Immunization Safety Office Updates

Centers for Disease Control and Prevention

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Advisory Commission on Childhood Vaccines (ACCV)
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Topics

- Update on selected sessions from the February 2016 Advisory Committee on Immunization Practices (ACIP) meeting
- Selected vaccine safety publications

February 2016 ACIP meeting summary

- **Human papillomavirus (HPV) vaccines**
  - **The United States has a 3-dose schedule for 4vHPV, 9vHPV and 2vHPV vaccines**
  - **Some countries are using a 2-dose schedule**
  - **Merck trial of 2-dose schedules for 9vHPV**
    - **0, 6 months and 0, 12 months schedule**
    - **2-dose schedules compared favorably to the 3-dose schedule**
    - **Results under review by FDA**
    - **Efficacy, durability and long term effectiveness to be evaluated in further studies**

http://www.cdc.gov/vaccines/acip/meetings/slides-2016-02.html

February 2016 ACIP meeting summary (cont.)

- **Human papillomavirus (HPV) vaccines (cont.)**
  - **Merck does not plan to submit 2-dose schedule to FDA for 4vHPV**
  - **Transition from 4vHPV to 9vHPV in the United States is in progress and expected to be complete by the end of 2016**
  - **GSK does not plan to submit 2-dose schedule to FDA for 2vHPV**
  - **2vHPV studies provide evidence for consideration of 2-dose schedule, will be discussed in future**

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February 2016 ACIP meeting summary (cont.)

- **Meningococcal vaccines**
  - **Risk of meningococcal disease in men who have sex with men (MSM)**
    - **Several recent outbreaks due to serogroup C**
    - **Risk for infection increases with HIV infection**
    - **During recent meningitis outbreaks, MenACWY vaccination recommended for MSM in response to outbreaks**
    - **Consider recommending meningococcal vaccine for HIV-infected persons and MSM**
    - **Further studies needed to better understand transmission and risk factors for this population**
  - **Next steps**
    - **Continue to vaccinate with MenACWY if additional outbreaks occur among MSM**
    - **Enhanced surveillance for cases in MSM and HIV-infected persons ongoing**
    - **Cost effectiveness and GRADE analysis in progress**

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February 2016 ACIP meeting summary (cont.)

- **Japanese Encephalitis (JE) Vaccine**
  - Ixiaro (Valneva) is the only JE vaccine available in US
    - 2009 – licensed for adults
    - 2011 – ACIP recommended booster dose for adults
    - 2013 – age extended to include children ≥2 months old
    - Goal is to update the ACIP recommendations last published in 2010
    - FDA currently reviewing data on safety and efficacy of booster dose for children
      - No off-label recommendation requested
      - Await FDA review of data

http://www.cdc.gov/vaccines/acip/meetings/slides-2016-02.html

February 2016 ACIP meeting summary (cont.)

- **Influenza**
  - **Influenza vaccine effectiveness**
    - Interim results for 2015-2016 season (through Feb 12, 2016) indicate vaccine effectiveness of 59% against medically attended influenza
    - End of season vaccine effectiveness estimates may differ from interim estimates
  - **Study presented by Protein Sciences Corp. on Flublok quadrivalent recombinant-IIV4 (RIV4) vs. IIV4**
    - 4,000 subjects in each arm of the study
    - PCR-confirmed influenza-like illness: RIV4 2.2% vs. IIV4 3.3%
    - Both vaccines had similar safety profiles
    - Injection site pain and tenderness significantly less with RIV4

http://www.cdc.gov/vaccines/acip/meetings/slides-2016-02.html

February 2016 ACIP meeting summary (cont.)

- **Influenza (cont.)**
  - **Reviewed data on use of influenza vaccine in egg-allergic recipients**

    Inactivated influenza vaccine (IIV) studies

    - **Data from multiple studies indicate low rate of minor reactions; serious adverse events are rare**
    - **Immediate hypersensitivity reactions, including anaphylactic reactions, do not appear to be more common in egg-allergic than non egg-allergic vaccine recipients**

    Live attenuated influenza vaccine (LAIV) studies

    - **No immediate systemic reactions observed**
    - **As with IIV, this is likely due to the very low amount of egg protein in LAIV**

http://www.cdc.gov/vaccines/acip/meetings/slides-2016-02.html

February 2016 ACIP meeting summary (cont.)

- **Influenza vaccine vote**
  - **Annual influenza vaccination recommended for all persons aged 6 months and older**
  - **Timing of vaccination: offer vaccine by the end of October if possible; should be offered as long as virus is circulating and vaccine is available**
  - **Remove 30-minute post-immunization observation period (keep 15-20 minutes for syncope)**

http://www.cdc.gov/vaccines/acip/meetings/slides-2016-02.html

February 2016 ACIP meeting summary (cont.)

- **Influenza vaccine vote (cont.)**
  - **Persons with history of egg allergy including those who required epinephrine or another emergency medical intervention may receive any licensed influenza vaccine**
    - **Vaccine should be administered in a setting with a healthcare provider with experience in recognizing and managing severe allergic conditions**
  - **Removed this wording**
    - **For persons with no known history of exposure to egg, but who are suspected of being egg-allergic on the basis of previously performed allergy testing, consultation with a physician with expertise in the management of allergic conditions should be obtained before vaccination. Alternatively, RIV3 may be administered if the recipient is aged ≥18 years.**
  - **Algorithm on egg allergy to be removed**

http://www.cdc.gov/vaccines/acip/meetings/slides-2016-02.html

Selected publications

- Haber et al. Post-licensure surveillance of quadrivalent inactivated influenza (IIV4) vaccine in the United States, Vaccine Adverse Event Reporting System (VAERS), July 1, 2013-May 31, 2015. Vaccine. 2016 Mar 23. pii: S0264-410X(16)30031-7. [Epub ahead of print]
  - In this review of VAERS reports quadrivalent inactivated influenza vaccine had a similar safety profile to trivalent inactivated influenza vaccine.
  - Most of the reported adverse events were non-serious.
  - The findings are consistent with data from pre-licensure studies of quadrivalent inactivated influenza vaccine.

Selected publications

- Miller et al. Post-licensure safety surveillance of 23-valent pneumococcal polysaccharide vaccine in the Vaccine Adverse Event Reporting System (VAERS), 1990-2013. Vaccine. 2016 Apr 14. pii: S0264-410X(16)30150-5. [Epub ahead of print]
  - This safety review did not identify any new or unexpected safety concerns for PPSV23.
  - The VAERS data are consistent with safety data from pre-licensure clinical trials and other post-licensure studies.
- Baxter et al. Case centered analysis of Optic Neuritis following vaccines. Clin Infect Dis. 2016 Apr 10. pii: ciw224. [Epub ahead of print]
  - The authors evaluated the risk of optic neuritis following vaccines using a large-linked database and did not detect any association between optic neuritis and receipt of any type of vaccine.

Selected publications

- Li et al. Post licensure surveillance of influenza vaccines in the Vaccine Safety Datalink in the 2013-2014 and 2014-2015. Pharmacoepidemiol Drug Saf. 2016 Apr 1. [Epub ahead of print]
  - No increased risks, other than for febrile seizures (which has been previously identified), were identified in influenza vaccine safety surveillance during 2013-2014 and 2014-2015 seasons in the Vaccine Safety Datalink.
- Gee et al. Quadrivalent HPV vaccine safety review and US safety monitoring plans for nine-valent HPV vaccine. Hum Vaccin Immunother. 2016 Mar 30:0. [Epub ahead of print]
  - With the exception of syncope, a known preventable adverse event after any injected vaccination, both pre-licensure and post-licensure 4vHPV safety data have been reassuring with no confirmed safety signals identified.

Selected publications

- Baxter et al. Sudden-Onset Sensorineural Hearing Loss after Immunization: A Case-Centered Analysis. Otolaryngol Head Neck Surg. 2016 Mar 29. pii: 0194599816639043. [Epub ahead of print]
  - A large-scale analysis in a large-linked database applying a case-centered method did not detect any association between sudden-onset sensorineural hearing loss and previous receipt of trivalent inactivated influenza vaccine or other vaccines.
- Moro et al. Enhanced surveillance of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccines in pregnancy in the Vaccine Adverse Event Reporting System (VAERS), 2011-2015. Vaccine. 2016 Mar 22. pii: S0264-410X(16)30032-9. [Epub ahead of print]
  - No new or unexpected vaccine adverse events were noted among pregnant women who received Tdap after routine recommendations for maternal Tdap vaccination.

Selected publications

- Schiffer et al. Recent developments in the understanding and use of anthrax vaccine adsorbed: achieving more with less. Expert Rev Vaccines. 2016 Mar 25:1-12. [Epub ahead of print]
  - Anthrax Vaccine Adsorbed (AVA, BioThrax™) is the only FDA approved vaccine for the prevention of anthrax in humans. Recent improvements in pre-exposure prophylaxis (PrEP) use of AVA include intramuscular (IM) administration and simplification of the priming series to three doses over 6 months. Administration IM markedly reduced the frequency, severity and duration of injection site reactions. Refinement of animal models for inhalation anthrax, identification of immune correlates of protection and cross-species modeling have created opportunities for reductions in the PrEP booster schedule and were pivotal in FDA approval of a post-exposure prophylaxis (PEP) indication. Clinical and nonclinical studies of accelerated PEP schedules and divided doses may provide prospects for shortening the PEP antimicrobial treatment period. These data may assist in determining feasibility of expanded coverage in a large-scale emergency when vaccine demand may exceed availability. Enhancements to the AVA formulation may broaden the vaccine's PEP application.

Selected publications

- Su et al. Notes from the Field: Administration Error Involving a Meningococcal Conjugate Vaccine - United States, March 1, 2010-September 22, 2015. MMWR Morb Mortal Wkly Rep. 2016 Feb 19;65(6):161-2.
  - This article describes reports to the Vaccine Adverse Reporting System (VAERS) of inappropriate administration of the meningococcal conjugate vaccine MENVEO® involving providers giving only one of the two components of the vaccine.
  - The vaccine's lyophilized component should be reconstituted with the liquid component prior to administration.

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Thank You

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