Vaccine Administration, Storage, and Handling Errors

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Disclosures

- Tina Objio is a federal government employee with no financial interest in or conflict with the manufacturer of any product named in this presentation

- The speaker will not discuss the off-label use of any vaccines

- The speaker will not discuss a vaccine not currently licensed by the FDA
VAERS Data

Vaccine Adverse Event Reporting System (VAERS)

- National Childhood Vaccine Injury Act of 1986
- Administered by CDC and FDA
- Began receiving reports in 1990
- Data available to the public

VAERS Strengths and Limitations

**Strengths**
- National data
- Accepts reports from anyone
- Rapidly detects safety signals
- Can detect rare adverse events
- Data available to public

**Limitations**
- Reporting bias
- Inconsistent data quality and completeness
- Lack of unvaccinated comparison group
- Generally cannot assess causality
- Coding practices can affect types and numbers of adverse events reported

Vaccination error reports\(^1\) number and percentage\(^2\) of all VAERS reports\(^3\) by year, 2000–2016

![Graph showing vaccination error reports by year]

\(^1\) 62,759 total vaccination error reports, primary U.S. VAERS 2000-2016
\(^2\) Percent of vaccination error reports among all primary U.S. VAERS reports by year
\(^3\) 433,116 total primary U.S. reports 2000-2016

## Vaccination Errors Categorized into 11 Error Groups, VAERS, 2000—2016

<table>
<thead>
<tr>
<th>Vaccination Error Groups¹</th>
<th>N (%)³</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Storage and dispensing</td>
<td>37,782 (57)</td>
</tr>
<tr>
<td>2. Inappropriate schedule</td>
<td>10,662 (16)</td>
</tr>
<tr>
<td>3. Wrong vaccine</td>
<td>4,996 (8)</td>
</tr>
<tr>
<td>Incorrect dose</td>
<td>4,772 (7)</td>
</tr>
<tr>
<td>Administration errors</td>
<td>3,382 (5)</td>
</tr>
<tr>
<td>General errors</td>
<td>2,634 (4)</td>
</tr>
<tr>
<td>Accidental</td>
<td>504 (1)</td>
</tr>
<tr>
<td>Product quality</td>
<td>442 (1)</td>
</tr>
<tr>
<td>Equipment</td>
<td>434 (1)</td>
</tr>
<tr>
<td>Contraindication</td>
<td>281 (&lt;1)</td>
</tr>
<tr>
<td>Product labeling/packaging</td>
<td>124 (&lt;1)</td>
</tr>
<tr>
<td><strong>Total errors²</strong></td>
<td><strong>66,013</strong></td>
</tr>
</tbody>
</table>

¹Vaccination error groups: Contain multiple MedDRA Codes. ²Vaccination error groups are not mutually exclusive. ³Total Vaccination Error Reports: 66,013. ⁴Percent of total errors.


## Top Vaccination Error Groups for Influenza Vaccine VAERS Reports 2018-2019

<table>
<thead>
<tr>
<th>Vaccine Error Group</th>
<th>Most Frequent MeDRA Preferred Terms</th>
</tr>
</thead>
</table>
| 1. Storage and Handling | - Product storage error  
                          | - Expired product administered |
| 2. Incorrect Dose | - Incorrect dose administered  
                        | - Under dose  
                        | - Extra dose |
| 3. Inappropriate Schedule | - Patient of inappropriate age |
| 4. Administration | - Product administered at inappropriate site  
                      | - Incorrect route of administration |
| 5. Wrong Drug | - Wrong product administered |
| 6. Equipment | - Syringe issue |
| 7. Product Labeling/Packaging | - Product container issue |

Top 5 Errors

- Storage and handling
- Inappropriate schedule
- Wrong vaccine/product
- Incorrect dose
- Administration

#1 Error: Storage and Handling
#1 Error: Storage and Handling

- Most involved patients receiving vaccines kept outside of proper storage temperatures
- Expired vaccines
- Clusters are common
- Automatic temperature data loggers and vaccine manufacturer reporting practices may account for report increase in recent years


VAERS Report Comments: Vaccine Transport

- “They transported the vaccine to a clinic packed with cold packs in a cooler without a thermometer”
- “Using dry ice to transport vaccines, which froze”

Recommendations for Vaccine Transport

Transport System Recommendations

<table>
<thead>
<tr>
<th></th>
<th>Emergency Transport</th>
<th>Transport for Off-Site Clinic, Satellite Facility, or Relocation of Stock</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portable Vaccine Refrigerator or Freezer</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Qualified Container and Packout</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Conditioned Water Bottle Transport System*</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Manufacturer’s Original Shipping Container</td>
<td>Yes (last resort only)</td>
<td>No</td>
</tr>
<tr>
<td>Food/Beverage Coolers</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

Temperature Monitoring during Transport

- **For any type of transport:**
  - Use a temperature monitoring device (DDL preferred)
  - Place buffered probe with vaccines
  - Keep display on top

https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
VAERS Report Comments: Shipment Management

- “After delivery, vaccine left out on counter all night and next morning”
- “When shipment of vaccine arrived 4–5 days after it was shipped, the medical assistant stated that the cold packs felt hot”


Recommended Practices for Handling Shipments

- Maintain cold chain; immediately check and store vaccines
  - Unpack
  - Examine and document
    - Condition, contents, cold chain monitor
  - Immediately store at recommended temperature

https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
VAERS Report Comments: Temperature Excursion

- “Power outage not noticed until after vaccination”
- “It was reported that the patient received above vaccine during time of refrigerator failure. Temps found to be <32”


Equipment: Temperature Monitoring Devices (TMDs)

- Recommended features
  - Detachable buffered probe
  - Alarm
  - Low battery indicator
  - Min/max display
  - Uncertainty of +/-0.5°C (+/-1°F)
  - 30-minute reading rate

https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
Recommendations for Handling a Temperature Excursion

Take Action!

- Notify
- Document
- Contact
- Correct

https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
http://www.immunize.org/handouts/temperature-logs.asp

Vaccine Administration Error Clusters:
Same Error, Multiple Individuals, Same Location

- 936 error clusters, all errors
  - Cluster size: 2–501 patients (median: 5)
  - 110 clusters involved 10+ patients
  - 586 clusters, the specific number of patients affected stated as “unknown” or “several”

- Storage errors most common error cluster (72% of all cluster reports)
  - Incorrect product storage (582 clusters, 1,715 patients)
  - Expired vaccine administered (96 clusters, 1,340 patients)
    - LAIV (45 clusters, 990 patients)

Do Storage and Handling Matter?

- Yes
  - Potency
  - Confidence
  - Cost (time, products, etc.)

https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

#2 Error: Inappropriate Schedule
#2 Error: Inappropriate Schedule

- **Inappropriate schedule errors included:**
  - Persons receiving vaccine not indicated for their age
  - Wrong timing/spacing between doses

Inappropriate Age: Influenza VAERS Reports 2018/19

- **Fluzone high-dose** given to patients <65 years old
- **Flublok** given to children <18 years old
- **Fluad** given to patients <65 years old
- **Flucelvax** given to children <4 years old

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Strategies to Prevent Wrong Age Errors

Vaccine-Specific ACIP Recommendations

- Anthrax
- BCG
- Cholera
- DTaP/Tdap/Td
- Hepatitis A
- Hepatitis B
- Hib
- HPV
- Influenza
- Japanese Encephalitis
- Measles, Mumps and Rubella
- MMRV
- Meningococcal
- Pneumococcal
- Polio
- Rabies
- Rotavirus
- Smallpox (Vaccinia)
- Typhoid
- Varicella (Chickenpox)
- Yellow Fever
- Zoster (Shingles)

- Manufacturer package inserts
- ACIP recommendations

#3 Error: Wrong Vaccine or Product Administered

https://www.cdc.gov/vaccines/hcp/acip-recs/index.html
#3 Error: Wrong Vaccine Administered

- **Mix-ups between vaccines such as varicella/zoster, DTaP/Tdap, and flu products**

<table>
<thead>
<tr>
<th>Common Vaccine Mix-Ups¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varicella</td>
</tr>
<tr>
<td>Diphtheria, tetanus, and pertussis (DTaP)</td>
</tr>
<tr>
<td>Trivalent inactivated influenza vaccine (IIV)</td>
</tr>
<tr>
<td>Pneumococcal conjugate</td>
</tr>
<tr>
<td>Hepatitis A</td>
</tr>
</tbody>
</table>

Vaccine mix-ups can be either combination (e.g., varicella vaccine instead of herpes zoster vaccine or herpes zoster vaccine instead of varicella vaccine)


Wrong Vaccine: Influenza VAERS Reports 2018/19

- **Fluzone quadrivalent and Fluzone HD mix-ups**
- **Tuberculin skin tests instead of various influenza vaccines**
- **Confusion between FluBlok quadrivalent and Fluzone quadrivalent products, some reports cited boxes looked alike (navy and white), patients <18 yrs received FluBlok**
- **Flu vaccines instead of pneumo vaccine**
- **Flu vaccine given to newborns instead of hepB vaccine**

Strategies to Prevent Vaccination Errors: Wrong Vaccine or Product

- Store some products on separate shelves:
  - Pediatric and adult formulations of the same vaccine
  - Sound-alike and look-alike vaccines
  - Other refrigerated products in vials (insulin, tuberculin)

- Label vaccines:
  - Color-coding labels can help

Strategies to Prevent Vaccination Errors: Wrong Vaccine

- Only administer vaccines you have prepared and triple-checked

- Use standardized ACIP vaccine abbreviations

- Consider using standing orders

IIV4 (Fluzone)
(Quadrivalent Inactivated Influenza Vaccine)
Ages: 6 months and older
Dosage: 0.25 ml for 6 months through 35 months
0.5 ml for 3 years and older
Route: Intramuscular (IM) injection
A maximum of 10 doses can be withdrawn from the multidose vial

LAIV4 (FluMist)
(Quadrivalent Live, Attenuated Influenza Vaccine)
Ages: 2 years through 49 years
Dosage: 0.2 ml 0.1 ml at each nostril
Do NOT give to: Pregnant, immunocompromised, children 2 through 4 years with allergies or any vaccine within last 12 months in medical record or by health care provider; influenza attenuated within past 48 hours; close contacts or caregivers of severely immunocompromised, child or adolescent taking corticosteroid or calcineurin inhibitor. Route: Intranasal (IN) Do NOT inject

CDC vaccine label examples www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf

ACIP vaccine abbreviations www.cdc.gov/vaccines/hcp/professionals/acip/abbreviations.html
Immunization Action Coalition standing orders www.immunize.org/standing_orders/
#4 Error: Incorrect Dose

- Common mistake for products with adult and pediatric formulations that have dose variations
  - Same product with adult and pediatric dosing
  - Different products for adults and children to prevent same disease with dosing variations
Incorrect Dose: Influenza VAERS Report 2018/19

- Persons age ≥3 years received 0.25 ml instead of 0.5 ml of Fluzone Quadrivalent
- Children age 6–35 months received 0.5 ml instead of 0.25 ml of Fluzone Quadrivalent
- Flucelvax incorrect dose given, including 1.5 ml instead of 0.5 ml given to patients in a cluster of linked reports
- Extra influenza dose administered

Strategies to Prevent Vaccination Errors: Incorrect Dose

- Check manufacturer package insert for dose
- Label vaccines
  - Include product name, type, and age indications
  - Color-coding labels can help

CDC vaccine label examples: [Link](www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf)
Strategies to Prevent Vaccination Errors: Incorrect Dose

- Before administering vaccines, all personnel who administer vaccines should:
  - Receive competency-based training
  - Have knowledge and skills validated

- Integrate competency-based training into:
  - New staff orientation
  - Annual education requirements

- Ongoing education:
  - When vaccine administration recommendations are updated
  - When new vaccines are added to the inventory

Skills Checklist for Vaccine Administration


#5 Error: Administration Errors
#5 Error: Administration Errors

- Inappropriate site
- Inappropriate route
- Inappropriate technique
- Adverse events

Administration Error: Influenza VAERS Report 2018/19

- Administration error group with highest percent of adverse events reported
  - Musculoskeletal disorders
  - Connective tissue disorders
  - “Too high”
  - Inappropriate site or route
  - Shoulder pain
  - Limb mobility decreased

Shoulder Injury Related to Vaccine Administration (SIRVA)

- Added to the Vaccine Injury Compensation Table March 2017
- Injuries to the musculoskeletal structure of the shoulder, including ligaments, bursa, and tendons
  - Result of the unintended injection of vaccine antigen and/or trauma from the needle going into and around the underlying bursa of the shoulder
  - Symptoms include shoulder pain and limited mobility after injection

Shoulder Injury Related to Vaccine Administration and Vaccine Administration Best Practices

- When administering a vaccine by intramuscular (IM) injection in the deltoid muscle, use:
  - Proper landmarks and technique to identify the injection site
  - Proper needle length based on the age, patient size, and injection technique

When administering vaccine by an intramuscular (IM) injection to an adult:

- Use the correct syringe and needle
  - Vaccine may be administered using either a 1-ml or 5-ml syringe
  - Use a 22 to 25 gauge needle
  - Use the correct needle size based on your patient’s size

Injection site: Deltoid muscle of upper arm

<table>
<thead>
<tr>
<th>Injection Site</th>
<th>1 in (25 mm)</th>
<th>1.5 in (38 mm)</th>
<th>2 in (51 mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men and women, less than 60 kg (132 lbs)</td>
<td>15 mg (0.5 mL)</td>
<td>25 mg (0.8 mL)</td>
<td>30 mg (1 mL)</td>
</tr>
<tr>
<td>Men and women, 60-90 kg (132-198 lbs)</td>
<td>25 mg (0.8 mL)</td>
<td>30 mg (1 mL)</td>
<td>40 mg (1.3 mL)</td>
</tr>
<tr>
<td>Women, 70-90 kg (154-198 lbs)</td>
<td>25 mg (0.8 mL)</td>
<td>30 mg (1 mL)</td>
<td>40 mg (1.3 mL)</td>
</tr>
<tr>
<td>Men, greater than 90 kg (200 lbs)</td>
<td>30 mg (1 mL)</td>
<td>40 mg (1.3 mL)</td>
<td>50 mg (1.7 mL)</td>
</tr>
<tr>
<td>Women, greater than 90 kg (200 lbs)</td>
<td>30 mg (1 mL)</td>
<td>40 mg (1.3 mL)</td>
<td>50 mg (1.7 mL)</td>
</tr>
</tbody>
</table>

*Some experts recommend a 5/8-inch needle for men and women who weigh less than 60 kg (132 lbs).
Clinical Resources for Shoulder Injury Related to Vaccine Administration

- CDC vaccine administration web page for information and materials for health care personnel, including:
  - IM demonstration video
  - Job aids and infographics
  - Vaccine administration e-Learn

www.cdc.gov/vaccines/hcp/infographics/call-the-shots.pdf
https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html

Resources
CDC Resources

Advisory Committee on Immunization Practices (ACIP)

Vaccine-Specific ACIP Recommendations

- Anthrax
- BCG
- Cholera
- DTaP/TdAP/Td
- Hepatitis A, UPDATED Feb 2019
- Hepatitis B
- Hib
- HPV
- Influenza
- Japanese Encephalitis
- Measles, Mumps and Rubella
- MMRV
- Meningococcal
- Pneumococcal
- Polio
- Rabies
- Rotavirus
- Smallpox (Vaccinia)
- Typhoid
- Varicella (Chickenpox)
- Yellow Fever
- Zoster (Shingles)

https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/index.html

CDC Resources

Vaccine Storage and Handling Toolkit

https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html
https://vaers.hhs.gov/
Immunization Action Coalition Resources

Ask the Experts

Experts from CDC Answer Questions About Vaccines

Answers to more than a thousand timely questions about vaccines and their administration:
- Administering Vaccines
- Disease and Precaution
- Combination Vaccines
- Immunization
- Cardiac Drugs
- Deciding Age
- Diphtheria
- Meningococcal
- Hib
- Polio
- Immunizations Comprises
- Rabies
- Influenza

http://immunize.org/askexperts/

Questions?

Still can’t find the answer?
Please e-mail us at:
NIPINFO@cdc.gov

For more information, contact CDC
1-800-CDC-INFO (232-4636)

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