

Immunization Safety Office Updates

Centers for Disease Control and Prevention

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Immunization Safety Office

Division of Healthcare Quality Promotion

National Center for Emerging and Zoonotic Infectious Diseases

Centers for Disease Control and Prevention (CDC)

Advisory Commission on Childhood Vaccines (ACCV)

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National Center for Emerging and Zoonotic Infectious Diseases

Division of Healthcare Quality Promotion – Immunization Safety Office



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

Presentations available at:

<http://www.cdc.gov/vaccines/acip/meetings/slides-jun-2013.html>

Live meeting available at:

<http://www.cdc.gov/vaccines/acip/meetings/live-mtg-jun-2013.html>

June 2013 ACIP meeting selected updates

- ❑ Human Papillomavirus (HPV) Vaccines
 - Merck Pregnancy Registry for qHPV Vaccine (Gardasil®):
Exposure During Pregnancy: June 1, 2006 through May 31, 2012
(<http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-jun-2013/02-HPV-Lievano.pdf>) (presented by Merck)
- ❑ 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

June 2013 ACIP meeting selected updates

□ Rotavirus Vaccines: Update on Intussusception

- Rotavirus Vaccines and Intussusception in the Vaccine Safety Datalink (VSD)
(<http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-jun-2013/02-Rotavirus-Weintraub.pdf>)
- Monitoring of Intussusception after Rotavirus Vaccines—United States, Vaccine Adverse Event Reporting System (VAERS), 2006-2012
(<http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-jun-2013/03-Rotavirus-Haber.pdf>)
- Risk of Intussusception after Rotavirus Vaccination: Results of a PRISM Study
(<http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-jun-2013/04-Rotavirus-Yih.pdf>)

June 2013 ACIP meeting selected updates

- ❑ Rotavirus Vaccines: Update on Intussusception (continued)
 - Intussusception and rotavirus vaccines in Australia (<http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-jun-2013/05-Rotavirus-McIntyre.pdf>)
 - Summary of Intussusception Risk and Benefits of Rotavirus Vaccination in the United States (<http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-jun-2013/06-Rotavirus-Cortese.pdf>)
- ❑ 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
(<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**
 - Available on VAERS website at:
http://vaers.hhs.gov/resources/SeasonalFluSummary_2013-2014.pdf

- ❑ **Febrile Seizures in Children Following Vaccination with Influenza Vaccines — 2012-2013 Influenza Season**
 - Available on the CDC website at:
<http://www.cdc.gov/vaccinesafety/concerns/FebrileSeizures.html>

Communications updates (general)

- ❑ Seasonal Influenza (Flu): 2013-2014 Flu Season
 - Available on the CDC website at:
<http://www.cdc.gov/flu/about/season/>
- ❑ CDC Newsroom (Press Release): HPV vaccine: Safe, effective, and grossly underutilized
 - Press release available at:
<http://www.cdc.gov/media/releases/2013/p0725-HPV-vaccine.html>
 - 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>

Selected publications

- ❑ **Dodd et al. International collaboration to assess the risk of Guillain Barré Syndrome following Influenza A (H1N1) 2009 monovalent vaccines. *Vaccine*. 2013 Sep 13;31(40):4448-58.**
 - **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**
- ❑ **Kharbanda et al. Inactivated influenza vaccine during pregnancy and risks for adverse obstetric events. *Obstet Gynecol*. 2013 Sep;122(3):659-67.**
 - **In this large cohort, influenza vaccination during pregnancy was not associated with increased risks for medically attended adverse obstetric events**

Selected publications

- ❑ Iqbal et al. Number of antigens in early childhood vaccines and neuropsychological outcomes at age 7-10 years. *Pharmacoepidemiol Drug Saf.* 2013 Jul 12.
 - No adverse associations between antigens received through vaccines in the first two years of life and neuropsychological outcomes in later childhood

- ❑ Greene et al. Guillain-Barré Syndrome, Influenza Vaccination, and Antecedent Respiratory and Gastrointestinal Infections: A Case-Centered Analysis in the Vaccine Safety Datalink, 2009-2011. *PLoS One.* 2013 Jun 26;8(6):e67185.
 - 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

- ❑ **McCarthy et al. Mortality rates and cause-of-death patterns in a vaccinated population. Am J Prev Med. 2013 Jul;45(1):91-7.**
 - **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**

- ❑ **Centers for Disease Control and Prevention (CDC). Human papillomavirus vaccination coverage among adolescent girls, 2007-2012, and postlicensure vaccine safety monitoring, 2006-2013 - United States. MMWR Morb Mortal Wkly Rep. 2013 Jul 26;62(29):591-5.**
 - **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**



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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.

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