News

- **Age-related variations in influenza vaccine effectiveness** (VE) were evident in final figures from the Centers for Disease Control and Prevention (CDC) for the 2016–17 season. Reported at the June meeting of the **Advisory Committee on Immunization Practices**, the adjusted VE and 95% confidence intervals were 42% (35%–48%) overall and 61% (49%–70%), 35% (13%–61%), 19% (–1% to 34%), 42% (26%–55%), and 25% (–5% to 46%) for these respective age groups: 6 months to 8 years, 9–17 years, 18–49 years, 50–64 years, and ≥65 years. Thus, for younger and older adults (the 18–49 years and 65 years or older age groups), the vaccine was not significantly effective. Overall, the influenza season was late, peaking in mid-February for A strains and in mid-March for B strains, and somewhat long, with cases extending from December to April. The calculations are based on a test-negative, case–control analysis of confirmed outpatient influenza cases at the five centers in the U.S. Flu VE Network.

- Problems such as this variation of VE have public health officials concerned. Annual influenza immunization remains the best option for preventing this potentially fatal disease, and as people try to make sense of VE variations, messaging needs to remain positive about the necessity for annual influenza immunizations. However, in a study reported in the *Journal of Infectious Diseases* (2017;215:1059–69; related editorial, pp. 1017–9), influenza vaccinations in consecutive years lowered VE in later seasons. This finding is predicted by the **antigenic distance hypothesis** (ADH), an effect that is evident when the vaccine strains are antigenically similar but circulating strains are not. Based on data from Canada in the seasons since the 2010–11 A/H3N2 epidemic, VE was reduced in some years consistent with ADH predictions.

Resources

- Vaccines were the focus of a June 25 segment on HBO’s *Last Week Tonight with John Oliver*. In the 27-minute segment, the host uses his characteristic off-color style to deconstruct common myths and misperceptions about immunizations.

- Influenza vaccination resources are available on the website of the **National Adult and Influenza Immunization Summit**, including materials for use by health professionals, screening checklists, and standing orders for administering the vaccine to adults.
The National Vaccine Advisory Committee’s Standards for Adult Immunization Practice include four steps: assess, share a strong recommendation, administer/refer, and document/report. Within this process, a key factor is whether a health professional gives a strong recommendation or merely suggests a vaccine.

For instance, a patient’s reaction can be quite different to a health professional saying, “You should think about getting the shingles vaccine,” instead of strongly advising, “Today, I recommend that you get the shingles vaccine.”

For many adults, hearing a strong recommendation from their provider is all that they need to accept the vaccine. But for those who have further questions, the CDC recommends using the SHARE model in communicating with patients.

According to the CDC website, SHARE involves clinicians and other vaccine advocates taking these proactive steps:

- **SHARE the tailored reasons** why the recommended vaccine is right for the patient given his or her age, health status, lifestyle, occupation, or other risk factors.
- **HIGHLIGHT positive experiences** with vaccines (personal or in your practice), as appropriate, to reinforce the benefits and strengthen confidence in vaccination.
- **ADDRESS patient questions** and any concerns about the vaccine, including side effects, safety, and vaccine effectiveness in plain and understandable language.
- **REMINd patients that vaccines protect them and their loved ones** from many common and serious diseases.
- **EXPLAIN the potential costs of getting the disease**, including serious health effects, time lost (such as missing work or family obligations), and financial costs.

A Medscape Education module provides excellent examples of how to use the SHARE model. Check it out!
Meeting in Atlanta in early May, the 2017 National Adult and Influenza Immunization Summit (NAIIS) provided some 350 attendees with information on creative innovations in the field of adult and influenza immunizations. Participants representing 150 organizations, companies, government agencies, academic institutions, and other entities learned from speakers during 13 sessions, engaged researchers in poster presentations, and networked with other vaccine advocates during breaks and an awards luncheon.

Slides from most presentations—all addressing the meeting theme of “Prioritizing Prevention: Strategies to Improve Adult Vaccination Within the Transforming Health System”—are available on the NAIIS website. This article provides summaries of presentations particularly relevant to GSA members.

In 2018, the NAIIS meeting will occur in conjunction with the National Immunization Conference, which is tentatively scheduled for May 15–17 of next year.

For Medicare providers, immunization activities can be important under the Quality Payment Program (QPP) being rolled out this year by the Centers for Medicare & Medicaid Services (CMS), Richard Wild, MD, JD, MBA, CMO for the Atlanta Region of CMS, told NAIIS attendees. Created as part of MACRA (Medicare Access and CHIP Reauthorization Act of 2015) to move health care toward payments based on quality rather than quantity of services, QPP provides incentive payments for Part B clinicians who report performance on six indicators of their own choice as part of the Merit-based Incentive Payment System (MIPS).

The quality category of MIPS determines 60% of the final score in QPP; it replaces the Physician Quality Reporting System and quality portion of the value modifier under the previous CMS pay-for-performance methodology, Wild said. The MIPS payments begin in 2019 and are determined by supporting data from this calendar year. Clinicians who submit a full year of data can earn a “moderate” payment adjustment; those who submit data for a time period of at least 90 days can earn a neutral or small positive payment. Those who submit some data—for any time period—will not be penalized, but those who submit nothing and without a waiver from CMS will receive a 4% decrease in payment. (Note: Based on the final rule issued by CMS on June 20 and related news reports, CMS has granted waivers to more than 800,000 U.S. physicians, leaving at most 400,000 who must implement reporting during 2017.)

Influenza vaccination provides an example of the nearly 300 QPP quality measures. For this metric, clinicians report the percentage of patients aged 6 months or older seen for a visit between October 1 and March 31 who received an influenza immunization or who reported previous receipt of an influenza immunization.
**BEHAVIORAL/SOCIAL SCIENCES**

CDC officials also previewed upcoming influenza product availability for other federal programs, including the important Vaccines for Children (VFC) program.

Orders for 64 immunization programs with more than 40,000 VFC provider sites and Section 317/Prevention and Public Health Fund (PPHF) programs (see June 2017 NAVP Immunizations Newsletter) are coordinated by CDC staff. Working through a centralized distributor, CDC enters allocations for state and local immunization programs for prebooked vaccine as supplies are received at distribution depots. Available doses are generally allocated to programs in 1 to 2 business days after receipt. State and local programs can then submit/approve provider vaccine orders.

**HEALTH SCIENCES**

Shipment of the 2017–18 influenza vaccine begins soon. At NAIIS, companies previewed the formulations that will be available and number of expected doses for this season.

Marketed under a number of trade names, influenza vaccine is available in trivalent and quadrivalent formulations, syringes pre-filled with adult or pediatric doses, multidose vials (which contain the preservative thimerosal), egg-free products made through cell culture, and high-dose products for older adults. All products are injectable. The intransal live attenuated influenza virus vaccine from MedImmune/AstraZeneca again will not be available in the United States because of efficacy concerns.

During 2017–18, Sanofi Pasteur expects to produce 70 million doses of its Fluzone product, the same number as during the last season. High-dose trivalent products accounted for 20 million of last season’s doses; these were used to vaccinate about 60% of Americans aged 65 years or older who received influenza immunizations.

GlaxoSmithKline has 35 million to 40 million influenza vaccine doses of FluLaval and Fluarix products on the way, the company reported at NAIIS. All of these are quadrivalent formulations.

Seqirus, a company formed when bioCSL and the Novartis influenza vaccines business combined in 2015, is the other large supplier of influenza vaccines. It did not project a specific quantity of vaccine for the upcoming season. Its brands include Fluad (an adjuvanted vaccine indicated for those aged 65 years or older), Flucelvax Quadrivalent, Afluria Quadrivalent, Afluria, and Fluvirin.

The Protein Sciences Flublok influenza vaccine quadrivalent uses cell-culture manufacturing processes and therefore contains no egg proteins, formaldehyde, virus, thimerosal, antibiotics, latex, gelatin, gluten, or endotoxins, the company said. The expected supply includes 600,000 prefilled syringes of quadrivalent product and limited quantities of a trivalent vaccine (approximately 100,000 doses).
Advances in vaccine technologies were highlighted in the session “What’s Coming in Adult Vaccines and Vaccinations?” Angela K. Shen, ScD, MPH, senior science policy advisor in the National Vaccine Program Office and a co-chair of NAIIS, reviewed new devices and products within the context of the business case for vaccines.

The perception of financial risk with regard to vaccines causes some clinicians who care primarily for adults to be hesitant about stocking and administering these products. The up-front investment in refrigerators, freezers, inventory, special needles and syringes, and waste disposal are relatively large. Billing is complicated; reimbursements can be limited. Product can be ruined when cold-storage units fail or power is interrupted. If a patient agrees to get a vaccine but becomes hesitant before administration, the vaccine is often unusable and also unbillable.

In this environment, several advances in vaccine technology could make the equation more favorable, Shen told NAIIS attendees. For biological scientists, improved vaccine-administration methods would enhance vaccine efficacy and decrease patient anxiety about “shots.” Shen listed several vaccine-delivery advances that could someday help this situation:

- Antigen-carrier systems—liposomes, microspheres, and nanoparticles that control how antigen is presented to the immune system, allowing for sustained release or cellular targeting.
- Needle-free patches—dendritic cells engaged to present antigen delivered by dissolving sugar microneedles.
- Inhaled or oral vaccines—delivery of antigen into lungs or the gastrointestinal tract, mimicking the natural entry of pathogens and initiating pulmonary or gut-associated lymphoid tissue immune responses.
- Microneedle arrays—engaging dendritic cells through “patches” of needles less than 1 mm in length.
- Transcutaneous immunization—creating skin abrasions through which antigens can pass.

Another potential development is smart refrigeration—pharmaceutical-grade vaccine storage and management systems with enhanced features that might ensure temperature stability; integrate with monitoring, inventory, or billing systems; or have back-up capabilities to keep product cold during power failures.
SOURCES AND RESOURCES

- National Adult and Influenza Immunization Summit website
- 2017 Summit Information