Post-Marketing Surveillance for Rotarix® Rotavirus vaccine

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Infrastructure for Rotarix® Vaccine Post-marketing Surveillance

- Vaccine Adverse Events Reporting System (VAERS)
- Vaccine Safety Datalink (VSD) Project
- Vaccine manufacturer systems
  - Dose distribution

VAERS Post-Marketing Surveillance for Rotarix® Vaccine

- CDC / FDA researchers will receive and review daily alerts of serious adverse event reports (AEs) as defined by the Code of Federal Regulation (CFR)* and other medically important conditions (OMIC)
  - Including:
    - Age at vaccination
    - Onset-interval (days)
    - Dose #
    - Vaccine co-administration
    - Pre-existing medical condition
  - VAERS nurses will obtain medical and immunization records and other relevant lab data for all serious and OMIC reports

*21CFR600.80 Serious adverse event defined as involving hospitalization or prolongation of hospitalization, death, life-threatening illness or permanent disability Serious reports are required by FDA to be reported within 15 days.

VAERS Post-Marketing Surveillance for Rotarix® Vaccine

- Review and verify reports indicating any possible:
- Intussusception
  - Based on Brighton case definition level 1*
- Pneumonia and lower respiratory events: serious reports
- GI bleeding outcomes, including gastroenteritis
- Kawasaki disease
- Seizures
- Other outcomes

* Available at http://www.brightoncollaboration.org/internet/en/index/definition___guidelines.html

VAERS Post-Marketing Surveillance (Cont.)

- *Compare proportion reported adverse events and safety profile of Rotarix® vs. RotaTeq® vaccines: by age and dose number and event severity**
- Calculate observed vs. expected reporting rates for intussusception after Rotarix®
- VAERS safety concerns (signals) will be assessed through VSD studies and other analyses

*Type of rotavirus vaccine confirmed by immunization records

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Intussusception lab testing

- CDC requests tissues samples when available for all reports of intussusception that occur within 1-21 days after rotavirus vaccine
- Immunohistochemistry (IHC) testing is done for adenovirus and rotavirus in order to determine if there are potential causes of the intussusception other than the rotavirus vaccine

Rotarix® Vaccine Safety Datalink (VSD) Monitoring*

- Begin rapid cycle analysis of Rotarix®
- Monitor for same adverse events as for RotaTeq®
- Additional outcome: hospitalized pneumonia
- VSD can distinguish between Rotarix® and RotaTeq® vaccinations

***Presented by Baggs, PhD to ACIP on June 25, 2008**

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Thank You