Immunization Safety Office Updates

Centers for Disease Control and Prevention

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Advisory Commission on Childhood Vaccines (ACCV)
June 4, 2015

Topics

- Immunization Safety Office highlights
- Preview of selected sessions for the June 2015 Advisory Committee on Immunization Practices (ACIP) meeting
- Selected publications

Immunization Safety Office (ISO) highlights

- ISO continues to work with FDA partners to prepare for implementation of manufacturer reporting to the Vaccine Adverse Event Reporting System (VAERS) using the E2B(R3) message standard
  - Implementation date is June 10, 2015
- ISO will present a 2014-15 end-of-season analysis of influenza vaccine safety at the June 2015 ACIP meeting on June 24, 2015

June 2015 ACIP meeting preview

- **Meningococcal vaccines**
  - **Policy options for routine use of meningococcal group B (MenB) vaccines in adolescents**
  - **GRADE presentation on evidence for use of MenB vaccine in adolescents and college students**
  - **Considerations for routine use of MenB vaccines in adolescents**
  - **Vote on proposed recommendations**

http://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2015-06.pdf

June 2015 ACIP meeting preview

- **Influenza**
  - Influenza surveillance update
  - Influenza vaccine safety update
  - High dose influenza vaccine update
  - Vote on proposed recommendations

- **Influenza A (H5N1) vaccine**
  - Influenza A (H5N1) epidemiology update
  - Vote on proposed recommendations

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June 2015 ACIP meeting preview

- **Pertussis**
  - **Cocooning and Tdap vaccination**
  - **Acellular pertussis vaccine effectiveness among children in the setting of pertactin-deficient B. pertussis, Vermont, 2011-2013**
- **Pneumococcal vaccines**
  - **Intervals between 13-valent pneumococcal conjugate (PCV13) and 23-valent pneumococcal polysaccharide (PPSV23) vaccines, and supporting evidence and rationale for change**
  - **Vote on proposed recommendations**

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June 2015 ACIP meeting preview

- **Herpes zoster**
  - **Update on herpes zoster epidemiology and vaccine uptake**
  - **Results of GSK Phase 3 study of investigational adjuvant-based zoster vaccine**

http://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2015-06.pdf

Selected publications

- Petrosky et al; Centers for Disease Control and Prevention (CDC). Use of 9-valent human papillomavirus (HPV) vaccine: updated HPV vaccination recommendations of the advisory committee on immunization practices. MMWR Morb Mortal Wkly Rep. 2015 Mar 27;64(11):300-4.

- Iqbal et al. Relationship between Guillain-Barré syndrome, influenza-related hospitalizations, and influenza vaccine coverage. Vaccine. 2015 Apr 21;33(17):2045-9.
  - Pneumonia and influenza hospitalization rates were significantly correlated with hospitalization rates for Guillain-Barré syndrome
  - Vaccine coverage did not significantly affect the rates of Guillain-Barré syndrome hospitalization at the population level

Selected publications

- McNamara et al. First Use of a Serogroup B Meningococcal Vaccine in the US in Response to a University Outbreak. Pediatrics. 2015 May;135(5):798-804.
  - No serogroup B meningococcal disease cases occurred in persons who received 1 or more doses of 4CMenB vaccine, suggesting 4CMenB may have protected vaccinated individuals from disease
  - However, a case occurred in an unvaccinated close contact of a vaccinated university student demonstrating that carriage of serogroup B Neisseria meningitidis among vaccinated persons was not eliminated

Selected publications

- Datwani et al. Chorioamnionitis following vaccination in the Vaccine Adverse Event Reporting System. Vaccine. 2015 May 11. [Epub ahead of print]
  - Chorioamnionitis was found to be uncommonly reported, representing 1% of pregnancy reports to VAERS; a majority of reports had at least one risk factor for chorioamnionitis.
- Hibbs et al. Vaccination errors reported to the vaccine adverse event reporting system, United States, 2000–2013. Vaccine (2015), http://dx.doi.org/10.1016/j.vaccine.2015.05.006
  - Vaccination error reports to VAERS have increased substantially from 2000-2013
  - Contributing factors might include changes in reporting practices, increasing complexity of the immunization schedule, availability of products with similar sounding names or acronyms, and increased attention to storage and temperature lapses

Selected publications

- **Miller et al. Deaths following vaccination: What does the evidence show? Vaccine. 2015 May 21. [Epub ahead of print]**
  - **Vaccines are rigorously tested and monitored and are among the safest medical products we use. Millions of vaccinations are administered to children and adults in the United States each year. Serious adverse reactions are uncommon and deaths caused by vaccines are very rare.**
  - **Rare cases where a known or plausible theoretical risk of death following vaccination exists include anaphylaxis, vaccine-strain systemic infection after administration of live vaccines to severely immunocompromised persons, intussusception after rotavirus vaccine, Guillain-Barré syndrome after inactivated influenza vaccine, fall-related injuries associated with syncope after vaccination, yellow fever vaccine-associated viscerotropic disease or associated neurologic disease, serious complications from smallpox vaccine including eczema vaccinatum, progressive vaccinia, postvaccinal encephalitis, myocarditis, and dilated cardiomyopathy, and vaccine-associated paralytic poliomyelitis from oral poliovirus vaccine.**
  - **The evidence for the safety and effectiveness of vaccines routinely given to children and adults in the Unites States is overwhelmingly favorable.**

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Thank You

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