



**National Vaccine Advisory Committee (NVAC)
September 14–15, 2010, Meeting Minutes**

Committee Members in Attendance

Guthrie S. Birkhead, M.D., M.P.H., Chair
Jon R. Almquist, M.D.
Tawny Buck
Richard D. Clover, M.D.
Mark Feinberg, M.D.
Clement Lewin, Ph.D., M.B.A.
James O. Mason, M.D., Dr.P.H.
Marie McCormick, M.D., Sc.D.
Julie Morita, M.D.
Christine Nevin-Woods, D.O., M.P.H.
Patricia Parnell (by phone)
Laura E. Riley, M.D.
Litjen Tan, M.S., Ph.D.

Executive Secretary

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

Assistant Secretary for Health (ASH)

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

NVAC Ex Officio Members

Norman Baylor, Ph.D., Food and Drug Administration (FDA)
Limone Collins, M.D., (for COL Renata Engler), DoD
Geoffrey Evans, M.D., Health Resources and Services Administration (HRSA), VICEP
Rick Hill, D.V.M., M.S., USDA
Margaret McCloskey, R.N., M.P.H., Agency for International Development (USAID)
Barbara Mulach, Ph.D., NIH
RADM Anne Schuchat, M.D., U.S. Public Health Service (USPHS), CDC
Richard Martinello, M.D., VA
CAPT Melinda Wharton, M.D., USPHS, CDC

NVAC Liaison Representatives

Anne Bailowitz, M.D., M.P.H., National Association of County and City Health Officials (NACCHO)
Anna DeBlois Buchanan, M.P.H., ASTHO
Magdalena Castro-Lewis, Advisory Commission on Childhood Vaccines (ACCV)
Claire Hannan, M.P.H., Executive Director, AIM
Alan Rosenberg, M.D. (for Wayne Rawlins, M.D., M.B.A.), America's Health Insurance Plans (AHIP)
Kathy Talkington, M.P.Aff., ASTHO
Jon Temte, M.D., Ph.D. (for Carol Baker, M.D.), Advisory Committee on Immunization Practices (ACIP)

Day 1—September 14, 2010

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

Dr. Birkhead welcomed the participants and summarized the agenda for the meeting. He emphasized that during the public comment period, NVAC members, liaisons, and presenters would not be taking questions from the general public or the media. Dr. Birkhead thanked Mark Feinberg, M.D., who will complete his term following this meeting.

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

Dr. Koh thanked the NVAC and NVPO leadership for helping the Department of Health and Human Services (HHS) address the H1N1 pandemic, coordinate vaccine safety monitoring, and update the National Vaccine Plan, among other efforts. He also thanked NVAC members Jon R. Almquist, M.D.; Cornelia L. Dekker, M.D.; Trish Parnell; and Andrew T. Pavia, M.D., whose terms expired but who have agreed to stay on for another 180 days.

Dr. Koh said that when he asked HHS Secretary Kathleen Sebelius to address the NVAC, she accepted on the spot, indicating her commitment to vaccine issues and her gratitude to the NVAC. Sec. Sebelius will speak about PPACA, which ensures that new insurance plans cover all ACIP-recommended vaccines with no cost-sharing. The Secretary recognizes the importance of prevention in health care reform, and she and Dr. Koh co-wrote an [editorial](#) published in the *New England Journal of Medicine* outlining that perspective.

Coordination of the seasonal influenza vaccination campaign has shifted back to the ASH from the Assistant Secretary for Preparedness and Response (ASPR), and HHS hopes to build on the successes of and lessons learned from the H1N1 pandemic. A new interagency task force on seasonal influenza has been established to bolster the efforts of CDC and increase collaboration among HHS agencies. Dr. Koh described some of the specific steps already taken toward improving vaccination rates among pregnant women, health care workers, and minority populations and involving more employers in vaccination efforts.

Vaccination is among the pillars of an effective public health system, said, Dr. Koh, and he hoped that the Healthy People 2020 guidelines would promote more adult immunization. Dr. Koh is eager to hear input from the NVAC on making Healthy People 2020 come alive and serve as an even more effective tool to improve public health. HHS also has a renewed emphasis on preventing viral hepatitis, and an interagency working group is meeting monthly to develop a proposed action plan, on which the NVAC will be asked to comment.

Discussion

Dr. Birkhead said the NVAC will review the Healthy People 2020 goals when they are finalized and determine a process for monitoring progress. The AIWG will address health disparities among minority populations and vaccination of health care workers as part of its charge. The NVAC stands ready to consider the action plan to prevent viral hepatitis. Dr. Birkhead emphasized that the NVAC looks forward to the opportunity to be involved in developing regulations guiding the implementation of PPACA and will provide assistance, input, or comment as needed. Julie Morita, M.D., said she has never before seen such a high level of engagement in the public health system to address influenza or hepatitis B.

In considering vaccination of health care workers, Dr. Koh said that NVPO could break down the statistical data to better identify who is getting vaccinated. He noted that mandates are a sensitive topic for

which all perspectives should be taken into account. The low rate of vaccination among health care workers is a concern for HHS.

Dr. Birkhead said there appears to be consensus around the need for a vaccine safety effort coordinated by HHS that enables cooperation among all the relevant agencies and departments—as the Vaccine Safety Risk Assessment Working Group (VSRAWG) did. Public confidence is critical to the vaccine enterprise, said Dr. Birkhead. The Vaccine Safety Working Group (VSWG) will seek stakeholder input and public engagement in making its recommendations.

Report of the Chair—Guthrie S. Birkhead, M.D., M.P.H.

Dr. Birkhead summarized the status of the NVAC work in progress, including new initiatives undertaken at the request of the ASH. In addition, at the July NVAC teleconference, NVPO asked the NVAC to evaluate the 2010–2011 seasonal influenza vaccination campaign in light of the universal vaccination recommendation. Dr. Birkhead summarized recent NVAC accomplishments, including interim recommendations on vaccine safety monitoring for the 2010–2011 seasonal influenza vaccination campaign and submission of two sets of comments on proposed rulemaking reiterating the NVAC’s earlier recommendations on vaccine financing.

For the 2010 State of the National Vaccine Program Report, Dr. Birkhead proposed a framework that addresses health care reform, lessons learned from the H1N1 pandemic, seasonal influenza issues, and vaccine safety. A draft report will be developed by the end of the year, circulated for comment among NVAC members, and presented for a vote at the February meeting.

Discussion

Members noted that vaccine supply and availability affect the success of vaccination campaigns, and it was suggested that the NVAC look at the dynamics of the influenza vaccine market. Providers need more evidence-based guidance on educating patients, especially older adults, about when to get the influenza vaccine.

Action Items

The following issues were suggested for inclusion in the draft 2010 State of the Program Report:

- Sustainability of infrastructure to support immunization programs (e.g., continued funding for local health departments)
- Acknowledgment of the efforts of the Federal VICP

The NVAC approved the minutes of meetings held from June through August 2010.

The following issues were suggested by NVAC members for possible consideration at future meetings:

- Supply and availability of thimerosal-free influenza vaccine
- Gaps in health care not addressed by PPACA to date and gaps that will likely not be addressed even when PPACA legislation is fully implemented
- Overview of the work of the VICP

Impact of the Medical Countermeasures Review on Future Influenza Vaccines—George Korch, Ph.D., Senior Science Advisor, Office of the ASPR

Dr. Korch summarized the conclusions of the comprehensive evaluation of the medical countermeasures development and procurement process that are described in the recent report, [The Public Health Emergency Medical Countermeasure Enterprise Review: Transforming the Enterprise to Meet Long Range National Needs](#) (see [Medical Countermeasures Review](#)). The essence of the report, he said, is that a product should never fail because of lack of attention to the business and regulatory aspects of development. That is, government entities should facilitate efforts to develop safe and effective medical countermeasures. The report envisions the development of a “nimble, flexible capacity to produce [medical countermeasures] rapidly in the face of any attack or threat, known or unknown, including a novel, previously unrecognized naturally occurring emerging infectious disease.”

The need to upgrade the scientific capacity of the FDA resonated with Congress and stakeholders, said Dr. Korch, and the FDA will receive \$170 million to invest in regulatory science. The FDA will also organize regulatory action teams around specific products, an approach that has worked well in the past. It will establish a new framework to address issues such as emergency use authorization data collection requirements as well as the animal efficacy rule (which allows manufacturers to submit efficacy data from animal studies instead of human studies in some cases).

HHS will also establish a center(s) for excellence in advanced development and manufacturing to expand the product pipeline. Dr. Korch described efforts underway throughout HHS to address gaps identified by the analysis and the findings of the President’s Council of Advisors on Science and Technology. He gave examples of how industry and government can work together to foster innovation and decrease the time it takes to move products from discovery to production, with attention to smaller businesses that lack the full spectrum of resources. For example, HHS will facilitate development of a nonprofit strategic investment initiative, modeled on other Federal programs that will provide venture capital and business expertise to help manufacturers pursue commercially viable products. In addition, the National Institute of Allergy and Infectious Diseases (NIAID) will create an incubator program that provides investigators with additional funds and resources to pursue research with potential for biodefense applications. Internally, HHS is working to streamline decision-making and other processes at the agency level.

Discussion

In response to questions from NVAC members, Dr. Korch described the roles of the Enterprise Governance Board and the Enterprise Executive Committee in overseeing medical countermeasures development efforts. He said HHS is revamping the enterprise on the basis of lessons learned from establishing the Biomedical Advanced Research and Development Authority (BARDA), responding to the H1N1 pandemic, and other events. Dr. Korch said that HHS hopes its investment in resources will stimulate interest among manufacturers and allow them to translate discoveries into new applications. Bruce G. Gellin, M.D., M.P.H., noted, for example, that findings related to pandemic influenza will be applied to seasonal influenza as soon as feasible—and some manufacturers already have done so. Dr. Korch anticipated that HHS’ investment could ultimately shave one to two months off the time needed to produce a countermeasure in an emergency.

Mandatory Influenza Vaccination of Health Care Personnel (HCP)—Hilary Babcock, M.D., Infectious Diseases Society of America (IDSA), Society for Healthcare Epidemiology of America (SHEA)

[Dr. Babcock](#) described the rationale behind SHEA’s support for mandatory vaccination of health care workers as a condition of employment and professional privileges, with medical exemptions and as part of a comprehensive plan to prevent the spread of influenza. She summarized the basic arguments and supporting data for mandatory vaccination, noting, for example, the persons can transmit influenza before

symptoms occur making self deferral from work by ill HCP an ineffective strategy to prevent HCP to patient transmission. Other data show that morbidity and mortality rates decrease when the percentage of vaccinated health care workers increases.

Vaccination rates among health care workers have not increased substantially over the past five years, despite extensive education and promotion. The success of some efforts to make vaccination mandatory varies according to the nature of the individual's right to refuse in the form of signed declination statements. Dr. Babcock pointed out that increasing vaccination rates dovetails with CMS efforts to decrease hospital-acquired infections. She summarized the ethical considerations of mandatory vaccination as well as some key legal opinions. Studies comparing voluntary and mandatory programs find that although some voluntary programs can achieve higher-than-average vaccination rates, mandatory programs achieve rates of 98–99 percent. Dr. Babcock described results from some mandatory vaccination programs and noted that a number of professional organizations are in favor of such programs.

Dr. Babcock highlighted the following:

- Most States allow exemption from school entry requirements on the basis of religious beliefs, and nearly half allow exemptions on the basis of philosophical beliefs.
- Published data show that the easier it is to obtain an exemption from mandatory vaccination for school entry, the higher the rates of unvaccinated children.

Finally, Dr. Babcock summarized the pros and cons and potential barriers and benefits of mandatory vaccination. She pointed out that employee vaccination rates may eventually become a quality measure.

Discussion

In response to questions from NVAC members, Dr. Babcock said that some mandatory vaccination programs faced challenges from employee unions, primarily over the lack of union involvement and negotiation regarding changes to the conditions of employment. Some people are concerned that with the implementation of mandatory vaccination programs, institutions will abandon other infection-control steps. SHEA recommends that employers bear the cost of vaccine for mandatory programs, which could have financial implications, but Dr. Babcock said much of the expense would be balanced out because there would be less need for intensive vaccination promotion and tracking of vaccinated and unvaccinated employees. Dr. Babcock said she would try to identify data on whether patient vaccination rates increase when their doctors and nurses are vaccinated. She noted that the longer a given vaccine mandate has been in place, the more acceptable it is to workers. It was suggested that potential cost savings from decreased illness be analyzed among organizations where mandates have been in place for some time.

Dr. Babcock said some organizations have succeeded in requiring all affiliated employees to be vaccinated, and some have linked vaccination with hospital privileges. It was suggested that if the government pursues a quality measure for worker vaccination, organizations should be rewarded for high vaccination rates, rather than penalized for low rates. The CDC and CMS are pilot-testing such a measure in several facilities, and the National Quality Forum is reviewing the issue. Dr. Babcock noted that New York is considering a State-wide mandatory vaccination policy for health care workers.

Strategies and Tactics to Implement and Monitor Healthy People 2020—Carter Blakey, Office of Disease Prevention and Health Promotion

Ms. Blakey said her office has incorporated thousands of public and stakeholder comments into the Healthy People 2020 objectives, and an interagency working group is addressing the comments raised by the internal clearance process. She hoped to present the final version to the Secretary in October and

publicly release Healthy People 2020 in mid-December. The initiative will center on a new website, Healthy People Online, which will be easier to update than previous versions and enables individuals and communities to take advantage of a rich statistical database. Ms. Blakey said that a user could, for example, specify the demographics of a community and quickly receive a list of objectives relevant to that community. As part of the HHS' new Community Health Data Initiative, Healthy People 2020 will launch in conjunction with the new Health Indicator Data Warehouse.

Ms. Blakey said HHS will establish an interagency working group to review the objectives periodically to determine whether they reflect the public health landscape. However, she called on the NVAC to monitor the progress of objectives over time. Ms. Blakey added that her office is working with various groups to develop companion materials that provide more detailed information about the objectives.

Discussion

NVAC members suggested combining various objectives on adult vaccines into a single category for adult immunization. The CDC will coordinate the Federal interagency working group that evaluates the objectives, and NVAC input is welcome. The CDC can provide data annually to inform the NVAC review of the progress toward the objectives.

Action Item

At the February 2011 NVAC meeting, CDC will provide data on the 2010–2011 seasonal influenza vaccination campaign.

Seasonal Influenza Vaccine Safety Monitoring—Dan Salmon, Ph.D., M.P.H., NVPO

Dr. Salmon provided an overview of vaccine safety monitoring plans for the 2010–2011 seasonal influenza vaccination program, distinguishing passive from active surveillance systems. Passive systems detect unanticipated signals that merit followup but cannot confirm them. Examples include the Vaccine Adverse Event Reporting System (VAERS) and the Real-Time Immunization Monitoring System. Active systems can be used to assess associations. Examples include the CDC's Vaccine Safety Datalink; systems developed by the Indian Health Service, CMS, VA, and DoD; and the Post-Licensure Rapid Immunization Safety Monitoring system.

Dr. Salmon said the Federal Immunization Safety Task Force H1N1 Working Group includes representatives from all relevant HHS agencies as well as DoD and VA. The group has presented data to the H1N1 Vaccine Safety Risk Assessment Working Group VSRAWG during the 2009-2010 H1N1 influenza vaccination program and will continue to review data regularly.

Discussion

More should be done to communicate the efforts to assess safety and the scientific proof supporting safety. The VSRAWG provided monthly, public updates on safety monitoring. The NVAC's interim recommendations to the ASH on the 2010-2011 seasonal influenza vaccine safety monitoring identified the VSRAWG as a model. The CDC recognizes the importance of communicating to the public that vaccines have proven to be safe. Several members agreed that communication to the public has emphasized risk but need to also emphasize safety.

Dr. Salmon noted that the larger databases allow researchers more capacity to study subpopulations. However, most of the databases were not designed for research, and not all capture ethnic/racial demographic information.

Action Item

Pursuant to the NVAC interim influenza vaccine safety monitoring recommendations, there will be detailed presentations on 2010-2011 seasonal influenza vaccine safety monitoring at the February and June 2011 NVAC meetings.

At the February 2011 NVAC meeting, NVPO staff will provide more detail about the representation of ethnic/racial subpopulations in vaccine safety databases.

H1N1 Vaccine Safety Risk Assessment Working Group (VSRAWG) Report—Marie McCormick, M.D., Sc.D.

Dr. McCormick described the VSRAWG’s charge and the process it has used since it was formed in January. She reiterated that VSRAWG has been evaluating three conditions that have emerged as signals of adverse events related to H1N1 monovalent inactivated vaccine: Guillain-Barré syndrome (GBS), thrombocytopenia/idiopathic thrombocytopenic purpura (TP/ITP), and Bell’s palsy (BP). Dr. McCormick summarized the process and criteria used to evaluate signals. End-of-season analyses are underway to help determine whether the signals identified are spurious or represent true associations. These analyses should be completed by mid-October, and the VSRAWG will consider the findings through the fall. The VSRAWG will provide the NVAC with a final report at the February 2011 NVAC meeting.

Discussion

NVAC members reiterated the importance of communicating about the safety of vaccines and highlighting how government entities and advisory bodies with public representatives worked in collaboration to address concerns about the H1N1 vaccine rapidly and thoroughly. The CDC could expand its communication about safety and incorporate more information from the rich experience with H1N1 vaccine. Information provided to the public should be engaging and understandable. Dr. Salmon noted that a publication is planned (in a supplement to *Pediatrics* that focuses on vaccine safety) that will describe H1N1 vaccine safety monitoring efforts; it includes a brief discussion of the VSRAWG. NVAC members discussed their desire to communicate not only the findings but also the successful process used by VSRAWG; however, findings from the various databases will likely be published independently of one another. Professional and medical societies may be helpful in expanding outreach and communication.

The VSRAWG is anticipating more data about miscarriages. The BARDA has funded a study of children of mothers who received the H1N1 vaccine while pregnant. Laura E. Riley, M.D., noted that no signals related to pregnant women have arisen in the data.

VSWG Report—Tawny Buck, Marie McCormick, M.D., Sc.D., and Janesse Brewer, The Keystone Center

Dr. Birkhead and others emphasized that VSWG is seeking input from the NVAC on the initial assumptions reflected in very rough drafts for discussion only, and the drafts do not represent a consensus of the VSWG. Ms. Buck summarized the VSWG’s charge of reviewing current Federal vaccine safety systems and its efforts to date.. The VSWG has identified several successes of the current system, as well as some areas for improvement:

Successes	Areas for Improvement
• Excellent vaccine safety profiles	• Gaps and uncertainties in the knowledge base
• Development of acellular pertussis vaccine	• Coordination of communication
• Switch from oral to inactivated polio vaccine	• Vaccine injury response (e.g., up-to-date VICP Vaccine Injury Table)

Successes	Areas for Improvement
• Rapid detection and action on intussusception related to RotaShield rotavirus vaccine	• Public confidence in vaccine safety
• H1N1 vaccine safety monitoring	• Decentralized leadership

Dr. McCormick outlined the proposed goals of an ideal vaccine safety system. Among the key functions and attributes identified, evidence-based decision-making, objectivity, and transparency appear to be the most significant. The VSWG is seeking feedback from the NVAC on some of its working assumptions about public confidence in vaccines:

- The general public does not distinguish between the safety of vaccines and the vaccine safety monitoring system.
- Improving the vaccine safety system should lead to increased knowledge about vaccines, more rapid detection and response to adverse events, and, ultimately, safer vaccines.
- Public confidence in vaccines themselves and the safety system affects willingness to be vaccinated.
- Primary care clinicians are generally parents’ most trusted source of information about vaccine safety.

Dr. McCormick and Ms. Buck summarized three draft recommendations and proposed action steps to achieve them. The recommendations address the need for improved leadership, coordination, and oversight of the Federal vaccine safety system; enhanced tools and resources; and more research to strengthen the scientific basis for vaccine safety. The VSWG recognizes that the recommendations are ambitious and require oversight to ensure success, which could be provided by an HHS entity, an advisory body outside of HHS, or an independent agency. The VSWG is still assessing data from multiple sources and will seek input from stakeholders.

Ms. Brewer reviewed some of the findings from the public engagement process conducted in the service of the VSWG’s first task (providing input on the CDC’s Immunization Safety Office’s scientific research agenda) and proposed some mechanisms for collecting stakeholder and public input on improving the vaccine safety system.. Among the issues identified were the need for transparency in reporting data and the importance of a trusted source for providing reliable information.

Initial efforts to gather stakeholder input specifically related to the vaccine safety system (via a meeting in early 2010) revealed consensus around the need to improve the governance and structure of the system as well as acceptance of an external body to assess the system. Ms. Brewer said the VSWG needs a better understanding of perspectives of both stakeholders and the general public to inform its development of recommendations and actions. In addition, the VSWG needs to further explore the options for oversight of a revamped vaccine safety system to determine what is administratively, fiscally, and politically feasible. Ms. Brewer asked for NVAC members’ opinions on the extent to which additional data from stakeholders and the public are helpful and the best methods for obtaining such data.

Discussion

Members discussed the source of the VSWG assumptions about public confidence, noting that qualitative information does not constitute strong evidence. There was disagreement as to whether increasing the focus on vaccine safety improves public confidence in vaccines. Some felt that clinicians need more education, especially during training, about the existing safety system and communicating with patients and parents about vaccine safety.

It was noted that professional organizations identified the need to improve the vaccine safety system, and advocacy groups have supported the idea. However, some suggested public confidence could be improved without overhauling the entire system—for example, by improving clinician education, communication, outreach, and research. There are few data about perceptions of the vaccine safety system; however, CDC is reviewing data from large-scale surveys to determine how attitudes about vaccines translate into actions. Some members noted that government’s rapid, effective responses to the H1N1 pandemic and to problems with the rotavirus vaccine have improved public confidence in the system. Some said the current system is robust and there is little evidence to support the need for restructuring it. Improving coordination of efforts among government agencies could address many of the outstanding concerns about the system.

Public Comment

Nancy McGrory Richardson, Hemispherx Biopharma, Inc., provided comment to inform the NVAC about her company’s products, including a broad-spectrum antiviral, a vaccine adjuvant and an injectable interferon product.

James Moody, SafeMinds, provided comment regarding the injury compensation claim paid to the family of Hannah Poling, the need to examine associations between vaccines and autism, and the need to utilize a “safety first” process for future medical countermeasures product development.

Dr. Paul G. King, Coalition for Mercury Free Drugs (CoMeD), provided comment regarding the effectiveness of influenza vaccines and referred to adverse events in pregnancy data reported by the National Coalition of Organized Women (NCOW), which was followed by comment from Eileen Dannemann, NCOW, regarding these same adverse events and whether the VSRAWG utilized VAERS data.

Day 2—September 15, 2010

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

Dr. Birkhead said that VSWG would postpone its plans to gather more stakeholder and general public input until after the group has further discussed its draft recommendations. As a result, the timeline for the VSWG’s final recommendations for NVAC review will likely be pushed back to the June 2011 meeting.

Second National Immunization Congress—Sarah Duggan Goldstein, M.P.H., American Medical Association; Julie Morita, M.D., NVAC, and CDR Angela Shen, NVPO

Ms. Goldstein explained that the Second National Immunization Congress sought to further the recommendations of the initial 2007 meeting. Congress participants agreed to address the following preliminary themes for adults: removing financial barriers (specifically in public financing), enhancing registries, improving access, educating providers, and increasing adult vaccination rates. The Congress established task forces to make recommendations and propose specific action steps. Proceedings and a full meeting summary of the Congress will be published in the fall, and a website will be established to support ongoing dissemination of information.

Discussion

Dr. Birkhead provided a copy of his presentation to the Congress. He noted that Patient Protection and Affordable Care Act (PPACA) requires that for 2013-14, Medicaid will reimburse providers for vaccine administrative fees at the Medicare level; gathering some baseline data now will help in assessing the impact of that legislation. Participation in registries will be one mechanism for measuring the effect of Federal reimbursement for vaccine administration fees. Structural changes, such as clinicians improving

their office refrigeration systems, could be a marker for the effect of PPACA on vaccine coverage. Another may be coverage of recently recommended vaccines for children and adolescents. The Government Accountability Office is currently evaluating the implications of including all recommended vaccinations in Medicare Part B coverage, which the NVAC recommended.

NVAC members discussed the success of school-based vaccination programs during the H1N1 pandemic. Sustainable funding mechanisms remain a concern. Mechanisms are needed to bill those who have insurance but receive vaccinations from public or alternative providers. A representative of NACCHO indicated that an upcoming meeting with the National Association of School Nurses, ASTHO, and others will address school-based programs. One member suggested that tying funding for school-based programs to registry participation would expand the database. Ms. Goldstein said she would remind the Congress about the need for guidance on meeting privacy requirements in school-based vaccination programs, and CDC is already evaluating the issue.

Action Items

At an upcoming NVAC meeting, CDC will describe the kind of data that will be collected as PPACA policies are implemented and how those data can be used to assess the effects of PPACA policies on vaccine uptake (e.g., participation in immunization registries or other process/structural changes that provide insight into changes in provider practice).

The NVAC will consider the feasibility of billing private insurers and Medicaid when their beneficiaries receive vaccinations in public health or alternative settings (a.k.a. roster billing) in the context of improving vaccination uptake.

AIWG—Julie Morita, M.D.

Dr. Morita said the AIWG has thoroughly reviewed adult vaccine recommendations made since 1990 and the barriers to their implementation. It presented draft recommendations to the National Immunization Congress for feedback, and the Congress did not identify any new themes. The AIWG's recommendations call for Federal leadership aimed at improving adult immunization rates, more resources and infrastructure to support immunization, a strategic national plan, and attention to operational issues using real and specific examples. The AIWG white paper under development will describe the potential impact of implementing recommendations, noting, for example, how a coordinated infrastructure for adult immunization would have helped during the H1N1 pandemic. The paper will also discuss the HHS priorities of preparedness, eliminating racial disparities, ensuring an adequate return on investment, and achieving Healthy People 2020 goals.

Discussion

Dr. Morita said that the recommendations are more likely to be implemented successfully if a Federal agency takes ownership of the issue and identifies an individual who will be accountable for implementation. The AIWG hopes to provide specific goals and timelines and to identify entities outside the Federal government to address some issues. Dr. Birkhead added that successful implementation requires collaboration across sectors. Monitoring adult vaccination will help identify who is not receiving needed vaccines. A broader focus on preparedness or health care reform may help the AIWG recommendations get more traction. Dr. Birkhead said he'd like to see a comprehensive rationale for adult vaccination that ties into the broader issues of prevention and preparedness. Demonstration of the return on investment (e.g., decreases in absenteeism and lost earnings) can be a compelling argument for adult vaccination programs.

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

Dr. Nevin-Woods said the AIWG formed a subgroup to recommend strategies to improve the rate of vaccination among health care providers. The group is discussing whether to invite representatives of health care worker unions to participate. The group proposes to evaluate the literature on the outcomes of voluntary strategies (including education, encouragement, and convenient access), declination statements, and mandates. Dr. Nevin-Woods said the group is considering developing a white paper. Dr. Birkhead added that the group is still developing its charge, membership, and stakeholder input process.

Discussion

Health care worker vaccination is a high priority for CDC; HHS interagency projects and pilot studies are assessing how evaluating vaccination rates as a quality measure can be used as an incentive. The city of Baltimore hopes to release the findings from its experience with such reporting in the near future.

Action Item

At an upcoming NVAC meeting, CDC will give a presentation on efforts to incorporate health care provider vaccination rates into quality reporting measures.

PPACA and Vaccines—Sec. Kathleen Sebelius, HHS

Sec. Sebelius thanked the members of the NVAC for their critical input. She noted that immunization transformed public health in the past century by saving incalculable numbers of lives and immeasurable costs, and she hoped to build on that legacy. However, despite the rapid response and support from the NVAC and others that informed HHS throughout the H1N1 pandemic, the timing of production of H1N1 vaccine was not optimal, and that experience prompted the review of the entire medical countermeasures pipeline. As a result, HHS has redirected \$2 billion in preparedness funds to bolster scientific discovery and regulatory science, create clear pathways to development, and ensure agile response mechanisms are available. The Federal government will assist developers with core product development and manufacturing services to meet evolving demands and prepare for the next pandemic. Surge capacity will be expanded so that we rely less on overseas capacity.

Sec. Sebelius said we need to give FDA more support for interactive review and applied research. The revamped medical countermeasures enterprise will provide more support to small companies with big ideas, which have a huge potential to improve public health but often lack the capital to move their products from the microscope to the marketplace. Improvements in potency and sterility assays, for example, will decrease the time it takes to get a new vaccine out to the people who need it. In addition, a modern, flexible public health system is needed to ensure we are prepared to respond quickly and effectively in an emergency. Government partners should work together to develop robust implementation plans and to communicate with the public.

Sec. Sebelius recommended that NVAC members and others visit Healthcare.gov to learn about the implementation of PPACA benefits, many of which address preventive services, such as vaccines. She asked NVAC members to help communicate with clinicians and patients about the safety and efficacy of vaccines. Progress made in convincing reluctant populations about the benefits of vaccines should not end with the H1N1 pandemic. Sec. Sebelius anticipated an ample supply of seasonal influenza vaccine for the upcoming season but said getting the word out about the universal recommendation for vaccination remains a challenge. Some strategies that were effective last year, such as school-based vaccination programs, are no longer available because of costs, and more must be done to improve vaccination rates among pregnant women, older Americans, and health care workers. Flu.gov was effective last year, and HHS will build on that success. Sec. Sebelius noted that the H1N1 pandemic helped the Federal government analyze the strengths and weaknesses of the medical countermeasures enterprise and build critical partnerships for the future.

In conclusion, the Secretary said she appreciated the NVAC's good scientific advice as well as its efforts to spread the word about the prevention benefits of PPACA and the benefits of vaccination. She stressed that we cannot let the extraordinary successes of the 20th century be whittled away in the 21st century by discussions that are not based on facts.

Agency, Department, Advisory Committee, and Liaison Reports

Dr. Feinberg pointed out that many of the issues discussed at this and previous NVAC meetings relate to Medicare and Medicaid programs, but the ex officio representative from the Centers for Medicare and Medicaid Services (CMS) has not been present to engage in discussion with the NVAC.

Action Item

NVPO will urge the ex officio member from CMS to participate in future NVAC meetings.

NVAC members reviewed written testimony from ACIP summarizing its June and August 2010 meetings. In October, ACIP plans to vote on issues related to vaccine schedules for children, adolescents, and adults; meningococcal, pertussis, and hepatitis vaccines; and the proposed framework for evidence-based recommendations.

NACCHO—Anne Bailowitz, M.D., M.P.H.

Dr. Bailowitz said the extension of some Public Health Emergency Response funds may be helpful to local health departments but more guidance is needed. She hoped more funds would be directed to school-based programs; in Baltimore, for example, most H1N1 vaccine was delivered in school settings. Without additional funds, local health departments will not have the resources to meet the influenza vaccination demands.

ASTHO—Kathy Talkington, M.P.Aff.

In July, ASTHO hosted a small meeting of government officials and stakeholders to discuss immunization registries (current status, goals, and barriers to use). Among the barriers are difficulties exchanging information across States, connecting registries with electronic medical records (EMRs), and funding. A summary of the meeting will be available online. Ms. Talkington said next steps were not determined, but a task force may be convened to consider capitalizing on the meaningful use criteria for EMRs.

Action Item

ASTHO will circulate to NVAC members the summary report of its July 2010 meeting on improving immunization registries.

AIM—Claire Hannan, M.P.H.

AIM will hold an immunization program managers meeting in Atlanta November 15–19 to discuss preparing States to move to a centralized vaccine ordering process (in addition to the centralized distribution process), health care reform, adolescent and adult immunization, and school-based programs. Also, AIM is working with CDC to monitor spending of Federal funds for vaccines provided through ARRA; State fact sheets are under development. RADM Schuchat added that centralized ordering is in the pilot stages but could revolutionize the process. It would improve forecasting, inventory management, and quality measurement.

Action Item

AIM will circulate to the NVAC its State fact sheets describing how ARRA funds for vaccines and infrastructure were spent.

CDC—RADM Anne Schuchat, M.D.

RADM Schuchat said some results from the National Immunization Survey on young children would be released on September 16. The survey shows higher, sustained coverage for most vaccines but does reflect the decline in *Haemophilus influenzae* type B vaccination that resulted from a vaccine shortage. In August, the CDC reported findings among adolescents indicating an increasing proportion of those ages 13–17 years are getting vaccinated, but only 27 percent of adolescent girls have received all three doses of human papillomavirus vaccine. RADM Schuchat said fewer than 1 percent of parents are opting out of vaccinations for their children.

California has seen a record number of cases of pertussis, which may be related to the fact that training to improve pertussis diagnosis was conducted in California. Still, the State is responding to an unusually high number of cases among Latino and other populations, including nine infant deaths. The CDC reaching out to communities and providers about vaccine recommendations and has launched a program to provide free tetanus/diphtheria/pertussis (Tdap) vaccine.

The CDC is providing technical monitoring for a global polio eradication effort with the World Health Organization (WHO) and others. Some countries have succeeded in decreasing polio cases; on the other hand, Tajikistan has not had polio cases for years but recently reported 400 cases.

Action Item

At a future NVAC meeting, the CDC will provide an update on global polio eradication efforts.

The CDC has been working with the American Red Cross, WHO, the United Nations, governments, and private-sector organizations to reduce deaths from measles by 90 percent by 2010, with some successes and some challenges. Internationally, there is discussion about a global measles eradication effort. The United States has no formal policy but is considering setting a goal that goes beyond reducing mortality. RADM Schuchat said indigenous transmission of measles in the United States seems to have been interrupted, and current cases are imported from other countries.

VA—Richard Martinello, M.D.

Dr. Martinello said vaccination is a high priority in the VA, and nearly 77 percent of VA health care workers were vaccinated against influenza without a mandatory program. This year, VA aims to reach 80 percent. The VA supports the use of high-dose vaccine consistent with the ACIP recommendations. Dr. Martinello said the issue of mandatory vaccination has been raised at the VA. He said the VA continues to work toward improving patient and provider compliance with seasonal influenza vaccination recommendations, with particular focus this year on women, especially pregnant women.

Action Item

A VA representative will join the NVAC's AIWG.

DoD—Limone Collins, M.D.

Dr. Collins said DoD's seasonal influenza vaccination program for 2009–2010 achieved better than 90-percent compliance in all of the services. Distribution of vaccine for 2010–2011 has already begun overseas. Discussion is underway about developing a single system for tracking immunizations across all of the services to improve monitoring; such a system would integrate with DoD's EMR.

Action Item

DoD will provide data and best practices about its initiative enabling Tricare beneficiaries to be reimbursed for vaccination provided at alternative sites.

USDA—Rick Hill, D.V.M., M.S.

Dr. Hill said USDA is hosting a workshop at NIH later in the week on validating alternative testing methods that would reduce the need to use animals in vaccine safety testing; the workshop recommendations workshop will be published. Also, USDA created an H1N1 influenza vaccine for pigs. It allows makers to combine the new influenza strain with existing strains that are more widely used. In response to the H1N1 pandemic, USDA took the unprecedented step of providing preapproved seeds to fast-track the development of the vaccine for animals.

Action Item

At a future NVAC meeting, USDA will provide an overview of animal health/infectious disease surveillance efforts.

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

Ms. McCloskey said USAID is active in the global polio eradication effort as well as distribution of malaria and HIV vaccines through the Global Alliance for Vaccines and Immunisation (GAVI). GAVI is a global consortium that USAID funds substantially along with Unicef to assist with distribution. GAVI recently reported high demand for TDaP vaccine but limited demand for rotavirus vaccine. A developing country vaccine manufacturing network plans to meet soon. Ms. McCloskey said USAID supports a military program that had success with a malaria vaccine in trials, and there has been significant progress in trials at the NIAID in collaboration with two universities. The International AIDS Vaccine Initiative (IAVI) and NIH have discovered neutralizing antibodies that will inform vaccine design and HIV prevention efforts. IAVI has also made important progress in research on aborted infections, which is cause for optimism.

NIH—Barbara Mulach, Ph.D.

Dr. Mulach said that in August, NIH announced awards of \$100 million over five years for six new Human Immune Phenotyping Centers, which will provide more information on human immune response with less reliance on animal markers. The Centers will broaden understanding of immune response differences among individuals. Dr. Mulach noted that the [NIH REPORTER](#) is a searchable web-based database of all the research supported by or conducted at NIH. In response to a question, Dr. Mulach said that as part of post-licensure evaluation, active surveillance sites are looking at the relationship between chickenpox vaccine and shingles later in life.

Action Item

NVPO staff will work with NIH to circulate a brief tutorial on using NIH's searchable database of NIH-funded research.

FDA—Norman Baylor, Ph.D.

Dr. Baylor noted that in recognition of the need for an alternative identification system for vaccines that better captures lot numbers, FDA recently issued draft guidance on exemptions from the use of linear bar codes for vaccines. Manufacturers must request the exemption, and FDA will review each manufacturer's proposal for a non-linear bar code that comports with the needs of pharmacies but could include product expiration dates, lot numbers, and other data. FDA is accepting comments on the draft guidance. Dr. Gellin added that manufacturers will work together to develop a standard non-linear bar code framework for vaccines. Dr. Almquist noted that the new approach would include identifying information directly on

a prefilled syringe, rather than the package, which will help providers better track syringes. Dr. Bailowitz said a standard format would boost data collection. Dr. Birkhead noted that the non-linear bar codes could be a natural fit for pharmacies that use EMRs.

VICP—Geoffrey Evans, M.D.

Dr. Evans noted that all of the proceedings related to autism have reached their conclusion, although one test case may be appealed to the U.S. Supreme Court. Of more than 5,600 autism claims filed since 1999, many have either 1) been dismissed, 2) been withdrawn by petitioners who wish to pursue the claim outside of the VICP, or 3) have gone beyond the statute of limitations. Dr. Evans said some autism claims remain, and it is unclear whether the petitioners will pursue those claims under a theory not already addressed by the VICP adjudication process. He noted that the VICP posted a redacted version of its adjudication table online indicating that the VICP paid compensation for one autism case. Court orders prevent the VICP from disclosing more information, but Dr. Evans emphasized that the claim was paid in relation to an injury from another factor, not autism. He said Internet searches mistakenly suggest that the VICP has paid out compensation for autism, but HHS has never concluded in any case that autism was caused by vaccination. The VICP has paid compensation for some claims for vaccine-related encephalopathy in children who later developed autism.

In its 22 years, the VICP has awarded \$2 billion. Dr. Evans anticipated that the VICP would award about \$165 million by the end of fiscal year 2010. In fiscal year 2009, the VICP paid \$9 million in attorneys' fees, which includes the autism hearings. The VICP program is unique in that it pays for attorneys' fees as long as the case was prosecuted in good faith, regardless of the outcome.

A Notice of Proposed Rulemaking has been published in the *Federal Register* that clarifies that vaccines recommended by CDC for routine use in children are covered under the VICP even when those vaccines are not yet listed individually in the VICP Injury Table. Finally, the VICP looks forward to the results of the Institute of Medicine's detailed findings on adverse events potentially related to 12 vaccines covered under the VICP.

ACCV—Magdalena Castro-Lewis

Ms. Castro-Lewis said the ACCV provided comments to CDC asking that the language in the influenza vaccine information statements for 2010–2011 be reviewed for accuracy and also for clarity for parents. The ACCV is working with a communications firm to develop a comprehensive national marketing and outreach campaign to publicize the VICP. Through focus groups and interviews, the ACCV has learned that knowledge about the VICP is limited among consumers, providers, and experts, and information about vaccine-related injuries and the VICP is limited. The ACCV will ensure that its messages are informative, fact-based, and tailored to the intended audience. Health care providers and consumers disagree on the level of detail needed in informative materials, when materials should be disseminated, and the effect of increased awareness on consumers' decision to be vaccinated. Finally, Ms. Castro-Lewis relayed results from an analysis by the Health Resources and Services Administration of VICP claims about shoulder pain from 2006 to 2010. It found that vaccines can be unintentionally injected into tissue other than the deltoid muscle because of needle length or inappropriate technique. The ACCV will provide recommendations that address those findings.

NVPO—Bruce Gellin, M.D., M.P.H.

Dr. Gellin reiterated that the interagency task force on seasonal influenza seeks to build on the 2009–2010 experience. It also applies the model of the Federal Immunization Safety Task Force, which worked well. As noted by the ASH, priority issues for HHS and the NVPO are health disparities and influenza vaccination, vaccination of health care workers and their role as advocates of vaccination, and vaccination of pregnant women. The National Vaccine Plan is under review.

Public Comment

Patrick Liedtka, Merck, provided comment regarding the use of quality initiatives and measures and potential impact on vaccination with wider use of these measures, as well as the possible inclusion of adult immunization measures in upcoming CMS regulations for assessing hospital inpatient influenza and pneumococcal vaccination.

Dr. Paul King, provided comment regarding the impact of varicella vaccination on zoster incidence and the possible impact on confidence in childhood vaccination with increased calls for adult vaccination, which may cause parents to no longer believe that childhood vaccination provides lifetime immunity. Additionally, Dr. King discussed the Hannah Poling vaccine injury compensation case.

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

Dr. Birkhead thanked all those who took part and adjourned the meeting at approximately 12:25 p.m.

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

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

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

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

Appendix: Summary of NVAC Action Items

2010 STATE OF THE NATIONAL VACCINE PROGRAM REPORT

The following issues were suggested for inclusion in the draft report, to be reviewed and finalized by the NVAC at the February 2011 meeting:

- Sustainability of infrastructure to support immunization programs (e.g., continued funding for local health departments)
- Acknowledgment of the efforts of the Federal Vaccine Injury Compensation Program (VICP)

STRATEGIES AND TACTICS TO IMPLEMENT AND MONITOR HEALTHY PEOPLE 2020

At the February 2011 NVAC meeting, the Centers for Disease Control and Prevention (CDC) will provide data on the 2010–2011 seasonal influenza vaccination campaign.

SEASONAL INFLUENZA VACCINE SAFETY MONITORING

At the February 2011 NVAC meeting, National Vaccine Program Office (NVPO) and other Federal Agency staff will provide an update on safety monitoring of the 2010-2011 seasonal influenza vaccine. Staff will provide more detail about the representation of ethnic/racial subpopulations in vaccine safety databases.

SECOND ADULT AND ADOLESCENT IMMUNIZATION CONGRESS

At an upcoming NVAC meeting, CDC will describe the kind of data that will be collected as Patient Protection and Affordable Care Act (PPACA) policies are implemented and how those data can be used to assess the effects of PPACA policies on vaccine uptake (e.g., participation in immunization registries or other process/structural changes that provide insight into changes in provider practice).

The NVAC will consider the feasibility of billing private insurers and Medicaid when their beneficiaries receive vaccinations in public health or alternative settings (a.k.a., roster billing) in the context of improving vaccination uptake.

ADULT IMMUNIZATION WORKING GROUP

At an upcoming NVAC meeting, CDC will give a presentation on efforts to incorporate health care provider vaccination rates into quality reporting measures.

AGENCY AND LIAISON REPORTS

NVPO will urge the ex officio member from the Centers for Medicare and Medicaid Services (CMS) to participate in future NVAC meetings.

The Association of State and Territorial Health Officials (ASTHO) will circulate to NVAC members the summary report of its July 2010 meeting on improving immunization registries.

The Association of Immunization Managers (AIM) will circulate to the NVAC its State fact sheets describing how American Recovery and Reinvestment Act (ARRA) funds for vaccines and infrastructure were spent.

At a future NVAC meeting, the CDC will provide an update on global polio eradication efforts.

A Department of Veterans Affairs (VA) representative will join the NVAC's Adult Immunization Working Group (AIWG).

The Department of Defense (DoD) will provide data and best practices about its initiative enabling Tricare beneficiaries to be reimbursed for vaccination provided at alternative sites.

At a future NVAC meeting, the U.S. Department of Agriculture (USDA) will provide an overview of animal health/infectious disease surveillance efforts.

NVPO staff will work with the National Institutes of Health (NIH) to circulate a brief tutorial on using NIH's searchable database of NIH-funded research.

ADMINISTRATIVE ISSUES

The NVAC approved the minutes of meetings held from June through August 2010.