



Vaccine Administration, Storage, and Handling Errors

National Adult and Influenza Immunization Summit

May 14, 2019

Content valid as of date of presentation.

Tina Objio, RN, MSN, MHA
CDR, U.S. Public Health Service
Nurse Educator
Immunization Services Division

Photographs and images included in this presentation are licensed solely for CDC/NCIDR online and presentation use. No rights are implied or extended for use in printing or any use by other CDC OIGs or any external audiences.

Disclosures

- Tina Objio is a federal government employee with no financial interest in or conflict with the manufacturer of any product named in this presentation
- The speaker will not discuss the off-label use of any vaccines
- The speaker will not discuss a vaccine not currently licensed by the FDA

VAERS Data



Vaccine Adverse Event Reporting System (VAERS)

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



What is VAERS?

Vaccine Adverse Event Reporting System <http://wonder.cdc.gov/vaers.html> and <https://vaers.hhs.gov/data/data>
<https://vaers.hhs.gov/index.html>

VAERS Strengths and Limitations

Strengths

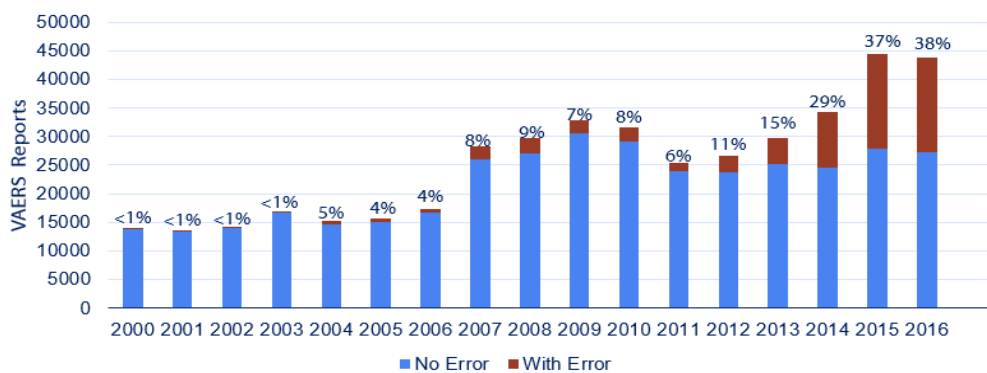
- National data
- Accepts reports from anyone
- Rapidly detects safety signals
- Can detect rare adverse events
- Data available to public

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>

Vaccination error reports¹ number and percentage² of all VAERS reports³ 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

Hbbs BF, Lewis P, Miller ER, Cano M. Vaccination Errors Reported to the Vaccine Adverse Event Reporting System (VAERS), 2000–2016. Presented at American Public Health Association Meeting, November 8, 2017.

Vaccination Errors Categorized into 11 Error Groups, VAERS, 2000–2016

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

81% of reported errors

¹Vaccination error groups contain multiple MedDRA Codes. ²Vaccination error groups are not mutually exclusive; Total Vaccination Error Reports = 63,759. ³Percent of total errors.
Hibbs BF, Lewis P, Miller ER, Cano M. Vaccination Errors Reported to the Vaccine Adverse Event Reporting System (VAERS), 2000–2016. Presented at American Public Health Association Meeting, November 8, 2017

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

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

Personal communication from Beth Hibbs, CDC Immunization Safety Office, Vaccine Adverse Event Reporting System (VAERS): 2018–19 Influenza Vaccine Safety Summary Report
Data through 3/29/2019, personal communication on April 22, 2019.

Top 5 Errors

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

#1 Error: Storage and Handling

#1 Error: Storage and Handling

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



Hibbs BF, Lewis P, Miller ER, Cano M. Vaccination Errors Reported to the Vaccine Adverse Event Reporting System (VAERS), 2000-2016. Presented at American Public Health Association Meeting, November 8, 2017.

VAERS Report Comments: Vaccine Transport

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

Hibbs, BF, et al. Safety of vaccines that have been kept outside of recommended temperatures: Reports to the Vaccine Adverse Event Reporting System (VAERS), 2008-2012. *Vaccine* 36(4):553-558.

Recommendations for Vaccine Transport

Transport System Recommendations

	Emergency Transport	Transport for Off-Site Clinic, Satellite Facility, or Relocation of Stock
Portable Vaccine Refrigerator or Freezer	Yes	Yes
Qualified Container and Packout	Yes	Yes
Conditioned Water Bottle Transport System[†]	Yes	No
Manufacturer's Original Shipping Container	Yes (last resort only)	No
Food/Beverage Coolers	No	No

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

Temperature Monitoring during Transport

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

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

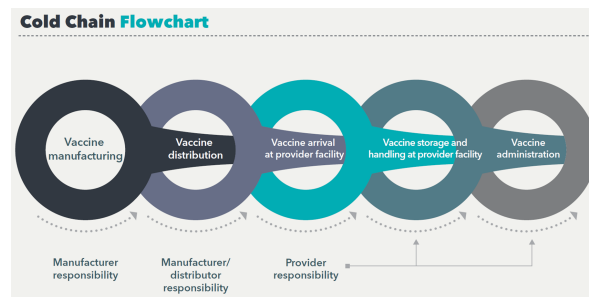
VAERS Report Comments: Shipment Management

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

Hibbs, BF, et al. Safety of vaccines that have been kept outside of recommended temperatures: Reports to the Vaccine Adverse Event Reporting System (VAERS), 2008–2012. *Vaccine* 36(4):553–558.

Recommended Practices for Handling Shipments

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



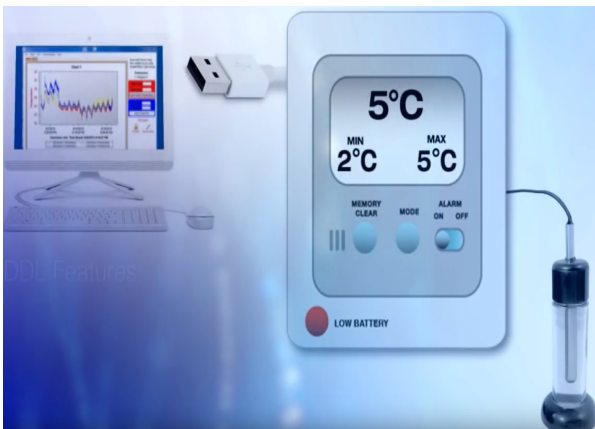
<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

VAERS Report Comments: Temperature Excursion

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

Hibbs, BF, et al. Safety of vaccines that have been kept outside of recommended temperatures: Reports to the Vaccine Adverse Event Reporting System (VAERS), 2008–2012. *Vaccine* 36(4):553–558.

Equipment: Temperature Monitoring Devices (TMDs)



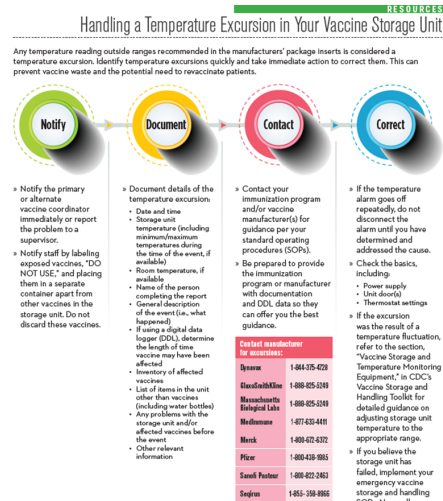
- **Recommended features**
 - Detachable buffered probe
 - Alarm
 - Low battery indicator
 - Min/max display
 - Uncertainty of +/-0.5° C (+/-1° F)
 - 30-minute reading rate

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

Recommendations for Handling a Temperature Excursion

Take Action!

- Notify
- Document
- Contact
- Correct



<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>
<http://www.immunize.org/handouts/temperature-logs.asp>
<http://www.immunize.org/catg.d/p3041.pdf>



VACCINE STORAGE AND HANDLING TOOLKIT

84

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)

Hibbs, BF, et al. Vaccination errors reported to the Vaccine Adverse Event Reporting System, (VAERS) United States, 2000–2013. *Vaccine* 2015 Jun 22;33(28):3171–8.

Do Storage and Handling Matter?

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



Vaccine Storage and Handling Toolkit



January 2018

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

#2 Error: Inappropriate Schedule

#2 Error: Inappropriate Schedule

Inappropriate schedule errors included:

- Persons receiving vaccine not indicated for their age
- Wrong timing/spacing between doses

Table 1 Recommended Adult Immunization Schedule by Age Group
United States, 2019

Vaccine	19–21 years	22–26 years	27–49 years	50–64 years	≥65 years
Influenza inactivated (IV) or Influenza recombinant (IR) or Influenza live attenuated (LA)			1 dose annually		
Tetanus, diphtheria, pertussis (Tdap or Td)			1 dose annually		
Tetanus, diphtheria, pertussis (Tdap, or Td)			1 dose Tdap, then Td booster every 10 yrs		
Measles, mumps, rubella (MMR)			1 or 2 doses depending on indication (if born in 1957 or later)		
Varicella (VAR)		2 doses (if born in 1980 or later)			
Zoster recombinant (RZV) (Shingrix)					2 doses
Zoster live (ZVL) (Zostavax)					1 dose
Human papillomavirus (HPV) Female	2 or 3 doses depending on age at initial vaccination				
Human papillomavirus (HPV) Male	2 or 3 doses depending on age at initial vaccination				
Pneumococcal conjugate (PCV13)					1 dose
Pneumococcal polysaccharide (PPSV23)			1 or 2 doses depending on indication		1 dose
Hepatitis A (HepA)			2 or 3 doses depending on vaccine		
Hepatitis B (HepB)			2 or 3 doses depending on vaccine		
Meningococcal A, C, W, Y (MenACWY)			1 or 2 doses depending on indication, then booster every 5 yrs if risk remains		
Meningococcal B (MenB)			2 or 3 doses depending on vaccine and indication		
Haemophilus influenzae type b (Hib)			1 or 3 doses depending on indication		

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection.
 Recommended vaccination for adults with an additional risk factor or another indication.
 No recommendation.

07/19/19 Centers for Disease Control and Prevention | Recommended Adult Immunization Schedule, United States, 2019 | Page 2

Hibbs BF, Lewis P, Miller ER, Cano M. Vaccination Errors Reported to the Vaccine Adverse Event Reporting System (VAERS), 2000–2016. Presented at American Public Health Association Meeting, November 8, 2017. <https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf>

Inappropriate Age: Influenza VAERS Reports 2018/19

- Fluzone high-dose given to patients <65 years old
- FluBlok given to children <18 years old
- Fluvad given to patients <65 years old
- Flucelvax given to children <4 years old

Personal communication from Beth Hibbs, CDC Immunization Safety Office, Vaccine Adverse Event Reporting System (VAERS): 2018–19 Influenza Vaccine Safety Summary Report
Data through 3/29/2019, personal communication on April 22, 2019.

Strategies to Prevent Wrong Age Errors

Vaccine-Specific ACIP Recommendations

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

- **Manufacturer package inserts**
- **ACIP recommendations**

<https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619541.pdf>
<https://www.cdc.gov/vaccines/hcp/acip-recs/index.html>

#3 Error: Wrong Vaccine or Product Administered

#3 Error: Wrong Vaccine Administered

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

Common Vaccine Mix-Ups ¹		
Varicella	with	Zoster
Diphtheria, tetanus, and pertussis (DTaP)	with	Tetanus, diphtheria, and pertussis (Tdap)
Trivalent inactivated influenza vaccine (IIV)	with	Another IIV with different age indications
Pneumococcal conjugate	with	Pneumococcal polysaccharide
Hepatitis A	with	Hepatitis B

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

Hibbs BF, Lewis P, Miller ER, Cano M. Vaccination Errors Reported to the Vaccine Adverse Event Reporting System (VAERS), 2000-2016. Presented at American Public Health Association Meeting. November 8, 2017.

Wrong Vaccine: Influenza VAERS Reports 2018/19

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



Personal communication from Beth Hibbs, CDC Immunization Safety Office, Vaccine Adverse Event Reporting System (VAERS): 2018-19 Influenza Vaccine Safety Summary Report Data through 3/29/2019, personal communication on April 22, 2019.

Strategies to Prevent Vaccination Errors: Wrong Vaccine or Product

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

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

LAIV4 (FluMist)
(Quadrivalent Live, Attenuated Influenza Vaccine)
Ages: 2 years through 49 years
Dosage: 0.2 mL (0.1 mL in each nostril)
Do NOT give to: Pregnant; immunocompromised; children 2 through 4 years with asthma or any wheezing within last 12 months in medical record or by health care provider; influenza antiviral taken within past 48 hours; close contacts or caregivers of severely immunosuppressed; children and adolescents taking concomitant aspirin- or salicylate-containing therapy.
Route: Intranasal (IN)
Do NOT inject

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

STANDING ORDERS FOR Administering Influenza Vaccine to Adults

Standing orders for other vaccine are available at www.immunize.org/standing-orders.cfm. The standing orders template may be adapted for a specific location without altering parameters from IAC. For more information, please contact IAC at www@immunize.org.

Purpose
 To reduce morbidity and mortality from influenza by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy
 Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g. pharmacists) to assess the need for vaccination and to vaccinate adults who meet any of the criteria below.

Procedure

- Assess Adults for Need of Vaccination against Influenza**
 - All adults are recommended to receive influenza vaccination each year.
 - Women who are or will be pregnant during the influenza season. Administer any recommended, age appropriate inactivated influenza vaccine (IIV) or recombinant influenza vaccine (RIV) to pregnant women in any trimester.
 - People who do not recall whether they received influenza vaccine this year should be vaccinated.
- Screen for Contraindications and Precautions**

Contraindications for use of all influenza vaccines
 Do not give influenza vaccine to a person who has experienced a serious systemic or anaphylactic reaction to a prior dose of any influenza vaccine or to any of its components (except egg). For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/products) or go to www.cdc.gov/vaccines/imz/pinkbook/downloads/appendices/1/vaccine-table2.pdf.

Contraindications only for use of live attenuated influenza vaccine (LAIV, FluMist, nasal spray)
 Do not give live attenuated influenza vaccine (LAIV, nasal spray) to a person who

 - is pregnant
 - is immunocompromised due to any cause (including immunosuppression caused by medications or HIV infection)
 - is age 50 years or older
 - received influenza antivirals (e.g., amantadine, rimantadine, zanamivir, oseltamivir, or peramivir) within the previous 48 hours
 - is a close contact of or who provides care for a severely immunosuppressed person who requires a protective environment.

Precautions for use of all influenza vaccines

 - Moderate or severe acute illness with or without fever
 - History of Guillain-Barre syndrome within 6 weeks of a previous influenza vaccination

Precautions for use of LAIV only

 - Active
 - Other chronic medical conditions that might predispose the person to complications of influenza infection (e.g., other chronic pulmonary, cardiovascular (including isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus))

More extensive patients with extra cautions: People with egg allergy of any severity can receive any recommended and age-appropriate influenza vaccine (i.e., any IIV, RIV, or LAIV) that is otherwise appropriate for their health status. For people with a history of severe allergic reaction to egg involving any symptom other than hives (e.g., angioedema, respiratory distress, lightheadedness, or recurrent anaphylaxis), or who required epinephrine or another emergency medical intervention, the selected vaccine should be administered in a medical setting (e.g., health department or physician office). Vaccine administration should be supervised by a healthcare provider who is able to recognize and manage severe allergic conditions.

Technical content reviewed by the Centers for Disease Control and Prevention. Immunization Action Coalition | Saint Paul, Minnesota | 651-640-9000 | www.immunize.org | www.vaccineinformation.org | www.immunize.org/standing-orders | Fax: 651-673-1070

IAC standing orders template

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

#4 Error: Incorrect Dose

#4 Error: Incorrect Dose

- **Common mistake for products with adult and pediatric formulations that have dose variations**
 - Same product with adult and pediatric dosing
 - Different products for adults and children to prevent same disease with dosing variations

Incorrect Dose: Influenza VAERS Report 2018/19

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

Personal communication from Beth Hibbs, CDC Immunization Safety Office, Vaccine Adverse Event Reporting System (VAERS): 2018–19 Influenza Vaccine Safety Summary Report
Data through 3/29/2019, personal communication on April 22, 2019.

Strategies to Prevent Vaccination Errors: Incorrect Dose

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

IIV4 (Fluzone) (Quadrivalent Inactivated Influenza Vaccine)

Ages: 6 months and older
Dosage: 0.25 mL for 6 months through 35 months
0.5 mL for 3 years and older
Route: Intramuscular (IM) injection

A maximum of 10 doses can be withdrawn from the multidose vial

LAIV4 (FluMist) (Quadrivalent Live, Attenuated Influenza Vaccine)

Ages: 2 years through 49 years
Dosage: 0.2 mL (0.1 mL in each nostril)
Do NOT give to: Pregnant; immunocompromised; children 2 through 4 years with asthma or any wheezing within last 12 months in medical record or by health care provider; influenza antiviral taken within past 48 hours; close contacts or caregivers of severely immunosuppressed; children and adolescents taking concomitant aspirin- or salicylate-containing therapy.
Route: Intranasal (IN)

Do NOT inject

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

Strategies to Prevent Vaccination Errors: Incorrect Dose

- Before administering vaccines, all personnel who administer vaccines should:

- Receive competency-based training
- Have knowledge and skills validated

- Integrate competency-based training into:

- New staff orientation
- Annual education requirements

- Ongoing education:

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

Skills Checklist for Vaccine Administration

The Skills Checklist is a self-assessment tool for healthcare staff who administer immunizations. To complete it, review the competency areas below and the clinical skills, techniques and procedures outlined for each area. Score yourself in the Self-Assessment column. If you check Needs 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 competency, or higher.

Supervisors: Use the Skills Checklist to identify responsibilities and expectations for staff who administer vaccines. When you use it to assist with performance reviews, give staff the opportunity to score themselves in the Self-Assessment column. Note, observe their performance as they administer vaccines to several patients, and score in the Superior Review column. If improvement is needed, meet with them to develop a Plan of Action (see bottom of page 10) to help them achieve the level of competency you expect, circle desired actions to write in others.

The COVID Immunization Technique Best Practices with Informed, Chilled, and Aided helps ensure that staff administer vaccines correctly. It may be ordered online at www.immunize.org/aid. Another helpful resource is CDC's Vaccine Administration eLearn course, available at www.cdc.gov/vaccines/imz/downloads/#vaccine-library.html.

COMPETENCY	CLINICAL SKILLS, TECHNIQUES, AND PROCEDURES	Self-Assessment		Superior Review	
		NEEDS TO IMPROVE	MEETS OR EXCEEDS	NEEDS TO IMPROVE	MEETS OR EXCEEDS
Patient/Parent Education	1. Welcomes patient/family, and establishes rapport.				
	2. Explains what vaccine will be given and which type(s) of injection(s) will be done.				
	3. Assesses questions and accommodation language/needs barriers and special needs of patient/parents to help make them feel comfortable and informed about the procedure.				
	4. Verifies patient/parents received Vaccine Information Statements (VIS) for indicated vaccines and has had time to read them and ask questions.				
	5. Screens for contraindications (if within employee's scope of work).				
	6. Reassures comfort measures and affirms instructions with patient/parents, and answers questions.				
Medical and Office Protocols	1. Identifies the location of the medical protocols (e.g., immunization protocol, emergency protocol, reference material).				
	2. Identifies the location of equipment, the 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 medical/child injury and to maintain a sharps injury log.				
	5. Demonstrates knowledge of proper vaccine handling, e.g., maintains vaccine at recommended temperature and protects BMBB from light.				

CONTINUED ON THE NEXT PAGE

IMMUNIZATION ACTION COALITION | Saint Paul, Minnesota | 651-547-9000 | www.immunize.org | www.vaccineinformation.org

Skills Checklist for Immunization <http://www.immunize.org/catg.d/p7010.pdf>

#5 Error: Administration Errors

#5 Error: Administration Errors

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

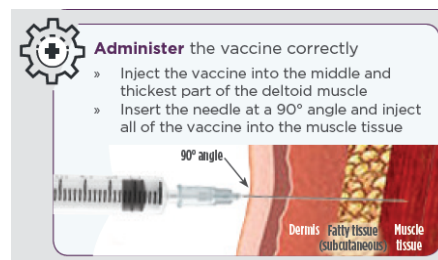
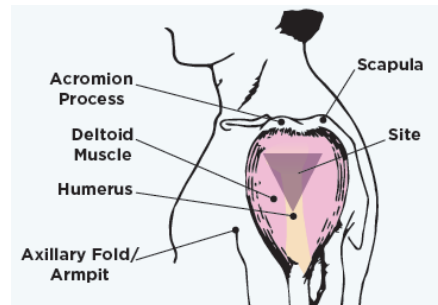
Administration Error: Influenza VAERS Report 2018/19

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

Personal communication from Beth Hibbs, CDC Immunization Safety Office, Vaccine Adverse Event Reporting System (VAERS): 2018–19 Influenza Vaccine Safety Summary Report
Data through 3/29/2019, personal communication on April 22, 2019.

Shoulder Injury Related to Vaccine Administration (SIRVA)

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



Shoulder Injury Related to Vaccine Administration and Vaccine Administration Best Practices

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

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

Use the correct syringe and needle

- » Vaccine may be administered using either a 1-mL or 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

Needle Length	Weight Category
1 in (25 mm)	Men and women, less than 60 kg* (130 lbs)
1.5 in (38 mm) O.R. 1 in (25 mm)	Men and women, 60-70 kg (130-152 lbs)
1.5 in (38 mm)	Men, 79-118 kg (152-260 lbs) Women, 79-90 kg (152-200 lbs)
1.5 in (38 mm)	Men, greater than 118 kg (>260 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

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

YOU CALL THE SHOTS
Shoulder injuries related to vaccine administration improper vaccine administration could result in shoulder injuries such as shoulder bursitis and tendinitis.

Make sure vaccination is safe. KNOW THE SITE. GET IT RIGHT!

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 2-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

Weight	Needle Gauge	Needle Length
1 to 25 (0 to 100 lb)	25	1 in (25 mm)
26 to 50 (10 to 200 lb)	23	1 in (25 mm)
51 to 75 (20 to 300 lb)	22	1 in (25 mm)
76 to 100 (30 to 400 lb)	22	1 1/2 in (38 mm)
101 to 150 (40 to 600 lb)	20	1 1/2 in (38 mm)
151 to 200 (60 to 800 lb)	18	1 1/2 in (38 mm)
201 to 300 (80 to 1200 lb)	18	2 in (50 mm)

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

Identify the injection site

- Locate the deltoid muscle of the upper arm
- Use anatomical landmarks to determine the injection site
- In adults, the midpoint of the deltoid is about 2 inches (or 2 to 3 finger-breadths) below the acromion process (bony prominence) and above the armpit in the middle of the upper arm

Administer the vaccine correctly

- Inject the vaccine into the middle and thickest part of the deltoid muscle
- Invert the needle at a 90° angle and inject all of the vaccine into the muscle tissue

IM injection best practices

- Administering the injection too high on the upper arm may cause shoulder injury
- If administering additional vaccines into the same arm, separate the injection sites

Always follow safe injection practices

- Maintain aseptic technique
- Perform hand hygiene before preparing and administering vaccines
- Use a new needle and new syringe for each injection
- If using a single-dose vial (SDV) discard after use
- SDV should be used for one patient only!

Report any clinically significant adverse event after vaccination to the Vaccine Adverse Event Reporting System (VAERS) at vaers.hhs.gov/

For additional information on proper vaccine administration,

Resources

CDC Resources

Advisory Committee on Immunization Practices (ACIP)

Vaccine-Specific ACIP Recommendations

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

Vaccine Recommendations and Guidelines of the ACIP

ACIP Recs Home > Comprehensive Recommendations and Guidelines

General Best Practice Guidelines for Immunization
 General Best Practice Guidelines for Immunization
 Ekanolue E, Harriman K, Hunter P, Kroger A, Pellegrini C
 Print: friendly version (1.05 MB, 191 pages)

Introduction
 Purpose and topics covered in this report...

Methods
 Method of development of: Timing and Spacing, Contraindications and Precautions, Preventing and Managing Adverse Reactions...

Timing and Spacing of Immunobiologics
 Vaccine scheduling, supply and lapsed schedule, spacing of doses, simultaneous and nonsimultaneous administration, licensed combination vaccines, interchangeability of formulations, extra doses, conjugate vaccines...

Contraindications and Precautions
 General principles, standards of valid contraindications and precautions, and conditions incorrectly perceived as contraindications...

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

CDC Resources

Vaccine Storage and Handling Toolkit

U.S. Department of Health and Human Services
 Centers for Disease Control and Prevention

- <https://www.cdc.gov/vaccines/hcp/index.html>
- <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>
- <https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html>
- <https://vaers.hhs.gov/>

CDC Centers for Disease Control and Prevention
 CDC.gov | Saving Lives. Protecting People™

Healthcare Providers / Professionals

Spotlights

- [Epidemiology and Prevention of Vaccine-Preventable Diseases \(Pink Book\) Land Based Course in Atlanta, GA](#) 16 hours of free CME (Mar 28-30, 2019) (Mar 26)
- [CINIC registration for March 13, 2019, noon-1pm EST](#) (open 2019 Child and Adult Immunization Schedule) (Feb 26)
- [Recommendations of the Advisory Committee on Immunization Practices for Use of Hepatitis A Vaccine for Persons Experiencing Homelessness](#) (Feb 15)
- [2019 Vaccine Schedules now available](#) (Feb 5)
- [MMWR Postlicensure Safety Surveillance of Recombinant Zoster Vaccine \(Shingrix\) — United States, October 2017–June 2018](#) (Feb 1)

See past spotlights

New Standards
 for Adult Immunization Practices
[CDC \(PDF\)](#)
[VACCINATE!](#)

CDC Vaccine Schedules App
 CDC Vaccine Schedules
 Version 5.0.2 (Available for iOS and Android devices)
 Free access to recommended child and adult immunization schedules, tables and footnotes on your tablet or smartphone.

PneumRecs VaxAdvisor **NEW Dec 2018**
 Version 1.0 (Available for iOS and Android devices)
 This mobile app helps vaccination providers quickly and easily determine which pneumococcal vaccines a patient needs and when.

Clinical Resources

- Immunization Schedules
- ACIP Vaccination Recommendations

Administration Tools

- Storage & Handling of Your Vaccine Supply
- Vaccine Administration Protocols
- Vaccines for Children (VFC)

Healthcare Providers / Professionals

Healthcare Professionals / Providers Home

Vaccine Administration

Vaccine Administration

Proper vaccine administration is critical to ensure that vaccination is safe and effective. CDC recommends that all health care personnel who administer vaccines receive comprehensive, competency-based training on vaccine administration before administering any vaccine. Comprehensive, skills-based training should be integrated into existing staff education programs such as new staff orientation and annual education requirements. If no vaccine administration training is available that offers continuing education for health care personnel including CME, CEU, CEU, CEU and CME.

REVIEW IMMUNIZATION HISTORY
 Reviewing and assessing a patient's immunization history should be done at every health care visit to help determine which vaccines may be needed.

ASSESS FOR NEEDED IMMUNIZATIONS
 Use the current Advisory Committee on Immunization Practices (ACIP) immunization schedule to determine what recommended vaccines are needed based on the patient's immunization history.

Vaccine Administration e-Learn

Immunization Action Coalition Resources

Immunization Action Coalition [Sign up for email newsletter](#)

[Favorites](#) |
 [Handouts & Staff Materials](#) |
 [Clinic Tools](#) |
 [Vaccine Information Statements](#)

IAC Home | [Ask the Experts](#)

Ask the Experts

Get new and updated Ask the Experts Q&As 5 times/year by subscribing to *IAC Express*

Experts from CDC Answer Questions About Vaccines

Answers to more than a thousand timely questions about vaccines and their administration

- Administering Vaccines
- Billing and Reimbursement
- Combination Vaccines
- Diphtheria
- Documenting Vaccination
- Hib
- Hepatitis A
- Hepatitis B
- HPV
- Influenza
- MMR
- Meningococcal ACWY
- Meningococcal B
- Pertussis
- Pneumococcal
- Polio
- Precautions/Contraindications
- Rabies
- Rotavirus
- Scheduling Vaccines
- Storage and Handling
- Tetanus
- Travel Vaccines
- Vac Recommendations
- Vaccine Safety
- Varicella (chickenpox)
- Zoster (shingles)

<http://immunize.org/askexperts/>
<http://www.immunize.org/catg.d/p3033.pdf>

Don't Be Guilty of These Preventable Errors in Vaccine Administration!

Is your healthcare setting making any of these frequently reported errors in administering vaccines? Although some of these errors are much more serious than others, none of them should occur. Be sure those who administer vaccines are not making any of these preventable errors in vaccine administration.

Note: Information about reporting vaccine administration errors is found at the end of this article.

ERROR: Not using a screening checklist to identify patients' contraindications and precautions to vaccination

How to Avoid This Error: Always use a reliable screening questionnaire to consistently avoid either 1) giving a vaccine to a patient for whom it is contraindicated (a serious, potentially life-threatening situation), or 2) missing opportunities to vaccinate because of false contraindications (which can also be life-threatening, as they can leave a patient exposed to a vaccine-preventable disease).

Helpful Resources: Use IAC's screening checklists, such as *Screening Checklist for Contraindications to Vaccines for Children and Teens* and *Screening Checklist for Contraindications to Vaccines for Adults* (both reviewed by CDC, available at www.immunize.org/handouts/screening-vaccines.asp, CDC Vaccine Contraindications and Precautions web page www.cdc.gov/vaccines/hcp/soip/recs/general/recs/contraindications.html).

ERROR: Administering the wrong vaccine due to similarities in vaccine names (e.g., DTaP for Tdap, zoster for varicella, PPSV23 for PCV13)

How to Avoid This Error: Check the label 3 TIMES! Such errors often involve vaccines whose generic or trade names look or sound alike (e.g., Tdap and DTaP, Adacel and Daptacel), or that have similar packaging, so store such vaccines separately and mark them clearly in your storage unit as well as on the patient's vaccine log. Other times, vaccines are mixed up when vaccinating multiple family members, such as siblings, on the same visit. Prepare vaccines needed for one family member at a time, and always verify names and formulations for the patient receiving the vaccines.

What to do after such an error: The parent/patient should be told the wrong vaccine was given. Provide the correct vaccine, if necessary, with correct spacing, if necessary. For more details about specific situations, check *Ask the Experts* (www.immunize.org/askexperts/) under the relevant vaccine section, or email cdc-nipinfo@cdc.gov for advice. Assess how this error happened to ensure it will not happen again.

Helpful Resources: Institute for Safe Medication Practices' (ISMP) *Recommendations for Practitioners to Prevent Vaccine Errors*; www.ismp.org/newsletters/updates/articles/showarticle.aspx?id=104

ERROR: Using the wrong diluent or administering the diluent only

How to Avoid This Error: Use careful labeling in your vaccine storage units. Keep vaccines and their diluents together if storage requirements are the same. Check the vial and diluent labels 3 TIMES before reconstituting vaccine. Administering the diluent only is most likely to happen with the two vaccines that include antigen in their liquid component, MMRv and Pertacel.

What to do after such an error: Diluent errors could affect the potency of the vaccine antigen administered, or the patient might not get the full benefit of the vaccine if the diluent not given contains antigen. If the wrong diluent is used, the vaccine needs to be repeated (except in the case of mixing up the diluent between MMR, MMRV, varicella, and zoster vaccines which are all made by Merck and use the same sterile water diluent).

If an INACTIVATED vaccine is reconstituted with the wrong diluent and is administered, the dose is invalid and should be repeated ASAP. If a LIVE vaccine is reconstituted with the wrong diluent and is administered, the dose is invalid and it can be repeated on the same clinic day. It needs to be repeated no earlier than four weeks after the invalid dose. This spacing is due to the effects of generating a partial immune response that could suppress the live replication of subsequent doses, even of the same live virus vaccine.

Merck's diluent contains the C, Y, and W-135 serogroups, and the lyophilized vaccine component (e.g., freeze-dried powder) contains serogroup A. If the patient receives only the diluent, he or she is not protected against invasive meningococcal disease caused by *Neisseria meningitidis* serogroup A. Serogroup A disease is very rare in the United States but common in some other countries. If the recipient of the C/Y/W diluent only dose does not plan to travel outside the U.S., then the dose does not need to be repeated. Otherwise, the dose should be repeated with either correctly reconstituted Merck or with a dose of Menactra.

There is no minimum interval between the incorrect dose and the repeat dose.

With Pertacel, the liquid DTaP/IPV component given alone can count as valid doses of DTaP and IPV vaccines. You cannot mix the leftover Hib component (lyophilized powder) with sterile water. ActHib must ONLY be reconstituted with either the DTaP/IPV solution supplied with Pertacel, or with a specific ActHib saline diluent. You must contact the manufacturer to obtain diluent for the extra ActHib dose.

Helpful Resources: *Vaccines with Diluents: How to Use Them* (www.immunize.org/catg.d/p3040.pdf)

CONTINUED ON THE NEXT PAGE ►



Technical content reviewed by the Centers for Disease Control and Prevention
 Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org
www.immunize.org/catg.d/p3033.pdf Item #93033 (04/17)

Questions?

Still can't find the answer?

Please e-mail us at:

NIPINFO@cdc.gov

For more information, contact CDC
 1-800-CDC-INFO (232-4636)
 TTY: 1-888-232-6348 www.cdc.gov

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.

Photographs and images included in this presentation are licensed solely for CDC/NCIRD online and presentation use. No rights are implied or extended for use in printing or any use by other CDC/IOs or any external audiences.

Acknowledgments:

- CDC Immunization Safety Office
- Beth Hibbs, RN, MPH
- Immunization Services Division/Communication Education Branch

