



**National Vaccine Advisory Committee (NVAC)
June 5–6, 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.
Charles Mouton, M.D., M.S.
Amy Pisani, M.S.
Thomas E. Stenvig, R.N., Ph.D., M.S.
Litjen Tan, Ph.D., M.S.
Catherine Torres, M.D.
Vish Viswanath, Ph.D.

NVAC Ex Officio Members

Matthew Burke, M.D., Health Resources and Services Administration (HRSA), Bureau of Primary Health Care (BPHC)
Carter Diggs, M.D., Ph.D., (for Margaret McCluskey, R.N., M.P.H.), U.S. Agency for International Development (USAID)
Geoffrey Evans, M.D., HRSA, Vaccine Injury Compensation Program (VICP)
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)
Mary Beth Hance, Centers for Medicaid and Medicare Services (CMS)
Iris Mabry-Hernandez, M.D., M.P.H., Agency for Healthcare Research and Quality (AHRQ)
Rick Hill, D.V.M., M.S., Department of Agriculture (USDA)
Richard Martinello, M.D., Department of Veterans Affairs (VA)
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)

NVAC Liaison Representatives

Anne Bailowitz, M.D., M.P.H., National Association of County and City Health Officials (NACCHO)
Carol Baker, M.D., Advisory Committee on Immunization Practice (ACIP)
Robert S. Daum, M.D., C.M., Vaccines and Related Biological Products Advisory Committee (VRBPAC)
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)
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

Executive Secretary

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

Day 1—June 5, 2012

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

Dr. Koh welcomed all the participants and thanked the NVAC members for their efforts. He noted that many of the lessons he learned early in his tenure as ASH, which began in the midst of the H1N1 influenza pandemic, have informed other areas, such as Healthy People 2020 goals and the Patient Protection and Affordable Care Act (ACA). Dr. Koh thanked Walter A. Orenstein, M.D., for taking on the role of NVAC chair, and welcomed new member Vish Viswanath, Ph.D., a leading expert in health communications and disparities. He also recognized and thanked outgoing NVAC members Lisa A. Jackson, M.D., M.P.H., James O. Mason, M.D., Dr.P.H., and Marie McCormick, M.D., Sc.D.

HHS believes that improving influenza vaccination rates among health care personnel (HCP) is critical, and it ties in with the goal of the CMS Partnership for Patients to decrease healthcare-associated infections (HAIs). Following the vigorous discussion and recommendations that came out of the February 2012 NVAC meeting on vaccination of HCP, HHS updated its [Action Plan to Prevent HAIs](#), which is now open for public comment. The Plan echoes NVAC recommendations on HCP immunization.

Dr. Koh also appreciated NVAC's recommendations on building a better system for adult immunization. He said this year's inaugural National Adult Immunization Summit in Atlanta represented the culmination of interagency efforts headed by Dr. Koh and NVPO Director Bruce G. Gellin, M.D., M.P.H. Dr. Koh applauded NVAC for addressing current issues at its meetings, as demonstrated by the agenda items on pertussis, infrastructure and funding, vaccine research prioritization, and global vaccine efforts. Finally, Dr. Koh thanked two NVPO staff members who are moving on: Dan Salmon, Ph.D., M.P.H., and CAPT Angela Shen.

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

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

Action Item

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

Dr. Orenstein recognized the new and outgoing NVAC members and briefly reviewed the status of NVAC action items and recommendations. He summarized the meeting agenda. The next NVAC meeting is scheduled for September 11–12, 2012. The meeting dates for 2013 are February 6–7, June 11–12, and September 10–11.

Recent Issues with Pertussis

American College of Obstetricians and Gynecologists (ACOG) Report on Efforts to Enhance Pertussis Vaccination in Pregnant Women—Laura Riley, M.D.

Dr. Riley explained that ACOG's efforts around immunization education for its 55,000 members currently include an Immunization Expert Work Group headed by ACOG's executive director. The Work Group grew out of a Task Force that began in 2006, and efforts around immunization have been gaining

traction in recent years. ACOG routinely collaborates with other organizations, such as the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN). Dr. Riley emphasized that obstetrician-gynecologists (ob-gyns) tend to read only ob-gyn journals and rely heavily on ACOG-generated guidelines, which often morph into standards of care. ACOG has undertaken special education/awareness projects that have been well received on such topics as HIV, group B streptococcus, and H1N1 influenza.

Recently, ACOG updated a [Committee Opinion](#) to support the use of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine for pregnant women. In addition to e-mail messages notifying all ACOG members when new or revised Committee Opinions are published in *Obstetrics and Gynecology* (a.k.a., the green journal), all members will receive a toolkit by mail that includes the following:

- A poster describing appropriate coding for Tdap administration
- Tear-sheets for patients answering frequently asked questions (FAQs) about Tdap vaccination in pregnancy
- Tear sheets for patients on vaccine safety issues
- Tdap vaccine information statement in English and Spanish
- Letter to clinicians signed jointly by ACOG and other medical specialty society leadership emphasizing the importance of maternal immunization to protect vulnerable newborns
- Fliers and cards promoting ACOG's new website, [Immunization for Women](#), which provides up-to-date information for both clinicians and consumers

Dr. Riley added that ACOG participated in the American Academy of Pediatrics' (AAP's) Cocooning Expert Meeting. The end result of that meeting, Dr. Riley said, was that the messages promoting cocooning (i.e., vaccinating a newborn's contacts, such as siblings, grandparents, and babysitters) have limited reach; therefore, ACOG will focus its efforts on vaccinating pregnant women as the most important step in protecting newborns from infection.

ACOG participates in the Text4Baby initiative, which sends pregnant women and new moms health information via text message; it is evaluating the Text4Baby messaging on immunization and may look more closely at pertussis. ACOG is considering developing a template for standing orders for pertussis vaccination. It will add links to the Vaccine Adverse Events Reporting System (VAERS) to the Immunization for Women website. Dr. Riley said many ob-gyns have not heard of VAERS, so more education is needed. Finally, ACOG is exploring collaborations to promote immunization through social media. Dr. Riley concluded that ACOG hopes to build on the enthusiasm for maternal immunization that arose from the H1N1 influenza pandemic.

Discussion

To better understand the barriers to ob-gyn vaccination of pregnant women, Dr. Riley said ACOG's Immunization Expert Work Group hopes to conduct a web-based survey of ob-gyns' involvement in immunization, which varies greatly across the country. Education continues to be a barrier to vaccination, as demonstrated by the lack of knowledge about VAERS. Providing ob-gyn offices with coding instructions has helped with reimbursement, but payment remains a sticking point. Dr. Riley said every office needs a champion for vaccines, but ob-gyn practices are spread thin; having a staff person dedicated to vaccine management, especially in a small office setting, poses a challenge. However, there does appear to be growing willingness to refer patients to a primary care doctor within the same multispecialty group, said Dr. Riley.

Dr. Riley said ACOG would likely support an opt-out immunization policy (that is, indicating that immunization will be provided unless the patient objects – as opposed to simply offering immunization

(opt-in)) if one were put forth by the CDC; she maintained that education is key to clinician changing clinician behavior. ACOG recognizes that it needs to work harder to educate nurses, midwives, and others who work with pregnant women about immunization; such an approach was helpful for influenza vaccination. AWHONN signed on to the letter supporting Tdap vaccination and has been a good collaborator around immunization, and there appears to be growing support from midwives for immunization, Dr. Riley said.

Several members noted that cocooning is an important step toward better vaccine coverage, and Dr. Riley clarified that ACOG still supports the practice. However, for financial and liability reasons, ob-gyns may be reluctant to pursue it. It was noted that multiple specialties converging around providing vaccination to the whole family—perhaps through an in-network pharmacist—could bring down some barriers. It was suggested that ACOG work with the AAP and American Academy of Family Physicians around cocooning. Dr. Riley did not think liability related to potential vaccine injury to the fetus or newborn was a big concern among ob-gyns; the law is unclear on the issue of liability in such cases.

ACOG recognizes the influence that doctors have on their patients; Dr. Riley noted that the toolkit for Tdap in pregnancy includes a physician script that directly states, “I recommend Tdap for you.” The time and knowledge needed to counsel patients about vaccination work together to pose a barrier for ob-gyns, but Dr. Riley hoped the online FAQs for clinicians and consumers would help address some issues. When ob-gyns do recommend immunization, they tend to refer patients to other providers. ACOG hopes to help ob-gyns give vaccines in the office, because some primary care providers refuse to vaccinate pregnant women. ACOG’s executive director sees immunization as a huge opportunity for ob-gyns to practice more preventive medicine, said Dr. Riley.

While vaccine safety concerns were a primary reason that pregnant women were reluctant to get influenza vaccination, such is not the issue for Tdap. In the case of pertussis, protecting the baby may be a stronger message for immunization than protecting oneself.

Washington State Perspective on Pertussis—Chas DeBolt, R.N., M.P.H., Washington State Department of Health

Ms. DeBolt described the current pertussis epidemic in Washington State, where the State Governor declared the current epidemic an emergency. She provided graphs that show the changes over time in pertussis cases and maps illustrating that the incidence is highest along the interstate between Los Angeles and Vancouver; surveillance data are available [online](#) and updated weekly. Ms. DeBolt pointed out that case reports include only confirmed and probable cases; her office is also collecting data on suspected cases. With more people being tested and treated for pertussis sooner, it is possible that fewer people will meet the case definition for pertussis (i.e., coughing for two weeks).

Pertussis affects infants more than any other age group, but the median age of incidence is moving up. Since 2011, Washington has been seeing more cases in school-aged children; the incidence among adolescents ages 10–13 years recently surpassed that among infants. Ms. DeBolt described infant deaths from pertussis since 1996, noting that two thirds of the infants who died were of Hispanic ethnicity. She cautioned that the variables surrounding the cases are complex; for example, local investigators apply their own judgment to determine whether an infant was up to date on vaccines. Ms. DeBolt said that from 2011 to 2012, fewer kids ages 7–10 years old were up to date on their vaccines.

Ms. DeBolt summarized some public health efforts to raise awareness about pertussis and vaccination through traditional and new social media, encourage HCP education, and update surveillance. New pertussis surveillance guidelines focus on people at high risk, said Ms. DeBolt. If a child in school has a disruptive cough, the school sends a letter to the parents advising them about the possibility of pertussis.

Word is getting out through public health and advocacy organizations about access to vaccine, including some free vaccine options. Washington's Secretary of Health, Mary Selecky, has called for more support for adult pertussis immunization. Ms. DeBolt said the State is at a critical point with messaging as it tries to explain why vaccinated children are getting whooping cough, and public health officials are frequently questioned about the effectiveness of the vaccine.

Discussion

Ms. DeBolt said uptake of pertussis vaccine is not easy to identify but appears to be fairly good; Washington State has a lot of people who seek exemption from mandatory vaccination, but there has not been a lot of concern about the pertussis vaccine. Washington State is now looking at granular data from every county to assess doses received by children at each year of age and is planning a case-control evaluation of its immunization registry to assess the effectiveness of Tdap. Not all HCP are participating in the State registry, so the Department of Health will follow up with providers as needed. The State is also looking more closely at why 67 percent of the infant deaths from pertussis occurred among Hispanics. Ms. DeBolt noted that in some cases, clinicians are treating suspected pertussis without testing first, which complicates data collection. The experiences of the State in managing the epidemic may help identify what works and where improvements are needed. Ms. DeBolt said public health authorities have difficulty explaining why immunity from vaccination appears to wane in older kids, but she emphasized that the disease is less complicated in vaccinated people than in those never vaccinated.

Action Item

When Washington State has new information on the uptake of pertussis vaccine by age, NVPO staff will provide an update to the NVAC.

Pertussis Epidemiology and Vaccination in the United States—Tom Clark, M.D., M.P.H., CDC

Dr. Clark described the increased burden of pertussis in the past 30 years, with peaks in 2004 and 2005 and even higher peaks in 2011 across the country. While outbreaks in California and Washington in the past few years have been well publicized, Minnesota and Wisconsin have seen even larger outbreaks. The highest rates of disease occur among infants, which led to recommendations for cocooning and maternal vaccination. The rates of disease among school-aged children, which were increasing over the past few years, appear to be coming back down. Deaths from pertussis, although rare, occur in the youngest infants—those least protected by the vaccine series, said Dr. Clark. Nationally, Hispanic infants have the highest rate of disease, but that disparity goes away in early childhood, and white children have the highest overall incidence of disease.

Dr. Clark summarized the evolution from whole-cell vaccine to DTaP (diphtheria, tetanus, and acellular pertussis) and then Tdap vaccine, noting that current recommendations for Tdap came out of the 2004–2005 pertussis epidemic. He pointed out that Washington State ranks among the highest in Tdap coverage and that Tdap appears to be about 70-percent effective. The data suggest that the Tdap recommendations that went into effect in 2006 appear to be tamping down the burden of disease among adolescents, but herd immunity—particularly for infants—did not reach the levels that public health authorities hoped they would.

Epidemiologic data suggest that immunity from pertussis wanes as kids age depending on the type of vaccine received, and waning immunity may be driving the high rates of disease. Dr. Clark said CDC's principle concern is the relationship of waning immunity to acellular vaccine. Other hypotheses that have been suggested, such as changes in the circulating strains and mismatches between the vaccine and the strains, are unlikely. Another is that pertussis has been in remission with limited boosting, but Dr. Clark said the overall pattern seems longer and the incidence of pertussis has not diminished that much. Others

posit that the incidence may reflect surveillance bias, but Dr. Clark said that theory did not hold up. Still another theory that has yet to be assessed is that immunity may be affected by the availability of various pertussis vaccines from multiple manufacturers.

Because the causes of waning immunity have not been pinned down, Dr. Clark said, efforts are focused on maximizing current vaccine program efforts by raising awareness about pertussis and the vaccine recommendations. Immunizing family members (cocooning) and postpartum mothers is challenging, so the ACIP recently revised its recommendations to emphasize that pregnant women should be vaccinated. The CDC is using its website, traditional and new social media, and partnerships to improve communication about pertussis and vaccination. The pertussis section of the CDC website was in the top five most viewed of the CDC sites in 2011. It also seeks to improve surveillance, evaluate the effectiveness of cocooning and maternal vaccination, assess the duration of vaccine protection, and improve the evidence base to support, for example, a new vaccine or a new disease control strategy or both. Dr. Clark emphasized that the duration of protection from the acellular pertussis vaccines is not ideal, but they are still effective.

Discussion

Dr. Clark said there are limited data on the cost of the epidemic to States, and it is not clear why some States are seeing dramatic changes in incidence. Dr. Orenstein and others emphasized the need for economic impact estimates to inform decision-making about developing new vaccines. Dr. Clark said the incidence in Hispanic infants is a cause for concern, so some communication efforts are targeting Hispanic media outlets, but there does not seem to be a genetic basis. Several people expressed support for cocooning; RADM Anne Schuchat, M.D., and Carol Baker, M.D., stressed that CDC and ACIP are not walking away from the cocooning strategy. However, RADM Schuchat said, adult Tdap vaccination rates are low and broad coverage is challenging. Public health messages can take advantage of the fact that people may be more motivated to be vaccinated for someone else's benefit than for their own, but herd immunity for pertussis is not as good as hoped.

To improve the chances for success with its communication efforts, it was suggested that the CDC examine 1) how people respond to the vaccine information they receive, 2) how best to communicate the complicated message around pertussis vaccine, and 3) who are the target audiences and what type of media are most effective in reaching those target audiences. As with influenza and other vaccines, the more complicated the message, the more difficult it is to communicate.

Phil Hosbach of Sanofi Pasteur said discussions are underway about developing a new or improved pertussis vaccine, but the costs of a placebo-controlled efficacy trial would be enormous. One suggestion has been to compare different vaccine products to determine the effect of switching brands, because the acellular vaccines differ more from one another than the whole cell vaccines did. Clement Lewin, Ph.D., M.B.A., noted that Novartis markets a recombinant acellular pertussis vaccine in Europe; he added that manufacturers consider the marketplace when determining what vaccines to pursue.

Marion Gruber, Ph.D., pointed out that there is some research underway on nonprimate models to evaluate effectiveness, and the FDA is open to discussion with manufacturers about new vaccines and licensure pathways. Barbara Mulach, Ph.D., added that the NIH is also pursuing various research efforts around pertussis and is making antigens available to researchers.

It was noted that research should consider why pertussis is occurring among people who are vaccinated. It was also noted that because infant deaths are occurring within the first month of life, postpartum immunization and cocooning may not be sufficient. Dr. Orenstein suggested NVAC look more closely at improving immunization rates among pregnant women.

Action Item

At the September 2012 NVAC meeting, NVPO staff will report on the status of efforts within HHS regarding pertussis vaccine, including implementation and communication of current vaccine recommendations and understanding of the economic burden of pertussis, identifying where NVAC may offer guidance or advice.

Lessons Learned from Influenza Immunization for Pregnant Women—Jennifer Read, M.D., NVPO

Dr. Read addressed barriers to pertussis immunization for pregnant women, and lessons learned from the October 2011 maternal influenza immunization conference. In 2011 new recommendations regarding pertussis immunization for pregnant women were issued by the ACIP, and these were published in the MMWR. However, influenza immunization for pregnant women has been recommended for over 50 years, and Dr. Read indicated that the experience to date with immunizing pregnant women against influenza helps in understanding potential barriers to implementation of the more recent pertussis immunization recommendations. The two types of barriers Dr. Read addressed were patient barriers and provider barriers. Patient barriers can be categorized into those that are not specific to pregnant women and those that are specific to pregnant women.

Patient barriers not specific to pregnant women include barriers relevant to adult immunization in general. Examples of such barriers would include the following:

- Fear of needles;
- No prior (adult) immunization history;
- Lack of an established relationship with a primary health care provider as a vaccine provider;
- Problems with access to health care (including lack of health insurance, problems with transportation); and
- General mistrust of the medical establishment represents a barrier to immunization.

Patient barriers specific to pregnant women include:

- Lack of knowledge (about risks associated with influenza during pregnancy, about benefits of immunization for both the mother and the infant); and
- Safety concerns (for the pregnant woman, for the fetus/infant).

In terms of overcoming patient barriers, and first focusing on those not specific to pregnant women, Dr. Read indicated that efforts can be directed both outside of the health care setting (community education regarding recommendations for adult immunization and the rationale behind those recommendations) and within the health care setting (those who provide health care to adults emphasizing the importance of immunization and actually offering immunizations).

In order to address patient barriers specific to pregnant women, patient centered education should address three areas:

- Recommendations for immunization for pregnant women;
- The pregnant woman's susceptibility to and morbidity from influenza; and
- The benefits of immunization for both the pregnant woman and her fetus or infant.

The health care provider (which, for pregnant women, is most often an obstetrician) both recommending and offering immunization is key.

Provider barriers can be categorized into three areas:

- Knowledge of recommendations regarding adult immunizations and immunization during pregnancy, as well as the benefits of such immunization;
- Financial issues related to providing immunizations to pregnant women; and
- Immunization program implementation.

There is a need for improvement in the provider, usually an obstetrician, as well as other staff within an obstetrician's office – for example, nurses, receptionists, clinical administrators – understanding of recommendations regarding adult immunizations and immunization during pregnancy, and the benefits of such immunization. Obstetricians with problems related to billing and payment for services they provide, such as immunization, will not be inclined to begin or continue provision of such services. There are significant costs involved in incorporating immunization into a practice, including the up-front costs of ordering vaccines, the cost of storing and maintaining a vaccine inventory, and inadequate or no payment for immunizations. Development of the concept of obstetricians as vaccinators is key to increasing the proportion of pregnant women who receive recommended vaccines. Routine provision of immunization services during obstetric visits is an evolving concept. Providers have cited such practice issues as a lack of an effective reminder system as a barrier to increasing the proportion of their patients who receive appropriate immunizations. The implementation of operational changes such as standing orders for recommended vaccines during routine obstetric visits have been shown to be effective.

Dr. Read concluded by emphasizing that, in order to implement existing recommendations for immunization of pregnant women, it is essential that both patient and provider barriers are understood and addressed.

Adult Immunization

Summary of the National Influenza Vaccine Summit and National Adult Immunization Summit— CAPT Angela Shen, CDC

CAPT Shen described the two summits, held back to back in May 2012; the agenda and presentations for both are available [online](#). The National Adult Immunization Summit was organized around five working groups representing multiple stakeholders and perspectives, each of which identified topics for review or concrete steps to be taken to improve adult immunization:

- Empowering providers:** Develop a searchable list of resources, provide practical business tools, spur system and culture change, define relevant quality measures, develop provider training tools, reach out to special populations, and promote a consistent message about the value of adult immunization.
- Developing quality and performance measures:** Address dispersed sources of care, harmonize existing measures, and involve CMS and others.
- Increasing access to immunization:** Collaborate across the “medical neighborhood” to raise awareness and increase interest in vaccination, address payment barriers, improve documentation (e.g., through lifetime immunization registries and immunization requirements in meaningful use standards), and evaluate State laws and policies.
- Educating patients and promoting adult immunization:** Improve messaging, address the supports that facilitate action (motivation, resources, convenience, educational materials, and awareness), and seek cultural and behavioral change.
- Educating decision-makers:** Address leadership gaps, distinguish adult from childhood vaccine issues, and address the supports needed to facilitate action (inclusion in national prevention policy, economic data, engagement with employers).

Improving communication emerged as an overarching theme of the summit. Other strong themes were the need to involve CMS; improve documentation; increase engagement with employers, unions, and other groups; decrease policy and legal barriers to vaccination; increase education of and incentives to HCP; decrease complexity of the ACIP schedule; and encourage leadership to promote adult immunization. The summit organizers are developing a list of key action steps, reaching out to participants to maintain momentum, and preparing a meeting summary for publication. Over the next year, working groups will focus on two to three action steps and report on progress at the 2013 Summit. The American Medical Association (AMA), CDC, and NVPO have committed to cosponsor the Summit annually and will create mechanisms to support ongoing working groups and facilitate action.

The National Influenza Vaccine Summit provided an overview of coverage for the past influenza season and preliminary data on cost-effectiveness of the U.S. influenza vaccination program. Manufacturers project that 146–149 million doses of influenza vaccine will be provided for 2012–2013, a decrease from the previous season. Carolyn Bridges of CDC noted that for the second consecutive year, the highest coverage rates for children are among Hispanics; in adults, the highest coverage rates are among whites. Many people at high risk still do not get vaccinated, said Ms. Bridges. For adult influenza vaccination, workplace vaccination programs remain key.

2011-2012 Seasonal Influenza Task Force and 2012 Adult Immunization Task Force—LCDR Shary Jones, NVPO

LCDR Jones summarized some of the achievements of the HHS Interagency Seasonal Influenza Task Force, such as its involvement in the CDC billables project (i.e., enabling public health providers to bill private insurers for services provided to their beneficiaries); providing guidance to pharmacists on participation in the Vaccines for Children (VFC) program; facilitating community outreach and partnerships to reach minorities and the underserved; advocating for maternal immunization; providing employers with tools to implement CDC vaccination recommendations; monitoring outcome measures for HCP vaccination; and raising awareness through communication efforts, media outreach, and partnerships.

In 2012, the group became the Adult Immunization Task Force. LCDR Jones said adult immunization requires a comprehensive approach and strong links to non-Federal partners. The Adult Immunization Task Force has four working groups that generally parallel those of the National Adult Immunization Summit, and the Task Force's activities will incorporate Summit feedback and NVAC recommendations. Over the coming year, the working groups will focus on two to three action items and collaborate with the National Adult Immunization Summit working groups.

Discussion

It was noted that disparities in health care should not be considered an isolated issue but rather an issue that cuts across all topics. Litjen Tan, Ph.D., M.S., who was heavily involved in organizing both of the Summits, said that making adult immunization part of routine care is key, and that involves raising awareness about immunization as well as focusing on wellness/preventive care. The two Summits involve nearly 400 partners, so it is hoped that all types of care providers are represented. The landscape for immunization is changing, and leadership and champions are still needed to support adult immunization. Even HCP who do not immunize patients should be aware of the recommendations and refer patients to other providers.

Pediatricians provide a medical home for children, but many adults do not have a medical home. Including adults in registries and taking advantage of electronic health records (EHRs) may improve our understanding of adult patterns of care, but capturing the data is complicated.

Vaccine Research and Development

Institute of Medicine (IOM) Committee on Identifying and Prioritizing New Vaccines for Development—Guru Madhavan, IOM

Mr. Madhavan explained NVPO charged the IOM with developing an analytical framework for prioritizing development of new and improved vaccines, in accordance with the goals of the 2010 National Vaccine Plan. The IOM's first draft of the framework is now available ([Ranking Vaccines: A Prioritization Framework](#)).

The IOM's previous approaches to ranking vaccine targets evaluated all the candidates against a single variable: infant mortality (as a proxy for quality-adjusted life years [QALY]) in the 1985 report and cost-effectiveness over QALY in the 2000 report. The Committee's current approach will not result in a single list, as the previous reports did. Rather, the Committee is overseeing the design of a software tool that supports decision-making by allowing each user to evaluate vaccine targets on the basis of variables of interest to that user.

The Strategic, Multi-Attribute Ranking Tool for Vaccines (SMART Vaccines) allows the user to select from among 29 variables of interest in eight domains; each variable draws information from existing, public data sources (e.g., World Health Organization [WHO] life tables). Users can also enter their own variables and supporting data or even input conjectures. Mr. Madhavan emphasized that the program is very malleable. The results appear as "soft" values—that is, there is no absolute zero, and scores are not relative to each other. SMART Vaccines enables users to manipulate variables to compare different scenarios. As noted in the IOM draft report, SMART Vaccines "should make it possible for decision-makers in a variety of circumstances to weigh competing values, test assumptions, and explore alternative scenarios to help guide the priority-setting process. Like all decision tools, SMART Vaccines is an aid for decision-making, not a substitute for sound judgment."

The IOM Committee is seeking feedback on its draft report and will present the first version of SMART Vaccines for public testing in the fall. It will then refine the model and conduct a usability evaluation. Then, the Committee will make strategic recommendations for improving the model and for moving toward the NVPO's ultimate goal of creating a catalogue of vaccine candidates.

Discussion

Dr. Orenstein expressed confusion about how SMART Vaccines assigns weight to each attribute and how those weights ultimately result in a score for the vaccine candidate. Mr. Madhavan explained that the software tool uses a complex algorithm to weight each variable and referred members to the draft report for a more thorough description. It was noted that user-input data can be highly subjective, and the software has no way of evaluating or correcting for the accuracy of that data. Better user-input data would improve the score for a given candidate. Users could input the attributes of an existing vaccine with good outcome data into the model for the sake of comparison, but the IOM Committee has not yet done so. Mr. Madhavan said the model could eventually be expanded to assess treatments for chronic disease.

PANEL DISCUSSION

Dr. Mulach said SMART Vaccines highlights the difficulty of prioritization. If you come up with a static list of vaccine targets, she said, you are stuck with that list, even as the variables change. The tool allows for adaptation for changing environments and recognition that different people have different priorities. Dr. Mulach foresaw graduate students using SMART Vaccines to explore hypotheses and stir discussion in numerous areas. She looked forward to seeing how the tool works when it is in practice.

Dr. Gruber agreed that it will be interesting to see what the software can do. FDA does not engage in ranking; it looks at all candidates the same way. Also, FDA receives different data from different regions,

and the output is only as good as the input. Therefore, in the next phase of development, Dr. Gruber recommended, the IOM should pay close attention to quality assurance and quality control, because data are subjective. There should be some consideration of what data should be incorporated.

In his presentation, Mr. Madhavan showed a comparison of multiple vaccines using SMART Vaccines; Dr. Gruber said that if there were multiple candidates in the research and development (R&D) stage for a malaria vaccine, for example, much of the data input about the impact of the disease and potential outcomes would be the same. Data would probably not be available for complications associated with the candidate vaccines, the required dose(s), or the duration of immunity, to name a few. Dr. Gruber wondered how SMART Vaccines would be applied to rank multiple vaccine candidates for a single disease.

RADM Schuchat thanked the IOM for taking on an extremely complicated issue and said she is excited that the IOM has come up with something to share. She said that to produce a relative ranking, you need good data on multiple things, and all of the data must be equally good. Unfortunately, said RADM Schuchat, we live in a world with a lot of data that are not comparable.

Also, while it is great to have a tool that lets you think about the vaccine candidate from different points of view, most of the variables will not be significant enough to drive vaccine development, so the question becomes, “What’s on the menu?” When the GAVI Alliance began offering vaccines to resource-poor countries, the menu was a key issue. Countries looked at their needs and the costs of the vaccine, and some chose to get the cheapest vaccines first. RADM Schuchat said the breadth of the population in question is an important relative concern that varies depending on whether the selection of a vaccine candidate is coming from the NIH, a country, or a company, for example.

SMART Vaccines helps make transparent the complexity of the decision for both development and use of vaccines. There are many stories about vaccines that do not work or have the impact projected; this model highlights the issues and makes clear at the outset what we do not know, said RADM Schuchat.

COL Scott A. Stanek, D.O., M.P.H., said he was pleased to see that the attributes in the model include variables specific to military personnel and national security/policy issues, although some of those fields may be difficult to populate. Whatever numbers you put in, you have to have confidence, said COL Stanek, and with so many variables in the model, the results may change. He pointed out that two people working on the same issue could input different variables and reach different conclusions.

Carter Diggs, M.D., Ph.D., predicted there will be lots of discussion about what to use the product for. He appreciated the potential for using SMART Vaccines to answer questions about vaccines already in development.

GROUP DISCUSSION

Seth Hetherington, M.D., and Dr. Lewin offered insights from the industry perspective. A document that lists priorities for vaccine development would make up a company’s target product profile for R&D, and in some cases, there would be a lot of overlap between public and private interests. For example, an innovative delivery system would be considered a benefit by industry, while long shelf life would be of interest to both the public and industry. Companies often focus not on the product they want but on the product that serves the unmet health needs identified by the customer (e.g., ACIP). It is important for the industry to understand what is important to the customer, said Dr. Lewin, such as the availability of vaccine in a single-dose format or a formula that is stable at room temperature.

Dr. Hetherington suspected that small biotech firms would use the scores from SMART Vaccines to raise money for development. Noting that the scores are only as good as the input, he further suspected that private consultants would offer to help firms improve their scores. Dr. Lewin added that because the software assumes that the data input are valid, it would be easy to manipulate. A product's SMART Vaccines score may be great with only the animal model data but decline as more data are gathered in the preclinical, manufacturing, and clinical research stages. In addition, some attributes of a candidate vaccine would not be known until the end of the development process, such as the frequency of rare, serious adverse events. It is not clear how the software would account for the high degree of uncertainty in the early stages of development.

The software provides a standardized model for assessment, which would make modeling easier for small companies that do not have health economists on staff. Dr. Lewin appreciated the transparency of the model and that it goes beyond cost-effectiveness data, but the weighting mechanism and the fact that the tool can be used to support different perspectives call into question the validity of the model. On the other hand, the model may help the vaccine community identify where it needs to collect better data.

Dr. Gellin pointed out that SMART Vaccines is still a work in progress. He hoped that NVAC members would offer input about what they would like to see as the product develops. Mr. Madhavan echoed that the IOM values stakeholder feedback and plans to hold a public workshop to demonstrate the model. In response to concerns about gaming the software, Mr. Madhavan said the Committee hoped it would be used primarily by high-level decision-makers for strategic analysis. He acknowledged that SMART Vaccines is a subjective, user-reliant tool, not an objective one. Dr. Lewin pointed out that if SMART Vaccines becomes widely accepted as a standard tool for public health, industry will use it, too, whether it is publicly available or not. Mr. Madhavan added that the Committee is considering an open-source approach that would enable users to modify the tool over time.

Dr. Orenstein said companies, NIH, CDC, and others prioritize R&D all the time; this tool is helpful because it lays out the variables. Cost-effectiveness is not the only variable on which policy is decided, and SMART Vaccines give the user more latitude to consider other values that may outweigh cost. One attribute in SMART Vaccines is the likelihood of a product successfully achieving licensure within 10 years; Mr. Madhavan clarified that the attribute combines both scientific feasibility and financial profitability, and it is determined by the user. It was noted that a lot of vaccine candidates would rank highly from the standpoint of desirability and potential impact, but if they are not feasible, those scores do not matter. Mr. Madhavan said that the user can add more attributes to the analysis, but the more attributes included, the more the weights decline for each attribute. Private companies, for example, could use feasibility as a sole attribute for ranking, he said; the model will have an advanced mode for those who want to rank a vaccine candidate using a single metric. It was suggested that for the next iteration, the IOM consider elucidating on the method, perhaps getting the user's perceived weights, and providing more detail about the sensitivity analysis.

SMART Vaccines could help public health authorities make the case for improving an existing vaccine rather than pursuing a new one (e.g., for pertussis). The software could help manufacturers better understand what is required to spur adoption or preferential use of a given product, such as an adjuvanted influenza vaccine or a better pertussis vaccine. Also, the NIH should be addressing the diseases for which feasibility is low, while private companies can focus on those candidates with moderate to high feasibility. However, objective assessments of feasibility are difficult to make. With some diseases, outcomes can be predicted, but for others, it may not be clear whether a vaccine would make a significant impact. Even promising developments sometimes go bust, and the situation is complicated by epidemiologic changes over time.

Robert S. Daum, M.D., C.M., said he was disappointed, because he did not get a sense of what purpose the software serves and what parameters would come from it. He suggested the IOM run an existing vaccine through the software to demonstrate better how it works. He questioned the utility of the scores. Mr. Madhavan emphasized that the tool is not intended to make decisions. He added that the IOM would like the tool to be modular so that individuals can tweak it to meet their own needs, but it would still be a tool for discussion only. Dr. Daum also wondered whether the SMART Vaccines score would be applied to grant application review and decision-making. Dr. Mulach assured that if the scientific community believes that a topic merits research, it will remain a priority, regardless of the IOM score.

Tom Metzger of Merck noted that models do not provide answers. He said the list produced by the IOM in the early 1990s was useful for industry in determining what to pursue, such as rotavirus vaccine and pneumococcal conjugate vaccine. He asked that NVAC or the IOM use the model to provide some guidance to industry for decision-making. Dr. Lewin added that the industry has used the IOM reports to understand the public sector's priorities. He felt that the tool can provide parameters of interest, but the industry wants more guidance. Dr. Metzger agreed that the industry is looking for signals. In assessing the possible rate of return on investment in the face of multiple priorities, the priorities of the public health community are key. He said there may be an opportunity to use the model to produce a priority list, because even the simplest (i.e., single-metric) IOM lists were used.

Dr. Orenstein said the report describing the model is difficult to read. He agreed with Dr. Daum that more illustrative examples are needed. He also suggested moving more of the technical jargon into appendices.

Mr. Hosbach noted that companies re-examine feasibility at every step of the process, because the cost of development goes up at every stage. Thus, companies could use elements of the tool at each stage to consider what variables have changed and whether that changes the score and priority. Dr. Lewin noted that there have been discussions with the NVPO about developing a roadmap. Having feedback at each point would signal to management when continued investment would be worthwhile.

CAPT Shen reminded the participants that NVPO charged the IOM with developing a conceptual framework for identifying priorities. IOM can address technical questions about how the tool works, but other questions, such as how the government will use the framework, may be better directed to the ASH or NVAC for consideration. She noted that the tool has evolved over the years on the basis of discussions between IOM and NVPO. The lack of clarity about how the tool works may stem from the fact that it is in such early stages of development.

Dr. Hetherington pointed out that some variables are relatively stable, such as the characteristics of the disease, while others may change over the course of product development. He suggested the tool provide scores separately for the relatively constant and the very variable so that the user can better see which variables affect the score.

Dr. Orenstein said it should be clear to the user that the tool does not provide a cut-and-dried analysis endorsed by the IOM. He reiterated that the tool formalizes the processes already in place for decision-making. The devil is in the details, he added, but the flexibility the tool offers is important and allows users to consider a lot of variables. CAPT Shen noted that stakeholders asked for a dynamic tool that accounts for multiple attributes and the long timeframe of development and that would yield a dynamic list.

Public Comment

Phyllis Arthur of the Biotechnology Industry Organization (BIO) said BIO supports the SMART Vaccines model. She noted that it takes 8–10 years and about \$1 billion to develop a new vaccine, so it is

important to industry to continuously reevaluate models during the development cycle. The model provides a mechanism for looking more systematically at development, and Dr. Hetherington's idea to distinguish constants from variables is helpful. Other industry-based constants that could be added to the model include the existence of other treatments and their efficacy (e.g., for tuberculosis and malaria). Also, industry needs to understand the likelihood that an advisory body would recommend the vaccine once developed, and that may be captured in the model currently.

Ms. Arthur said she is happy to see an attribute that captures value, because that is important to meeting public health needs, and she applauded its inclusion. Regarding the suggestion that the IOM run the model using an existing vaccine to see whether one would have reached the same decision (e.g., with rotavirus vaccine or other well-studied, globally used vaccines). Ms. Arthur suggested that such a test compare results with those of other assessments, such as WHO's Grading of Recommendations, Assessment, Development and Evaluation (GRADE) or the National Institute for Health and Clinical Excellence (NICE).

Regarding transparency, Ms. Arthur agreed that data are very subjective. Inputs should include documentation of the assumptions, data sources, etc., so that users can follow the thought process. The assumptions behind the inputs should be as clear as possible—even the guesses. As to whether companies would use the tool, Ms. Arthur said at first BIO believed they would not because too many factors are not included, but on further consideration, she said, a lot of companies would probably use the tool as a source of input into their own models for decision-making.

Day 2—June 6, 2012

Update from the NVAC Global Immunization Working Group (GIWG)—Philip S. LaRussa, M.D., NVAC

Dr. LaRussa reiterated the purpose and charge of the new Working Group. It focuses on the role of the U.S. government in global vaccination, the effects of global vaccination around the world and domestically, and how best to communicate information to decision-makers and the general public to ensure continued sufficient resources for global vaccination. Within that broad scope, said Dr. LaRussa, the challenge is to make feasible recommendations for improvement in areas in which HHS has some control or influence.

GIWG will invite experts to provide input and propose recommendations for discussion by the members. Ideally, GIWG will develop consensus recommendations for consideration by NVAC as early as September 2012. Its goal is to present final recommendations on which NVAC members will vote at the February 2013 meeting as well as a white paper to accompany the recommendations.

Discussion

Dr. LaRussa clarified that GIWG is looking at U.S. efforts to support global vaccination but also the impact of global vaccination efforts on domestic issues. He believed that GIWG would likely recommend maintaining and strengthening domestic vaccination infrastructure as well as building infrastructure overseas. He also noted that regulatory agencies are making it easier to register vaccines for licensure on the basis of data gathered in other countries as a way to reduce regulatory burden. FDA has released guidelines on making vaccines available overseas.

Old Business

Maternal Immunization Working Group (MIWG)—Walter A. Orenstein, M.D., NVAC Chair

NVAC members reviewed a proposal to establish an MIWG. Several NVAC members presented a draft rationale and charter for such a group.

Discussion

Members discussed suggestions for revising the draft rationale and charter, such as emphasizing that vaccine development offers opportunities as well as barriers. Members differed on whether the group should focus exclusively on vaccination during pregnancy or address also postpartum vaccination and cocooning. Ultimately, members agreed that “maternal immunization” appropriately covers vaccination during pregnancy and postpartum.

Action Item

NVAC members unanimously approved the following resolution:

Background

The U.S. 2010 National Vaccine Plan indicates the need to develop new and improved vaccines (Goal 1) and specifies the need to advance the science of neonatal and maternal immunity, including immunization and the development of immunological models to study maternal immunization and effects on offspring (section 1.2.3). The National Vaccine Plan recommends supporting communications to enhance informed vaccine decision-making (Goal 3) and states that the United States should ensure access to and better use of recommended vaccines in the United States (Goal 4). The National Vaccine Plan highlights the need to address disparities in vaccination rates among racial and ethnic minorities (section 4.2.2) and to educate and support health care providers in vaccination counseling and vaccine delivery for their patients and themselves (section 4.6). Healthy People 2020 objectives include reducing incidence of preventable infectious diseases with the goal of a 10-percent improvement in (reduction of) pertussis cases in children under the age of 1 year.[1]

Pregnant women are at increased risk of complications from some vaccine-preventable diseases, such as influenza.[2, 3] In addition, other serious infectious diseases can impact young infants before they can be actively immunized and for whom maternal vaccination may be protective. For instance, following recent outbreaks of pertussis that have resulted in infant deaths, in 2011, ACIP recommended Tdap vaccine for pregnant women during late pregnancy to protect infants through placental transfer of antibodies.[4] Despite both influenza and pertussis immunizations being recommended during late pregnancy, vaccine coverage remains unacceptably low. Alarming, recent outbreaks of pertussis have affected Hispanic infants disproportionately.

There is a need to further bring prenatal care into the culture of immunization and prevention to achieve goals outlined in the National Vaccine Plan and Healthy People 2020, reduce socioeconomic disparities, reduce morbidity and mortality, and encourage development of new vaccines, essentially establishing a national platform for maternal immunization. Monitoring the impact of maternal immunization on prevention of morbidity and mortality in both the mother and her infant is also important. There is also a need to ensure vaccine safety systems are adequate to detect any causally related adverse events either in the newborn or the pregnant women.

Resolution

The ASH charges NVAC to review the current state of maternal immunization[§] and existing best practices. Therefore, NVAC resolves to establish the Maternal Immunization Working Group (MIWG). The MIWG should first identify programmatic barriers to implementation of current recommendations regarding maternal immunization and make recommendations for overcoming these barriers. Efforts to identify barriers to and opportunities for developing vaccines for pregnant women should then be identified as well as ways to overcome these barriers and leveraging the opportunities.

The MIWG should complete its work and make its final report to NVAC by the June 2013 NVAC meeting. This report should provide recommendations to the ASH on how to implement the recommendations.

1. Healthy People 2020 Topics and Objectives. *Department of Health and Human Services*. 2010.
2. Zaman K, Roy E, Arifeen SE, et al. Effectiveness of maternal influenza immunization in mothers and infants. *N Engl J Med*. Oct 9 2008;359(15):1555-1564.
3. Siston AM, Rasmussen SA, Honein MA, et al. Pandemic 2009 influenza A(H1N1) virus illness among pregnant women in the United States. *JAMA*. Apr 21 2010;303(15):1517-1525.
4. Updated recommendations for use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) in pregnant women and persons who have or anticipate having close contact with an infant aged <12 months --- Advisory Committee on Immunization Practices (ACIP), 2011. *MMWR Morb Mortal Wkly Rep*. Oct 21 2011;60(41):1424-1426.

Dr. Catherine Torres, volunteered to be the Chair of the new MIWG. NVAC members who wish to serve on the MIWG should contact Mark Grabowsky of NVPO. The group will present a progress report at the September 2012 NVAC meeting.

Immunization Infrastructure

Vaccine Management—RADM Anne Schuchat, M.D., CDC

RADM Schuchat said proper vaccine storage and handling protects the substantial investment in VFC program vaccines; it requires reliable and appropriate equipment, knowledgeable staff, and written storage and handling plans that address both routine and emergency situations. The HHS Office of the Inspector General (OIG) recently released a [report](#) evaluating VFC providers' adherence to vaccine management requirements. The OIG identified deficiencies and recommended that the CDC ensure that grantees 1) meet VFC storage and handling requirements, 2) improve their processes for handling expired vaccines, 3) improve management of vaccine inventories, and 4) adhere to program oversight requirements. In response, the CDC is undertaking a comprehensive review of all aspects of vaccine storage and handling in the provider setting. Key corrective actions include the following:

- Review and revise CDC's current temperature monitoring recommendations.
- Make recommendations about refrigeration, freezing, and temperature monitoring equipment.
- Standardize tools and training for field staff who conduct VFC provider site visits.
- Review and update requirements for corrective action for providers who are out of compliance.

[§] "Maternal immunization" refers to immunization of pregnant and postpartum women.

- Use new Prevention and Public Health Fund (PPHF) money to improve vaccine storage and handling by VFC providers.
- Update CDC's Vaccine Storage and Handling Toolkit.
- Consider offering a certification program in vaccine storage and handling.

RADM Schuchat emphasized that vaccines administered by VFC providers are safe and effective; surveillance suggests that vaccines are performing as expected and most diseases are at record low levels. Studies support that vaccines are safe and effective when stored under "routine use" conditions. Problems in storage and handling are not limited to public providers but rather represent a national vaccine management issue. Efforts made by CDC will likely improve storage and handling of vaccine in all settings. However, public health authorities cannot do it alone, said RADM Schuchat; providers in private office settings, NVAC, and other partners and stakeholders can help.

CDC has many working groups with both public- and private-sector representation that are looking at ways to streamline the vaccine management requirements to focus only on efforts that protect people. The move toward centralized distribution has eliminated State-level vaccine inventories, which has helped. Also, CDC is rolling out its Vaccine Tracking System (VTrckS) to individual providers and health departments in many States. It will assist providers with inventory management, decreasing the amount of excess or expired vaccine on hand.

RADM Schuchat described the history of payment for vaccines and vaccine administration as the number of recommended vaccines and costs of vaccination have increased. Private providers face the challenges of upfront investment needed to order vaccine, storage costs, and inadequate or unreliable reimbursement. VFC grew to help provide more vaccine in the public sector, but the budget for Section 317—which supports all the infrastructure needed to administer vaccines and monitor vaccine safety—has not increased. In addition, some underinsured children are not eligible for VFC, although it is hoped that the ACA will address the issue by requiring insurers to cover all recommended vaccines fully.

There is a perception among policymakers that the ACA will address all the gaps in vaccine coverage and that Section 317 will no longer be needed, RADM Schuchat noted. However, challenges remain, even if the ACA coverage stands. For example, insurers will only cover vaccine administered by an in-network provider; not all insured people have access to an in-network provider who offers all ACIP-recommended vaccines, and some beneficiaries choose local health departments over private, in-network providers for convenience and accessibility. RADM Schuchat outlined some steps to ensure that every insured person has access to an in-network provider in his or her community who provides all recommended vaccines and how NVAC members and stakeholders can play a role. These steps are as follows:

- In-network providers need to be accessible in every community (AHIP)
- In-network providers need to provide all recommended vaccines (AHIP, Professional societies)
- Medical organizations need to help providers learn to become immunizers (Professional societies)
- Industry needs to help providers obtain initial vaccine stocks (Pharma)
- Public health departments that serve insured people need to do so as in-network providers (AIM, ASTHO, NACCHO, CDC ARRA/PPHF billing projects)
- Policymakers need to establish policies that facilitate these steps (NVAC)

She noted that NVAC can help by continuing to identify gaps and make policy recommendations.

Beginning in 2013, Section 317 funds can no longer be used to support vaccines for the fully insured. RADM Schuchat emphasized that the VFC program remains unchanged and the ACA should address the needs of underinsured children, but Section 317 is critical to support the infrastructure of childhood

immunization regardless of who pays for the vaccine. It is hoped that public health providers will see the limits on Section 317 funding as an opportunity to stop subsidizing private payers who are ready and willing to pay for vaccination. Public health providers will continue to provide a safety net by directing vaccine to those with the greatest need.

RADM Schuchat said Section 317 funding remains essential to provide 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. Section 317 also supports public-private partnerships, evidence development for policymaking, collaborations to raise awareness, and response to public health emergencies. By continuing to share responsibility across the public and private sector, said RADM Schuchat, we can continue to protect communities, especially the most vulnerable.

Discussion

VACCINE STORAGE AND HANDLING

RADM Schuchat explained that the OIG staff visited offices of 45 VFC providers and attached thermometers to vaccine products, then evaluated the daily temperature for a 2-week period; they also evaluated paperwork processing and met with the providers' vaccine program staff but did not observe the daily operations of the office. Notably, CDC conducts periodic site visits, but field staff did not observe the same problems that the OIG did, said RADM Schuchat; the CDC will evaluate more closely what happens during its site visits and the training of the staff who perform them. She said clinicians are more likely to listen to their peers in the field than to government program staff about issues such as storage and handling guidelines, appropriate administration, and keeping the whole office staff up to date; she hoped leaders at medical professional societies would step forward to partner with CDC and champion vaccine management issues among their peers.

RADM Schuchat did not believe that storage and handling problems were responsible for any decreased effectiveness of pertussis vaccine 5 years after administration. The CDC does not have plans to sample vaccines for potency to assess the effects of improper storage and handling; Dr. Orenstein hoped the CDC would consider it. Providers may benefit from more information on how to get backup generators to protect stored vaccine and guidance on the correct storage temperature of each vaccine, as well as how long each vaccine can be left at room temperature. RADM Schuchat said a lot of resources are available online, for example, from the [California Department of Health](#). More strong guidance from CDC and standardized practices are needed.

Centralized distribution helps avoid redistribution among providers, which in turn decreases the risk of storage and handling problems, and the VTrckS system encourages States to order vaccine as needed instead of stocking up. RADM Schuchat was not sure whether VTrckS could be modified to account for local health departments exchanging vaccine in an emergency. When providers order vaccines through VTrckS, they must submit temperature logs from the previous month, which gives CDC an ongoing look at storage temperatures for each practice.

CDC working groups addressing vaccine storage and handling include liaison members representing various specialties so that provider concerns (particularly about burdensome regulations) are taken into account. It may be helpful for CDC to look at accountable care organizations (ACOs) or Medicare demonstration projects to see whether large provider groups have systems in place for vaccine management. CDC should consider some mechanism for embedding the vaccine management guidelines into The Joint Commission accreditation process.

The OIG's findings make a strong case for the role of public health in immunization to help standardize vaccination practices, educate providers, and monitor vaccine use. RADM Schuchat noted that modernization of the distribution system and information technology have resulted in massive improvements over a few years' time. Refrigeration issues (such as cycling times) have been largely resolved, and no concerns have been raised about potency. RADM Schuchat agreed that evaluating potency would be worthwhile, although funding may be difficult to secure; however, she believed that most vaccine product is fine. A potency study could provide reassurance to the public. Manufacturers have data on potency, and when providers have questions about storage issues (e.g., what to do following a power outage), they are encouraged to call the manufacturer. At present, providers call their local health departments for advice. RADM Schuchat said efforts are underway to communicate about vaccine storage and handling and the findings of the OIG without eroding the credibility of the public health system.

VACCINE FINANCING

Basic infrastructure funds do not cover the investments needed to improve storage and handling at the provider level. While Section 317 funding can be used to support adult immunization, it has always focused on programs for children. When public health providers received additional funds through the American Recovery and Reinvestment Act, the purchase of vaccines for adults spiked. The PPHF encourages sustainable strategies for adult immunization, e.g., through employers, pharmacies, community providers, and private providers.

RADM Schuchat described some of the mechanisms through which the CDC gets information about public attitudes and concerns around vaccine issues. For many years, people were focused on vaccine safety and the rationale for vaccine use; more recently, public questions focus on costs. The issues are changing as the ACA rolls out and the landscape of health care changes.

The ACA aimed to improve access; payers, providers, public health entities, and others should come together to address the costs of ensuring widespread access to vaccines and the payment needed to support it. RADM Schuchat noted that in some cases the local health department is the only vaccine provider, but it is not easy to get the public health provider designated as in-network. Some members of the public are getting a negative message that as of 2013, they will not be able to get immunized because of the ACA. RADM Schuchat emphasized that the ACA does the right thing for vaccine coverage, and insurers are willing to pay for vaccinating their beneficiaries. She added that even with the ACA, Section 317 funds will be needed to support operations and to help uninsured adults.

The public health system is facing a complex transition period, and not just for vaccines. Even when the ACA is fully enacted, as many as 30 million people will not have insurance. Not all children will have insurance right away, and not all insured people will have access to an in-network provider immediately. Public health providers will still be providing vaccine and may have to charge on a fee-for-service basis, which they may not be well prepared to do. Systems are needed to help health departments contract with multiple insurers, credential clinicians, establish electronic billing and cash management systems, and conduct insurance verification. Public health departments have no experience with billing for services; AHIP is working with CDC to provide educational opportunities around credentialing, coding, etc. for public health providers.

RADM Schuchat believes that immunization is ahead of the curve in these respects, as some health departments took on vaccine billing 10 years ago. She agreed that public health remains vital in the era of the ACA, and more education is needed to raise awareness about ongoing infrastructure needs. To draw attention to the problem, Dr. Orenstein suggested publicizing instances of public funding used to pay for the care of privately insured patients. Wayne Rawlins, M.D., M.B.A., noted that only children and sometimes pregnant women have medical homes; it can be a disservice to promote medical homes when

in reality most adults get care from providers in various settings. From the H1N1 pandemic, we learned the importance of engaging all kinds of providers to vaccinate, and adults should be encouraged to get immunized wherever they can, said Dr. Rawlins.

Action Items

A CDC representative will provide an update at the September 2012 on the progress of CDC's corrective actions for improving vaccine storage and handling by providers.

CDC will send the most recent report on the status of Section 317 to NVPO, which will distribute it to NVAC members.

Draft Report of the Immunization Infrastructure Working Group (IIWG)—Litjen Tan, Ph.D., M.S., and Catherine Torres, M.D., NVAC

Dr. Torres said IIWG aims to publish a revised version of the draft report in the *Federal Register* in July for public comment, then present a further revised version to NVAC for a final vote at the September 2012 meeting. She noted that IIWG is still seeking examples from States and Tribes to include in the report. Dr. Tan summarized the recommendations in the draft report:

- Assess the funding needed to support immunization infrastructure (with specific examples).
- Request Federal financial support to maintain and strengthen immunization infrastructure (with specific examples of what immunization infrastructure enables at the local, State, and Federal levels).
- Maintain Section 317 funding at optimal levels as requested.
- Because current Section 317 funding is inadequate to meet all public health needs, ensure that State and local entities continue to fund their portion.
- Align Federal policies with allocation of funds.
- Ensure that State and local public health departments continue to provide a critical safety net.
- Identify efficiencies and innovations in the current immunization delivery system (with specific examples).
- Monitor immunization infrastructure as coverage and access to vaccines shift and include the findings as part of the annual National Vaccine Plan report to NVAC.
- Address gaps in knowledge through research by Federal agencies (with specific examples).

Discussion

Dr. Tan noted that NVAC members can provide comments immediately but will also have the opportunity to give feedback during the public comment period. It was suggested that improving vaccine safety systems and surveillance be specified as an example of the important activities facilitated by financial support for immunization infrastructure. It may be necessary to describe what Section 317 supports. Some members suggested approaching the AMA's Relative Value Scale Update Committee (RUC) to develop codes that cover vaccine infrastructure costs, although the RUC's coding decisions only apply directly to private providers. For reimbursement issues, it may be more helpful to undertake an analysis of the components of vaccine administration so that both public and private payers can make evidence-based decisions about reimbursement. The NVAC could consider reconstituting the Vaccine Financing Working Group to address reimbursement, which falls outside the charge of IIWG.

Mr. Hosbach asked that the report include support for robust adult and child immunization registries that link with EHRs. He noted that manufacturers have a lot of anecdotal evidence regarding billing and infrastructure. He also suggested that the report stress the economic benefits of the immunization

infrastructure in terms of jobs, community health, school attendance, etc. Finally, Mr. Hosbach pointed out that providers are paid to vaccinate patients, they are not “reimbursed.”

The report should include more concrete examples of infrastructure that illustrate the role of public health departments. NVAC members (especially liaisons) should submit examples, such as the impact on a given county of closing a public clinic. Dr. Tan asked for suggestions to reword the report to make a more compelling argument. Ms. Arthur of BIO said those who advocate for vaccines would like the report to spell out a clear message that it can use to make the case for funding immunization infrastructure. Dr. Lewin suggested using positive rather than negative examples, such as the success of rotavirus and H1N1 vaccines, and making a simple case that demonstrates what taxpayer dollars pay for. The term “infrastructure” may not be clear enough; something like “basic building blocks” may be preferable.

Action Item

NVAC members should provide written comments on the IIWG draft report and recommendations by June 20, 2012, via e-mail (angela.shen@hhs.gov).

National Vaccine Program Topics

Update from the VICP—Geoffrey Evans, M.D., VICP

The key feature of the VICP, established by the National Childhood Vaccine Injury Act of 1986, is the table of compensable injuries, which was among the mechanisms intended to streamline the litigation process, said Dr. Evans. He described the VICP framework, administrative entities, eligibility requirements, awards, and appeals process. Dr. Evans noted that the United States is the only country that pays the claimant’s attorneys’ fees as long as the case was considered to be brought to the VICP in good faith. Awards are paid for by a trust fund that comes from a vaccine tax. Dr. Evans described the process of adding new vaccines to the table of compensable injuries.

Among the significant events that have shaped the VICP was the one and only case that proceeded to the U.S. Supreme Court (*Whitecotton v. Shalala*, 1995). The court found in favor of HHS, and the case led to the establishment of four criteria for determining significant aggravation. With the shift from whole-cell to acellular diphtheria, tetanus, and pertussis vaccine and the addition of nine more vaccines to the table of compensable injuries in 1996, the VICP evolved into a program for evaluating claims for vaccines not included on the table. Other important events were the influx of cases related to hepatitis B vaccine in the late 1990s, the Omnibus Autism Proceeding to adjudicate thousands of claims from 2001 through 2010, and the addition of influenza vaccine to the table in 2005 (which now account for 50 percent of all filings annually). Also in 2005, a Federal court decision led to a three-pronged approach to the burden of proof of causation; as a result of the decision, Dr. Evans said, the VICP has gone from settling about 20–30 percent of compensable claims to about 70–80 percent.

In 2011, IOM updated the table of compensable injuries, and the Advisory Commission on Childhood Vaccines unanimously approved the proposed changes at its most recent meeting. Dr. Evans noted that the VICP serves many families that may never have been able to get injury compensation in the past, and the average time from filing to payment is one-and-a-half years. The process is relatively streamlined and has contributed to market stability. Civil litigation around vaccines has decreased.

Discussion

The question of whether VICP applies to the fetus of a pregnant woman has been raised many times over the past 15 years, said Dr. Evans. The law states that an individual can petition for compensation through the VICP on behalf of the vaccinee. Court rulings have varied on whether fetal injury qualifies, and no

clear precedent has been set. A legislative change would be needed to clarify whether a baby harmed by maternal immunization can be considered the vaccinee.

Update from the IOM Committee on Feasibility of Studies to Examine the Immunization Schedule—Ada Sue Hinshaw, Ph.D., R.N., IOM Committee Chair

Dr. Hinshaw clarified the task of the IOM Committee to review scientific findings and stakeholder concerns related to the safety of the recommended childhood immunization schedule, identify potential research approaches to address the issue, assess the financial and ethical feasibility of potential research approaches, and summarize the findings. She described the Committee membership and process, noting that the Committee has both public and closed meetings.

The Committee commissioned and published a paper for public comment in May 2012, *Study Designs for the Safety Evaluation of Different Childhood Immunization Schedules*. A revised version will be published for additional comments in mid-June 2012. Dr. Hinshaw said the revised paper will include more discussion of ethical issues and resource constraints. The Committee intends to release its final consensus report in late 2012. The public is invited to provide comments or suggestions to the Committee by e-mail (HealthOutcomes@nas.edu).

Discussion

Dr. Hinshaw noted that the Committee is considering all types of study designs, as directed by the charge to the Committee.

Agency, Department, Advisory Committee, and Liaison Reports

ACIP—Carol Baker, M.D.

At its February 2012 meeting, ACIP focused on Tdap vaccine, voting to expand the recommendation to include adults age 65 years and older and to state that adults age 19 years and older who have not received a dose of Tdap should get a single dose. Dr. Baker said a lot of issues are coming up around re-immunization with Tdap, and it is unlikely that ACIP will recommend a single lifetime dose of Tdap. ACIP intends to consolidate all of its reports and recommendations on vaccine for pertussis into one document.

Pneumococcal conjugate vaccine (PCV13) was recently licensed for use in adults age 50 years and over, but ACIP is awaiting more evidence on the indirect effects of PCV13 compared with PCV7 before making a recommendation. At the June 2012 meeting, ACIP will vote on the use of PCV13 in immunocompromised adults. At that meeting, ACIP will also consider the new strain added to the influenza vaccine for 2012–2013 and discuss an algorithm proposed by AAP for use of influenza vaccine in children less than 9 years old.

AHIP—Wayne Rawlins, M.D., M.B.A.

AHIP is working with 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). The two are also co-hosting a three-part webinar training series for public health departments on the contracting process, credentialing, and coding. AHIP is working with ASTHO to educate pharmacies about contracting with health plans and billing for vaccines provided to insured people. Finally, AHIP has compiled an online compendium of best practices for measuring and improving immunization, [Immunization Innovations](#).

VRBPAC—Robert S. Daum, M.D.

At its February 2012 meeting, VRBPAC reviewed the results of a site visit to the Laboratory of Mycobacterial Diseases and Cellular Immunology and approved the quality of its research. It endorsed the proposal to retain the current strain for H1N1 influenza in the 2012–2013 influenza vaccine. VRBPAC also endorsed the proposal to replace the current H3N2 influenza strain with another strain. For influenza B, VRBPAC followed WHO’s lead and voted to replace the current vaccine strain with another.

FDA asked VRBPAC to advise on two options for making a rapid licensure decision about adjuvanted vaccine in the case of pandemic influenza:

- Infer the effectiveness of the adjuvanted vaccine on the basis of U.S.-licensed unadjuvanted seasonal vaccine produced by the same manufacturer *or*
- use observational effectiveness data from the 2009 H1N1 influenza pandemic of non-U.S.-licensed adjuvanted monovalent vaccine made by the same manufacturer.

Dr. Daum said VRBPAC members believed that it is reasonable to infer effectiveness from unadjuvanted seasonal vaccine, but safety and immunogenicity data are needed. Views differed on what observational data include; in-depth review would be needed to assess such data. The availability of sera would reduce variability among serology data generated in different laboratories.

FDA also asked VRBPAC to advise on approaches to infer effectiveness for pandemic influenza vaccines manufactured using a process not licensed in the United States for use in vaccines that are or are not dependent on hemagglutinin (HA) antibody response. VRBPAC determined that if the manufacturer made a seasonal influenza vaccine, effectiveness could be inferred on the basis of HA response, but it is premature to consider the question of effectiveness for a vaccine that is not dependent on HA response.

AIM—Claire Hannan, M.P.H.

Ms. Hannan said many of the issues raised during this meeting are significant concerns for AIM’s membership, such as the drain on health departments caused by responding to the pertussis outbreak. Fewer than 20 CDC grantees have fully transitioned to the VTrckS ordering system so far, but it is hoped that all will do so by May 2013; AIM is providing a lot of training and working to ensure communication between VTrckS and IIS. A new funding announcement for cooperative agreements with immunization program grantees is being posted; it will help programs maintain services after the ACA is implemented by supporting development of billing procedures, enhanced and interoperable IIS, vaccine bar coding, and improved storage and handling. The new cooperative agreements will also help programs support hepatitis B vaccination, improve adolescent vaccination rates, implement school vaccination programs, and assess and improve vaccine coverage in rural areas.

CDC’s new guidance on deputization arrangements under VFC aligns with the 5-year grant program under Section 317. The next 5-year cycle represents a new way of doing business and a cultural change for public health. Instead of focusing on avoiding missed opportunities, health departments will aim to create systems to ensure vaccine coverage without spending public dollars on the privately insured. With more mechanisms in place to cover children, the system will shift its focus to the needs of adults. AIM is looking at grantees who are already making the transition to this new culture and will host a seminar to share lessons learned regarding provider education, billing mechanisms, and adult immunization.

AIM is collaborating with various organizations, such as ACOG. Its policy committees are addressing adult immunization issues, and AIM is represented on NVAC’s IIWG. AIM has created fact sheets describing how each State and grantee benefits from PPHF and how the funds support transitional efforts. AIM submitted comments on stage 2 of meaningful use of EHR technology and will also submit comments on payments for vaccine under Medicaid beginning in 2013. Finally, Ms. Hannan noted that

many policy and funding recommendations and proposals are based on assumptions about implementation of the ACA, so it behooves NVAC to monitor closely political and policy developments affecting the ACA.

ASTHO—Kathy Talkington, M.P.A

With NVPO, ASTHO has conducted a series of meetings with State health officials, State Medicaid directors, and provider organizations to gain baseline information regarding the potential impact of an ACA provision that would increase Medicaid reimbursement rate for the administration of vaccine. Ms. Talkington said ASTHO will publish its findings from these meetings. To explore other venues for increasing access to vaccination, ASTHO has established a pharmacy advisory committee to address barriers for incorporating pharmacies into pandemic vaccination response and routine vaccination efforts. ASTHO engaged in National Adult Immunization Summit working groups to discuss education and promotion of adult immunizations to decision-makers and increasing patient access to immunizations. The organization has focused on issues such as communication and information exchange through IIS.

NACCHO—Anne Bailowitz, M.D., M.P.H.

NACCHO is participating in IIWG and will provide examples from county and city health departments to include in the IIWG draft report. In response to member needs, NACCHO developed a billing toolkit that includes helpful documents and resources. NACCHO is moving two policy statements forward in its adoption process expressing support for a national adolescent immunization program and a national adult immunization program, respectively. A third policy statement, supporting influenza immunization for HCP, has been drafted and is in the internal review process. NACCHO is participating in the adjustment of Section 317 funding to focus more on infrastructure and less on vaccine purchasing.

CDC—RADM Anne Schuchat, M.D.

The 2011 U.S. experience with measles was reported in the April 20, 2012, issue of the *Morbidity and Mortality Weekly Report*. The report describes a measles outbreak linked to refugee resettlement, and RADM Schuchat said NVAC's IIWG or GIWG will consider the findings. A new funding opportunity announcement for a cooperative agreement between CDC and State and local health department grantees is expected to be posted in June 2012; it will focus on transforming information technology by expanding funds to connect EHRs with IIS and promote ordering through registries and VTrckS. RADM Schuchat said CDC hopes all States will use VTrckS for ordering by late 2013.

Several years ago, NVAC worked on addressing vaccine supply problems. As a result, the Strategic National Stockpile was established, and CDC, FDA, manufacturers and others formed a standing workgroup to address supply issues. RADM Schuchat said those efforts are working. However, the supply of Pentacel (Dtap-IPV-Hib) from Sanofi Pasteur has been interrupted. AAP has disseminated information to providers on how to give patients the components of this combination vaccine. The interruption is expected to resolve by September.

The GAVI Alliance's next board meeting will be held in Washington, D.C., June 12–13; it will highlight the impact of vaccines on childhood survival rates. The World Health Assembly endorsed the Decade of Vaccines proposal. RADM Schuchat said many countries look to the United States as a model for strengthening the vaccine system, ensuring communication, and involving consumers. RADM Schuchat said India has not had a case of polio since January 2011, and work to eradicate polio in Afghanistan, Pakistan, and Nigeria continues.

FDA—LT Valerie Marshall, M.P.H., FDA

LT Marshall announced that Dr. Gruber is now the director of the CBER Office of Vaccines Research and

Review. That office has not approved any new vaccines since the last NVAC meeting, but many are under review. FDA's Global Engagement report was released on April 23 and describes actions FDA has taken to ensure that imported products within its regulatory purview meet the same quality and safety standards as products manufactured domestically.

NIH—Barbara Mulach, Ph.D.

Dr. Mulach said the National Institute of Allergy and Infectious Diseases (NIAID) supports various types of research at all stages around pertussis. It is currently funding a Phase-I study evaluating the safety and immunogenicity of Tdap vaccination in pregnant women and the effects of maternal immunization on infants, which may help inform recommendations. Another study will assess Tdap vaccines given postpartum. In March, NIAID began recruiting participants for a trial of a hepatitis C vaccine. It is a small Phase-I/II study, but the research progress is encouraging. NIAID has several efforts underway looking at new vaccine technology, such as microneedle skin patches for delivering influenza vaccine and thermostabilization technology to protect vaccines against temperature extremes. Dr. Mulach encouraged NVAC members and others to watch the archived videocast of a lecture delivered by the CEO of the GAVI Alliance at NIH in May titled "Getting the Miracle of Vaccines to Those Who Most Need Them." It offers a good summary of the global effort to implement vaccines and what is coming in the next 5–10 years. Also, the 2012 Jordan Report on accelerated development of vaccines is available [online](#). Limited printed copies are available for NVAC members.

HRSA BPHC—Matthew Burke, M.D.

Dr. Burke explained that HRSA does not develop strategies but rather encourages implementation of best practices. BPHC oversees 1,130 community health centers that serve 20 million Americans—40 percent of whom have no health insurance. Most clients have incomes below the Federal poverty level. BPHC intends to align its health centers with the patient-centered medical home (PCMH) concept. At present, 8 percent of BPHC grantees are recognized as PCMHs; Dr. Burke said BPHC's goal is to reach 13 percent this year. About half of BPHC's grantees have implemented the requirements for meaningful use of EHRs; Dr. Burke said BPHC is pushing for implementation by all grantees by 2015.

As a measure of performance internally, BPHC will evaluate the percentage of grantees that meet Healthy People 2020 immunization targets. However, Dr. Burke noted, those targets differ from the meaningful use standards. He asked for NVAC input on how to create aggressive standards for grantees that are also reasonable and align with other Federal expectations. Normally, BPHC grantees reach 70-percent compliance with Healthy People goals, but adding two hepatitis A vaccine doses by 6 months of age, for example, will be difficult to achieve, said Dr. Burke. BPHC appreciates the scientific merit of such targets and does not want to remove parts of the recommended immunization schedule, he emphasized, but grantees may need help to adhere to best practices.

BPHC agrees with the importance of the medical neighborhood, which recognizes that people receive services like vaccines in multiple settings. EHRs will help BPHC identify unmet vaccine needs and facilitate cooperation across settings. Currently, the community health centers feel siloed, said Dr. Burke.

CMS—Mary Beth Hance

Ms. Hance said CMS published a notice of proposed rulemaking in May for public comment on increasing payment for vaccine administration by Medicaid providers (in accordance with Section 1202 of the ACA). Ms. Hance said CMS wants to get the issue right in its final rule. CMS also aims to update the fee schedule for VFC providers, which has not been updated since 1994.

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.

VA—Richard Martinello, M.D.

Dr. Martinello said VA sees cases of pertussis among patients and HCP sporadically, as the average age of its patients is 65 years. Nonetheless, VA is working to ensure that staff and patients are aware of ACIP recommendations for vaccination. Dr. Martinello did not know of any access issues around Tdap, but many providers have taken measures to open up clinics to provide Tdap vaccine.

VA vaccinated about 1.9 million people against influenza. Only about 54 percent of VA HCP received the influenza vaccine, and VA is working to optimize HCP uptake. This year, the leadership of the Veterans Health Administration met with subject matter experts, occupational health experts, front-line staff, and others to refine the strategies to improve HCP influenza vaccine uptake.

IHS—Amy Groom, M.P.H.

Ms. Groom said IHS recently saw pertussis in a multigenerational Native American family (in an unvaccinated grandmother and her 6-month-old grandchild). She said she would summarize the case and make it available to others. Two IHS pharmacists were recognized at the National Influenza Vaccination Summit for establishing a vaccine clinic. The clinic started with influenza vaccination but has expanded to include other vaccines and now reaches clients as young as 15 years old. The IHS hopes to set up similar clinics in other facilities. Ms. Groom said vaccine coverage efforts focus on children and adolescents but some also reach adults. The influenza vaccination rate among IHS HCP is 74 percent but has not budged in 3–4 years, and the IHS is looking for ways to increase uptake.

USAID—Carter Diggs, M.D., Ph.D.

Dr. Diggs said USAID's mission is to assist other countries with health care and preventive medicine, and immunization plays a big part. Uptake of pneumococcal conjugate is increasing in the developing world, and there has been some progress on HPV vaccination among girls ages 9–10 years old. At the upcoming GAVI meeting in Washington, D.C., there will be discussion about increased support by GAVI for second doses of measles and rubella vaccines and support for measles outbreaks. An upcoming UNICEF/USAID conference will present encouraging news about polio eradication (e.g., in India). Also, the World Health Assembly adopted a vaccine action plan; the real work of implementation begins now, said Dr. Diggs.

In terms of R&D, Dr. Diggs said, USAID has made some progress on HIV and malaria. He and his colleagues have been pleased with the results so far of public-private partnerships, such as the Malaria Vaccine Initiative and the International AIDS Vaccine Initiative.

DoD—COL Scott A. Stanek, D.O., M.P.H.

COL Stanek said DoD received 4 million doses of influenza vaccine for the 2011–2012 season. The vaccine was available earlier than usual, which is beneficial for the military, because it allows more time to reach personnel overseas. DoD aimed for 90-percent vaccine coverage by December 1, 2011, and achieved that by late October. Each service has its own electronic tracking system. For 2011–2012, 97 percent of DoD personnel were vaccinated. COL Stanek noted that vaccination is required for military service. However, the uptake rate is up from 96 percent last year. Immunization is now available through pharmacies, and since January 2010, over 515,000 beneficiaries (mostly retirees and family members) have received vaccination at a pharmacy. COL Stanek hoped for continued success for the upcoming

vaccine. He reiterated that early arrival of the vaccine helps a lot, and he hoped that the change in strains would not delay production.

In response to a question, COL Stanek summarized the unfortunate case of a soldier who died from rabies contracted overseas while he was trying to break up a dog fight. The symptoms of disease did not become apparent until the soldier returned to the United States, indicating that the disease had probably progressed too far for effective treatment. DoD stresses the importance of avoiding contact with animals while in the field. Other members of the soldier's unit were surveyed for potential exposure, and some were offered post-exposure prophylaxis. DoD is still monitoring the case.

USDA—Rick Hill, D.V.M., M.S.

Dr. Hill said USDA is preparing a summary of surveillance activities around swine influenza. The Swine Influenza Virus (SIV) Surveillance Program began in mid-2009 as an extension of a previously planned pilot program in response to the 2009 human influenza pandemic and in cooperation with CDC. The hallmark of the program is the detection of isolates among pigs with illness or with links to SIV in humans. The program receives thousands of submissions, which are tested at a national laboratory in Iowa or at one of a network of laboratories. Dr. Hill said 98 percent of isolates are maintained in an influenza repository.

Action Item

When USDA publishes the final report of the SIV Surveillance Program, Dr. Hill will send a copy to NVPO, which will distribute it to NVAC members.

Periodically, USDA conducts national surveys of animal vaccine coverage. Swine vaccines were last assessed in 2006. Dr. Hill believed the 2012 swine survey would find very different vaccine coverage rates as a result of the 2009 event.

Public Comment

Theresa Wrangham of the National Vaccine Information Center (NVIC) said her organization submitted a written request for access to the public comments on NVAC's report, *Strategies to Achieve the Healthy People 2020 Annual Goal of 90% Influenza Vaccination Coverage for Health Care Personnel*, which NVAC approved at its February 2012 meeting. The Federal Register notice stated that public comments would be available to the public. However, said Ms. Wrangham, only comments submitted by individuals are available; comments submitted by organizations are only available in the context of an executive summary. Ms. Wrangham stated, "NVIC wants the organization comments made available, as stated in the *Federal Register* and required by the Federal Advisory Committee Act (FACA)". Also, Ms. Wrangham noted that the public's ability to purchase recordings of NVAC meetings is considered optional because summary minutes are provided. Audio recordings or transcripts would be better, but they go beyond FACA requirements. For the sake of transparency, NVIC, which represents thousands of consumers and interested parties, would like the ability to purchase meeting recordings; it does not expect NVAC to pay for such services. Ms. Wrangham said there has been no response to this request in the past, and she would like a response.

Ms. Wrangham further asked that NVPO post the meeting materials online in advance and all other materials as soon as possible. She thanked Dr. Evans for his presentation on VICP injury claims, particularly for noting that influenza injury claims are the most common type of claim in the program—a statement that was questioned in Colorado during a board of health hearing. The VICP claims are an important part of NVAC's support for HCP influenza vaccination. Ms. Wrangham hoped NVAC and others would consider situations such as a person being fired for refusing vaccination and then denied

unemployment benefits or an individual being injured by vaccination. Ms. Wrangham noted that NVIC is opposed to any mandate for influenza vaccination of HCP that lacks flexible exemptions for medical reasons or ethical or philosophical beliefs.

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

Dr. Orenstein thanked the NVPO staff for all their hard work, particularly LCDR Guillermo J. Avilés-Mendoza, J.D., LL.M., LaKeesha Stewart, LaForest Dupree, and Viola Davis, who handle meeting logistics. He also thanked Katy Seib, assistant to the NVAC chair. Dr. Orenstein reminded members to submit comments on IIWG's draft report and IOM's vaccine prioritization framework. Finally, he thanked all the NVAC voting members, liaisons, and ex officio members, particularly the outgoing members, for their hard work. He adjourned the meeting at approximately 12:55 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 in September 11, 2012, 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

Chair's Report

Action Item

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

Recent Issues with Pertussis

Action Items

When Washington State has new information on the uptake of pertussis vaccine by age, National Vaccine Program Office (NVPO) staff will provide an update to the NVAC.

At the September 2012 NVAC meeting, NVPO staff will report on the status of efforts within the Department of Health and Human Services regarding pertussis vaccine, including implementation and communication of current vaccine recommendations and understanding of the economic burden of pertussis, identifying where NVAC may offer guidance or advice.

Maternal Immunization Working Group (MIWG)

Action Item

NVAC members unanimously approved the following resolution:

Background

The U.S. 2010 National Vaccine Plan indicates the need to develop new and improved vaccines (Goal 1) and specifies the need to advance the science of neonatal and maternal immunity, including immunization and the development of immunological models to study maternal immunization and effects on offspring (section 1.2.3). The National Vaccine Plan recommends supporting communications to enhance informed vaccine decision-making (Goal 3) and states that the United States should ensure access to and better use of recommended vaccines in the United States (Goal 4). The National Vaccine Plan highlights the need to address disparities in vaccination rates among racial and ethnic minorities (section 4.2.2) and to educate and support health care providers in vaccination counseling and vaccine delivery for their patients and themselves (section 4.6). Healthy People 2020 objectives include reducing incidence of preventable infectious diseases with the goal of a 10-percent improvement in (reduction of) pertussis cases in children under the age of 1 year.^[5]

Pregnant women are at increased risk of complications from some vaccine-preventable diseases, such as influenza.^[2,3] In addition, other serious infectious diseases can impact young infants before they can be actively immunized and for whom maternal vaccination may be protective. For instance, following recent outbreaks of pertussis that have resulted in infant deaths, in 2011, the Advisory Committee on Immunization Practice recommended tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine for pregnant women during late pregnancy to protect infants through placental transfer of antibodies.^[4] Despite both influenza and pertussis immunizations being recommended during late pregnancy, vaccine coverage remains unacceptably low. Alarming, recent outbreaks of pertussis have affected Hispanic infants disproportionately.

There is a need to further bring prenatal care into the culture of immunization and prevention to achieve goals outlined in the National Vaccine Plan and Healthy People 2020, reduce socioeconomic disparities, reduce morbidity and mortality, and encourage development of new

vaccines, essentially establishing a national platform for maternal immunization. Monitoring the impact of maternal immunization on prevention of morbidity and mortality in both the mother and her infant is also important. There is also a need to ensure vaccine safety systems are adequate to detect any causally related adverse events either in the newborn or the pregnant women.

Resolution

The Assistant Secretary for Health (ASH) charges NVAC to review the current state of maternal immunization[§] and existing best practices. Therefore, NVAC resolves to establish the Maternal Immunization Working Group (MIWG). The MIWG should first identify programmatic barriers to implementation of current recommendations regarding maternal immunization and make recommendations for overcoming these barriers. Efforts to identify barriers to and opportunities for developing vaccines for pregnant women should then be identified as well as ways to overcome these barriers and leveraging the opportunities.

The MIWG should complete its work and make its final report to NVAC by the June 2013 NVAC meeting. This report should provide recommendations to the ASH on how to implement the recommendations.

1. *Healthy People 2020 Topics and Objectives*. Department of Health and Human Services, 2010.
2. Zaman, K., et al., *Effectiveness of maternal influenza immunization in mothers and infants*. N Engl J Med, 2008. **359**(15): p. 1555-64.
3. Siston, A.M., et al., *Pandemic 2009 influenza A(H1N1) virus illness among pregnant women in the United States*. JAMA, 2010. **303**(15): p. 1517-25.
4. *Updated recommendations for use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) in pregnant women and persons who have or anticipate having close contact with an infant aged <12 months --- Advisory Committee on Immunization Practices (ACIP), 2011*. MMWR Morb Mortal Wkly Rep, 2011. **60**(41): p. 1424-6.
5. *Health People 2020 Topics and Objectives*. Department of Health and Human Services, 2010.

Walter A. Orenstein, M.D., NVAC Chair, designated Catherine Torres, M.D., as chair of the new MIWG. NVAC members who wish to serve on the MIWG should contact Mark Grabowsky of NVPO. The group will present a progress report at the September 2012 NVAC meeting.

Immunization Infrastructure

Action Items

A representative of the Centers for Disease Control and Prevention (CDC) will provide an update at the September 2012 on the progress of CDC's corrective actions for improving vaccine storage and handling by providers.

CDC will send the most recent report on the status of Section 317 to NVPO, which will distribute it to NVAC members.

[§] "Maternal immunization" refers to immunization of pregnant and postpartum women.

NVAC members should provide written comments on the Immunization Infrastructure Working Group draft report and recommendations by June 20, 2012, via e-mail (angela.shen@hhs.gov).

Agency, Department, Advisory Committee, and Liaison Reports

Action Item

When the U.S. Department of Agriculture publishes the final report of the Swine Influenza Vaccine Surveillance Program, Rick Hill, D.V.M., M.S., will send a copy to NVPO, which will distribute it to NVAC members.