

2008 National Influenza Vaccine Summit
May 12-13, 2008
Atlanta, Georgia

Executive Summary

Introduction

The 2008 National Influenza Vaccine Summit, a partnership of public and private stakeholders committed to achieving the *Healthy People 2010* goals for influenza vaccine, was convened on May 12-13 in Atlanta, Georgia. The Summit, which has been cosponsored by the American Medical Association (AMA) and Centers for Disease Control and Prevention (CDC) since 2001, was well attended; 214 experts representing over 110 diverse organizations participated.

During the 2-day Summit, attendees were provided updates by experts in several vaccine-related fields, including medicine, vaccine manufacturing, vaccine distribution, and public health. The Summit was organized into sessions, during which the following topics were covered: using data, targeting specific age groups, and other ways to increase coverage; increasing healthcare provider participation to increase coverage; and strategies to overcome myths and misconceptions to increase coverage. An additional session was dedicated to the 2nd Annual Summit Excellence Awards and recognition program. Awards were presented to two programs that demonstrated innovative approaches to increasing vaccination rates in different settings during the 2007-08 influenza season, and other outstanding programs were formally recognized or given honorable mention. Throughout the meeting, participants were encouraged to provide feedback and pose topic-specific questions to presenters during organized discussion sessions.

Session I

During the first session of the 2008 Summit, participants were provided with background information about the impact of influenza and influenza vaccination in the United States. Summit attendees were then updated regarding the initiatives that recently have been undertaken by the Department of Health and Human Services (HHS) to increase immunization levels among healthcare workers both within the Department and in other non-federal health care organizations. This initiative consists of three focus areas: a) developing office and agency-specific strategies to improve vaccination levels, b) measuring employee vaccination rates, and c) disseminating a toolkit containing vaccine-related materials.

An update regarding the Advisory Committee on Immunization Practices' (ACIP's) 2008 influenza vaccine recommendations was also given during the first session of the Summit. During this presentation, ACIP's vaccine recommendation milestones were discussed; in addition, rationale was provided for the Committee's decision to expand its existing influenza vaccine recommendation to include children aged 6 months through 18 years beginning no later than the 2009-2010 season. ACIP considered several critical factors in their decision to expand the recommendation, including disease burden, vaccine effectiveness and safety, cost-effectiveness, vaccine supply, and feasibility of sustained implementation. The new recommendations were made based on evidence that influenza has substantial adverse impacts on school-aged children and their contacts and that influenza vaccine is effective and safe for these children. Other potential outcomes also were considered in the development of the new recommendation, including the expectation that a simple, age-based influenza vaccine recommendation will improve current, low vaccine coverage levels and the potential for the indirect effect of reducing influenza among persons who have close contact with children, which would reduce overall transmission within communities. Other changes to existing influenza vaccine recommendations were outlined (i.e., the addition of the statement recommending that TIV or LAIV be used when vaccinating healthy persons aged 2-49 years, that children aged 6 months-8 years

receive 2 doses separated by ≥ 4 weeks, and that children aged 2-4 years be screened for reactive airways disease before receiving LAIV), and the strains chosen for inclusion in the 2008-09 vaccine were announced (i.e., A/Brisbane/59/2007 [H1N1]-like, A/Brisbane/10/2007 [H3N2]-like, and B/Florida/4/2006-like). Finally, outcomes of studies conducted to determine influenza vaccine effectiveness were presented.

Session II

Several presentations made during the second session of the Summit facilitated an informed discussion on ways to increase vaccine coverage in 2008-09. Summit participants were informed about innovative approaches that have successfully increased vaccination rates in specific populations, particularly among young children. Specifically, New Jersey's mandate requiring annual influenza vaccination among children attending pre-school and licensed day care centers in New Jersey was discussed. This legislation, which will become effective in September 2008, was created for the following reasons: children in this age group (age 56-59 months) are respiratory pathogen "super spreaders," high hospitalization and mortality rates are observed in these children, vaccination in this group increases caregivers' productivity and reduce absenteeism, and ACIP and CDC now recommend that these children receive annual influenza vaccination. As the New Jersey regulation unfolds, several issues will be considered, including monitoring the effectiveness of the mandate, determining the impact of thimerosal on the effectiveness of the policy, and working out logistics associated with vaccinating substantial numbers of children in a timely manner.

Programs illustrating other ways to increase vaccination coverage were presented to Summit participants during Session II. Participants were informed about CDC's National Influenza Vaccination Week (NIVW), the American Lung Association's Faces of Influenza campaign, and initiatives undertaken by the Children's Influenza Immunization Coalition (CII) and the National Foundation for Infectious Disease (NFID). Insights from a claims data study conducted by vaccine manufacturer sanofi pasteur also were shared during this time.

The discussion session held after Session 2 provided Summit attendees with the opportunity to provide feedback regarding the presentations, ask questions of the panel members, and provide suggestions on ways to improve vaccination rates. Several themes emerged during this session, including the need to

- increase provider and patient education regarding the influenza vaccine;
- increase collaboration between healthcare providers and other stakeholders (e.g., vaccine manufacturers, distributors, health departments, and community-based vaccinators);
- reduce the financial pressure and risk associated with vaccine purchase and re-order;
- ensure that community vaccinators improve communication with the medical home and adopt better vaccination documentation protocols;
- better educate patients, particularly parents, on the thimerosal issue;
- improve vaccine-related terminology, including avoidance of the term "high risk" when referring to patients who should receive vaccine;
- balance vaccine supply and demand;
- create positive and consistent vaccine-related messages for the public; and
- create a recognizable logo or "catch phrase" that can be printed and worn by healthcare providers to communicate their own vaccination status (e.g., "I got my flu vaccine, did you?").

During the first day of the Summit, representatives from vaccine manufacturing and distribution companies (i.e., MedImmune, sanofi pasteur, CSL Biotherapies, Novartis, GlaxoSmithKline, and the Health Industry Distributor's Association [HIDA]) gave vaccine supply updates and discussed other pertinent production-related topics. Overall, manufacturers are on target for producing sufficient doses of influenza vaccine for the 2008-09 influenza season. It is anticipated

that 143-146 million doses will be manufactured in total this year. No substantial problems in the manufacturing process have occurred to date, and most manufacturers anticipate vaccine delivery to begin as early as the end of August. This year, MedImmune has produced all of its vaccine strains using a new, reverse-genetics technique, which likely will be employed by other manufacturers in upcoming seasons. New reverse-genetics technologies result in the more predictable and timely manufacture of vaccine and will play a key role in the production of both seasonal and pandemic influenza vaccine.

Summit participants were informed about the Department of Defense's (DoD's) mandate requiring all of its active duty personnel and healthcare workers to receive seasonal influenza vaccination. To evaluate the effects of this mandate, DoD investigated vaccine effectiveness and coverage levels among its uniformed personnel during the past influenza season. DoD has determined that 70%-88% of its personnel were vaccinated with either TIV or LAIV by December 2007, and 86%-94% were vaccinated by February 2008; more than 90% of uniformed healthcare workers had received vaccine by December. Vaccine effectiveness against H1 and H3 was demonstrated to be 71% and 84%, respectively; the vaccine was 48% effective in cases of nonspecific influenza. This is in contrast to data for TIV recently published from the Marshfield Clinic and may reflect the healthy young adult population in the military.

During the 2nd Annual Summit Excellence Awards and recognition program, awards were presented to two programs that demonstrated innovative approaches to increasing vaccination rates in different settings during the 2007-08 influenza season. The State of Hawaii's Stop Flu at School campaign was awarded for being the "Best Overall Campaign," and Western Pennsylvania's Raising Immunization Safely and Effectively (RISE) -- Healthcare Workers program was given the award for "Best Healthcare Worker Campaign." Honorable mention was given to several additional programs, including Minnesota's Faith Health Consortium, Rhode Island's Immunize for Life program, and Children's Hospital and Regional Medical Center's immunization initiative; recognition was given to HIDA for their Flu Vaccine Business Practices initiatives, Novartis Vaccines' Spread the Word - Not the Flu campaign, and ALA's Faces of Influenza campaign. During the awards ceremony, attendees were encouraged to consider sharing their successful 2008-09 vaccination campaigns with Summit organizers.

Session III

The goal of Session III was to better elucidate ways to increase healthcare provider participation in increasing coverage in the upcoming influenza season. Participants were asked to consider current challenges, past efforts, and additional steps that should be taken. Summit participants heard presentations representing several different perspectives, including occupational medicine, family medicine, community vaccination, pediatrics, internal medicine, pharmacies, and HHS. Presenters discussed their own experiences with vaccine coverage-related issues within the context of these sectors. After the presentations, Summit attendees were asked to participate in a discussion session to provide feedback about ways to improve healthcare worker participation in efforts to increase vaccination rates. Several themes emerged during the discussion, many of which echoed those raised in the earlier discussion session, including the need to

- ensure that all staff members working within the medical home communicate the importance of vaccination to patients;
- create state-based vaccination registries to improve documentation of vaccinations received outside of the medical home;
- enhance collaboration between pharmacist vaccinators and physicians;
- address financial-related concerns, including making the cost of vaccine more consistent for patients, making vaccine purchase and administration more affordable for providers, and ensuing better reimbursement from insurance companies;

- clarify vaccine supply and distribution practices to address the common perception that certain providers receive vaccine doses earlier than others;
- increase vaccination opportunities by embracing all immunization settings, not just the medical home, and encouraging patients to receive seasonal vaccination at any setting they choose;
- create a recognizable symbol, or slogan, to be worn by healthcare workers who have been vaccinated;
- better communicate the effectiveness of the influenza vaccine, even when a match between virus and vaccine is suboptimal;
- consider delivering immunization messages in nontraditional settings, including through corporations (e.g., Disney and NASCAR) and other popular web-based communication venues (e.g., MySpace and YouTube);
- re-think immunization-related technology by avoiding use of the term “late season,” which could be replaced with more positive terms (i.e., “winter and spring vaccination”), and discontinuing use of the term “flu shot,” particularly in light of the newly available intranasal vaccine formulation.
- address thimerosal-related issues, including the excessive amounts of time required for parent education during pediatric visits;
- improve education among both providers and patients about the importance of receiving yearly influenza immunization;
- extend the immunization season from early fall through the spring; and
- clarify reimbursement and other issues associated with federal vaccine programs (i.e., Medicare and the Vaccines for Children Program).

Session IV

The focus of Session IV was to address strategies to overcoming myths and misconceptions to increase coverage in 2008-09. The presentations and discussion periods within this session centered around identification of these myths and misconceptions, methods that have been used to reeducate the public and healthcare personnel, and next steps. Several specific myths were addressed by presenters, including the belief that a) the influenza vaccine can cause influenza or cause illness, b) strong, healthy people are not at risk for the disease, c) practicing good hand hygiene provides adequate protection against influenza, and d) the vaccine is unsafe, particularly for pregnant women and infants. A final presentation addressed CDC’s efforts to “market the truth” about influenza and the influenza vaccine to the public; as part of the presentation, Summit participants were given a preview of CDC’s new vaccination marketing video. After the presentations, Summit attendees were asked to participate in a discussion session to provide feedback about ways to dispel common myths and misconceptions. Several themes emerged during the discussion, including the need to

- clarify which medical conditions (e.g., fever and respiratory infections) serve as contraindications to influenza vaccination and communicate this to patients and providers;
- better educate the public about the truths associated with influenza vaccination, and ensure that patients understand the relationship between vaccination and herd immunity;
- plan extensive distribution of CDC’s marketing video to increase vaccine uptake in children in a variety of diverse media outlets;
- further elucidate the logistics of implementing the ACIP’s expanded vaccine recommendations to ensure that substantial numbers of children are vaccinated in a timely manner;
- forge strong relationships with media groups at the community level;
- better communicate the truths associated with thimerosal in an effort to slow the growing anti-vaccine movement among concerned parents;
- begin to manufacture more thimerosal-free vaccine; and

- increase vaccination compliance among healthcare workers.

Several additional vaccine-related myths and misconceptions were identified by Summit participants during the discussion session. These include the belief that a) the vaccine is ineffective, b) Tamiflu is an appropriate substitution for influenza immunization, c) the influenza vaccine causes patients to feel sick, and d) vaccination weakens the immune system. Any effort to increase patients' acceptance of influenza vaccine should take these additional misconceptions into account.

General Outcomes from the 2008 National Influenza Vaccine Summit

The following bullets reflect other common thoughts and concerns that were echoed throughout the 2-day Summit.

- A paradigm shift is needed. Moving from a crisis of shortage to a crisis of surplus. Both patients and providers should be better educated on the need to vaccinate throughout the entire influenza season. Higher vaccination rates can easily be achieved with the surplus of vaccine that is being produced by manufacturers. Although regional vaccine shortages have occurred in previous seasons, last year, more than 27 million doses of vaccine were discarded, which is unacceptable. Vaccine supply must be better matched with demand. This effort must be undertaken by all stakeholders; for instance, providers need to improve vaccination rates and manufacturers must address barriers faced by vaccine providers.
- The traditional paradigm of influenza vaccination is no longer a valid model. In the past, vaccine delivery typically has been completed by September and October, and typically, immunization efforts have ended in November. As manufacturers produce more vaccine, vaccine will have to be released into December. Also as providers begin to change vaccination behaviors and begin to offer patients vaccine later in the season, influenza vaccine supply will be required over a longer period of time (into January and beyond).
- Vaccine distribution can be improved by improving vaccine production. It is anticipated that more manufacturers will become involved in the production process in future seasons, and existing manufacturers likely will be capable of producing more doses using new technologies. More time may be required to allow for the distribution of these additional doses of vaccine.
- To reduce influenza-related morbidity and mortality in the United States, immunization rates must be increased through the expansion of the influenza vaccination season. Although studies have shown that providers are hearing the message regarding the need to expand the vaccination season, these messages are not resulting in behavior change. Providers must be better educated about the need to increase coverage rates within their practices by vaccinating additional patients over a longer period of time.

Actions Being Considered By the Summit

- Task Communications WG to craft specific messages (maybe one-page fact sheets?) targeted at: (1) the general public regarding vaccine effectiveness; (2) general myths regarding influenza and influenza vaccine (which are probably also adaptable to HCWs); (3) educating on thimerosal in influenza vaccine; (4) the importance of vaccinating all children under 19 years of age; and (5) the influenza vaccine supply chain to defuse persistent beliefs that vaccine is prioritized to different provider groups.

- Create a subcommittee to work on creating a consistent, persistent universal message on influenza immunization. Same subcommittee would be responsible for work on a national logo.
- Create a targeted message to providers regarding the need to use the entire season to improve coverage of the high priority populations, not maintain current vaccination levels, while balancing a need to emphasize vaccinating all comers.
- Harness Occupational Health WG to create an incentive program that employers can use to improve influenza immunization rates (eg, a Summit award for most improved influenza immunization rates?).
- Work with Summit partners (eg, NACCHO) to facilitate and begin implementation of the ACIP's 6 month through 18 year recommendation.
- Seek ways to improve vaccination in non-traditional settings, eg, NASCAR events; NFL partners; Disney; tie into the election process recognizing that vaccination at polling places may not be allowed in certain jurisdictions.
- Continue existing Summit efforts on improving HCW influenza immunization rates, including dissemination of NFID's Best Practices produced via collaboration with the Summit partners; re-emphasize that best practices are being collected on the Summit web site.
- Reestablish Summit Payment Working Group to work on several issues surrounding financing to improve access:
 - Make sure providers are being appropriately reimbursed at the state level.
 - Pull in the new recs and how a provider can best perform financially
 - ACP has looked at QI programs on this issue for the past 6 years and can help with this?
 - Improve financial return on influenza immunization for providers by identifying and disseminating best practices for small and medium sized providers to improve efficiencies in influenza vaccination (role here for Summit partner, eg, NFID?)
- Re-establish informal Summit legislative working group to evaluate various regulatory/legislative issues that may impede access to influenza vaccination:
 - Concern circulating about vaccinations under standing orders (identify to Brian Whitman at ACP)
 - Old legislation regarding influenza vaccine as a "dangerous drug" impeding transport by non-pharmacists and non-physicians in GA (anywhere else?).
- Evaluate creative ways of increasing awareness of influenza vaccine retailers that have vaccine-return policies, especially for vaccine ordered in December and beyond.
 - Need to be cautious to not violate anti-trust.
 - Can we encourage providers to ask where return policies exist with a parallel message to be responsible when ordering?