and NVPO, said Dr. Mullen, it is striking how much Dr. Gellin has influenced the work that will be acknowledged today. She presented Dr. Gellin with a plaque acknowledging his outstanding service to NVPO, NVAC, and the nation over the last 15 years.

In closing, Dr. Mullen thanked six retiring members of NVAC, acknowledging their individual contributions during their terms: Sarah Despres, J.D., Philip Hosbach, Ruth Lynfield, M.D., Yvonne Maldonado, M.D., Wayne Rawlins, M.D., M.B.A., and Mitchel C. Rothholz, R.Ph., M.B.A.

Chair's Report—Kimberly M. Thompson, Sc.D., NVAC Chair

Dr. Thompson gave an overview of the agenda and meeting proceedings. She noted that the public comment period is not a question-and-answer session; rather, it is an opportunity for the public to give comments that will appear in the public record. Time for public comment is limited; written comments can be sent to the NVAC for consideration by e-mail (nvpo@hhs.gov). The minutes and presentations of past meetings are available online at http://www.hhs.gov/nvpo/nvac/index.html.

Dr. Thompson called for review of the September 2016 NVAC meeting minutes. NVAC members unanimously approved the minutes with no changes. The next two NVAC meetings are June 6–7 and September 26–27, 2017.

Many of the six NVAC members who are retiring from Committee had agreed to extend their service beyond their original terms so that NVAC would continue to have a quorum while it confirmed new members. Dr. Thompson thanked them for their service. She announced the four new voting members of the NVAC: Steve Black, M.D., Jay C. Butler, M.D., C.P.E., FAAP, FACP, FIDSA; Melody Anne Butler, B.Sc.N., RN; and Robert H. Hopkins, Jr., M.D., MACP, FAAP. When this meeting ends, seven new members will be sworn in and begin their NVAC terms: John Dunn, M.D., M.P.H., Leonard Friedland, M.D., Mary Anne Jackson, M.D., F.A.A.P., F.P.I.D.S., F.I.D.S.A., Melissa Martinez, M.D., F.A.A.F.P., Cody Meissner, M.D., F.A.A.P., Larry Pickering, M.D., F.A.A.P., F.I.D.S.A., and Geeta Swamy, M.D., F.A.C.O.G.

Dr. Thompson expressed appreciation for Dr. Gellin's impact in making NVAC's work visible. Since 2002, more than 25 NVAC reports have been published in the medical literature.

NVAC at 30

Remarks—Bruce G. Gellin, M.D., M.P.H., Deputy ASH and Director, NVPO, HHS

Dr. Gellin said that when he began at the NVPO in 2002, the National Vaccine Plan, published in 1994, was in need of updating. By the time the new plan was published in 2010, it was thorough and comprehensive enough to serve as the foundation for the NVPO's and NVAC's work and as a framework for the vaccine enterprise.

The 30th anniversary of NVPO and NVAC is an opportunity to reflect on the changes in the landscape since the National Vaccine Plan was published in 2010. Dr. Gellin said the vaccine enterprise is like an engine; to ensure the best function, all the gears must do their part. It is NVAC's role to look at the engine and make sure the National Vaccine Program is doing what it is intended to do.

National Vaccine Program and NVAC: Beginnings and Highlights—Alan Hinman, M.D., M.P.H., Senior Advisor, Center for Vaccine Equity, Task Force for Global Health

Dr. Hinman described the events leading up to the passage of the National Childhood Vaccine Injury Act in 1986, which created the NVPO, NVAC, the Vaccine Injury Compensation Program (VICP), and the Vaccine Adverse Events Reporting System (VAERS) and mandated a 6-month vaccine stockpile. These events included a high-profile controversy over the potential long-term harm of a vaccine (for pertussis), acknowledgement of the inherent risks of vaccines, calls for better information about risks, and the need for a no-fault injury compensation system.

Dr. Hinman described his early experience working with the NVPO. The NVPO was charged with optimizing the prevention of human infectious diseases through immunization and preventing adverse reactions to vaccines. It was given a broad list of responsibilities touching on every aspect of the vaccine enterprise. The NVPO was also required to develop a National Vaccine Plan. The NVPO reported to Congress in 1988, outlining eight priority areas that would become the framework for the first National Vaccine Plan in 1994.

The first NVAC meeting took place in June 1988 with Dr. Hinman serving as coordinator of the NVPO. Beginning with a 1991 report on the measles epidemic, the NVPO and NVAC published numerous influential reports covering a range of topics, which Dr. Hinman highlighted. Dr. Hinman concluded that vaccine hesitancy and opposition were important issues at the onset of NVAC and remained important throughout the years. While many financial barriers to vaccination were overcome by the Vaccines for Children (VFC) program and the Affordable Care Act (ACA), the future is uncertain. However, vaccine coverage among children has reached an all-time high, and most vaccine-preventable diseases in children are at a record low (except pertussis).

NVAC and the Future of Vaccinology—Stanley Plotkin, M.D., Emeritus Professor, University of Pennsylvania

Dr. Plotkin described several advances in vaccinology that may address current challenges.

> **Influenza**: Instead of targeting the "head" of the virus, which changes every year, a promising approach under study would use chimeric proteins to change the hemagglutinin to one never seen before by the vaccine. The vaccine would elicit immune response to the "stalk" of the virus, and the vaccine would not have to be revised every year.
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> **Pertussis**: Many efforts are underway to address the waning immunity of pertussis vaccine over time. Several companies are seeking to change from formalin inactivated pertussis toxin to a genetically inactivated pertussis toxin. Other techniques include adding virulence factors, using prime-boost regimens, and using attenuated *Bordetella pertussis* as a boost to inactivated vaccination.
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> **HIV**: Building on the moderate success of an experimental vaccine in trials in Thailand, future research must recognize the important role of non-neutralizing antibodies. The way forward for an HIV vaccine may be the induction of broadly neutralizing antibodies

through envelope trimer structures, building on prime-boost antibody-dependent, cell-mediated cytotoxicity induction with better vectors and adjuvants, or inducing effector CD8+ cells to kill first infected cells using cytomegalovirus (CMV) vectors.

Rotavirus: To address the decreased effectiveness of rotavirus vaccine in tropical countries, researchers are looking to the microbiome. A recent study found that infants with more Bacteroides than other organisms in the gut respond poorly to the vaccine.

Dengue: Half of the world needs a vaccine against dengue. One vaccine has been licensed in a number of countries. However, there is a striking difference in efficacy for different serotypes and noted that the most important issue is the titer (that is, more antibody maybe needed to prevent type 2 infection) and the need for T-cell response.

CMV: An attenuated strain of CMV can be used to prevent the disease in transplant recipients. However, evidence indicates that additional antigens must be added to CMV vaccine to increase its effectiveness.

Respiratory syncytial virus (RSV): A new line of research into RSV stresses the importance of structural biology. It has determined that epitopes in the pre-fusion form of the F glycoprotein induce a high level of neutralizing antibodies. A vaccine using the pre-fusion (rather than post-fusion) form could potentially prevent RSV.

T-cell responses: Few vaccines depend on T-cell immunity. For tuberculosis, researchers are seeking a way to induce T-cell responses that prevent the persistence of tuberculosis organisms in macrophages. For malaria, on the other hand, experimental vaccines do induce T-cell responses to some degree.

Dr. Plotkin noted that only a few vaccine manufacturing companies are investing in research and development (R&D). Future industry growth in India, China, and Brazil may boost R&D. Vaccines must be profitable, or companies will lose interest in producing them. Dr. Plotkin outlined the market forces around vaccines, including the substantial investment required and long timeline for development. Recommendations and requests from government and advisory bodies like NVAC have a strong impact on manufacturers and may appear to serve as an advanced market commitment. Such recommendations should not be made lightly.

Dr. Plotkin mentioned the recent creation of The Coalition for Epidemic Preparedness Innovations (CEPI), an international vaccine development fund that will carry vaccines from conception in academic, government, and biotechnology laboratories to development and licensure by industry. The goal of CEPI is to advance promising products through Phase II clinical trials (and possibly through Phase III studies and licensure) so they could be manufactured and stockpiled for emergency use.

To advance the future of vaccinology, Dr. Plotkin suggested that NVAC identify important targets for vaccine development in the United States, promote the need for new vaccine delivery systems, and urge U.S. Government (USG) support for CEPI in developing vaccines against

emerging diseases. Also, NVAC should support research into personalized medicine that affects vaccines. Dr. Plotkin saluted NVAC members for their work.

Discussion

Much discussion ensued about the role of CEPI, with some NVAC members pointing out the complexities and barriers to successful vaccine development and marketing. Others pointed to the importance of investing in effective delivery systems, adequate infrastructure, personnel, and training.

Further discussion revolved around the purpose of a vaccine priority target list. Much attention is paid to emerging infections and epidemics, with less attention to the most significant burden of disease. Creating a balanced list of targets without a firm advanced market commitment is challenging. Such lists cannot predict the uncertain course of emerging diseases. Also, forming and maintaining stockpiles is difficult and costly. It was suggested that regulatory harmonization would benefit new and existing vaccine technology.

Dr. Thompson pointed out that NVAC plays a critical role by taking into account all the aspects of the system. Marion Gruber, Ph.D., said FDA is working toward regulatory convergence with other countries and has had some success. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) can be a forum for more collaboration.

Dr. Hinman said the Global Vaccine Action Plan sets targets, but the only one being met addresses new vaccine development. More attention should be paid to improving coverage with existing vaccines. Dr. Plotkin said NVAC faces an uncertain future; it will take a lot of work, courage, and insight to respond in a useful way. Dr. Gellin closed the session by recognizing that the vaccine landscape has changed dramatically since NVAC was formed, but NVAC has a role in identifying where more changes are needed. He added that the National Vaccine Plan calls on non-Federal entities to play their part going forward.

Vaccine Safety Science and Personalized Vaccinology

The Case for Personalized Vaccinology in the 21st Century—Gregory Poland, M.D., Mary Lowell Leary Emeritus Professor of Medicine, Distinguished Mayo Investigator, Director, Mayo Vaccine Research Group, Mayo Clinic

Dr. Poland indicated that vaccine development has historically ignored the complexity and diversity of human immune response. Dr. Poland described the early, relatively simple vaccine development approaches as "isolate, activate or attenuate, and inject." He highlighted some relatively recent innovations in vaccine development, including reverse vaccinology, and the development of subunit vaccines and recombinant technology. Dr. Poland observed that most existing vaccines focus on preventing diseases of childhood, and recognized the opportunity to develop therapeutic vaccines for adults recognizing that the number of older and immunocompromised people continues to grow.

Dr. Poland suggested that as medicine becomes more personalized, vaccination will follow and he offered a new paradigm for vaccine development of "discover, validate, characterize, apply." Dr. Poland indicated that in the future, vaccines will focus more on adult and special population

Dr. Gellin said the new legislation dedicates 20 pages to vaccines, thanks to work by HHS and NVAC. The legislation calls for a report from the HHS Secretary on vaccine innovations that describes the status of development, the optimal process for determining safety, obstacles to innovation, and how to overcome them. Dr. Gellin said NVAC has a role to play in developing the report, because it has broad stakeholder representation and a working group that can bring in more stakeholder insights. The draft report should go to the Secretary by October to ensure it is cleared in time to meet the due date in December 2017.

Impact on the VICP—Narayan Nair, M.D., CAPT, DICP, HRSA

Dr. Nair explained that a few provisions of the act affect the VICP—some on covered vaccines that are administered to pregnant women and some on new vaccines recommended only for pregnant women. It requires revising the Vaccine Injury Table to include vaccines recommended by CDC for routine use in pregnant women. Such inclusion means that manufacturers and those who administer vaccines to pregnant women would not be liable for injuries (that is, injury claims would go to the VICP).

The act also clarifies that when a vaccine is administered to a pregnant women, the recipients are both the woman and her fetus. Until now, neither statute nor court decisions resolved the question of who received the vaccine and was thus eligible for compensation. Previously, compensation was limited to one injury claim per individual; this new legislation treats the pregnant woman and her fetus as two individuals, allowing for separate injury claims for the mother and her child.

Impact on CDC—Nancy Messonnier, M.D., CAPT, CDC

Dr. Messonnier said the legislation calls for predictable review of vaccines by ACIP. She said ACIP tries to review new vaccine licenses and indications in a timely manner, but a transparent review process requires some time. The legislation also calls for a review of ACIP processes and tools for making recommendations, with the goal of ensuring consistency across ACIP working groups. Input from stakeholders will be used to improve processes.

The act requires CDC to encourage vaccine innovation by meeting with stakeholders and aiming to coordinate efforts across the field. Dr. Messonnier said CDC works closely with stakeholders and communicates about epidemiology, prevention, and control. She appreciated the need to coordinate requests so that all stakeholders have equal access to data and know how to get the data they need for vaccine development and administration. Staff from CDC are requesting input from vaccine developers about their experience with the ACIP process; the input will be used to ensure that ACIP working groups deal with all companies openly and in the same manner. Other CDC divisions play a role, so the goal is to ensure that stakeholders have a similar experience no matter what division they contact.

Additional Comments from NIH—Barbara Mulach, Ph.D., NIH

Dr. Mulach pointed out that the legislation does not address vaccine innovation at NIH, but it does talk about NIH's role in innovation generally, including the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) initiative, All of Us (formerly the Precision Medicine Initiative), the Cancer Moonshot, and the Regenerative Medicine Program. Current NIH Director Francis Collins, M.D., Ph.D. has been asked to stay on as NIH Director for now.

Additional Comments from FDA—Marion Gruber, Ph.D., FDA

Dr. Gruber said the act dictates many changes to FDA regulations; she focused on four areas related to trial design and evidence development. Under the new legislation, FDA is required to hold public meetings and issue guidance on novel clinical trial designs that can meet FDA evidence criteria. Also, FDA must establish a program to evaluate the potential use of real-world evidence to support new indications for an approved drug. Such evidence could include data from safety surveillance mechanisms, observational studies, registries, claims, and patient outcomes. Within 5 years, FDA must issue draft guidance on use of real-world evidence.

The act requires HHS and FDA to update and harmonize regulations on human subjects protections, modernizing them and reducing duplication. It directs HHS and FDA to allow joint or shared institutional review board (IRB) evaluation. The act allows clinical trials to be exempt from informed consent requirements when the study poses no more than minimal risk and has appropriate safeguards in place to protect the rights, safety, and welfare of subjects. Dr. Gruber noted ongoing discussion of whether the informed consent waiver applies to vaccines; FDA has always maintained that vaccines pose more than minimal risk to recipients.

Discussion

Dr. Thompson noted that the 21st Century Cures Act requires HHS to establish a task force on research for pregnant and lactating women that will inform the HHS Secretary on relevant research. She said NVAC should receive briefings from the NVPO Director about the new task force and work to ensure that NVAC's recommendations for maternal immunization are addressed. Dr. Thompson also mentioned that issuance of the final rule of the Common Rule, which removed pregnant women from the classification of "vulnerable" populations. Dr. Thompson suggested NVAC monitor how that provision plays out.

Dr. Gellin discussed the prioritization of vaccine development efforts. He reminded the NVAC about the SMART Vaccines project that the Institute of Medicine initiated and NVPO sponsored and mentioned that the World Health Organization (WHO) is piloting the tool in the context of WHO's R&D blueprint to determine if it can be used to assist with decision-making more broadly.

NVAC Liaison and Ex Officio Updates

Dr. Thompson invited some of the liaisons and ex officios to give highlights on some initiatives undertaken by their organizations.

VA Retail Immunization Program—Troy Knighton, M.Ed., Ed.S., LPC, VA

Mr. Knighton explained that VA first piloted a retail immunization program to increase veterans' access to influenza vaccine in 2014 with Walgreens in Florida, which it subsequently expanded nationally with Walgreens as a partner. As of December 2016, 66,000 veterans received influenza vaccines from Walgreens this influenza season. Currently, the pharmacy notifies VA about the vaccination, and VA pays for the vaccine if the veteran meets the criteria for coverage. The individual's medical record is updated to reflect the immunization. Eventually, the program will support automated bidirectional data exchange, which would allow the pharmacy to see the medical record and offer other vaccinations on the basis of the veteran's vaccine history.

Walgreens has been the only retail partner since the program started, but the VA hopes other pharmacies will join the program. The program requires investment not only in technology to support information exchange but also marketing and training for pharmacists and VA staff. It is hoped that the program will be cost-effective for both retailers and the VA. Challenges remain around information systems and bidirectional data exchange.

DISCUSSION

Discussion centered around reporting retail-based vaccinations to State IISs. Mr. Knighton acknowledged the difficulty of getting data out of the VA system to share with other agencies. Mr. Rothholz noted that providers at community pharmacies report to State IISs, but it would help to distinguish the veterans from other groups. He added that a quality measure in development will incentivize more reporting to IIS and use of that data. Dr. Thompson suggested NVAC address questions around IISs again in the near future, and she welcomed input from NVAC members.

PHAC Immunization Partnership Fund—Rhonda Kropp, B.Sc.N., M.P.H., PHAC

Ms. Kropp noted that PHAC received $25 million to develop immunization coverage targets to reduce vaccine-preventable diseases, identify under-immunized populations, and create a program to support improved immunization coverage in Canada. To meet the latter goal, PHAC established the Immunization Partner Fund, a grant program for scaling up best practices. The fund will provide as much as $3 million annually to help providers to vaccinate clients, increase demand for immunization, and enhance access to immunization services.

As part of these efforts, PHAC launched the CANimmunize mobile application, a free service Canadians can use to store immunization records on their mobile devices. Ms. Kropp noted its growing popularity and that the application gives information on recommended vaccinations depending on the immunization schedule in the individual's province and territory, plus personalized reminders and notifications of outbreaks. Work is underway to allow users to submit and retrieve vaccination information between the application and the province's or territory's record system, which would be very helpful for Canadians when they move to other provinces and territories.

In addition, PHAC funded an external review of the influence of current immunization policies and practices in each jurisdiction. The agency also called for proposals for the grants to improve and support health care providers in immunizing clients. Ms. Kropp said the response was very positive, and PHAC is in the process of making awards. The proposals included projects such as active recall reminder systems, efforts to address vaccine-hesitant clients, and creation of a national repository of evidence-informed tools and strategies. The Immunization Partner Fund's goal is to serve as a one-stop-shop where providers can learn about best practices that may be applicable to their local populations. All the information gathered from funded projects will be shared across all the provinces and territories. Awards focused on increasing demand for and access to immunizations will be given in 2018.

DISCUSSION

In response to Dr. Thompson, Ms. Kropp said the uptake of the mobile application has been strong. Currently, it is mostly used by families to keep track of needed and past vaccinations. Schools and other organizations do not have access to individuals' vaccine records, but that could be considered for future versions.

Asked to discuss the differences among the provinces and territories in terms of vaccine schedules and requirements, Ms. Kropp said the grant program deliberately focused on broad topics so that funded projects would be applicable to other jurisdictions. She noted that representatives from the provinces and territories are regularly at the table with Federal partners, which provides another platform for sharing experiences.

Vaccine Supplies and Stockpiles—Nancy Messonnier, M.D., CAPT, CDC

Dr. Messonnier clarified that the VFC program maintains a stockpile of pediatric vaccines; it is distinct from the Strategic National Stockpile (SNS). The pediatric stockpile is available for outbreaks and to mitigate unintended shortages. To ensure the stockpile is constantly replenished, CDC uses a modeling process to ensure a supply that would serve the VFC program for about 6 months (equivalent to about a 3-month supply for combined public and private use). The amount stockpiled depends on the disease; for example, there is a large supply of measles vaccine because of the high potential for infection.

Vaccines from the stockpile can be provided to State health departments for their VFC programs to prevent shortages. With CDC's permission, vaccine manufacturers can borrow from the stockpile to sell vaccine to the private sector and then replenish the stockpile. The stockpile also holds some seasonal influenza vaccine as strategic reserve for late-season use in the event of a shortage or unexpected demand. The influenza vaccine reserve has been funded since 2004, in response to the shortages experienced in the 2003–04 influenza season. The vaccine remains in the stockpile until it is used or expires.

In other CDC news, Dr. Messonnier reported, as part of the national survey of poliovirus in laboratories, CDC completed the survey of its laboratories, identifying a large amount of infectious or potentially infectious material and ensuring that all type-2 poliovirus is contained. The next phase of the national effort is an audit to ensure that laboratories that want to keep poliovirus meet the containment requirements. Dr. Messonnier said CDC is establishing an auditing unit and a Federal advisory committee to oversee the audit.

Dr. Messonnier described a specific operational problem of great importance: some manufacturers assign lot numbers to their vials and syringes but use a different lot number for the unit of sale (e.g., a carton). This practice has contributed to confusion in monitoring inventory in relation to vaccine coverage. Manufacturers are working closely with FDA, CDC, and AIRA to sort out the issue.

DISCUSSION

Mary Beth Kurlio said AIRA hopes to convince manufacturers to use a single lot number for both the unit of use and unit of sale. Mr. Hosbach noted that the products comply with Federal regulations, but manufacturers want to lessen the chance for error and confusion that arises at the provider level.

Dr. Messonnier observed that the pediatric vaccine stockpile has run relatively smoothly and cooperation with manufacturers is good. Dr. Gellin pointed out that the pediatric stockpile includes routinely used vaccines, and the SNS includes vaccines for emergencies. Some things fall through the cracks, such as rabies vaccine, and NVAC may want to look more closely at those, Dr. Gellin suggested. He added that pandemic influenza vaccine is unique; the SNS has bulk antigens stockpiled that would be used to produce such a vaccine rapidly if needed. Dr. Gellin noted that BARDA and FDA are working together to ensure that stockpiled antigens are effective and usable.

Dr. Maldonado hoped NVAC would address concerns about maintaining adequate supplies of vaccines for adults that are not included in the SNS. A representative of Sanofi Pasteur acknowledged the ongoing shortage of yellow fever vaccine. In response, the company has applied to FDA to use in the United States the yellow fever vaccine it supplies to other countries.

AHIP—Christopher Regal

Mr. Regal said AHIP named a new liaison to NVAC, James David Nordin, M.D., M.P.H., from HealthPartners in Minnesota. He will be at the next NVAC meeting.

AIM—Kristen R. Ehresmann, RN, M.P.H.

Ms. Ehresmann reported that AIM is holding its business and leadership meeting in Charleston, SC. She said the Prevention and Public Health Fund (PPHF) created in 2010 as part of the ACA is very important to State immunization programs, which received roughly 47 percent of their funding from the fund. Losing that money would have a significant impact at the State level on program activities, vaccine coverage, and outbreak response.

AIRA—Mary Beth Kurilo, M.P.H., M.S.W.

Ms. Kurilo echoed concerns about the impact of PPHF dollars on immunization programs and IISs specifically. She said AIRA released guidance recently on confidentiality protocols and privacy for IISs; a companion document on security is in development. AIRA is continuing its measurement improvement efforts under the umbrella of assessment and certification. It published baseline measures for transport (i.e., sending messages from one system to another) and is currently measuring bidirectional exchange and submission and query, which will be reported next month.

Recently, AIRA completed a pilot project for a data quality initiative, providing access to a shared service for address cleansing. Four States participated in that pilot. It will roll out community-wide in 2017. The Joint Public Health Informatics Taskforce has been discussing interjurisdictional information exchange. The Network for Public Health Law and AIRA are drafting an issue brief that will explore a model law to support exchange. Ms. Kurilo concluded that AIRA's national meeting will be in Chicago April 11–13, 2017, and registration is open.

ASTHO—Kimberly Martin

Ms. Martin said ASTHO has been working to find best practices to help public health and pharmacies plan for and respond to a pandemic. To that end, ASTHO developed a memorandum

of understanding (MOU) that clearly outlines the rules and responsibilities of each entity during a pandemic. A few States have implemented the MOU. Based on experiences in those States, ASTHO developed a toolkit, available on its website, to help other States considering a similar MOU.

The Network for Public Health Law and ASTHO developed an IIS inter-State data-sharing MOU, and ASTHO continues to work with AIRA to create a community of practice around the issue. Five out of the six States involved in the community of practice have signed the MOU. Now, ASTHO is helping those States think about how to implement the MOU.

Shortly, ASTHO will release a report detailing best practices among State public health programs that have adult vaccine programs for the uninsured. It is based on interviews with State programs that vaccinate uninsured adults and their partner organizations, such as community health centers. The report will address how States identify uninsured adults in the community and how they get services to them, as well as unique vaccine programs for this population.

NACCHO—Gillian Stoltman, Ph.D., M.P.H.

Dr. Stoltman said NACCHO recently published three new policy statements that particularly affect local health departments. The first addresses the need for continued improvement in both information and the safety of vaccines. Local health departments are intimately involved in vaccination at the local level, although less often as vaccine providers but certainly as the local coordinator in terms of education about vaccination and responses to questions and concerns about vaccination and vaccine shortages. Safety is a big issue for all local health departments.

The second policy statement encourages requiring influenza vaccine for all employees of local health departments, not just those who have direct client contact. The third policy statement addresses access to school health data for public health surveillance. Lack of access is often a problem when dealing with disease outbreaks. Federal law prohibits local health departments' access to a lot of school-based information.

Dr. Stoltman echoed concerns about the future of the PPHF and its funding for vaccination programs. NACCHO is surveying local health departments about their concerns and upcoming challenges to implementing their immunization programs. Recently, NACCHO put out a position statement, "Protecting the Public's Health: The Power of Vaccination," which is available on the NACCHO website. Also, NACCHO is working with a number of health departments across the country to see how they can work with private and other partners to implement new ACIP HPV vaccination recommendations and increase vaccine coverage, particularly for adolescents.

PHAC—Rhonda Kropp, B.Sc.N., M.P.H.

Ms. Kropp said PHAC is setting new immunization coverage goals and targets for reducing vaccine-preventable disease. Canada's last set goals and targets in 2005; they will serve as a benchmark for measuring progress. The aim is to have the goals and targets approved through the public health governance structure in Canada, including provinces, territories, and the Federal government, by December of this year.

VRBPAC—Kathryn M. Edwards, M.D.

Dr. Edwards said the 144th VRBPAC meeting was held by teleconference on October 13, 2016. Members discussed the selection of strains to be included in vaccines for the 2017 Southern Hemisphere, which has not been done previously, in preparation for the possibility of American companies providing Southern Hemisphere vaccine for both U.S. citizens and visitors. Presenters gave an excellent overview, using global surveillance data to help members understand each of the variants and their relevance. The committee voted unanimously in favor of proposed changes to the Southern Hemisphere formulations of trivalent and quadrivalent influenza vaccines that included one change in the H1N1 strain, but the other strains will remain the same.

AHRQ—Justin Mills, M.D., M.P.H.

Dr. Mills said AHRQ funds investigator-initiated research grants and conferences on vaccine topics such as looking at the impact of infant vaccination with a 13-valent pneumococcal conjugate vaccine, improving immunization rates in young children, and examining higher refusal rates in pneumococcal vaccination among African Americans. Also, AHRQ supports knowledge generation through conducting evidence reviews.

CMS—Mary Beth Hance

Ms. Hance said an updated Healthcare Effectiveness Data and Information Set (HEDIS) measure has been adopted for adolescent vaccines. She said CMS has a core set of pediatric measures for the Medicaid program for which reporting is voluntary; CMS has updated the core set and now uses the combined adolescent measure, which includes HPV vaccination. The separate HPV vaccination measure has been retired.

DoD—Margaret Yacovone, M.D., M.S.P.H.

Dr. Yacovone reported that DoD met its goal of vaccinating 90 percent of the force by mid-December, thanks to industry, which worked closely with DoD to fill gaps so that DoD could provide injectable vaccine for all age groups. In addition, DoD developed some educational programs and tools for providers about minimizing pain associated with injections.

Also, DoD requires health care workers to complete an educational program before delivering influenza immunizations. The program includes five modules with quizzes for influenza plus a cold-chain management educational tool. So far, 23,000 health care providers have completed the educational programs, and 11,000 more have completed the cold-chain management training.

Dr. Yacovone said DoD included information about the importance of immunizations and available services into education that is part of the deployment cycle. In addition, DoD embraces the One Health concept that seeks to solve critical global health challenges through integration of human medicine, veterinary medicine, and environmental sciences. It invited leaders to come to DoD to talk about the One Health approach to increase awareness about this interdisciplinary approach to reducing overall burden of disease throughout the world.

Lastly, like others, DoD is also struggling with concerns about data sharing and quality improvement and indicated that DoD would like to have an IIS connection to all 50 States, because DoD delivers care in every State. Dr. Yacovone asked that NVAC address the barriers to information exchange.

FDA—Marion Gruber, Ph.D.

Dr. Gruber reported that in November, FDA approved a supplement for the license application for FluLaval and FluLaval quadrivalent influenza vaccine so that the products can now be used in children 6 to 35 months of age. FluLaval is now the second seasonal influenza vaccine for that age range. This vaccine was previously approved for individuals 3 years of age and older.

Also last fall, FDA approved a supplement for Gardasil 9, the HPV 9-valent vaccine to include a two-dose regimen for individuals between the ages of 9 through 14 years. For Daptacel (diphtheria, tetanus toxoids, and Acellular pertussis vaccines), FDA also approved coadministration of Meningococcal vaccine (Menactra) with a fifth dose of Daptacel in children 4 to 6 years of age.

Lastly, FDA approved an extension of the age range for influenza A virus monovalent vaccine, which addresses the pandemic H5N1 virus. The age range now includes those 6 months through 17 years of age who are at increased risk of exposure to the influenza A virus H5N1 subtype, which was previously approved for use in persons 18 years of age and older.

HRSA BPHC—Judith Steinberg, M.D., M.P.H.

Dr. Steinberg said data from community health centers for 2015 indicate 77.6 percent of children served are fully immunized by the age of 3 years. The goal is to reach the Healthy People 2020 target of 80 percent. Data for 2016 will be available later this year.

Dr. Steinberg said BPHC has invested in initiatives to improve the quality of care delivered, including the provision of immunizations. Support is provided to help health centers become patient-centered medical homes, an advanced primary care delivery model that uses a multidisciplinary team and health information technology (HIT) to improve quality. So far, 67 percent of health centers are recognized as patient-centered medical homes.

In addition, BPHC supports optimal use of HIT and development of control networks that work together with health centers to optimize HIT and its use. To date, 70 percent of health centers are enrolled in a health center control network. Lastly, BPHC is expanding health centers. In December, it approved 75 new access points, which improves access to affordable quality care, including immunizations, to underserved areas.

HRSA DICP—Narayan Nair, M.D., CAPT

Dr. Nair said the DICP continues to see an increase in the number of claims received. Historically, and particularly in the early part of this decade, a typical year would bring 400 to 500 claims. In 2014, the DICP received 633. In fiscal year (FY) 2016, 1,120 claims were filed—the highest number received since the program began. In FY 2016, 856 claims were adjudicated, and 677 (more than 70 percent) were compensated, while 179 were dismissed.

In FY 2016, the DICP spent $250 million on compensation for vaccine injuries and attorneys' fees. The DICP is unique among compensation programs in that it pays attorneys' fees regardless of whether injuries are compensated. Also, the DICP published a final rule in January that updates the Vaccine Injury Table, adding a few injuries to the table.

Dr. Edwards asked for more details about the claims filed. Dr. Nair said that although claims are increasing, in the context of the number of doses of vaccines distributed, the number of claims is relatively small. The increases are primarily coming from claims related to seasonal influenza among adults. Historically the program was focused on alleged injuries in children. Now, almost 80 percent of claims are for adults, and most of those are related to seasonal influenza vaccine. Many claims involve Guillain-Barre syndrome and other demyelinating conditions as well as shoulder injuries related to vaccine administration.

IHS—Jeffrey McCollum, D.V.M., M.P.H.

Dr. McCollum said that IHS established a mandatory influenza vaccine for all of its health care workers in 2015 and has been working through labor relations processes since then to implement the mandate. The current influenza season reflects the first year in which approximately 97 percent of IHS clinical staff are impacted by the rule.

Also, IHS collects influenza coverage data on staff twice during the influenza season. For many years, coverage percentages hovered in the mid-70s. Preliminary data for this year show IHS close to 90-percent coverage among personnel, and IHS is very proud of that. An analysis of more comprehensive data will be conducted at the end of the influenza season.

NIH—Barbara Mulach, Ph.D.

Dr. Mulach highlighted a September article in the *New England Journal of Medicine*, co-written by NIH, HHS, and FDA, which talked about considerations for developing a Zika vaccine, such as who would receive the vaccine and which vaccines might be used in which cases. Also, NIAID announced its new director of the Division of Microbiology and Infectious Disease, Emily Erbelding, M.D., M.P.H. She comes from the Division of AIDS at NIAID and prior to that spent 14 years at Johns Hopkins University.

USDA—Donna Malloy, D.V.M., M.P.H.

Dr. Malloy said the United States experienced its worst highly pathogenic avian influenza (HPAI) outbreak in history between December 2014 and June 2015, with an isolated outbreak in 2016. Preparedness and response planning for foreign animal diseases is crucial to protect animal health, public health, the food supply, and the environment. Based on these experiences and the lessons learned last fall, USDA's Animal and Plant Health Inspection Service revised its Foreign Animal Disease Framework Response Plan.

The revised plan includes lessons learned from the HPAI outbreak; incident coordination, authorities, funding, relationships, and roles among Federal departments; incident management; and communication strategies during a foreign animal disease outbreak. Vaccine and disease prevention, including emergency vaccination, are among the control points in any animal disease response plan. The National Veterinary Stockpile also has sufficient amounts of animal vaccines, antivirals, and therapeutic products for responders to use appropriately as needed.

VA—Troy Knighton, M.Ed., Ed.S., LPC

As of January 21, the VA vaccinated over 1.56 million veterans in outpatient settings, and 16.6 thousand of those received the high-dose influenza vaccine. Last year, the VA initiated a policy

requiring health care providers to be vaccinated for influenza. The VA has approximately 315,000 employees. The policy has reached the upper echelons of the Veterans Health Administration for approval and will go to labor relations next. Mr. Knighton said the VA hopes to implement the policy in fall of 2017.

NVPO—Bruce G. Gellin, M.D., M.P.H.

Dr. Gellin said NVPO is announcing an awards program on behalf of all the agency partners to support non-Federal entities, which aligns with the goals of the National Vaccine Plan. The award seeks to identify people who are demonstrating leadership, promoting collaboration, encouraging innovation, advancing research, or improving practice. Also, NVPO recently released its guide to implementation of the National Adult Immunization Plan. As with the National Vaccine Plan, the effort calls for national, not just Federal, work. Dr. Gellin hoped NVAC would continue to focus on what non-Federal partners can do to advance the field.

Other Liaison Reports

The ACIP, the Advisory Commission on Childhood Vaccines, and the Pan American Health Organization submitted written reports.

Childhood Immunizations: Taking the Pulse of the Public

Public Views about the Measles-Mumps-Rubella (MMR) Vaccine and Trust in Medical Scientists and Their Research on Childhood Vaccines—Cary Funk, Ph.D., Associate Director, Research on Science and Society, Pew Research Center

Dr. Funk presented some key findings from a recently published Pew Research Center that found that most Americans (82 percent) agree that healthy children should be required to have the MMR vaccine to attend public school because of the potential health risk of infection to others. A minority believe parents should decide whether to have their children vaccinated, even if it creates health risks for others. Parents with young children perceive the risks of MMR vaccine as higher and the benefits lower than other Americans, and they are less likely to believe the benefits outweigh the risks.

Dr. Funk said all of Pew's studies on vaccines expose generational differences about the benefits of vaccines. African Americans express more concern about risks compared with Whites; Dr. Funk noted that it is not uncommon to see differences between African Americans' and Whites' Pew found mixed results around public trust in medical scientists related to MMR vaccine. For example, asked how well they thought medical scientists understand the health risks and benefits of MMR vaccine, 47 percent said "very well," 43 percent said "fairly well," and 10 percent said "not at all well." Dr. Funk said it is concerning that respondents did not express more confidence in medical scientists. Ratings of trust show more confidence in medical scientists than in pharmaceutical industry leaders, alternative health advocates, media, and elected officials, but trust overall (in government, media, industry) is low right now.

The survey revealed some skepticism that medical scientists' research findings on the health risks and benefits of childhood vaccines are influenced by the best evidence and conducted out of concern for the best interests of children's health (55 percent responded "most of the time", 35 percent "some of the time" and 9 percent "not to often/never"). Again, age influences perceptions—younger people, including parents with young children age 0 to 4 years, express more skepticism than older people about the abilities and motivations of medical scientists [46

percent responded "most of the time" to the same question]. Those with more knowledge about science have more confidence in medical scientists, and those with less science knowledge tend to be more skeptical.

Dr. Funk said that facts are not going to be enough to convince the public of the safety of the MMR vaccine. The patterns demonstrated in the research suggest that people with more science knowledge tend to be more educated and may harbor more general support for science—that is, the willingness to give scientists the benefit of the doubt—than for industry, media, or the government. However, a large share of the public (those with low to medium science knowledge) is not strongly convinced that there is strong consensus among medical scientists around MMR vaccines. Most of the respondents believe medical scientists should be involved in policy decisions about childhood vaccines. Finally, the Pew study found that medical scientists ranked second, after the military, in terms of public confidence that they would act in the best interests of the public. Medical scientists are often seen in a more positive light than other occupational groups, including other scientists. However, the survey indicates there is room for improvement.

Discussion

Dr. Omer expressed disappointment with the way the study results were presented, highlighting the concerns of parents with young children, who made up only 8 percent of the sample. He acknowledged that the findings were interesting but other studies with more parents indicate that childhood vaccination remains a social norm. Dr. Omer emphasized that the perceptions of 122 parents should not be overstated as representing the general public on this topic, which has real consequences for policy-making. Dr. Funk defended the methods, interpretation, and presentation of the data.

Wayne Rawlins, M.D., M.B.A., noted that people may perceive "medical scientists" differently than "doctors." He hoped researchers would delve more deeply into respondent characteristics to provide more nuanced interpretations of the results (e.g., opinions of African Americans with high science knowledge). Dr. Funk said the terminology was tested; Pew sought to gather perceptions that distinguished medical scientists from other scientists and from one's own doctor. Dr. Thompson hoped that in future iterations of the study, NVAC would have the opportunity to give input on questions that might elicit more information about public perceptions that could inform NVAC deliberations.

Public Comment

No public comments were offered.

Closing Remarks and Adjournment—Bruce G. Gellin, M.D., M.P.H., Deputy ASH and Director, NVPO, HHS, and Kimberly M. Thompson, Sc.D., NVAC Chair

Dr. Thompson thanked all the meeting participants. She said all should feel free to give input about the meetings, especially reactions to changes in the meeting format and agenda. Dr. Gellin thanked Lauren Chambers and her team at NVPO for their work. Dr. Thompson thanked Dr. Gellin for his many years of hard work and adjourned the meeting at 12:48 p.m.