

2009 National Influenza Vaccine Summit

June 29--July 1, 2009
Dallas, Texas

Meeting Summary

Introduction

The 2009 National Influenza Vaccine Summit (NIVS), a partnership of public and private stakeholders committed to achieving the *Healthy People 2010* goals for influenza vaccine, was convened on June 29--July 1 in Dallas, Texas. The Summit, which has been cosponsored by the American Medical Association (AMA) and Centers for Disease Control and Prevention (CDC) since 2001, was well attended. Nearly 300 experts representing over 110 diverse organizations participated, representing a 50% increase over the number participating in 2008.

During the 3-day Summit, attendees were provided updates by experts in several professional fields, including private medicine, public health, health communication, vaccine manufacturing, vaccine distribution, and vaccine-related policy. The Summit was organized into sessions, during which the following topics were covered:

- novel H1N1 influenza,
- the immunization of persons working in healthcare settings,
- vaccine manufacturers' perspectives of the 2009-10 influenza season,
- best practices for ensuring influenza vaccinations for patients of private health care providers,
- influenza vaccine-related communication strategies,
- strategies for increasing vaccine coverage in persons aged ≤ 18 years of age,
- vaccine delivery (including late season vaccination and retrospective coverage data), and
- Summit positions and future directions.

An additional session was dedicated to the 3rd Annual Summit Excellence Awards and Recognition Program. Awards were presented to the programs that demonstrated innovative approaches to increasing vaccination rates in different settings during the 2008-09 influenza season, and other outstanding programs were formally recognized or given honorable mention.

Throughout the 2009 National Influenza Vaccine Summit, participants were encouraged to provide feedback and pose topic-specific questions to presenters, or panelists, during organized discussion sessions. Summit attendees also were given the opportunity to craft Summit-based recommendations.

Session I: Novel H1N1 Influenza

Moderator: Dr. LJ Tan

Because of the emergence of the novel H1N1 influenza strain among humans beginning in mid-April 2009, several hours of the 2009 Summit were dedicated to H1N1-related updates. Summit participants were given opportunity to engage in discussion at the end of the Session.

Novel H1N1 Influenza and Advisory Committee on Immunization Practices (ACIP) Recommendations

Dr. Raymond Strikas

Dr. Raymond Strikas, a representative from the National Vaccine Program Office within the Department of Health and Human Service (HHS), opened the session by presenting worldwide H1N1 surveillance data through the week of June 27, 2009, by which time more than 55,000 cases of H1N1 influenza had been reported. Unknown subtypes of influenza A were first reported beginning in November 2008, and by the end of December, several cases of H1N1 influenza had been detected. Cases of H1N1 continued to be reported around the globe throughout the spring and into early summer, when almost all cases of influenza reported (97%) tested positive for this novel strain.

In the United States, the U.S. Outpatient Influenza-like Illness (ILI) Surveillance Network collected data regarding the percentage of visits for ILI from October 2008 through June 13, 2009. Data from this network revealed that ILI peaked during January through early April 2009 and then peaked again during early May.

Rates of ILI in individual states were shared by Dr. Strikas, along with state-based rates of probable and confirmed novel H1N1 cases as of June 24, 2009. States reporting the highest numbers of cases included Texas, New York, Washington D.C., Utah, Wyoming, Wisconsin, Illinois, New Hampshire, and Massachusetts.

The number of seasonal and H1N1 influenza-associated pediatric deaths was presented for the past several years. The number for 2008-09 remained lower than the number reported during 2007-08, at 83 cases and 88 cases, respectively. Of these 83 deaths during 2008-09, 17 were among children known to be infected with the H1N1 strain.

Dr. Strikas presented the Summit with a summary of pandemic-related events as they unfolded beginning in April 2009. During the week of April 15, two cases of febrile respiratory illness were reported among residents of southern California; these cases were later confirmed to be novel influenza A/H1N1 virus. The virus was resistant to amantadine and rimantadine and contained a unique combination of gene segments previously not recognized among swine or human influenza viruses in the United States. By April 26, additional cases were confirmed in California, Texas, and Ohio, and other cases were under investigation in another six states. By June 17, 2009, almost 28,000 probable cases of H1N1 had been reported in the United States.

Of the H1N1 cases reported to CDC, about 3,000 (or 11%) required hospitalization, and 127 (0.4%) resulted in death. Half of all cases were among males, and the median age of all case-patients was 12 years. The median age of persons hospitalized as a result of infection was 20 years, and the median age of persons who died from influenza H1N1 was 37 years. CDC data regarding race/ethnicity of case-patients revealed that 40% of all deaths occurred among non-Hispanic whites, and an additional 40% occurred in Hispanics. Most deaths occurred among persons with underlying conditions, such as pulmonary disease, diabetes, and chronic cardiovascular disease. Obesity was associated with 34% of all deaths attributable to H1N1 influenza.

Because H1N1 influenza is expected to continue to circulate into the months associated with seasonal influenza, HHS plans to continue to conduct enhanced surveillance for this disease. Other surveillance plans for the upcoming months include convening a Council of State and Territorial Epidemiologists (CSTE)-CDC working group to solidify surveillance plans for fall and winter 2009, focusing on severe outcomes, syndromic surveillance data, and laboratory data, continuing to conduct enhanced virologic surveillance, and developing revised screening recommendations and guidance for the prioritization of laboratory testing. In addition, CDC will continue to work with the World Health Organization to control and prevent cases of H1N1 in other countries; currently CDC has assigned experts to dozens of international influenza study sites around the world to assist with the H1N1 pandemic.

Planning for Novel Influenza A H1N1 Vaccine Distribution and Administration

Dr. Tom Shimabukuro

Dr. Tom Shimabukuro with CDC's Immunization Services Division discussed the planning taking place at the Agency regarding distribution of the H1N1 influenza vaccine as it becomes available from manufacturers. Because experts expected that the H5N1 strain of the influenza virus would serve as the strain responsible for a pandemic, planning for vaccine distribution was based on several assumptions. It was thought that the pandemic would begin overseas, would likely rate a 5 on the Pandemic Severity Index, and would have potential to cause significant economic and social disruption. In addition, it was assumed that pre-pandemic vaccine doses would be available for 20 million persons supporting critical infrastructure and key resources.

The emergence of H1N1 as a potential pandemic strain resulted in substantial reworking of strategic plans for pandemic influenza. Because no doses of vaccine had been produced at the onset of the pandemic in April 2009, the production of vaccine is being pushed forward rapidly to prepare for a fall 2009 vaccination campaign. In addition, it is assumed that with the H1N1 strain, economic and social disruption will likely not be as severe as was anticipated with the H5N1 strain, although pandemic severity remains unknown and will necessitate planning for several scenarios.

Fortunately, the initial supply of H1N1 vaccine is expected to be large. In addition, the seasonal influenza vaccine supply is expected to be only minimally affected by novel H1N1 vaccine development and production. Despite these expectations, however, several

uncertainties remain. For instance, the exact timing of vaccine availability remains unknown, the formulation has yet to be finalized, priority groups for vaccination have not been identified, the severity of illness is unknown, the timing of vaccine availability for H1N1 and seasonal strains remains unclear, and the demand for an H1N1 vaccine has not been elucidated. Delivery of the vaccine to healthcare providers also must be determined, although two strategies have been identified to date: a) manufacturer-direct distribution and b) centralized distribution, where a single supplier funnels vaccine to CDC and individual states.

Several challenges are associated with the H1N1 vaccination effort. Potentially, 600 million doses would need to be administered, which is substantially greater than the number administered annually for all childhood vaccine-preventable diseases (n=150 million). In addition, the pandemic has come at a time of reduced public health infrastructure at both local and federal levels.

HHS is working to address several key issues that will need to be resolved once H1N1 vaccine has been produced. Healthcare providers must be engaged and informed about administering the vaccine, payment mechanisms for vaccination must be identified, and allocation and ordering mechanisms must be elucidated. Once vaccination has begun, vaccine-related recordkeeping will be critical to the success of vaccination campaigns, along with respecting vaccine prioritization, assuring receipt of a second dose, and following Emergency Use Authorization requirements when applicable. To ensure the success of these activities, HHS has implemented the Vaccine Implementation Steering Committee, is working with provider organizations, is engaged in distribution planning, and is developing scenarios to guide planning efforts.

The Kaiser Permanente Northern California Epidemiologic Experience: Novel H1N1 Outbreak Spring 2009

Dr. Randy Bergen

Kaiser Permanente of Northern California's experience with novel H1N1 was shared by Dr. Randy Bergen. Upon learning of the first cases of H1N1 in April 2009, Kaiser Permanente initiated national, regional, and local responses. At the national level, a clinical workgroup was formed that held daily teleconferences to ensure that the healthcare group remained informed about recent H1N1 developments. Regionally, emergency operation centers (EOCs) were activated, and daily teleconferences were held. At the local level, local EOCs were activated and daily meetings were held, during which hospital and outpatient operations were considered.

To meet patient demand, local Kaiser Permanente facilities created a single influenza A/H1N1 point of service for both pediatrics and adult patients; in most facilities, tents were used to service patients suspected of having been infected with H1N1. All personnel staffing these temporary service venues were fit tested for respirators and followed OSHA protocols.

Key to Kaiser Permanente's H1N1 response activities was the use of an existing call center for patients. Teleservice providers delivered "flu scripts" to help assist patients and then referred them to the appropriate medical personnel. Kaiser Permanente's call center has the capacity to handle up to 50,000 calls per day. The number of calls increased during spring 2009; after the H1N1-related death of a child in Texas on April 27, the number of calls increased dramatically from 8,000 to 10,000 per day.

Kaiser Permanente conducted a coordinated response to H1N1 influenza. Specifically, the group developed strict protocols for determining whether patients were categorized as suspected case-patients, provided daily updates on the virus to communities, and ensured thorough communication with patients calling the call center. In addition to these activities, the Northern California Kaiser Permanente group engaged in surveillance activities to help monitor the prevalence of this virus in their patient population. Patients suspected of having H1N1 were tested with commercially available PCR tests, and all tests identified as being influenza A were sent to the state lab for further investigation. Because of the uncertainty associated with the availability of Tamiflu and other antivirals, Kaiser Permanente chose to take a modest approach to treating patients testing positive for H1N1 influenza.

Several challenges were faced during Kaiser Permanente's H1N1 response. Primarily, the overall level of preparedness proved to be inadequate; disaster preparedness work had focused too heavily on the inpatient setting, equipment was insufficient or inadequate, and the EOCs tended to concentrate on inpatient and outpatient service provided at medical centers. In addition, problems were encountered at the federal and state levels, including the overstated value and supply of Tamiflu, unrealistic expectations regarding the use of infection control measures, an inadequate testing system, and a lack of communication regarding the importance of social distancing during school closures.

Despite these challenges, Kaiser Permanente found CDC's and other federal and state agencies' response activities valuable. Specifically, the communication originating from CDC proved to be concise and effective, and a consistent message was delivered by public health representatives at all levels.

Guiding Principles for Pandemic H1N1 Influenza Communication: CDC's Response to Date and Preparing for What Lies Ahead

Drs. Glen Nowak and Kris Sheedy

CDC's H1N1-related communication strategies were outlined by communication experts from the Agency. Drs. Nowak and Sheedy discussed CDC's response to date and revealed communication plans for the upcoming influenza season.

Several principles guide CDC's communication response to novel infectious diseases. The Agency strives to acknowledge these threats early in the event, maintain transparency, identify and acknowledge uncertainties and the unpredictable nature of infectious diseases like influenza, prepare guidance to help prepare the media and public for what may lie ahead, and involve and empower others. Although these principles can

help create an effective public health communications foundation, challenges to influenza pandemic-related communications can be expected to persist. These challenges could include an increased demand for instant, immense, and ongoing communications (e.g., daily press briefings, requests for information, and millions of website visits, and thousands of daily inquiries to CDC INFO); frequent and rapid change in the epidemic or outbreak; the need for rapid coordination; and the need for pre-prepared pandemic influenza messages that are not always easy to adapt.

As cases of H1N1 influenza emerged, CDC employed several strategies and actions. The Agency activated its EOC; provided frequent updates to the media, public, and partners; invited news media to CDC; worked to accept all media invitations; engaged experts to assist in media interviews; and actively assessed the communication environment. CDC also used numerous channels for disseminating its messages.

CDC is working to become better prepared for communicating future H1N1-related events in recognition that the situation likely will evolve unexpectedly and public perceptions will have a strong influence on influenza-based communication efforts. For instance, according to recent Gallup poll, Americans are becoming less concerned about the H1N1 pandemic as time passes; in addition, a widespread public perception exists that novel H1N1 is a “mild” disease, which may complicate efforts to vaccinate the public against this disease.

In light of these perceptions and limitations, CDC has identified key considerations for pandemic influenza vaccine communications, as follow.

- Initial cases matter.
- In practice, it will be difficult to differentiate between seasonal and pandemic H1N1 illness.
- Many high risk patients do not self-identify as such.
- Vaccination recommendations for children and pregnant women may generate vaccine safety concerns.
- Different vaccine formulations will have different communication issues.
- Similarity between H1N1 influenza and seasonal flu vaccines will likely lead to greater comfort level with the new vaccine.
- Availability of antivirals might reduce demand for vaccine.
- Widespread support is essential, and actions are more important than statements from healthcare experts and providers.

CDC’s communication experts have also crafted the following key messages and themes to be used during the H1N1 pandemic.

- There are reasons to be worried when it comes to the HN1 influenza virus and the upcoming flu season.
- The novel virus warrants aggressive public health actions.
- Strong actions are taken to protect people from seasonal flu and should be taken in response to this pandemic virus.

- When it comes to reducing influenza transmission, vaccines are the most important tool available.
- The pandemic H1N1 influenza virus serves as a reminder of the ever-changing nature of influenza.

Because the H1N1 strain is anticipated to be circulating at the same time as seasonal strains, influenza-related communications must address both of these viruses. CDC plans to promote seasonal flu vaccine as a core that can be adapted and expanded; if seasonal influenza vaccine is available first, CDC will urge providers to begin promoting seasonal influenza vaccine as soon as it is available and to keep vaccinating through spring 2010. Regardless of the severity of H1N1 into the 2009-10 season, CDC will continue to encourage providers to provide patients with seasonal vaccine. If the novel strain is severe and widespread, CDC will communicate the importance of receiving both vaccines, emphasizing that vaccination against seasonal influenza is not expected to provide protection from novel H1N1 influenza.

Community Immunizers and H1N1

Mr. Steve Pellito

Mr. Steve Pellito informed Summit participants about the important role that community immunizers play in ensuring appropriate levels of vaccine coverage, particularly during years in which vaccine for both seasonal and H1N1 influenza will be available. Community-based immunizers are uniquely positioned to help administer both types of vaccine, as they have access to diverse public venues (like senior centers, grocery and other retail stores, and places of worship) and have experience conducting large-scale vaccination programs. With the expected increase in vaccine demand for the 2009-10 season due to the overlap of H1N1 influenza with seasonal disease, community immunizers will likely be even more valuable to the overall influenza immunization effort.

Despite the need to increase access and support in the delivery of influenza vaccine in the United States, current legislation in several states limits the ability of community-based immunizers to provide vaccine. This policy serves as a critical limitation to current and future efforts to increase vaccine coverage in the United States.

Mr. Pellito concluded his presentation by stressing that no one sector alone can meet the demand for large scale vaccination initiatives (like those that will likely be required for an influenza pandemic), particularly in light of waning public health resources and budgets. Community-based immunizers can mobilize quickly and have been shown to play a key role in increasing immunization rates.

2009 H1N1 Vaccine and Immunization Strategy

Dr. Bruce Gellin

The Director of HHS's National Vaccine Program Office, Dr. Bruce Gellin, informed Summit participants about H1N1-specific vaccine supply and policy and the use of a

pandemic plan. In November 2005, a national strategy for pandemic influenza was created with the goal of producing enough vaccine for all Americans within 6 months of pandemic onset. With the more than \$1 billion that has been designated for vaccine purchase, immunization planning, and other public-health-related initiatives, HHS has the resources to work towards this goal. Currently, the U.S. Department of Health and Human Services (DHHS) is contracted with five different vaccine manufacturers, all of which are at different stages of the production process. Although the initial reference strain has been identified, manufacturers must engage in a series of activities before vaccine can be produced and distributed. Fortunately, identifying the H1N1 reference strain has not interfered with production of the seasonal influenza vaccine for the upcoming year.

Session I Discussion

The following bulleted list represents a summary of the discussion that took place following the presentations made during Session I.

The Novel H1N1 Virus, Surveillance, and Vaccine

- Dr. Ray Strikas was asked to clarify his statement that CDC estimates that 1 million people have been infected with H1N1. Dr. Strikas clarified that the estimate is based on ILI data; serologic studies are underway that will provide more accurate estimates.
- Dr. Strikas discussed the ability of seasonal vaccine to protect against the H1N1 strain. Studies to date have suggested that people vaccinated with the 2007-08 vaccine had antibodies against a California strain, which may help explain why older people are less likely to get infected with H1N1. It does not appear that the 2008-09 vaccine offered any protection, although people with a long history with vaccine might theoretically be more protected.
- A Summit participant from the San Francisco Unified School District inquired about the level of protection offered after one dose of influenza vaccine. Dr. Strikas noted that communication messages about the required doses and levels of protection should be crafted with care, because persons with naïve immune systems are assumed to remain unprotected after a single dose. Dr. Strikas also discussed the use of non-injectable vaccine in children, stressing that non-injectable technologies are available through intranasal sprays.

National H1N1 Vaccine Strategy

- A representative from MedImmune asked Dr. Gellin whether manufacturers are investigating different vaccine dosing levels. According to Dr. Gellin, all manufacturers will be working to determine dosing levels, but these levels should be consistent across the manufacturers.
- Dr. Gellin was asked to discuss prioritization plans for H1N1 vaccination. He informed the group that because states have asked for guidance regarding priority

vaccination groups during an H1N1 pandemic, ACIP will meet in July or August 2009 to evaluate the data that would help define target groups. ACIP will also look at vaccine availability to determine how many groups could be offered vaccine. Dr. Gellin emphasized that realistically, the H1N1 vaccine will not be available until mid-October; ACIP should have recommendations regarding priority groups by that date.

- A National Association of City and County Health Officials (NACCHO) representative asked which advisory groups are involved in making decisions to begin administering vaccine. He was told that HHS is ultimately responsible for making this decision after consulting with other agencies and groups, such as the Food and Drug Administration (FDA) and ACIP.
- A representative from NACCHO voiced the need for a coordinated pandemic influenza response; local and state health departments should be involved in planning efforts.
- A CDC representative expressed the need for providers to become familiar with VAERS as they begin to vaccinate patients.
- Dr. Gellin was asked to clarify whether HHS would continue to recommend vaccination against H1N1 regardless of the safety profile and effectiveness of the vaccine. Dr. Gellin informed the group that CDC is examining different planning scenarios to determine demand for vaccine based on these factors. A manufacturing representative added that FDA has already validated assays from every vaccine manufacturer; FDA's effort in ensuring the safety of these vaccines, including the agency's timetable for conducting immunogenicity and safety testing, should be respected. The exact availability of the vaccine cannot be predicted or rushed. However, it is safe to assume that seasonal influenza vaccine will be available before the H1N1 vaccine. In light of this assumption, vaccine messaging should focus on seasonal influenza.

H1N1 Vaccine Manufacturing

- Concern was expressed that vaccine manufacturers are cutting back on seasonal vaccine production to focus on pandemic vaccine. Dr. Gellin responded that manufacturers are being careful not to let the manufacture of pandemic vaccine interfere with production of seasonal vaccine.
- One Summit participant asked about the capacity for testing amino assays, suggesting that perhaps there is insufficient capacity for ensuring that vaccines are effective and safe.

Collaboration and the Role of Community Immunizers

- A Summit participant asked Mr. Pellito about how he envisions community immunizers will partner with public health in the administration of H1N1 vaccine. Mr. Pellito responded that until plans are made for vaccine administration and reimbursement, it is hard to determine how these groups will collaborate.
- It was stressed that local coalitions will be critical partners in ensuring H1N1 vaccine delivery.

H1N1 Vaccine Distribution

- Dr. Bergen emphasized the need to develop a hybrid model for vaccine distribution of the pandemic vaccine.
- Dr. Shimabukuro noted that the vaccine process must be managed to ensure that critical priority groups and infrastructure personnel are vaccinated. It is anticipated that a broad segment of the population will be recommended to receive vaccine.
- Several Summit participants discussed the need to create a centralized vaccine distribution system to ensure that end-users (healthcare providers) receive vaccine in a timely manner.
- Dr. Shimabukuro discussed plans to vaccinate children against H1N1 within the school setting. He emphasized that schools are considered public settings, so distributors are working with states and departments of education to investigate offering vaccine in schools. Schools likely will serve as a valuable setting for ensuring high levels of vaccine coverage in children.
- The distribution of pandemic vaccine was discussed. Dr. Gellin noted that regardless of whether a centralized distribution system is employed, HHS will continually monitor this effort to determine which strategies are effective. Dr. Shimabukuro emphasized the importance of managing distribution at the federal, state, and local levels, particularly if demand exceeds vaccine supply.
- A State of Alabama health officer stressed that demand for vaccine will almost surely exceed supply; although 40 million doses of pandemic vaccine will likely be available by mid-October, more than 100 million persons living in the United States could potentially be identified as a “priority” vaccine recipient (e.g., children and adults with underlying conditions).
- Dr. Bergen was asked about the use of rapid influenza tests to triage potential H1N1 influenza patients. Dr. Bergen noted that although these tests are not currently used at Kaiser, many hospitals do. The use of these tests can be advantageous in some settings.

H1N1 Vaccine Communication

- A MedImmune representative expressed support for CDC’s communication plan and asked panelists to explain how CDC plans to urge providers to step up their efforts to vaccinate during the 2009-10 season. Dr. Kristine Sheedy stated that CDC is “laying the foundation” by letting providers know what to expect for the upcoming season; providers must “expect the unexpected.” In addition, providers are being encouraged to expand the vaccination season in both directions.
- Several attendees stressed the need for clear, consistent pandemic influenza vaccination messages, particularly in light of the overlap with seasonal influenza. Communications experts should anticipate the confusion that likely will arise. Dr. Sheedy stated that CDC’s research to determine the level of public knowledge of vaccines, antibiotics, and antivirals has revealed that many people remain

- unaware of the distinction between these prevention and treatment tools. It was noted by one meeting attendee that many providers are also improperly informed about this distinction.
- Dr. Philip Baseil suggested that a joint meeting, or Summit, between the Southern Hemisphere and Northern Hemisphere be held to address communication and messaging strategies.

2009 Dinner Program

Part I: Distributor, Manufacturer, and Department of Defense Presentations

Moderator: Gina T. Mootrey

Healthcare Industry Distributors Association (HIDA)

Dr. Andrew Van Ostrand

Dr. Andrew Van Ostrand, Vice President of Policy for HIDA, gave a brief update about the role that distributors and suppliers play in the vaccine supply chain. He began by providing background information about the Association.

HIDA is a professional trade association representing more than 160 medical products distributors and about 150 medical products manufacturers, including those that produce and distribute influenza vaccine. Actively involved in the Summit since its inception, HIDA formed the Flu Vaccine Business Practices Initiative 3 years ago to help educate stakeholders about the role of member companies in increasing vaccination rates across the country.

The influenza vaccine supply chain is unique, as the vaccine can be distributed to healthcare providers directly from manufacturers and through medical products distributors. During the 2007-08 influenza season, about half of all vaccine doses were distributed through each of these channels.

Despite the diverse distribution channels currently available for influenza vaccine, a gap continues to exist between supply and demand. For the 2007-08 influenza season, although almost 141 million doses of vaccine were produced, only about 113 million were distributed to healthcare providers. This discrepancy reflects a trend that has been growing since the 2004-05 influenza season. The existing gap between supply and demand can be partly attributed to the inherently unpredictable supply of influenza vaccine from season to season.

Several challenges to vaccine distribution persist. These include the need to close the supply and demand gap by increasing vaccination rates, the emergence of the H1N1 influenza strain, the unpredictability of vaccine supply, and state and federal legislative activity. Despite these challenges, HIDA has identified several opportunities for distributors during the upcoming influenza season that will likely result in higher vaccine coverage rates. HIDA has obtained strong commitments from its distributor and

manufacturer member companies, which ensures ongoing collaboration in vaccine distribution efforts. In addition the organization has developed strong relationships with non-member partners, such as CDC/AMA, the National Foundation for Infectious Diseases (NFID), and the Immunization Action Coalition.

GlaxoSmithKline

Dr. Tosh Butt

Summit participants were provided with an update on GlaxoSmithKline's (GSK's) recent influenza vaccine-related activities by Dr. Tosh Butt, Executive Director of GlaxoSmithKline's Influenza Franchise. Dr. Butt stressed GSK's commitment to the influenza vaccine market, stating that GSK partners with public health in delivering solutions across the broad spectrum of influenza needs.

GSK manufactures inactivated influenza vaccine in two facilities located in Dresden, Germany and Quebec, Canada; products include Fluarix® and FluLaval® for seasonal influenza and Prepandrix/Panemrix™ for pandemic strains of influenza. In addition, the company is planning to manufacture Q-PAN (adjuvanted split-virus pandemic vaccines) at its Quebec facility in the near future. Both seasonal influenza vaccines manufactured by GSK are indicated for persons aged ≥ 18 years. Fluarix® is available in prefilled syringes that will be thimerosal free for the 2009-10 season; FluLaval® is available in a multidose vial and contains thimerosal, which is added as a preservative (25 μg of mercury in each 0.5 mL dose). GSK anticipates producing up to 20 million doses of these seasonal influenza vaccines for the upcoming season. Delivery of the seasonal influenza vaccines will begin during summer 2009; GSK estimates that 1 million doses will be ready for shipment and CBER release by the end of July and that 80% of GSK's manufactured doses will be supplied by the end of August.

In addition to the seasonal influenza vaccines, GSK plans to produce a pandemic influenza vaccine containing a monovalent antigen and an adjuvant, which must be mixed together prior to vaccine administration. Both of GSK's manufacturing facilities will produce this vaccine.

GSK also has the capacity to produce doses of Relenza® -- an antiviral that was shown to be effective against seasonal and H1N1 strains of influenza as of spring 2009. Since the spring 2009 outbreak of novel H1N1, GSK has reactivated all of its Relenza® production lines; this manufacturer has the global capacity to produce between 50-60 million treatment courses per year. To further increase its capacity, GSK is exploring alternative delivery methods for zanamivir (Relenza®).

GSK values its public health partnerships and is committed to the influenza market. The manufacturer continues to improve vaccine effectiveness and product processes, is involved with the comprehensive influenza preparedness effort, and is exploring new avenues for improving influenza vaccination coverage rates.

Novartis Vaccines

Dr. Nima Farzan

The Novartis Vaccines update was provided by Dr. Nima Farzan, Vice President of U.S. Marketing for Novartis Vaccines and Diagnostics. Dr. Farzan informed the Summit about Novartis' commitment to preventing influenza in the United States and provided information about vaccine supply for the coming influenza season.

Novartis has established long-time partnerships with public and private stakeholders to help protect the health of the public and has been producing influenza vaccine for more than 20 years in the United States. To meet public health goals and to support a universal influenza vaccination recommendation, Novartis has increased its supply of seasonal vaccine. In addition, to address the emergence of H1N1 influenza in the United States, Novartis is partnering with HHS to manufacture H1N1 vaccine; the manufacturer has produced its first lots of cell-culture-based H1N1 vaccine, which is awaiting clinical trial. Novartis is working to build capacity for the production of this vaccine; the manufacturer now has a facility in Germany capable of producing cell-culture-based H1N1 vaccine and is developing a facility in Holly Springs, NC, which is supported by a \$486 million grant from HHS. When online, these facilities will have the capacity to produce 150 million doses.

For the 2009-10 influenza season, Novartis is planning to manufacture 30 million doses of Fluvirin®; a thimerosal-free, egg-based vaccine (Agriflu) has been submitted to CBER for approval for use against novel influenza A. Novartis expects that 10 million doses of Fluvirin® will be available to providers by August 30, 2009, and most doses should be available by the end of September.

In response to the emergence of the novel H1N1 influenza virus, Novartis is developing several vaccines under two HHS contracts. The H1N1 vaccine production is based on Novartis' Fluvirin egg-based platform, which is already licensed in the United States. In addition, the manufacturer is working with other H1N1 antigen production platforms, including AgriFlu® and Optiflu, which has been approved in the EU and in the United States. As part of the vaccine development process, Novartis has proposed the conduct of several clinical development programs, including dose-finding studies in adult and pediatric populations intended to provide safety and immunogenicity data for both antigen and adjuvant treatment groups. Other ongoing trials examining the use of adjuvant MF59 among pediatric populations also are being conducted.

Sanofi Pasteur

Dr. William Averbeck

The Sanofi Pasteur update was presented by Dr. William Averbeck, who began his discussion by outlining the manufacturer's pandemic preparedness plans. Sanofi Pasteur is communicating and collaborating with health authorities and is committed to supporting public health efforts. Sanofi Pasteur began manufacturing H1N1 vaccine within a week of receiving HHS' initial order for a vaccine against novel influenza virus

and plans to increase its capacity to produce seasonal and pandemic influenza vaccine upon FDA license of its new manufacturing facility. The manufacturer expects to produce a total of approximately 150 million doses of vaccine in its existing and new facilities during 2009. Sanofi Pasteur anticipates that after clinical trials are conducted to determine the dosing and schedule for the novel influenza H1N1 vaccine, production for the novel influenza A/H1N1 virus vaccine will take 4-5 months.

Sanofi Pasteur recognizes that although the influenza pandemic has raised concerns, manufacturers cannot lose focus on seasonal influenza. Production for the 2009-10 seasonal influenza vaccine remains on track. Sanofi Pasteur will produce 50 million doses for the upcoming season and will ship 50% of its Fluzone doses in August. All shipments should be completed by the end of October. For the upcoming season, Sanofi Pasteur plans to increase its production of preservative-free Fluzone and will fully convert to preservative-free formulations with adequate levels of provider demand.

The emergence of H1N1 virus underscores the need for manufacturers to provide seasonal vaccine to healthcare providers early (i.e., from August through October) this season. Several factors regarding the H1N1 influenza vaccine remain to be elucidated, including distribution strategies, the required immunization process, and the timing of the influenza A/H1N1 epidemic. Providing vaccine during these months ensures increased vaccination opportunities while minimizing any interference with H1N1-related vaccination initiatives.

Sanofi Pasteur has defined future vaccine-related activities, including engaging in a robust research and development program to investigate product innovations that address the special medical needs of specific populations and provide enhanced delivery methods. The manufacturer also plans to produce a high-dose, intramuscular Fluzone vaccine comprised of high-dose trivalent, inactivated split influenza virus vaccine formulated with no preservatives or adjuvants. This new formulation, indicated for active immunization against influenza disease among older adults, will be available in a single 0.5-mL pre-filled syringe.

CSL Biotherapies

Dr. Robert Lefebvre

Dr. Robert Lefebvre, Vice President and General Manager of CSL Biotherapies, spoke to the Summit about CSL's vaccine manufacturing activities for the upcoming influenza season. He began by providing an overview of CSL's involvement in national efforts to prevent influenza.

CSL Biotherapies has a long tradition of delivering influenza vaccine to the healthcare marketplace. The company produced the first vaccine to combat Spanish influenza in 1918, providing 3 million doses between October 1918 and March 1919. CSL began producing seasonal influenza vaccine using an egg-processing method in 1944, which led to the licensing of modern egg-processing production techniques in the late 1960s. Currently, CSL manufactures Afluria®, a thimerosal-free vaccine, in facilities based in

Germany, the United States, and China and sells vaccine in 27 countries around the globe. The company plays a key role in providing seasonal influenza vaccine in both Northern and Southern Hemispheres.

For the 2009-10 season, CSL plans to have more than 8 million doses available to U.S. healthcare providers, most of which will be thimerosal-free and packaged in single-use, pre-filled syringes. To date, the manufacturer is on target for reaching this goal, as the 2009-10 strains (as selected by the World Health Organization and FDA) have shown good growth. Seasonal delivery of the influenza vaccine will begin in early August pending licensure.

In addition to producing seasonal influenza vaccine, CSL is working to develop vaccine for use against novel H1N1 virus for use in both Hemispheres. To date, much progress has been made -- development of the H1N1 "egg-adapted" antigen was begun in May, Australian clinical trials involving both adults and children were underway beginning in July 2009, and a contract with HHS to supply bulk doses of antigen has been established.

CSL has defined several influenza vaccine priorities for the future. Clinical studies currently are underway to provide evidence for a pediatric indication for Afluria®, and studies are being conducted to investigate ways of improving vaccine efficacy (i.e., through use of new adjuvants).

MedImmune

Dr. Kathleen Coelingh

MedImmune's FluMist® update was provided by Dr. Kathleen Coelingh, Senior Director of Medical and Scientific Affairs. She began by giving an overview of the manufacturer's vaccine selection and production process, noting that one new strain is included in MedImmune's 2009-10 FluMist® vaccine and that all strains are produced using reverse genetics. Dr. Coelingh also discussed MedImmune's projected supply of influenza vaccine for the 2009-10 season; MedImmune plans to supply the marketplace with 10-11 million doses of vaccine, and shipping is anticipated to begin in August. Several distributors, including McKesson, Besse, ASD, and Moore Medical, will be employed to bring the vaccine to customers.

Through federal funding, MedImmune is developing a vaccine for use against novel H1N1 influenza. Ideally, MedImmune will produce approximately 35 million doses of this new vaccine to help prevent H1N1 influenza in the upcoming months. The live-attenuated H1N1 vaccine is similar to FluMist®, except it is monovalent. It is anticipated that the 0.2-mL dose of H1N1 vaccine will be delivered by nasal spray, produced using egg-based techniques, and free of all preservatives and adjuvants. Two clinical studies aimed at investigating vaccine attenuation and assessing serum immune response in adults and children are planned.

Several activities are underway to support public awareness of the need for influenza vaccination in light of the new pediatric recommendations. MedImmune has launched the “Choose Your Administration” campaign with the objective of urging eligible adults and families to elect to get vaccinated against influenza, particularly during the earlier months of the influenza season. Through this campaign, MedImmune connected immunization messages with the U.S. Presidential election to leverage the high level of enthusiasm associated with this national event. Messages were delivered via the media, websites, blogs, and election “buttons,” and attention was given to influenza vaccination during the Democratic and Republican National Conventions. Several additional efforts to increase awareness of the need for influenza vaccination were undertaken by MedImmune, including the “Don’t Play with the Flu” campaign (initiated to raise awareness among mothers), consumer education programs, and the “Teach Flu A Lesson” campaign (a school-based program to encourage school-based professionals to implement influenza vaccination programs).

To better understand the behavior of pediatricians who offer in-office influenza vaccines, MedImmune initiated the Pediatric Influenza Coverage (PIC) study. The goals of the study were to describe vaccine coverage levels among children visiting pediatricians’ offices and to examine correlations between in-office influenza vaccine uptake and the use of various methods to increase vaccine coverage. MedImmune’s PIC study revealed that for the 2007-08 and 2008-09 seasons, most vaccinated children received TIV that was not administered as part of the Vaccines for Children (VFC) program. Substantially more children received live, attenuated vaccine through the VFC program during 2008-09 than did those who were vaccinated in the previous influenza season. The PIC study also yielded data regarding the timing of vaccination for the two study years (2007-08 and 2008-09); most children received vaccine during the last few weeks of October during 2007-08, whereas most children received vaccine during the first weeks in October during 2008-09. Several conclusions were associated with MedImmune’s study: pediatric practices might increase in-office vaccination by offering vaccines for a longer period of time (particularly at the start of the season), and the administration of vaccine through the VFC program was delayed compared with the administration of privately purchased vaccine.

Department of Defense (DOD)

Dr. Wayne Hachey

Dr. Wayne Hachey, Director of Preventive Medicine in DOD’s Office of the Assistant Secretary of Defense, informed Summit participants about DoD’s unique mandatory influenza immunization program.

Influenza vaccine has been mandatory for all active duty personnel since 1940. DoD’s policy also includes healthcare workers who provide direct patient care. This program has resulted in active duty vaccine uptake rates ranging from 76% to 100%, depending on the Service, or an overall DoD immunization rate across Services of 97%.

DoD's mandatory vaccination policy has resulted in invaluable surveillance data regarding the effectiveness of each seasonal vaccine formulation; all Services must report their compliance rates, and all suspected cases are tested through DoD's Global Influenza Surveillance Program. Trend data from DoD indicate that vaccine effectiveness has varied for the past several years, ranging from 79% in the 2008-09 season to 94% during the 2003-04 season. Data regarding vaccine effectiveness by type of vaccine received (TIV versus LAIV) also have been collected and analyzed for the years 2005-06 and 2006-07; overall, LAIV significantly reduced ILI rates compared with TIV in both influenza seasons among recruits, whereas TIV significantly reduced ILI rates among non-recruits.

DoD's influenza surveillance systems have played a valuable role in detecting the emergence of novel H1N1 influenza. These systems identified the first four cases of disease in the United States – three among children of military personnel and one among a child identified via a DoD infectious disease surveillance program conducted by the Naval Health Research Center.

Beyond surveillance, DoD is preparing to mitigate pandemic influenza by maintaining antiviral, antibiotic, and personal protective equipment stockpiles; procuring vaccine for operational requirements; conducting public health education initiatives; and developing extensive plans and guidance materials to be used by healthcare professionals and others involved in pandemic influenza prevention and response. DoD has been engaged in pandemic influenza mitigation planning at both federal and local levels for more than a decade and is ready to function in a pandemic influenza environment to meet any mission requirements (e.g., supporting National Defense, supporting national response efforts, and protecting service members and their families).

Discussion:

Vaccine Manufacturing

- Dr. Ray Strikas asked vaccine manufacturers Novartis and Sanofi Pasteur why H1N1 studies involve only children aged 3 years and older, particularly because most cases are happening among younger children. Dr. Farzan with Novartis Vaccines replied that Novartis excluded younger children because their vaccine contains Thimerosal; Dr. Averbeck with Sanofi Pasteur informed the Summit that its trials have included children as young as 6 months of age.
- A Summit participant asked MedImmune's Dr. Kathleen Coelingh about how MedImmune's campaigns will address the disparity that exists in vaccine availability between patients receiving vaccine through VFC and those who are private payers. Dr. Coelingh responded that as the nation moves towards universal influenza vaccination, sources of vaccine funding for non-VFC children must be identified to ensure that both groups of children are vaccinated.
- Dr. Butt with GSK was asked to clarify how adjuvant is used with their licensed vaccine. Dr. Butt explained that the adjuvant, which is contained in a separate vial, must be added to the vaccine upon vaccine administration.

- Several manufacturers voiced support for the move towards universal influenza vaccination, emphasizing that vaccine supply remains greater than vaccine demand.

Part II: Summit Award Winner and Summit Recognition Presentations

Moderator: LJ Tan

Dr. LJ Tan, Director of Infectious Disease, Immunology, and Molecular Medicine with AMA, served as moderator for the 3rd annual Summit excellence awards and recognition program. This program was established in 2007 in an effort to recognize and encourage education, advocacy, and the delivery of influenza vaccination. It recognizes individuals and organizations that have made extraordinary contributions towards improving vaccination rates within their communities. For the 2007-08 season, the program presented awards for campaigns addressing various topics, including vaccination among persons aged 18 and younger, overall seasonal activity, vaccination of healthcare workers, and influenza vaccine coalitions. This year, the Summit received many nominations for programs that demonstrated innovative approaches to improving influenza vaccination rates; of these nominees, four were chosen as award winners, and two others were given recognition. The 2008 Summit award winners, Randall Linn, Douglas Shenson, Patricia Stinchfield, and Tiffany Tate, provided the Summit with information about their innovative vaccine initiatives, as did representatives whose programs received formal Summit recognition.

Awardee for the “18 and Younger” Campaign: The Wellness Company, RI

Mr. Randall Linn

The Wellness Company’s Mr. Randall Linn discussed his organization’s attempt to increase vaccine coverage rates among both children and adults. He began by providing a timeline of the Community Flu Site Program, which began in 2006 as a “one stop” venue for influenza vaccination at a single storefront site. By 2007, the program had been expanded to 10 sites and had begun to accept online registration; that year, approximately 7,000 people received vaccination at these community-based sites. In 2008, 21 sites were established, registration was expanded to cover entire family groups, and more than 42,000 persons were vaccinated. The program is expected to grow during 2009, as nine additional sites will be added and partnerships with local businesses will be established.

Additional initiatives have been undertaken by the Wellness Company to increase seasonal influenza vaccine uptake, including the company’s Worksite Flu Program (which involved the establishment of more than 500 worksite-based vaccination locations), the Adult Immunization Program (which focused on offering year-round immunizations at local colleges and senior community programs), and the nationally recognized Vaccinate Before You Graduate Program. The latter initiative involved 78 participating schools, at which six different clinic dates were designated. A total of nine

vaccines were offered during these clinics, including influenza vaccine, and students were able to register to receive vaccinations on-line.

Underpinning each of its efforts to increase vaccine coverage rates are a few critical “components for a successful program” as identified by the Wellness Company. The Wellness Company recognized the need to include persons in all age groups, hold multiple clinics per week, recruit medical community support, provide easy parking and clinic access, have adequate vaccine supply, provide on-line registration, maintain patient friendly hours, hire staff with experience treating children, and transmit data electronically to vaccine registries.

Discussion:

- Mr. Linn was asked to clarify how money is collected for vaccinations. He informed the Summit that insurers have provided the Wellness Company with “provider status;” therefore, vaccine recipients are required to pay administration fees only.

**Awardee for the Overall Season Campaign: Vote and Vax
Sickness Prevention Achieved through Regional Collaboration (SPARC), CT and MA**

Dr. Douglas Shenson

Dr. Shenson informed Summit attendees about SPARC’s Vote and Vax initiative, an effort to increase vaccination rates among voters by providing them with convenient vaccination sites located at their voting polls. First piloted in 1997 in Litchfield County, Connecticut, by 2004, projects were underway at 60 polling places in 12 states; that year, more than 1,000 influenza vaccines were delivered (despite a nationwide vaccine shortage), along with many PPV, hepatitis A, and hepatitis B vaccines. The Vote and Vax program was expanded to include 127 polling places in 14 states by 2006, and that year, about 13,800 influenza vaccinations were delivered.

For the 2008 election, SPARC identified inherent several challenges in its Vote and Vax campaign. For instance, this large undertaking would require the recruitment of hundreds of local health providers located around the country, the education of providers regarding how to work with local election officials, the maintenance of a non-partisan, non-political posture in a highly politicized media environment, and the potentially unprecedented number of voters expected to visit the polls. To meet these challenges, SPARC realized the need to collaborate with national partners (e.g., the American Association of Retired Persons [AARP], the American Public Health Association [APHA], NACCHO, and CDC), conduct comprehensive provider outreach to members of national partner organizations, provide technical assistance to local providers, and provide outreach to national and local media.

To increase vaccine uptake at the polls, SPARC developed simple messages for the community and for providers. Members of the community were informed that receiving

influenza vaccination through the Vote and Vax initiative is an effective way to extend protection to others who might not receive vaccine. Healthcare providers were encouraged to participate in the Vote and Vax campaign because it is a valuable way to become better known throughout their communities as being a responsive and dependable source of healthcare services. SPARC provided participating healthcare workers with extensive technical assistance and promotional/educational materials to ensure that they remained knowledgeable about influenza and the influenza vaccine.

Data from the 2008 Vote and Vax campaign have been analyzed and reveal that more than 21,400 influenza vaccinations were administered to voters visiting 331 polling locations across the country. Of vaccines, 67% were in CDC's priority vaccination groups, and almost half represented populations that typically do not receive seasonal influenza vaccine (e.g., African Americans, Hispanics, and the uninsured).

As it continues to gain recognition and momentum, the Vote and Vax campaign has the potential to reach an even larger segment of the population in upcoming elections. Polling places provide healthcare providers with access to the 120 million Americans who typically vote in national elections, 70% of which are aged >50 years (a demographic group with suboptimal influenza vaccination coverage rates).

Discussion:

- Dr. Shenson clarified that the vaccines offered through the Vote and Vax program were not free of charge to recipients; they were delivered via the same policies in place within the community.
- Dr. Shenson stressed that the project was done in partnership with local election officials; all public health providers sent in forms verifying permission from these officials before they participated in the Vote and Vax program.
- One participant asked why Texas was excluded from the program. Dr. Shenson informed the Summit that although the effort was well received in Galveston during 2006, problems were encountered in Houston during that year; influenza vaccinations were offered for free in Houston, and some constituents perceived the Vote and Vax effort as being a political tool used to increase democratic voter turn-out.

Awardee for the Healthcare Personnel Campaign: Children's Hospitals and Clinics, MN

Ms. Patricia Stinchfield

Summit participants were informed about Children's Hospitals and Clinics of Minnesota's (Children's) efforts to increase influenza vaccination rates among healthcare personnel. Ms. Patricia Stinchfield first presented general information about Children's, noting that her hospital, located in the Minneapolis/St. Paul metropolitan area, represents the 6th largest children's hospital in the United States. Children's has 300 acute-care beds, more than half of which are for critical care patients. The facility employs more than

4,000 staff members, including nurses, administrative personnel, physicians and advanced-practice registered nurses, and support staff.

Children's healthcare personnel vaccination campaign employed several influenza vaccination interventions, including pre-season education and marketing to promote vaccination, on-site vaccination clinics for all staff on each shift, roving vaccination carts, an influenza deputy program, staff meetings, and vaccine availability at the facility's Occupational Health Clinic. In addition, the hospital established the FluVaxTrax™ program, an internal web-based application used to help track eligible vaccinees based on employee ID, determine the need for injectable versus nasal formulations, auto-generate e-mail proof of vaccination for persons receiving vaccine, and provide a declination form to those declining vaccine (the program also was used to urge decliners to reconsider their position). A web-based "immunization thermometer" pictogram depicting real-time immunization rates and declinations at the facility was also used to help encourage healthcare personnel to receive seasonal influenza vaccine.

Vaccination coverage data for the 2008-09 influenza season reveal that approximately 80% of all healthcare personnel received influenza vaccine last season. Only 9% declined vaccine, and 11% of these employees had an unknown vaccination status. Data obtained for the Clinic's St. Paul Departments demonstrated a 100% vaccination rate among staff members working in the pediatric clinic; pharmacy staff had a 90% coverage rate, followed by specialty clinic personnel (88%). By job category, rates of vaccination were highest among MDs (83%), followed by RNs (76%), APRNs (72%), and RTs (57%).

Overall, the Children's effort to improve influenza vaccination coverage rates among its healthcare personnel was successful. The facility achieved its goal of vaccinating 80% of healthcare workers overall. The FluVaxTrax™ mechanism enabled effective communication and feedback, resulting in a 13% increase in coverage over last season's rate.

Discussion:

- Ms. Stinchfield noted that the FluVaxTrax software is trademarked.
- One participant commended Children's effort, particularly the mailing of "love note" reminders to employees who had yet to receive vaccine.
- A Summit participant asked whether data on illness rates at the facility prior to the campaign are available. According to Ms. Stinchfield, these data are not available because the facility is prohibited from inquiring about why employees are not attending work. However, the hospital does keep track of nosocomially transmitted influenza; only one case has been reported in the last 10 years.
- The question was raised regarding whether worker productivity is tracked as part of the healthcare worker campaign. Ms. Stinchfield informed the Summit that productivity currently is not tied directly to the influenza program, but linking workers' productivity to illnesses is desired for the future.

Awardee for the Coalitions Initiative: Maryland Partnership for Prevention, Inc., MD

Ms. Tiffany Tate

Information regarding the Maryland Partnership for Prevention (MPP), a 501c3 organization established to support preventive health efforts in Maryland by organizing various collaborative campaigns, was provided by Ms. Tiffany Tate. She began by providing an overview of MPP's seasonal influenza activities, which include the Maryland Healthcare Workers Influenza Initiative, the "Gift of Prevention" campaign, extended season vaccination mini-grants, local health department assessments, an influenza season "wrap-up" meeting, and a "What's New with Flu" teleconference.

MPP's Healthcare Workers Influenza Initiative, cosponsored by the Maryland Department of Health and Mental Hygiene (DHMH) represented an effort to recruit "registered" vaccination partners through collaborations with professional associations. Registered partners, who were provided with a toolkit containing resources and strategies, ACIP Recommendations, Maryland's Code of Regulations, standing orders, vaccine information sheets, vaccine administration records and consent forms, and document templates, completed influenza vaccine-related baseline and "wrap-up" surveys for the season. Several incentives were offered to participants, including eligibility for a \$1,000 grant. This initiative was successful, resulting in the vaccination of more than 14,000 healthcare workers during the 2008-09 influenza season; participants' efforts were acknowledged during a wrap-up meeting and awards ceremony.

Conducted to promote extended-season influenza vaccination, MPP's "Gift of Prevention" Campaign provided gift cards to members to be presented to employees, clients, and other members of the community. The cards served as reminders, encouraging recipients to seek vaccination during the later months of the vaccination season if they haven't already been immunized. During the 2008-09 season, a total of 10,000 gift cards were distributed to MPP members, and countless additional gift cards were distributed by these members to their own personal contacts within the community.

Recognition Recipient: "Flu-Free and a Mom-to-Be," National Women's Health Resource Center (NWHRC), NJ

Ms. Elizabeth Cahill

Ms. Elizabeth Cahill updated the Summit on the NWHRC/Association of Women's Health, Obstetric, and Neonatal Nurses (AWHONN) collaborative "Flu-Free and A Mom-to-Be" program, a campaign sponsored by CSL Biotherapies designed to improve vaccination coverage rates among pregnant women. She began by providing the rationale for targeting pregnant women in prevention efforts, noting that although CDC has designated these women as being a priority group for influenza vaccination, vaccination rates among pregnant women remain at <15% each influenza season. Barriers to vaccination in this population include misinformation, misperceptions, vaccine safety concerns, and a lack of communication between pregnant women and their healthcare providers.

The NWHRC/AWHONN program was designed to meet several objectives. It aimed to uncover attitudes, barriers, and opportunities to influenza vaccination among pregnant women; generate awareness of expert recommendations; and create a sense of urgency surrounding influenza vaccination among pregnant women. To meet these goals, NWHRC focused on addressing the gap between pregnant women's knowledge and expert recommendations. NWHRC also educated audiences about the benefit of influenza vaccination to mothers and babies by providing patients with expert articles, tip cards, posters, and postcards, all of which were made available through the NWHRC and AWHONN websites. Materials also were disseminated in practice settings around the country, and the media was engaged through consumer and trade publications, satellite radio broadcasts, and web casts.

The Flu-Free and A Mom-to-Be program reached almost 83 million Americans during the 2008-09 influenza season. The program's web pages were viewed 18,000 times, and NWHRC's website received 1,523 views; more than 52,000 tip cards and 26,500 posters were distributed to clinics and physicians' offices.

For the upcoming season, NWHRC and AWHONN plan to continue to focus their influenza prevention efforts on pregnant women. These groups plan to expand the reach of the campaign messages and resources to priority healthcare providers and consumers through ongoing communications and grassroots programs. In addition, initial education efforts to mobilize healthcare providers and motivate pregnant women to become immunized will be expanded.

Discussion:

- Ms. Cahill was asked when the campaign was initiated. She informed the Summit that the campaign began before influenza season began and continued into the spring; orders for posters and tip cards are being received through the summer.
- One participant asked how she might receive posters and tip cards from NWHRC. According to Ms. Cahill, order forms for these materials are available at www.healthywomen.org.

Recognition Recipient: "Flu Shots Made Simple," MinuteClinic and CVS Pharmacy
Ms. Donna Haugland

Ms. Donna Haugland presented to the Summit on behalf of CVS Pharmacy's Minute Clinic. She informed attendees about MinuteClinic's/CVS Pharmacy's "Flu Shots Made Simple" campaign, which was initiated during the 2008-09 influenza season.

Created to increase seasonal influenza vaccine uptake around the country, Flu Shots Made Simple is a collaborative marketing campaign involving both CVS Pharmacy and CVS-based MinuteClinic. More specifically, the campaign publicized influenza vaccine-related messages through print, television, public relations, and in-store promotion. Last

season, more than 6,000 nurse practitioners, registered nurses, and pharmacists participated in the Flu Shots Made Simple initiative to help administer influenza vaccine to patients seeking immunization. By December 30, 2008, more than 1.1 million patients had received vaccination through the Flu Shots Made Simple campaign.

CVS and MinuteClinic have begun planning for the 2009-10 influenza season. In addition to publicizing the need for seasonal influenza vaccination, the 2009-10 Flu Shots Made Simple campaign will incorporate H1N1-related messages to ensure that patients remain informed about the need to protect themselves against both types of influenza. MinuteClinic is prepared to test for influenza A and provide vaccine (when available) and will conduct continued influenza surveillance by submitting laboratory results to health departments located in 25 states around the country.

Discussion:

- CVS/MinuteClinic representative Ms. Donna Haugland was asked to list some of the states for which CVS has no market presence. Ms. Haugland identified Washington, Oregon, Idaho, Arkansas, and Colorado as some of these states.
- Ms. Haugland was asked to clarify CVS's testing for influenza A in the context of H1N1. She explained that the MinuteClinic routinely tests for influenza A, but nasal-swab samples obtained from patients with suspected cases of H1N1 are sent for culture.
- One Summit participant asked for clarification regarding the demographic being targeted by the Flu Shots Made Simple campaign. Ms. Haugland explained that the target audience for the campaign included persons at all ages, including children and older adults.
- A question was asked regarding whether CVS/MinuteClinic billed Medicare or private insurance. Ms. Haugland clarified that MinuteClinic bills both entities; approximately 80% of vaccines were covered by insurance.
- Ms. Haugland was asked whether CVS/MinuteClinic will be able to share statistics from this initiative with other partners. She indicated that her organization will gladly share data with CDC and state/local health departments, as doing so will help move all involved organizations towards a shared goal.

SESSION II

Moderator: Dr. LJ Tan

Session II of the 2009 National Influenza Vaccine Summit was dedicated to presentations and discussion regarding seasonal influenza. This session provided attendees with information regarding ACIP recommendations, last years' vaccination rates, and other background information pertinent to forthcoming Summit sessions dedicated to detailed discussion about the upcoming influenza season.

ACIP Update and Future Directions

Dr. LJ Tan (for Dr. Tony Fiore)

On behalf of Dr. Tony Fiore, AMA's Dr. LJ Tan provided information about the influenza-related activities being undertaken by the ACIP, particularly the Committee's Influenza Vaccine Workgroup. Chaired by Dr. Kathy Neuzil, the Influenza Vaccine Workgroup was involved in ensuring that the larger Committee remained updated about the 2009 influenza season.

With the overall goals of discussing and voting on antiviral guidance for both seasonal and pandemic H1N1 virus infection and informing ACIP activities and decision-making regarding pandemic H1N1, the group provided ACIP with seasonal vaccine safety data, arranged for presentations from various vaccine manufacturers, discussed antiviral issues (e.g., antiviral resistance among seasonal H1N1, interim guidelines for pandemic H1N1 treatment, and annual treatment and chemoprophylaxis recommendations), and discussed several aspects of the H1N1 pandemic, including immunology, epidemiology, vaccine development, and program planning.

The ACIP Influenza Vaccine Workgroup identified several factors that must be considered when developing an A/H1N1 vaccination program, including the need to clearly define program goals, roles, and responsibilities. In addition, because an "early wave" of disease remains possible, all vaccine programs must consider which vaccines will be available, when they will be available, and the number of doses of vaccine to be expected from manufacturers; this planning will also require programs to consider the types of information needed to ensure informed decision-making regarding vaccine use. Finally, vaccine program planning must account for the likelihood of an overlap between pandemic and seasonal influenza.

During the Influenza Session of the 2009 ACIP meeting, the Influenza Vaccine Workgroup encouraged ACIP to continue emphasizing the importance of receiving vaccination during the "early" months of the influenza season. The influenza vaccine provides protection even during early circulation of the virus; in addition, data indicates that immunity among persons vaccinated in late summer and early fall persists throughout the entire influenza season. Particularly relevant to the 2009-10 influenza season, early vaccination also reduces the overlap between pandemic and seasonal vaccine campaigns. Ample doses of vaccine are expected to be available for the 2009-10 season; manufacturers project that a total of 120 million doses will be produced, 14 million of which will be available by mid-August. These initial shipments will include preservative-free and infant/toddler formulations. A total of 40 million are anticipated to be shipped by September 1, and almost all doses will be available by the end of October 2009.

ACIP will continue to focus on influenza vaccine-related issues during upcoming months. The Committee will review epidemiologic data, vaccine studies, and program planning considerations; develop and review plans for vaccination programs targeting early receipt of vaccine, identify ways to reduce H1N1's impact on the seasonal vaccination program, begin development on guidance for the use of H1N1 vaccine use, and hold a public meeting in July or August 2009 to address the development of an H1N1 vaccine.

Influenza Vaccine Use by U.S. Adults during the 2008-09 Vaccination Season

Dr. Katherine Harris

Dr. Katherine Harris discussed the results of a survey conducted to provide timely data on influenza vaccine uptake and to identify key subgroups in need of targeted interventions. Designed and analyzed by the RAND Corporation and supported by GlaxoSmithKline, the influenza uptake survey project consisted of three nationally representative surveys of U.S. adults aged ≥ 18 years; more than 5,200 adults were included in the 2008-09 survey. The influenza survey project is unique, in that it provided data in just over 1 month from the time of survey administration; surveys were administered to members of a “knowledge panel,” or members of the 40,000 households recruited for the study.

Coverage rate estimates from the rapid survey project compare favorably to data obtained by NHIS. The 2008-09 End-of-Season Survey, representing data collected between March 4 and April 7, 2009, indicated that just over one third of sampled adults were vaccinated during the 2008-09 season; 22% were adults not covered by a specific ACIP recommendation, and 46% fell within one of ACIP’s recommendation categories. The survey revealed that uptake among the elderly (i.e., those aged ≥ 65 years) exceeded that for other ACIP recommended groups. Uptake also was higher among persons who visited a healthcare provider during the fall months and among those who received vaccine reminders from healthcare providers. Of persons with underlying conditions, vaccination coverage rates were lower for those with asthma than for those with chronic lung disease, diabetes, heart disease, and other underlying health conditions.

The influenza vaccine coverage study also collected data about vaccine-related perceptions and behaviors. For instance, the study revealed that a substantial proportion of persons who did not receive vaccine had no intention of ever being vaccinated, that strong vaccination recommendations from healthcare providers can influence vaccine acceptance, and that healthcare workers are more likely to view influenza vaccine favorably than other adults. The study also collected data regarding the rationale for not seeking vaccination among persons who remained unvaccinated at mid-season; most persons who intended to become vaccinated at a later date reported that they “just didn’t get around to it” (46%), whereas most people who had no intention to receive vaccine reported that they “didn’t need vaccine” (29%). Finally, the study revealed that the rationale for being unvaccinated differed between healthcare workers and other adults; most healthcare workers cited the possibility of getting sick and other vaccine-related side effects as the reason for not receiving vaccine, whereas the most commonly cited reason reported among other unvaccinated adults was the belief that they did not need the vaccine.

Overall, the rapid uptake survey resulted in several key findings that were consistent with other influenza coverage studies. The survey revealed that among adults recommended to receive vaccine by ACIP, uptake rates varied substantially. Contrary to conventional

wisdom, the study also demonstrated that patients accepted vaccine late into the influenza season.

Data obtained from the survey can be used to inform efforts to increase vaccination rates among U.S. adults. For instance, data that link provider recommendations and reminders to vaccine acceptance highlight the importance of these tools in vaccination efforts. Similarly, data revealing that healthcare workers have positive attitudes about vaccine but remain somewhat misinformed might help guide efforts to improve vaccine delivery in this population by highlighting the need for an educational component in such initiatives.

Timely Estimation of U.S. Influenza Vaccine Administrations using Medical Claims Data and the FluSTAR Surveillance System

Dr. Lone Simonsen

Dr. Lone Simonsen provided an overview of SDI, the private-sector data warehouse business located in Pennsylvania that enabled the analysis of medical claims data to determine influenza vaccine uptake. Experienced in providing innovative healthcare information solutions to private and public organizations, including FDA, CDC, and National Institutes of Health (NIH), SDI has the capacity to analyze more than 650 million physician's office-based medical claims per year (approximately 50% of those made in the United States) along with 8 million hospital-based claims and approximately 2 billion prescriptions filled by retail pharmacies. SDI is able to cleanse, de-identify, match, and integrate data from each of these sources and obtain data based on a wide range of demographic variables.

For the past decade, influenza vaccine-related claims data from physicians' offices have been obtained through SDI in near real-time (i.e., within 2 weeks of patient visit). Data are extracted through the use of influenza vaccine CPT codes that include vaccines covered by either private insurance or Medicare/Medicaid; these data are stratified by age, gender, state, 3-digit zip code, type of influenza vaccine administered, and provider type. According to SDI data, of the 115 million doses of vaccine produced by manufacturers during 2008, 30.6 million doses of vaccine were administered in physicians' offices during the 2008-09 influenza season. Vaccine administration peaked during October among adults, but remained level through November for children aged ≤ 18 years. Data for 2007-08 and 2008-09 reveal an 8% increase in the administration of influenza vaccine in physicians' offices during 2008-09; this increase likely can be attributed to increased vaccine administration earlier in the influenza season (i.e., during September and October). The monthly uptake patterns revealed using SDI data have been similar to those obtained by NHIS and the Behavioral Risk Factor Surveillance Survey (BRFSS) for the past two influenza seasons.

SDI data has enabled estimations to be made regarding the type of facility in which vaccine was administered during the 2008-09 season. Of the 115 million available doses, 51.4 million were administered in a community, employer, or public health setting; 30.6 million were administered in physicians' offices; approximately 10 million were administered through the VFC program; and 23 million doses were wasted.

SDI's network of approximately 400 physician's offices in 44 states also enabled the development of FluSTAR, a primary surveillance system that provides age-specific influenza vaccine coverage estimates. Data for FluSTAR is gathered from four different surveillance methods including rapid assay data, laboratory confirmation, and clinical diagnosis data. Specifically, FluSTAR consists of data obtained from approximately 20,000 patients with influenza-like illness who were provided with a Quickvue rapid influenza test; patients also were administered a questionnaire, which was used to collect patient information regarding demographics, medical history, symptoms, travel history, vaccination status, and type of vaccine received.

Data obtained through FluSTAR for 2008-09 revealed influenza vaccination coverage rates by age group at mid- and late-season (i.e., December 31, 2008 and April 3, 2009). At mid- and late-season, more persons aged ≥ 65 years had received vaccine than persons in any other age group; 65% of this population received vaccine during the 2008-09 influenza season. The lowest vaccination coverage levels at both points in the influenza season were observed among persons aged 19-34 years, followed by those 10-18 years of age.

In summary, SDI is a useful tool for tracking patterns in vaccine dose administration and for providing vaccine coverage estimates for seasonal influenza. In the near future, SDI data likely will be leveraged to obtain valuable information about novel H1N1 influenza, including the number and timing of antiviral prescriptions, daily/weekly spread of influenza-like illness, the number and severity of hospitalizations (including rates of in-patient mortality), laboratory testing, co-morbidities, and vaccine-related adverse events.

Session II Discussion

Summit participants and panel members engaged in discussion about the presentations made during Session II of the NIVS, which is summarized in the following bulleted statements.

ACIP Recommendations

- One Summit participant asked that the ACIP consider providing influenza vaccine dosing information in both pounds and kilos. Dr. Tan informed her that he would provide this suggestion to Dr. Fiore at the upcoming ACIP meeting.
- Regarding ACIP's recommendations, Dr. Tan was asked whether time must lapse between administering seasonal and pandemic influenza vaccines. Dr. Tan and other Summit participants reiterated that these vaccines can be administered at the same time, or within 4 weeks of each other.
- Dr. Tan was asked whether ACIP discussed the use of N95 respirators; according to Dr. Tan, this discussion did not take place.
- Dr. Tan was asked whether ACIP had engaged in discussions with CMS regarding insurance coverage of the pandemic vaccine. Dr. Tan indicated that CDC and CMS are working together to address this issue.

Rapid Influenza Uptake Survey

- Dr. Harris was asked to explain data demonstrating a high level of vaccine-related misinformation among providers. She was asked whether data can be stratified by type of provider. According to Dr. Harris, separate estimates by specialty and profession were not obtained.
- A Summit participant asked for clarification regarding how the term “healthcare provider” was defined in the rapid influenza uptake survey. Dr. Harris responded that in the rapid uptake survey, the term not only encompasses physicians, but other types of providers as well.

Claims Data Study

- A representative from Merck asked about the generalizability of SDI data. Dr. Simonsen responded that the SDI studies have yielded data comparable to data from other studies; private and public sector infants are vaccinated at the same rates.
- Dr. Simonsen was asked about how vaccine wastage estimates were derived. Dr. Simonsen responded that these estimates were obtained from manufacturers.
- A representative from Getaflushot.com asked Dr. Simonsen to clarify the sampling of CMS forms as part of the SDI effort. She was asked whether this type of sampling was done for all types of billing. Dr. Simonsen indicated that all types of billing, including third payer and private sector billing, were analyzed.

Protecting Individuals and Families: Families Fighting Flu

Mr. Joe Lastinger

Representing the Families Fighting Flu organization, Mr. Joe Lastinger relayed his own personal experience with seasonal influenza. Five years ago, Mr. Lastinger’s preschool-aged daughter Emily died as a result of influenza. She had no underlying conditions, which led the Lastinger family to begin engaging experts to better understand the cause of Emily’s death. The Lastingers joined a support program, through which parents shared similar stories about the tragic implications influenza has had on their families. This support program led to the formation of Families Fighting Flu – a non-profit organization comprised of families affected by influenza and healthcare professionals committed to educating people about the severity of influenza and the importance of receiving influenza vaccine each year.

Families Fighting Flu is engaged in several efforts to increase public awareness of the implications that influenza can have on children. The organization created a radio-based public service announcement that was distributed to more than 2,000 radio stations across the country and aired more than 5,000 times. In addition, through its website (familiesfightingflu.org), viewers are provided with medical information about the influenza virus and the influenza vaccine. To increase vaccination rates, website visitors

are also given the opportunity to send vaccination “e-cards” to remind friends and family of the need to receive vaccine each year.

SESSION III: Addressing Challenges and Implementing Initiatives to Immunize Persons Working in Healthcare Settings

Moderator: Dr. Ray Strikas

Because rates of influenza vaccination have been low among healthcare workers in a variety of care settings, Session III of the 2009 NIVS highlighted studies designed to uncover barriers to vaccination in this population and provided an overview of successful initiatives to improve coverage rates. Summit participants were given the opportunity to provide feedback on these topics during a discussion panel at the end of the session.

Influenza Prevention Survey at the Mayo Clinic

Ms. Cori Ofstead

Ms. Cori Ofstead, Visiting Scholar with the Vaccine Research Group, discussed a Mayo Clinic study that was conducted to learn more about effective influenza prevention strategies through uncovering RNs’ perceptions, knowledge, behaviors, and opinions associated with influenza vaccination. Researchers set out to identify any existing associations between healthcare worker vaccination status and levels of education, knowledge, and personal experience; they hypothesized that vaccination rates would be higher among certain groups of RNs (e.g., those who were knowledgeable about influenza, had contact with high-risk patients, and had received vaccine in the past) than others (e.g., those who remain less knowledgeable about influenza, do not have contact with high-risk persons, and have observed adverse reactions to the influenza vaccine).

For their Influenza Prevention Survey, Mayo Clinic decided to focus on nurses for several reasons, including the wide range of vaccination coverage rates in this population, the typically low vaccination rate among RNs as compared with other healthcare professionals, and the substantial amount of contact that RNs have with patients and their close contacts. The survey was first pilot tested with nurses at a local clinic, and after being refined, it was administered to a random sample of 1,000 RNs working at Mayo. Of these 1,000 nurses, 513 completed surveys.

Characteristics of the survey respondents varied widely. Most nurses (89%) were female, and their ages ranged from 22 to 69 years. Of surveyed nurses, 63% had at least a BSN degree. Almost all of the nurses provided direct patient care and worked with persons at high risk for influenza, but only about half reported ever having had influenza themselves. Regarding nurses’ experience with influenza vaccination, more than 80% had administered influenza vaccine; almost 90% of the nurses had received a vaccination themselves. A total of 65% of surveyed nurses reported that they intended to receive vaccination during the current influenza season.

The Influenza Prevention Study revealed that of the nurses declining influenza vaccination, the most frequently cited reason for declination was that they thought the vaccine should be used for other people at higher risk, followed by a concern about the side effects associated with vaccination. Almost 45% of nurses reported that they did not consider themselves at high risk for influenza.

Data were obtained regarding other aspects of influenza vaccination, including the types of educational/promotional materials to which nurses were exposed during the influenza season. Most nurses (92%) reported having seen posters and bulletins, whereas many others reported being offered free vaccine at work, being encouraged to receive vaccine by a supervisor, and receiving vaccination reminders. More specifically, 90% of nurses exposed to influenza-related educational materials reported having received information on the time and location of influenza vaccination clinics, and more than half reported receiving other types of vaccine-related information. When asked whether Mayo Clinic had provided them with all the information needed to make an informed decision about influenza vaccination, 85% of the surveyed nurses answered “yes,” demonstrating that most nurses had reached the “saturation point” regarding influenza vaccine information.

Survey data demonstrated no association between vaccination status and several characteristics, including education level, gender, amount of vaccine information received, influenza knowledge, contact with high-risk persons, having experienced a local reaction to vaccine, or observing a serious vaccine-related adverse event. However, the study revealed that an association does exist between vaccination status and age, having received information about vaccine safety and effectiveness, having received “all the information needed to make good decisions,” past receipt of influenza vaccine, and having experienced side effects or a severe reaction to vaccine themselves.

Study participants were asked about whether healthcare workers should face mandatory vaccination against several infectious diseases. Their responses varied based on type of infectious disease, with most support for mandatory vaccination expressed for hepatitis B. Of five infectious diseases (hepatitis B, rubella, measles, varicella, and influenza), influenza was associated with the lowest percentage of nurses supporting mandatory vaccination. However, when asked how they would prevent influenza if given a choice, most healthcare workers (83%) reported that they would become vaccinated; only 4% of survey respondents indicated a preference for wearing a mask or engaging in some other type of prevention strategy, and 8% responded that none of the options for prevention were acceptable.

To elucidate even more about how nurses make decisions regarding influenza vaccination, Mayo is conducting additional, on-going research. For instance, in one follow-up study, 14 RNs who did not receive seasonal influenza vaccine were interviewed and asked to elaborate on their rationale for declining the vaccine. Many noted that the influenza vaccine was not a priority, believed that they were young and healthy and therefore not at risk, misunderstood the disease and vaccine, did not perceive the vaccine would benefit them, and were afraid of the vaccine and concerned about the side effects.

Several conclusions can be drawn from Mayo's Influenza Prevention Study. First, traditional interventions do not provide a sufficient basis for vaccination programs. Also, there is a saturation level beyond which the provision of further educational materials does not increase vaccination rates, even when vaccine is offered at the worksite. Study results support the theory that an ecological model (i.e., one that engages not only individuals, but also organizations, communities, and policymakers to create environments conducive to risk reduction) would be more effective in increasing vaccination rates than any attempt to change individual behaviors and beliefs.

Impact of State Legislation

Ms. Lisa Brill

Ms. Lisa Brill with Kaiser Permanente of Northern California discussed the impact of influenza-vaccine legislation in California. She explained how this legislation affects healthcare providers in California, identified obstacles and opportunities for increasing healthcare provider vaccination through the use of an employee declination form, and outlined lessons learned.

California Senate Bill 739, which aimed to prevent influenza infections in general acute-care hospitals, was passed and implemented as California State Health and Safety Code 1288.7 on January 1, 2007. The code requires acute-care hospitals to offer free, on-site influenza vaccinations, implement respiratory hygiene and cough etiquette protocols, adopt a seasonal influenza plan, and revise or create a disaster plan that includes a pandemic influenza component. The code also requires employees of these facilities to be either vaccinated annually or provide a written rationale for not wishing to receive vaccine.

Upon implementation of the new health and safety code, Kaiser Permanente of Northern California decided to add an additional component to their existing efforts to prevent and control influenza within their facilities. In addition to offering free influenza vaccination, creating respiratory etiquette protocols, developing a seasonal influenza plan, and having a disaster plan with a pandemic component in place, Kaiser began to offer a declination form to employees who preferred to remain unvaccinated. The declination form was integrated into existing strategies (e.g., administering vaccine from October through January, having key leadership endorse the vaccine, educating staff about the benefits of influenza vaccination, making vaccine readily available, and providing roving influenza vaccination stations), but was not offered to employees until December in an attempt to discourage declination as an early option. The declination form incorporated State-mandated language and encouraged employees wishing to decline vaccination to indicate their rationale for this decision.

Kaiser's declination forms revealed that of healthcare workers wishing to remain unvaccinated, more than half did not indicate their reason for declining vaccine (59%). A total of 12% expressed fear of becoming infected with the influenza virus upon being

vaccinated, 4% indicated a medical contraindication, 4% indicated a dislike of needles, and another 2% refused vaccine because of religious/philosophical beliefs.

Kaiser's efforts to promote influenza vaccination among healthcare workers at its Northern California facilities, including implementation of a declination form, have resulted in a slight increase in vaccination rates, particularly among RNs. Kaiser Permanente attributes this success not only to the declination forms, but to defining clear consequences to non-compliance and following through on them and to encouraging increased coordination of employee influenza vaccination with patient vaccination programs. The managed care group also recognizes the importance of having a pandemic emergency response plan in place before the initial H1N1 outbreak.

Several lessons have been learned by Kaiser Permanente. The group recognizes the need to better phrase questions about reasons for vaccine refusal among those completing declination forms; as currently phrased, these employees did not provide meaningful information to be used to improve vaccine coverage rates. In addition, Kaiser learned that managers need clear guidelines to ensure consistent vaccination efforts across the organization and that declination forms must be integrated into an established program in which vaccine is conveniently offered to healthcare workers free of charge. Finally, Kaiser recognized the need to adapt existing data collection systems to ensure the optimal analysis and reporting of meaningful vaccine-related information.

Healthy People 2010 and 2020: Healthcare Personnel Influenza Vaccination

Dr. Faruque Ahmed

CDC's Dr. Faruque Ahmed reviewed the *Healthy People 2010* and *2020* goals for influenza vaccination among healthcare personnel. In addition, he provided background information on influenza vaccination rates among these professionals, discussed the new Joint Commission on Accreditation of Healthcare Organizations (JCAHO) monograph on strategies for immunizing healthcare workers, and presented information on the new National Quality Forum (NQF) measure on influenza vaccination among healthcare workers.

The *Healthy People 2010* target for influenza vaccination among healthcare workers is 60%; for 2020, a target of 90% has been proposed. Despite the Healthy People target, vaccination rates in this population remain low, at around 50%. Rates are particularly low among certain subgroups of healthcare workers, particularly those working in nursing and residential care settings and those providing ambulatory care.

To help increase immunization rates among healthcare workers, in November 2009 JCAHO asked facilities to submit details of their influenza immunization initiatives; successful initiatives would be published in a new JCAHO monograph. The request resulted in receipt of 229 submissions from facilities with varying coverage rates, 28 of which were selected for inclusion in the monograph.

Based on the successful initiatives published in the JCAHO monograph, several strategies and factors were found to be associated with high rates of influenza immunization among healthcare workers. The strategies/factors include:

- Supportive leadership
- Healthcare provider education
- Social marketing
- Successful delivery of immunization messages
- Strong campaign momentum
- Convenient vaccine delivery
- Free vaccinations
- The use of role models
- Use of signed declination forms
- Influenza vaccination policy
- Focused responsibility
- Incentives
- Linking vaccination to required activities
- Measurement/feedback.

To help standardize the way influenza vaccination coverage rates are calculated in healthcare facilities, NQF has implemented a new measure. Co-sponsored by CDC, the measure applies to hospitals and other facilities providing medical care. The denominator defined by the NQF measure is all healthcare providers working in a designated facility between October 1 and March 31 (the influenza season); three potential numerators exist, including the number of providers vaccinated during this time period, the number of providers declining vaccination, and the number of healthcare workers with medical contraindication to vaccination. The NQF measure will be field tested to determine whether it is feasible; evaluate whether it is applicable to a variety of settings; identify the types of providers to be included in calculations; determine how to count new staff members and staff who left a facility and have returned; and assess the number of vaccinations received outside of the work setting, the number of declinations, and the number of medical contraindications.

The Flu Vaccination Challenge

Dr. Ray Strikas

Dr. Ray Strikas, with HHS' National Vaccine Program Office, discussed the Joint Commission Resources (JCR) Flu Vaccination Challenge campaign, an initiative designed to increase annual influenza vaccination rates among healthcare workers across the country. JCR, an organization that provides support to JCAHO, JCAHO-accredited organizations, healthcare organizations, and other healthcare facilities, focused its initiative on healthcare workers for several reasons. JCR recognized the need to a) ensure that healthcare workers remain healthy during the influenza season and prevent influenza transmission to their patients and b) help healthcare organizations meet the JCAHO influenza vaccination standard, which requires hospitals to offer influenza vaccine to licensed independent practitioners and hospital staff.

The approximately 1,700 hospitals participating in JCR's Flu Vaccination Challenge campaign were challenged to exceed the average national influenza vaccination coverage rate of 42%. As part of the campaign, these hospitals were provided with resources, education, and best practices to help in the implementation of effective vaccine programs. Hospitals who met or exceeded the challenge were provided with a certificate of achievement from JCR.

JCR's Flu Vaccination Challenge proved successful in increasing influenza vaccination rates among participating hospitals. The average overall response rate all participating hospitals was 70%; of these hospitals, 94% reported meeting their "challenge" of exceeding the current average coverage rate. In addition, approximately 78% of participating facilities increased their vaccination rate, and 1% maintained their current rate. Only 15% reported a decreased influenza vaccine coverage rate over previous influenza seasons.

Because the campaign was successful in improving influenza vaccine coverage among hospitals, JCR plans to expand its effort for the 2009-10 season. The Challenge will be extended beyond the hospital setting to ambulatory and long-term care facilities and likely will define a new vaccination "target" of 60% coverage rates for all participating facilities. JCR recognizes the need to make adjustments to the campaign as it moves forward; for instance, the term "healthcare worker" will be better defined to encourage vaccination among all staff members who have direct contact with patients. In addition, JCR plans to provide participating facilities with more resources and provide them with ongoing encouragement and support throughout the influenza season.

Influenza Vaccination of Healthcare Personnel: An HHS Initiative

Dr. Ray Strikas

HHS' Dr. Ray Strikas provided the Summit with information about his department's initiative to improve influenza vaccination rates among healthcare providers employed by HHS. The 2-year initiative, which was first implemented for the 2008-09 influenza season, was successful in significantly increasing rates during its first year.

Understanding that several strategies are associated with increase vaccination rates among healthcare personnel, including the use of education campaigns, role models, easy access to vaccine, measurement and feedback, and declination forms, HHS incorporated two primary components into its vaccination campaign. First, HHS focused on improving vaccination rates among its healthcare employees, primarily among those working in the Federal Occupational Health Service, the Indian Health Service, HRSA-funded community health centers, and the NIH's Clinical Center. The second component of this HHS initiative consisted of promoting influenza vaccination to non-federal healthcare organizations and healthcare providers; critical to this effort are HHS' partnerships with several key organizations, including the AAFP, the American Academy of Pediatrics (AAP), the American College of Obstetrics and Gynecology (ACOG), AMA, and NIVS.

To increase influenza vaccination rates among specific groups of HHS-employed healthcare-providers, HHS focused on three primary areas: developing office- and agency-specific strategies to improve vaccination levels, measuring employee vaccination rates, and disseminating a toolkit, which contained relevant articles, posters, fact sheets, vaccine information statements, and links to other resources. The toolkit was available to all HHS employees through the HHS OPHS website.

HHS' initiative yielded agency-specific data regarding influenza vaccination coverage rates. At the Federal Occupational Service, the HHS influenza vaccination effort resulted in a 74.4% vaccination rate, representing an increase over the 2007 rate; at the Indian Health Service, the HHS initiative resulted in the vaccination of 71% of healthcare employees overall, although rates varied by facility. At HRSA's Community Health Centers, an average of 72.7% of healthcare personnel received influenza vaccine. Finally, the HHS initiative resulted in high vaccination levels at the NIH Clinical Center; at this facility, 88% of the 2,754 healthcare providers had received vaccine by February 2009.

HHS also is involved in an effort to increase vaccination coverage at U.S. health professional schools. Specifically, the agency set out to characterize the student immunization requirements associated with health professional schools in the United States and Puerto Rico by conducting a web-based survey, which was made available to all medical, baccalaureate nursing, and osteopathic medical programs. The HHS study revealed that in 2008, although almost all of these schools required students to be vaccinated against MMR and hepatitis B, <20% required students to receive influenza vaccine before being enrolled in healthcare programs. Although many schools (particularly medical schools) offer influenza vaccination to their students either free of charge or for a fee, for those schools that don't offer vaccine, most consider seasonal influenza vaccination as being the responsibility of the student rather than the school.

HHS will continue efforts to increase influenza vaccination rates among healthcare workers into the upcoming influenza season. The Department aims to make presentations at upcoming meetings highlighting the need for vaccination initiatives aimed at healthcare providers. In addition, HHS plans to identify additional non-Federal partners for more focused promotion of its initiatives, review data with CMS to discuss offering influenza vaccine at institutions receiving CMS funds, and extend vaccination efforts beyond HHS employees to include government contractors working in healthcare settings. Other planned activities include expanding the conduct of surveys to reach associate-degree nursing schools, pharmacy schools, physician assistant schools, and allied health professions schools; publishing HHS' vaccination rates along with the 2008-09 activities undertaken to increase vaccine coverage; and reviewing data from the 2008 National Health Interview Survey and other surveys that collect influenza vaccination data for healthcare providers.

Session III Discussion

The following bulleted statements summarize the discussion that took place during the Session III panel, which involved Summit participants, Session III presenters, and Session Moderator Dr. Ray Strikas.

Healthy People 2010 and 2020

- Session moderator Dr. Ray Strikas asked Dr. Ahmed to update the Summit about the *Healthy People 2010* immunization goals. According to Dr. Ahmed, these goals have been proposed by CDC, but nothing has been decided as of yet.

Vaccination Coverage among Healthcare Workers

- A Summit participant expressed concern that healthcare providers cited “concern about adverse events” as a barrier to vaccination in The Mayo Clinic study, noting that more work must be done to dispel myths about adverse events circulating in this population of professionals. Ms. Ofstead clarified that only 6% of surveyed healthcare workers reported having ever seen a serious vaccine-related adverse event (i.e., an event requiring hospitalization or treatment).
- Ms. Ofstead was asked about the decision to focus only on nurses for the Mayo Clinic study, particularly because many other types of clinic personnel can transmit influenza to patients. Ms. Ofstead noted that Mayo decided to focus on nurses because vaccination rates were especially low in this population of healthcare workers; other groups, including office staff, had higher immunization rates. Ms. Ofstead added that the Mayo vaccination campaign targeted all healthcare workers.
- Several other Summit participants asked for clarification about the definition of “healthcare worker” used in the Mayo Clinic study. Specifically, Ms. Ofstead was asked to explain what was meant by the 73% of personnel who reported working with “high-risk” patients. Ms. Ofstead clarified that the term “high risk patient” referred to a patient at high risk for influenza complications as a result of medical complications. Ms. Ofstead was also asked to explain which providers were considered “direct patient care providers;” she informed the group that because it was difficult to “draw those lines,” the category was broadly inclusive.
- Ms. Ofstead was asked to explain why rates of influenza vaccination were lower among less experienced nurses than others. She explained that although no data are available to explain this discrepancy, it is likely that these nurses were not exposed to influenza vaccination messages or offered vaccine at their nursing schools or within the community.
- A Sanofi Pasteur representative emphasized the need to address the myth that influenza vaccination is not effective, particularly in light of last year’s overlap in strains and the anticipated presence of both seasonal and H1N1 influenza during the upcoming season. Ms. Ofstead concurred that these situations complicate influenza-vaccine-related education and communication efforts.
- A participant posed a question to all panelists, asking whether their facilities include community providers who provide care to their patients, including medical and nursing students conducting rotations, in their vaccination

campaigns. According to Mayo Clinic representative Ms. Cori Ofstead, because influenza vaccination is not required for students or community providers, the campaign did not include these groups. Kaiser representative Ms. Lisa Brill noted that because her organization is a “closed system,” these types of providers typically do not provide patient care.

- Panelists were asked about their experience with using FluMist in their vaccination campaigns. Kaiser representative Ms. Lisa Brill noted that at her managed care organization, employees working with immunocompromised patients expressed concern about receiving FluMist; however, when provided with the facts (i.e., FluMist CAN be administered to contacts of immunocompromised patients), many employees requested this form of the vaccine.
- Ms. Olfstead relayed her understanding of why nurses continue to have skepticism towards the influenza vaccine. She explained that although they are trained in scientific “facts,” nurses care for patients as a primary function of their jobs and therefore may be more sensitive to emotion and feeling over logic. It is also possible that nurses mistakenly believe that if the government is not mandating influenza vaccination, it must mean the vaccine isn’t safe.
- A representative from the Massachusetts Department of Public Health emphasized the importance of additional measures for increasing vaccination rates among healthcare workers.
- Dr. Palache with Solvay Biologicals noted the need to improve current influenza vaccine perceptions among medical school students and students in other medical fields. Improving the education of these students is critical to improving overall vaccination rates among healthcare workers.

Mandatory Influenza Vaccination among Healthcare Workers

- Support for mandatory seasonal influenza vaccination at the workplace was voiced by several Summit participants. Education alone does not seem to be effective in significantly increasing vaccination coverage at healthcare facilities.
- A Summit participant expressed the need to create influenza vaccination policies for EMTs and paramedics.
- AMA representative Dr. Tan emphasized the need to develop a Summit philosophy regarding the mandatory vaccination of healthcare workers to ensure that this topic receives appropriate attention during the upcoming season.
- Ms. Anita Friedman suggested that declination forms for healthcare workers state that in the event of an influenza outbreak in a facility, the unvaccinated healthcare worker would have a choice of either receiving vaccine or being furloughed.

SESSION IV: Mandatory Vaccination for Persons Working in Healthcare Settings – Ethical and Legal Perspectives *Moderator: Dr. Ray Strikas*

During Session IV, Mr. Ross Silverman provided the Summit with information about the ethics and legal implications of mandatory vaccination for healthcare personnel. Summit participants were given a chance to provide feedback and ask questions after Mr. Silverman's presentation.

Ethics and Legal Implications of Mandatory Vaccination for Healthcare Personnel

Mr. Ross Silverman

Mr. Silverman provided Summit participants with the legal perspective of mandatory influenza vaccination for healthcare workers. He provided the public health and legal rationale for these mandates, presented ethical arguments (including the benefits and burdens of mandates), discussed mandate structure options, and addressed the ways in which pandemic influenza mandates differ from mandates for other vaccines.

From a public health perspective, mandatory seasonal influenza vaccination among healthcare workers is advantageous for several reasons. First, other non-mandatory programs (e.g., educational campaigns) often are unsuccessful. In addition, protecting employees from influenza is prudent, because of the high morbidity, mortality, and costs associated with this infection; vaccination of healthcare workers also helps to protect the health of their patients. Other reasons for implementing mandatory vaccination of healthcare workers include the need to improve institutional safety, decrease employee absenteeism, and increase the demand for vaccine from manufacturers.

In addition to being advantageous from a public health perspective, requiring healthcare workers to receive seasonal influenza vaccination can be rationalized from a bioethical point of view. Healthcare providers assume certain professional duties and obligations as members of healing professions; as part of their core duties, these professionals are expected to be trustworthy, benevolent, and free of self-interest. Collectively, healthcare workers also have a duty to be altruistic, to care for their patients, to promote the health of their patients.

From a legal perspective, mandates for influenza vaccination can be rationalized. State police powers give deference to public health decisions by states, as evidenced by past cases (e.g., *Jacobson v. Massachusetts*). Mandating influenza vaccination among healthcare workers supports the Universal Declaration of Human Rights, which places limitations on individual rights to meet the "just requirements of morality, public order, and general welfare;" vaccine mandates also can be viewed as a component of national security efforts.

Despite the public health, bioethical, and legal rationale for mandatory vaccination, creating and defending such a mandate would likely be burdensome. Healthcare workers subject to a vaccine mandate might perceive it as being a threat to their autonomy, which could result in distrust and disrespect of the government and the workplace. The mandate could also be perceived as being intrusive, coercive, and unjust.

In developing any mandatory vaccination statute or regulation, the right to conscientious objection would need to be acknowledged and addressed in influenza vaccination programs. In past efforts requiring healthcare workers to receive vaccines, exceptions were granted to those with medical contraindications, religious objections, and others who sign an informed declination.

Mandatory vaccination against the novel H1N1 influenza strain would be justified in the face of an epidemic. However, an employee's "right to refuse" would need to be protected, and the vaccine would first need to be approved by FDA as being safe; any investigational or unauthorized administration of such a vaccine would pose constitutional concerns, including concerns associated with fundamental liberty and due process.

Session IV Discussion

- A representative from Novartis posed a question about the rights of those who remain unvaccinated. Are they entitled to remain anonymous? If so, how will facilities become informed about which employees remain susceptible to influenza? According to Mr. Silverman, providing facilities with names of those providers who refuse vaccine is problematic because of individual privacy rights.
- Mr. Silverman was asked to comment on whether a distinction can be made between the invasiveness of a TB skin test and an influenza vaccination. Mr. Silverman replied that although he is unsure about whether the court has made a distinction in these procedures, TB testing would be considered diagnostic, whereas influenza vaccination would be considered a preventive measure.
- Dr. Tan asked about the ethical implications associated with providing priority pandemic vaccine to healthcare providers despite the low seasonal vaccination rates observed for this group as a whole. Dr. Tan suggested that the need to provide healthcare workers with pandemic vaccine could be leveraged to justify the need for a seasonal vaccine mandate. Mr. Silverman commented that having a largely vaccinated healthcare workforce would almost certainly help justify preparedness activities, including H1N1 vaccination campaigns.

SESSION V: Best Practices and Continuity of Care – Ensuring Influenza Vaccination for Patients of Private Healthcare Professionals

Moderator: Dr. Andy Eisenberg

This session of the Summit was dedicated to a discussion of vaccination-related "best practices" among providers with diverse specialties, including obstetrics, family practice, oncology, nursing, physician assistance, and cardiology. Representatives from each of these healthcare fields made presentations and then served as panelists during the Session's discussion period.

The Obstetric Experience: Pregnancy is not a Contraindication to Vaccination

Dr. Scott Roberts

The vaccination of pregnant women against seasonal influenza was discussed by Dr. Scott Roberts with the University of Texas Southwestern Medical Center at Dallas. He began his presentation by emphasizing that according to the American College of Obstetricians and Gynecologists (ACOG), women who are pregnant during the influenza season should be vaccinated. This recommendation, made in 2004, was based on data indicating that any theoretical risk that the vaccine could pose to the woman or infant is far outweighed by its potential benefits. Further, no evidence of perinatal morbidity from maternal vaccination has been documented anywhere in the literature.

Despite ACOG's 2004 recommendation, many obstetricians and gynecologists fail to offer their pregnant patients vaccine. Providers who chose not to administer influenza vaccination did so on the basis of various rationales, including inadequate reimbursement from insurance companies, lack of patient-oriented vaccine information, liability concerns, guideline ambiguity, patient refusal, and concerns about vaccine efficacy; none of the identified primary barriers to vaccination were related to pregnancy.

Becoming vaccinated against seasonal influenza is particularly important among pregnant women. Pregnant women who become infected with the influenza virus have more frequent and longer hospital stays, are at risk for maternal death, and are at increased risk for preterm delivery. During the 1957 pandemic, 20% of all maternal deaths could be attributed to influenza, and during the 1918 pandemic, maternal mortality was an estimated 30%-50% (overall mortality across the population was substantially lower, at 5%).

The physiologic changes that accompany pregnancy (e.g., a mildly compromised immune system, increased heart rate, increased stroke volume, and decreased lung capacity) place pregnant women at increased risk for adverse influenza-related outcomes. Certain subsets of pregnant women are at even higher risk, such as women who are in their second or third trimester when they become ill and women who have chronic high-risk medical conditions, including asthma and diabetes.

A recent study published in the *New England Journal of Medicine* confirms the importance of universal vaccination in all pregnant women, regardless of gestational stage. Data indicate that seasonal influenza is common in neonates and can be transmitted vertically and nosocomially after birth; neonates of mothers who receive influenza vaccination have been shown to be significantly less likely to become infected after birth. Data also demonstrate that infants up to age 24 weeks whose mothers received influenza vaccine are significantly less likely to experience respiratory illness accompanied by fever than infants of mothers who remain unvaccinated.

The Family Practice Experience: To Immunize or Not to Immunize – That is the Question

Dr. Andrew Eisenberg

Dr. Andrew Eisenberg discussed the American Academy of Family Physicians (AAFP) survey on the immunization practices undertaken by family physicians during 2004-2009. The AAFP Immunization Survey, conducted in 2008 as part of a cooperative agreement with CDC, examined a random sample of 2,000 AAFP members; family physicians from all 50 states and the District of Columbia were represented.

Physicians were asked several influenza-vaccine-related questions as part of the 2008 AAFP Immunization Survey. They were asked whether their practice administered influenza vaccine during the 2007-08 influenza season and if so, whether vaccine was left over. Of all physicians surveyed, 91% responded that their offices provided patients with influenza vaccination; of these, about 44% had vaccine left over at the end of the season. Physicians also were asked about plans for the 2008-09 influenza season; specifically, they were asked whether they planned to administer vaccine. Of respondents, 89% planned to administer influenza vaccine. Of the physicians who did not plan to offer their patients vaccine, most cited the ability of their patients to receive vaccine elsewhere as being the primary reason for their decision, followed by concerns about vaccination reimbursement.

The AAFP Immunization Survey collected data regarding physicians' attitudes certain aspects of influenza vaccination. For instance, respondents were asked whether, assuming an adequate supply of vaccine, a universal influenza vaccination recommendation should be made for persons 6 months of age and older; a total of 73% of participating physicians indicated support for universal vaccination. Participating physicians also were asked about "acceptable sites" for the administration of vaccine to children, adolescents, and adults. Survey respondents most frequently "approved" vaccination within physician's offices for persons of all ages, followed by public health clinics, nursing homes (for adults), and hospitals. More respondents found it acceptable for adults to receive vaccine at retail health sites than children and adolescents (62% versus 55%, respectively).

The Oncology Experience: Immunocompromised Persons should be Vaccinated

Dr. Kathleen Sullivan

The vaccination of immunocompromised patients with seasonal influenza vaccine was discussed by Dr. Kathleen Sullivan with the Children's Hospital of Philadelphia. Specifically, Dr. Sullivan discussed a recent study conducted to determine the immune response associated with vaccinating chemotherapy patients with influenza vaccine.

Assessing the immune response of chemotherapy patients to influenza vaccine is important, because influenza disease is more serious in patients who are receiving chemotherapy; these patients also experience prolonged viral shedding, which can place their contacts at greater risk for infection. Existing data on the efficacy of influenza vaccine is limited. For adult patients receiving chemotherapy for lymphoma or for solid tumors, seroconversion rates have been demonstrated to be 20%-60% and 50%-70%, respectively. Among children with solid tumors, 70% seroconversion rates have been observed; rates have been slightly lower for children with lymphoid malignancies and miscellaneous tumors (50% and 60%, respectively).

To better understand the immune response associated with the receipt of influenza vaccine, Children's Hospital of Philadelphia studied three patient populations who had been diagnosed with malignancies and were undergoing treatment: adults with multiple myeloma, adult patients with ovarian cancer, and children diagnosed with ALL and AML. The study demonstrated that seroconversion responses vary widely depending on patient malignancy. For example, for the H1N1 influenza strain, a four-fold increase in titers was observed after vaccination among 70% of adults with myeloma, whereas a similar increase was observed in only about 15% of ovarian cancer patients and 32% of children with ALL or AML. Overall, patients being treated for malignancies did not respond as well to influenza vaccine when compared with healthy controls, although titers to the H1N1 strain among patients with myeloma were higher than those of controls.

For pediatric patients, phase of chemotherapy was associated with immune response. Seroconversion rates in this population varied depending on time of vaccination – rates among patients vaccinated during the Induction Phase approached 70% for the H1N1 strain but dipped down to only about 10% among those vaccinated during Phase III (the phase during which chemotherapy treatment has been stopped). Rates for other influenza vaccine strains were also higher when administered during the Induction Phase versus other treatment phases. Overall, seroconversion rates were substantially lower among pediatric patients receiving chemotherapy at any stage than those observed among healthy controls; seroconversion rates for the H1N1 strain were an exception, as rates were higher among patients in the Induction Phase of chemotherapy than those demonstrated among controls.

In summary, the study conducted by Children's Hospital of Philadelphia demonstrated that oncology patients represent a particular challenge for vaccination programs. Responses to influenza vaccination are poor and have been demonstrated to vary by patient population and by chemotherapy regimen, including phase of treatment.

The Nursing Experience: Advocacy and Counseling

Ms. Nancy Hughes

Representing the American Nurses Association (ANA) (the only full-service professional organization representing the interests of almost 3 million registered nurses in the United States), Ms. Nancy Hughes discussed ANA policy and campaigns designed to increase seasonal influenza vaccination rates.

ANA is committed to advocating for the health of registered nurses, their patients, and their families. Therefore, ANA strongly urges all RNs involved in direct patient care to receive seasonal influenza vaccination each year. In 2006, ANA created a policy on pandemic and seasonal influenza, which defined the nurse's role in relation to patient transmission, outlined non-vaccine control measures, discussed the stable supply and equitable distribution of vaccine, and outlined educational efforts. During the same year, ANA released a policy statement addressing seasonal influenza vaccination for registered

nurses, which defined ANA's position on the vaccination of RNs by supporting aggressive and comprehensive influenza vaccination programs that aim for 100% vaccination rates. The policy describes the need for an "opt out" for RNs upon the completion of an informed declination form, outlines the need for vaccine education, and emphasizes that vaccine should be made available free of charge and accessible to RNs. The policy is consistent with legal rights, including those defined under labor law.

In addition to creating policy regarding influenza vaccination, ANA has been involved in several vaccine campaigns, including the 2005 "Everyone Deserves a Shot at Fighting Flu" campaign and the "Best Practices in Seasonal Influenza Vaccination" campaign, which has been conducted every season since 2006-07 to identify successful immunization programs and provide tools for effective implementation.

The Physician Assistant Experience: Policy, Practice, and Promotion

Mr. Bob McNellis

Mr. Bob McNellis began his presentation on the role of physician assistants (PAs) in the administration of influenza vaccine by providing the Summit with background information about the American Academy of Physician Assistants (AAPA), a group formed to ensure the professional growth, personal excellence, and recognition of physician assistants and to support them in their provision of quality, accessible, cost-effective healthcare. Mr. McNellis also provided general facts about PAs, informing the group that more than 85,000 PAs are eligible to practice in the United States. In 2008, PAs reported engaging in more than 257 million patient visits and providing more than 332 million prescriptions and recommendations to patients.

PAs can be found working across many specialties, including family medicine, surgery, pediatrics, emergency medicine, and internal medicine. According to the 2008 AAPA Physician Assistant Census Survey, these professionals work in a variety of settings, including single-specialty physicians' offices, urgent care centers, hospitals, solo physician practices, and multi-specialty physician groups.

AAPA recognizes the importance of child and adult immunization programs and the need to educate individual PAs and the public about these programs. Therefore, in 1994, AAPA created an "Immunizations in Children and Adults" policy. Amended in 2006, this policy states that PAs should be aware of current medical guidelines for the immunization of children and adults. In addition, it emphasizes that a) PAs should promote public information campaigns to increase the awareness of the importance of immunizations and to allay fear and doubts about potential vaccine-related side effects and b) PAs should be immunized against vaccine-preventable diseases themselves.

Recent data indicate that overall, only 56% of PAs report providing vaccine or ensuring that their patients have received the recommended vaccinations. This percentage varies by specialty, with 94% of PAs who work in pediatric practices reporting this behavior, and only 18% of orthopedic specialists reporting administering vaccine or discussing the need for immunization with patients.

Other types of data also have been collected from PAs to determine behaviors associated with vaccinations. For instance, data demonstrate that 67% of PAs reported receiving an influenza vaccine themselves during the 2008-09 influenza season and that most PAs had not received any training regarding a potential influenza pandemic, regardless of their professional specialty. Only 22% of PAs report having been trained to deal with an influenza pandemic, and 3% report having responded to an influenza pandemic in the past.

In partnership with several organizations and efforts aimed at increasing influenza vaccine awareness and coverage (e.g., the NIVS), AAPA has begun to promote influenza vaccination in several ways. The topic of influenza vaccine is now being featured in *PA Professional* (a monthly news magazine), on an AAPA immunization webpage, through a monthly electronic news blast to members, via a daily e-mail, and through various social media outlets (e.g., Facebook, Twitter, and YouTube).

The Cardiology Experience: Influenza Vaccination and Cardiovascular Disease

Dr. Clyde Yancey

Influenza vaccination among patients with cardiovascular disease (CVD) was discussed by cardiologist Clyde Yancey, Medical Director of the Baylor University Heart and Vascular Institute. He first provided the Summit with a rationale for the importance of vaccinating this population against seasonal influenza, noting that annual vaccination prevents cardiovascular-associated morbidity and mortality (from all causes) among patients with CVD. Despite the proven benefits of vaccinating CVD patients against influenza, vaccination levels in these patients remain lower than national goals; in fact, only half of all cardiologists report stocking the vaccine in their offices. Of providers who report vaccinating their CVD patients, data demonstrate that practitioners disparately administer vaccine to different subpopulations of CVD patients depending on age, gender, and race/ethnicity.

Several studies have been conducted to elucidate the benefits associated with vaccinating cardiology patients against seasonal influenza. In one study involving persons with acute coronary syndromes, 301 patients were randomly assigned either to receive influenza vaccine or to receive no vaccine. At 1 year, the relative risk for composite endpoint of cardiovascular-associated death, nonfatal myocardial infarction, or severe ischemia was 0.59 among the unvaccinated group, whereas among vaccinated patients, the relative risk of cardiovascular-associated mortality was 0.25. In other observational, case-control studies, influenza vaccination has been shown to be associated with a decrease in hospitalizations and for patients at risk for stroke, vaccination was associated with decreased risk for this health event. A UK study, which followed 39,000 CVD patients who received seasonal influenza vaccination, demonstrated no increased risk of myocardial infarction at 90 day follow-up; in fact, rates of both myocardial infarction and stroke were shown to be lower at 28 days post-vaccine than rates among patients who had not received the vaccine.

These data led the American Heart Association (AHA) and the American College of Cardiology (ACC) to recommend that the 12 million persons with CVD in the United States receive annual influenza vaccination. Despite this recommendation, however, several barriers to vaccination among CVD patients exist. Currently, vaccine is available in only about 50% of all cardiology offices, and certain groups of CVD patients are less likely to be offered vaccine than other groups; studies demonstrate that Hispanic CVD patients and CVD patients in younger age groups (i.e., age 18-49 years) are offered seasonal influenza vaccine at significantly lower rates than their counterparts in other racial/ethnic and age groups.

Session V Discussion

Session V Panelists and Summit participants engaged in discussion after formal presentations were made. The following bulleted statements reflect this exchange.

Obstetrics

- Dr. Eisenberg asked Dr. Roberts a question about why pregnant patients don't typically ask to be vaccinated by their obstetricians. Dr. Roberts explained that OBs traditionally have been less concerned about women's preventive health and more about obstetrics. However, participation by these specialists in vaccination efforts would help move the nation towards *Healthy People 2010* goals.
- Dr. Roberts commented about the OB perspective regarding offering influenza vaccines to pregnant women, emphasizing that many OBs are so concerned with liability issues that they chose not to offer vaccine to their patients.

Vaccination in a non-Primary-Care Setting

- A representative from the American Pharmacists Association commented on the importance of capturing vaccination information in patient records regardless of where vaccine is received. He asked panelists whether they have reached outside of their professional organizations to collaborate on this issue. Dr. Yancey remarked that the AHA has partnered with other organizations to advocate for greater vaccination coverage by distributing vaccination messages. AAFP representative Dr. Eisenberg clarified that a patient's "medical home" should be patient-centered, regardless of where care is received. The concept of a medical home must be expanded to ensure that vaccination goals are met.
- DoD representative Dr. Hachey noted that within DoD, service members are required to become vaccinated each year. Reservists are allowed to get vaccinated at places outside of the DoD's treatment facilities, but these personnel must prove that they've been vaccinated elsewhere. He asked Dr. Eisenberg whether any initiative has been undertaken to encourage patients to notify primary care providers that they have received vaccine outside of their medical homes. Dr. Eisenberg concurred that there is a need to share information and communicate about the receipt of influenza vaccine. Recent data indicate that 50% of patients

- believe it is acceptable for patients to receive vaccine outside of physician's offices. Although it may be easier for patients to receive vaccine at alternative sites (e.g., retail settings), information must be shared.
- Dr. Tan asked about whether referring patients to other providers for influenza vaccination increases the risk for missed vaccination opportunities. Several panelists discussed the association between referrals and missed vaccine opportunities; Dr. Eisenberg suggested that when patients are referred elsewhere, many "fall out," or fail to follow through. Mr. McNellis commented that often times, healthcare providers provide referrals because better resources are available elsewhere in the community.
 - Dr. Eisenberg emphasized that many patients remain unaware that they fall into the "high risk" influenza category (e.g., diabetics and persons with CVD) because they have yet to be diagnosed. These patients likely would fail to seek vaccination unless a universal recommendation were established.

SESSION VI: Influenza Vaccine Communication: Evolution and Adaption
Moderator: Dr. Kristine Sheedy

Influenza vaccine-related communication served as the focus of Session VI. Representatives from CDC and other organizations involved in crafting influenza vaccine messages presented recent approaches to vaccine communication and engaged in a panel session, during which time additional discussion involving Summit participants took place.

News, Views, and Media Cues: Current Influenza Vaccine Communications
Dr. Michael Greenwell

Dr. Mike Greenwell with Danya, Inc. updated the Summit about media trends and the relationship between these trends and influenza vaccine messaging. He began his presentation by emphasizing that the public is moving away from print media as a source of news and information. 2008 was the worst on record for the U.S. newspaper industry – total revenues declined 16.6%, 5,900 full-time print jobs were eliminated, and newspaper stock prices dropped 83%. Despite this decline, readership of local daily newspapers has only dropped slightly in the past few years, perhaps because web-based newspapers have not penetrated most smaller communities around the country.

Despite the overall trend away from print media, according to a recent poll, many Americans (40%) continue to rely on television, radio, and newspapers as their primary source for health-related information. Other media trends include a shift away from individual journalists towards blogs, online news destinations, and cable personalities. National websites and aggregators (e.g., Google) are making inroads in attracting local advertising, which ensures a steady source of funding; these websites are not only being accessed via computer, but through mobile phones. More than 40 million Americans use the mobile web, and advertisers are actively pursuing this new market.

Understanding recent trends in media facilitates the creation and delivery of effective influenza vaccine campaigns. For instance, because community papers are maintaining their readership better than other newspapers that target bigger markets, health communicators should consider working with community papers to publish influenza-related articles. In addition, because of the popularity of Twitter and other social networking sites, these media outlets can be leveraged to deliver influenza-vaccine messages to a targeted audience. Health communicators can post Twitter information on an organization's website to enable the news media to follow these communications, or use web-based blogs to attract the attention of the media and other specific segments of the population, including new mothers. Other communications options that would likely be more effective given recent media trends include a presence on local morning shows, community affairs programs, and local cable channels.

Media-based health communications have been demonstrated to be instrumental in eliciting behavioral change; in one study, more than one third of respondents reported speaking with a doctor about a medical condition as the result of a media report, and more than half said they changed a health-related behavior as a result of such a report. To be effective, health messages should be crafted to include several key components. Messages should be easy to say and easy to remember, contain a single overriding communications objective (SOCO), remain short and concise, speak to shared values, highlight what is at stake, use reasonable language, use irony and quotable language, be delivered in a conversational tone, and contain supportive facts, statistics, examples, and anecdotes. Further, effective health messages should evoke pictures for target audiences and frame the particular health problem and the proposed solution in terms of institutional, rather than individual, responsibility.

Persons crafting messages about influenza vaccine should remain aware of the aforementioned components and ensure that all related communications efforts address the following questions:

- Who is the audience?
- If the audience only remembers one thing, what should that be?
- What action do you want the audience to take?
- Of what are you certain?

Wikis, Widgets, and Web: Emerging Influenza Communications

Ms. Holli Seitz

CDC's Ms. Holli Seitz discussed the role of interactive media in promoting seasonal influenza vaccination. She began by providing statistics regarding the use of social networking and interactive media in the United States. Recent research indicates that 22% of Americans report using social networking sites, and 85% use a mobile phone. In addition, 15-30 million blogs have been authored by U.S. internet users, 10 billion text messages are sent from American cell phones each month, 17 million Americans have downloaded a podcast at least once, and 200,000 e-cards are sent each month.

To better leverage emerging forms of electronic communication, CDC has established an “eHealth” goal of making CDC content, tools, and services available when, where, and how users want them. The agency is making progress towards reaching this goal by maintaining and continually updating the CDC.gov website. In addition, “graphical buttons” – or graphical “links” to specific electronic content -- have been added to more than 100 web pages belonging to organizations with similar missions (such as health departments and other public health partners). CDC has also leveraged other internet-based tools to share health-related information, including creating a presence on social networking sites (e.g., MySpace and Twitter), creating a “webinar” for certain groups of blog writers (e.g., “Mommy Bloggers” and “Healthcare Bloggers), making “health e-cards” available via CDC’s internet site, creating “widgets” (mini-applications on CDC’s web pages that allow users to interact), and syndicating their internet-based health content to enable other organizations to place the information on their own sites.

In response to the recent U.S. trend towards cell phone-based communications, CDC is now using mobile phone applications to disseminate its web-based content. All internet-based content is now available to cell phone users through the m.cdc.gov site.

Additional strategies have been employed by CDC to disseminate timely influenza-related information. For instance, the agency is posting online videos to spread vaccination messages; CDC has uploaded videos sharing personal stories of families affected by influenza to the popular YouTube internet site. To target children ages 8-12 years with influenza-vaccine and other health-related messages, CDC has created a virtual world called “Whyville.” The goal of this initiative is to promote science and health-related knowledge among this group, including an understanding of the importance of preventive measures (e.g., handwashing and vaccination) in preventing seasonal influenza.

Key to the success of CDC’s electronic communications strategies are the agency’s partnerships. CDC is currently partnering with several organizations to promote influenza vaccination, including WebMD and Health Central, both of which provide trustworthy health-related information to visitors.

Faces of Influenza Campaign

Ms. Susan Davis and Ms. Deborah Brown

The American Lung Association’s (ALA’s) Faces of Influenza campaign was outlined by Ms. Susan Davis (ALA’s Chief Development Officer) and Ms. Deborah Brown (Vice President of Community Outreach and acting CEO for the American Lung Association of the Mid-Atlantic). Launched in collaboration with Sanofi Pasteur in 2006, ALA’s Faces of Influenza campaign was created to “put a face” on influenza, or to help Americans relate to those who have been negatively impacted by the disease and to prompt them to seek annual influenza vaccination. Specifically, through the campaign, ALA and Sanofi Pasteur aim to help consumers see themselves and loved ones as being included in CDC’s recommendations for immunization, understand the seriousness of influenza, and recognize that vaccine can be received at any time during the influenza season.

Recognizing that mothers are often the “healthcare decision-makers” for their families, the Faces of Influenza campaign is focusing on reaching mothers with influenza-vaccine messages. Through this initiative, multiple activities have been conducted to reach this specific population of women at both local and national levels.

Through the Faces of Influenza campaign, ALA acknowledges the value of diverse and numerous partnerships in efforts to increase vaccination coverage rates in the United States. Working together, partner organizations can successfully educate communities about the importance of influenza vaccination and ensure the delivery of consistent messages. Local partnerships are particularly key to the grassroots, community-based efforts being undertaken as part of the Faces of Influenza campaign, which often require identification of hard-to-reach audiences, an understanding of the local influenza-related history and infrastructure, and knowledge of community-based immunization access points.

Along with developing partnerships, ALA works to align closely with its stakeholders, who play an important role in ensuring the success of ALA’s influenza vaccine initiatives. ALA aims to set achievable goals and define working relationships with stakeholders, assess programming needs and compliment existing stakeholder efforts, and maintains an ongoing dialogue with these organizations.

Part of any successful health campaign is a post-initiative evaluation of successes and challenges. ALA is committed to this type of follow-up and recognizes the need to assess and apply lessons learned on an ongoing basis, determine successes and failures, plan for sustainability, and explore ways to enhance efforts with existing and new relationships.

Session VI Discussion

The following bulleted statements reflect the discussion that took place during Session VI of the 2009 NIVS.

Faces of Influenza Campaign

- Dr. Strikas asked whether ALA used local celebrities to promote vaccine in their local communities. He was informed that ALA did indeed use local “faces” in their campaigns when possible.

Influenza Vaccine Communication Tools

- Ms. Seitz was asked to clarify how the concept of content syndication is applied to CDC’s internet-based material. Ms. Seitz explained that specific codes can be added to CDC’s web content to enable other organizations to import the content into their own sites.

- One Summit participant inquired about how to learn more about web 2.0. Ms. Seitz suggested that persons interested in web 2.0 visit www.technolati.com, which provides in-depth information about blogging and social marketing.

Role of the Media in Vaccination Messages

- Summit participant Alicia Snider asked Dr. Greenwell about whether CDC has addressed recent media coverage of celebrities who are speaking out against vaccination. According to Dr. Greenwell, reacting to this type of media takes much planning and fact-checking and must be done carefully. Other Summit participants also commented, noting that vaccine experts must avoid engaging in any type of vaccination “debate” with celebrities or television personalities; instead, experts should focus on providing the public with the facts.

CDC’s Influenza Vaccination Communication Strategies

- A Summit attendee asked how CDC plans to communicate with high-school-aged teens. Particularly, is the agency prepared to deliver messages to this group about the importance of social distancing in preventing influenza transmission? Dr. Sheedy responded that CDC has not yet targeted older teens with influenza vaccine messages, but that the agency will likely use alternative forms of communication (mobile phones and social networking sites) to engage this population.
- Dr. Greenwell was asked to discuss the nomenclature being used to refer to the novel H1N1 influenza pandemic; the name “H1N1 influenza” is likely to cause confusion, because H1N1 can also occur as a seasonal influenza virus. Dr. Greenwell agreed that the nomenclature must be simplified; audience research must be conducted to determine the best name for this novel influenza virus.
- Dr. Tan asked panelists to consider the single most important message regarding seasonal influenza that must be delivered this season. CDC representatives commented that for the upcoming season, the importance of vaccination against seasonal influenza (rather than pandemic influenza) throughout the entire season will be the focus of national messaging efforts.

SESSION VII: Increasing Vaccine Coverage in Persons 18 Years and Younger *Moderator: Dr. Matthew Daley*

The purpose of Session VII was to update the Summit and stimulate discussion about ways to increase vaccination coverage rates among children and teens. Several examples of successful initiatives to reach this goal were provided, along with information about the role of school nurses, parents, and other professionals in the vaccination of children.

New Jersey Day Care Center Experience

Ms. Angela Sorrells-Washington

Ms. Angela Sorrells-Washington with the New Jersey Department of Health and Senior Services provided an overview of New Jersey's new influenza vaccine mandate for children attending day care centers. She described New Jersey's rule-making process, provided detailed information about the vaccination mandate, discussed actions taken within New Jersey's Vaccine Preventable Disease (VPD) Program, provided vaccine coverage data, and outlined lessons learned.

On January 26, 2007, the New Jersey Department of Health and Senior Services held a public hearing on a proposed amendment requiring that children 6 months through 59 months of age attending any licensed child care center or licensed preschool facility receive at least one dose of influenza vaccine at some point from September through December of each year. A total of 17 persons made verbal comments at the public hearing; three of these people were supporters of the proposed mandate, whereas 14 opposed it. Additional comments were received during the 60-day public comment period, an overwhelming majority of which expressed opposition to the mandate because of concerns about the thimerosal contained within the influenza vaccine. Additional comments addressed the need for conscientious, philosophical, and moral exemptions from the mandate.

New Jersey's VPD Program engaged in several activities to prepare for implementation of the state mandate. More than 50 in-services were held throughout the state to ensure that school nurses, parent organizations, and daycare staff were knowledgeable about the proposed requirement; in addition, extensive Q&As were developed and posted on the VPD website. The health department engaged professional organizations to provide support in these efforts, including the New Jersey Department of Education. Recognizing the need for a religious exemption, the VPD Program also helped craft New Jersey's Religious Exemption Rule, which currently states, "A child shall be exempted from mandatory immunization...in a written statement submitted to the school, preschool, or child care center...explaining how the administration of immunizing agents conflicts with the pupil's exercise of bona fide religious tenets or practices."

In preparation for vaccinating all of New Jersey's children attending day care centers, the New Jersey Department of Health and Senior Services ordered more than 300,000 doses of vaccine to be administered before January 1, 2009; VFC providers ordered an additional 240,000 doses. Despite these measures, daycare centers and preschools requested that they be given more time to secure parental consent and compliance. In addition, parents began to report shortages of influenza vaccine, particularly doses that were thimerosal-free. Representatives from several state agencies collaborated to address this issue, ultimately deciding to extend the deadline to January 31, 2009. As the deadline approached, however, it was clear that these many children attending childcare facilities had not yet been vaccinated. As a result, high-level officials, health officers, and federally qualified health centers joined forces to ensure that these children were in compliance with the New Jersey mandate. Local health departments scheduled more than 20 clinics

around the state, ordered more influenza vaccine, held Saturday vaccination clinics, and administered privately purchased vaccine.

New Jersey's VPD Program has gathered data to track progress made towards meeting the influenza mandate. A survey revealed that lack of parental awareness was the primary barrier to vaccination of their children, and that only 25% of participating schools met the January 31st deadline. All but one school reported that their vaccination records contained the compliance date.

To evaluate the implementation and effectiveness of the New Jersey influenza vaccine mandate, the New Jersey Department of Health and Senior Services plans to administer an influenza requirement implementation survey to a representative, random sample of schools. Ideally, this survey will enable VPD staff to assess requirement compliance and to stratify compliance by setting (e.g., urban vs. non-urban, public vs. private school, and large vs. small capacity). The VPD Program recognizes the need for additional considerations associated with the new mandate, including the health impact on the community, use of the religious exemption, the inclusion of other vaccines (e.g., MMR and polio) into the mandate, and disease surveillance for this population of children.

The New Jersey mandate is in place for the 2009-10 influenza season. Therefore, all students attending licensed day care facilities in the state must have proof of vaccination by December 31; after this date, unvaccinated children will be excluded from school for the duration of the influenza season (through March 31st) or until they receive at least one dose of vaccine. No additional grace period will be allowed for the upcoming season; even students enrolling after December 31st will be required to have proof of vaccination before attending.

More than 350,000 doses of vaccine have been ordered by the New Jersey VFC program in preparation for the upcoming season. In addition, plans are in place to expand the number of locations that will have vaccine available to ensure that students and their parents are able to comply with the influenza vaccine mandate.

Vaccination of School-aged Children

Dr. Matthew Daley

The logistics of universal childhood influenza vaccination were discussed by Dr. Matthew Daley, Associate Professor of Pediatrics at the University of Colorado, Denver. He first provided a timeline of the expansion of vaccination recommendations by ACIP and discussed the number of children that are now included within these recommendations. With the ACIP recommendation of universal vaccination for all children aged 6 months to 18 years beginning in the 2008-09 season, approximately 74 million U.S. children are now encouraged to receive influenza vaccine each year. However, less than one third of these recommended children report receiving vaccine. Achieving a 50% coverage rate among children in this age group would require a 300% increase in the number of children vaccinated.

Ensuring that children aged 6 months to 18 years receive annual influenza vaccine requires the implementation of new strategies for influenza vaccine delivery in the primary-care setting. In addition, new vaccination settings such as schools will need to be leveraged; better financial incentives for influenza vaccination must be offered; and vaccination efforts must remain broad, community-based, and collaborative.

Data were collected in 2002 regarding the number of children receiving influenza vaccination within the primary-care setting. Regardless of age, most children are vaccinated within primary care clinics. Younger children, however, are more likely to receive vaccine from pediatricians, whereas older teens tend to visit family practitioners for their seasonal influenza vaccination. Data also demonstrate that younger children (i.e., those aged ≤ 5 years) are more likely to visit doctors for preventive care at least once during the influenza season. About 70% of infants aged ≤ 12 months visit a primary-care provider at least twice during this period, whereas less than 25% of 18-year-olds do so.

Research has shown that the time required to administer the influenza vaccine in the primary-care setting varies by clinic location. Although the actual time required for vaccination is minimal for providers in both urban and suburban areas (2.3 and 1.4 minutes, respectively), wait time is substantially greater for patients receiving care in urban facilities (21.8 versus 9.4 minutes, respectively).

These data help inform decisions to expand the capacity of primary-care practices in the provision of seasonal influenza vaccination to U.S. children. These clinics could potentially add visits during regular hours, extend the vaccination season, and dedicate influenza vaccination clinics that are held outside of regular hours. However, providing additional vaccinations during the regular work day can impair clinic flow and tie-up rooms needed for other patients; in addition, because most school-aged children do not visit providers during the influenza season, extending the vaccination season might not significantly impact vaccination rates in this population. The option to increase the number of vaccination clinics held outside of regular hours also can be problematic. Although these clinics are advantageous in some ways (e.g., by increasing efficiency in the vaccine administration process, enabling linkage to provider-initiated reminder calls and letters, and ensuring less interference with other office functions), weekend or evening vaccination clinics require providers to pay overtime rates, pay increased administrative costs, and plan well in advance to ensure adequate supplies and staffing levels.

Only a few studies have been undertaken to determine the most efficient influenza vaccination strategies within pediatric practices. However, studies involving adult vaccines demonstrate that although influenza vaccine clinics are more efficient, documentation of the immunization was poorer than that occurring in the office setting. These studies also indicate that although it has been assumed that vaccination clinics are associated with lower administrative costs, the administration costs for office-based and vaccine-clinic based immunizations are comparable.

Best practices and lessons learned from school-based vaccination initiatives can help inform the expansion of influenza vaccination into the school setting. In Knox County, Tennessee, a campaign recently was undertaken to vaccinate the entire public school system against influenza. A total of 76 schools participated, representing an enrollment of 53,420 students. As part of this campaign, which resulted in an overall immunization rate of 45%, students were provided intranasal vaccine free of charge; no billing was done. Despite the high vaccine coverage rate achieved with the Knox County campaign, the initiative proved to be expensive and disruptive. The effort was time consuming for both health department staff (4,200 person hours) and school nursing staff (2,700 person hours), and it resulted in the temporary closure of other vaccine clinics aimed at adults and indigents.

In Denver, a school-based influenza immunization project revealed additional challenges. School nurses reported being “spread thin” with competing priorities, and school administrators were hesitant to support the project because of the perceived high costs and less tangible benefits. Billing also proved problematic, as difficulties were encountered when dealing with contracts, managed care plans, and denials.

Additional data has been gathered from other school-based vaccination initiatives. A middle-school-based hepatitis B vaccination program resulted in an 85% rate of completion of a 3-dose series; vaccination was billed to private insurance companies, which proved challenging because of the amount of staff time required. A national survey revealed that most school-based vaccination initiatives (62%) do not involve the billing of private insurance companies.

When considering alternative settings such as schools for childhood influenza vaccination programs, the need to maintain consistent, up-to-date medical records and documentation of vaccination must be addressed. Currently, only about 45% of persons who receive influenza vaccine do so in a physician’s office; others receive vaccine at the workplace, hospitals, health departments, clinics, stores, and other non-traditional settings. The “scattering” of patients’ medical records resulting from this expanded medical home has been problematic for primary-care providers. Providers often remain unaware of whether individual patients have been vaccinated, and therefore cannot predict the number of doses needed for their offices during the influenza season. In addition, when patients receive vaccination away from the traditional medical home, physicians are unable to adequately assess vaccination coverage rates within their practices; this lack of knowledge complicates any effort to improve vaccination rates, including the mailing of patient reminders.

In summary, many barriers are associated with efforts to achieve universal childhood vaccination for influenza. Primary-care providers often have competing priorities, limited vaccination capacity, and limited financial incentive to provide vaccine. These barriers could possibly be overcome by encouraging physicians to hold after-hours vaccination clinics and order adequate amounts of vaccine at the start of the season; insurance companies could also work to improve reimbursement for vaccine administration.

Vaccination in the school setting is also problematic, as this type of effort requires parental consent, poses time-consuming billing-related challenges, and requires substantial resources and infrastructure. However, these challenges could be overcome by systematically obtaining parental consent upon school registration, engaging in centralized billing, and engaging community immunizers.

The Role of School Nurses in Influenza Vaccination

Ms. Lynda Boyer-Chu

The role of schools and school nurses in the delivery of influenza vaccine was discussed by Ms. Lynda Boyer-Chu on behalf of the National Association of School Nurses (NASN). She outlined the benefits and opportunities associated with school-based vaccination, barriers to vaccination, and the role of school nurses; she also discussed the types of activities that can be undertaken now, given current resources and infrastructure.

Vaccinating children in the school setting is advantageous. Schools provide access to 97% of school-aged children during the influenza season and are organized in an age-based infrastructure, which facilitates efforts to deliver vaccine to specific age groups. In addition, schools allow some access to parents and other family members, which may create additional vaccination opportunities.

Although delivering influenza vaccine in the school setting can be advantageous, several barriers to school-based vaccination exist. Resources often fall short, as many schools have no mandates regarding pupil-to-school nurse ratio and provide little or no funding for prevention activities; schools in under-served areas often have limited partnership opportunities, which further limits access to needed resources. Other barriers to school-based vaccination programs include parental consent (which is paper intensive), lack of billing mechanisms, lack of availability of and access to the vaccine registry, school staff resistance, and cultural and language barriers.

Ideally, school nurses would play a critical role in the delivery of influenza vaccine to children in the school setting. However, most school nurses are overwhelmed with providing a wide variety of services to their students, parents, and communities. Nurses can be responsible for providing health, nutrition, and counseling services; ensuring a healthy school environment; promoting health among staff members; becoming involved in health issues affecting families and communities; and delivering health and physical education to students. Nurses providing influenza immunizations would be responsible not only for these activities, but assessing student eligibility for vaccines; administering the vaccine; coordinating with the local health department and registry; educating staff members, students, and parents about influenza vaccine; and collaborating with medical associations, hospitals, and parent-teacher associations.

Putting several measures into place before initiating a school vaccination program could be helpful in addressing some of the associated barriers and relieving the burden that such a program can place on school nurses. First, sustained sources of stable funding must be

tapped to ensure that sufficient doses of vaccine can be offered to students. In addition, linking vaccination to “back to school” activities could help streamline the process, and ensuring a workable school-nurse to student ratio of 1:750 would help reduce workload for these professionals. Other measures to be considered include developing a paperless consent process, ensuring registry accessibility, and implementing school-based vaccine mandates.

Even without these additional measures, many steps can be taken to facilitate vaccination within schools using existing resources and infrastructure. For instance, school staff, teachers, parents, and the community can be better educated about influenza vaccine, and vaccination promotion methods (e.g., those involving school bulletins and newspapers, e-mail blasts, child-friendly science-based websites, and peer-to-peer programs) can be better leveraged.

Speaking in Harmony: Consistent Messages for Parents and Professionals

Dr. Carol Baker

Dr. Carol Baker, representing NFID’s Childhood Influenza Immunization Coalition (CIIC), discussed the Coalition’s approach to delivering consistent influenza vaccine messages to parents and professionals. She first outlined CIIC’s mission, which is to protect infants, children, and adolescents from influenza by communicating with “one strong voice” the need to make influenza immunization a national priority.

In collaboration with 32 organizations, CIIC is working to deliver effective influenza vaccine messages by building on a strong foundation, involving key stakeholders, providing channels for communication, and reinforcing national milestones and announcements. More specifically, CIIC members work to reach consensus on influenza-vaccine-related topics, develop messages and educational materials, adapt messages and materials to target audiences, and distribute vaccine-related information through several channels.

The Coalition also aims to increase the retention of their vaccination messages by the public by ensuring repeated exposure to consistent messages and works to inform their key messages with market research. Each year, focus groups are formed, healthcare providers are interviewed, and national surveys are conducted to provide deeper insight into the factors and triggers that motivate or inhibit behavior. The data gathered as a result of these activities help identify the optimal communication messages for integration into CIIC’s activities. For the 2009-10 season, CIIC is working to tailor and deliver several messages, including the need to differentiate novel H1N1 from seasonal influenza, combat common vaccine misconceptions, implement the universal pediatric influenza vaccination recommendation, vaccinate all children and reduce missed vaccination opportunities, affirm vaccine safety and efficacy, and elucidate vaccine availability.

ACIP’s Expanded Influenza Vaccination Recommendations

Dr. Paul Etkind

The implementation of ACIP's expanded influenza vaccination recommendations was discussed by NACCHO representative Dr. Paul Etkind. He briefly outlined a NACCHO-sponsored, collaborative meeting held in July 2008 to discuss the development of a national strategy regarding the implementation of ACIP's expanded recommendations.

At this meeting, a broad range of stakeholders worked together to identify coordinated next steps for implementing universal influenza vaccination recommendations. Meeting attendees discussed five primary topics: a) financing, policy, and legislation; b) public and provider education; c) industry accountability and product control; d) applied research; and e) building and supporting the capacity for action.

As a result of in-depth discussions, several "top concerns" were identified by participants as needing attention, including schools as vaccination settings, health-care issues (including insurance reimbursement), vaccine data, vaccine supply, and infrastructure. These concerns were further examined, and key issues, solutions, and concerns for each topic were identified. Regarding vaccinating in the school setting, participants noted the need to identify and disseminate best practices to give school systems ideas on how to implement and sustain school-based vaccination programs. The key solution provided was creating a centralized database of best practices and peer-to-peer exchange mechanisms. Specific concerns included the need to address a spectrum of issues related to logistics and communications with parents, schools, administrators; consent forms; sustained funding; and working with mass vaccinators.

Meeting participants defined the key issue associated with health care as being the need to expand access points for vaccine. The proposed key solution was to target groups identified to accomplish such an expansion, such as mass vaccinators, community partners, and pharmacists. Key health-care-related concerns included public misconceptions, missed opportunities, physician buy-in of vaccination outside of the medical home, insurance reimbursement, insurance barriers to reimbursement, improving access, and safety/liability concerns.

Regarding vaccine supply, distribution, and financing, meeting participants identified the key issue as being the need for improved communications between manufacturers and public health experts regarding supply and distribution challenges. Given this issue, key concerns include eliminating insurance/reimbursement barriers and improving communications between payers and public health entities.

Session VII Discussion

The presentations made during Session VII were followed by a discussion session that facilitated the exchange of ideas between session panelists and Summit participants. The following statements summarize this discussion.

School-based Vaccination Mandates

- Dr. Tan commented that states that are prepared to vaccinate children against seasonal influenza, such as New Jersey, will be prepared to protect this population against the novel H1N1 virus.
- Dr. Steve Pellito asked Ms. Sorrells for additional information regarding the types of baseline data collected by New Jersey's VPD Program as part of the new influenza vaccine mandate. Ms. Sorrells informed the group that the New Jersey health department requires the reporting of influenza-like illnesses, but not influenza itself. However, with the emergence of H1N1, more reporting is taking place; the New Jersey health department is working closely with CDC to ensure that samples are verified.
- One Summit participant, whose family was affected by the New Jersey school mandate regarding influenza vaccine, noted that communication about the requirement was a bit too passive. It was communicated verbally and did not emphasize the rationale behind the mandate. This participant also suggested that local newspapers be leveraged to communicate information about new mandates. According to Ms. Sorrells, her department is considering placing small ads and articles in local papers to help educate readers about immunization mandates. In addition, the health department has already compiled a letter and provided it to the New Jersey Department of Education for distribution in the school setting.
- A representative from Novartis asked the Panel to consider whether implementing mandatory influenza vaccination for pre-school children will result in higher parental acceptance of mandates for older children. Ms. Sorrells responded that hopefully, a pre-school recommendation will benefit children of all ages; there is evidence with hepatitis B vaccination that as vaccinees age, their siblings are vaccinated by their parents proactively.
- The Summit was informed that the State of Texas has a mandate for middle school students to receive several vaccines before school entry; this model should be used to approach influenza mandates. Ideally, within the next 5 years, parents will view influenza vaccination as being just as important as protecting their children against meningitis and other vaccine-preventable diseases.
- It was suggested that because many states have mandates requiring students to receive physical exams before starting school, encouraging schools to align this activity with the influenza season would create additional vaccination opportunities.

School-based Vaccination Programs

- A representative from MedImmune asked Dr. Boyer-Chu to clarify her request for needle-free vaccines. He emphasized that FluMist has been available through MedImmune since 2003 and spoke about the importance of avoiding the word "shot" when referring to influenza vaccination; vaccination now is available in two forms – intranasal and intramuscular. This representative also stressed that many school-based vaccine programs have achieved high vaccination rates using intranasal vaccine.
- Dr. Katherine Harris with RAND Corporation shared her past experience with creating school-based vaccine programs. Sanofi Pasteur asked RAND to help

create a school-based vaccination framework, which revealed that many of the barriers to vaccination in this setting were associated with parental consent laws. Therefore, RAND made two recommendations. The first is the need to develop a model state statute to modernize parental consent laws, and the second is to find a means of populating vaccine registries with school enrollment data. RAND also recognized the need to obtain more buy-in from adolescent health experts and to add vaccination to a list of routine activities performed by school nurses.

- A representative from Kaiser Permanente of Northern California shared Kaiser's experience with vaccinating children. During the 2009-09 season, Kaiser Permanente held mass influenza clinics each Saturday in October and November to meet the vaccination needs of the children covered in ACIP's expanded vaccine recommendation. These clinics proved to be very successful, and patient demand for vaccine at these clinics increased over time; not only were children vaccinated, but their parents and other family members.
- Dr. Daley commented on the Kaiser experience, noting that most small practices do not have the infrastructure in place to set up large-scale vaccination clinics. Dr. Daley asked whether Kaiser Permanente discouraged children from obtaining vaccine during regular clinic hours. He was informed that member patients were provided with information about the vaccination clinics and given a choice about when and where to receive vaccine.
- A representative from a small community immunizer informed the Summit that his company has conducted pediatric influenza vaccination programs for offices that choose not to administer vaccine. This program involves mailing out cards to patients to inform them about the need for vaccine and the dates of upcoming vaccination clinics. Vaccination is provided for patients paying cash; no insurance is billed. Response rates have been high using this strategy.
- Dr. Daley concurred that a cash-based program for influenza vaccination is appealing, but this type of program can create financial barriers for families.
- A representative from the Chicago Department of Health commented on school-based vaccination programs, emphasizing the need to involve school nurses at the early stages in any such effort. School nurses are key players in this type of vaccination initiative.
- Dr. Eisenberg shared an anecdote regarding school-based vaccination programs, noting that in his rural community, vaccine was administered free of charge to a school comprised of 750 students. The local health department donated vaccine to the school, involved school nurses in administering vaccine, and obtained buy-in from the school administration. As a result, 80% of the students and staff were vaccinated.
- Dr. Eisenberg stressed the dual role school-based education programs: increasing vaccine uptake and teaching children about health and immunology.
- A MedImmune representative stressed the need for the Summit to recommend that an evaluation of insurance payment rates be conducted to determine whether providers are being adequately reimbursed for administering influenza vaccine. ACIP representative Dr. Baker responded, noting that although ACIP is unable to make finance-related recommendations, other professional organizations can. She

- suggested that AAFP, the National Vaccine Advisory Committee, and other similar groups investigate the financing of influenza vaccine.
- Several Summit attendees discussed the important role that community-based providers can play in increasing vaccine coverage rates; these providers often can work through VFC programs to provide vaccine to students who otherwise would remain unvaccinated. Community-based providers should be engaged in H1N1 vaccination efforts as this disease continues to emerge.

SESSION VIII: 2009-10 Service Delivery, Late-Season Vaccination, and Retrospective Coverage Data

Moderator: Ms. Heather McKenzie

During Session VIII of the NIVS, participants were provided with information about monthly rates of vaccine uptake, which underscore the need to expand the influenza vaccination season. This session also featured a discussion about the National Influenza Vaccination Week (NIVW) – an HHS effort to extend the season into December and beyond.

Game Plan and Concepts for Next Season’s National Influenza Vaccine Week

Dr. Alan Janssen

Summit participants were updated about the upcoming NIVW by Dr. Alan Janssen, who first provided background information about this CDC/HHS-sponsored vaccination campaign. NIVW was begun during the 2006-07 influenza season to help encourage more Americans to seek influenza vaccination later in the season – when substantial cases of influenza continue to be reported.

Each year during the designated “vaccination week,” CDC and HHS issue messages that emphasize the importance of continuing to vaccinate and receive vaccine into December and beyond. Past efforts have included press events and media interviews; television, radio and print ads; partner and provider communications; and web-based strategies. Last season’s NIVW, which was held the week of December 8--14, employed an additional strategy -- certain populations (e.g., healthcare providers, seniors, and children) served as the focus for communication efforts on specific days of the week. This strategy helped generate vaccine interest among these targeted groups, in whom vaccination coverage rates have been low.

The 2009-10 NIVW is scheduled for the week of December 6--12. This season, CDC plans to continue its strategy of matching certain populations to specific days: Children’s Vaccination Day is scheduled for Tuesday, Healthcare Worker Day for Thursday, and Senior Day for Friday. In addition, CDC plans to continue NIVW campaign activities beyond this designated week and into January 2009 or later, depending on vaccine supply and disease circulation.

Monthly Vaccine Coverage Data

Dr. Gary Euler

The purpose of Dr. Euler's presentation was to show the Summit recent national monthly distribution of influenza circulation data obtained through NHIS, BRFSS, and SDI; he also compared SDI's estimated monthly pattern of vaccination uptake to data obtained through the other two systems.

SDI, a healthcare analytics organization that utilizes insurance claims data to analyze health trends, collected data regarding the number of influenza vaccinations administered in physicians' offices during the 2007-08 and 2008-09 influenza seasons. For both seasons, more than 80% of all doses of vaccine (1.6 million and 1.8 million, respectively) were administered before December; almost all doses (95% were administered by January 1st). Data revealed an 8% increase in uptake in 2008-09 over the previous year.

CDC's National Health Interview Survey (NHIS) also collected data regarding seasonal influenza vaccine uptake. According to NHIS data from 2007-08, of 3,807 vaccinees aged ≥ 6 months, most were vaccinated during October (regardless of age), followed by November; relatively few vaccines were administered during the months of December through March. NHIS also collected data regarding vaccination month by race/ethnicity; these data demonstrate that regardless of race/ethnicity, most vaccine is received before December. They also reveal that vaccine coverage is substantially lower among certain ethnic groups, such as Hispanics.

The Behavioral Risk Factor Surveillance System (BRFSS) revealed similar patterns in vaccine uptake for the seasons 2007-08 and 2008-09. Among adults aged 19-64 years vaccinated during both seasons, most vaccine was received during the month of October, followed closely by November. When examined by race, BRFSS data reveal that Hispanics tended to receive vaccine during the earlier months (August and September) when compared with other races, whereas blacks were more likely to seek vaccination during the months of January and February.

In summary, all three surveillance mechanisms revealed similar monthly vaccination patterns for 2007-08 and 2008-09. In addition, these mechanisms reveal that insurance claims and self-reporting yield similar data, although insurance claims indicate lower vaccine uptake in October and higher uptake during November and December when compared with information obtained through self-report.

Session VIII Discussion

The following ideas were exchanged during the Session VIII discussion panel.

Monthly Vaccine Uptake Data

- Dr. Eisenberg asked Dr. Euler for clarification about the absolute number of minority groups receiving vaccination during the past two influenza seasons. Dr. Euler clarified that minorities were over-represented in the data because the white

- population was concentrated in October. More Hispanics were immunized in the early months, and more blacks were vaccinated in February.
- Dr. Friedman asked Dr. Euler a question about the SDI data. What are the costs associated with obtaining this data set? Also, who is responsible for the initial “cleaning” of the data? Dr. Euler noted that the data are cleaned before they are released from SDI; he could not provide a cost estimate, but could confirm that CDC must pay SDI to clean and provide the data.
 - A representative from the Tennessee Department of Health informed the Summit that this department has been doing a 24-month-long survey regarding vaccination; specifically, the department has examined racial disparities in the receipt of influenza vaccine. Data have revealed that an alarming racial disparity exists in the uptake of two doses of vaccine. Last year, the rate of uptake among black children was half that of white children. This disparity is concerning and must be addressed. Dr. Euler noted that counter-marketing efforts have greatly affected vaccination uptake rates, particularly in the African American community. CDC and other groups must work to balance these messages by communicating facts about the influenza vaccine; the agency has worked with ethnic/minority media outlets to reach targeted audiences. The message that influenza vaccination is important in protecting the health of loved ones seems to be well accepted by the African-American community and might motivate behavioral change.
 - A representative from AccelImmune commented on the SDI data, asking whether SDI data could potentially be leveraged in gathering information about vaccine safety. Dr. Euler commented that although SDI is an excellent source of data, it remains underused. Currently, it is cost prohibitive to use this data to investigate vaccine safety, as CDC funds are limited.

National Influenza Vaccination Week

- It was noted that the effectiveness of the NIVW should be evaluated. Although proponents of this vaccination campaign did not expect immediate results from this campaign, sufficient time has passed since campaign inception to enable an evaluation of the impact it has had on late-season vaccination uptake.

Influenza Vaccine Messaging

- Dr. Eisenberg expressed concern about the current “H1N1” terminology; patients and providers may be confused with this nomenclature. Perhaps CDC and AMA can work together to develop a new term.
- Dr. Eisenberg stressed the importance of conveying an additional vaccine-related message to family practitioners: influenza vaccine can be administered at the same time as other routine vaccines. He also noted the need to improve reimbursement for influenza vaccination.

Extending the Vaccination Season

- Dr. Eisenberg stressed the importance of avoiding discussion about “early” and “late” season vaccination. Instead, vaccination activities should occur year-round.
- Dr. Greenberg with Sanofi Pasteur emphasized that providers still are not ordering enough vaccine to last through the entire influenza season. He asked that the Summit communicate the importance of providers having sufficient doses on hand to ensure year-round vaccination. Ms. McKenzie concurred, noting that providers’ perspectives must change regarding “upfront” vaccine ordering. However, many physicians and providers might be experiencing fatigue with influenza vaccine administration by the later months of the traditional vaccination season, which would limit their desire to order more doses.
- A representative from getaflushot.com stressed the importance of vaccine returnability in physician’s ordering behavior. Manufacturers and distributors are beginning to allow providers to return unused doses, making it financially feasible for providers to order more doses of vaccine upfront.
- It was noted that Sanofi Pasteur has conducted research on vaccination messaging and has learned that although providers now understand the need to extend the vaccination season, these providers are not necessarily immunizing more people. It is important to convey the message that providers should immunize additional patients during the entire vaccination season, not just existing patients at a later date.
- A vaccine manufacturing representative suggested that providers begin to focus on offering vaccine to their patients earlier in the season as well; with the new cell-based technologies and supply chain improvements that have recently been realized, vaccine will likely be available much earlier in the season. Earlier vaccine availability opens up new opportunities for vaccination, including campaigns that coincide with the start of the school year. Although egg-based production has dictated vaccination timelines for years, new cell-based technologies will provide an opportunity for vaccine to be offered much earlier. Dr. Tan commented, noting that the Summit has advocated for both early and late expansion of the vaccination season; with earlier vaccine availability, messages stressing the importance of vaccinating school-aged children at the start of the school year will be developed and delivered.
- Regarding the new manufacturing technologies, it was noted that new production methods likely will not drastically change traditional vaccination timelines, as new seasonal vaccines will still be subject to a federal regulatory and approval process, which can be time consuming.
- One Summit participant asked whether providers and the public will need to be reeducated regarding vaccination timing. Should new messages be crafted to encourage early vaccination? According to Dr. Tan, this issue was raised at the recent ACIP meeting. Data reveals that there is no evidence of waning immunity among persons vaccinated earlier in the season; this data must be translated into effective messages. ACIP will continue to address this topic.
- Dr. Murphy with Healthy Solutions suggested that ACIP create materials that highlight existing data demonstrating that immunity does not wane with early administration of vaccine.

- Another participant expressed concern about encouraging early vaccination campaigns and clinics. Despite promises from manufacturers that the vaccine will be available in August, the timing of availability remains unknown. CDC's Dr. Kris Sheedy commented that CDC will continue to encourage patients to seek vaccine "as soon as it becomes available." Dr. Ross with Sanofi Pasteur suggested that CDC make an official statement urging healthcare providers to begin immunizing in August (or when the vaccine is available).
- The need to better educate insurance companies about earlier influenza vaccine administration was identified. Providers and patients must be guaranteed that insurance companies will reimburse for vaccine administered before October 1st. Medicare Part B billing for influenza and pneumococcal vaccination also must be addressed; currently, Medicare will not pay for influenza vaccines administered before September 1st.

SESSION IX: Moving Forward

Moderator: Dr. LJ Tan

Session IX

Session IX of the 2009-10 National Influenza Vaccine Summit was dedicated to a discussion about the top vaccine-related issues as determined by Summit members. Summit representatives worked to craft messages summarizing the Summit's position on these issues, reflected in the following statements.

- The Summit acknowledges that great work has been done to increase vaccine delivery in many settings through diverse and innovative initiative. However, despite these successes and the identification of numerous best practices, data continues to demonstrate that vaccine coverage rates among healthcare workers and other groups continue to plateau at rates that are substantially lower than the Healthy People 2010 objective of 60%. Therefore, the Summit believes that additional methods will be required to better protect healthcare workers and their patients.
- Summit members recognize that use of incentives in campaigns to motivate healthcare workers to receive influenza vaccine typically do not work in the long run. Alternative efforts should be sought by any organization wishing to improve vaccine coverage rates.
- The Summit agreed that to ensure successful healthcare-facility based initiatives to increase vaccination coverage levels, the terms "healthcare worker" and "direct and indirect patient contact" must be clarified. Currently, efforts to vaccinate within the healthcare setting are inconsistent, because the types of employees targeted for vaccination differs by institution and setting. Instead, facilities should consider requiring that all of their employees, regardless of level of patient contact, receive annual influenza vaccination.
- In light of the two types of influenza that are anticipated to circulate within the upcoming months, the Summit encourages healthcare providers to continue to

provide patients with vaccine against seasonal influenza, regardless of developments in influenza A/H1N1 and the availability of an H1N1 vaccine. Ample doses of seasonal vaccine will be available from manufacturers beginning at the end of August. Providers should be encouraged to begin vaccinating as soon as vaccine is available and to continue to vaccinate through late spring and beyond.