New Developments in Adult Immunization

Initiative Faculty

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Key vaccine-preventable diseases were the subject of one of four CE in the Mornings topics at the 46th ASHP Midyear Clinical Meeting and Exhibition in New Orleans, Louisiana, in December 2011. The program was presented by Dennis M. Williams, Pharm.D., BCPS. Attendees submitted questions about unresolved issues and controversies that were later addressed by Dr. Williams in a live webinar conducted on February 23, 2012. Some of the highlights of the webinar pertaining to immunization of healthcare personnel and recommendations for immunization against influenza and pertussis (whooping cough) were described in an **e-Newsletter released in March 2012** (PDF). Highlights of the webinar pertaining to immunization against pneumococcal disease, hepatitis B, and herpes zoster (shingles) and new vaccines in development are described in this e-Newsletter.

Expand Your Knowledge

On-demand CPE Activities

If you were unable to attend the live symposium, *Targeting Optimal Protection for Adult Patients: Immunization Strategies in the Health System,* conducted at the 2011 ASHP Midyear Clinical Meeting, a 1-hour CPE activity is available on demand at **www.ashpmedia.org/symposia/cemornings**

Faculty Podcast Interviews

Visit the CE in the Mornings **web portal** to listen to podcast interviews with the faculty. Four interviews, each lasting approximately 5 to 14 minutes, are available.

Question: What is the role of the new 13-valent pneumococcal conjugate vaccine (PCV13) in adults?

Invasive disease caused by Streptococcus pneumoniae is a major cause of morbidity and mortality in the United States despite the availability of vaccines against the disease. An estimated 43,500 cases and 5000 deaths were attributed to invasive pneumococcal disease in 2009.[1] Most cases (84%) and deaths occurred in adults.

Historically, a 7-valent pneumococcal conjugate vaccine (PCV7) was used as part of a primary immunization series for infants and children, and a 23-valent pneumococcal polysaccharide vaccine (PPSV23) was used for adults and children 2 years of age or older with selected chronic conditions (e.g., asthma) and all elderly persons 65 years of age or older. A new 13-valent pneumococcal conjugate vaccine (PCV13) was approved by the Food and Drug Administration (FDA) in February 2010 for administration to children as a four-dose series at 2 months, 4 months, 6 months, and 12-15 months of age.[q] This product replaced PCV7 and protects against pneumococcal disease caused by a larger number of serotypes (i.e., strains) than PCV7.

The incidence of invasive pneumococcal disease caused by the serotypes in PCV7 has decreased in infants and children less than 5 years of age and elderly patients 65 years of age or older since the introduction of PCV7 in 2000.[3] The incidence of invasive pneumococcal disease caused by other serotypes (especially 19A) has increased in these patient populations since 2000.

In the fall of 2011, FDA approved PCV13 for prevention of pneumococcal pneumonia and invasive pneumococcal disease in persons 50 years of age or older based on immune responses, not data demonstrating a reduction in the incidence of these diseases.[2] In February 2012, the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP) postponed a decision about the role of PCV13 in adults. The committee is awaiting further data, including the results of the Community-Acquired Pneumonia Immunization Trial in Adults, a large, randomized, parallel-group, placebo-controlled study of PCV13 known as CAPiTA involving patients 65 years of age or older.[4] ACIP could make no changes in its recommendations for pneumococcal immunization of adults or recommend replacement of PPSV23 with PCV13, sequential use of PCV13 and PPSV23, or use of PCV13 in specific populations. Lack of ACIP recommendations for use of PCV13 in adults does not preclude its use in this patient population in accordance with FDA-approved labeling.

> **"Pay-for-performance programs and the potential loss of up to 2% of inpatient payments from CMS create opportunities to justify to health-system administrators new pneumococcal immunization initiatives that improve the quality of patient care."**
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> — Dennis M. Williams, Pharm.D., BCPS

Question: What can pharmacists do to improve pneumococcal immunization rates in their institution?

An estimated 70 million Americans with indications for pneumococcal vaccination (e.g., asthma, smoking, age 65 years or older) are unvaccinated.[5] As part of efforts to improve the quality of care in health systems, the Centers for Medicare and Medicaid Services (CMS) has established pay-for-performance (P4P) programs that link inpatient payments to performance and quality. Failure to attain established thresholds for performance or meet goals for improvement could result in the loss of up to 2% of inpatient payments from CMS. Pneumococcal vaccination is one of several clinical process measures used by CMS to assess quality.

Pharmacists can play an integral role in devising strategies to improve immunization rates in the institution. The need to meet P4P program requirements and the potential loss of CMS payments should be emphasized to health-system administrators when seeking support for new immunization initiatives. Pharmacists can explain the proper use of available pneumococcal vaccines and the importance of immunization to other members of the health care team.

Question: What is the rationale for the new hepatitis B vaccine recommendations from ACIP for patients with diabetes?

Outbreaks of acute hepatitis B infection have been associated with the improper use of blood glucose monitoring equipment for institutionalized patients with diabetes who require assistance with monitoring. Infections were attributed to the use of a fingerstick device intended for use by a single person by multiple patients or the use of a handheld blood glucose meter for multiple patients without cleaning and disinfection between each use.[6] Infections were reported in at least 147 persons (six of whom died) in hospitals, nursing homes, and assisted living facilities in the United States between 1990 and 2008.[7]

Hepatitis B is highly infectious and environmentally stable. Hepatitis B vaccine has been recommended for health care personnel since 1982.[8] After two outbreaks of acute hepatitis B infection in 2005 at assisted living facilities in Virginia, education about infection control guidelines and recommendations for blood glucose monitoring were provided to staff at these facilities.[9] A follow-up survey of assisted living facilities in central Virginia revealed that 17 (34%) of 50 assisted living facilities did not offer employees the hepatitis B vaccine, and glucose monitoring devices were shared among residents without cleaning the device at 7 (16%) of 45 facilities. Thus, additional efforts are needed to educate staff about the need for immunization and adherence to guidelines and procedures to prevent transmission of hepatitis B infection in these facilities.

Hepatitis B vaccine has been part of universal childhood vaccination programs, and it has been recommended for "at risk" adults (e.g., patients beginning hemodialysis, people who practice unsafe sex, travelers to certain areas with high endemicity of hepatitis B infection).[8] New recommendations from ACIP released in December 2011 and incorporated into the new 2012 recommended adult immunization schedule call for hepatitis B vaccine administration to unvaccinated adults with diabetes who are 19-59 years of age.[8,10] Use of the vaccine in unvaccinated adults with diabetes who are 60 years or older is recommended at the discretion of the treating clinician based on a need for assisted blood glucose monitoring in long-term-care facilities; the likelihood of acquiring hepatitis B infection, its complications, and chronic sequelae; and the likelihood of immune response to vaccination.[10] Giving hepatitis B vaccine as a one-time 3-dose series provides a protective response in ≥90%, 80%, 65%, and <40% of adults with diabetes (but no comorbid conditions) who are 40 years of age or younger, 41-59 years of age, 60-69 years of age, and 70 years of age or older, respectively.[8] From a lifetime perspective, providing the one-time 3-dose vaccine series to 10% of unvaccinated American adults with diabetes who are 20-59 years of age (approximately 528,000 patients) is expected to prevent 4271 hepatitis B infections, 467 hospitalizations, 256 chronic cases, 33 cases of hepatocellular carcinoma, 13 liver transplants, and 130 deaths.[8]

Question: I read that the herpes zoster vaccine was recently approved by FDA for people in their 50s, and my patients in this age group have been asking about it. When will it be available for this age group?

Herpes zoster is caused by reactivation of the varicella zoster virus associated with chickenpox. It typically affects older persons and can lead to debilitating postherpetic neuralgia that lasts for months.

A live, attenuated zoster vaccine was approved by FDA in 2006 for people 60 years of age or older. The vaccine is contraindicated in patients who are immunosuppressed or immunodeficient.[11] In March 2011, FDA approved the zoster vaccine for persons 50-59 years of age based on efficacy and safety data.[12] In a large retrospective cohort study of immunocompetent community-dwelling adults 60 years of age or older, vaccination reduced the risk of herpes zoster by 55%.[13] In the Zostavax Efficacy and Safety Trial, a large phase 3, randomized, double-blind, placebo-controlled study known as ZEST, the vaccine significantly reduced the risk of developing zoster by 69.8% compared with placebo, with a similar rate of serious adverse events.[11]

Although FDA approved the zoster vaccine for patients 50-59 years of age, ACIP declined to recommend it for this age group in June 2011 because of sporadic vaccine supply problems and low rates of immunization of persons 60 years of age or older.[12,14] Older persons have a higher incidence of herpes zoster and are at greater risk for morbidity than younger persons 50-59 years of age.

The lack of an ACIP recommendation for zoster vaccine in patients 50-59 years old does not preclude administration to selected individuals in this age group. These individuals include persons who might be unable to tolerate the symptoms of herpes zoster or postherpetic neuralgia (e.g., because of preexisting chronic pain, severe depression, or other comorbid conditions) or take the medications used to treat herpes zoster or postherpetic neuralgia (e.g., because of hypersensitivity or interactions with medications needed to treat other chronic conditions).[14] However, health insurers are unlikely to cover the zoster vaccine for persons 50-59 years of age until ACIP recommends it for this age group.

ACIP will continue to monitor the zoster vaccine supply and might update the recommendations for vaccination to include adults 50-59 years of age when an adequate supply of the vaccine can be assured.[14] The supply of the vaccine is expected to increase during the next several years.[14] Enough vaccine product had become available by April 2012 that a television advertising campaign was begun by the manufacturer to increase consumer awareness of the pathogenesis and symptoms of herpes zoster.[15] This campaign is likely to increase the number of questions from patients about availability of the vaccine.

An inactivated zoster vaccine that can be given as a three-dose series to immunocompromised persons is in development. Trials of the currently available live, attenuated zoster vaccine are under way in persons with mild rheumatoid arthritis (i.e., mild immunosuppression).[16]

Practice Changes Related to Adult Immunizations

In a survey conducted approximately 8 weeks after the December 2011 CE in the Mornings symposium on new developments in adult immunizations, attendees were asked what practices they had implemented or improved based on the knowledge acquired by participating in the program. Many attendees had already made practice changes that should improve immunization awareness and rates in their institutions, and other respondents had made plans to do so. These practices include:

- Collecting a history about the relevant immunization status of patients,
- Advocating for up-to-date immunizations for patients based on their medical condition and health status,
- Proposing processes to improve immunization practices in the institution to meet pay-for-performance standards, and
- Consulting the Centers for Disease Control and Prevention website periodically to stay informed on current immunization recommendations.

Barriers to implementation of or improvement in practices reported by survey respondents included a lack of time, personnel experience, and financial resources. Information on adult immunizations provided in the CE in the Mornings educational initiative should help overcome some of these barriers and improve patient care and outcomes.

Question: What vaccine-preventable diseases are the targets of new vaccine products in development?

Current vaccine research focuses on problematic health-care-associated pathogens (e.g., methicillin-resistant Staphylococcus aureus, Clostridium difficile) and infectious diseases (e.g., malaria, tuberculosis, and human immunodeficiency virus, which are commonly referred to as the big three).[17,18] Vaccines for use in combating non-infectious diseases that are major causes of morbidity and mortality (e.g., addiction to nicotine, alcohol, or other addictive substances) also are in development.[19]
New vaccine delivery systems allowing the use of unconventional routes of administration (e.g., transcutaneous delivery) that may be better tolerated than intramuscular injection are under investigation.[20] New vaccine products containing adjuvants have been developed to augment the immune response to antigens.[21] New vaccine production methods (e.g., plasmid DNA vaccines, plant-derived products) also have been explored.

Additional ASHP Advantage Educational Activities

Visit the ASHP Advantage website to browse listings of convenient on-demand continuing education (CE) activities as well as publications, podcasts, and live webinars. More than 40 hours of free on-demand CE programming are available. Learn more and find a full listing of topics and activities at www.ashpadvantage.com.

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