Vaccine Administration Errors: Best Practices and Resources

Immunization Action Coalition Webinar
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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.
Vaccine Administration Errors – Background

- Institute of Medicine (IOM) reports focused national attention on medical errors and medication errors\(^1\)
- Previous studies in VAERS 1990-2002 identified few reported errors (<100\(^2,3\)

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Children Likely Given Wrong Vaccines at Salem County 'Shots for Tots' Clinic Audit Finds

The most egregious error, officials said, was when a toddler boy was likely given an excessive dose of a cervical cancer vaccine.

Morbidity and Mortality Weekly Report (MMWR)

Notes from the Field: Injection Safety and Vaccine Administration Errors at an Employee Influenza Vaccination Clinic — New Jersey, 2015

Weekly
December 18, 2015 / 64(49);1363-4
**Definitions**

- **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 (vials, needle, syringes), storage, dispensing, and administration*

- **Vaccine adverse health events (AHEs)**
  - Health effects that occur after immunization that may or may not be causally related to the vaccination

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Vaccine Adverse Event Reporting System (VAERS)

- National post-marketing passive reporting system since 1990 for adverse events receiving US-licensed vaccines
- Authorized by National Childhood Vaccine Injury Act of 1986
- Jointly administered by CDC and FDA
- Receives an average ~36,000* reports/year (2009-2013)
- Data available to the public
  - [http://wonder.cdc.gov/vaers.html](http://wonder.cdc.gov/vaers.html)
  - [https://vaers.hhs.gov/data/data](https://vaers.hhs.gov/data/data)
- * Annual estimate includes both U.S. and foreign reports, primary and non-primary

*Includes U.S. and foreign reports
Top 3 Pediatric Vaccine Administration Errors Reported to VAERS 2000 – 2013

- **Inappropriate schedule errors (3,385; 36%)**
  - Most commonly occurs with:
    - Rotavirus vaccines
    - Inactivated Influenza vaccine
    - DTaP
    - Quadrivalent human papillomavirus (4vHPV)

- **Wrong vaccine administered** (1,981; 21%)
  - Occurs among vaccines with similar names, acronyms, antigens

- **Storage errors (1,402; 15%)**
  - Expired vaccine administered
  - Incorrect storage of vaccine
    - Vaccines kept outside of proper storage temperature – storage units out of proper range

* Based on clinical review of all reports 0-6 years of age and random sample of 107/637 reports for 7-18 years of age. Specific vaccine trade name that was confused was not specified in most reports.
Errors and Adverse Health Events (AHEs)

- Reports of an AHE (1,877; 20%)
  - Most common AHEs, all reports:
    - Pyrexia (371; 20%), injection site erythema (211; 11%),
    - Injection site swelling (152,8%), injection site pain (138,7%), vomiting (135,7%)
  - Serious reports* (175, 9%) reported an AHE
    - Pyrexia (59,34%), vomiting (30,17%)

- Error groups and reported AHEs
  - Inappropriate schedule group AHEs (725, 21%)
  - Highest % of AHEs for a group (contraindication to vaccination 37 (53%)

*If one of the following is reported: death, life-threatening illness, hospitalization, or prolongation of hospitalization or permanent disability (Code of Federal Regulations)
Conclusions

- Vaccination error reports (9,338, 6%) of all reports in children to VAERS during 2000-2013. (12% report average during 2010-2013)

- No reported AHE in 80% of vaccination error reports in children

- Common types of vaccination errors reported to VAERS include: inappropriate schedule, wrong vaccine, improper storage
Advisory Committee on Immunization Practices
General Recommendations on 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.

- Recommendations for route, site, and dosage of vaccines are derived from data from clinical trials, practical experience, preventative health care visits, schedule, and theoretical considerations.

*MMWR* 2011;60(2):17
Vaccine Administration
Comprehensive Resources

- ACIP General Recommendations on Immunization: [Link](https://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf)
Key to ensuring vaccination is 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

CDC Injection Safety website
www.cdc.gov/injectionsafety/
Infection Control

- Perform hand hygiene:
  - Before preparing vaccines
  - Between patients
  - Any time 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

- 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

*MMWR 2011;60(2):17*
Injection Safety Best 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

- Single-dose vial is approved for use in a SINGLE patient for a SINGLE procedure or injection:
  - Discard after “entering” the vial, even if there is leftover vaccine

- A multiple-dose vial (MDV) may be used more than once:
  - Double-check the expiration date and the beyond-use date if it was previously opened, and visually inspect to ensure no visible contamination
  - Only the number of doses indicated in the manufacturer’s package insert should be withdrawn from a MDV. After the maximum number of doses has been withdrawn, the vial should be discarded, even if the expiration date has not been reached

CDC Vaccine Storage and Handling Toolkit  www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
Injection Practices Resources

One and Only Coalition and Campaign Materials

CDC Safe Injection Practices
HCP web page

CDC Safe Injection Practices Information for Providers www.cdc.gov/injectionsafety/providers.html

One and Only Campaign www.oneandonlycampaign.org/

NAIIS: Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations
www.izsummitpartners.org/content/uploads/2016/08/NAIIS-Vaccination-Clinic-Checklist_8-24-2016-FINAL.pdf
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

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

- AND establish an environment that values reporting and investigating errors as part of risk management and quality improvement

Skills checklist for immunization

Immunization Action Coalition: Skills Checklist for Immunization
www.immunize.org/catg.d/p7010.pdf
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

- Educate staff who administer immunizations 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

ACIP General Recommendations on Immunization, Table 1 [www.cdc.gov/mmwr/pdf/rr/rr6002.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf)
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)
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, age, and gender (if applicable):
  - Color coding labels can help

CDC vaccine labels

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
Immunization Action Coalition: standing orders templates www.immunize.org/standing-orders/
Strategies to Prevent Vaccination Errors
Storage and Handling

- Check expiration dates weekly. Promptly remove expired vaccines from the storage unit.

- Designate a person to be the 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: 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

- Monitor the vaccine storage unit temperature:
  - Read temperature monitoring devices in storage units a minimum of 2 times each workday, in the morning and at the end of the workday
  - Record temperature readings on temperature log, along with time reading taken 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

CDC: Vaccine Storage and Handling Toolkit  www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
What if a Vaccination Error Occurs?

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

Next steps:
- Inform the patient/parent of the error
- Determine the status of the patient
- Know how to “correct” the error
  - Contact your local health department, vaccine manufacturer, or nipinfo@cdc.gov for guidance
  - Not all errors require revaccination
- Explain any needed next steps to staff and the parent/patient
- Record the vaccine as it was given on the medical record and in immunization information system

Epidemiology and Prevention of Vaccine-Preventable Diseases  www.cdc.gov/vaccines/pubs/pinkbook/index.html
Reporting Vaccination Errors to Vaccine Adverse Event Reporting System (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

There are 3 ways to report to VAERS – online, fax or mail

www.vaers.hhs.gov/esub/index
IMMUNIZATION RESOURCES
Vaccine Administration

Vaccine Storage and Handling

CDC Vaccine Administration web page: [www.cdc.gov/vaccines/recs/vac-admin/default.htm](http://www.cdc.gov/vaccines/recs/vac-admin/default.htm)

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)
Vaccine and Immunization Resources

- **Questions? E-mail CDC**
  - Providers: nipinfo@cdc.gov
  - Parents and patients: www.cdc.gov/cdcinfo

- **CDC website**: www.cdc.gov/vaccines

- **Twitter for health care personnel**: @DrNancyM_cdc

- **Influenza**: www.cdc.gov/flu

- **Vaccine Safety**: www.cdc.gov/vaccinesafety

- **State Immunization Programs**: www.cdc.gov/vaccines/imz-managers/awardee-mz-websites.html