Autism Reports to VAERS

Emily Jane Woo, MD, MPH
Research Fellow

Office of Biostatistics and Epidemiology
Center for Biologics Evaluation and Research
Food and Drug Administration
Vaccine Adverse Event Reporting System (VAERS)

• National system for passive surveillance of adverse events after vaccination
• Jointly managed by FDA and CDC
• Reports received from health professionals, vaccine manufacturers, and the public
• All deaths and other serious events (permanent disability, life-threatening illness, hospitalization, prolongation of hospitalization) are reviewed by FDA medical officers
• All deaths and other serious events receive follow-up
Uses of VAERS

- Monitor known adverse events
- Detect unrecognized adverse events
- Identify possible risk factors for adverse events
- Maintain vaccine lot surveillance
Limitations of VAERS

• Reported diagnoses are not always verified
• Lack of consistent diagnostic criteria
• Wide range in data quality
• Underreporting
• Inadequate data about denominator
• Usually not possible to assess whether a vaccine caused the reported adverse event
Analysis of VAERS Data

• Describe characteristics and look for patterns to detect signals of adverse events plausibly linked to a vaccine
  – Age, sex, clinical characteristics, symptom codes, time to onset, dose, and “positive rechallenge” reports
  – Biological plausibility, pre-existing conditions, concurrent illness, and concomitant medications

• Signals detected through analysis of VAERS data almost always require confirmation through a controlled epidemiological or other (e.g., laboratory) study
Identification of Cases

• Search the VAERS database
  – Coding Symbols for Thesaurus of Adverse Reaction Terms (COSTART)
  – Search text fields for “autism,” “autistic,” “pervasive developmental disorder,” and “developmental delay”

• MMR and other vaccines
Autism Reports to VAERS through December 2000 (n=253)

Number of Reports

Year

Vaccination Date
Report Date

1991 Pre 91 92 93 94 95 96 97 98 99 '00
Purpose of Follow-up Study

- Describe reports of autism after vaccination
- Explore risk perception by reporters of autism to VAERS
Follow-up Study Using Survey Questionnaire

- **First part: clinical data**
  - Use brief questionnaire derived from Autism Diagnostic Interview
  - Describe clinical characteristics
    - communication/language
    - social interaction
    - behavior
    - regression
  - Temporal relationship with vaccination
Follow-up Study Using Survey Questionnaire

• First part: clinical data (continued)
  – Review medical records and home videotapes
  – Identify unusual patterns which suggest that autism might plausibly be linked to vaccination
Follow-up Study Using Survey Questionnaire

- Second part: risk perception
  - Develop questionnaire
  - Collect information on how the reporter associated vaccine with autism
  - Identify parental concerns

Information obtained might be used to improve risk communication.
Collaborators

• Robert Ball, MD, MPH, ScM, FDA/CBER/OBE/DE
• M. Miles Braun, MD, MPH, FDA/CBER/OBE
• Andrew Zimmerman, MD, Johns Hopkins University
• Rebecca Landa, Ph.D., Johns Hopkins University
• Leslie K. Ball, MD, FDA/CBER/OVRR
• Geoffrey Evans, MD, HRSA/VICP
• Beth Hibbs, RN, MPH, CDC
• Ann Bostrom, Ph.D., Georgia Institute of Technology
Summary of Study

• Not designed to determine whether vaccines cause autism
• Will clinically characterize cases of post-vaccination autism, with particular emphasis on regression
• Can generate hypotheses for future research
• Will identify parental concerns about vaccination