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)[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**

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

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

October 2015 ACIP meeting summary (cont.)

- **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

October 2015 ACIP meeting summary (cont.)

- **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.**

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

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**

[1]Arnheim-Dahlstrom et al. Autoimmune, neurological, and venous thromboembolic adverse events after immunisation of adolescent girls with quadrivalent human papillomavirus vaccine in Denmark and Sweden: cohort study. BMJ 2013.

[2]Scheller et al. Quadrivalent human papillomavirus vaccine and the risk of venous thromboembolism. JAMA 2014.

[3]Naleway et al. Absence of venous thromboembolism risk following quadrivalent human papillomavirus vaccination, Vaccine Safety Datalink, 2008-2011. Vaccine (in press).

[4]Chao et al. Surveillance of autoimmune conditions following routine use of quadrivalent human papillomavirus vaccine. J Intern Med 2012.

[5]Arnheim-Dahlstrom et al. Autoimmune, neurological, and venous thromboembolic adverse events after immunisation of adolescent girls with quadrivalent human papillomavirus vaccine in Denmark and Sweden: cohort study. BMJ 2013.

[6]Grimaldi-Bensouda et al. Autoimmune disorders and quadrivalent human papillomavirus vaccination of young female subjects. J Intern Med 2013.

[7]Scheller et al. Quadrivalent HPV vaccination and the risk of multiple sclerosis and other demyelinating diseases of the central nervous system. JAMA 2015.

[8]Garland et al. Pregnancy and infant outcomes in the clinical trials of a human papillomavirus type 6/11/16/18 vaccine: a combined analysis of five randomized controlled trials. Obstetrics & Gynecology 2009.

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

October 2015 ACIP meeting summary (cont.)

- **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**

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Selected publications

- **Sukumaran et al. Association of Tdap Vaccination With Acute Events and Adverse Birth Outcomes Among Pregnant Women With Prior Tetanus-Containing Immunizations. JAMA. 2015 Oct 20;314(15):1581-7.**
  - **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

- McNeil et al. Risk of anaphylaxis after vaccination in children and adults. J Allergy Clin Immunol. 2015 Sep 28. pii: S0091-6749(15)01160-4.
  - 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

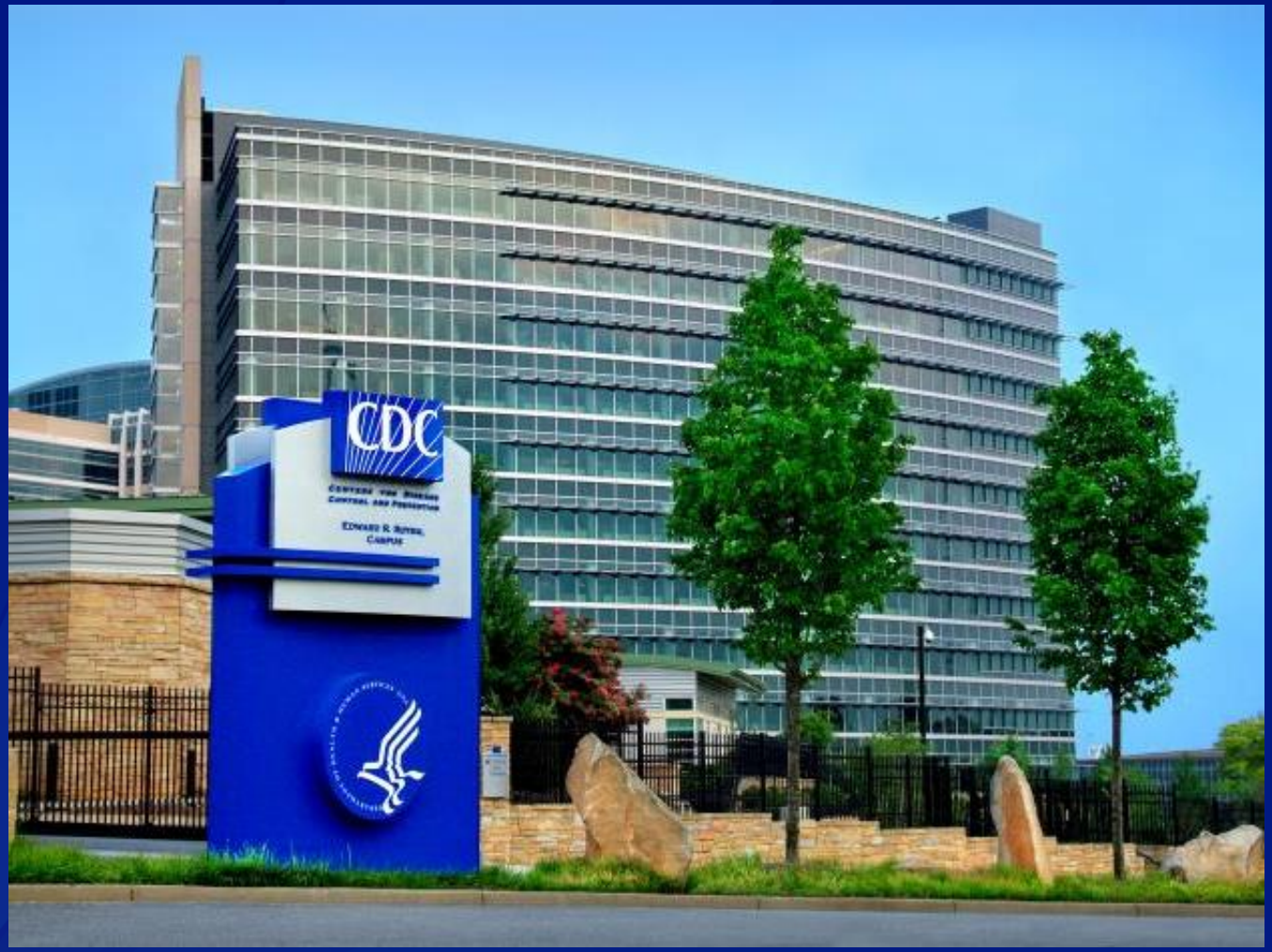
- Sukumaran et al. Safety of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis and Influenza Vaccinations in Pregnancy. Obstet Gynecol. 2015 Nov;126(5):1069-74.
  - Concomitant administration of Tdap and influenza vaccines during pregnancy was not associated with a higher risk of medically attended adverse acute outcomes or birth outcomes compared with sequential vaccination

Selected publications

- Moro et al. The Centers for Disease Control and Prevention's public health response to monitoring Tdap safety in pregnant women in the United States. Hum Vaccin Immunother. 2015 Sep 17:1-8. [Epub ahead of print]
  - 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

- Naleway et al. Absence of venous thromboembolism risk following quadrivalent human papillomavirus vaccination, Vaccine Safety Datalink, 2008-2011. Vaccine. 2015 Nov 5. pii: S0264-410X(15)01417-6.
  - 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
- Yih et al. Evaluation of the risk of venous thromboembolism after quadrivalent human papillomavirus vaccination among US females. Vaccine. 2015 Nov 5. pii: S0264-410X(15)01377-8.
  - 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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