

Vaccine Safety Update

Advisory Committee on Immunization Practices
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Overview

- General information about vaccine safety topics of current interest
- Outline of presenters and topics for remainder of vaccine safety session



Safety of quadrivalent human papillomavirus vaccine (Gardasil®)

- Updates now regularly posted on ISO website
 - www.cdc.gov/vaccinesafety/vaers/gardasil.htm
 - Most recent data updated through April 30, 2008



Status of CDC sponsored research on thimerosal and autism

- Neurodevelopmental status at age 7-10 years
 - Published in NEJM September 2007 (Thompson et al.)
- Italy neurodevelopmental status study
 - Data submitted for publication by Italian researchers
- Autism case/control study
 - Data collection completed early 2008
 - External advisory panel recommending additional analyses



Components of vaccines (additives/excipients)

- Subject of recent media and advocacy group attention (including thimerosal, aluminum, and formaldehyde)
- FDA is lead agency for vaccine components information
 - FDA requires manufacturers to extensively test for safety, purity, potency and efficacy. Testing includes laboratory, animal and clinical studies. Data are reviewed by FDA scientists and clinicians.
 - Inquiries and requests for information should be directed to octma@cber.fda.gov, 800-835-4709 or 301-827-1800
- Supplemental web-based resources:
 - www.cdc.gov/vaccines/vac-gen/additives.htm (NCIRD)
 - www.vaccinesafety.edu/components.htm
(Institute for Vaccine Safety, Johns Hopkins University)



Recent vaccine safety publications of interest

- Haber P, Patel M, Izurieta HS, et al. Postlicensure monitoring of intussusception after RotaTeq vaccination in the United States, February 1, 2006, to September 25, 2007. *Pediatrics*. 2008 Jun;121(6):1206-12.
- Nachamkin I, Shadomy SV, Moran AP, et al. Anti-Ganglioside Antibody Induction by Swine (A/NJ/1976/H1N1) and Other Influenza Vaccines: Insights into Vaccine-Associated Guillain-Barré Syndrome. *J Infect Dis*. 2008 Jun 3.



Topics and Presenters

- ISO Scientific Agenda development:
 - Dr. Karen Broder (5 minutes)
 - Rapid Cycle analysis for adverse events after Tdap: Dr. James Nordin (15 minutes)
 - Update on CDC vaccine safety activities from the Chief Science Officer: Dr. Tanja Popovic (10 minutes)

