

Vaccine Administration Errors: Best Practices and Resources

Immunization Action Coalition Webinar

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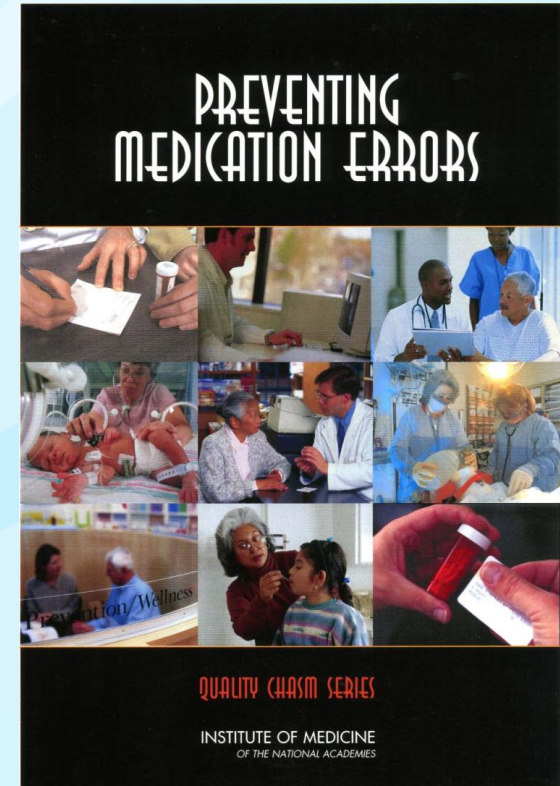


Disclosures

- ❑ 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 errors¹
- ❑ Previous studies in VAERS 1990-2002 identified few reported errors (<100)^{2,3}



1 Institute of Medicine. Preventing Medication Errors, 2007. <http://www.nap.edu/>.

2 Varricchio F. Medication errors reported to the Vaccine Adverse Event Reporting System (VAERS). Vaccine 2002 Aug 19;20(25-26):3049-51.

3 Varricchio, F, Reed J. Follow-up study of medication error reported to the Vaccine Adverse Event Reporting System (VAERS). South Med J 2006 May;99(5): 486-9.

Human error to blame for vaccine mix-up that killed 15 children in Syria, says Western-backed opposition

THE TELEGRAPH | September 18, 2014 11:49 AM ET
More from The Telegraph



Anti-Assad activist group, shows two Syrian children in a second round of measles vaccinations, in Idlib

AP Photo/Edith News Network ENN

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measles in Syria accidentally gave up to 15 children a vaccine

Morbidity and Mortality Weekly Report (MMWR)

CDC > MMWR

Notes from the Field: Administration Error Involving a Meningococcal Conjugate Vaccine — United States, March 1, 2010 –September 22, 2015

Weekly / February 19, 2016 / 65(6):161–162



Format: Select one

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)

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



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>
 - <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

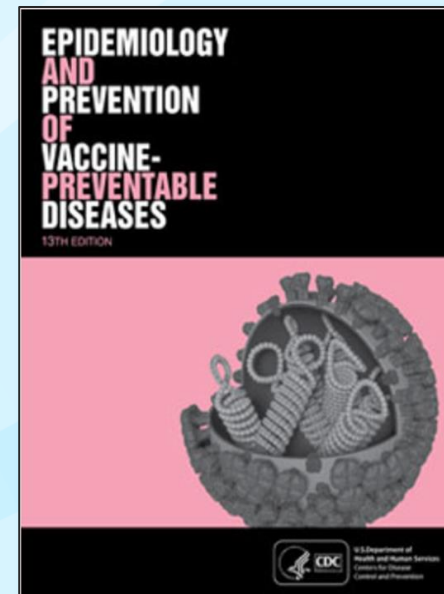


General Recommendations
on Immunization

Vaccine Administration Comprehensive Resources



ACIP General Recommendations on
Immunization



Epidemiology and Prevention of Vaccine-
Preventable Diseases,
13th Edition "Pink Book"

ACIP General Recommendations on Immunizations www.cdc.gov/mmwr/pdf/rr/rr6002.pdf

Epidemiology and Prevention of Vaccine-Preventable Diseases www.cdc.gov/vaccines/pubs/pinkbook/index.html

Safe Injection Practices

❑ **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

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

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

Injection Practices Resources

The screenshot shows the 'Injection Safety' section of the CDC website. It includes a sidebar with links to 'Injection Safety', 'CDC's Role', 'CDC Statement', 'Information for Providers', 'FAQs regarding Safe Practices for Medical Injections', 'Information for Patients', 'Preventing Unsafe Injection Practices', 'Drug Overuse', 'Injection Prevention during Blood Glucose Monitoring and Insulin Administration', 'Recent Publications', 'Recent Meetings', 'The One & Only Campaign', and 'Patient Notification Toolkit'. The main content area is titled 'Information for Providers' and features a 'Get Email Updates' section with a text input field and a 'Submit' button. Below this is a 'Continuing Education Activity (CME/CNE/CEU)' section with a link to 'Unsafe Injection Practices: Outbreaks, Incidents and Root Causes II'. At the bottom, there are 'Related Links' and 'Slide Presentations'.

CDC Safe Injection Practices HCP web page

The screenshot shows the 'One and Only Campaign' website. The header includes a navigation menu with links to 'About the Campaign', 'Safe Injection Practices', 'Healthcare Provider Information', 'Patient Information', 'Campaign Resources', 'News', and 'Contact Us'. The main content area features a large banner with the text 'HELP ENSURE PATIENT SAFETY. MAKE EVERY INJECTION A SAFE ONE.' and a graphic of a healthcare provider and a patient. Below the banner is a section titled 'About the Campaign' which describes the campaign's goal to eliminate infections from unsafe injection practices. To the right of the banner is a 'Become a Member' section. Below the banner is a 'Featured Content' section with links to 'New Resources for Ambulatory Settings: "It Takes A Team?"' and 'An unsafe injection was no joke for #HandHygiene! Follow his journey on Facebook and Twitter.' To the right of the featured content is a 'Spread the Word' section with a link to 'Do your part to make healthcare safe, one injection at a time. Order FREE materials from the CDC: CDCInfoOnDemand@InjectionSafety'. To the right of the spread the word section is a 'Translated Campaign Resources' section with a link to 'The One & Only Campaign has translated materials in Spanish and Japanese! Access translated resources here.'

One and Only Coalition and Campaign Materials

The checklist is titled 'Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations'. It is a step-by-step guide to help clinic coordinators/supervisors oversee vaccination clinics held at satellite, temporary, or off-site locations. The checklist outlines CDC guidelines and best practices for vaccine shipment, transport, storage, handling, preparation, administration, and documentation. It includes instructions for completing the checklist, a list of critical guidelines for patient safety and vaccine effectiveness, and a section for signing and submitting the checklist. The checklist is created by the Influenza Workgroup of the National Adult and Influenza Immunization Summit, Version 1 (updated 8/24/2016).

OVERVIEW OF THIS DOCUMENT

This checklist is a step-by-step guide to help clinic coordinators/supervisors overseeing vaccination clinics held at satellite, temporary, or off-site locations follow Centers for Disease Control and Prevention (CDC) guidelines and best practices for vaccine shipment, transport, storage, handling, preparation, administration, and documentation. This checklist outlines CDC guidelines and best practices that are essential for patient safety and vaccine effectiveness. A clinic coordinator/supervisor at the site should complete, sign, and date this checklist EACH TIME a vaccination clinic is held. To meet accountability and quality assurance standards, all signed checklists should be kept on file by the company that provided clinic staffing.

INSTRUCTIONS

1. A staff member who will be at the vaccination clinic should be designated as the clinic coordinator/supervisor. (This individual is responsible for completing the steps below and is referred to as "you" in the instructions.)
2. Review this checklist during the planning stage of the vaccination clinic—well in advance of the date(s) when the clinic will be held. This checklist includes sections to be completed before, during, and after the clinic.
3. Critical guidelines for patient safety and vaccine effectiveness are identified by the stop sign icon: . If you check "NO" in ONE OR MORE answer boxes that contain a , DO NOT move forward with the clinic. Follow your organization's protocols and/or contact your state or local health department for guidance before proceeding with the clinic. Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.
4. Contact your organization and/or health department if you have any concerns about whether vaccine was transported, stored, handled, or administered correctly, or any concerns about whether patients' personal information was protected appropriately (i.e., if you have concerns about other responses that you have marked as "NO" on rows that did not have the).
5. This checklist should be used in conjunction with CDC's Vaccine Storage and Handling Toolkit: www.cdc.gov/vaccines/imz/downloads/pdf/vaccine-storage-handling-toolkit.pdf. For information about specific vaccines, consult the vaccine manufacturer's guidelines and/or package insert.
6. This checklist applies ONLY to vaccines stored at REFRIGERATED temperatures.
7. Sign and date the checklist on completion of the clinic or upon completion of your shift (whichever comes first). (If more than one clinic coordinator/supervisor is responsible for different aspects of the clinic, you should complete only the section(s) for which you were responsible.)
8. Attach the staff sign-in sheet (with shift times and date) to the checklist (or checklists if more than one clinic supervisor was overseeing different shifts), and submit the checklist(s) to your organization to retain for accountability.

Name and credentials of clinic coordinator/supervisor: _____

Name of facility where clinic was held: _____

Address where clinic was held (street, city, state): _____

Time and date of vaccination clinic shift (the portion you oversaw): _____ Time (AM/PM) _____ Date (MMDDYYYY)

Time and date form was completed: _____ Time (AM/PM) _____ Date (MMDDYYYY)

Signature of clinic coordinator/supervisor: _____

This checklist was created by the Influenza Workgroup of the National Adult and Influenza Immunization Summit, Version 1 (updated 8/24/2016)

Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations

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

One and Only Campaign www.oneandonlycampaign.org/

NAIS: Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations

www.izsummitpartners.org/content/uploads/2016/08/NAIS-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

The Skills Checklist is a self-assessment tool for health care staff who administer immunizations. To complete it, review the competency areas below and the clinical skills, techniques, and procedures outlined for each of them. Score yourself in the Self-Assessment column. If you check **Need to Improve**, you indicate further study, practice, or change is needed. When you check **Meets or Exceeds**, you indicate you believe you are performing at the expected level of competence, or higher.

Supervisors: Use the Skills Checklist to clarify responsibilities and expectations for staff who administer vaccines. When you use it for performance reviews, give staff the opportunity to score themselves in advance. Next, observe their performance as they provide immunizations to several patients and score in the Supervisor Review column. If improvement is needed, meet with them to develop a **Plan of Action** (p. 2) that will help them achieve the level of competence you expect; circle desired actions or write in others. The DVD "Immunization Techniques: Best Practices with Infants, Children, and Adults" ensures that staff administer vaccines correctly. Order online at www.immunize.org/ivd

Competency	Clinical Skills, Techniques, and Procedures	Self-Assessment		Supervisor Review		Plan of Action*
		Need to Improve	Meets or Exceeds	Need to Improve	Meets or Exceeds	
A. Patient/Parent Education	1. Welcomes patient/family, establishes rapport, and answers any questions.					
	2. Explains what vaccines will be given and which type(s) of injection will be done.					
	3. Accommodates language or literacy barriers and special needs of patient/parents to help make them feel comfortable and informed about the procedure.					
	4. Verifies patient/parents received the Vaccine Information Statements for indicated vaccines and had time to read them and ask questions.					
	5. Screens for contraindications. (MSK score NA-not applicable-if this is MD function.)					
	6. Reviews comfort measures and after care instructions with patient/parents, inviting questions.					
B. Medical Protocols	1. Identifies the location of the medical protocols (i.e. immunization protocol, emergency protocol, reference material).					
	2. Identifies the location of the syringe, its administration technique, and clinical situations where its use would be indicated.					
	3. Maintains up-to-date CPR certification.					
	4. Understands the need to report any needlestick injury and to maintain a sharps injury log.					
C. Vaccine Handling	1. Checks val expiration date. Double-checks vial label and contents prior to drawing up.					
	2. Maintains aseptic technique throughout.					
	3. Selects the correct needle size for IM and SC.					
	4. Shakes vaccine vial and/or reconstitutes and mixes using the diluent supplied. Inverts vial and draws up correct dose of vaccine. Rechecks vial label.					
	5. Labels each filled syringe or uses labeled tray to keep them identified.					
	6. Demonstrates knowledge of proper vaccine handling, e.g. protects MMR from light, logs refrigerator temperature.					

Adapted from California Department of Public Health - Immunization Branch
 Immunization Action Coalition • Saint Paul, Minnesota • (651) 647-9009 • www.vaccineinformation.org • www.immunize.org
www.immunize.org/catg.d/p7010.pdf • Item #P7010 (2/14) page 1 of 2

Skills checklist for immunization

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

TABLE 1. Recommended and minimum ages and intervals between vaccine doses^{1†}

Vaccine and dose number	Recommended age for this dose	Minimum age for this dose	Recommended interval to next dose	Minimum interval to next dose
HepB-1 [§]	Birth	Birth	1-4 months	4 weeks
HepB-2	1-2 months	4 weeks	2-17 months	8 weeks
HepB-3 [§]	6-18 months	24 weeks	—	—
DTaP-1 [§]	2 months	6 weeks	2 months	4 weeks
DTaP-2	4 months	10 weeks	2 months	4 weeks
DTaP-3	6 months	14 weeks	6-12 months	6 months ^{§§}
DTaP-4	15-18 months	12 months	3 years	6 months ^{§§}
DTaP-5	4-6 years	4 years	—	—
Hib-1 ^{§§§}	2 months	6 weeks	2 months	4 weeks
Hib-2	4 months	10 weeks	2 months	4 weeks
Hib-3 ^{§§}	6 months	14 weeks	6-9 months	8 weeks
Hib-4	12-15 months	12 months	—	—
IPV-1 [§]	2 months	6 weeks	2 months	4 weeks
IPV-2	4 months	10 weeks	2-14 months	4 weeks
IPV-3	6-18 months	14 weeks	3-5 years	6 months
IPV-4 ^{***}	4-6 years	4 years	—	—
PCV-1 ^{§§}	2 months	6 weeks	8 weeks	4 weeks
PCV-2	4 months	10 weeks	8 weeks	4 weeks
PCV-3	6 months	14 weeks	6 months	8 weeks
PCV-4	12-15 months	12 months	—	—
MMo-1 ^{†††}	12-15 months	12 months	3-5 years	4 weeks
MMo-2 ^{†††}	4-6 years	13 months	—	—
Varicella-1 ^{††††}	12-15 months	12 months	3-5 years	12 weeks ^{§§§}
Varicella-2 ^{††††}	4-6 years	15 months	—	—
HepA-1	12-23 months	12 months	6-18 months ^{§§}	6 months ^{§§}
HepA-2	≥18 months	18 months	—	—
Influenza, inactivated ^{§§§}	≥6 months	6 months ^{****}	1 month	4 weeks
LAV (intranasal) ^{§§§}	2-49 years	2 years	1 month	4 weeks
MCV4-1 ^{†††††}	11-12 years	2 years	5 years	8 weeks
MCV4-2	16 years	11 years (+8 weeks)	—	—
MPSV4-1 ^{†††††}	—	2 years	5 years	5 years
MPSV4-2	—	7 years	—	—
Td	11-12 years	7 years	10 years	5 years
Tdap ^{§§§§}	≥11 years	7 years	—	—
PPSV-1	—	2 years	5 years	5 years
PPSV-2 ^{§§§§}	—	7 years	—	—
HPV-1 ^{*****}	11-12 years	9 years	2 months	4 weeks
HPV-2	11-12 years (+2 months)	9 years (+4 weeks)	4 months	12 weeks ^{†††††}
HPV-3 ^{†††††}	11-12 years (+6 months)	9 years (+24 weeks)	—	—
Rotavirus-1 ^{§§§§§}	2 months	6 weeks	2 months	4 weeks
Rotavirus-2	4 months	10 weeks	2 months	4 weeks
Rotavirus-3 ^{§§§§§}	6 months	14 weeks	—	—
Herpes zoster ^{*****}	≥60 years	60 years	—	—

See table footnotes on page 37

General Recommendations:

Table 1

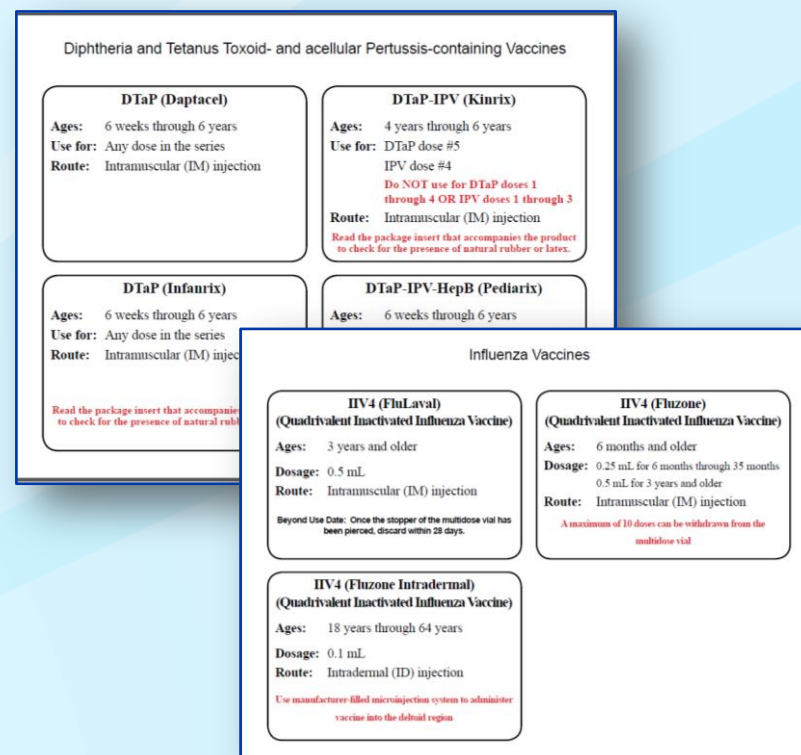
ACIP General Recommendations on Immunization, Table 1 www.cdc.gov/mmwr/pdf/rr/rr6002.pdf

ACIP Immunization Schedules for Children and Adults www.cdc.gov/vaccines/schedules/

Immunization Information Systems 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

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

May 1, 2015

Vaccine Acronyms Page 1 of 5

Advisory Committee on Immunization Practices
VACCINE ACRONYMS
Vaccines Included in the
Immunization Schedules for Children, Adolescents, and Adults

Following is a table of standardized vaccine acronyms, which was developed jointly by staff of the Centers for Disease Control and Prevention, ACIP Work Groups, the editor of the *Morbidity and Mortality Weekly Report (MMWR)*, the editor of *Epidemiology and Prevention of Vaccine-Preventable Diseases* (the "Pink Book"), ACIP members, and liaison organizations to the ACIP.

These acronyms are intended to provide a uniform approach to vaccine references used in ACIP Recommendations that are published in the *MMWR*, the *Pink Book*, the *American Academy of Pediatrics Red Book*, and in the United States, immunization schedules for children, adolescents, and adults.

Vaccine	PePedi
Diphtheria, tetanus and pertussis-containing vaccines	
• Diphtheria and tetanus toxoids adsorbed (P)	
• Diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed (P)	
• Tetanus and diphtheria toxoids adsorbed (A)	
• Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed (A)	
• Tetanus toxoid (P,A)	
• Diphtheria and tetanus toxoids and acellular pertussis adsorbed, hepatitis B and inactivated poliovirus vaccine (P)	
• Diphtheria and tetanus toxoids and acellular pertussis adsorbed and inactivated poliovirus vaccine (P)	
• Diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus and <i>Haemophilus influenzae</i> type b conjugate vaccine (P)	
<i>Haemophilus influenzae</i> type b-containing vaccines¹	
• <i>Haemophilus influenzae</i> type b conjugate vaccine	
• <i>Haemophilus influenzae</i> type b conjugate and hepatitis B vaccine	

* In descriptions of combination vaccines, dash (-) indicates products in which the active components from the manufacturer, slash (/) indicates products in which active components must be from several manufacturers; for complete listing, see <http://www.cdc.gov/vaccines/pdts/book/index.html>

¹ For additional Hib vaccine acronym, see <http://www.cdc.gov/vaccines/pdts/book/index.html>

Standing Orders for Administering Human Papillomavirus Vaccine to Children and Teens

Purpose: To reduce morbidity and mortality from human papillomavirus (HPV) infection by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate children and teens who meet the criteria below.

Procedure

- Identify all children and teens ages 11 years and older who have not completed the HPV vaccination series.
- Screen all patients for contraindications and precautions to HPV vaccine:
 - Contraindication:** a history of a serious allergic reaction (e.g., anaphylaxis) after a previous dose of HPV vaccine or to a HPV vaccine component (e.g., yeast for quadrivalent or 9-valent HPV vaccine [4vHPV or 9vHPV: Gardasil, Merck] or latex for bivalent HPV vaccine [2vHPV: Cervarix, GSK]). For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/packages/inserts) or go to www.cdc.gov/vaccines/pdts/pinkbook/downloads/appendices/B/escip-table-2.pdf.
 - Precautions:**
 - Moderate or severe acute illness with or without fever
 - Pregnancy; delay vaccination until after completion of the pregnancy
- Provide all patients (or, if minors, their parent or legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at www.immunize.org/vis.
- Provide 1) either 2vHPV, 4vHPV, or 9vHPV to girls or 2) 4vHPV or 9vHPV to boys. Provide either vaccine in a 3-dose schedule at 0, 1-2, and 6 calendar months. Provide routine vaccination with HPV vaccine to girls and boys at age 11 or 12 years; vaccine may be administered to girls or boys as young as age 9 years. Administer 0.5 mL HPV vaccine intramuscularly (22-25g, 1-1½" needle) in the deltoid muscle; the anterolateral thigh muscle may be used if deltoid is inadequate. (Note: a ½" needle may be used for children and teens weighing less than 110 lb [66 kg] for injection in the deltoid muscle only if the subcutaneous tissue is not bunched and the injection is made at a 90° angle.)
- For children and teens who have not received HPV vaccine at the ages and/or intervals specified in #4, administer one dose at the earliest opportunity and then schedule subsequent doses to complete the 3-dose schedule by observing a minimum interval of 4 weeks between the first and second doses, 12 weeks between the second and third doses, and at least 24 weeks between the first and third doses.
- Document each patient's vaccine administration information and follow up in the following places:
 - Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Children and Teens," go to www.immunize.org/iac/dp3082a.pdf. To prevent syncope, vaccinate patients while seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.
- Report all adverse reactions following the administration of HPV vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ (name of practice or clinic) until rescinded or until _____ (date).

Medical Director's signature: _____ Effective date: _____

For standing orders for other vaccines, go to www.immunize.org/standing-orders

IMMUNIZATION ACTION COALITION Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

Technical content reviewed by the Centers for Disease Control and Prevention
www.immunize.org/iac/dp3090.pdf • Item #P2000 (5/17)

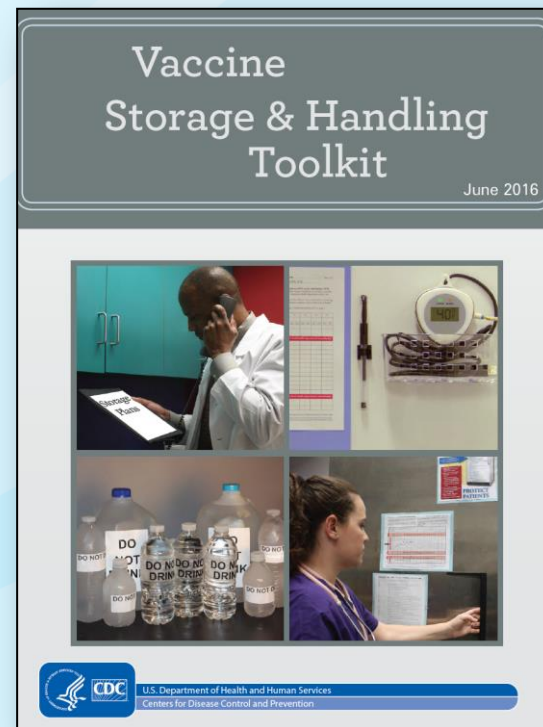
ACIP vaccine abbreviations www.cdc.gov/vaccines/acip/committee/guidance/vac-abbrev.html
Immunization Action Coalition: standing orders templates www.immunize.org/standing-orders/

IAC standing orders
template

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

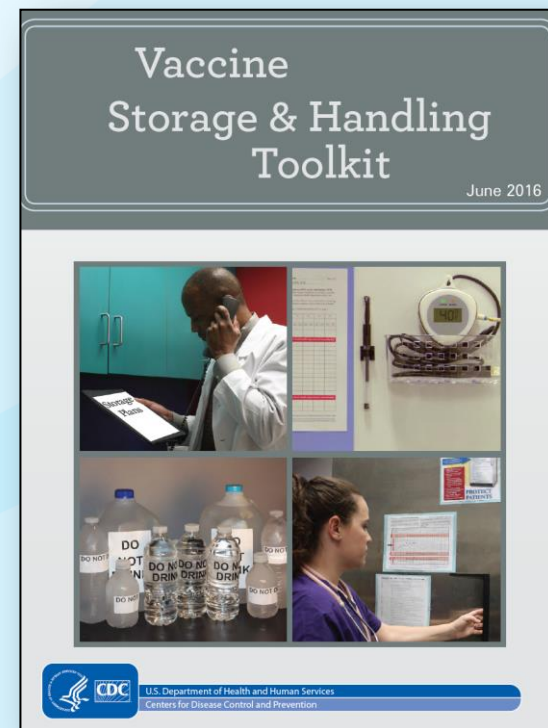


CDC Vaccine Storage and Handling Toolkit

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

What if a Vaccination Error Occurs?

❑ First step:

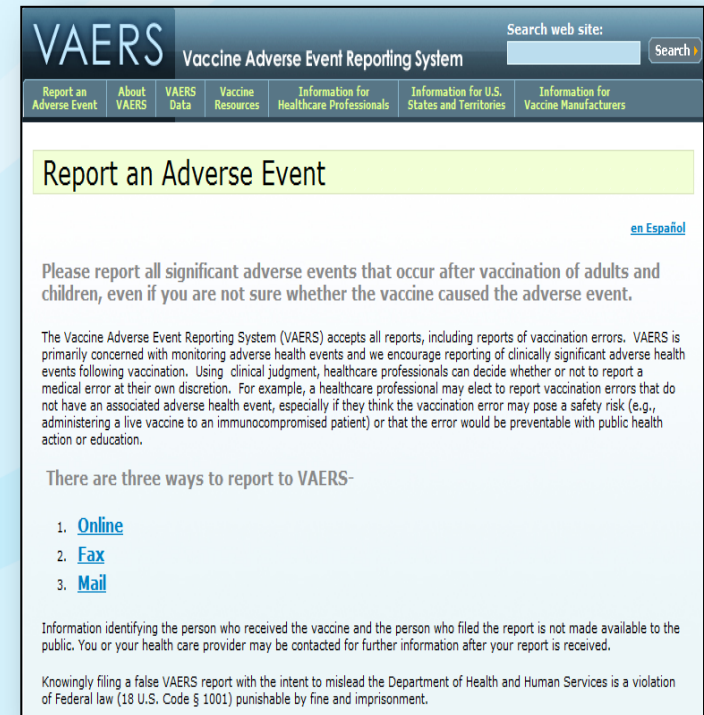
- Establish an environment that values reporting and investigating errors as part of risk management and quality improvement

❑ 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

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



The screenshot shows the VAERS (Vaccine Adverse Event Reporting System) website. The header includes the VAERS logo and a search bar. Below the header is a navigation menu with links: Report an Adverse Event, About VAERS, VAERS Data, Vaccine Resources, Information for Healthcare Professionals, Information for U.S. States and Territories, and Information for Vaccine Manufacturers. The main content area is titled 'Report an Adverse Event' and includes a link to 'en Español'. The text explains that VAERS accepts all reports, including vaccination errors, and encourages reporting of clinically significant adverse health events. It also lists three ways to report: Online, Fax, and Mail. A disclaimer at the bottom states that knowingly filing a false report is a violation of federal law.

VAERS Vaccine Adverse Event Reporting System

Search web site:

[Report an Adverse Event](#) [About VAERS](#) [VAERS Data](#) [Vaccine Resources](#) [Information for Healthcare Professionals](#) [Information for U.S. States and Territories](#) [Information for Vaccine Manufacturers](#)

Report an Adverse Event

[en Español](#)

Please report all significant adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.

The Vaccine Adverse Event Reporting System (VAERS) accepts all reports, including reports of vaccination errors. VAERS is primarily concerned with monitoring adverse health events and we encourage reporting of clinically significant adverse health events following vaccination. Using clinical judgment, healthcare professionals can decide whether or not to report a medical error at their own discretion. For example, a healthcare professional may elect to report vaccination errors that do not have an associated adverse health event, especially if they think the vaccination error may pose a safety risk (e.g., administering a live vaccine to an immunocompromised patient) or that the error would be preventable with public health action or education.

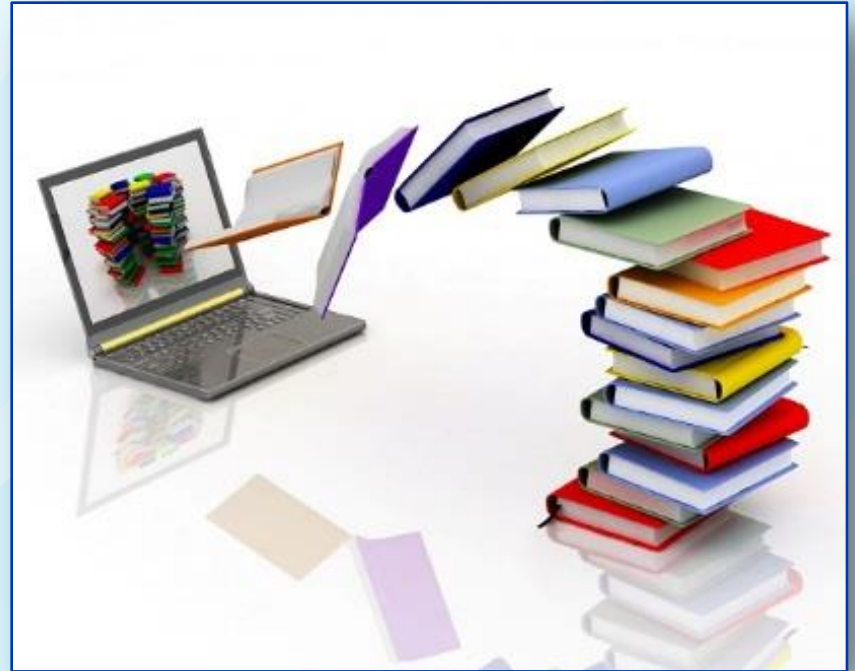
There are three ways to report to VAERS-

1. [Online](#)
2. [Fax](#)
3. [Mail](#)

Information identifying the person who received the vaccine and the person who filed the report is not made available to the public. You or your health care provider may be contacted for further information after your report is received.

Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

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



IMMUNIZATION RESOURCES

Vaccine Administration Vaccine Storage and Handling

The screenshot shows the CDC Vaccine Administration web page. The header includes the CDC logo and the text "Centers for Disease Control and Prevention CDC 24/7: Saving Lives. Protecting People.™". A search bar is located in the top right corner. The main navigation menu on the left lists various topics under "Vaccines and Immunizations Home", including "Immunization Schedules", "Recommendations and Guidelines", "Advisory Committee on Immunization Practices (ACIP)", "Vaccine Storage & Handling", "Vaccine Administration", "Reminder Systems and Strategies for Increasing Vaccination Rates", "Vaccines & Preventable Diseases", "Basics and Common Questions", "Vaccination Records", "Vaccine Safety and Adverse Events", "For Travelers", "For Specific Groups of People", "Campaign Materials", "Publications", "News and Media Resources", "Calendars and Events", "Education and Training Programs and Tools", "Statistics and Surveillance", and "About NCIRD". The main content area is titled "Vaccine Administration Recommendations and Guidelines" and features a "Guidelines" section with links to "Vaccine Administration from Pink Book (includes pictures of sites)", "Vaccines with Diluents: How to Use Them", "It's Federal Law - use of VISs and more in Pink Book appendix E", "Dosage, Route, Site", "Immunization Site Maps", "Indications", "Managing vaccine reactions", and "Sample vaccine record form for CHILDREN and TEENS". A sidebar on the right contains a "Print page" button, a "Get email updates" form, and "Contact Us" information for the Centers for Disease Control and Prevention.

Vaccine administration web page

The screenshot shows the CDC Vaccine Storage and Handling web page. The header includes the CDC logo and the text "Centers for Disease Control and Prevention CDC 24/7: Saving Lives. Protecting People.™". A search bar is located in the top right corner. The main navigation menu on the left lists various topics under "Vaccines and Immunizations Home", including "Immunization Schedules", "Recommendations and Guidelines", "Advisory Committee on Immunization Practices (ACIP)", "Vaccine Storage & Handling", "Vaccine Administration", "Reminder Systems and Strategies for Increasing Vaccination Rates", "Vaccines & Preventable Diseases", "Basics and Common Questions", "Vaccination Records", "Vaccine Safety and Adverse Events", "For Travelers", "For Specific Groups of People", "Campaign Materials", "Publications", "News and Media Resources", "Calendars and Events", "Education and Training Programs and Tools", "Statistics and Surveillance", and "About NCIRD". The main content area is titled "Vaccine Storage and Handling Recommendations and Guidelines" and features a "Guidelines" section with links to "Vaccine Administration from Pink Book (includes pictures of sites)", "Vaccines with Diluents: How to Use Them", "It's Federal Law - use of VISs and more in Pink Book appendix E", "Dosage, Route, Site", "Immunization Site Maps", "Indications", "Managing vaccine reactions", and "Sample vaccine record form for CHILDREN and TEENS". A sidebar on the right contains a "Print page" button, a "Get email updates" form, and "Contact Us" information for the Centers for Disease Control and Prevention.

Vaccine storage and handling web page

CDC Vaccine Administration web page 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>

Vaccine and Immunization Resources

❑ Questions? E-mail CDC

- Providers
- Parents and patients

nipinfo@cdc.gov

www.cdc.gov/cdcinfo

❑ CDC website

www.cdc.gov/vaccines

❑ Twitter for health care personnel

[@DrNancyM_cdc](https://twitter.com/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