Vaccine Administration: Make No Mistake!

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Disclosures

- JoEllen Wolicki 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?

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

Recommendations for route, site, and dosage of vaccines are derived from data from clinical trials, practical experience, preventive health care visits, schedule, and theoretical considerations.
During a worksite occupational flu vaccination clinic, 67 persons were vaccinated:

- With improperly stored vaccine
- Using the same syringe
- Using an incorrect dosage (amount)
Real-Life Vaccine Administration Error

- Menveo (MCV4; GSK) must be reconstituted prior to administration
  - Lyophilized component: MenCWY
  - Diluent: MenA vaccine

- Administration error: Administering diluent alone
39 reports of injecting rotavirus vaccines
• 33 for RV1 and 6 for RV5
• This included a cluster of 6 reports involving RV1 by a nurse who did not receive proper training or read the package insert

19 (49%) documented an adverse event following the administration error

27 reports of splashes into HCP’s eyes
Real-Life Vaccine Administration Error

- Unintentional administration of insulin instead of influenza vaccine

Data and Research
Vaccine Adverse Event Reporting System (VAERS)

- Authorized by National Childhood Vaccine Injury Act of 1986
- Jointly administered CDC and FDA
- National, post-marketing, 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 at [http://wonder.cdc.gov/vaers.html](http://wonder.cdc.gov/vaers.html) and [https://vaers.hhs.gov/data/data](https://vaers.hhs.gov/data/data)

\(^1\)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](http://vaers.hhs.gov)
Results: Vaccination Error Reports to VAERS 2000-2016

Primary U.S. VAERS reports
433,116

Vaccination error reports¹
63,759 (15%)

No adverse health event
56,418 (88%)

Adverse health event²
7,341 (12%)

Non-serious reports
6,813 (93%)

Serious reports³
528 (7%)

¹Vaccination error reports defined using Medical Dictionary for Regulatory Activities (MedDRA) codes.
²Adverse Health Event
³Serious reports: death, life-threatening illness, hospitalization or prolongation of hospitalization or permanent disability (based on the Code of Federal Regulations)
Vaccination Error Reports\(^1\) Number and Percentage\(^2\) of All VAERS reports\(^3\) 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>4,382 (5)</td>
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<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></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 = 63,759
³Percent of total errors
Top 3 Vaccination Error Reports
1. Inappropriate Schedule

- 27% of VAERS error reports¹

- Inappropriate schedule errors included:
  - Wrong age
  - Wrong timing/spacing between doses in a series

- Wrong age errors were most common for children 0–18 years (57%)
  - 53% of these errors were reported in children younger than 1 year of age

- Wrong timing errors were most common in:
  - Quadrivalent human papillomavirus vaccine
    - Third dose given too soon (12-week minimum interval)
  - Rotavirus vaccine
    - First dose given after 15 weeks¹
    - Last dose given after 32 weeks¹

¹Based on 5% random sample review of reports wrong age inappropriate schedule (n=297)

Top 3 Vaccination Error Reports

2. Storage and Handling

- 23% of VAERS error reports\(^1\)

- Storage and handling errors reported included:
  - Expired vaccine (55%)
    - Live, attenuated influenza vaccine most common
  - Vaccines exposed to inappropriate temperatures (44%)
    - Vaccines kept outside of proper storage temperatures commonly reported (88%)\(^1\)
    - 55% of these reports involved vaccine exposed to temperatures below recommended storage temperature

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\(^1\)Based on 5% random sample review of reports
Top 3 Vaccination Error Reports

3. Wrong Vaccine Administered

- 15% of VAERS administration error reports

- Occurred among vaccines with similar names, acronyms, antigens

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

¹Vaccine 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

- Most common adverse health events (AHEs) included:
  - Injection site erythema (13%)
  - Injection site pain (11%)
  - Pyrexia (11%)

- All serious reports\(^1\) were clinically reviewed and reports included:
  - Injection site reactions (25%)
  - Musculoskeletal (e.g., shoulder pain) (13%)
  - Neurological (e.g., headache) (12%)

- Error groups and reported AHEs
  - Administration errors (e.g., wrong site, wrong technique, incorrect route) had the highest percentage of AHEs for its group (1,176 of 1,951 error reports; 60%)

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\(^1\)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.
Vaccine Administration Error Reports: Adverse Health Reports

- **Wrong site:** Shoulder injuries related to vaccine administration are injuries to the musculoskeletal structure of the shoulder, including the ligaments, bursa, and tendons
  - They are thought to occur as a 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 the injection

- **Shoulder injury related to vaccine administration (SIRVA) was added to the Vaccine Injury Compensation Table in March 2017**
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)
Best Practice Strategies and Resources
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
Strategies to Prevent Vaccination Errors

Knowledgeable Staff

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

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

Skills Checklist for Immunization

Strategies to Prevent Vaccination Errors

Knowledgeable Staff

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

- Don’t forget to assess vaccine administration skills of temporary staff
Perform hand hygiene:
- Before preparing and administering vaccines
- Between patients
- Anytime hands become soiled

Gloves are not required to be worn when administering vaccines unless the person administering the vaccine is likely to come into contact with potentially infectious body fluids or has open lesions on hands
- If gloves are worn, they should be changed between patients
- Perform hand hygiene between patients even if wearing gloves
Infection Control

- **Maintain proper infection control practices while preparing and administering vaccines**
  - Draw up and prepare vaccines in a clean medication preparation area

- **Equipment disposal:**
  - Puncture-proof biohazard container
  - Empty or expired vaccine vials are medical waste
Safe Injection Practices

- To ensure vaccination is as safe and effective as possible, incorporate:
  - Professional standards for medication administration
  - Manufacturer’s vaccine-specific guidelines
  - Evidence-based safe medication administration practices, including proper injection practices
Prepare and administer vaccines using aseptic technique:
• Use a new needle and syringe for every injection
• Disinfect the medication vial by rubbing the diaphragm with a sterile alcohol wipe

Use a single-dose vial for a SINGLE patient for a SINGLE procedure or injection:
• Discard after “entering” the vial, even if there is leftover vaccine

CDC Injection Safety website: https://www.cdc.gov/injectionsafety/providers.html
Additional Safe Injection Practice Resources

One and Only Coalition materials

One and Only Campaign www.oneandonlycampaign.org/

Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations
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
Clinical Resource: Know The Site. Get It Right!

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

www.cdc.gov/vaccines/hcp/admin/administer-vaccines.html
www.cdc.gov/vaccines/hcp/infographics/call-the-shots.pdf
Intramuscular Injection Sites

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Vaccine administration resource library: https://www.cdc.gov/vaccines/hcp/admin/resource-library.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](http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html)

ACIP Immunization schedules for children and adults [www.cdc.gov/vaccines/schedules/](http://www.cdc.gov/vaccines/schedules/)

Immunization information systems [www.cdc.gov/vaccines/programs/iis/index.html](http://www.cdc.gov/vaccines/programs/iis/index.html)
A Word about Electronic Medical Systems ...

- 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
Childhood Immunization Schedule Job Aids
Catching Up DTaP, Tdap, Hib, and PCV13 Vaccines

Catch-Up Guidance for Children 7 through 18 Years of Age
Tetanus, Diphtheria, and Pertussis-Containing Vaccines: Tdap/Td

<table>
<thead>
<tr>
<th>If current age is</th>
<th>AND1</th>
<th>AND2</th>
<th>THEN</th>
<th>Next Dose Due</th>
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<tbody>
<tr>
<td>7 through 10 years of age</td>
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<td>Does a child have 4 doses of DTP or DTPw before 12 months of age?</td>
<td>Give Dose 1 of Tdap today</td>
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<tr>
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<td>Give Dose 1 of Tdap today</td>
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<tr>
<td>Does a child have 1 doses of DTP or DTPw before 12 months of age?</td>
<td>Give Dose 1 of Tdap today</td>
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<tr>
<td>Does a child have 4 doses of DTP or DTPw before 12 months of age?</td>
<td>If the child was born on or after January 1, 2010</td>
<td>Give Dose 1 of Tdap today</td>
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</tr>
<tr>
<td>Does a child have 3 doses of DTP or DTPw before 12 months of age?</td>
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<td>7 years of age</td>
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<td>Does a child have 4 doses of DTP or DTPw before 12 months of age?</td>
<td>Any dose was Tdap</td>
<td>Give Dose 4 of Tdap today</td>
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<td>10 through 18 years of age</td>
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<td>15 years of age</td>
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<td>Any dose was Tdap</td>
<td>Give Tdap 10 years after Dose 4</td>
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<td>11 years of age</td>
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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 label examples  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:**
  - If using a digital data logger (DDL) to monitor the storage unit temperature, read the minimum and maximum temperatures each workday—preferably in the morning before clinic opens.
  - If NOT using a DDL to monitor the storage unit temperature read the temperature TWICE each work day—in the morning and at the end of the workday.
  - Record temperature readings on temperature log, along with time of the reading and initials of person recording data.
  - Review electronic temperature data at least 1 time each week.

- **Take immediate action and isolate vaccine(s) exposed to improper temperatures**
Strategies to Prevent Vaccination Errors: Storage and Handling

- Check expiration dates weekly and promptly remove expired vaccines from the storage unit

- Designate a primary vaccine coordinator for your facility
  - Choose a second staff member to act as an alternate vaccine coordinator

- Use a continuous temperature monitoring device
  - CDC recommends using digital data loggers

CDC You Call the Shots [https://www.cdc.gov/vaccines/ed/youcalltheshots.html](https://www.cdc.gov/vaccines/ed/youcalltheshots.html)
Multidose Vials and Expiration Dates

- A multidose vial (MDV) that has been stored and handled properly may be used more than once
- Double-check the manufacturer’s package insert (PI) for information on beyond-use date or dose limits (if applicable)
  - IPV MDV may be used through the expiration date if stored and handled correctly and not contaminated
- Some IIV products have a beyond-use date and should be used within a certain number of days after being entered
- Fluzone inactivated influenza vaccine PI indicates only 10 doses may be withdrawn from an MDV
  - After the maximum number of doses has been withdrawn from the MDV, the vial should be discarded, even if the expiration date has not been reached or there is vaccine left in the vial
Strategies to Prevent Vaccination Errors: Adverse Health Events

- Use standing orders
- Comprehensive standing order includes:
  - Who should be vaccinated
  - Indications, contraindications, and precautions
  - Procedures for administering the vaccine
  - Federal requirements (e.g., Vaccine information statement)
  - Documentation in the patient record
  - Protocol for the management of any medical emergency related to the administration of the vaccine
  - Reporting possible adverse events occurring after vaccination

IAC Standing orders http://www.immunize.org/standing-orders/
Strategies to Prevent Vaccination Errors: Adverse Health Events

- Screen for contraindications and precautions every time vaccines are needed
- Use a standardized form
- Integrate into office procedures and flow

IAC Screening Checklist for Contraindications and Precautions to Vaccines for Adults: http://www.immunize.org/catg.d/p4065.pdf
Strategies to Prevent Vaccination Errors: Adverse Health Events

- Administer injectable vaccines in the correct site based on the age, muscle mass, and size of the patient.

- Identify IM injection site using anatomical landmarks:
  - Vastus lateralis muscle (anterolateral thigh)
  - Deltoid muscle (upper arm)

IAC How to Administer Intramuscular and Subcutaneous Vaccine Injections

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

Vaccine Adverse Event Reporting System [www.vaers.hhs.gov/esub/index](http://www.vaers.hhs.gov/esub/index)
Take Home Messages

- Vaccination error reports comprised 6-15% of all reports to VAERS
  - The number and percentage of vaccination error reports have increased significantly in VAERS during the period 2000–2016

- Approximately 75% 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 administer 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
Vaccine Administration
Comprehensive Resources

ACIP General Best Practice Guidelines

General Best Practice Guidelines for Immunization [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html]
Epidemiology and Prevention of Vaccine-Preventable Diseases [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

CDC Vaccine Administration: [www.cdc.gov/vaccines/hcp/admin/admin-protocols.html](http://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html)
A self-paced vaccine administration course that provides comprehensive training using videos, job aids, and other resources.
Vaccine Storage and Handling


CDC Vaccine Storage and Handling web page: [http://www.cdc.gov/vaccines/recs/storage/default.htm](http://www.cdc.gov/vaccines/recs/storage/default.htm)
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 begins in June
  - 2017 archived presentations available online now

- Free continuing education

- For more information: www.cdc.gov/vaccines/ed/webinar-epv/index.html

Course text available online — view, print, or download
Bound copies may be purchased
Questions?

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

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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