

Autism Reports to VAERS

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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

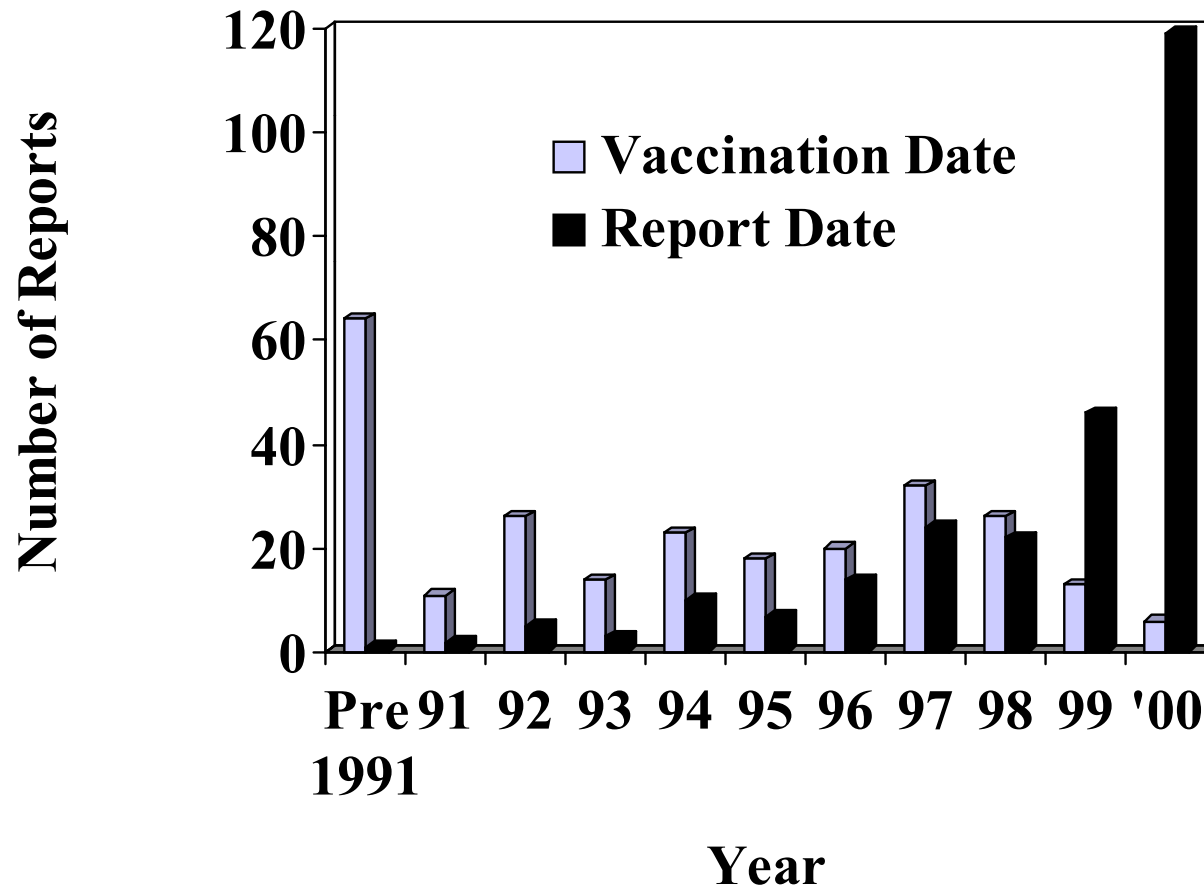
- Describe characteristics and look for patterns to detect signals of adverse events plausibly linked to a vaccine
 - Age, sex, clinical characteristics, symptom codes, time to onset, dose, and “positive rechallenge” reports
 - Biological plausibility, pre-existing conditions, concurrent illness, and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



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