

2007 National Influenza Vaccine Summit
April 19--20, 2007
Atlanta, Georgia

Minutes of Meeting

SESSION ONE

Facilitator: Dr. Litjen Tan

Introduction

Drs. Gina Mootrey and Ronald Davis

Dr. Gina Mootrey, Associate Director for Adult Immunizations within the Center for Disease Control and Prevention's (CDC's) National Center for Immunization and Respiratory Diseases (NCIRD), opened the 2007 National Influenza Vaccine Summit by welcoming all Summit attendees. She outlined the objectives for the 2-day meeting, including addressing the challenges of the 2006-07 influenza season, establishing plans for next year's season, informing Summit participants about successful vaccine-related initiatives conducted in past influenza seasons, and developing innovative ideas for addressing new influenza-vaccine-related concerns and implementing new recommendations.

American Medical Association (AMA) President-Elect Dr. Ronald Davis iterated the importance of AMA/CDC's partnership in sponsoring the 2007 National Influenza Vaccine Summit. AMA is a key player in influenza immunization, having focused on public health issues for 160 years. This commitment is inherent in AMA's mission statement, which is to promote the science and art of medicine and the betterment of public health. AMA also recognizes the importance of partnerships, which is reflected in the Association's new slogan, "together we are stronger."

Since 2001, CDC and AMA have been partnering each year to host the National Influenza Summit, which is continuing to expand. The first meeting was attended by 30 stakeholders representing 15 organizations; this year, however, the number has grown to more than 225 participants representing more than 115 diverse organizations. AMA also has been partnering with other organizations to engage in influenza-vaccine-related activities. For example, in 2004, the influenza season in which severe vaccine shortages occurred, the Association partnered with the Henry Ford Health System to provide 12,000 doses of vaccine to local health departments that had exhausted their supply of vaccine.

Dr. Davis reiterated the key issues to be addressed during the current Summit. Summit participants were asked to consider ways to improve the supply and timely distribution of influenza vaccine, bolster the national infrastructure for adult immunization, and prepare for pandemic influenza. AMA has established policies that strengthen its commitment to these influenza vaccination-related issues. The Association's House of Delegates recently approved a comprehensive report on influenza vaccine supply, which proposes strategies for strengthening the infrastructure for adult immunization. In addition, the Association is preparing an informational report on adult immunization to be presented at the upcoming annual AMA meeting.

Key Note Address

Dr. Anne Schuchat

Dr. Anne Schuchat, Director of CDC's NCIRD, delivered the key note address for the 2007 Summit. Dr. Schuchat spoke on behalf of CDC Director Dr. Julie Gerberding, who was unable to attend the Summit due to last-minute obligations.

Dr. Schuchat began by thanking the manufacturers, distributors, and providers of influenza vaccine. In addition, she emphasized the key role of health communicators in ensuring that increasing numbers of Americans receive vaccine, and she acknowledged AMA and CDC for taking leadership roles and establishing partnerships to coordinate the 2007 National Influenza Vaccine Summit.

Influenza poses unique public health problems. Because the influenza virus, vaccine, and epidemiology changes each year, persons involved in every aspect of influenza prevention and control must remain flexible and work quickly and efficiently. Also challenging is the delicate balance that must be achieved between supply of and demand for influenza vaccine. The supply and demand challenges associated with influenza are unique; both supply and demand are affected by many unpredictable factors (e.g., new vaccine recommendations, delayed growth of viral strains, and disease severity) that must be elucidated within an extremely limited timeline. From season to season, manufacturers often can not ensure predictability regarding the amount of vaccine that will be available and the timeframe for vaccine distribution. Other decisions also must be made on a year-by-year basis, including how much vaccine to make and buy, who should get vaccine, when vaccination should occur, and how vaccine-related messages should be communicated to the public. Each of these decisions has substantial public health and financial implications.

Despite these challenges, more Americans are being protected from influenza. During the previous influenza season, 102 million doses of vaccine were manufactured, representing a 20-million-dose increase over previous years; more vaccine is expected to be produced in the upcoming season. Manufacturers are working to ensure that each of the 218 million Americans who currently are recommended to receive vaccine can become immunized, as well as the millions of Americans who wish to receive vaccine to reduce the likelihood of becoming infected and transmitting disease. Increasing the seasonal influenza vaccine uptake is advantageous, because influenza vaccination reduces illness, death, and health-care costs and improves societal and workplace productivity.

The 2007 National Influenza Summit provides an opportunity for leaders involved in all aspects of influenza immunization to work together to help improve influenza vaccination rates and improve public health. The Summit also provides a forum for the sharing of different perspectives, which is critical to the success of any public health initiative. Partnering with advocates for health creates opportunities to lead by example. Currently, only 40% of the Nation's health-care workers receive influenza vaccination themselves, which is a percentage that likely could increase through consistent messages issued by a consolidated partnership of health-care leaders. In time, ensuring that all health-care workers are vaccinated likely will have a substantial effect on patient behavior and result in increased vaccination rates throughout all sectors of the U.S. population.

To ensure that more Americans are protected from disease in the upcoming influenza seasons, Summit partners must focus on several areas. First, partners should work together to find creative and innovative approaches to existing and anticipated problems and to find answers to questions that to date have remained unanswered. Also key to answering challenging influenza-related questions is effective communication; although communication has greatly improved since formation of the Summit, efforts should be made to ensure innovative and real-time communication, particularly when new vaccine-related problems arise unexpectedly. New, non-traditional partners also are needed, particularly persons who influence the behavior of others within their local communities (e.g., in workplaces and college campuses). In addition, new technologies for vaccine production are needed, specifically those that make vaccine easier and faster to produce. Summit partners also should think about ways to expand the length of the influenza vaccination season, which will help improve vaccination rates and ensure a better balance between vaccine supply and demand.

Manufacturer Projections

Med Immune

Dr. Kathleen Coelingh

Dr. Kathleen Coelingh updated Summit attendees about MedImmune's manufacture of FluMist[®] for the 2007-08 influenza season. FluMist[®] is a live, intranasal vaccine indicated for healthy persons aged 5-49 years. Although the vaccine traditionally has been available only in frozen form, for the 2007-08 season, MedImmune is launching a new refrigerated version of this vaccine. As with the frozen version, the FluMist[®] vaccine contains no thimerosal or other preservatives, and each dose contains less than half of the volume of vaccine used in the previous version of vaccine.

This year, MedImmune plans to expand the indication of FluMist[®] to healthy children aged 1-4 years (e.g., those without asthma or wheezing) pending Food and Drug Administration (FDA) approval and plans to manufacture approximately 7 million doses to ensure availability for children in this age group. With this increased supply, the projected demand for vaccine among children for the 2007-08 season will be almost met by the FluMist[®] vaccine alone; supply is no longer a barrier for expanding influenza vaccine recommendations for children.

MedImmune has determined pricing for the new FluMist[®] formulation. The cost to commercial purchasers will be \$17.95 per dose, and each dose of vaccine for the Vaccines for Children (VCF) contract will cost \$16.90.

The availability of influenza vaccine likely will increase in upcoming seasons due to MedImmune's new plasmid rescue technique. This technique was approved by FDA in 2006 as an alternate method for production of seasonal vaccine strains; it is also the required method for the production of high pathogenic avian influenza (HPAI) virus pandemic strains. The new plasmid rescue technique enables laboratorians to clone genes into plasmids, which are then introduced into cells along with other plasmids that contain the influenza genes responsible for growth characteristics. This technique yields only one possible seed strain, which will eliminate guess work and introduce a greater level of predictability in the vaccine production process. Use of plasmid rescue will allow manufacturers to begin production earlier (which will help extend the vaccination campaign season), result in earlier release of vaccine to the end user, and allow for the maximum number of delivered doses. In addition, the plasmid rescue method removes the risk of exposure to adventitious agents in the wild-type isolate, results in fewer random mutations, and uses the same bulk production process as classical reassortment techniques.

Sanofi Pasteur

Mr. Philip Hosbach

Mr. Phil Hosbach discussed Sanofi Pasteur's overarching goals, influenza vaccine production during the 2006-07 season, and plans for the upcoming season.

Sanofi Pasteur's primary goal as a vaccine manufacturer is to increase immunization rates across broad customer segments --- a goal that becomes more important as vaccine supply increases. Currently, the manufacturer supplies vaccine to more than 40% of the marketplace. Sanofi Pasteur also strives to remain open and transparent about their production capacity and about problems that are encountered during the manufacturing process. For more than 40 years, the company has been managing every aspect of the vaccine distribution process and has demonstrated a strong commitment to influenza vaccine production. Currently, a new facility is being constructed that will double production capacity. In addition, a new filling facility that will increase single- and unit-dose syringe capacity will be available next year. Sanofi Pasteur also is focusing on next-generation vaccines using new production processes (e.g., cell culture);

the company recently licensed the first H5N1 vaccine, which represents a first step towards bringing these new vaccines to the marketplace.

The concept of partial shipments of vaccine was introduced during the first National Influenza Vaccine Summit in 2001. Since then, Sanofi Pasteur has been following this immunization principle to help ensure that vaccination rates are increased to meet CDC's Healthy People 2010 goals. The manufacturer aims to reach all segments of the population and is in full support of CDC's influenza immunization recommendations. In addition, Sanofi Pasteur is trying to prepare the market for growth by involving vaccinators in non-traditional settings, including retailers, grocery stores, and drug stores.

Two strain changes occurred in influenza season 2006-07. The new A/Wisconsin strain was slow growing, which resulted in a 3-week delay in the production of vaccine and a shortage in supply early in the season. Despite this problem, Sanofi Pasteur exceeded its production goals by producing 54 million doses, all of which were shipped by the third week of November. Approximately 87% of the doses were supplied to office-based physicians; public health organizations; and hospitals, long-term care facilities, and institutions. Only 5% of doses were distributed to retail settings.

Sanofi Pasteur plans to produce 50 million doses for the 2007-08 influenza season, contingent on demand and production factors. Currently, all three influenza strains for the vaccine are in production, one of which is new (A/Solomon Islands). To date the strains are performing well, which indicates that Sanofi Pasteur will meet its production goals. CDC will be kept informed about all production-related accomplishments and challenges as the season unfolds.

GlaxoSmithKline

Mr. John Neal

GlaxoSmithKline (GSK) is a new vaccine supplier in the U.S. marketplace. The manufacturer, which is headquartered in Belgium, has a proven track record of providing vaccine to the global market. GSK's primary vaccine products are Fluarix[®] (indicated for adults aged ≥ 18 years and available in pre-filled syringes), FluLaval[®] (a thimerosal-containing vaccine available in multi-dose vials for adults aged ≥ 18 years), and Relenza[®] (an antiviral indicated for the prophylaxis and treatment of persons aged < 5 years with influenza types A or B). To expand its capacity, GSK has invested \$2 billion in the manufacture of influenza vaccine and antivirals. Recently the company acquired ID Biomedical in Canada and bought a facility in Pennsylvania to be used for the production of cell-culture vaccine, which will increase GSK's ability to supply vaccine to the United States. During the last 2 years, GSK has received two FDA approvals for its two seasonal vaccines, Fluarix[®] and FluLaval[®]. In addition to seasonal vaccine, GSK hopes to manufacture vaccines and antivirals (Relenza[®]) for pandemic strains and is committed to partnering with federal, state, and local governments to prepare for a potential influenza pandemic.

GSK is committed to the U.S. influenza vaccines marketplace. Last year, the manufacturer produced 25 million doses of Fluarix[®] and FluLaval[®]. It is projected that 35 million doses will be manufactured for the 2007-08 influenza season, although this estimate is contingent upon manufacturing yield and demand. GSK will continue to increase capacity in the years to come to meet public health needs and market demands.

The 25 million doses of vaccine produced by GSK during 2006-07 were distributed to many sectors. Most doses were distributed to physicians (38%) and hospitals (29%); the remaining doses were distributed to public health departments, the federal government, and retail vaccinators. GSK began shipping vaccine in September (4 million doses) and continued to distribute vaccine into October (approximately 8 million doses), and November (approximately 12 million doses).

For the 2007-08 season, GSK plans to manufacture and distribute 30-35 million doses of Fluarix® and FluLaval®. Most doses of Fluarix® will be distributed directly by GSK, whereas FluLaval® will be distributed by and sold through three independent distributors (ASD Healthcare, Henry Schein, and McKesson).

In addition to manufacturing vaccine, GSK is focused on improving influenza vaccination rates throughout the country. To help increase rates during the last influenza season, GSK engaged in several activities associated with the 2006 National Influenza Vaccination Week. The manufacturer co-chaired the Summit's "Extending the Season" workgroup, worked across sales forces to raise awareness about National Influenza Vaccination Week, supported the development of an information website (www.preventinfluenza.org), and developed a holiday-themed poster in collaboration with other Summit participants. GSK plans to continue its commitment to increasing influenza vaccination rates by developing healthcare worker toolkits to assist in the implementation of JCAHO recommendations, support programs and advocacy to increase rates of influenza vaccination among persons with chronic disease, participate in influenza-related public relations efforts, and support innovative influenza vaccination programs for later-season vaccination.

In the future, GSK will focus on innovative vaccine-associated activities to help increase vaccination rates for influenza and prevent disease. The company plans to address the unmet vaccine needs in children by developing a thimerosal-free pediatric influenza vaccine, improve vaccine effectiveness through the use of novel adjuvants, explore new vaccination delivery systems, and accelerate the vaccine manufacturing process (e.g., through cell-based technology).

Novartis

Mr. Tom Gibbs

Mr. Tom Gibbs provided Summit participants with the Novartis perspective and insights into the 2006-07 influenza vaccine season, gave projections regarding the upcoming season, described the manufacturer's plan to increase awareness about the need to protect more people from influenza, and discussed Novartis' commitment to bringing new influenza vaccine products to the market.

Novartis Vaccines, which was formed only 1 year ago, has already played an important role in supporting public health. In 2006, the company's shipment of FluVirin® marked the beginning of the influenza vaccine supply for the marketplace. Novartis met and exceeded its production projections, delivering more than 31 million doses. Novartis Vaccines also has strongly supported public health efforts for early immunization planning. In 2006, the company was given an HHS award to further develop MF59, Novartis' proprietary vaccine adjuvant, to potentially extend vaccine supplies in the case of a pandemic. Novartis was also awarded an HHS contract to help fund the development of the company's proprietary cell-culture-derived influenza vaccine; the company has now broken ground on the first U.S. cell-culture-derived influenza vaccine manufacturing facility, which is located in North Carolina.

Broadening access to influenza vaccine through a variety of channels is another Novartis objective. The manufacturer also has supported CDC and local health departments by raising public awareness of the importance of extending the vaccination season by participating in grassroots programs.

Although more people were protected from influenza in 2006 than ever before, Novartis recognizes that much work must still be done. Novartis plans to continue its commitment to increasing production for 2007-08 to 40 million doses. In addition, the company will engage in several other vaccine-related activities in the upcoming season, including communicating with CDC to keep stakeholders informed of supply and timing issues, continuing to support physicians to increase vaccination rates, working to expand access through alternative delivery channels, executing multifaceted programs to increase

vaccination rates, and providing healthcare professionals and other vaccinators with patient education materials and resources to increase customer demand.

In upcoming years, Novartis plans to further protect the public from influenza by introducing new vaccines. The manufacturer is currently investigating new preservative-free egg-based products (i.e., AGRIPPAL[®]), enhanced products containing adjuvants (FLUAD[®]), cell-culture derived vaccines, and vaccines for pandemic strains. Novartis expects to receive FDA approval for its new products by 2008.

CSL Biotherapies

Mr. Paul Perreault

Mr. Paul Perreault provided Summit attendees with an overview of CSL Biotherapies. CSL Biotherapies is one of the three companies that operate under the CSL Limited umbrella. CSL Limited, which is headquartered in Melbourne, Australia, employs more than 8,500 persons in 25 countries around the globe. The company has more than 90 years' experience in the development and manufacture of vaccines and plasma protein biotherapies. Although CSL's products are new to the U.S. market, the company has manufactured influenza vaccine since 1968 and has sold vaccine in 16 countries. During the 2005-06 influenza season, 25% of vaccinees in the United Kingdom were immunized using a CSL product.

CSL Biotherapies is working to increase its manufacturing capability. It recently completed renovation of a modern egg-processing facility to ensure that the company has sufficient capacity to produce vaccine strains for countries in the Northern and Southern Hemispheres; in addition, the company is investing \$60 million to double capacity in its Australian plant.

Efforts are underway to commercialize CSL's influenza vaccine in the United States. CSL Biotherapies recently collaborated with NIH to conduct a clinical trial involving 1,400 U.S. patients, and the manufacturer is planning to make two preparations of vaccine available to U.S. providers in the 2007-08 season (a thimerosal-free, pre-filled syringe and a multi-dose vial) pending FDA approval.

Beyond the manufacture of vaccine, CSL is focusing on its saponin-based adjuvant, which has been named ISCOMATRIX[®]. This adjuvant is unique, in that it improves antigen delivery and has immunomodulatory properties (i.e., enhances the immune response on cellular and T-cell activity). More than 20 companies have expressed interest in using CSL's adjuvant in the manufacture of their vaccines.

Discussion

- It was reiterated that a projected 132 million doses of influenza vaccine will be available for the upcoming season.
- Dr. Martin Levine asked manufacturers how many delivered doses went unused during 2006-07. He also asked whether vaccination in doctors' offices is decreasing in response to the availability of vaccine in non-traditional settings. He was told that physicians do not report the number of vaccine doses that are left over during a season. Dr. Levine encouraged manufacturers to create a program in which the supply and demand issues being faced in private physicians' offices can be better monitored. This type of information would enable physicians to make more informed decisions regarding prebooking of vaccine. CDC's Dr. Jeanne Santoli also responded, noting that monitoring each provider's supply is nearly impossible. However, CDC is attempting to sample doctors to get a general sense of the magnitude of the doses that are going unused. Reducing the amount of wasted vaccine is part of the rationale behind extending the length of the influenza vaccination season. Doctors are being encouraged to keep and administer vaccine until it expires.

- Dr. Tan emphasized that physicians should keep vaccine until the expiration date for use in patients who are traveling to the Southern Hemisphere. A Summit participant noted that although he would like to extend the vaccination season into the summer for travelers, most vaccines expire before June 30.
- Feedback was received regarding the number of doses going unused in physicians' offices. Dr. Roger Baxter with Kaiser Permanente noted that 1 million doses were purchased by his organization, and only 900,000 were used. Kaiser Permanente typically has 10% of vaccine left over at the end of the season. He also stressed that in his experience, vaccine uptake increases when vaccine is available early in the season.
- Dr. Baxter asked whether FluMist® will be available earlier than other vaccines. Dr. Kathleen Coelingh with MedImmune noted that the company is planning to have FluMist® available in August, primarily because MedImmune recognizes that vaccine must be available early to ensure increased uptake.
- Steve Allred with Getaflushot.com commented on the issue of leftover vaccine, noting that the number of unused doses for each physician likely can be tracked. Doctors all pay a tax at the time of purchase that is refundable when doses are returned; this information could be tracked and made available to the public. This type of tracking system could help distinguish between vaccine production and actual use.

National Foundation for Infectious Diseases' Pediatric Influenza Coalition
Drs. Carol Baker and Richard Carmona

Dr. Carol Baker, President of the National Foundation for Infectious Diseases (NFID), provided Summit participants with information regarding the Pediatric Influenza Immunization Coalition, which was established to protect children against influenza-related morbidity and mortality. Dr. Richard Carmona, Chair of the Pediatric Influenza Immunization Coalition, who was unable to attend the Summit in person, provided attendees with a prerecorded presentation about the Coalition.

Influenza substantially impacts the U.S. pediatric population each season. Infants and toddlers 6-23 months of age have hospitalization rates similar to persons aged ≥ 65 years, and substantial numbers of children aged 24-59 months visit clinics, hospitals, and emergency departments to seek treatment for influenza-related illnesses. Children with underlying medical conditions (e.g., asthma, diabetes, and cardiovascular disease) are at particularly high risk for influenza-related adverse outcomes, including exacerbation of the underlying condition and increased rates of morbidity. Particularly concerning is illness in infants <6 months of age, a population for which no influenza vaccine currently has been approved.

Influenza-related deaths occur in children. The largest number of flu-associated deaths in this population was reported in the 2003-04 season, when 153 children died from this infectious disease; 63% of deaths were among children <5 years of age. Substantial numbers of deaths have occurred in other seasons; computer models estimate that 92 U.S. children aged <5 years die every year from influenza.

Although influenza vaccination does not provide 100% protection, the rates of influenza immunization in pediatric populations must be improved to reduce influenza-related death and illness. Surveys conducted in 2005 revealed that of children aged 2-17 years, only 29% of asthmatic children and 35% of children with other high-risk conditions received vaccine; only 18% of children aged 6-23 months were vaccinated.

Immunizing children benefits more than just those children that are vaccinated. Widespread immunization has the potential to interrupt disease transmission to others, particularly in this population; children shed virus at higher titers and for longer periods of time than do adults, and outbreaks that begin in pediatric populations often spread to the community at large. In one study involving Japanese schoolchildren, vaccination reduced excess mortality in both children and older persons. Increasing the immunization rates in children also will help create valuable infrastructure to support future expansions of pediatric influenza recommendations and will ensure that delivery channels are in place in the event of a future influenza pandemic.

The Pediatric Influenza Immunization Coalition was founded to develop “one strong voice” from medical professional and patient/parent groups regarding the need to improve the alarmingly low influenza immunization rates among children and to help make immunization a public health priority. Dozens of organizations are involved in the Coalition, including the American Academy of Family Physicians (AAFP), AMA, CDC, and the American Academy of Pediatrics (AAP). The Coalition currently is led by Dr. Richard Carmona, who served as the 17th U.S. Surgeon General and is currently president of the Canyon Ranch Institute’s Center for Prevention and Health Promotion, and by Dr. Baker, who is a professor at Baylor College of Medicine, an Advisory Committee on Immunization Practices (ACIP) member, and the Associate Editor of AAP’s *Red Book*.

The Coalition is taking a new approach to influenza prevention in U.S. children by reaching beyond traditional healthcare partners and into the community. The goal of the coalition is to protect children, prevent school absenteeism, and save lives by increasing rates of vaccination in the pediatric population. To meet these goals, the Coalition is supporting efforts to extend the traditional vaccination season and to ensure that vaccine is offered and administered at routine doctor visits.

American Lung Association Initiatives

Dr. Terri Weaver

Dr. Terri Weaver, Chair of the Board of Directors for the American Lung Association (ALA), discussed the organization’s recent initiatives to help educate the public about influenza immunization and increase vaccination rates. These initiatives serve as examples of the progress that can be made through partnership, creativity, and outreach.

The Faces of Influenza Campaign represents a partnership between ALA and vaccine manufacturer Sanofi Pasteur. This educational initiative was created in response to the excess vaccine that went unused during the past season and the need to reach out more broadly within the community to increase vaccine demand and to ensure that more people are protected against disease. Specifically, the goal of the Faces of Influenza Campaign was to enable people to identify with others at risk and to help them view themselves as needing to be vaccinated for influenza; ALA and Sanofi Pasteur wanted to “put a face” on influenza illness and help Americans understand the need for annual vaccination.

The 2006 Faces of Influenza Campaign was kicked off in New York City and became a substantial media event. The Campaign then was taken to other parts of the country, resulting in more than 550 million total media impressions. Six key cities served as sites for regional Campaign events (Phoenix, Detroit, Minneapolis/St. Paul, Philadelphia, Seattle, and Houston), and the local media coverage at these sites resulted in 36 million media impressions. Campaign-related activities conducted in these cities during December and January emphasized the need to extend the traditional influenza vaccination season into later months.

ALA is now moving into its second year of the Faces of Influenza initiative. The organization is considering several issues in creating the 2007-08 season campaign, including the critical need for education regarding influenza immunization and the seriousness of influenza. In addition, the upcoming

campaign must focus on extending the current vaccine season; the public will be encouraged to receive vaccine in December, January, and beyond to ensure optimal protection against disease. The 2007-08 Faces of Influenza Campaign will continue to work to increase consumer awareness, particularly among Americans at high risk and among persons who care for others who are at high risk for influenza-related morbidity and mortality. Like the 2006-07 initiative, the upcoming Campaign will help influence behavior and increase awareness by exposing Americans to people who have compelling influenza-related stories; messages will be delivered through intense media outreach activities (e.g., via television and radio public service announcements) and through celebrity spokespersons. The 2007-08 Campaign will be kicked off in New York City, and media events will be held across the country throughout the influenza season. ALA will also be trying to develop regional Faces of Influenza programs through developing coalitions of interested organizations in various markets across the country; regional coalitions would conduct extensive media outreach and promotional activities, host media events and vaccination clinics, and engage in other activities to encourage vaccination into January and beyond.

Another vaccination-associated initiative recently undertaken by ALA is the creation of the web-based Flu Clinic Locator. This internet site provides users with information regarding where vaccine is being offered in their geographic area. In 2006-07, more than 90,000 clinics were posted on the site. The Flu Clinic Locator will continue to operate during the upcoming vaccine season.

ACIP Recommendations Update

Dr. Anthony Fiore

CDC's Dr. Tony Fiore presented a summary of the ACIP's 2007-08 influenza vaccine recommendations. He provided an overview of changes in recommendations over the past several years, highlighted the changes reflected in the updated recommendations, and discussed timelines for implementation.

Several milestones in influenza vaccine recommendations have been reached in the last few years beginning in 2000, when all adults aged ≥ 50 were recommended to receive vaccine. In 2004, ACIP recommended that all children aged 6-23 months be vaccinated, along with all contacts of children aged 0-23 months and all women who are or anticipate being pregnant during the influenza season. The following year, ACIP recommended influenza vaccine for all persons with any condition that compromises respiratory function or the handling of respiratory secretions; in 2006, the Committee further expanded its guidelines by recommending that all children aged 25-59 months, along with their out-of-home caregivers and household contacts, receive influenza vaccine. As a result of these changes, approximately 220 million Americans (73%) currently are recommended to receive annual influenza vaccination.

The age and risk groups recommended for vaccination have not changed in the updated ACIP guidelines. ACIP continues to recommend that the following groups receive influenza vaccine: a) children aged 6-59 months; b) all persons aged ≥ 50 years; c) healthy household contacts and caregivers of infants who are younger than 6 months old; d) children and adolescents who are receiving long-term aspirin therapy; e) women who will be pregnant during the influenza season; f) adults and children with chronic pulmonary, cardiovascular, renal, hepatic, hematological, or metabolic disorders; g) adults and children who have immunosuppression; h) adults and children who have any condition that can compromise respiratory function or the handling of respiratory secretions; and i) residents of nursing homes and other chronic-care facilities. In addition to these groups, the Committee continues to recommend vaccination for healthcare workers, healthy household contacts and caregivers of children aged 6-59 months and ≥ 50 years of age, and healthy household contacts and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza.

Several broad changes are reflected in the Committee's 2007 influenza vaccine recommendations. First, the Committee recommends a new vaccine composition through the addition of a new H1N1 component.

Additionally, because of the high rate of drug resistance, ACIP continues to recommend against the use of adamantanes for treatment or prophylaxis. The recommendations regarding the vaccination of children also has changed; the new guidelines recommend that children aged 6 months through 8 years who received a single dose during the first year of vaccination receive two doses in the second year of vaccination. The following recommendation represents another key update to the 2006 guidelines: “vaccination is recommended for persons, including school-aged children, who want to reduce the likelihood of becoming ill with influenza or transmitting influenza to others should they become infected...” With this new recommendation, ACIP hopes to facilitate efforts to vaccinate all persons who want to receive vaccine in addition to those persons who are in high risk groups.

Although the 2007 ACIP recommendations expand the groups of persons for which influenza vaccine is indicated, several groups are still excluded, including children aged 5-18 years of age, adults aged 19-49 years, and infants <6 months of age – a group for whom vaccine has yet to be approved.

Expanding the current recommendations to include routine vaccination of all school-aged children has been discussed by the Committee. Several factors must be considered before such a recommendation is made. First, vaccinating school-aged children would reduce morbidity and mortality among these children and likely would reduce community-wide morbidity and mortality. However, issuing this recommendation might create an expectation of immediate implementation that can not be met and might exacerbate vaccine supply shortages and distribution delays. Therefore, several activities must be undertaken to help set the stage for a new recommendation, including improving existing surveillance, developing implementation strategies, planning for impact evaluation, and assessing capacity (e.g., vaccine manufacturing and the immunization delivery infrastructure).

Expansion of the influenza vaccine recommendations to school-aged children will be extensively discussed at a meeting planned for September 2007. The objectives for this meeting will be to a) summarize current evidence (e.g., burden of disease, vaccine effectiveness and safety, and cost analyses); b) identify current and potential implementation challenges, infrastructure and resource needs, priority communication messages, impact assessment studies, and gaps in evidence; and c) provide a report summary to ACIP at the October 2007 meeting.

ACIP has developed a timeline for future modifications to the current influenza vaccination recommendations. During 2007-2008, the Committee plans to consider expanding recommendations to include all children aged 6 months to 18 years. In 2010-2011, ACIP will consider expanding recommendations further to include household contacts and caregivers of school-aged children, and in 2012-2013, the Committee may recommend universal vaccination.

Expansion of the current ACIP recommendations for influenza vaccination will present many future challenges. The implementation of large-scale vaccination programs is difficult, because it would require flexibility in scheduling and capacity, result in supply delays, and create unpredictable public demand and sustainability. In addition, expanded recommendations would require the crafting of unique communication messages and the creation of nationwide vaccine registries. ACIP recognizes that moving towards universal vaccination also will complicate the issuing of recommendations, because the indications change with each new influenza season; different vaccines will be indicated for different people depending on factors such as age and health status, and new vaccines (e.g., cell-culture-based vaccines) likely will be targeted to specific groups.

Session One Discussion

- Dr. Jeff Duchin with the University of Washington relayed his experience with influenza during the 2006-07 season. School-aged children were substantially impacted by the 2006-07 outbreak in Washington, resulting in the closing of several local schools due to absenteeism. In one high school of 900 students, investigators determined that although 66% of the students had an indication for influenza vaccine, only 13% of them had been immunized. When parents were asked about why their children did not receive vaccine, 40% reported that their provider never suggested influenza vaccination, and another 40% said that they didn't think about taking their child to be vaccinated. Many parents indicated, however, that they would like to have vaccine available in the school setting.
- Ms. Bonnie Thomas, President and CEO of Colorado Wellness Connection, posed a question for Dr. Weaver with the American Lung Association. She inquired about whether the public awareness campaign materials (e.g., public service announcements [PSAs] and displays) are available to cities that currently are not on the campaign schedule. Dr. Weaver responded that the PSAs are nationally broadcasted, and the materials are available through local ALA chapters. Additional information can be found on the Internet at www.facesofinfluenza.org. Cities also are welcome to schedule a visit from the ALA's portrait gallery.
- Dr. Tan noted that the Summit should unify the resources presented at the meeting and make them available over the Summit website.
- Kaiser Permanente's Ms. Laura Peterson echoed comments made regarding the substantial pediatric disease burden experienced during last year's influenza season. She commented on the need to simplify ACIP recommendations, suggesting that there is a difference between public and provider messages regarding vaccination recommendations. The general public should receive a simple message urging them to get a flu shot. Recommendations regarding which vaccine to administer should be made at the provider level. Dr. Andy Eisenberg concurred with Ms. Peterson's comment, emphasizing the importance of keeping influenza messages simple. However, messages become complicated when recommendations are made for vaccine tiering. Both providers and patients should be given the message that vaccination is recommended for all persons who do not want to become infected with or transmit influenza. Dr. Eisenberg further stressed that in the absence of a simplified message, the number of wasted doses of vaccine will increase.
- CDC's Dr. Fiore commented about the need to reduce vaccine wastage, noting that the Committee is attempting to increase demand through its new recommendation that encourages providers to administer vaccine to anyone who wishes to protect themselves and others from influenza.
- Ms. Denise Palmer spoke as a member of Families Fighting Flu, an organization comprised of families that have experienced an influenza-related death in a child. Ms. Palmer, who lost her 15-month-old daughter to influenza, emphasized the importance of communicating to the public the need to vaccinate against influenza. No doses of vaccine should go unused. Another Families Fighting Flu member, whose grandson died from influenza, suggested that providers donate excess doses of vaccine to schools and other organizations within the community that might not be able to afford to purchase vaccine. He also emphasized the importance of vaccinating caregivers.
- A practicing family physician relayed his experience as a public health practitioner and school physician. He noted that he can make a case for almost all of his patients to receive

influenza vaccine. In fact, when making house visits he often has an opportunity to vaccinate several generations of family members, so he makes sure to bring along multi-dose vials of vaccine. This Summit participant voiced concern that he has received “mixed messages” from CDC regarding which patients should receive vaccine; patients also are hearing mixed messages, often stating that they “are not supposed to get vaccinated.” CDC’s decision to implement a tiering system has been problematic.

- Immunization Action Coalition executive director Dr. Deborah Wexler informed Summit participants that many influenza-related deaths have occurred in children who do not have risk factors. Although 73% of Americans currently are recommended to receive vaccine, this percentage should be increased to 100%. Vaccinating all persons would make decisions regarding vaccine administration easier for physicians and other health care providers; efforts should be made to move away from risk-based considerations.
- Mr. Phil Hosbach commented on universal vaccination. He stressed the need for action regarding universal vaccination regardless of whether plans for implementation have been established. Many practitioners are ready to begin vaccinating all of their patients, and they should not wait for a formalized implementation plan to start doing so. Perhaps valuable lessons will be learned by “doing.”
- Dr. Ed Lewin spoke about the vaccination of children, stating that there are two reasons for vaccinating children in the school setting: a) because children can be accessed easily in schools and b) because data indicate that vaccination of children will have a positive impact on the wider community. Perhaps the Summit should think creatively about vaccination initiatives and avoid being overly conservative.
- It was noted that most patients who are offered vaccine accept it. This Summit member relayed his experience with vaccine campaigns, stating that one 3-hour school visit resulted in 84% vaccine uptake.

SESSION TWO: 2006-07 INFLUENZA VACCINE SUPPLY CHAIN

Facilitator: Dr. Greg Wallace

Pediatric Vaccine Supply Issues

Dr. Sally Goza

Dr. Sally Goza provided Summit attendees with a pediatrician’s perspective of vaccine supply issues by discussing an AAP survey of pediatric vaccine use and other vaccine-related issues experienced during the 2006-07 influenza season. This survey revealed that of pediatricians in 43 states, most vaccinated using FluZone® because this vaccine is licensed for use in children. The AAP survey also demonstrated that pediatricians often had difficulties with the vaccine prebooking process, particularly when it came to ordering the appropriate number of doses for the upcoming influenza season.

The AAP survey revealed that pediatricians experienced vaccine shortages early in the 2006-07 influenza season. Physicians from many states received insufficient numbers of vaccine doses for patients qualifying for the VFC program; more than 50% of pediatricians had not received any VFC vaccine by October 15. Distribution for private vaccination also was problematic last year; 24% of physicians surveyed had received no private stock by mid-October, and 62% had received less than 2%. Only one third of the physicians had received at least 75% by November 15. This delay in vaccine distribution and availability resulted in missed opportunities for vaccination.

During the 2006-07 season, pediatricians were concerned about inconsistent messages regarding vaccine availability. Although CDC announced that the vaccine was available to children in October, many parents were unable to obtain vaccine in their children's medical homes; instead, parents sought vaccination for family members in retail and other settings where vaccine was offered (e.g., pharmacies and public health departments). Complicating this scenario was CDC's expanded recommendation to vaccinate children as young as 5 years of age, which created even more demand for influenza vaccine.

Pediatricians also have concerns about the cost of vaccine administration during a season in which vaccine supply is limited. Physicians and office support staff must invest extensive amounts of time rescheduling and conducting other activities to ensure that their patients can receive vaccine as it becomes available.

The 2006-07 survey demonstrated that pediatricians across the country perceived retail and pharmacy-based clinics as receiving more doses of vaccine from distributors and manufacturers than did doctors and other traditional healthcare providers. Although inconsistencies in distribution likely result from differences in supplier, parents unable to obtain vaccine from doctors' offices are left with the perception that their medical homes are inadequate. For every patient that can not obtain vaccine in their medical home, another dose goes unused by their doctor, resulting in vaccine wastage.

In response to this survey, AAP has developed suggestions and guidance that might help health advocates reach the goal of immunizing all children aged ≥ 6 months in future influenza seasons. First, pediatricians must be better informed by manufacturers and distributors about when to expect vaccine shipment so that parents can be adequately informed. AAP and CDC also should work to tailor messages about pediatric vaccine, specifically regarding the availability and dosing of thimerosal-free vaccines. In addition, parents and other caregivers should be given refined messages regarding the benefits of vaccination for children the importance of receiving vaccine throughout the influenza season as necessary.

AAP also recommends that decisions be made regarding how to use or compensate doctors for leftover vaccine. Pediatricians often have high overhead costs with low profit margins, making prebooking and prepaying financially restrictive, particularly when no refunds are offered for unused doses of vaccine.

Finally, AAP recommends that children be vaccinated in their medical home. Each visit to a pediatrician creates an opportunity for communication about the need for children to receive a second dose of influenza vaccine and the importance of vaccinating other family members. To ensure that patients receive care from their physicians, doctors should be assured the same vaccine supply as providers in non-traditional settings.

Complexities of Influenza Vaccine from Production through Delivery

Manufacturers' Perspective

Mr. Philip Hosbach

Mr. Phil Hosbach presented the manufacturers' perspective on vaccine production and delivery. He began by stressing the challenges that are associated with making vaccine for a virus as unpredictable as influenza, which responds differently within the vaccine production process depending on the season.

Mr. Hosbach briefly explained how inactivated vaccine is produced. Manufacturers must first grow the live influenza virus by injecting it into eggs; the virus replicates as the embryo grows within the egg, and it is then harvested. This process is complex, and manufacturers have applied new technologies to make the process more efficient.

Production of the influenza vaccine is a year-long endeavor. First, CDC and the World Health Organization (WHO) conduct surveillance to identify the strains most likely to circulate in the upcoming influenza season and those most likely to grow in eggs. The FDA then identifies the three strains to be included in the vaccine and distributes seed strains to manufacturers to enable them to begin vaccine production. Strain selection, which typically occurs during the first months of the year, affects the timing of production; if the strains are poor performers (i.e., grow slowly), vaccine supply delays are likely, particularly if the low yielding strain is last to be identified. Because of these types of timing issues and the tight production timeframe, manufacturers often begin producing strains in December that they predict will be selected for the upcoming season, even though FDA has not announced their official strain selection. From June through October, manufacturers remove the virus from the eggs and employ purification processes and chemical treatments to inactivate and split the virus.

Most of the time required for vaccine production is spent on testing. Quality control and potency tests are performed for each individual strain, and manufacturers then combine each monovalent strain and retest the combined vaccine. Both the manufacturer and FDA test and release vaccines; vaccines that do not pass manufacturer or FDA tests are discarded.

By July, manufacturers receive vaccine approval and approval for the package inserts that accompany vaccine. Manufacturers then fill and package vaccine, placing highest priority on packaging pediatric doses of vaccine, and vaccine is shipped to distributors from August through December and beyond, if needed.

Distributors' Perspective

Mr. Andrew Van Ostrand

Mr. Andrew Van Ostrand explained the role of distributors in the vaccine supply chain. He began by discussing the Health Industry Distributor's Association (HIDA), a non-profit trade association founded in 1902 that represents medical products and distributors. HIDA is comprised of 200 member companies that operate 432 distribution centers in the United States; the association serves 159,000 physician offices, 5,200 hospitals, and 19,500 long-term care facilities. Currently, 25 vaccine distribution companies operate nationwide, many of which are HIDA members.

Mr. Van Ostrand provided Summit attendees with information about the two ways that the influenza vaccine gets to the market. Approximately 50% of vaccine is distributed to providers directly from the manufacturer; lots are released and distributed each week. Another 50% of vaccine is shipped to providers via distributors, which ship vaccine within 1-3 days of receipt from the manufacturer. Because such a substantial amount of vaccine is shipped each season within a short timeframe, distribution companies play a valuable role in ensuring that individual providers receive vaccine in a timely manner.

Most vaccine shipped by distributors (80%) is delivered to physicians' offices, clinics, and other providers that serve small numbers of patients. Distributors ship an additional 20% of vaccine to hospitals, public health departments, long-term care facilities, and retail/mass immunizers. These percentages exemplify the role of the distributor, which is to reach far into the provider community to facilitate vaccine delivery, even in single-physician offices. Distribution companies acknowledge the importance of supplying individual physicians with vaccine; in 2005-06, more Americans received influenza vaccine from a physician's offices than any other setting.

In summary, distribution companies are customers of the vaccine manufacturers. Distributors ship to providers within 1-3 days of receiving doses from manufacturers, providing most doses directly to physicians' offices. Because vaccine providers have expressed frustration regarding the distribution process (e.g., perceptions that certain providers take priority over others), improved communication and education are needed to ensure that public health goals are achieved.

Session Two Discussion

- Summit participants discussed communication of vaccine-supply-related issues. A Sanofi Pasteur representative noted that his manufacturing company tries to keep HHS and CDC informed as early as possible regarding vaccine supply delays. However, in certain instances, the government is not alerted because the vaccine supply problems are quickly resolved. During the 2006-07 season, Sanofi Pasteur created a press release to inform providers about potential delays at the start of the season resulting from inadequate strain growth. However, consistently communicating vaccine supply levels throughout the influenza season can be challenging, and often these messages must remain broad and unspecific.
- Mr. Van Ostrand also commented about vaccine supply communication. Distributors are working to increase communication regarding vaccine supply; these companies are using CDC's vaccine tracking system to help determine supply issues. However, these companies face challenges in understanding the relationship between the lot release data collected by CDC and the actual impact of the data within the provider community. Released lots of vaccine do not necessarily translate into doses of vaccine within provider's offices, because much time is spent obtaining FDA approval, packaging vaccine, and shipping.
- Mike Cheney from the Georgia AAP chapter reiterated Dr. Goza's concern that physicians are pressured for time when discussing influenza vaccination with parents. Perhaps AAP and CDC could work together to develop talking points that could be used by providers to deliver consistent messages to patients.
- Dr. Don Williamson, a health officer in Alabama, noted that although the statistics presented regarding vaccine distribution are reassuring, the data is inconsistent with "on the ground" experience within state health departments. Are there additional factors that affect distribution (i.e., differential commitments to purchasers based on the size of their orders)? Do providers that purchase large amounts of vaccine receive a firm delivery date from manufacturers and distributors, ensuring them preferential treatment? Dr. Williamson was told that this type of practice is not necessarily taking place; in many instances, small orders are filled first because manufacturers are hesitant to split orders. Some distributors do have contracts with providers, in which delivery dates are identified. These contracts enable providers to refuse vaccine if it is delivered past the contract date, but they also give providers the right to accept vaccine before it is delivered to others.
- Phil Hosbach from Sanofi Pasteur also commented on the perception of preferential treatment in vaccine shipping. He noted that his company makes sure that smaller clinics and practices (i.e., those that order 250-500 doses) receive their doses first. Each contract between providers and manufacturers is unique, and some include target delivery dates (e.g., those involving some states and the military); however, because Sanofi Pasteur aims to avoid "over promising and under delivering," the company rarely specifies dates for delivery.
- A GSK representative noted that within his company, some federal customers have contracts in place. He added that because of the logistics of shipping, it is often easier to ship a certain percentage of vaccine to large practices first and fill smaller orders later. However, this practice can lead to the perception by physicians with smaller practices that other providers are receiving preferential treatment. Perhaps the logistics of shipping should be reexamined.

- A CDC representative provided a different perspective, stating that CDC does not enter into contracts with manufacturers or distributors; instead, the agency's influenza distribution data has helped hold these companies accountable.
- It was emphasized that many providers receive vaccine through an additional layer of distribution (e.g., through health departments), which slows down the delivery process.
- Summit attendees were reminded that prior to the formation of the Summit, vaccine was shipped first to the largest customers; these practices are changing.
- Immunization Action Coalition's Diane Peterson discussed left-over vaccine. She suggested that children aged <9 years be included in efforts to use excess later-season vaccine; first time vaccinees in this age group who need to receive a second dose would be an ideal target for left-over vaccine. Perhaps this recommendation could be published in CDC's *Morbidity and Mortality Weekly Report (MMWR)* as a Notice to Readers to encourage increased vaccination rates.
- One participant asked distributors and manufacturers about their plans to smooth out the delivery system in light of the ample supply of vaccine expected for the upcoming season. Mr. Van Ostrand noted that at the industry association level, no radical changes in strategy have been made for the 2007-08 season. However, it is critical that the supply stays robust and consistent to enable distributors to ship vaccine in a predictable and timely manner. He also informed Summit attendees that one distributor likely will not be delivering vaccine in the upcoming season, which could potentially create distribution challenges.
- Distributors and manufacturers were asked about whether providers must order a "magic number" of doses during prebooking to ensure timely vaccine delivery. A member of the panel responded that although no specific number exists, it is crucial that demand matches supply. If supply and demand are mismatched, manufacturers produce either too much or too little vaccine; prebooking is a key factor in maintaining this delicate balance. Another manufacturer added that demand for vaccine keeps the process working smoothly; distribution is not the bottle-neck in the supply chain.
- A Kaiser Permanente representative noted that a few years ago, providers were told that vaccine-supply problems would be eliminated with increased supply. However, problems have persisted despite this increased production of vaccine. Perhaps it is not the supply but the timing of vaccine manufacture that is most critical to the distribution process. Efforts should be made to speed up the vaccine production process. Although manufacturers are exploring new production techniques (e.g., plasmid rescue), a significant amount of time is spent waiting for FDA approval. Can the FDA approval process be made more efficient and less time consuming?
- Several Summit participants commented about the FDA's role in vaccine production. One attendee relayed FDA's desire to shorten the timelines while still ensuring vaccine safety and potency. FDA has been working hard to make the approval process and testing more efficient, although new processes would likely only shorten production by a few weeks.
- A vaccine manufacturer representative emphasized that many steps in the vaccine production process can cause delays that create anxiety in the marketplace.
- It was noted that the vaccine supply situation will improve as manufacturers create indications and establish consistent recommendations.

- One participant stressed that speeding up the vaccine production process by two weeks could make a huge difference to providers.
- A Novartis Vaccines representative asked about whether the new centralized distribution system would have an impact on the distribution of influenza vaccine to public health providers. Dr. Greg Wallace responded that the new system, which will be implemented in most states within the next year, likely will speed up distribution to health departments. However, much work must be done over the next few years to ensure optimal operation of the system.
- AAFP's Dr. Andy Eisenberg concurred that shortening the vaccine production and distribution timeline is a good goal. However, he emphasized the importance of eliminating vaccine waste. Efforts to change expectations might help reduce excess doses of vaccine. A perception has been created that the sooner vaccine is given, the better; this is not always the case. Often, influenza incidence does not peak until mid February; a later start to influenza vaccination campaigns (i.e., during November versus October) would alleviate pressure on the supply and delivery chain. Dr. Eisenberg stressed the financial losses that physicians are facing because of the small profit margins associated with vaccination. Perhaps this financial burden can be alleviated by vaccinating later in the season. Dr. Greg Wallace concurred, noting that messages regarding the timing of vaccination are changing; patients should be better educated about the importance of receiving vaccine into November and December.
- Ms. Deborah Kilgo with the Alabama Department of Public Health relayed her health department's experience in educating private providers. In this state, providers historically have relied upon the local public health departments to provide vaccine because of the challenges associated with billing and paperwork. In 2004, when high influenza-related mortality rates were reported among children, demand for vaccine increased, resulting in more visits to local health departments. During the following season, a vaccine shortage prompted the state to pull vaccine from rural health departments to facilitate mass vaccination clinics, at which 25,000 doses of vaccine were administered. To increase physicians' desire to administer vaccine within their offices, the State undertook activities to ensure that these providers pre-booked vaccine orders. However, many providers were left with an insufficient supply, whereas others had leftover vaccine by the end of the season. To eliminate vaccine wastage, perhaps a broker could be positioned to receive vaccine and reroute it to providers who have a need for more doses. Dr. Wallace responded to this suggestion, stating that although creating a vaccine brokerage process would be difficult, efforts are underway to examine this type of system. It was emphasized that many of these activities are being conducted already at the local level.
- Clarification was provided regarding the role of community immunizers in efforts to increase vaccination rates. "Nontraditional" immunizers are routinely vaccinating patients in schools, churches, and other community-based settings into February and beyond.
- A Novartis Vaccines representative commented on vaccine supply. He stressed that manufacturers now are focusing on smoothing out timing issues instead of increasing the number of doses. In 2006, Novartis Vaccines made its first delivery of vaccine in early August, and the company plans to do so even earlier in the coming season. He noted that although Summit attendees have expressed interest in speeding up the production process to ensure early-season delivery, the manufacturing cycle typically requires an entire year. It would be more advantageous and feasible to extend the vaccination season through December. Other manufacturers concurred, noting that adding time before and after the vaccination season is equally important. Dr. Tan responded by reiterating that the Summit

recommends broadening the season instead of extending it, particularly in light of the new recommendations and vaccines for children. Consistency in messaging also is crucial.

- Kris Ehresmann from the Minnesota Department of Health noted that six pediatric influenza-related deaths occurred within Minnesota during the past season, which began later in the year than usual. She has observed that providers who had had a negative experience with vaccine administration at the start of the season were unlikely to engage in late-season vaccination efforts. Many pediatricians refused to order more influenza vaccine for their patients late in the season, despite increased demand, because they had experienced frustration and vulnerability when trying to obtain vaccine early on.
- Ms. Rosalyn Stone with Corporate Wellness commented on the need to broaden the season. She emphasized that many parents take school-aged children to a pediatrician in August for a back-to-school check-up, particularly parents of children who play sports. These parents likely would appreciate being offered influenza vaccine during this visit because it would save them another trip.
- Ms. Annemarie Beardsworth with the Rhode Island Department of Health suggested that the Summit could work to develop creative public messages and ad slogans that coincide with the specific holidays (e.g., “Give your Valentine a flu shot”).

SESSION THREE: DIFFERENT PERSPECTIVES REGARDING VACCINE DISTRIBUTION

Facilitator: Dr. Litjen Tan

IVATS

Mr. Jim Harrison

Mr. Jim Harrison, with CDC’s National Center for Immunization and Respiratory Diseases, updated Summit attendees about the agency’s Influenza Vaccine Tracking System (IVATS), providing them with a spreadsheet that is reflective of the electronic form available electronically to IVATS users.

IVATS was created by CDC for use during the 2006-07 influenza vaccination season in response to the need to better track vaccine availability. The IVATS electronic spreadsheet enables distributors to enter data regarding their current vaccine supply levels; the information available over IVATS is useful for healthcare providers who need to obtain additional doses of vaccine. The system is voluntary, and it is not intended to be used to promote a specific distributor or vaccine product. The IVATS spreadsheet contains several columns that provide vaccinators with critical information, including the date of report, name of distributor, the distributor’s preferred method for vaccine ordering, vaccine availability, and type of vaccine available (by manufacturer and specific formulation). The IVATS electronic spreadsheet also provides immunizers with information regarding when distributors expect to receive new shipments of vaccine.

Maintained and hosted by AMA, IVATS is user friendly for both distributors and healthcare providers. Providers can easily access IVATS data via the Internet (www.ama-assn.org/ama/pub/category/16919.html) by clicking on the hyperlink “Influenza Vaccine for Sale?” Distributors can enter their data electronically by visiting the same website and clicking on the hyperlink “How do I enroll?”

IVATS proved to be a success during last year’s vaccine season, with 64% of distributors participating. Despite this success, CDC is working to modify and improve IVATS for 2007-08. Summit participants

are encouraged to provide feedback regarding IVATS. Suggestions for the upcoming influenza season should be directed to Mr. Jim Harrison at 404-639-8250 (jrh3@cdc.gov).

Overview of Influenza Vaccine Legislation

Ms. Karen Mason

CDC's Karen Mason provided the Summit with an update on recent vaccine-related legislation at both state and federal levels. She emphasized the objective of her presentation, which is to present data rather than express her opinion about the proposed laws. She also noted that data regarding legislation differs by source.

Vaccine legislation has been introduced at the federal level within the past few years. During the 108th Congress (2003-2004), a total of 26 bills were introduced for a wide range of vaccine-related topics, including vaccine distribution and priority groups, biodefense/pandemic vaccines, appropriations, and the use of thimerosal in vaccine manufacturing. Examples of distribution and priority-group bills during this Congress include the Emergency Flu Response Act, the Flu Protection Act, the Influenza Vaccine Emergency Act, the Improved Vaccine Availability and Affordability Act, the Vaccine Access and Supply Act, and FLU-VIA. Biodefense and pandemic-related bills included the Pandemic Preparedness and Response Act, Bioshield, the Seasonal Influenza and Preparedness Preparation Act, and the Pandemic and All Hazards Preparedness Act. Of these numerous bills, only a few were signed and passed (i.e., Bioshield and the Pandemic and All Hazards Preparedness Act); some appropriations bills for flu-related issues also were passed into law, particularly those focusing on the potential influenza pandemic.

In 2005-2006, although the same topics were covered, many more bills were introduced (n=42), and the 109th Congress began to participate more heavily in vaccine-related issues (e.g., through increased numbers of letters sent to CDC from constituents and increased vaccination-associated federal hearings). The 110th Congress has been less active concerning vaccine-related legislation. Thus far, only seven bills have been introduced, none of which address vaccine distribution or prioritization of groups.

At the state level, many bills have been introduced covering similar vaccine-related issues as those introduced at the federal level (e.g., long-term care, thimerosal, and prioritization of groups). In 2003, eight states introduced influenza vaccine-related legislation, only one of which enacted this type of law. The number of vaccination-related bills increased during 2004 and 2005, with 17 and 31 states introducing bills, respectively, and eight and five passing the proposed legislation into law. During 2006, states introduced bills on diverse influenza-related topics, including long-term care, thimerosal, pandemic/bioterror, hospitals, distribution, childcare requirements, teacher vaccination, and health insurance requirements. Of the 35 proposed bills, most dealt with thimerosal (n=23); one thimerosal bill was signed into law. Although several of the same topics were covered in state-based legislation proposed during 2007, additional issues were addressed, including school-based pilot projects, prioritization of providers and patients, Flu Shots for Kids Month, and bulk purchase of vaccine. Thimerosal bills continued to represent the majority of influenza-vaccine legislation at the state level (n=17); to date, none of these bills have passed.

Rationale Behind and Policy Implications of Proposed Legislation

Mr. Andrew Van Ostrand

HIDA representative Mr. Andrew Van Ostrand discussed the rationale behind and implications associated with proposed influenza-vaccine legislation. Distributors have determined that 90 influenza-vaccine-related bills have been proposed at the local and national levels; legislation has been proposed or passed within 35 states. Legislative trends can be observed and have been analyzed by distributors, who have determined that most bills can be categorized into five primary categories: priority distribution for

physicians, priority distribution for public health entities, state bulk purchasing and distribution, increased reporting regulations, and thimerosal regulation or elimination.

Distributors have identified several dangers inherent in the trend towards increased influenza-vaccine legislation. First, a “patchwork” of competing legislation will further complicate an already delicate balance between supply and demand; state-based legislation could compete with public health priorities at the state and federal levels. Sporadic and uncoordinated legislative efforts will likely add cost to the vaccine delivery system; these efforts could result in financial burden for manufacturers and distributors and redirect resources away from groups that have alternate priorities (e.g., the Summit). Uncoordinated legislation also will create a disincentive for companies that are considering entering the vaccine manufacturing and distribution marketplace.

Many stakeholders, including CDC, are working to better inform state legislators about the influenza vaccine production and distribution processes. However, there is an additional need for basic education of the public and healthcare providers. Bills often are created in response to concerns expressed by healthcare providers who have a misunderstanding of the distribution process and by public health agencies that hope to streamline the system. Many pieces of proposed legislation are based on inaccurate information, such as legislation that requires distributors to prioritize vaccine distribution to providers despite the fact that this practice already is being undertaken. The commonly held sentiment that the influenza vaccine delivery system can be revised at the state level (reflected in the increasing number of local vaccine-related bills) must be reversed to ensure a consolidated approach to vaccine delivery in the United States; this type of reversal likely will require action and coordination from CDC and other agencies at the federal level.

Examples of State-based Legislation

Legislation in Rhode Island

Ms. Annemarie Beardsworth

Ms. Annemarie Beardsworth gave an update on the vaccine-related legislation that has been proposed in Rhode Island, which is the smallest of all 50 states and has no local health departments. Rhode Island is a supporter of childhood immunization, as illustrated by its designation as a “universal vaccine” state.

In response to the 2004 influenza vaccine shortage, Rhode Island passed legislation that mandates Rhode Island’s public health department to purchase and distribute vaccine; the bill was strongly supported by local physicians and the Governor of Rhode Island. Although the legislation does not mandate participation by providers, it mandates that specific vaccine-related efforts be undertaken by the state health department. The rationale behind this legislation, which was passed into law during 2006, is primarily to ensure equity in vaccine distribution. The law also will result in cost savings and the creation of a stronger adult immunization infrastructure within the state.

Several initial challenges were faced by Rhode Island’s Department of Health in response to the 2006 legislation. The Department attempted to answer many influenza-vaccine-related questions, including a) who gets vaccine, b) how much vaccine to order, c) who pays for vaccine, d) how to identify providers, e) how to communicate with providers, and f) how to evaluate the program. The health department began by identifying key partners in vaccination efforts (e.g., health insurers, CDC, the Ocean State Adult Immunization Coalition [OSAIC], professional societies, and internal colleagues). Through the support of these partners, the Rhode Island Department of Health developed the Immunize for Life Program, an adult influenza program for a) Rhode Island residents who have some type of health insurance and b) adults working for or insured by a Rhode Island company.

To date, many activities have been conducted to help facilitate the development of Rhode Island's Immunize for Life Program. The program name was determined, insurers were assessed regarding their premiums, vaccine was pre-booked (250,000 doses), a provider database was purchased, an on-line enrollment system was developed, and a distribution mechanism was identified (a third-party distributor is being solicited). In addition, the health department strengthened its partnership with the OSAIC through a contract to help coordinate adult immunization efforts, responded to providers located on the borders of Rhode Island, identified means of coverage for uninsured patients, and determined that participation would be voluntary.

The Rhode Island Department of Health is dealing with many ongoing challenges associated with last year's influenza vaccine legislation. Reimbursement coding has proven problematic, because many insurance companies do not allow providers to administer vaccine for free. The Department also continues to work out vaccine distribution problems, develop appropriate vaccine wastage policies for providers, extend the vaccination season, provide education for providers and the public, conduct a program evaluation, and provide coverage for uninsured persons.

Legislation in Texas

Dr. Andrew Eisenberg and Ms. Claire Hannan

Dr. Andy Eisenberg, a member of the Texas Medical Association and the American Academy of Family Physicians (AAFP), discussed influenza-related vaccine legislation in Texas. Claire Hannan, the executive director of the Association of Immunization Managers also updated Summit members about legislative efforts in this state.

Dr. Eisenberg began by discussing Texas House Bill 1059, which would require school districts to maintain a website containing information for students and parents about student vaccination (e.g., the vaccinations required for school entry and the health clinics offering vaccine). The website would also inform parents and students of the new requirement that influenza vaccination be administered to all students before attending any public school.

Senate Bill 164 calls for the conduct of a study to examine the feasibility of giving physicians and other healthcare providers' priority to receive influenza vaccine before retail establishments. This proposed legislation illustrates that legislative efforts often are based on misinformation; the practice of prioritizing vaccine distribution to retail and other mass immunizers has been found to be a misperception. Despite these findings, however, a recent Texas Medical Association survey revealed that 60% of physicians received insufficient amounts of vaccine, only 20% received all pre-booked vaccine, and 73% were forced to send patients elsewhere for vaccination. Of respondents, 84% were concerned about receiving vaccine in a timely manner, and 51% believed that influenza vaccine should be distributed in the same manner as other childhood vaccines. This common misperception, along with the challenges associated with vaccine distribution (e.g., lack of physician confidence in the vaccine supply, inconsistent vaccine supply, and phased vaccine shipments), must be changed to ensure that legislation remains consistent with public health priorities.

The Texas Resolution is calling on AMA to oversee and guide the creation of an enforceable and efficient distribution system. This system would ensure that physicians and other healthcare professionals who care for high-risk patients receive priority shipments of influenza vaccine. Several mechanisms are currently in place in Texas to help achieve this goal, including electronic vaccine tracking systems (e.g., IVATS). Other programs also have been implemented to improve vaccine coverage to underserved populations, such as state-wide public awareness campaigns (e.g., the "Be Wise Immunize" campaign) and collaborative strategies to promote health and wellness through provider and patient education prevention. Other mechanisms for increasing vaccination rates in Texas are needed for the future (e.g.,

distribution procedures that allow providers to secure vaccine delivery dates and increased physician education regarding the vaccine supply and distribution chain).

As the executive director of the Association of Immunization Managers, Claire Hannan discussed the public health perspective on influenza vaccine legislation in Texas. She began by providing Summit attendees with background information regarding Texas' public health infrastructure. Texas has 254 counties that are organized into 11 health service regions. A total of 65 health departments receive funding through the state health department, and an additional 84 health departments operate independently throughout the state. Texas, which is not a universal vaccination state, has more than 3,000 Vaccines for Children (VFC) providers; insured children living in Texas receive vaccine through private providers, and uninsured, non-VFC eligible children receive vaccine through public health departments that purchase influenza vaccine using federal and state funds.

Ms. Hannan focused on a proposed piece of legislation that will require a study to examine the feasibility of the wholesale distribution of influenza vaccine and establishing a system that prioritizes the distribution of influenza vaccine to physicians and other licensed healthcare providers (i.e., those providing care to high-risk patients) over retail-based immunizers. Many other states have introduced legislation to address the perception that mass immunizers and retail establishments are receiving vaccine before physicians in more traditional settings. Although it is perceived that public health entities can solve distribution-related problems, ensuring equitable distribution of vaccine is a complex issue that can not be addressed solely by public health organizations. From the public health perspective, legislation is not the answer to influenza-vaccine distribution challenges and misperceptions. However, this type of legislation is being introduced in many states throughout the country, and often the bills are inconsistent and based on misinformation; public health representatives are becoming increasingly concerned about the current legislative trend and recognize the need for collaboration to address the issue of equitable distribution and to limit state-based legislation.

Thimerosal Legislation

Ms. Diane Peterson

Ms. Diane Peterson, representing the Immunization Action Coalition, updated Summit participants about anti-thimerosal legislation and the need to ensure that these bills do not become signed into law. She began by giving brief background information about the origin of thimerosal-related concerns in the United States. In 1999, in response to the concern about the cumulative qualities of ethyl mercury that infants receive through vaccination during the first 6 months of life, ACIP and AAP issued a statement encouraging manufacturers and providers to move towards using thimerosal-free vaccines. This recommendation has had a dramatic impact on the public perception of vaccines, which in turn has resulted in increased involvement from policymakers and politicians. Legislators are now making decisions that will detrimentally impact access to injectable influenza vaccine and influence public and provider perception regarding vaccine safety.

By 2004 and 2005, several states had introduced anti-thimerosal legislation; California and Iowa were the first states to enact these laws, followed by Missouri, Illinois, Delaware, and New York. This legislation caught many providers and public health professionals off guard, who had been focusing on increasing influenza vaccination rates among children to reduce morbidity, mortality, and disease transmission. Thimerosal-related legislation is increasing at an alarming rate; by 2006, 23 bills had been introduced across the country, and one bill was passed into law in Washington State. To date, many additional bills have been proposed in 20 states, several of which are still viable (n=6); many more pieces of legislation are expected for the upcoming year.

State laws prohibiting thimerosal differ by age and type of patient and allowable amount of thimerosal. Many of these state-based laws apply to children <8 years of age, whereas others specifically target those

aged <3 years; almost all states with anti-thimerosal legislation, with the exception of Iowa, regulate the administration of thimerosal-containing vaccines to pregnant women. In addition, most of these states designate specific limits for the amount of thimerosal allowed in influenza and other vaccines, ranging from trace amounts to 1.25µg/dose.

Anti-thimerosal laws will compromise vaccine supply and availability. For the 2006-07 influenza vaccination season, 110 million doses were produced; most of these doses contained thimerosal as a preservative and were licensed for use in children 36 months of age. Only a small percentage of thimerosal-free vaccine (approximately 8 million doses) was available during the 2006-07 season.

State legislators and other policymakers face several issues when dealing with thimerosal-related concerns among constituents. Complex communication issues are inherent, because the science behind vaccine safety is not easily conveyed by politicians or understood by the general public. In addition, legislators face intense advocacy from well organized groups of parents and other constituents, who have unanswered questions about autism and the unmet needs of families affected by this developmental disorder.

Public and private healthcare providers and vaccine manufacturers can help deter legislative efforts by partnering to become vocal advocates for safe and effective vaccines. Advocates for influenza immunization also should work to communicate the need for sound public policy based on science.

Influenza Vaccine Distribution

Dr. Jeanne Santoli

CDC's Dr. Jeanne Santoli presented data and discussed issues related to the distribution of influenza vaccine during the 2006-07 season. She began by discussing CDC's system for tracking doses of influenza vaccine.

Distribution data tracking began in 2004-05, the season following a severe vaccine supply shortage. CDC developed this system to better inform state and local health departments about vaccine distribution and to help them manage problems with vaccine availability and supply within their jurisdictions. Although CDC collected data from only a single manufacturer during the 2004-05 season, data collection efforts were expanded in the following years. As of this year, data from all manufacturers and distributors is included in the tracking system and posted on a weekly basis, the data collection and posting period have been expanded to cover the entire season, and some pre-booking data are now included.

Efforts have been made to study trends in the timing of vaccine distribution. Data reveal that during the 2006-07 season, most vaccine was distributed by the end of October. In contrast, during 2000, a significant delay in distribution occurred; only about 30% of the total doses of vaccine were distributed to providers by November 1. Data indicate that manufacturers and distributors have moved towards more timely distribution of vaccine within the past few influenza seasons.

The distribution of vaccine by provider type also has been examined in past influenza seasons. Data indicate that by the end of the season, private provider offices and outpatient settings had received 42% of the total doses of vaccine produced, hospitals had received 10%, and state and local health departments had received 11%. An additional 15% of the manufactured doses were provided to second-tier distributors (i.e., companies that buy vaccine from larger distribution companies and sell directly to providers).

Information also has been collected regarding how influenza vaccine is used. A telephone-based Gallup survey was conducted in 2005, during which adults were asked questions about where they received influenza vaccination. Most adults (39%) reported that they received vaccine at a doctor's office or HMO, 10% received vaccine at hospitals, and 8% were vaccinated at health departments. Although these data

are somewhat limited because they do not reflect persons in long-term care settings, data from this survey are consistent with CDC's vaccine distribution data and other information collected through CDC's Behavioral Risk Factor Surveillance System (BRFSS).

Trends in the timing of vaccine distribution during the vaccination season have been examined by specific provider type. Several providers have received vaccine consistently throughout the last several seasons, including corrections departments and public and private providers and clinics. Hospitals and dialysis centers tend to receive vaccine primarily during mid-season, whereas distributors, long-term care facilities, and pharmacies begin the season with increased amounts of vaccine, but experience decreasing supply as the season progresses. In contrast, federal governments, the Military, and state/local health departments tend to receive a smaller amount of vaccine at the start of the season, but experience an increase in supply by the end of the season.

Efforts have been made to compare vaccine production and distribution. During the 2006-07 season, approximately 120.9 million doses were produced, and 102.5 doses were distributed; leftover vaccine represented unsold doses and doses left over from the prior year's strategic vaccine reserve.

CDC recently has had the opportunity to evaluate how states use the distribution data provided by the agency and to identify ways to improve CDC's system for tracking doses of vaccine. A two-step process was used to evaluate use of distribution data during the 2006-07 influenza season. First, a workshop was conducted to gather qualitative data about how grantees used data and feedback regarding benefits and limitations. An e-mail survey was then sent to FluFinder users to gather information about data use and the benefits and limitations of the current distribution data available on the FluFinder tracking system. Several preliminary results were obtained during this process. Frequency of access to FluFinder was examined, revealing that of 20 grantees, more than 40% reported accessing FluFinder on a weekly basis. The types of analyses carried out by FluFinder users also was elucidated; data indicated that most users (>70%) accessed FluFinder to find information about vaccine supply by type of provider. Other users searched for data regarding vaccine availability by zip code, county, and product type. Of survey responders, two reported using data to redirect patients to settings where vaccine was available, and one grantee reported using data to redistribute doses of vaccine.

CDC has used survey information to determine how distribution data are used to communicate to selected groups. Most grantees reported using data to communicate with local health departments (63%), other providers (59%), and the media (59%). Respondents also indicated that they use distribution data to communicate vaccine supply information to other groups, including coalitions, medical advisory boards, and state legislatures. Most grantees shared data regarding state-level vaccine supplies with health departments, although they also gave local information. Other healthcare providers and members of the media most often were given information regarding state-level vaccine availability and general vaccine supply-related data

Grantees that responded to CDC's surveys provided information regarding other ways in which they use the agency's distribution data. Respondents reported using it to communicate with a provider who expressed concern about vaccines going to community vaccinators, monitor available doses of vaccine for hospitals and local health departments, calculate total influenza vaccine need for adults in future influenza seasons, and locate providers following vaccine-related adverse events. Grantees also provided information regarding their use of pre-book data. Only 18% indicated that they use pre-booking data, and two respondents specified that these data are helpful in determining the scheduling of additional clinics with community partners in the state and in providing additional insight about where vaccine is located within the community.

Several additional suggestions were made by grantees. Survey respondents suggested that more specific provider data would be helpful, particularly regarding the redistribution of vaccine. In addition, feedback

was received regarding the need to a) provide tracking system users with potential approaches to data use and b) provide additional county-level data.

Session Three Discussion

- Dr. Roger Baxter with Kaiser Permanente presented the HMO perspective on partnering. He expressed concern that private physicians are frustrated about retailers and other mass immunizers having more doses of vaccine than providers in more traditional settings. He stressed the need to remember the goal of influenza vaccination initiatives, which is to vaccinate more people; “big-box” retailers administer vaccine to substantial numbers of patients, who might not receive vaccine otherwise. Financial incentives should not serve as the primary motivation behind vaccination efforts. In fact, many retailers routinely administer vaccine at a loss, with the objective of bringing customers into their stores. A Summit participant agreed that the overarching goal of vaccination initiatives is to administer more doses of vaccine. However, several challenges are associated with relying on mass immunizers to administer vaccine (e.g., the inability to track patients who have adverse reactions and the missed opportunity for additional health assessments and communication). Persons who receive influenza vaccine outside of the medical home are missing opportunities for their doctors to provide other crucial preventive services.
- A private physician added that physicians realize that their patients (including those that are healthcare workers) will not obtain influenza vaccine if they are required to see a doctor; instead, these patients agree to vaccination only if it is convenient and inexpensive. The underlying principal to consider when attempting to increase vaccination rates is the need to eliminate barriers to obtaining influenza vaccine. Providers should offer vaccine in the absence of a formal medical visit, because scheduled visits are a barrier to vaccination.
- Kris Ehresmann with the Minnesota Department of Health was asked to further explain efforts to ensure that community vaccinators within her state are properly educated. Ms. Ehresmann remarked that in the absence of adequate doses of vaccine, providers have indicated a willingness to send patients to alternative, nontraditional settings for vaccination; however, referring patients elsewhere is cost-prohibitive and wasteful when vaccine is on order from the manufacturer and has already been paid for. This practice results in excess vaccine wastage at the end of the season. Despite physician’s experiences, however, public health experts are conflicted regarding this issue. Public health professionals understand the value of the medical home and the financial risks that confront private physicians, but they also recognize that vaccination initiatives in nontraditional settings can significantly increase influenza vaccination rates. Relying on nontraditional immunizers also creates a novel opportunity for partnership. Perhaps the practice of vaccination in nontraditional (e.g., retail) settings or by mass-immunizers can be improved by providing these vaccinators with more education regarding vaccine administration, including storage and handling. This type of educational initiative has been undertaken in Minnesota and has resulted in substantial changes in vaccination practices and improved outcomes.
- Dr. Tan emphasized the need for collaboration in efforts to increase vaccine uptake. A report will be submitted to the AMA House of Delegates this summer in which the contentious issues regarding vaccination setting will be discussed. The AMA recognizes that as providers encourage their patients to receive vaccine, they should also tell them that it is acceptable to wait to be vaccinated later in the season. This message from providers could help ensure that patients return to their medical homes for influenza vaccine instead of rushing to receive vaccine in other settings. There is a need for preservation of the “medical home,” which can be achieved through better communication with patients.

- A representative with the American Pharmacists Association expressed concern that pharmacists are being viewed as providing suboptimal care to vaccine recipients. She stressed that pharmacists receive intense training regarding vaccine administration and are required to provide physicians with documentation within 48 hours of vaccination. Pharmacists are not trying to shift the channels through which Americans receive vaccine; instead, they are attempting to increase the number of vaccine delivery channels to ensure that more people are protected.
- AAFP member Dr. Andy Eisenberg noted that as a private physician, he encourages patients to receive vaccination through pharmacists as long as he is not left with doses of unused vaccine. Private physicians do not intend to prevent any provider from administering vaccine; instead, physicians realize the need for preventive care that often is given at the time influenza vaccine is administered. Perhaps physicians throughout the country should focus on improving the way they provide vaccination services within their offices. There is also a need for manufacturers to revise their current policies regarding vaccine buyback and return.
- A Summit participant from Maxim Healthcare stated that last year, more doses of vaccine were produced than ever before, and more people were immunized. A total of 132 million doses are expected for 2007, which indicates that manufacturers are meeting production goals. The participant stressed that although progress is being made towards increasing supply, distribution-related legislation is continuing to focus on past events. Prioritization practices for vaccine distribution should happen only in emergency situations or situations when vaccine supply is limited. For years when vaccine supply is adequate, the Summit should put out statements encouraging all persons to receive vaccine, regardless of high-risk status. Barriers to distribution resulting from legislation will result in the administration of fewer doses of vaccine. He also expressed concern that legislation also will serve as a disincentive for vaccine manufacturers, resulting in the production of fewer doses of vaccine.
- It was suggested that the Summit establish a workgroup to focus on educating legislators regarding influenza-vaccine-related issues.
- A pharmacist with the American Society of Consultant Pharmacists emphasized that pharmacists work in a variety of settings, including assisted living facilities and other types of senior centers. These professionals collaborate with physicians and public health professionals on a daily basis and could serve to better educate patients about the need to receive influenza vaccine. She expressed frustration, however, in the common misperception that pharmacists are not willing to partner in efforts to increase influenza vaccination rates.
- AMA's Dr. Ron Davis stressed the importance of partnership in achieving Summit goals. He also responded to an earlier comment about the financial incentives offered to physicians who vaccinate patient in private offices, noting that doctors make only a minimal amount of money from each dose of vaccine administered; physicians do not typically vaccinate their patients for financial gain, although they do not want to pay for vaccine that is going unused. Dr. Davis emphasized that doctors encourage their patients to receive vaccine in their medical home in an attempt to preserve an already fragmented healthcare system.
- A Summit attendee who works as a private physician and community vaccinator stated that ideally, all patients should receive vaccine from their doctors. However, many providers are unable to meet their patients' immunization needs. Perhaps more patients would receive influenza vaccine in their medical home if vaccination were made more convenient and affordable in this setting.

- Kaiser Permanente's Ms. Laura Peterson suggested that in the face of increasing vaccine supply, it is likely that many different types of vaccinators will be needed in the future, including private physicians, mass immunizers, and those providing vaccine in other nontraditional settings.
- Dr. Tan mentioned that AMA currently is collaborating with the University of California at San Diego and the California Department of Health Services to examine economic models associated with vaccination. Pilot studies will be undertaken in small private practices using different types of economic models to help determine the most cost-effective practices.
- It was stressed that physicians should have access to vaccine. Perhaps physicians with small practices should routinely order vaccine from several manufacturers to ensure that they receive vaccine. Another participant added to this comment, noting that perhaps distribution companies should order from diverse manufacturers to ensure that they receive a sufficient vaccine supply.
- One meeting attendee emphasized the important role that large corporations play in ensuring that Americans receive influenza vaccine. Many companies launch intensive vaccination campaigns and offer vaccine to employees at the workplace because they realize that it is beneficial to invest in preventive health. Dr. Tan responded, noting that a Summit workgroup has been working to examine the administration of influenza vaccine in corporations.
- Mr. Van Ostrand reiterated the need to create cohesive communication and education plans to ensure that legislative efforts do not interfere with the goal of increasing vaccination levels throughout the country. These plans should not only target legislators and other policymakers, but the private physicians and physician groups that often are the impetus behind vaccine-related legislation. Dr. Tan reminded the Summit that as a federal agency, CDC can not participate in efforts to stop legislation. However, the Summit can help organize a workgroup to address legislation-associated issues and develop plans for influenza vaccine education.

SESSION FOUR: INCREASING DEMAND FOR VACCINATION THROUGH PARTNERSHIPS

Facilitator: Dr. Kristine Sheedy

In 2006, the Summit solicited candidates for the 2007 Immunization Excellence Awards to recognize those who have made extraordinary contributions towards improving vaccination rates within their communities. More than 35 solicitations were submitted to Summit representatives, who evaluated candidates based on originality, collaboration, participation, impact, and challenges/opportunities. Winners were selected in three categories: healthcare worker campaigns, late season activities, and overall activities; they were presented with awards at the National Immunization Conference in Kansas City.

During Session Four of the Summit, the winners of the 2007 Immunization Excellence Awards presented specific information about their efforts to increase demand for influenza vaccine. Each presenter shared a unique success story with Summit attendees and participated in a question and answer session.

Community Vaccinator Partnerships

Creating Partnerships to Increase Immunization Rates during the Late Season

Mr. Stephen Allred

Stephen Allred, director and founder of “getaflushot.com,” informed Summit participants about his efforts to increase local vaccination rates in Oregon. The vaccination initiative was launched during January 2006 to help improve late-season (i.e., “winter season”) vaccine uptake by eliminating cost barriers; free flu shots, which were donated by local physicians, were administered to any person who wanted to protect themselves and others from influenza.

Key to the success of the free flu shot clinic was the establishment of a relationship with a local food bank. This organization helped increase project visibility by guiding getaflushot.com organizers in the conduct of public relations activities, including television and radio coverage. The food bank also played a crucial role in eliminating barriers to cost; as part of the vaccination initiative, donations of food or money were accepted in exchange for doses of vaccine, which ultimately benefited both the food bank and vaccinees. No insurance was accepted, and the nurses who administered vaccine as part of the initiative worked as volunteers.

During the first day of the free flu shot clinic, 180 people came to the food bank to receive vaccine; during the following weeks, 45-50 vaccines were administered at clinics placed within local food distribution centers where food was distributed to underserved populations. A total of 625 doses of vaccine were delivered during nine separate vaccination clinics – a stark contrast compared with the average of five shots given per day in the private clinic.

As a result of the free flu shot clinic, many groceries were donated, and more than \$1,000 in cash was collected. In addition, many of the vaccinees expressed gratitude and were surprised to learn that they could receive vaccine as late as January. Similarly, nurse volunteers felt that the experience was rewarding and expressed the desire to participate again in the future.

The free flu shot initiative was successful, because it resulted in the immunization of hundreds of residents of Oregon and Washington, and it revealed that people are willing to obtain vaccine into the winter months. Several challenges were faced, however, primarily problems associated with the legalities of offering vaccine for free; clinic organizers had to agree to offer free vaccine only at sites where vaccine would not be sold in the future. This challenge likely can be avoided in future vaccination efforts through the involvement of CMS.

Organizers of the free flu shot clinic plan to expand the project for the upcoming season. The model used in Oregon can easily be emulated nationwide, particularly during years in which vaccine supply is ample.

Implementing a Mandatory Medical Center Influenza Immunization Program: Insights from Virginia Mason Medical Center

Ms. Beverly Hagar

Ms. Beverly Hagar discussed the award-winning program that was implemented in Seattle’s Virginia Mason Medical Center to increase vaccination rates among healthcare workers. She provided background information about the Virginia Mason Health System. The System consists of a main clinic and a 336-bed tertiary care hospital. The System employs 480 physicians and more than 5,000 full time employees. More than 1 million visits are made to the clinic and hospital per year, 16,000 of which result in inpatient admissions. Virginia Mason strives to be a quality leader by improving the health and wellbeing of their patients. To achieve this objective, in 2002, the System employed the Toyota Production System philosophies and practices and applied them to healthcare (i.e., customer first, highest quality, obsession

with safety, highest staff satisfaction, and successful economics). Medical center employees also participated in a 5-day rapid process improvement workshop. In 2004, in response to literature indicating that immunizing healthcare workers can result in a safer patient environment, Virginia Mason ran three additional rapid process improvement workshops to examine ways to improve the delivery of influenza vaccine to patients and staff. Comprehensive change management methods were also used to engage the organization. Because scientific literature has revealed that voluntary programs to immunize healthcare workers usually are unsuccessful, Virginia Mason Medical Center administrators decided to implement an annual respiratory campaign and a mandatory influenza immunization policy. This Comprehensive Fitness for Duty Policy applied to all staff members working within the facility, including vendors, community volunteers, and contingent labor.

The Fitness for Duty Policy outlines exemptions from mandatory vaccination. According to the policy, staff members can request an accommodation on religious or medical grounds. Requests for policy exemption are evaluated on a case-by-case basis in consultation with representatives from Employee Health, Human Resources, and the medical director of the Virginia Mason Infectious Disease Department. Staff members who are approved are required to wear a mask while at work during the entire influenza season.

To prepare staff members for the new vaccine policy and ensure their support, comprehensive change management methods were used. Management and staff meetings included open forums to discuss the program. Teams used Edward DeBono's "Six Hats" discussion techniques to gather input from staff throughout the organization. In addition, several collaborative efforts were undertaken, including a campaign kick-off "tailgate" party, presentations by Dr. Greg Poland and an expert in ethics, and educational sessions.

The Fitness for Duty Policy and the associated vaccination campaign that was implemented within the Virginia Mason health system are unique and original. The initiative represents the first effort in the country to mandate vaccination among all employees. In addition, Virginia Mason was the first healthcare facility to implement drive-through vaccination clinics for patients and staff. Creative methods were used to publicize the campaign to increase vaccination rates, including creating a partnership with Tully's coffee to promote a "double-shot" campaign, vaccinating celebrities (e.g., Seahawks and Seagals players) during the campaign kick-off, providing lunch for persons attending the kick-off event, and providing take-home souvenirs. Other creative methods were used to promote the program, including a "name the campaign" contest, a teaching video emphasizing the importance of influenza vaccination, peer vaccinators, mobile flu carts, and respiratory kiosks placed on hospital units to promote and support respiratory etiquette and hand hygiene. Staff members also were provided with education modules, quizzes, and a website; prizes were awarded to employees who participated in on-line education.

Several challenges were associated with the influenza vaccination initiative at Virginia Mason. Dealing with the bargaining unit was problematic, as well as managing medical and religious accommodations; conducting allergy screening for patients who were unaware of their allergy status also was difficult. Administrators of the vaccine campaign also were required to debunk many common myths associated with influenza vaccination, and they faced logistical challenges when attempting to vaccinate more than 5,000 persons in a limited timeframe.

Maryland Elementary School Influenza Vaccination Project

Mr. Greg Reed

Mr. Greg Reed discussed Maryland's award-winning project to increase vaccination rates among school-aged children. He provided Summit attendees with background information, the model used in the initiative, results, and lessons learned.

During the 2005-2006 influenza season, Maryland undertook two pilot programs to vaccinate children in school settings; these programs yielded successful results, which served as the justification for the implementation of a state-wide, school-based vaccination project during the following season. Although the school-based initiative would be based on previous efforts, several caveats were outlined by the State of Maryland: a) the project would target children aged 5-11 years; b) the vaccine would be available free of charge to the parent, school system, and local health department; and c) the project would begin during the 2006-07 influenza season.

Beginning in April 2006, Maryland's public health department began to work to provide project oversight and coordination to help meet the objectives and conditions set forth by the State. Perhaps most challenging was the requirement that the influenza vaccine be made available free of charge. To address this challenge, the health department sought help from vaccine manufacturers and identified other sources of funding; by August 2006, MedImmune had committed to provide doses of FluMist[®], the State of Maryland had purchased vaccine for the project, CDC had committed to providing FluMist[®] to children receiving immunizations through VFC, and the Maryland Partnership for Prevention and AAP had agreed to provide additional support. Also key to the success of the project was ensuring that each local health department within the State agreed to provide support through dedicating human resources; by the time of project implementation, each of Maryland's 24 local health departments had agreed to actively participate in the state-based program. Finally, as the project was implemented, local physicians volunteered to participate in vaccine administration efforts in exchange for free doses of FluMist[®], which they later administered free of charge to their patients.

The Maryland school-based vaccination project was based on previous pilot projects that employed two different models. For one of the pilot projects, vaccine was provided to school-aged children on the school's campus after normal school hours (i.e., on weekends and evenings). Parents were informed about the influenza vaccination clinics in advance, and they were asked to provide on-site consent on the day of vaccine administration. Although this model resembles that used for other types of mass vaccination campaigns, it differs in that the school is used as the vehicle for communicating with parents about the need to vaccinate and informing them of the upcoming on-site clinics. Through this model, most parents felt comfortable bringing their children back to the familiar school setting to receive vaccine. Several advantages are associated with this model; for instance, because vaccine is offered after hours, the project did not interfere with classroom instruction. The disadvantages of this model were associated with vaccine delivery during the clinics; at times, inadequate staffing levels resulted in long wait times for vaccinees and their parents.

The second model used for the pilot projects resembled a more typical school-based campaign. As part of the pilot project employing this model, students were vaccinated at school during school hours by local health department employees. Although more typical, this model required a substantial amount of planning. For instance, consent forms had to be sent home to parents through the school and returned on time by the students; distributing, tracking, evaluating, and verifying these forms proved to be time consuming. Other challenges also were associated with use of this model, including loss of classroom time. Advantages to this model were easier access to the population of vaccinees and a more predictable stream of patients (resulting in less staffing demand and increased efficiency).

Final results from Maryland's state-wide, school-based influenza vaccination effort are still being determined, although some preliminary information has been gathered. Data reveal that many of the local health departments vaccinated a substantial number of children in the targeted age group; vaccination estimates range from 30% to >40% of school-aged children. The project was well received in the state; it was strongly supported by local health departments, school systems, and parents. Feedback from parents revealed that they were pleased that the vaccine was offered free of charge; many admitted that they would not have paid to have their children vaccinated for influenza. In addition, most parents indicated

that they preferred the model in which vaccine was offered during school hours, because it eliminated the need for parents and students to return to school on evenings or weekends.

Several lessons were learned through implementation of the school-based influenza vaccination project in Maryland. First, the State faced an unanticipated, yet substantial amount of resistance from private providers. Although the local AAP organization was involved in the project before it was implemented, many private physicians felt that the state was interfering with their practices by taking away their school-aged patients. Many physicians expressed frustration with the financial loss that they would face when left with unused vaccine that had been pre-ordered for their patients. They were also concerned about the future impact of this program and inquired whether the State planned to conduct the program every year; they asked for guidance regarding the number of doses to order for their patients. In response to this feedback, the state health department involved thousands of local physicians in the project in exchange for free doses of vaccine to provide to their patients.

Additional valuable lessons were learned, including the importance of proper advance planning. Because each individual school operated in accordance with its own set of bureaucratic procedures, the health department often faced logistical obstacles before the clinics could be implemented. The need to develop clear guidance materials (e.g., consent forms and educational materials) also was realized as the project was undertaken. Although the state health department tried to ensure that the paperwork that would be distributed to parents and students was accurate and user-friendly, local lawyers who reviewed these materials made substantial changes. Also challenging was the group of parents who were “anti-vaccine;” these parents often were extremely vocal about their vaccine-associated attitudes, at times involving the media to help spread their messages. Project organizers had to put substantial amounts of effort into balancing these messages by creating a media campaign to provide parents with accurate public health information.

As the project was implemented, the importance of school nurses was recognized. These school staff members were valuable to the entire effort, often coordinating the distribution of thousands of consent forms and other materials, reviewing consent forms, and serving as the point of contact for parents who had questions and concerns. Nurses and other volunteers also are critical to the success of any type of school-based vaccination initiative. For the Maryland project, these volunteers, who were participants in the State’s Emergency Preparedness Team, were utilized to test the effectiveness of this system in bringing together volunteers to achieve a specific public health objective.

Maryland’s health department currently is making decisions about how the project will be implemented in the upcoming influenza season. Most likely, the state-wide effort will not be duplicated; however, many local health departments have expressed an interest in carrying out a similar program within their jurisdictions.

Session Four Discussion

- Dr. Ray Strikas asked Ms. Hagar about the vaccination campaign initiated at Virginia Mason. He asked for clarification about the 98% compliance rate. Ms. Hagar clarified that 2% that were not vaccinated because it was decided that they were exempt from the requirements based on religious beliefs or medical contraindications. These persons were required to wear masks throughout the influenza season.
- Dr. Strikas posed a question for Mr. Reed, asking whether data collected during school-based vaccine clinics were reported back to the Maryland Registry or to individual providers. Mr. Reed indicated that parents were given a receipt after their children were vaccinated to serve as documentation. Data are still being collected from providers who received free influenza vaccine.

- Dr. Eisenberg with the Texas Medical Association asked Mr. Reed about data concerning the association between influenza vaccination and absenteeism. Mr. Reed responded that during the initial pilot projects, findings indicated that increased vaccination coverage in the school setting resulted in reduced absenteeism; these data served as a justification for state-wide expansion.
- Dr. Eisenberg asked Ms. Hagar about the requirement that unvaccinated healthcare workers wear masks. Specifically, he asked about the length of time that these persons were expected to wear them. Ms. Hagar noted that all staff members were given a time frame in which they had to receive vaccine. Staff members who were not vaccinated by the deadline were either terminated or required to apply for an exemption. The hospital's infectious disease doctor and the Medical Director of Employee Health were responsible for determining specific cut-off dates for masking requirements. These experts communicated with the local health department to determine when influenza activity had ceased in the community. Last year, this date was May 19; this year, workers could unmask on April 17. Ms. Hagar stressed that it was difficult to handle the masking requirement; many complaints were received from staff members. However, this year, the rate of vaccine uptake improved, likely because many employees who had been required to wear a mask during the previous influenza season decided to get a flu shot.
- A representative from MedImmune stressed the need for determining the role of healthcare worker vaccination in reducing rates of nosocomial influenza. In a previous study, increased rates of influenza immunization resulted in "plummeting" rates of nosocomial disease. It is crucial to evaluate this type of outcome. He also discussed the issue of volunteerism, noting that because Americans inherently embrace this concept, perhaps volunteers should be relied upon more heavily in influenza vaccine campaigns.
- Ms. Hagar was asked about how hospital administrators chose the type of vaccine to be offered to employees. Ms. Hagar responded that because vaccination was mandatory at Virginia Mason, it was felt that employees should be given options regarding the type of vaccine they received. Staff members were offered FluMist[®], thimerosal-free vaccine, and other types of influenza vaccine.
- A representative from MedImmune noted that more than 414,000 American children have been vaccinated in a school setting. He stressed that most children were accepting of the vaccine, particularly because it was offered in an intranasal formulation. He also emphasized that several studies indicate that school-based influenza vaccine initiatives result in decreased absenteeism; this data could be leveraged as a selling point, or incentive, to school administrators, particularly because most public schools are reimbursed based on attendance rates.
- A meeting attendee posed a question for Greg Reed. He asked about why the coverage rate was only 40% and asked whether the lack of an official ACIP or AAP recommendation for influenza vaccination in this population negatively impacted acceptance rates. According to Mr. Reed, the lack of formal ACIP recommendations likely did not affect parents' attitudes regarding the need to obtain vaccine for their children. In addition, local doctors were supportive of increased vaccination efforts targeting children in this age group.
- Mr. Reed was asked about which vaccine was offered to children that had contraindications to FluMist[®] vaccine. Mr. Reed noted that all consent forms were reviewed by school nurses and local health department personnel; children who had contraindications for FluMist[®] were

given the option of receiving inactivated vaccine within the school setting. In some cases, these children were referred to a more traditional clinic.

- Ms. Hagar was asked about the percentage of employees who were terminated as a result of vaccine refusal. Ms. Hagar responded that seven employees were terminated, none of which pursued legal action. She also answered a question regarding vaccine tracking at the hospital, noting that a software system was used to determine compliance. Supervisors used these data to follow-up with employees who had not yet received vaccine.
- Claire Hannan, who is a mother living in Maryland, provided feedback regarding the Maryland school-based influenza vaccine initiative. She took her children to be vaccinated at the school outside of school hours as part of the initiative, and she was impressed with how well the clinic was organized. As part of the project, parents were sent e-mails from the school's principal about the need to vaccinate; many of the parents who were unable to attend the school-based clinic took their children to physicians' offices to be vaccinated, which resulted in increased vaccination rates.
- A Summit participant asked Mr. Reed why the state-based program is not being planned for the upcoming season. According to Mr. Reed, financial limitations have rendered the project unfeasible. Summit members stressed the need to advocate for increased funding for these types of projects and to help identify available revenue streams.
- Ms. Hagar was asked about the funding associated with Virginia Mason's vaccination initiative. Ms. Hagar informed the Summit that the entire campaign was done on a "shoestring" budget (i.e., only \$8,000 for the second year). Money and other resources were obtained through creative efforts. For example, many hospital-based doctors donated prizes that helped keep the campaign going.
- Mr. Reed was asked about how second doses were administered to children participating in Maryland's school-based campaign. He responded that children needing a second dose were rescheduled to receive doses at later clinics.
- Ms. Hagar was asked about patients' responses to seeing masked healthcare workers. According to Ms. Hagar, masked workers communicated with patients using a script developed by the hospital's communication department.
- Mr. Jim Bender posed a question for Ms. Hagar, asked about the non-monetary costs associated with Virginia Mason's program (e.g., the time dedicated by staff members for training and planning). Ms. Hagar stressed that the success of the program can largely be attributed to top management support and buy in; management acknowledged that project planners would need to invest time in this effort.
- One meeting attendee asked whether physicians in Maryland were indeed left with doses of unused vaccine as a result of the school-based vaccination project. Mr. Reed informed the Summit that this information has not yet been collected. However, anecdotal evidence suggests that physicians were vaccinating more children than they anticipated because of the increase in community awareness regarding the need to vaccinate school-aged children.
- It was suggested that for future school-based vaccination campaigns, private physicians could be even more involved in the program. Local pediatricians could participate in vaccine efforts in schools and be allowed to submit insurance claims for those children who have coverage.

- In light of further expansion of the FluMist indications to children aged >1 year, one participant asked Mr. Reed whether future school-based efforts could also target children in younger age groups. Mr. Reed agreed that there is a need to vaccinate this population; many siblings accompanied their older brothers and sisters to after-hours vaccination clinics, indicating that this population might be easily accessed.
- It was noted that many years ago, it was routine for physician and state organizations to offer vaccine through clinics located at the state capitol in an effort to increase awareness. However, these physicians were faced with similar CMS-related challenges as those experienced in the Oregon-based initiative to provide free vaccine at local food banks.
- One attendee commented on the Summit's immunization award process. He noted that vaccination projects should be evaluated not only on originality, but on sustainability. Projects that can be easily implemented in future influenza seasons should be rated higher than those that are shown to be of limited use in upcoming years. In addition, award administrators should evaluate projects on the basis of applicability to wider settings. It is also crucial that award recipients report back to the Summit regarding the way their projects have evolved. Dr. Tan clarified that candidates for the 2006 Summit Immunization Awards were evaluated on the basis of sustainability and creativity.
- Mr. Reed was asked about whether teachers were vaccinated as part of Maryland's school-based campaign. According to Mr. Reed, teachers were not offered vaccine. Another Summit participant emphasized the importance of vaccinating school system employees, an effort that results in less absenteeism and better community health.
- A question was posed regarding whether Maryland high schools have been interested in offering similar school-based vaccination programs. Mr. Reed reported that many jurisdictions have shown an interest.
- It was noted that the types of projects conducted by the award recipients are "infectious." Projects done on a small scale will have a substantial effect downstream.
- Dr. Tan suggested that for the Maryland school-based initiative, family physicians could be brought in to participate in the clinics by providing vaccine to parents.
- Dr. Tan emphasized the need to further involve private family physicians in future efforts to increase vaccination rates. It is also crucial to involve nurses in vaccination campaigns. Dr. Tan asked Ms. Hagar for insight about why nurses have been hesitant to participate in vaccination efforts. Ms. Hagar responded that nurses, particularly those who are older, tend to be misinformed about the influenza vaccine; others are opposed to being "forced" to do anything. Therefore it is critical to provide these staff members with up to date information about the benefits of vaccination; healthcare workers should take responsibility for educating each other to achieve optimal vaccination rates in their workplaces.
- One Summit participant commented on the private-physician-related challenges associated with Maryland's school-based project. He stressed the need for private doctors to be involved early in any state-based initiative, and noted that despite early involvement, some physicians might remain opposed to any vaccination effort conducted outside of the medical home. To ensure the success of any non-traditional vaccination campaign, the support of these physicians must be enlisted. In Maryland, the AAP recently instituted a questionnaire-based study to uncover physicians' attitudes regarding vaccination within non-traditional settings.

Although data from this survey are not currently available, perhaps the Summit can be updated at a future meeting.

- A representative from the Utah Department of Health posed a question for Mr. Allred. She explained that her local coalition discussed implementing a similar program to make use of excess late-season vaccine. However, the coalition was met with challenges from local providers. Providers who still had vaccine available at the end of the season were concerned that if vaccine were to be offered free of charge elsewhere, they would be left with unused vaccine and suffer financial loss. This representative asked Mr. Allred whether this challenge was faced by coordinators as they conducted the free vaccine clinics in Oregon; she also asked where vaccine was obtained for use in the program. Mr. Allred responded that the vaccines used in the free clinics were obtained by the group of physicians that sponsored the campaign; all of the doses were left over vaccine that would have been discarded or returned for excise tax credit. He also explained that local physicians were not concerned that their doses of vaccine would go unused, because many of these doctors already considered their unused, late-season doses to be “wasted;” they did not view the free clinics as competition.
- Kris Ehresmann from Minnesota provided comments regarding the Virginia Mason initiative. She voiced frustration about healthcare worker vaccination in Minnesota and noted that perhaps misinformed nurses should be provided with better influenza-vaccine-related information. Immunization is not taught in nursing or medical schools, and these professionals must be better educated. It would be advantageous to involve the nursing community in immunization-related efforts; perhaps nurse educators could be invited to the next Summit.
- An AAFP representative echoed comments about the need to involve local pediatricians in any community effort to increase vaccination rates. Private physicians must be prepared for any potential decrease in vaccine demand to ensure that they do not overbook. AAFP members acknowledge the need to provide vaccine in non-traditional settings, but they would like to be kept better informed.
- Ms. Peterson with Kaiser Permanente suggested that large-scale publicity programs could be held to increase late-season vaccination rates; in addition, vaccine could be donated to school-based and other community-based programs. However, large vaccine purchasers (e.g., Kaiser and other HMOs) often remain unidentified or face barriers to donating their unused vaccine. For instance, Kaiser Permanente’s pharmaceutical contracts prohibit the company from donating. The Summit should work to identify these barriers and increase awareness and tracking of large numbers of available doses. Although Dr. Tan concurred, he noted that last season, Maxim Health Services donated 50,000 doses. Several opportunities for vaccine donation exist.
- Diane Peterson with the Immunization Action Coalition and the Minnesota Coalition of Adult Immunization voiced her appreciation to Summit organizers for providing attendees with success stories. She stressed the importance of learning how vaccination rates are increased on the front line. Ms. Peterson also reminded meeting attendees of the Summit website (www.preventinfluenza.org); all meeting materials will be available via the internet in the near future.
- Ms. Bonnie Thomas with Colorado Wellness addressed the previously raised issue of cost as being a barrier to vaccination. She informed attendees that Colorado’s statewide coalition purchases several thousand doses each year; members of the coalition request a specific number of doses for their clinics, and nurses at these clinics then make decisions regarding

which patients to vaccinate free of charge based on need. This system ensures that free vaccine is available throughout the entire community. Dr. Tan suggested that more information about these types of initiatives be linked to and made accessible through the Summit website.

SESSION FIVE: INCREASING VACCINATION COVERAGE THROUGH OTHER ACTIVITIES

Facilitator: Dr. Gina Mootrey

Systems to Assess Influenza Coverage

Mr. James Singleton

CDC's Mr. Jim Singleton provided an overview regarding the systems CDC uses to assess influenza coverage across the country. He began by emphasizing the value of having an assessment component for any public health activity and the importance of answering several vaccination-specific surveillance questions, including a) what proportion of persons are vaccinated, b) what groups are undervaccinated, and c) what are the facilitators and barriers to vaccination?

A variety of assessment platforms are used to examine influenza-vaccine coverage. To gather data regarding the vaccination of young children, CDC employs the National Immunization Survey (NIS), which is a telephone survey conducted among parents of children aged 19-35 months. During the interview, parents are asked for information regarding their child's healthcare provider and are asked to grant consent for survey administrators to contact these physicians. If consent is given, survey administrators mail surveys to providers requesting information regarding types and dates of vaccinations for each patient. These provider-reported vaccine histories are then used to estimate vaccine coverage. Data collected through NIS enable the estimation of vaccination coverage for more than 56 geographical areas, including all 50 U.S. states, and help measure progress towards *Healthy People 2010* objectives. NIS data for the past several influenza seasons indicate that vaccine coverage among children aged 6-26 months is increasing.

Recently, CDC also began to use NIS to collect information about immunization coverage among U.S. teenagers. In 2006, an NIS survey was conducted among the same group of parents that participated in the infant-based surveillance effort; these parents were also asked whether they had a child aged 13-17 years of age and whether they would agree to allow survey administrators to contact their child's healthcare provider. Providers were then asked for information about their patients' last three influenza vaccinations and about their patient's asthma status. CDC plans to conduct the NIS-Teen study annually.

Another survey employed to collect vaccination data is the National Health Interview Survey (NHIS), which consists of household, face-to-face interviews of the civilian, non-institutionalized U.S. population. The interviews, which are conducted by employees of the U.S. Census Bureau, are conducted among one sampled adult and one child in each household; all responses are self-reported. The NHIS enables the estimation of national levels of vaccine coverage and helps measure progress towards the *Healthy People 2010* objectives, specifically those pertaining to the vaccination of adults.

NHIS has been enhanced over the past few years. The system now allows the estimation of vaccine coverage by season, monitors vaccination throughout the extended vaccination season, enables estimates to be made for children, and enables data to be coordinated with that obtained by the National Center for Health Statistics (NCHS).

The CDC-directed Behavioral Risk Factor Surveillance System (BRFSS) is a state-based telephone survey conducted each year; the survey is completed by one randomly selected adult per household. BRFSS is unique, in that it provides estimation of vaccine coverage at the state level; each year, states include questions that specifically address influenza vaccination. BRFSS also collects information regarding patient indications, including asthma, diabetes, heart disease, and pregnancy. The System has recently been enhanced and will facilitate the monitoring of season-specific vaccination data throughout the extended influenza season. Optional modules, which are supported by CDC, also can be used by states to collect additional data; these modules enable data collection regarding the setting where vaccine was received, influenza-related high-risk conditions (available in 2008), and healthcare worker status (also available in 2008).

BRFSS has been used during past influenza seasons to facilitate the rapid assessment of vaccination levels; for instance, the system was used to examine vaccination levels of children in the 2004-05 influenza season, in which children experienced increased morbidity and mortality. The survey's flexibility enabled situation-based modifications, including asking parents for additional information about their children. In some areas, the system also has been used to collect data for adults aged ≥ 65 years.

Vaccination coverage data for the institutionalized U.S. population, including those persons living in long-term care facilities and nursing homes, has been collected using other surveys. Progress towards the *Healthy People 2010* objective that addresses vaccination in this group of people has been measured by the National Nursing Home Survey (NNHS); the survey revealed that in 1999, 66% of persons living in these institutions had received influenza vaccine. Information regarding vaccination coverage among healthcare workers in institutionalized settings is also measured. In 2004, the National Nursing Assistant Survey, which is a supplement to the 2004 NNHS, collected vaccination-specific data for these providers. Finally, the Medicare-sponsored Nursing Home Compare enables web-based access to vaccination coverage data for specific nursing homes across the country.

CDC plans to rely on additional, one-time surveys to provide vaccine coverage data for the upcoming 2006-07 influenza season. CDC will use the NIS Adult Survey to obtain age and race/ethnicity-specific data regarding vaccination levels. The National Survey of Children's Health (conducted by NCHS and sponsored by HRSA) also will be employed. The survey, which will include approximately 26,000 children aged < 18 years, will enable the analysis of influenza vaccination data by age and high-risk status.

Several challenges are inherent to assessing influenza vaccine coverage levels. First, the current systems provide seasonal estimates 14-19 months after the end of the season; ideally, flu coverage should be monitored during the season, with estimates available before the start of the next influenza season. In addition, although NHIS enables coverage to be tracked for children aged 3-17 years, the validity of parental reports of influenza vaccination is questionable. NHIS also does not ascertain specific information regarding healthcare workers or whether patients are pregnant during the influenza season.

The current assessment systems have additional limitations. No system currently provides estimates for out-of-home caregivers of young children or household contacts of high-risk persons. In addition, state-specific data are only available for certain populations (i.e., children aged 6-35 months [NIS] and adults [BRFSS]), and county or local-based data are limited to a few selected areas included on NIS and BRFSS.

National Influenza Vaccination Week (NIVW), Summit Awards, and Other Activities to Increase Vaccination Coverage

Dr. Kristine Sheedy

CDC's Dr. Kristine Sheedy discussed events that have been held to increase influenza vaccination coverage, focusing primarily on CDC's National Influenza Vaccination Week (NIVW) initiative that was held during the week November 27th, 2006.

The concept for NIVW originated during early November of 2006. CDC envisioned creating an annual media campaign to help raise awareness of the importance of influenza vaccination and of continuing vaccination throughout the extended influenza season; the agency planned to develop partnerships to assist in planning and implementation. Staff members in the Office of Health Communications within CDC's NCIRD, in collaboration with other experts, identified several messages that would be key to this type of campaign. Communications experts agreed that the public would need to be made aware that influenza is a serious disease, vaccination is the best way to prevent influenza, vaccination supply was expected to be high, everyone wishing to avoid influenza should get vaccinated, vaccine is effective and recommended through the winter months (when disease incidence typically peaks), and vaccination helps protect not only individuals but entire communities. Providers also would need to be reminded that they should vaccinate anyone seeking vaccine, regardless of whether patients are at increased risk.

NIVW planning took place in less than four weeks. On November 6, 2006, HHS and CDC formally agreed to support the initiative, and immediately thereafter, partners were brought on board (e.g., NACCHO, ASTHO, AIM, and the Influenza Vaccine Summit). A press briefing to announce NIVW was held November 13, and announcements were made through CDC's *MMWR*, HAN, the Summit newsletter, and the Internet. Campaign materials were then created and pitched through diverse media outlets, including television and radio public service announcements (PSAs), print advertising, and posters. In addition, meetings were held with three major television networks in New York City, all of which agreed to run PSAs during NIVW and beyond.

Other media efforts took place to increase public awareness of the upcoming NIVW initiative. CDC partnered with the National Foundation for Infectious Diseases to conduct a satellite media tour with Dr. Agwunobi, which was held on November 16th. To help provide additional information about events that would be held during NIVW, CDC created an on-line calendar, which could be accessed and updated by federal, regional, and state/local health departments; the agency also ensured that providers were up to date by distributing "Dear Colleague" letters that provided them with specific guidance regarding potential vaccine shortages during NIVW. Finally, the agency used "new media" to increase awareness, including CDC's home page, a snowman "graphical bug," podcasts, and webinar (for blog writers).

During the first day of NIVW, HHS held a press conference to kick off the campaign. The conference was followed by radio and television advertisements, which were played in 96 markets that covered approximately 67% of the U.S. population; these radio and television ads resulted in more than 156 million audience impressions. Influenza vaccination awareness also was increased through print advertisements, which ran in the November 28th issue of *USA Today* and reached a potential audience of 2.2 million readers. During the week, CDC spokespeople also conducted radio interviews in English and Spanish, and a Summit newsletter was distributed on a daily basis.

CDC's Hotline number was included in all media efforts conducted during NIVW, which allowed for a comparison of the frequency of telephone and e-mail inquiries received during NIVW versus other weeks during the influenza season. An analysis of these calls and electronic inquiries revealed that interest in influenza vaccination peaked dramatically during NIVW; most inquiries were from people wanting additional information about where influenza vaccine could be obtained.

The impact of NIVW was also evaluated in other ways. Before the initiative was implemented, several assumptions were made regarding campaign objectives. It was determined that the goal of NIVW would be to change the way people view the timing of influenza vaccination; because changes in awareness and understanding typically occur before actual behavior changes, it was understood that this goal likely would require multiple years of intensive media efforts. Therefore, NIVW organizers aimed to evaluate the level of public awareness resulting from the campaign instead of vaccination levels.

CDC created a specific approach to evaluating NIVW. The agency planned to conduct surveys to evaluate awareness of NIVW and collect self-reported activities from public health officials, private providers, and others. In addition, surveys to assess awareness among the public were planned, along with surveys to obtain baseline estimates of annual vaccination (including timing).

In January 2007, CDC followed through with its evaluation plan by conducting a national survey of adults. This survey employed a random-digit dial telephone sample (n = 1,247) and a web-based panel (n = 1,290); 70% of respondents were white, 50% were male, and 50% were aged ≥ 18 years. Survey data revealed that 24% of the telephone-based respondents and 9% of those who responded via the Internet had heard of CDC's NIVW initiative.

NCIRD's Immunization Services Division also employed an e-mail survey of state immunization programs to facilitate campaign evaluation. The survey indicated that almost all state programs were aware of NIVW; however, 34% responded that they did not take any special actions to promote influenza vaccination during this week, likely because of the short time frame in which the public awareness campaign was promoted. However, 45% of these programs promoted the program and collaborated with private providers, and 40% responded that they conducted promotional or media activities during NIVW.

In addition to surveying state immunization programs, CDC contacted NACCHO to conduct an e-mail survey of local public health officials. A total of 54% of these officials responded, and of these respondents, 96% were aware of NIVW. Most reported that they had heard of CDC's campaign through state health departments and CDC, although others were made aware through professional organizations, television and radio, and print media. Survey results reveal that 57% of local public health officials did not engage in any additional activities to promote NIVW during the designated week. However, 23% conducted extra clinics, and 23% held promotional and media events.

The American College Health Association was also contacted to participate in a web-based survey to help evaluate the NIVW campaign. Although only 8% of Association list-serve members participated, 56% of respondents indicated that they were aware of NIVW; most college health professionals heard about NIVW through professional organizations and local health departments. NIVW prompted college health professionals to hold extra clinics (15% of respondents) and conduct additional outreach (13%). In addition, 10% of survey respondents reported vaccinating persons who typically are not vaccinated.

Through the evaluation process, feedback was received regarding ways to improve the NIVW initiative in future years. The following suggestions were received:

- Provide more notice of NIVW
- Consider an even later time for the week
- Distribute a communication packed with CDC messages for distribution to the public
- Provide a way for public health departments to share creative ideas for raising public awareness
- Create PSAs for prime-time television
- Ensure that timing-related messages from CDC are consistent
- Schedule the week consistently from year to year
- Clarify the purpose of the NIVW campaign (e.g., increasing awareness versus providing vaccinations)

CDC realizes the importance of beginning to plan for the 2007 NIVW. In addition, the agency recognizes that the initiative must be collaborative, involving many diverse partners.

In addition to NIVW, other activities have been planned to help increase awareness regarding the importance of influenza vaccination and to increase later-season vaccination rates. The National Influenza Vaccination Summit has formed a team that is focusing on increasing public awareness to help extend the vaccination season. In addition, the Summit has begun to formally recognize innovative vaccination campaigns through its Immunization Excellence Awards.

Messaging to Increase Coverage

The Public Perspective

Dr. Glen Nowak

Dr. Glen Nowak, CDC's Director of Media Relations, discussed the messaging used by the agency to increase influenza vaccination coverage. His presentation focused on three facets of communications: consumers, media, and messages.

During 2006-2007, two studies (a random-digit-dialed [RDD] survey of 1,247 people and a web panel survey of 1,290 people) were conducted to gather information regarding influenza vaccination behaviors; approximately half of the respondents were male, and most respondents were white. The RDD survey revealed that 43% of respondents obtained a flu shot during the 2006-07 season, and 36% of the web-based respondents had done so. Among web panel respondents, whites were more likely than Hispanics to receive vaccine, although no significant racial differences were observed among respondents participating in the RDD. For both studies, respondents aged ≥ 65 years were more likely than any other group to seek vaccination. All respondents were asked about influenza vaccination over the past 5 years; data indicated that three different types of people exist: people that fervently believe in the vaccine, those that fervently do not believe in the value of the vaccine, and those who weigh current seasonal trends to determine whether to obtain vaccine.

The 2006-2007 studies revealed that about one third of respondents believed it was very likely that someone like themselves would get seasonal influenza. In addition, most respondents (76%) believed that seasonal influenza can lead to severe health consequences. However, most respondents indicated having no strong or significant concern about getting ill with seasonal influenza; females were more likely to have a concern, as well as married persons and those aged ≥ 65 years. Survey respondents also provided reasons why they chose not to obtain vaccination; most failed to seek vaccination because they did not believe they needed it. Others believed that the vaccine didn't work, that the vaccine makes patients sick, and that it is cost prohibitive.

Survey participants were asked about prior patient-provider discussions regarding influenza vaccine. Most (slightly more than half) revealed that they had not discussed influenza vaccination with their healthcare providers during the influenza season, whereas one third indicated that they had engaged in this type of discussion. Both surveys also asked participants to list actions they would take to help prevent the spread of an influenza pandemic. The following top four measures were identified most frequently: washing hands, staying home, maintaining good hygiene, and getting vaccinated. However, a substantial percentage of respondents (18%) indicated that they did not know what measures to take to prevent influenza transmission.

The media's role in influencing influenza vaccination behavior also is being investigated. A recent content analysis of about 23,000 media stories has revealed that negative information about the influenza vaccine (e.g., insufficient supply and increased influenza-associated morbidity and mortality) attracted

more media coverage than did those events that were positive. The content of seasonal influenza-related news messages has also been examined. A study conducted of the past several influenza seasons revealed that much information is distributed through the media, particularly regarding the timing and availability of vaccine and the places where vaccinations are being offered. This survey also revealed that for these consecutive seasons, media coverage concerning influenza vaccine decreased dramatically after the first week of January, indicating that media efforts should be stepped up during January and February to help facilitate increased demand for late-season vaccine.

The media has been engaged in several efforts to increase public awareness regarding influenza vaccination. For instance, on March 22, 2007, CNN ran a story called “Five Flu Myths Debunked.” Through this media, a reporter identified common myths (e.g., influenza vaccination can give patients a mild form of the flu) and then provided accurate information to viewers.

Communication experts have identified several influenza vaccination messages that could be provided to the public through various media outlets. Effective messaging would include the following statements: a) everyone should get an annual vaccination, b) all children between 6 months and 18 years of age should receive vaccine each year, and c) the more people who are vaccinated, the more people who are directly and indirectly protected from influenza. These messages can be strengthened even further by highlighting the specific health benefits of influenza vaccination, particularly for individuals and their families and loved ones, as well as healthcare professionals. Other communications principles should be considered in crafting influenza vaccine messages. For instance, although health professionals seek to prevent illness, most people seek to “avoid illness.” In addition, health advocates must be mindful that “influenza viruses drift, influenza viruses shift, and influenza viruses can cause “rifts” (i.e., much of the factors that affect consumer interest and demand for vaccine is beyond the control of health experts).

The Private Perspective

Ms. Susan Vassallo

Ms. Susan Vassallo, representing vaccine distributor Henry Schein, presented the private industry perspective on messages to increase vaccination coverage. Ms. Vassallo first emphasized that the role of the private sector is to support the public health efforts undertaken throughout the year; therefore, it is critical that the private sector remains apprised of these initiatives and activities.

Although the influenza season changes from year to year, Henry Schein believes that regardless of the seasonal characteristics, influenza-vaccine-related messages must remain constant. The messages include emphasizing the importance of receiving the vaccine each year, the health risks posed by influenza (especially among persons at high risk), and the efficacy of late-season vaccination. Henry Schein also acknowledges the need for strong public-private partnerships to strengthen influenza messages. Specifically, this distributor believes that private industry should support public sector efforts by proactively reinforcing messages to customers and society; Henry Schein is committed to providing this type of reinforcement. Vaccine manufacturers and distributors should communicate their role as a reliable provider of influenza vaccine that is committed to delivering product to healthcare practitioners as quickly and efficiently as possible. They should serve as strong advocates for CDC guidelines and recommendations for influenza vaccination, and they should be dedicated to working together with all influenza vaccine stakeholders to communicate the importance of vaccination and to help increase vaccination rates.

From the private industry perspective, it is critical to keep lines of communication open and to reinforce public health messages, regardless of current business conditions. Communication can be facilitated through the provision of educational web-based materials, direct marketing materials, and one-on-one interaction with customers. Influenza-vaccine-related discussions also can take place during key

stakeholder initiatives, including the NFID and the National Influenza Vaccine Summit. Private companies also can engage in proactive social and media outreach; additionally, manufacturers and distributors can release press statements containing influenza statistics and current events, offer to participate in interviews as experts, and build relationships with reporters and columnists.

Henry Schein has used its expertise and resources to help increase public awareness regarding the importance of influenza vaccination. For instance, the distributor donated substantial amounts of vaccine (more than 2,000 doses) to be administered to dental professionals attending the annual American Dental Association Convention; Henry Schein then asked that these dentists encourage all of their patients to receive vaccine during the influenza season.

Session Five Discussion

- Mr. Jim Bender asked Dr. Nowak for advice regarding public health messages about the importance of hand washing. Dr. Nowak concurred that this area is problematic, noting that perhaps the available data sets could be analyzed to examine the correlation respondents' views on hand washing and vaccination; it is likely that persons who believe that hand washing is effective are less likely to find value in the influenza vaccine. Hand washing requires small changes in behavior, and most people want to believe that simple actions can have a big payout. CDC wants people to do engage in both types of preventive measures by emphasizing that they must undertake many activities to increase their chances of staying healthy.
- It was asked whether Dr. Agwunobi had been invited to attend the Summit. Dr. Mootrey responded that although he was invited, he had previous obligations. She concurred that Dr. Agwunobi is a great advocate for raising vaccine awareness.
- One attendee asked about whether CDC has created its marketing campaign for the upcoming influenza season. He emphasized that the agency must provide messages early and that these messages should remain consistent. Giving the private sector access to communication materials early in the year would help these companies in their effort to reinforce public health messages. Dr. Nowak responded that CDC is in the process of developing its 2007-08 campaign; however, because influenza seasons are inherently unpredictable, the agency must not act prematurely when developing season-specific messages. CDC is committed to creating a core set of communication materials that can be used from season to season, regardless of the characteristics; CDC will participate in a Summit workgroup to exchange ideas about the types of messages that should be included in standardized communication materials. Dr. Sheedy noted that as part of next year's campaign, CDC will conduct focus groups to further study the public's perception on influenza vaccination; results from these studies will be made available. Dr. Sheedy also stated that the agency plans to stress the importance of protecting the family in its communication efforts.
- A meeting participant commended Dr. Nowak on the data that have been collected regarding patient vaccination behaviors. He reiterated that two thirds of patients reported that they did not discuss the influenza vaccine with their physicians, which points to a need to encourage providers to engage in these discussions. Perhaps healthcare providers should be given communication tools to assist them in communicating the importance of influenza vaccination.
- CDC's Dr. Carolyn Bridges stressed the importance of remembering the "inconvenient truths" about influenza, including the severity of the season, timing issues, and the groups of persons at high risk. Although it is difficult to make societal value judgments, decisions must

be made regarding prioritization during vaccine supply shortages. A meeting attendee commented on Dr. Bridges statement, stressing that many patients (particularly elderly persons) are unaware of what “high risk” or “increased risk” means; therefore, use of these terms by public and private health professionals should be avoided.

- A Summit attendee with the Utah Department of Health discussed the data that have been collected regarding influenza vaccination. She suggested that it would be helpful to get NIS data for children earlier in the season. She asked why this data was delayed. She also asked why CDC’s internet-based prevalence data (i.e., data from BRFSS) includes only persons aged ≥ 65 years, suggesting that the agency begin to post information for adults of all ages on its website. Mr. Singleton noted that the pediatric NIS data likely can be made available earlier; these data were analyzed later in the season because of efforts to coordinate publication in *MMWR*. Making these data available sooner is important, because they can be used to promote influenza vaccination for use in media events. Mr. Singleton addressed the question regarding BRFSS prevalence data; he stated that although he is not directly involved with the posting of these data, he will relay the suggestion to the appropriate CDC staff.
- Novartis Vaccines’ Mr. Tom Gibbs applauded HHS and CDC for their work on NIVW. He also proposed that the term “late season vaccination” be removed from all Summit communications, because the Summit is promoting use of the entire season (i.e., August through February).
- Ms. Annemarie Beardsworth from Rhode Island’s health department commented that states are receiving inconsistent messages. State health departments have been told to begin to expect to vaccinate patients from mid-October throughout the season; however, there is a national press conference scheduled for September 19. Although the conference is scheduled to help increase public awareness, many people will start to seek vaccination immediately after they hear anything about vaccine availability, before vaccine is distributed. Dr. Nowak responded that press conferences are designed to call attention to what can be expected in the upcoming weeks; specifically, the influenza vaccination press conference was scheduled to inform patients about what is anticipated for the upcoming flu season. An update likely will be given 7-10 days later. Ms. Beardsworth emphasized that although CDC’s intent is to set the stage for the upcoming season, she believes that the press conference will create demand for a product that is not yet available. Kris Ehresmann concurred, stating that the Minnesota Department of Health has requested that the press conference be scheduled for a later date. AMA’s Dr. Litjen Tan suggested that perhaps messages delivered during the press conference could emphasize the benefits of obtaining vaccination later in the season; this type of message could reduce the amount of demand for vaccine during September.
- Dr. Nowak was asked about survey questions regarding whether respondents thought hand washing would prevent disease transmission during pandemic influenza. This meeting attendee expressed concern that respondents might have indicated that they would engage in hand washing because they felt that no vaccine would be available; perhaps the hand washing questions should have pertained to seasonal influenza instead of a pandemic situation. Dr. Nowak agreed that the data might be skewed; however, he emphasized that other studies have also demonstrated that people place high value on the concept of hand washing to prevent disease transmission.
- A Department of Defense (DOD) representative provided insight into DOD’s activities for assessing vaccine coverage. DOD maintains real-time information on the vaccination status of all active duty staff members; vaccine is provided to employees and beneficiaries nearly year round. The Department also tracks vaccine effectiveness, adverse events, and vaccine

failure. Summit participants suggested that it would be advantageous for DOD to provide a formal update during future Summits.

- Dr. Roger Baxter with Kaiser Permanente noted that his HMO likely will move towards universal influenza vaccination in the near future. However, he stressed the importance of avoiding sending “mixed messages.” In the past, when vaccine shortages have occurred, the influenza season was moved later (i.e., November); however, influenza activity has peaked in early November in past influenza seasons. Ideally, people should be vaccinated by November 1. Although late-season vaccination is also important, the goal should be to vaccinate most people earlier. Perhaps messages from CDC and private industry should stress the need to receive vaccine beginning in October. Vaccine campaigns should not begin in September if vaccine is not available; patients who hear any information about vaccination will assume that they need to become vaccinated, regardless of whether vaccine is available. It is important for providers to have vaccine available when messages are communicated to the public, because most patients who present to physicians offices to be vaccinated will not return at a later date after being turned away. The most important vaccine message should be that patients should receive annual influenza vaccinations; these messages should continue throughout the entire influenza season.
- Summit participants engaged in discussion regarding appropriate messaging during a vaccine shortage. Some experts voiced concern that patients lose confidence in their healthcare providers when they are not able to receive vaccine in a timely manner; others disagreed, urging that most patients understand that prioritization must be made during vaccine shortages.
- Several Summit participants stressed the need for the Summit to take an official position on universal influenza vaccination. It was suggested that the Summit endorse this recommendation, despite potential vaccine shortages in future influenza seasons.
- Dr. Mootrey noted that the use of specific dates should be avoided in any vaccination campaign. She also clarified that no data exist to support the theory that late season vaccine is more effective against late season disease.
- Dr. Herb Young with the American Academy of Family Physicians emphasized that early vaccine-related press events may cause unwanted focus on distribution issues that could be erroneously perceived as being problematic. Perhaps events should be scheduled for specific locations only after vaccine is available within those communities.
- Texas Medical Association’s Dr. Andy Eisenberg stated his philosophy on influenza vaccine, which is to “give it as soon as you have it and give it until it is gone.” He also commented on influenza vaccination surveillance, stressing that the need for an improved surveillance system had not yet been raised by the Summit. Public health professionals and other partners must know where influenza is occurring throughout the country to enable the crafting of regional or local influenza-vaccine messages. Data obtained through the current system represents a lag of at least 2 weeks, which does not facilitate the development of accurate location-based communication.
- An American Healthcare Association representative expressed that the Association likely would support the concept of universal influenza vaccination, with the caveat that providers are provided with strong communication tools and messages to use in seasons in which vaccine shortages occur.

- Dr. Glen Nowak reminded Summit participants that no consensus has been achieved regarding the “trigger point” at which supply levels must fall for healthcare professionals to recommend vaccine prioritization. Theoretically, this trigger point has been met for the upcoming season, with only 75% of persons being recommended for vaccination and a shortage of 100 million doses. It will be challenging to ensure that consistent messages are issued.
- Dr. Deborah Wexler with the Immunization Action Coalition asked about ACIP’s upcoming recommendations about the timing of vaccination in light of the early availability of FluMist®. Typically, ACIP has recommended that patients receive vaccine in October and November; however, FluMist® is expected to be available as early as August, which will create opportunities for back-to-school vaccination. She urged that messages should be made consistent with recommendations. Dr. Wexler was told that this information could be provided to her at a later date.
- A meeting attendee with the Indian Health Service (IHS) provided an update of IHS-related influenza activities. IHS monitors influenza vaccination data on a yearly basis, and many IHS facilities are engaged in unique influenza vaccination efforts. For instance, at an Arizona facility, “phenomenal” measures are being taken to increase vaccination rates among employees and members of the community.
- Mr. Jim Bender emphasized that the central messaging issue concerns whether to encourage everyone to receive influenza vaccine or only those persons in certain groups. Although public health advocates want to provide the public with detailed information about vaccine supply and demand, members of the community need a simple, clear message, even if that message is imperfect in certain situations. He also stressed that the information relayed during mass media events and during patient encounters with private providers does not need to be the same; providers can provide their patients with vaccination-related details (e.g., why certain groups are at higher risk), but messages delivered through mass media events should be kept simple (i.e., “everyone should get a flu shot”).
- Denver Colorado’s Ms. Sunny Hines asked why ACIP is waiting to issue universal recommendations in light of the 132 million doses that are expected for the upcoming influenza season. In 2004, substantial doses of vaccine went unused, and the demand for the vaccine in the upcoming season is expected to be lower than the supply. Placing unneeded restrictions on vaccination will only serve to decrease demand even further. Dr. Hines stressed the effectiveness of herd immunity, which is the goal of universal vaccination recommendations.
- Dr. Eisenberg reiterated that the use of priority groups in vaccination efforts sends the public a negative message and promotes discrimination against persons who wish to become vaccinated but are turned away because they don’t belong to a specific high-risk group.

Analysis of the Data Supporting the Need to Extend the Influenza Vaccination Season
Mr. Philip Hosbach

Sanofi Pasteur’s Mr. Phil Hosbach presented the Summit with information about the need to extend the influenza vaccination season. Mr. Hosbach began by providing the rationale behind a proposed shift in the vaccine paradigm.

Several factors are contributing to the need for a new influenza-vaccine paradigm. First, the current influenza immunization recommendations now apply to 218 million Americans; with the push for universal vaccine recommendations in the near future, this number will increase to more than 300 million. In addition to expanded recommendations, vaccine supply is improving. Although a record 120 million doses were available in 2006, an increase in manufacturers committed to producing influenza vaccine and improvements in the vaccine manufacturing process likely will result in the availability of 150-170 million doses in the next few years. If the length of the influenza vaccination season remains 2-3 months, expanded recommendations and increased supply will result in logistical vaccine administration challenges. Therefore, vaccination activities should cover the entire influenza season in future years.

Sanofi Pasteur has identified several keys to a successful paradigm shift. First, patient demand for vaccination must be increased; manufacturers and providers must be able to sell vaccine to their customers. In addition, influenza vaccine supply and distribution must continue to improve, and public health advocates must take advantage of all vaccination opportunities.

Recent surveys of 2,000 consumers have indicated that physician recommendation is a key driver in patient demand. Of adult consumers, 80% reported that they typically follow recommendations from their physicians. For influenza vaccination specifically, respondents whose doctors recommended that they receive vaccine were substantially more likely to be vaccinated than were those who had not received physician-based recommendations. Children aged 6-17 years were 13 times more likely to become vaccinated, those aged 2-5 years were seven times more likely, and adult were four times more likely to get vaccinated when told to do so by their providers.

These surveys of consumers also have revealed that several misperceptions persist regarding the severity of influenza and the safety of influenza vaccine; these misperceptions have been associated with vaccine-related behavior. When asked why they did not receive influenza vaccination, most adult respondents (60%) indicated that they didn't need the shot; another 10% were concerned that the vaccine would cause them to become infected with the influenza virus. The same study demonstrated that most respondents (93%) were not aware of the existing influenza immunization recommendations.

Several activities likely will facilitate increased consumer demand for influenza vaccine. Because data reveal that physician recommendation significantly drives consumer demand for influenza vaccination, healthcare providers should promote influenza immunization throughout the entire season. In addition, consumer advertising is needed to educate/motivate consumers to seek immunization; examples of educational efforts include the National Influenza Vaccination Week, the Faces of Influenza consumer campaign, and NFID's annual influenza press event.

Data have been collected regarding vaccine supply. CDC has determined that a record 120 million doses were supplied during 2006-07, and manufacturers expect increases in the following seasons. Sanofi Pasteur expects to make an additional 50 million doses in both 2007 and 2008, and other manufacturers plan to make 97 and 170 million additional doses for 2007 and 2008, respectively. Increases in vaccine supply will present logistical challenges that require the product to be delivered into November and December. Currently, most vaccine is delivered to providers in October; although 53% of vaccine is expected to be delivered during this month in 2007, an additional 42% will be supplied in November and December.

The current 2-month influenza season must be expanded to accommodate increases in supply. Recommendations to lengthen the season are medically relevant; CDC data reveals that during the past 30 influenza seasons, peak activity has occurred most frequently in February. Activity peaked later than December in 25 of the 30 seasons. However, data from an electronic medical claims database indicate that influenza immunization rates peak in mid-November, well before the typical peak in influenza activity. Claims data also have been analyzed to determine rates of influenza-related medical care. These data

indicate that for 3 years, vaccine payment claims have peaked during October, whereas claims for influenza-related illness are not submitted until December; these claims continue to be submitted through March. These data reveal a 16-week gap between vaccine delivery and disease, which presents an opportunity for additional vaccination activities. Additional vaccination opportunities also are being missed; data demonstrate that many high-risk Americans are not immunized against influenza, representing 55 million patient visits. The public and private sectors must ensure that these prevention needs are met.

Discussion

- Dr. Andy Eisenberg concurred with Dr. Hosbach's position that doctors miss opportunities for vaccination, noting that in the current healthcare system, many physicians are required to focus more on acute care than preventive care. He reiterated that the current healthcare delivery system must be reengineered to stress prevention.
- Dr. Eisenberg also voiced concern for the use of the terms "high risk" and "vaccine prioritization." All professionals involved in medical practices (e.g., front office clerks and nurses) should be empowered to promote vaccination to all patients who enter the office; authority should be shared with all levels of staff.
- Dr. Eisenberg identified payment as an issue that negatively affects vaccination in physicians' offices. Providing influenza vaccine should be financially beneficial to the primary care doctors rather than a financial liability.
- Mr. Hosbach emphasized that physician behavior is affected by reimbursement from insurance companies and the current structure of the healthcare system. Manufacturers aim to increase vaccination rates without leaving doctors with excess doses. However, conflicting messages from CDC and manufacturers have affected the way that physicians behave.
- Dr. Deborah Wexler asked vaccine manufacturers to support initiatives to provide vaccine directly to the consumer. Another participant suggested that keeping the vaccine messages simple would facilitate consumer-direct distribution of vaccine.
- It was noted that although many participants stressed the importance of a medical home in vaccination efforts, as many as 40% of Americans do not have a designated healthcare provider.
- Ms. Jenny Riley with e-flu clinic discussed the lack of data available regarding immunization. Hard data, such as those provided by Mr. Hosbach, are needed to help guide decisions regarding influenza season expansion. Mr. Hosbach responded that substantial amounts of information are available on immunization rates; perhaps these data are not being appropriately distributed.
- Mr. Hosbach emphasized the need to move towards universal vaccination recommendations and the need to provide the public and providers with one simple message, even in the face of a vaccine shortage.
- An ASTO representative noted that direct-to-consumer advertising does not need to be done through the Summit, AMA, or CDC. Instead, manufacturers can advertise directly by placing their names on commercials. Mr. Hosbach responded that although Sanofi Pasteur has not marketed vaccine directly to the public through commercials, the company has created educational materials that are designed specifically for HMOs and other providers. Sanofi

Pasteur avoids using its name on materials that promote its vaccines, because the public often perceives private industry as having misguided intentions. Mr. Hosbach also explained that although pharmaceutical companies often sponsor television advertising for their products, this type of advertising is cost prohibitive when used to promote influenza vaccine.

- Kris Ehresmann with the Minnesota Department of Health suggested that manufacturers create advertising to encourage people to ask their healthcare provider if they have been vaccinated. This type of message would increase interest in vaccination among the public and hold healthcare workers accountable for taking responsible preventive health measures.
- Dr. Roger Baxter commented on Mr. Hosbach's graphs, stating that the curves that indicate uptake of vaccine prior to influenza outbreaks seem ideal. He also emphasized the tremendous progress that health advocates have made in the area of influenza vaccination. Currently, one third of the country is vaccinated against this disease. Mr. Hosbach responded to Dr. Baxter's first comment, noting that the 16-week gap between peaks in vaccine uptake and disease incidence presents more opportunities for vaccination.
- Summit participants stressed the need for the Summit to create a united voice concerning the need for universal influenza vaccine recommendations. A unified voice is sure to be heard, even by ACIP. Dr. Tan reiterated that because CDC is a Summit cosponsor, Summit messages should not conflict with ACIP's recommendations. The official position of the Summit must be carefully considered.

Overview of All Summit Sessions

Dr. Litjen Tan

Dr. Tan concluded the meeting by providing a summary of the primary issues identified during the Summit. Summit participants largely focused their presentations and discussion on the following topics and suggestions.

- Vaccine supply for the 2007-08 influenza season is expected to be optimal; more than 132 million doses are in production and no substantial delays are expected.
- The vaccination season must be broadened. The season should be extended into January, February, and March depending on the season's peaks.
- Intensive educational campaigns must be initiated to communicate the importance of "later season" vaccination to providers and patients.
- Manufacturers should work to identify ways to distribute vaccine earlier in the influenza season; FDA's approval process should be made more efficient, and new technologies should be employed.
- Manufacturers and distributors should work to stabilize the timing and distribution of vaccine.
- Vaccine-related legislative initiatives must be addressed. Because CDC is a cosponsor of the Summit, the Summit can not directly sponsor a workshop dealing with these issues. However, unofficial groups can be convened (e.g., through HIDA).
- Summit resources (e.g., handouts, an Executive Summary, and Minutes of Meeting) will be posted on the AMA website. Information submitted by Summit award winners also will be made available through this site.

- Methods for determining how many doses of vaccine go unused within specific sectors should be developed.
- The Summit should create a unified message stating that all providers should vaccinate any person who wants to reduce the likelihood of getting ill or transmitting disease to others.
- Influenza vaccination rates must be improved among healthcare workers; researchers are encouraged to partner together to undertake creative, community-based projects to improve vaccination rates among healthcare workers and others.