

# 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)**

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Division of Healthcare Quality Promotion – Immunization Safety Office



# Topics

- ❑ **Highlights from the Oct 2011 Advisory Committee on Immunization Practices (ACIP) meeting**
  - **Gardasil safety review and ACIP recommendations for vaccination of males**
  - **Update on the Vaccine Safety Datalink (VSD) investigation of febrile seizures in young children following 2010-11 trivalent inactivated influenza vaccine and 13-valent pneumococcal vaccine**
- ❑ **CDC support for the Institute of Medicine report generated Task Force**
- ❑ **Selected recent publications**

# Gardasil (HPV4) safety review during the October 2011 ACIP meeting\*

## □ Data/data sources

- Pre-licensure studies
- Data from the Vaccine Adverse Event System (VAERS) for males and females
- Vaccine Safety Datalink (VSD) rapid cycle analysis in females
- Nordic long-term follow-up study
- Long-term study of Gardasil in adolescents

\* Gee J. Safety of Quadrivalent Human Papillomavirus (HPV4) Vaccine. Available at: <http://www.cdc.gov/vaccines/recs/acip/downloads/mtg-slides-oct11/02-HPV-Gee.pdf>

# HPV4 safety review summary

- ❑ No new adverse event concerns or clinical patterns identified in VAERS review
- ❑ VSD rapid cycle analysis confirmed no significant risk for pre-specified adverse events\* after vaccination for females 9-17 years and 18-26 years
  - \* GBS, seizures, syncope, appendicitis, stroke, venous thromboembolism (VTE) and other allergic reactions
  - Non-statistically significant increased relative risk of VTE among 9-17 year-olds
- ❑ Further evaluation of VTE post-vaccination ongoing
- ❑ Long-term follow-up of adolescents have not identified any safety concerns

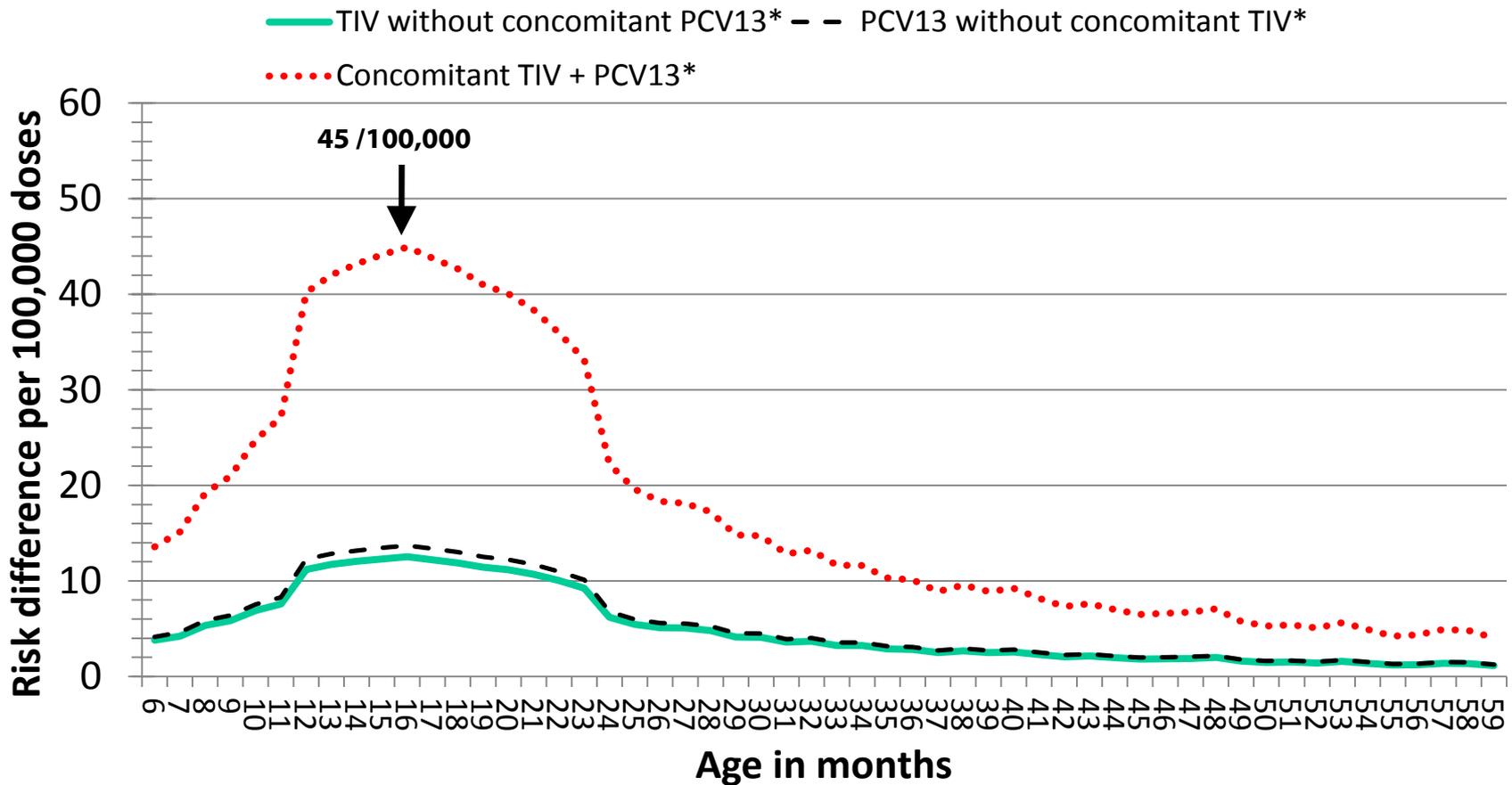
# ACIP HPV4 recommendations

- ❑ Routine recommendation for HPV4 (3 dose series) for males ages 11 to 12 years
- ❑ HPV4 series can be started in males as early as age 9 years
- ❑ Males aged 13-21 years who have not been vaccinated should be given catch-up HPV4
- ❑ Males aged 22-26 may be vaccinated but HPV4 is not recommended for routine use

# VSD monitoring for febrile seizures after 2010-11 trivalent inactivated influenza vaccine (TIV)

- VSD monitored 9 outcomes after TIV, including seizures
  - ICD9 code for convulsion (780.3)
  - Inpatient and emergency department setting
  - First event in 42 days to identify incident cases
- Detected possible increased risk of febrile seizures on days 0-1 post-vaccination among 6-59 mo who received 1<sup>st</sup> dose of TIV (*signal*)
  - Chart review verified most seizures were febrile
  - Risk appeared higher in 6-23 month old children
  - Most had received other vaccines, most commonly 13-valent pneumococcal conjugate vaccine (PCV13) and DTaP

# Attributable Risk (AR) estimates for febrile seizures following 1<sup>st</sup> dose TIV, 2010-11<sup>^</sup>



<sup>^</sup>Tse A and Lee G for the VSD

\*Vaccines may have been received concomitantly with non-TIV, non-PCV13 vaccines

# Summary on febrile seizures

- ❑ **Based on the available information, no changes in the childhood immunization schedule are necessary at this time**
- ❑ **Getting recommended childhood vaccines during a single healthcare visit has important benefits**
- ❑ **Timely influenza and pneumococcal vaccination may prevent febrile seizures by protecting young children against influenza and pneumococcal infections, both of which can cause fever**
- ❑ **Scientific studies have not shown that fever-reducing medicines (e.g., acetaminophen, ibuprofen) will prevent febrile seizures**
- ❑ **Aspirin and aspirin-containing products should not be used to reduce fever in children because of the increased risk for Reye syndrome with aspirin ingestion and viral infections**
- ❑ **Further investigation is underway to determine if other childhood vaccines besides TIV and PCV13 may be contributing to the febrile seizures**

# **Institute of Medicine report generated Task Force**

- Sixteen Immunization Safety Office/CDC staff currently assigned to the HRSA-CDC Task Force to support the review of the IOM report “Adverse Effects of Vaccines: Evidence of Causality” August 25, 2011, and development of proposals to update the Vaccine Injury Table**

# Selected publications

- ❑ **Duderstadt et al. Vaccination and risk of type 1 diabetes mellitus in active component U.S. Military, 2002-2008. Vaccine. 2011 Nov 7. [Epub ahead of print]**
  - **No increased risk of diagnosed type 1 diabetes in any of the study vaccines (anthrax , smallpox, typhoid, HepB , MMR, yellow fever).**
  
- ❑ **Mullooly et al. Wheezing lower respiratory disease and vaccination of premature infants. Vaccine. 2011;29:7611-7.**
  - **No evidence of increased wheezing lower respiratory diseases risk following routine vaccinations of premature infants. Wheezing lower respiratory diseases risk among non-fragile premature infants appears to be reduced for a few weeks after live attenuated vaccinations.**

# Selected publications

- ❑ **Gee et al. Monitoring the Safety of Quadrivalent Human Papillomavirus Vaccine: Findings from the Vaccine Safety Datalink. Vaccine. 2011;29:8279-84.**
  - **600,000 HPV4 vaccine doses administered among 9 to 26 year-old females, no statistically significant increased risk for pre-specified adverse events after vaccination detected**
  - **Non-statistically significant increase relative risk of venous thromboembolism following HPV4 among 9-17 year-olds. Further study warranted (and currently underway).**
  
- ❑ **Huang et al. Adherence to the Advisory Committee on Immunization Practices Recommendation to Prevent Injuries from Postvaccination Syncope: A National Physician Survey. Am J. Prev Med. 2011;41:317-21.**
  - **Few physicians aware of recommendations for post-vaccination observation for syncope and even fewer adhere. Strategies to improve this should be developed and tested.**



## 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](mailto:cdcinfo@cdc.gov)**

**Web: [www.cdc.gov](http://www.cdc.gov)**

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