ISMP National Medication Error Reporting Program and Vaccine Error Reporting Program

Operated by the Institute for Safe Medication Practices

www.ismp.org

ISMP is a federally certified patient safety organization (PSO)
ISMP Vaccine Error Reporting Program

VERP Background

• Vaccine administration errors (VAEs) are preventable events that could lead to reduced vaccine effectiveness or adverse patient outcomes, mainly patients who are unprotected

• Other existing surveillance systems have not been designed specifically to collect data on vaccine-related errors (e.g., FDA-CDC VAERS)

• Identifying trends could result in practice changes and targeted efforts to prevent errors, including changes to product labeling, naming and design when identified as contributors to errors
The Institute for Safe Medication Practices (ISMP) partnered with the California Department of Public Health (CDPH) to develop a web-based VAE surveillance tool, the Vaccine Error Reporting Program (VERP)

VERP collects data on VAEs, including type and description of error, implicated vaccine, and provider information

VAEs are self-reported online at verp.ismp.org

US providers notified of VERP by email in October of 2012, and the Immunization Action Coalition and ISMP notified subscribers via their newsletters in December 2012.

Error alerts and review of VERP data has been published in ISMP Medication Safety Alert! Publications at ismp.org
More than 35 years ago, ISMP started a cornerstone of its medication error prevention efforts—a voluntary practitioner error-reporting program to learn about errors happening across the nation, understand their causes, and share “lessons learned” with the healthcare community. Today, ISMP has two reporting programs—the National Medication Errors Reporting Program (ISMP MERP) and the National Vaccine Errors Reporting Program (ISMP VERP).

Reporters are encouraged to submit associated materials (e.g., product photographs, containers, labels, de-identified prescription order scans) that help support the information being submitted.
<table>
<thead>
<tr>
<th>vepID</th>
<th>Submitted</th>
<th>State</th>
<th>Event Type</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4861</td>
<td>9/14/2016</td>
<td>MA</td>
<td>Wrong vaccine</td>
<td>A 37 year old man was given Fluzone High-Dose instead of Fluzone Quadrivalent.</td>
</tr>
<tr>
<td>4860</td>
<td>9/12/2016</td>
<td>WA</td>
<td>Vaccine/component omission - Diluent given without the vaccine</td>
<td>HIB was given to patient mixed with the sterile water diluent not the diluent provided with the HIB.</td>
</tr>
<tr>
<td>4859</td>
<td>9/12/2016</td>
<td>MI</td>
<td>Wrong dose - over dosage</td>
<td>I administered a 3 and older 0.5ml dose of Flu vaccine to a patient 24 months old.</td>
</tr>
<tr>
<td>4858</td>
<td>9/9/2016</td>
<td>IL</td>
<td>Wrong vaccine</td>
<td>Patient was given MMR-V even though they were on hydroxyurea for sickle cell. Hematologist was notified of the potential contraindication. Hydroxyurea was not discontinued and patient's mother was told to inform them if any fever occurred.</td>
</tr>
<tr>
<td>4857</td>
<td>9/8/2016</td>
<td>MO</td>
<td>Wrong vaccine</td>
<td>Administered ProQuad vaccine and Varicella vaccine to same individual. Nurse thought she was administering MMR and Varicella separately but upon review it was noted she administered MMRV in one arm and Varicella in the other.</td>
</tr>
<tr>
<td>4856</td>
<td>9/8/2016</td>
<td>WA</td>
<td>Wrong age (patient not correct age for vaccine given)</td>
<td>16 year old patient was given a dose of ProQuad.</td>
</tr>
<tr>
<td>4855</td>
<td>9/8/2016</td>
<td>MI</td>
<td>Extra dose</td>
<td>Pt was due for DTaP, Hep B, IPV and HIB. Clinical staff member grabbed the combination vaccine Pediarix (DTaP, HepB, IPV). What was supposed to be administered with that was an HIB but staff member grabbed an additional HepB instead. Pt received two HepB's and no HIB.</td>
</tr>
<tr>
<td>4854</td>
<td>9/7/2016</td>
<td>WA</td>
<td>Vaccine/component omission - Only one component of multi-component vaccine administered</td>
<td>Pt was given a HIB vaccination with the incorrect diluent. It was given with sterile water instead of the diluent provided with the vaccination.</td>
</tr>
<tr>
<td>4853</td>
<td>9/7/2016</td>
<td>ID</td>
<td>Wrong vaccine</td>
<td>I thought I had the Pentacel vaccine for a patient and administered the Gardasil 9.</td>
</tr>
<tr>
<td>4852</td>
<td>9/7/2016</td>
<td>IA</td>
<td>Wrong vaccine</td>
<td>Patient is 4 months old. Kinerix was given in error. Patient should have received Pediarix.</td>
</tr>
<tr>
<td>4851</td>
<td>9/6/2016</td>
<td>WA</td>
<td>Extra dose</td>
<td>Pt was given this vaccine and had already received it.</td>
</tr>
<tr>
<td>4850</td>
<td>9/6/2016</td>
<td>MA</td>
<td>Vaccine/component omission - Only one component of multi-component vaccine administered</td>
<td>Pentacel was reconstituted incorrectly. The Hib component was mixed with saline diluent. The DTaP and IPV component was not mixed or used. The dose is considered null/void. Patient will need to be revaccinated.</td>
</tr>
</tbody>
</table>
**Vaccine Error Report Details**

Submission ID: 380   Submitted on: 10/2/2013   Printed: No

1. Submission Type: Hazardous condition (no error, but situation warrants concern)
2. Event Date: 10/1/2013
3. Vaccines Involved:

<table>
<thead>
<tr>
<th>Brand name</th>
<th>Generic name</th>
<th>Manufacturer</th>
<th>Dosage</th>
<th>Lot#</th>
<th>Exp. Date</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluzone</td>
<td>Influenza Virus Vaccine (Trivalent, Types A and B)</td>
<td>Sanofi Pasteur, Inc</td>
<td>0.5 ml</td>
<td>UH895AB</td>
<td>30 JUN 14</td>
<td>49281-013-88</td>
</tr>
</tbody>
</table>

4. Event Description: [Edit/De-identify]

Vaccine given at 9:45 a.m. at place of employment. Pt. didn’t feel well after receiving it but did not return because she had a subsequent doctor’s appointment at 1:30 p.m. the same day. She arrived at the doctor’s office with chills, shaking, body aches. She was given epinephrine and benadryl. She went home, felt worse and later was admitted to the hospital with temp of 104 F.

5. Age of patient at time of event: 43 years
6. Type of event: Event type not listed (please specify in event description in question 4 above)
7. Contributing Factors:
   - No known contributing factors.
8. Type of facility where the event occurred: Wellness Center
9. Type of provider: Worksite Wellness Center
10. Type of practitioner involved in the event:
    - Registered Nurse (RN)
ISMP Vaccine Error Reporting Program

RESULTS

• VERP went live on September 12, 2012
• Nearly 2,000 unique errors reported from September 2012–present
• 90% of reports are errors that reached the patient, 6% errors that did not reach the patient, and 4% categorized as hazardous conditions where no error occurred, but was a situation that warranted concern
ISMP Vaccine Error Reporting Program

- Frequent errors reported to VERP: “Wrong Age”, “Wrong Vaccine, Wrong Route,” Expired product,” one vial of 2 component vaccine
- Vaccinator knowledge deficiency contributed to the majority (40%) of “Wrong Age” vaccines but schedule complexity and variety of products is an issue
- Labeling and packaging problems contributed to the majority of “Wrong Vaccine” error types
- Pertussis containing vaccines and influenza vaccines were associated with the greatest number of errors
Look-alike Fluzone
(Quadrivalent and high dose for age over 65)
DTaP and Tdap mix-ups

| DTaP (Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed) |
| DTaP-HepB-IPV (Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed, Hepatitis B [recombinant] and Inactivated Poliovirus Vaccine Combined) |
| DTaP-IPV (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine) |
| DTaP-IPV/Hib (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate [Tetanus Toxoid Conjugate] Vaccine) |

Tdap (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed)
Packaging issues – one component of two component vaccine given

Menveo container labels identical
Bar codes identical

Some other vaccines with diluent or two components:

- ActHIB
- MMR II
- Menomune
- Rabies
- Pentacel
- Rotarix (oral)
- Varivax
- Zostavax (frozen)
Packaging issue – RotaTeq vs. Rotarix

• Rotarix injected instead of given orally

RotaTeq diluent in between other GSK vaccines that ARE injected
Packaging issues

• Unreadable bar code on Tenivac (Tetanus & Diphtheria Toxoids Adsorbed – Sanofi Pasteur) and Fluzone High Dose
Insulin or other substance instead of influenza vaccine:
Drug and vaccine storage


• October 2014 - St. Louis County Missouri occurred where five teachers received insulin instead of influenza vaccine (http://www.kctv5.com/story/26724632/teachers-seeking-flu-shots-instead-given-insulin).


• In 2007 case where a teacher in nearby Attleboro received insulin instead of flu vaccine.


• In 1997, in country C, 21 infants died out of 70 infants supposedly given DTP vaccine. Insulin was stored in similar vials and in the same refrigerator as the DTP vaccine. http://www.who.int/vaccine_safety/publications/Global_Manual_on_Surveillance_of_AEFI.pdf
Name or Abbreviation Confusion

• DTaP-Tdap
• Adacel (Tdap) - Daptacel (DTaP)
• Kinrix (DTaP/Polio) – Pediarix (DTaP/Polio/hepatitis B)
• Hep B – Hib
• HPV - “HBV”
• Varicella virus vaccine – varicella zoster immune globulin (VZIG)
• Varivax – Zostavax
Process for administering vaccines
Process for administering vaccines