Immunization Safety Office Updates
Centers for Disease Control and Prevention

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Advisory Commission on Childhood Vaccines (ACCV)
December 8-9, 2012
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

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 1st 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\textsuperscript{st} dose TIV, 2010-11\textsuperscript{^T}

\[\text{Risk difference per 100,000 doses}\]

\begin{figure}
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\includegraphics[width=\textwidth]{chart.png}
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\[45/100,000\]

\textsuperscript{T}\text{se 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.
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

  - No increased risk of diagnosed type 1 diabetes in any of the study vaccines (anthrax, smallpox, typhoid, HepB, MMR, yellow fever).

  - 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

  - 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).

  - Few physicians aware of recommendations for post-vaccination observation for syncope and even fewer adhere. Strategies to improve this should be developed and tested.
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Thank You

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