NEWS

• **Looking to increase adult immunization rates?** Participate in a one-half day Immunization Champions, Advocates & Mentors Program (ICAMP) training. ICAMP is a multidisciplinary program designed to equip health care professionals to champion adult immunization practices that improve public health and the quality of care for the people they serve. Trainings will be held in Miami (September 14), San Antonio (September 28), Chicago (October 10), and New York City (November 2). A $175 registration fee includes program materials, live program and action planning, snack, and ongoing dialogue with 2016 and 2017 champions. Attendees are required to participate in a pre-program webinar and respond to 3 surveys over 12 months on adult immunization rate changes. Visit [https://www.navp.org/training-for-champions](https://www.navp.org/training-for-champions) to register. *ICAMP is developed by The Gerontological Society of America and supported in part by Pfizer and Merck.*

RESOURCES

• **A wealth of data on immunizations in older adults** is available in the recently released data brief from the 2015 National Health Interview Survey. Available from the National Center for Health Statistics, the survey shows these vaccination patterns among Americans aged 65 years or older: 69% received an influenza vaccination in the prior 12 months; 57% had received a vaccine covering tetanus in the prior 10 years; 64% had ever had a pneumococcal vaccine; and 34% had ever had a shingles vaccine.
August is National Immunization Awareness Month (NIAM). With influenza season approaching, you can join all of your colleagues in the immunization neighborhood by communicating with older adults about the importance of vaccines to their health and well-being. Even if you do not administer vaccines, your interactions with older adults who value your advice could be critical in their decision to get immunized.

Each week of NIAM focuses on promoting the importance of vaccines among a different population. August 14–20 is dedicated to vaccinations for adults.

One way to promote vaccines is to provide a ready-to-publish article for health or community newsletters that reminds adults why vaccines are needed and which ones are recommended. You can also post a quick Facebook or Twitter note to personal and professional contacts that reinforces these ideas.

The Centers for Disease Control and Prevention (CDC) and the National Public Health Information Coalition have a toolkit with ready-to-go messages, responses to frequently asked questions, and more.

Whatever your interaction with older adults, join the campaign and plan on devoting some extra time to talking about vaccines during August. Your trusted recommendation or referral could be the reason they get protected from serious illness.

With a second herpes zoster vaccine nearing an approval decision at the U.S. Food and Drug Administration (FDA), the Advisory Committee on Immunization Practices (ACIP) heard six presentations on prevention of shingles during its June meeting at CDC headquarters in Atlanta. An ACIP work group has been compiling data for several months in preparation for making recommendations to the full committee about how the new zoster vaccine should be incorporated into the adult immunization schedule.

The currently marketed shingles product, Merck’s Zostavax, is a live-attenuated zoster vaccine (ZVL) first licensed by FDA in 2006. It is approved by FDA for use in people aged 50 years or older, but recommended by ACIP for those aged 60 years or older.

GlaxoSmithKline submitted an application last October for a herpes zoster subunit vaccine (HZ/su) that is expected to be licensed soon for marketing under the trade name Shingrix. The antigenic portion of the vaccine is the viral glycoprotein E subunit, and the product contains the adjuvant system AS01B, which enhances immunologic response to the product. The vaccine is administered in a two-dose series, with doses administered 1 month apart.
Providing a useful framework for considering zoster vaccine through the lenses of GSA’s sections, four central questions promulgated by the work group will be considered if the new vaccine has been licensed by FDA by the time ACIP reconvenes in October:

- Should ACIP recommend HZ/su for administration to immunocompetent persons, and if so, should the recommendation be for all persons in an age or risk group (category A) or for consideration on an individual patient basis (category B)?
- At what age should HZ/su be recommended (50 versus 60 years)?
- Should ACIP state a preference for one vaccine over the other?
- Should ACIP recommend vaccination with HZ/su for people who previously received ZVL?

Concerning whether to add HZ/su to the adult immunization schedule for immunocompetent adults, the interim ACIP work group perspective is favorable toward a category A recommendation, according to Kathleen Dooling, MD, MPH, medical epidemiologist in the CDC’s Division of Viral Diseases.

Summarizing the work group’s discussions, Dooling reminded ACIP members of the overall incidence of herpes zoster (4 cases per 1,000 population, or about 1 million cases annually in the United States) and increased incidence with age (up to more than 15 cases per 1,000 population in those aged 80 years or older). Postherpetic neuralgia (PHN) occurs in 10% to 18% of those with herpes zoster, she said, and the incidence of this painful, potentially debilitating condition also increases with age.

Based on the high vaccine effectiveness against shingles seen in clinical trials of HZ/su (97% in adults aged 50–69 years and 91% in those aged 70 years or older), Dooling estimated that vaccination of a cohort of 10,000 people aged 60 years would avert 310 cases of shingles and 33 cases of PHN over the following 4-year period. The number needed to vaccinate (NNV) to prevent 1 case of shingles would thus be 32, and the NNV to prevent 1 case of PHN would be 303.

Dooling also presented data based on Merck and GlaxoSmithKline models for each of their zoster vaccines over the lifespan of the same cohort described above. Shingles cases averted would be 780 for ZVL and 1,036 for HZ/su; PHN cases averted would be 70 and 112, respectively. The NNVs would thus be 10–13 for shingles and 89–143 for PHN, Dooling said.
Zostavax, the Merck ZVL product, was licensed by FDA for use in adults aged 50 years or older. However, Dooling noted, postmarketing data showed considerable waning of its effects over the decade following vaccination, especially after year 4. This led to a 2011 ACIP decision to recommend its use only after adults reach 60 years of age.

The Affordable Care Act, signed into law in 2010, requires provision of ACIP-recommended vaccines at no cost, which for ZVL would mean at age 60. Dooling noted that about 1 in 5 cases of shingles occurs in people in their 50s; as a result, clinicians often recommend that patients get the vaccine before age 60 but individuals then discover that their insurance will not pay for it. The situation has been further complicated since the Merck zoster vaccine is more available in pharmacies than in physicians’ offices because it is covered under Medicare Part D rather than Part B, and it is a frozen product that pharmacies are better equipped to handle. In most states, patients get a prescription from a physician or other prescriber and take it to the pharmacy for administration.

FDA is considering the GlaxoSmithKline HZ/su product for adults aged 50 years or older; the ZOE-50 efficacy study included patients in this age group. If FDA licenses the vaccine, that is likely the age at which use of the product would be approved.

Since only 4 years of vaccine effectiveness data are currently available for HZ/su, ACIP will have to go out on a limb if it varies from its Zostavax recommendation by advising use of Shingrix for adults starting at age 50. The ACIP work group generally prefers a firm evidence base for its recommendations, and it also likes clarity and simplicity in its recommendations. If one vaccine is recommended at age 50 and the other at age 60, some patients and professionals are sure to be confused.

Considering all the available evidence, the ACIP work group is leaning toward recommending use of the HZ/su product starting at age 50, Dooling said. Arguments favoring age 50 for HZ/su include these:

- With some 42 million Americans currently between 50 and 60 years of age, many cases of shingles and PHN could be averted with greater vaccination at younger ages.
- The minimal waning seen with the HZ/su product in younger people and its high initial efficacy rate indicate that most patients would maintain acceptable effectiveness levels far past the 4 years studied so far. In addition, immunologic (not clinical) data are available that indicate protection may extend to 9 years.
Stating a preference for one vaccine over another is something ACIP generally avoids. For example, high-dose influenza vaccine is considerably more effective in older adults, yet ACIP does not recommend it over other products in this age group.

The situation may be different for zoster vaccines. With higher effectiveness rates for HZ/su and the lack of waning as discussed above, a majority of work group members favor stating a preference for it over the ZVL product. Initial cost-effectiveness analyses, conducted by the vaccine manufacturers but using an estimate of the final GlaxoSmithKline price, show that HZ/su is more cost-effective than ZVL in many of the scenarios tested. Over the lifespan in a cohort of 10,000 adults at age 60 years, 360–715 cases of herpes zoster and 10–63 cases of PHN could be averted, according to Merck and GlaxoSmithKline analyses. The new product can also be stored in refrigerators, which could increase availability.

Other members of the work group favor stating no preference at this time; Dooling listed several considerations that favor making sure that both products stay on the U.S. market. Key among these is the possibility of an adverse effect emerging during widespread use of the GlaxoSmithKline product. In addition, HZ/su has been more reactogenic than ZVL, with increased frequency of severe adverse effects.

The work group’s final recommendation will be made after GlaxoSmithKline provides a price for its product.

The final question facing ACIP is whether those who have received the ZVL product should receive the new vaccine if it is licensed by FDA. Based on data presented to ACIP, the work group is likely to recommend revaccination, perhaps after 5 years have elapsed.

In the Zoster-048 trial of 430 adults aged 65 years or older, those who had received the Merck vaccine at least 5 years earlier were compared with previously unvaccinated individuals. Immune responses to HZ/su were similar in the two groups, and adverse events were similar through 1 month following administration of the second dose of the new vaccine.

ACIP meets again on October 25–26 at CDC in Atlanta. Assuming a favorable FDA decision in the intervening months, a CDC cost-effectiveness analysis will be completed and the work group will finalize its recommendations. ACIP will then be prepared for an informed debate over these four central questions concerning the place of HZ/su in the adult immunization schedule.
SOURCES AND RESOURCES

- ACIP meetings homepage
- ACIP GRADE procedures for making evidence-based recommendations
- ZOE-50 and ZOE-70 efficacy studies of HZ/su vaccine
- Zoster-048 trial news release

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