Vaccine Administration: Make No Mistake!

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Disclosures

- Raymond A. Strikas 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
What is a Vaccine Administration Error?

- **Vaccination Error**
  - Any preventable event that may cause or lead to inappropriate use or patient harm. Such events may be related to professional practice, immunization products (e.g., vials, needles, syringes), storage, dispensing, and administration

- **Vaccine Adverse Health Events**
  - Health events that occur after immunization that may or may not be causally related to the vaccination

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Advisory Committee on Immunization Practices (ACIP)
General Best Practice Guidelines for Immunization

- Failure to adhere to recommendations for storage and handling of vaccines can reduce or destroy their potency, resulting in inadequate or no immune response in the recipient

- Best practice guidance for route, site, and dosage of immunobiologics is derived from data from clinical trials, practical experience, timing of routine healthcare visits, and theoretical considerations

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General Best Practice Guidelines for Immunization: [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html](http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html)

ACIP vaccine recommendations and guidelines: [https://www.cdc.gov/vaccines/hcp/acip-recs/index.html](https://www.cdc.gov/vaccines/hcp/acip-recs/index.html)
Real-Life Vaccine Administration Errors

- During an employee influenza vaccination clinic, 67 persons were “vaccinated”
- Errors included:
  - Infection control
  - Reuse of syringes and/or needles
  - Storage and handling
  - Vaccine stored at private residence
  - Improperly transported and stored for flu clinic
  - Insufficient dose
  - Two multidose vials = 20 doses, not 67 doses

Real-Life Vaccine Administration Error

- 390 reports of administration of only one component of Menveo to a total of 407 recipients
- 85% experienced no adverse event
- Menveo (MCV4; GSK) must be reconstituted prior to administration
  - Lyophilized component: MenCWY
  - Diluent: MenA vaccine
155 reports to VAERS regarding Shingrix, 13 (8%) documented an administration error, including:

- **Improper storage**: Administered after frozen storage
- **Wrong preparation**: Administered the adjuvanted diluent alone
- **Wrong route**: Given by SC rather than IM route
- **Wrong age**: Administered to wrong age group
- **Wrong vaccine**: Shingrix instead of varicella
Vaccine Adverse Event Reporting System (VAERS)

- Authorized by National Childhood Vaccine Injury Act of 1986
- Jointly administered by CDC and FDA
- National, postmarketing, passive reporting system for adverse events occurring after receipt of U.S.-licensed vaccines
- Began receiving reports in 1990
- Receives average ~40,000\(^1\) reports/year (2009—2016)\(^1\)
- Data available to the public

\(^1\)Numbers include both U.S. and foreign reports, primary and non-primary


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

Vaccine Adverse Event Reporting System: http://vaers.hhs.gov
Results: Vaccination Error Reports to VAERS, 2000-2016

Primary U.S. VAERS reports
433,116

Vaccination error reports
63,759 (15%)

No adverse health event
56,418 (88%)

Adverse health event
7,341 (12%)

Non-serious reports
6,813 (93%)

Serious reports
528 (7%)

1 Vaccination error reports defined using Medical Dictionary for Regulatory Activities (MedDRA) codes
2 Adverse health event
3 Serious reports: death, life-threatening illness, hospitalization or prolongation of hospitalization, or permanent disability (based on the Code of Federal Regulations)


Vaccination error reports number and percentage of all VAERS reports by year, 2000–2016

1 63,759 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 US 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 errors</strong>²</td>
<td><strong>66,013</strong></td>
</tr>
</tbody>
</table>

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


### Top 3 Vaccination Error Reports

1. **Storage Errors**

- 57% of VAERS error reports
- Most involved patients receiving vaccines kept outside of proper storage temperatures
- Often impacts multiple patients before error is identified
- Automatic temperature data loggers and vaccine manufacturer reporting practices may account for report increase in recent years
Top 3 Vaccination Error Reports

2. Inappropriate Schedule

- 16% of VAERS error reports
- Inappropriate schedule errors included:
  - Persons receiving vaccine not indicated for their age
  - Wrong timing/spacing between doses

Top 3 Vaccination Error Reports

3. Wrong Vaccine Administered

- 8% of VAERS administration error reports
- Mix-ups between vaccines such as varicella/herpes zoster, DTaP/Tdap

<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)

Vaccine Administration Error Reports: Adverse Health Events and Errors

- Adverse health events reported in 7,341 (12%)
  - Serious\(^1\) reports: 528 (7% of reports with adverse events)

- Most common adverse health events
  - Injection site erythema (12%), injection site pain (12%), pyrexia (9%)
  - Similar to what’s observed in non-error reports

- Error groups and reported adverse health events
  - “Administration Errors” (e.g., wrong site, incorrect route, wrong technique) had the highest percent of adverse health events for its group (1,851 of 3,382 error reports; 55%)

\(^1\)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.


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
Best Practice Strategies and Resources

Causes of Dispensing Errors

- Failure to double-check orders, medication, and labels
- High workload/low staffing
- Interruptions and distractions
- Problematic aspects of packaging and labeling such as look-alike packaging and obscure print
- Poor work environment (clutter, space, light)
- Outdated/inaccessible references/resources

Preventing Medication Errors IOM 2007, and To Err is Human: Building a Safer Health System 2001 http://www.nap.edu/
Preventing Medication Errors

- Institute of Medicine recommends implementing proven medication safety practices, including:
  - Reducing reliance on memory
  - Standardization
  - Protocols and checklists
  - Differentiating look-alike and sound-alike products
  - Monitoring error frequencies and correcting system problems associated with errors

Preventing Medication Errors IOM 2007, and To Err is Human: Building a Safer Health System 2001 http://www.nap.edu/

Staff Training and Education

- 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

Vaccine Administration

- Key to ensuring vaccination is as safe and effective as possible

- Incorporate:
  - Professional standards for medication administration
  - Manufacturers’ vaccine-specific guidelines
  - Evidence-based safe injection practices on CDC’s Injection Safety Information for Providers web page

https://www.cdc.gov/injectionsafety/providers.html

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 3-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
    - 1 in (25 mm):
      - Men and women, less than 60 kg (132 lbs)
      - Men, 70-100 kg (154-220 lbs)
      - Women, 70-90 kg (154-200 lbs)
    - 1.5 in (38 mm): QID
      - 1 in (25 mm):
        - Men and women, 60-10 kg (136-22 lbs)
        - Women, 60-10 kg (136-22 lbs)
      - Men, greater than 110 kg (240 lbs)
      - Women, greater than 90 kg (200 lbs)

*Some experts recommend a 5/8-inch needle for men and women who weigh less than 60 kg (130 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

Clinical Resources for Shoulder Injury Related to Vaccine Administration

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

Strategies to Prevent Vaccination Errors: Schedule and Timing

- Keep current reference materials available for staff, including:
  - Recommended childhood and adult schedules
  - Minimum age and interval table (Table 1)

- Educate staff administering vaccines about vaccines in the facility’s inventory

- Educate staff to schedule immunization appointments AFTER the child’s birthday

- Assess for indicated vaccines using your state’s immunization information system

General Best Practice Guidelines for Immunization www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html
ACIP immunization schedules for children and adults www.cdc.gov/vaccines/schedules/
Immunization information systems www.cdc.gov/vaccines/programs/iis/index.html
If your EMR assesses for needed vaccines, ask:

- What recommendations or schedule is this function based on?
- How often is this function updated?
- Will this happen automatically with system updates?

And often an immunization information system includes school requirements.

Strategies to Prevent Vaccination Errors: Wrong Vaccine

- Store some vaccines on separate shelves:
  - Pediatric and adult formulations of the same vaccine
  - Sound-alike and look-alike vaccines

- Label vaccines with type and age:
  - Color-coding labels can help

CDC vaccine labels

Visit CDC vaccine label examples at [www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf)
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

ACIP vaccine abbreviations  [www.cdc.gov/vaccines/acip/committee/guidance/vac-abbrev.html](http://www.cdc.gov/vaccines/acip/committee/guidance/vac-abbrev.html)

Strategies to Prevent Vaccination Errors: Storage and Handling

- Monitor the vaccine storage unit temperature:
  - Digital data logger (DDL) - check and record storage unit min/max temperatures at the start of each workday
  - Device does not display min/max temperatures - check and record the current temperature a minimum of 2 times (at the start and end of the workday)
- Take immediate action and isolate vaccine(s) exposed to improper temperatures

CDC Vaccine Storage and Handling Toolkit  [www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html)
Strategies to Prevent Vaccination Errors: Storage and Handling

- Check expiration dates weekly and remove expired vaccines from the storage unit
- Designate a primary and alternate vaccine coordinator for your facility
- Use a continuous temperature monitoring device
  - CDC recommends using digital data loggers (DDLs)
- Remove expired vaccines
- Use proper vaccine storage equipment

CDC You Call the Shots web-based education program: Storage and Handling

Reporting Vaccine Administration Errors
Reporting Vaccine Administration Errors

First step:
- Establish an environment that values reporting and investigating errors as part of risk management and quality improvement

What if a Vaccination Error Occurs?

- Inform the patient/parent of the error
- Determine the status of the patient
- Know how to “correct” the error
  - Contact your local health department, the vaccine manufacturer, or nipinfo@cdc.gov for guidance
  - Not all errors require revaccination!
- Explain any needed next steps to the patient/parent
- Record the vaccination as it was given on the medical record
- Contact the immunization information system (IIS) for additional information as needed
- Follow the policies and procedures of your facility for medication errors
Reporting Vaccination Errors to VAERS

- Report all significant adverse events that occur after vaccination of adults and children
- VAERS accepts all reports, including reports of vaccination errors

How to Report Adverse Events to VAERS

There are three ways to submit a report to VAERS:

- Report Online
  Complete a VAERS form online at: [http://vaers.hhs.gov](http://vaers.hhs.gov)
- Report by Mail (available through December 2017)
  Mail a completed [VAERS Form](http://vaers.hhs.gov) to VAERS, P.O. Box 1100, Rockville, MD 20849-1100

- Providers are encouraged to report vaccination errors without health events if they believe the error may pose a safety risk


Key Messages

- Vaccination error reports comprised up to 15% of all reports to VAERS
  - The number and percentage of vaccination error reports have increased significantly in VAERS during the period 2000–2016
- 88% of vaccination error reports have no reported adverse health event
  - However, errors can affect cost, convenience, effectiveness, and confidence in vaccination programs
- Comprehensive, skills-based education is needed for all staff that administers vaccines
- Integrate best practice strategies into clinical procedures and office flow
  - Check the IIS BEFORE administering vaccines
  - Use immunization job aids and resource materials to keep staff on the same page
- Report administration errors to VAERS
Additional Immunization Resources

CDC Resources for Staff Education

- Competency-based education for staff is critical
- Multiple educational products available free through the CDC website:
  - Immunization courses
  - You Call the Shots self-study modules
  - Netconferences
- Continuing education is available

CDC Immunization Education and Training web page  www.cdc.gov/vaccines/ed/index.html
**Epidemiology and Prevention of Vaccine-Preventable Diseases Webinar Series**

- **Provides:**
  - Information about vaccine-preventable diseases and the vaccines that prevent them
- **2018 series began in June**
  - Archived presentations available online
- **Free continuing education**
- **For more information:**
  www.cdc.gov/vaccines/ed/webinar-epv/index.html

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**Vaccine Administration Comprehensive Resources**

- **ACIP General Best Practice Guidelines**
  - General Best Practice Guidelines for Immunization
  - Vaccine Administration
  - Vaccine Recommendations and Guidelines of the ACIP
  - Continuing Education

- **Epidemiology and Prevention of Vaccine-Preventable Diseases**
  - 3rd Edition (the "Pink Book")
  - www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html
  - www.cdc.gov/vaccines/pubs/pinkbook/index.html
Vaccine Administration Resources for Health Care Personnel

- CDC vaccine administration materials for health care personnel include:
  - Printable clinical job aids
  - Vaccine administration e-Learn
  - Videos

Vaccine Storage and Handling Best Practices

https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm
Questions?

Can’t find the answer in one of these vaccine resources? Please e-mail us at: NIPINFO@cdc.gov

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

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