

Immunization Safety Office Updates

Centers for Disease Control and Prevention

Tom Shimabukuro, MD, MPH, MBA

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)

September 3, 2015

National Center for Emerging and Zoonotic Infectious Diseases

Division of Healthcare Quality Promotion – Immunization Safety Office



Topics

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

June 2015 ACIP meeting summary

❑ Meningococcal vaccines (vote)

- Serogroup B meningococcal (MenB) vaccine series may be administered to persons 16 - 23 years of age to provide short term protection against most strains of serogroup B meningococcal disease
- Preferred age for MenB vaccination is 16 - 18 years
- Category B recommendation (made for individual clinical decision making)

June 2015 ACIP meeting summary (cont.)

□ Influenza (vote)

- Algorithm for determining which children aged 6 months - 8 years need 2 doses of influenza vaccine was updated
- New products incorporated into recommendations
 - Quadrivalent inactivated influenza vaccine (IIV)
 - Intradermal IIV
 - Trivalent recombinant influenza vaccine (FluBlok®) recommendation expanded to ages 18 and older
 - AFLURIA® recommended via jet injector for ages 18 - 64 years

June 2015 ACIP meeting summary (cont.)

□ Influenza (vote)

- Endorsed strain selection for the 2015-16 season, made previously by WHO and FDA
 - A/California/7/2009 (H1N1) pdm09-like virus
 - A/Switzerland/9715293/2013 (H3N2)-like virus
 - B/Phuket/3073/2013-like virus (a B/Yamagata lineage virus)
 - 2015-2016 quadrivalent flu vaccine also includes an additional B virus (B/Brisbane/60/2008-like virus, a B/Victoria lineage virus)

June 2015 ACIP meeting summary (cont.)

- **Influenza (vaccine safety presentation)**
 - 2014-2015 end-of-season update
 - Update on the Vaccine Safety Datalink (VSD) study:
 - Donahue* et al. “Evaluating the risk of spontaneous abortion following administration of influenza vaccines containing H1N1pdm09 and H3N2 viral antigens”

<http://www.cdc.gov/vaccines/acip/meetings/slides-2015-06.html>

<http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2015-06/flu-04-shimabukuro.pdf>

June 2015 ACIP meeting summary (cont.)

□ Pneumococcal vaccines (vote)

- Change interval between PCV13 and PPSV23 in adults aged ≥ 65 years to:
 - “A dose of PPSV23 should be given at least 1 year following a dose of PCV13. The two vaccines should not be co-administered. If a dose of PPSV23 is given earlier than the recommended interval, the dose need not be repeated.”
- Previously the interval in adults from PCV13 to PPV23 was 6 - 12 months

June 2015 ACIP meeting summary (cont.)

□ Smallpox vaccine (vote)

- Updated the smallpox vaccine recommendations (last update was in 2001 and since then ACAM2000 replaced Dryvax)
 - Healthcare personnel (e.g., physicians and nurses) that currently treat or anticipate treating patients with vaccinia virus infections whose contact with replication-competent vaccinia viruses is limited to contaminated materials (e.g., dressings) and persons administering ACAM2000 smallpox vaccine who adhere to appropriate infection prevention measures can be offered vaccination with ACAM2000 (category B recommendation)

Selected publications

- ❑ **Sukumaran et al. Demographic characteristics of members of the Vaccine Safety Datalink (VSD): A comparison with the United States population. *Vaccine*. 2015 Jul 23. pii: S0264-410X(15)00984-6. [Epub ahead of print]**
 - **The VSD population is representative of the general US population on several key demographic and socioeconomic variables.**
 - **Despite a few specific groups being underrepresented in the VSD compared to the US, the absolute number of VSD members is large enough to ensure significant representation of these groups in vaccine safety studies that use VSD data.**

Selected publications

- ❑ **Miller et al. Vaccine Safety Resources for Nurses. Am J Nurs. 2015 Aug;115(8):55-8.**
 - **Describes the CDC's vaccine safety monitoring systems, explain how nurses and others can access the CDC's inquiry channels and other resources, and give examples of recent inquiries and their resolution.**

- ❑ **Grohskopf et al. Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2015-16 Influenza Season. MMWR Morb Mortal Wkly Rep. 2015 Aug 7;64(30):818-25.**

Selected publications

- ❑ Shimabukuro et al. Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS). *Vaccine*. 2015 Jul 22. pii: S0264-410X(15)00982-2. [Epub ahead of print]
 - We describe fundamental vaccine safety concepts, provide an overview of VAERS for healthcare professionals who provide vaccinations and might want to report or better understand a vaccine adverse event, and explain how CDC and FDA analyze VAERS data.
 - We also describe strengths and limitations, and address common misconceptions about VAERS. Information in this review will be helpful for healthcare professionals counseling patients, parents, and others on vaccine safety and benefit-risk balance of vaccination.

Selected publications

- ❑ Baker et al. Advanced Clinical Decision Support for Vaccine Adverse Event Detection and Reporting. Clin Infect Dis. 2015 Jun 9. pii: civ430. [Epub ahead of print]
 - We developed an open-source, generalizable clinical decision support system called Electronic Support for Public Health-Vaccine Adverse Event Reporting System (ESP-VAERS) to assist clinicians with AE detection and reporting.
 - An open-source, electronic health record-based clinical decision support system can increase AE detection and reporting rates in VAERS.

Selected publications

- ❑ **Moro et al. Deaths Reported to the Vaccine Adverse Event Reporting System, United States, 1997-2013. Clin Infect Dis. 2015 May 28. pii: civ423. [Epub ahead of print]**
 - **No concerning pattern was noted among death reports submitted to VAERS during 1997-2013. The main causes of death were consistent with the most common causes of death in the US population.**

- ❑ **Haber et al. Intussusception after monovalent rotavirus vaccine-United States, Vaccine Adverse Event Reporting System (VAERS), 2008-2014. Vaccine. 2015 Aug 11. pii: S0264-410X(15)01015-4. [Epub ahead of print]**
 - **We observed a significant increased risk of intussusception 3–6 days after dose 1 of RV1. The excess risk ranged from 1.2 to 2.8 per 100,000 in sensitivity analysis.**
 - **The estimated small number of intussusception cases attributable to RV1 is outweighed by the benefits of rotavirus vaccination.**

Selected publications

- ❑ **Iqbal et al. Preparation for global introduction of inactivated poliovirus vaccine: safety evidence from the US Vaccine Adverse Event Reporting System, 2000-12. *The Lancet Infectious Diseases*. 2015. doi: 10.1016/S1473-3099(15)00059-6.**
 - **Fairly few adverse events were reported for the more than 250 million IPV doses distributed between 2000 and 2012.**
 - **Sudden infant death syndrome reports after IPV were consistent with reporting patterns for other vaccines.**
 - **No new or unexpected vaccine safety problems were identified for fatal, non-fatal serious, and non-serious reports in this assessment of adverse events after IPV.**



Centers for Disease Control and Prevention Atlanta, GA

National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion – Immunization Safety Office



Thank You

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333

Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348

E-mail: cdcinfo@cdc.gov

Web: www.cdc.gov

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.

National Center for Emerging and Zoonotic Infectious Diseases

Division of Healthcare Quality Promotion – Immunization Safety Office

