Immunization Safety Office Updates
Centers for Disease Control and Prevention

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Advisory Commission on Childhood Vaccines (ACCV)
September 5, 2013
Topics

- June 2013 Advisory Committee on Immunization Practices (ACIP) meeting summary
- Communications updates
- Selected publications
June 2013 ACIP meeting: sessions with safety presentations

- Japanese encephalitis vaccine
- General recommendations on immunization
- Human papillomavirus (HPV) vaccines
- Rotavirus vaccines
- Influenza


Human Papillomavirus (HPV) Vaccines


- Gardasil not recommended for use during pregnancy, but inadvertent exposures may occur

- Merck Pregnancy Registry part of regulatory commitments with FDA and other international regulatory agencies

- Data from >6 years of surveillance are reassuring with respect to safety after pregnancy exposures

- Rates of spontaneous abortions, fetal deaths, and overall congenital anomalies compare favorably to background rates
June 2013 ACIP meeting selected updates

- Human Papillomavirus (HPV) Vaccines (continued)
- Merck Pregnancy Registry for qHPV Vaccine (Gardasil®) will be discontinued
  - Rationale:
    - Registry fulfilled regulatory obligation of 5 years
    - Largest vaccine pregnancy registry to date
    - No clustering of malformations
    - No identified patterns of birth defects
    - Overall rates of spontaneous abortions, fetal deaths and congenital anomalies at or below background rates
    - Continuation of the registry will not significantly increase power to detect adverse pregnancy outcomes
Rotavirus Vaccines: Update on Intussusception


Rotavirus Vaccines: Update on Intussusception (continued)


- A small excess risk for intussusception detected following RV5 (RotaTeq®) and RV1 (ROTARIX®) in post-marketing surveillance

- CDC continues to recommend that all US infants (following the age and precaution/contraindication criteria) receive rotavirus vaccine – the benefits of RV5 and RV1 outweigh the small excess risk of intussusception
June 2013 ACIP meeting selected updates

- **Influenza**
  - End-of-season update: 2012-2013 Influenza Vaccine Safety Monitoring
    [Link](http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-jun-2013/05-Influenza-Shimabukuro.pdf)
  - No new safety concerns detected for inactivated or live attenuated influenza vaccine during the 2012-13 influenza season
  - Review of pregnancy reports in VAERS for the 2012-13 influenza season identified no unusual patterns
  - No safety signals or elevated risk observed for febrile seizures in young children following inactivated influenza vaccine for the 2012-2013 influenza season
Communications updates (safety)

- Seasonal Flu Update: Summary of 2013-2014 Influenza Vaccine Information

- Febrile Seizures in Children Following Vaccination with Influenza Vaccines — 2012-2013 Influenza Season
Communications updates (general)

- **Seasonal Influenza (Flu): 2013-2014 Flu Season**
  - Available on the CDC website at: [http://www.cdc.gov/flu/about/season/](http://www.cdc.gov/flu/about/season/)

- **CDC Newsroom (Press Release): HPV vaccine: Safe, effective, and grossly underutilized**
  - Press Briefing Transcript (CDC Telebriefing on human papillomavirus (HPV) vaccination coverage and vaccine safety monitoring) available at: [http://www.cdc.gov/media/releases/2013/t0725-Human-papillomavirus.html](http://www.cdc.gov/media/releases/2013/t0725-Human-papillomavirus.html)

- International collaboration to evaluate serious outcomes using a common protocol is feasible
- Significance and consistency of findings support a conclusion of an association between 2009 H1N1 vaccination and GBS
- Given the rarity of the event, the relative incidence found does not provide evidence in contradiction to international recommendations for the continued use of influenza vaccines


- In this large cohort, influenza vaccination during pregnancy was not associated with increased risks for medically attended adverse obstetric events
Selected publications

  - No adverse associations between antigens received through vaccines in the first two years of life and neuropsychological outcomes in later childhood

  - After adjusting for antecedent infections, no evidence for an elevated GBS risk following 2009-10 MIV/2010-11 TIV influenza vaccines
  - However, the association between GBS and antecedent infection was strongly elevated
Selected publications

  - VSD mortality rates demonstrate a healthy vaccinee effect, with rates lowest in the days immediately following vaccination, most apparent in the older age groups
  - The VSD mortality rate is lower than that in the general U.S. population, and the causes of death are similar

  - Despite availability of safe and effective vaccines and ample opportunities for vaccine delivery in the health-care setting, HPV vaccination coverage among adolescent girls failed to increase from 2011 to 2012
Thank You

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