Vaccination Errors

Advisory Committee on Immunization Practices
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Disclaimer

The findings and conclusions in this presentation are those of the authors and do not necessarily represent the official position of CDC.
Topics

- Background on the CDC Immunization Safety Office (ISO)
- Vaccination errors reported to the Vaccine Adverse Event Reporting System (VAERS)
- Case series reports of vaccination errors
- Summary and prevention strategies
Background on the CDC Immunization Safety Office
Immunization Safety Office (ISO)

- **Mission**
  - Assess the safety of vaccines administered to children, adolescents and adults

- **Post-licensure vaccine safety monitoring activities**
  - Rapidly identify new or rare adverse events of clinical importance
  - Monitor changes in patterns for known adverse events
  - Assess safety in special populations (e.g., pregnant women)
  - Determine patient risk factors for particular adverse events
### ISO’s post-licensure vaccine safety monitoring infrastructures

<table>
<thead>
<tr>
<th>System</th>
<th>Collaboration</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Vaccine Adverse Event Reporting System (VAERS)</td>
<td>CDC and FDA</td>
<td>US frontline spontaneous reporting system to detect potential vaccine safety problems</td>
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<tr>
<td>Vaccine Safety Datalink (VSD)</td>
<td>CDC and healthcare plans</td>
<td>Large linked database system used for active surveillance and research</td>
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<tr>
<td>Clinical Immunization Safety Assessment (CISA) Project</td>
<td>CDC and academic medical centers</td>
<td>Expert collaboration which conducts individual clinical vaccine safety assessments and clinical research</td>
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</tbody>
</table>
Vaccination errors\textsuperscript{1} reported to the Vaccine Adverse event Reporting System (VAERS)

\textsuperscript{1} Vaccination error is defined as a preventable event that might reflect incorrect use and/or potentially result in patient harm.
**Vaccine Adverse Event Reporting System (VAERS)**: co-administered by CDC and FDA

### Strengths
- National data; accepts reports from anyone
- Rapid signal detection
- Can detect rare adverse events (AE)
- Collects information about vaccine, characteristics of vaccinee, adverse event†
- Data available to public

### Limitations
- Reporting bias
- Inconsistent data quality and completeness
- Lack of unvaccinated comparison group
- Generally cannot assess if vaccine caused an AE
- Pregnancy inconsistently reported

*VAERS website: [http://vaers.hhs.gov](http://vaers.hhs.gov)*

†Some reports have no adverse event
Vaccination errors reported to the Vaccine Adverse Event Reporting System (VAERS) United States, 2000–2013

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ABSTRACT

Importance: Vaccination errors are preventable events. Errors can have impacts including inadequate immunological protection, possible injury, cost, inconvenience, and reduced confidence in the healthcare delivery system.

Objectives: To describe vaccination error reports submitted to the Vaccine Adverse Event Reporting System (VAERS) and identify opportunities for prevention.

Methods: We conducted descriptive analyses using data from VAERS, the U.S. spontaneous surveillance system for adverse events following immunization. The VAERS database was searched from 2000 through 2013 for reports of vaccination errors. Data were analyzed to determine the types of errors and the types of outcomes associated with errors.

Results: A total of 97,275 errors were identified, with 32,348 unique adverse events reported. Of the errors, 20% were related to improper administration, 15% to incorrect vaccine type, 14% to incorrect dose, and 13% to wrong time of administration. Adverse events included 12% allergy, 8% rash, 5% anaphylaxis, and 3% severe injury.

Conclusions: These data demonstrate the importance of vaccination error reporting and the need for improved systems and training to prevent errors and adverse events. Further research is needed to understand the underlying causes of errors and to develop effective prevention strategies.
Vaccination error reports to VAERS, 2000-2013

Total US VAERS reports\(^1\)
311,185

Vaccination error reports\(^2\)
20,585 (7% of total)

No adverse health event
15,381 (75% of error reports)

Adverse health event\(^3\)
5,204 (25% of error reports)

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\(^1\) Primary US VAERS reports
\(^2\) Primary US VAERS reports with one or more codes describing vaccination errors
\(^3\) Adverse health event (health problem) following vaccination
Total reports to VAERS\(^1\) with breakdown of error reports\(^2,3\), 2000-2013

![Diagram showing vaccination errors reported to VAERS from 2000 to 2013.]

\(^{1}\) 311,185 total primary US VAERS reports 2000-2013
\(^{2}\) 20,585 total vaccination error reports, primary US VAERS 2000-2013
\(^{3}\) 20,585 total vaccination error reports, primary US VAERS 2000-2013

### Reports by error group in VAERS, 2000-2013

<table>
<thead>
<tr>
<th>Vaccine error group</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inappropriate schedule</td>
<td>5,947  (27%)</td>
</tr>
<tr>
<td>Storage and dispensing</td>
<td>4,983  (23%)</td>
</tr>
<tr>
<td>Wrong vaccine</td>
<td>3,372  (15%)</td>
</tr>
<tr>
<td>General error</td>
<td>2,526  (12%)</td>
</tr>
<tr>
<td>Incorrect dose</td>
<td>2,002  (9%)</td>
</tr>
<tr>
<td>Administration error</td>
<td>1,951  (9%)</td>
</tr>
<tr>
<td>Accidental exposure</td>
<td>373    (2%)</td>
</tr>
<tr>
<td>Product quality</td>
<td>239    (1%)</td>
</tr>
<tr>
<td>Contraindication</td>
<td>215    (1%)</td>
</tr>
<tr>
<td>Equipment</td>
<td>205    (1%)</td>
</tr>
<tr>
<td>Product labeling/packaging</td>
<td>30     (&lt;1%)</td>
</tr>
<tr>
<td><strong>Total errors</strong></td>
<td><strong>21,843</strong></td>
</tr>
</tbody>
</table>
Top three vaccination errors reported to VAERS, 2000-2013

1. Inappropriate schedule errors (includes wrong age and wrong timing between doses) (5,947, 27% of total)
   - Children aged 0-18 years old (3,385, 57%)
     - 53% of these errors reported in children aged <1 year old
   - Most common vaccines associated with wrong timing
     - Quadrivalent human papillomavirus vaccine (1,516)
       - Delays between dose 1 and dose 2\(^1,2\)
       - 3\(^{rd}\) dose given too soon (12 week minimum interval)
     - Rotavirus vaccine (880)
       - First dose given after 15 weeks\(^1\)
       - Last dose given after 32 weeks\(^1\)

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1 Based on 5% random sample review of reports wrong age inappropriate schedule (n=297),
2 Reporter documented a delay in administration of 2\(^{nd}\) dose (median 577 days, range 179-2067 days)
Top three vaccination errors reported to VAERS, 2000-2013 (cont.)

2. Storage and dispensing errors (4,983, 23% of total)
   - Expired vaccine administered (2,746, 55%)
     - Seasonal live attenuated influenza (978)
     - Herpes zoster (332)
     - Measles, mumps and rubella (218)
   - Incorrect storage of vaccine (2,202, 44%)
     - Vaccines kept outside of proper storage temperatures commonly reported (88%\(^1\))
       - In 55% of these reports vaccine exposed to temperatures below recommended storage temperature

\(^1\) Based on 5% random sample review of reports

Top three vaccination errors reported to VAERS, 2000-2013 (cont.)

3. Wrong vaccine administered errors (3,372, 15% of total)
   - Appears to occur among vaccines with similar names, acronyms and antigens

<table>
<thead>
<tr>
<th>Common wrong vaccine mix-ups¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varicella (VARIVAX®)</td>
</tr>
<tr>
<td>Diphtheria, tetanus and pertussis (DTaP)</td>
</tr>
<tr>
<td>One type of trivalent inactivated influenza vaccine (IIV3)</td>
</tr>
<tr>
<td>Pneumococcal conjugate</td>
</tr>
<tr>
<td>Hepatitis A</td>
</tr>
</tbody>
</table>

¹ Vaccine mix ups can be either combination (e.g. varicella vaccine instead of herpes zoster vaccine or herpes zoster vaccine instead of varicella vaccine)
Adverse health events reported in 25% (5,204 of 20,585) of error reports to VAERS, 2000-2013

- Non-serious 92%, serious\(^1\) 8%,
  - Similar percentages to non-error reports to VAERS

- Most common adverse health events
  - Injection site erythema (13%), injection site pain (11%), pyrexia (11%)
    - Similar to what’s observed in non-error reports

- “Administration errors” error group had the highest percentage of reports with a documented adverse health event
  - 1,176 of 1,951 (60%) reports
  - Includes wrong site, wrong technique, incorrect route

\(^1\)Based on the Code of Federal Regulations a report is classified as serious if one of the following is reported: death, life-threatening illness, hospitalization or prolongation of hospitalization or permanent disability
Reports of error clusters\(^1\) to VAERS, 2000-2013
(same error, multiple individuals, same location/clinic)

- 936 error clusters involving at least 6,141 patients
  - Cluster size ranged from 2 to 501 patients (median 5)
  - 110 clusters involved 10 or more patients
  - In 586 clusters, the specific number of patients affected was stated as “unknown” or “several”

- Storage errors were the most common type of error cluster (678, 72% of all cluster reports)
  - Incorrect storage (582 clusters, 1,715 patients)
  - Expired vaccine administered (96 clusters, 1,340 patients)
    - Live attenuated influenza vaccine (45 clusters, 990 patients)

\(^1\) Error clusters can also include events not necessarily related to vaccine itself that can have consequences that are unrelated to vaccine adverse events or effectiveness (e.g., bloodborne pathogen exposure and patient notification).
Case series reports of vaccination errors
Rotavirus vaccine errors* (reports of vaccine being injected)

Notes from the Field

Rotavirus Vaccine Administration Errors — United States, 2006–2013

Beth F. Hibbs, MPH1, Elaine R. Miller, MPH1, Tom Shimabukuro, MD2 (Author affiliations at end of text)

Two live rotavirus oral vaccines, RotaTeq (RV5) (Merck & Co., Inc.) and Rotarix (RV1) (GlaxoSmithKline Biologicals) (Figure), are approved for prevention of rotavirus gastroenteritis (1) and recommended at ages 2, 4 (RV5/RV1), and 6 (RV5) months by the Advisory Committee on Immunization Practices. Because most childhood vaccines are injectable, vaccination providers might have less experience administering oral vaccines. To assess that hypothesis, CDC searched for reports to the Vaccine Adverse Event Reporting System (VAERS) (2) of rotavirus vaccine administration errors involving injection and eye splashes in the United States during the period January 1, 2006–August 1, 2013. A total of 66 reports were found.

There were 39 reports of administration by injection (33 for RV1 and six for RV5). This included a cluster of six reports involving RV1 by a nurse who did not receive proper training or read the package insert. Nineteen of the 39 reports (49%) documented an adverse event: irritability (seven cases) and injection site redness (five) were the most commonly reported adverse events. Thirty of 39 reports (77%) did not have an

Example of Rotarix current packaging

- The Peel-Off-Film label used in packaging the blister of the prefilled syringe diluent clearly indicates “FOR ORAL USE ONLY” in all caps, red, bold font

Graphics courtesy of GSK.
Meningococcal conjugate vaccination errors

Menveo is supplied in two vials that must be combined before administration (liquid component used to reconstitute lyophilized component)

Administration errors involved only one component of Menveo being given to patients

Changes to Menveo packaging after publication of “Notes from the Field” MMWR

Old label

New label

Warning text font size increased; label font color changed to highlight warning sentence

Graphics courtesy of GSK.
Unintentional administration of insulin instead of influenza vaccine: a case study and review of reports to US vaccine and drug safety monitoring systems

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Abstract

Introduction There have been isolated case reports of medication product mix-ups involving insulin unintentionally given to patients when the intent was to administer vaccines. Information on how and why these types of errors occur is limited.

Objective To describe incidents of unintentional administration of insulin instead of influenza vaccine and identify possible causes for errors.

Results Investigation of the primary cluster incident revealed deviations from recommended practices for storage, handling, preparation, and administration of drugs and searched Centers for Disease Control and Prevention (CDC) and US Food and Drug Administration (FDA) vaccine and drug safety monitoring databases from January 2005 to April 2015 in order to identify other incidents. We classified cases as either ‘highly suggestive’ or ‘suggestive’ of insulin and influenza vaccine mix-ups.

Summary

- Vaccination error reports comprised 6-15% of all reports to VAERS during the period 2007-2013.
- The number and percentage (of total VAERS reports) of vaccination error reports have increased substantially from 2000-2013.
- 75% of vaccination error reports to VAERS did not document an adverse health event.
- Of the 25% of vaccination error reports to VAERS that did document an adverse health event, the adverse health events were generally similar to non-error reports.
Summary (cont.)

- Based on reports to VAERS, vaccination errors usually don’t appear to pose a substantial safety risk
  - However, errors do have an impact in terms of additional costs, possible effect on immunological protection, patient/parent inconvenience, and loss of confidence in the healthcare delivery system

- Some errors do (or have the potential to) cause patient harm
  - Reuse of syringes on multiple patients at a vaccination clinic (www.cdc.gov/mmwr/preview/mmwrhtml/mm6449a3.htm)
  - Incorrect reconstitution of measles-rubella vaccine using atracurium instead of the approved diluent (Syria) (http://www.who.int/mediacentre/news/statements/2014/interim-findings-idleb-syria/en/)
Strategies for reducing vaccination errors

- **Present**
  - Education and training on vaccine timing and spacing, especially for vaccines with complex schedules
  - Training on proper administration technique (including general injection safety)
  - Improved monitoring of vaccine storage temperatures and expiration dates
  - Improvements in differentiating vaccines and other products with similar sounding names and acronyms
  - Implementation and enforcement of procedures to properly screen for vaccine contraindications

- **Future**
  - Passive engineered interventions
Resources

- VAERS guidance on reporting vaccination errors

- Strategies to Prevent Administration Errors (in the Pink Book)
  www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html

- CDC Vaccine Storage & Handling Tool Kit
  www.cdc.gov/vaccines/recs/storage/toolkit

- One & Only Campaign
  www.cdc.gov/injectionsafety/1anonly.html

- Technically Speaking: Vaccine Administration Errors (CHOP)
  http://www.chop.edu/news/technically-speaking-vaccine-administration-errors

CDC activities

- CDC Vaccination Error Work Group
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Thank You

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E-mail: cdcinfo@cdc.gov  Web: www.cdc.gov

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Extra slides
Groupings of vaccine error codes (11 groups)

**Accidential**
- Accidental exposure
- Accidental exposure to product
- Accidental needle stick

**Administration errors**
- Drug administered at inappropriate site
- Drug administration error
- Incorrect drug dosage form administered
- Incorrect drug administration duration
- Incorrect route of drug administration
- Multiple use of a single-use product
- Wrong technique in drug usage process

**Contraindication**
- Contraindication to vaccination
- Documented hypersensitivity to administered drug
- Labeled drug-drug interaction medication error

**Equipment**
- Injury associated with device
- Medical device complication
- Needle issue
- Syringe issue

**General**
- Medication error
- Vaccination error

**Inappropriate schedule**
- Inappropriate schedule of drug administration
- Drug administered to patient of inappropriate age

**Incorrect dose**
- Accidental overdose
- Drug dose omission
- Extra dose
- Incorrect dose administered
- Underdose
- Overdose
- Multiple drug overdose

**Wrong drug**
- Drug dispensed to wrong patient
- Wrong drug administered

**Product quality**
- Product contamination,
- Product contamination microbial
- Product contamination physical
- Product quality issue

**Product labeling/packaging**
- Drug name confusion
- Product label confusion
- Product name confusion
- Product container issue
- Product label issue
- Product label on wrong product
- Product outer packaging issue
- Product packaging issue
- Product packaging confusion

**Storage and dispensing**
- Drug dispensing error
- Expired drug administered
- Incorrect product storage
- Incorrect storage of drug
- Poor quality drug administered
- Product reconstitution issue
Contraindication error group (215, 1% of total)

- Drug exposure during pregnancy (120, 56%)
  - 93% involved live attenuated influenza vaccine
  - Adverse health events described in 15% of reports (18)
    - 7 adverse health events were pregnancy related:
      - Spontaneous abortion (6)
      - Vaginal bleeding (1)

- Other contraindication errors reported
  - Live vaccines given to persons with immunodeficiency conditions
  - Vaccines given to persons with a history of an allergic reaction to a vaccine component
  - Live attenuated influenza administered to persons with asthma

Reporting vaccination errors to VAERS

- Please report all significant adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event. The Vaccine Adverse Event Reporting System (VAERS) accepts all reports, including reports of vaccination errors.

- VAERS is primarily concerned with monitoring adverse health events and we encourage reporting of clinically significant adverse health events following vaccination. Using clinical judgment, healthcare professionals can decide whether or not to report a medical error at their own discretion.
  - For example, a healthcare professional may elect to report vaccination errors that do not have an associated adverse health event, especially if they think the vaccination error may pose a safety risk (e.g., administering a live vaccine to an immunocompromised patient) or that the error would be preventable with public health action or education.

VAERS web site [https://vaers.hhs.gov/index](https://vaers.hhs.gov/index)