healthy

People 2020 goal of 90-percent HCP vaccine coverage. The VHA will partner with labor leaders and veterans service organizations to communicate the expectation of responsibility for annual influenza vaccination. The VHA will ensure that resources are available to improve access to vaccine, enhance measurement methods, and raise awareness about the impact and importance of vaccine in preventing influenza. Dr. Martinello emphasized that while vaccination is the most effective method for preventing influenza, it is just one part of a comprehensive infection control program that includes education on, for example, respiratory hygiene.

USAID—Susan McKinney

Ms. McKinney said USAID just finalized a 5-year follow-up with the International AIDS Vaccine Initiative to develop an AIDS vaccine and ensure access to it. The organization also has several initiatives around malaria vaccine, including interagency agreements with the Walter Reed Army Institute of Research, the Naval Medical Research Center, and NIAID and a cooperative agreement with the Malaria Vaccine Initiative at PATH. Last summer, USAID committed \$450 million to the GAVI Alliance over 3 years; it recently finalized a \$90-million portion of that commitment. USAID is also working on a roll-out of new vaccines, including pneumococcal and pentavalent vaccine. It is finalizing a joint effort with UNICEF in five countries. It is also active with the Decade of Vaccines Initiative and the GAVI Alliance's Executive Committee and Programmes and Policy Committee.

DoD—COL Scott A. Stanek, D.O., M.P.H.

COL Stanek said DoD's influenza immunization efforts are going well. The vaccine was available earlier than usual, which is beneficial for the military, because it allows more time to reach personnel overseas. DoD met its goal of 90-percent vaccine coverage by December 1, 2011, among the active duty personnel and came very close to the goal among reservists and guard units. In the fall of 2011, DoD started using the adenovirus vaccine. Historically, adenovirus causes significant morbidity among recruit populations; outbreaks among young recruits can lead them to miss out on training days. The vaccine effort is promising, said COL Stanek, and he believes it will eliminate some missed training days. The vaccine was approved in the spring of 2011. While DoD has only been giving the vaccine for a few months, the number of cases appears to be going down. COL Stanek hoped he would be able to give an update in the future comparing adenovirus rates before and after the vaccine initiative began. He added that adenovirus typically spreads in the fall, similar to influenza.

USDA—Cyril Gay, D.V.M., Ph.D.

Animal vaccines primarily fall under the purview of two offices within USDA: the Animal and Plant Health Inspection Service (APHIS) and the Agriculture Research Service (ARS). The United Nations and the World Organization for Animal Health recently declared the eradication of rinderpest the first global animal disease eradication, and efforts are underway to eradicate others. Seventy percent of new and emerging diseases are vector-driven or zoonotic diseases, said Dr. Gay. Many developing countries depend on livestock; ARS is highly involved in controlling disease at the source as a mechanism for biodefense. Hoof and mouth disease, for example, affects a lot of people who deal with livestock, said Dr. Gay. The goal of ARS is to engineer vaccines to control and eradicate animal diseases; it is fairly advanced in development of molecular vaccines and seeks to develop vaccines that stop disease transmission. ARS uses a differentiate-infected-from-vaccinated-animal (DIVA) control strategy. APHIS is the USDA's regulatory arm; in 2011, it authorized 80 billion doses of vaccine for 214 different diseases. It also approved master seeds for pandemic H1N1 for swine.

Under Homeland Security Presidential Directive 9, USDA was directed to develop a U.S. National Veterinary Stockpile capable of deployment within 24 hours of an outbreak. Funds are appropriated strictly for stockpiling vaccine. However, not a lot of vaccines or countermeasures are available, so ARS

is working on research and development and in conjunction with pharmaceutical companies to develop vaccines for the new stockpile.

Discussion

It was noted that there are a lot of rabies exposure cases in New Mexico because people do not choose to vaccinate their dogs. Dr. Gay pointed out that rabies vaccination is a locally-enforced mandate. He said rabies is a global problem that continues to arise and may be more prevalent than previously realized in the United States and globally. Dr. Gay noted while there is no official, mandatory surveillance program for H1N1 among animals, there are ongoing efforts to monitor it, and some new influenza strains have been identified, such as H3N2 in pigs. The animal health world does not have the same surveillance infrastructure that the public health world does, and reporting is voluntary. Some companies have licensed vaccine that is being used by livestock farmers. Dr. Gay also noted that there is no avian influenza in the United States but it is prevalent in Southeast Asia and Africa, where vaccination does occur. The United States does have H5N1 vaccine available in the new stockpile.

Public Comment

Theresa Wrangham said she is the parent of children who were vaccinated until they were injured and that both she and her husband have suffered vaccine reactions. There seems to be a move toward more vaccination in the absence of research on individual susceptibility to vaccine harm. Ms. Wrangham said she applauds NVAC's support for research. She reminded the participants that the lives that are changed by vaccine injury are as precious as those that are lost to disease, but without sound research and adequate reporting, we don't know how many are injured. Injury and death are not acceptable collateral damage, said Ms. Wrangham. We should prioritize research, not just vaccine development. The IOM report on AEFI noted that 85 percent of the literature did not have scientific methodology sound enough for making recommendations, Ms. Wrangham said. She said her family took on the responsibility of learning effective, alternative ways to protect against infectious disease, such as healthy food choices, good sanitation, knowledge of and access to health care, reducing exposure to infection, etc., but these mechanisms are not being discussed. There is little global effort to address scientific gaps about outcomes, risks, compensation for injury, or other health promotion efforts. NVAC should expend as much effort on these aspects as it does on vaccine, said Ms. Wrangham. People have a right to exercise informed consent for medical risk-taking with accurate and complete information on vaccine risks and benefits and the option of conscientious objection.

Ms. Wrangham said that although NVAC's working groups are not subject to FACA guidelines, nothing prevents NVAC from making them transparent, and other advisory committees have done so. She also requested that an audio recording of this and future NVAC meetings be provided to make up for what is not captured by summary minutes and to be consistent with the spirit of the law.

Jim Moody of the National Autism Association said he was struck by how little emphasis there was on the discussion of adequate safety systems as part of the national and international plans. An effective surveillance program that takes into account vaccinated and unvaccinated children and a generous injury compensation program are needed. Concerns about safety must be viewed as an integral part of vaccination—not ignored, mocked, or regarded by the government and the media as an issue raised by selfish parents. There must be an equal commitment to preventing vaccine injury and providing injury compensation.

The vaccine safety guidelines fuel more concern, said Mr. Moody. The CDC says there is no evidence linking autism with vaccine, but the government has spent hundreds of millions of dollars on compensation based on injury. The data are not being acknowledged. The recent IOM report on AEFI disavowed the MMR studies that disclaimed the link between autism and vaccine. A growing body of

scientific literature is linking mercury (which is still present in some influenza vaccines) with AEFI. Mr. Moody called on NVAC to lead a rigorous vaccine safety agenda as part of a comprehensive vaccination plan and to ensure generous compensation of the injured.

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

Dr. Orenstein thanked the NVPO staff for all their hard work, particularly Dr. Salmon and Guillermo J. Avilés-Mendoza, J.D., LL.M. He also praised Katy Seib, assistant to the NVAC chair. Dr. Orenstein thanked the new NVAC members for their active participation and Dr. Nevin-Woods for her handling of an issue that draws many polarizing views. Finally, he reiterated some of the key action items from this meeting and adjourned the meeting at approximately 2:35 p.m.

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

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

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

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

**National Vaccine Advisory Committee (NVAC)
February 7–8, 2012
Summary of Action Items and Recommendations**

Chair's Report

Action Items

NVAC approved the September 2011 minutes with the following revision:

Add as an appendix to the report slide 18 of the presentation titled “Health Care Personnel Influenza Vaccine Subgroup (HCPIVS)” by subgroup co-chairs Julie Morita, M.D., and Christine Nevin-Woods, D.O., M.P.H., presented to the NVAC on September 13, 2011, describing the Subgroup members’ support for various exemption options.

NVAC will work with National Vaccine Program Office (NVPO) staff to provide meeting materials in advance when possible.

NVAC unanimously approved the 2011 State of the Program Report.

Immunization Programs

Action Items

NVAC unanimously approved the following resolution:

Background

The Affordable Care Act provides for a significant expansion of insurance coverage for immunization services, which will—when fully implemented—improve payment for vaccines for children and adults and significantly reduce the substantial population of underinsured children in the United States. As a result, it is expected that the need for public sector purchase of vaccine for underinsured children will be reduced. However, there will remain other critical functions for immunization programs that will need to be developed, maintained, or improved. In addition, Goal 4 of the National Vaccine Plan specifically is to “ensure a stable supply of, access to, and better use of recommended vaccines in the United States.” In order to accomplish this goal, and in particular, objectives 4.2, 4.4, 4.5, 4.6, and 4.7, and in consideration of the changing environment, it is fundamentally important that we improve understanding of the significant roles that these immunization programs play in ensuring continued success of the country’s immunization effort.

Resolution

NVAC charges a working group with the task of identifying and describing critical functions of immunization programs at the national, State, and local level. The working group should complete its work and make its report to NVAC by the September 2012 meeting. This report should provide recommendations to the Assistant Secretary for Health (ASH) on methods to develop, maintain, and improve the nation’s immunization programs in light of environmental changes forthcoming.

Walter Orenstein, M.D., NVAC Chair, designated Litjen Tan, Ph.D., M.S., and Catherine Torres, M.D., as co-chairs of the new working group. NVAC members who wish to serve on the working group should contact Melinda Wharton, M.D., M.P.H., of the Centers for Disease Control and Prevention (CDC). Suggestions for potential non-NVAC members who should be represented on the working group should be sent to Dr. Wharton. The group will provide an interim report of its progress at the June 2012 NVAC meeting.

H1N1 Vaccine Safety Risk Assessment Working Group (VSRAWG)

Action Item

NVAC unanimously approved the VSRAWG *Final Report*, dated January 31, 2012 to be transmitted to the ASH.

National Adult Immunization Summit

Action Item

For the June 5–6, 2012, NVAC meeting, NVPO staff will schedule a report on the status of CDC's implementation of the June 2011 NVAC recommendations for adult immunization.

International Vaccine Issues

Action Items

For an upcoming NVAC meeting, NVPO staff will schedule an overview of the United Nations Foundation's Shot@Life campaign.

For the June 5–6, 2012, NVAC meeting, NVPO staff will provide an update on the Institute of Medicine's committee tasked with evaluating priorities in vaccine research and development.

NVAC unanimously approved the following resolution:

Preamble

Goal 5 of the U.S. 2010 National Vaccine Plan specifies that the United States should increase efforts towards global prevention of death and disease through safe and effective vaccination. The role of the U.S. government in global vaccination should be reviewed to ensure that we are on track to fulfill our responsibilities and meet these goals and objectives.

Resolution

NVAC charges a working group with the tasks of reviewing the role of the Department of Health and Human Services (HHS) in global vaccination, the effects of global vaccination on global populations, and the effects of global vaccination on U.S. populations and recommending how HHS can best continue to contribute, consistent with its newly established Global Health Strategy and Goal 5 of the National Vaccine Plan. The working group should also make recommendations on how best to communicate this information to decision-makers and the general public to ensure continued sufficient resources for the global vaccination effort.

The working group should complete its work and make its report to NVAC by the February 2013 NVAC meeting. This report should provide recommendations to the ASH on how to implement the recommendations.

Dr. Orenstein designated Philip S. LaRussa, M.D., as chair of the new working group on global vaccination. NVAC members who wish to serve on the working group should contact Dr. LaRussa. NVPO staff will work with Dr. LaRussa to identify potential non-NVAC members of the working group.

Adult Immunization Working Group HCPIVS

Recommendations

NVAC recommends the following to the ASH, as described in the report *Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccination Coverage for Health Care Personnel*:

Recommendation 1:

NVAC recommends that health care employers (HCEs) and facilities establish comprehensive influenza infection prevention programs that include education of health care personnel (HCP) as a key component. Comprehensive influenza infection prevention plans are recommended by the CDC as an essential step for all HCEs and facilities to achieve the Healthy People 2020 influenza vaccine coverage goal.

NVAC recommends that the ASH strongly urge all HCEs and facilities to adopt these recommendations.

Recommendation 2:

NVAC recommends that HCEs and facilities integrate influenza vaccination programs into their existing infection prevention programs or occupational health programs.

NVAC also recommends that the ASH assure that this recommendation is implemented in HHS facilities and services (including the Public Health Service, HHS staff, and Federally qualified health centers) and strongly urges all HCEs and facilities to do the same.

Recommendation 3:

NVAC recommends that the ASH encourage CDC and the Centers for Medicare and Medicaid Services to continue to standardize the methodology used to measure HCP influenza vaccination rates across settings.

Recommendation 4:

For those HCEs and facilities that have implemented Recommendations 1, 2, and 3 above and still have not consistently achieved the Healthy People 2020 goal for influenza vaccination coverage of HCP in an efficient and timely manner, NVAC recommends that HCEs strongly consider an employer requirement for influenza immunization. In addition to medical exemptions, HCEs may consider other exemptions in their requirement policies.

NVAC also recommends that the ASH assure that this recommendation is implemented in HHS facilities and services (including the Public Health Service, HHS staff who are HCP, and Federally qualified health centers) and urge all other HCEs and facilities to do the same.

Recommendation 5:

NVAC recommends that the ASH encourage ongoing efforts to develop new and improved influenza vaccines and vaccine technologies, including support for research, development, and licensure of influenza vaccines with improved effectiveness and duration of immunity, as well as steps that improve the immunogenicity and rapid production of existing influenza vaccines.

NVAC approved the report, *Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccination Coverage for Health Care Personnel*, with two changes. First, the document will refer to the Healthy People 2020 goal for influenza vaccine coverage of HCP without the phrase “of 90 percent.” Second, the following sentence will be inserted into the first paragraph of the Executive Summary:

HCP who are committed to promoting the welfare of patients and the health of the public, and to safeguarding their own and their colleagues’ well-being, have an ethical responsibility to take appropriate measures, including vaccination, to prevent the spread of influenza infections in health care settings.