Immunization Safety Office Updates

Centers for Disease Control and Prevention

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Advisory Commission on Childhood Vaccines (ACCV)
December 3, 2015
Topics

- Update on selected sessions from the October 2015 Advisory Committee on Immunization Practices (ACIP) meeting
- Selected vaccine safety publications
October 2015 ACIP meeting summary

- Meningococcal
  - Men B vaccine
    - Permissive recommendation (Category B)\textsuperscript{1, 2}
    - May be administered to persons aged 16-23 years to provide short-term protection against MenB disease
    - No recommendations on routine use at this time due to limited data and low prevalence of disease

\textsuperscript{1}Recommendations available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm
\textsuperscript{2}Category B recommendations are made for individual clinical decision making

http://www.cdc.gov/vaccines/acip/meetings/meetings-info.html
Influenza

- Activity in United States low at the time
- Most currently circulating viruses similar to those in 2015-16 vaccines; may offer significantly more protection vs. last season’s vaccine
- Vaccine manufacturer study on cost effectiveness of high dose vs. standard dose vaccine in persons aged ≥65 among 32,000 persons
  - High dose more cost effective than standard dose based on reductions in cardiovascular complications

http://www.cdc.gov/vaccines/acip/meetings/meetings-info.html
Influenza (cont.)

- Novartis adjuvanted trivalent inactivated influenza vaccine (aTIV)*
  - MF59 adjuvant contains squalene, surfactants, citrate
  - Enhances immune response
  - Generated higher antibody titers
  - Safety profile similar to other licensed vaccines
  - Under review by FDA

*Currently licensed in 35 countries in Europe, Latin America, Asia Pacific and Canada, and indicated in individuals aged ≥65 years.
October 2015 ACIP meeting summary (cont.)

- **Human papillomavirus (HPV) vaccine**
  - National coverage is increasing
    - Estimated 34.4% in girls, 20.6% in boys for ≥3 doses (2014)
  - Parents’ main reasons for not vaccinating
    - Believe not needed for both boys and girls (~18%)
    - Safety concerns for girls (~16%)
    - Believe not recommended for boys (~18%)
  - Programmatic strategies put in place to increase coverage
    - Communication campaign targeted to public
    - Immunization Information System-based reminder

http://www.cdc.gov/vaccines/acip/meetings/meetings-info.html
October 2015 ACIP meeting summary (cont.)

- Update on HPV vaccine safety
  - No elevated risk for venous thromboembolism (VTE), GBS, autoimmune and/or neurologic conditions after HPV4 \(^1\)\(^-\)\(^7\)
  - No increased risk of fetal loss, spontaneous abortion (SAB), congenital anomalies in phase III trials \(^8\)
  - Recent safety concerns: primary ovarian insufficiency, complex regional pain syndrome, postural orthostatic tachycardia syndrome (POTS)
  - HPV9 monitoring currently underway

7. Scheller et al. Quadrivalent HPV vaccination and the risk of multiple sclerosis and other demyelinating diseases of the central nervous system. JAMA 2015.
Japanese encephalitis (JE) vaccine
   - MMWR Recommendations from 2010 to be updated to remove mouse brain-derived JE vaccine and add inactivated Vero cell culture-derived JE vaccine Ixiaro (Valneva - new distributor)

Combination vaccines
   - Pediatric hexavalent vaccine: DTaP-IPV-Hib-HepB
     - Merck and Sanofi Pasteur partnership
     - Under review by FDA

Cholera vaccine
   - Not currently licensed in US
   - CVD 103-HgR is oral cholera vaccine anticipated to be licensed in the United States in 2016

Ebola vaccine
   - >5,550 health care workers vaccinated as of October 18, 2015
   - No serious adverse events
   - 8 deaths, none vaccine-related, no Ebola deaths in vaccinated

- Among women who received Tdap vaccination during pregnancy, there was no increased risk of acute adverse events or adverse birth outcomes for those who had been previously vaccinated less than 2 years before or 2 to 5 years before compared with those who had been vaccinated more than 5 years before.

- These findings suggest that relatively recent receipt of a prior tetanus-containing vaccination does not increase risk for adverse events after Tdap vaccination in pregnancy.
Selected publications

  - Rate of vaccine related anaphylaxis for any vaccine was approximately 1-2 cases per million vaccine doses administered
  - Anaphylaxis after vaccination is rare in all age groups; despite its rarity, anaphylaxis is a potentially life-threatening medical emergency that vaccine providers need to be prepared to treat
Selected publications

  - Concomitant administration of Tdap and influenza vaccines during pregnancy was not associated with a higher risk of medically attended adverse acute outcomes or birth outcomes compared with sequential vaccination.

- In response to the new ACIP recommendations, the Centers for Disease Control and Prevention (CDC) implemented ongoing collaborative studies to evaluate whether vaccination with Tdap during pregnancy adversely affects the health of mothers and their offspring and provide the committee with regular updates.

- The paper describes the public health actions taken by CDC to respond to the ACIP recommendation to study and monitor the safety of Tdap vaccines in pregnant women and describes the current state of knowledge on the safety of Tdap vaccines in pregnant women.
Selected publications

  - The risk of developing VTE among 9- to 26-year-olds was not elevated following HPV4 exposure
  - Sample size limited our ability to rigorously evaluate potential effect modifiers, such as gender, through stratified analysis

  - No evidence of an increased risk of VTE associated with HPV4 among 9-26-year-old females
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Thank You

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.