

# Vaccine Storage and Handling and Administration

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# VACCINE STORAGE AND HANDLING

# Vaccine Storage & Handling Toolkit

June 2016



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

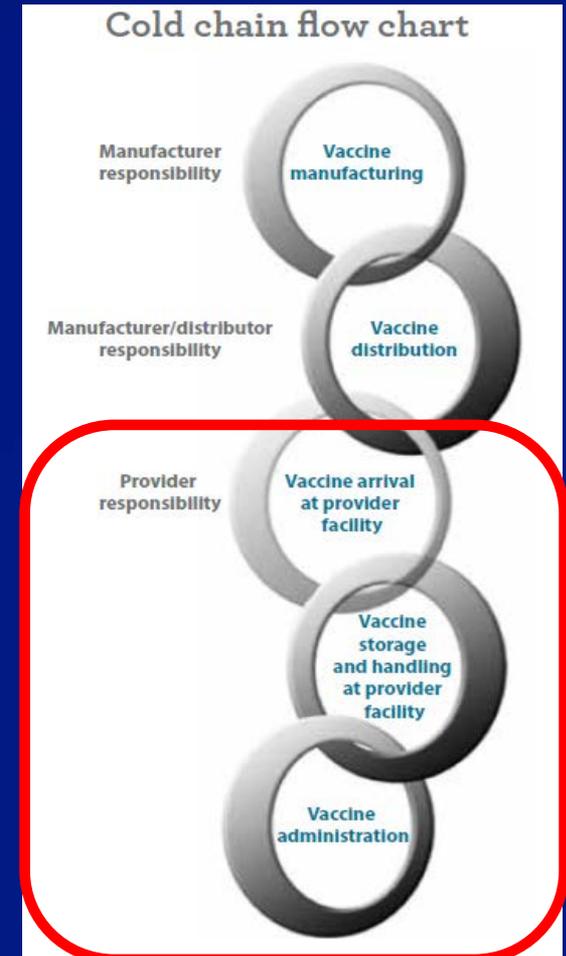
<http://www.cdc.gov/vaccines/recs/storage/toolkit/default.htm>

<http://www.immunize.org/packageinserts/>

<http://www.cdc.gov/vaccines/programs/vfc/contacts-state.html>

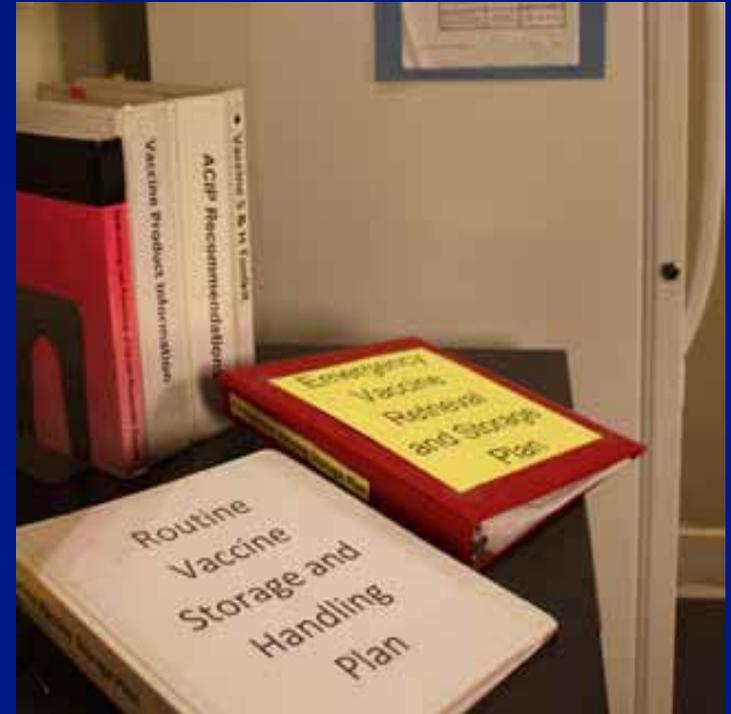
# Vaccine Storage and Handling Cold Chain (Temperature-controlled Supply Chain)

- Vaccines must be stored properly from manufacturer to administration
- Shared responsibility among manufacturers, distributors, public health staff, and health care providers
- An effective cold chain relies on three main elements:
  - Well-trained staff
  - Reliable storage and temperature monitoring equipment
  - Accurate vaccine inventory management



# Vaccine Storage and Handling Standard Operating Procedures (SOPs)

- **Develop, follow, and update SOPs annually:**
  - Routine SOPs
  - Emergency SOPs
- **Keep SOPs near storage unit(s):**
  - Ensure staff knows where to find SOPs and is familiar with their contents
  - Ensure custodial/security staff knows how to notify appropriate staff if there is a problem



# Staff Training and Education

- Designate a primary coordinator and at least one alternate (backup) coordinator
- A physician partner or member of management should be directly involved with responsible clinical staff
- Provide training for all staff that receives, deliveries, and handles or administers vaccines:
  - New employee orientation
  - Annual updates
  - When recommendations are updated or when new vaccines are added



Immunization Education & Training

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[You Call The Shots](#)

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**You Call The Shots**

[f](#) [t](#) [+](#)

**Web-based Training Course**

**Note:** You Call the Shots is updated regularly to include the latest guidelines and recommendations in vaccine practice. The latest 2015 modules are below.

**Come back every month for the latest training to stay up to date on the immunization practice.**

**At a Glance**

You Call the Shots is an interactive, web-based immunization training course. It consists of a series of modules that discuss vaccine-preventable diseases and explain the latest recommendations for vaccine use. Each module provides learning opportunities, self-test practice questions, reference and resource materials, and an extensive glossary.

[Immunization You Call the Shots](#)

## Vaccine Ordering and Deliveries

- Conduct a monthly vaccine and diluent inventory
- Avoid overstocking
- Arrange for vaccine deliveries when vaccine coordinator or alternate (backup) coordinator is on duty and notify them when delivery arrives
- Immediately unpack and examine container, contents, and temperature monitors when delivery arrives
- If there are concerns:
  - Label vaccines “Do NOT Use”
  - Store under appropriate conditions, separate from other vaccines
  - Consult immunization program, distributor, and/or vaccine manufacturer for guidance



# Vaccine Storage Equipment

- CDC recommends the following freezers and refrigerators:
  - Purpose-built (stand-alone or combination)
  - Household stand-alone

**Store in freezer**  
Between -50°C and -15°C (-58°F and +5°F)

VAR<sup>†</sup>  
HZV<sup>†</sup>  
MMRV<sup>†</sup>  
MMR<sup>†§</sup>

**Store in refrigerator**  
Between 2°C and 8°C (35°F and 46°F)

MMR<sup>†§</sup>  
HepA    HepB    HepA-HepB  
Hib<sup>†</sup>    Hib-HepB  
Human papillomavirus (2vHPV, 4vHPV, 9vHPV<sup>†</sup>)  
Influenza (LAIV,<sup>†</sup> IV,<sup>†</sup> RIV<sup>†</sup>)  
IPV<sup>†</sup>  
Meningococcal (Hib-MenCY,<sup>†</sup> MenACWY-D, MenACWY-CRM,<sup>†</sup> MPSV4, MenB-4C, MenB-FHbp<sup>†</sup>)  
Pneumococcal (PCV13, PPSV23)  
Rotavirus<sup>†</sup> (RV1, RV5)  
Diphtheria toxoid, Tetanus toxoid, and Pertussis (DT, DTaP, DTaP-HepB-IPV, DTaP-IPV, DTaP-IPV/Hib, Tdap, Td, TT)

## Vaccine Storage Equipment

- If existing equipment is a household combination refrigerator/freezer, use only the refrigerator compartment for storing vaccines
- Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances



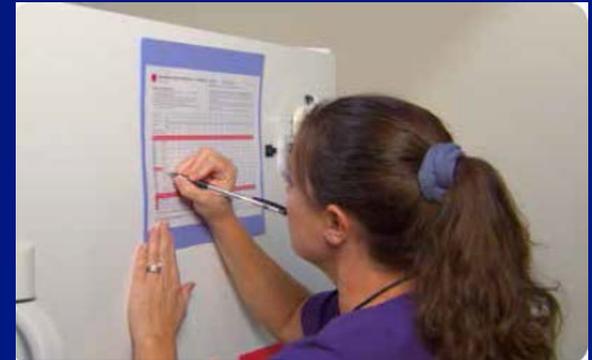
# Temperature Monitoring Equipment

- CDC recommends digital data loggers with a current and valid Certificate of Calibration Testing (Report of Calibration) with these characteristics:
  - Detachable probe in a thermal buffered material (e.g., glycol, glass beads, sand, Teflon®)
  - Alarm for out-of-range temperatures
  - Low-battery indicator
  - Current, minimum, and maximum temperature indicator
  - Recommended uncertainty of  $\pm 0.5^{\circ}\text{C}$  ( $\pm 1^{\circ}\text{F}$ )
  - Logging interval (or reading rate) that can be programmed by user



## Temperature Monitoring

- Post temperature log on each storage unit door or nearby in readily accessible, visible location
- Read temperature monitoring devices in storage units a minimum of 2 times each workday, in the morning and before leaving at end of workday
- Record temperature readings on temperature log, along with time reading taken and initials of person recording data
- If a temperature reading is missed, leave log entry blank
- Review electronic temperature data at least 1 time each week
- Keep ongoing file of temperature data, including hard copies and electronic data, for 3 years (unless state statutes or rules require longer)



# Temperature Excursion

- If stored vaccines have been exposed to temperatures outside recommended ranges:
  - Immediately label the vaccines “Do NOT Use”
  - Store vaccines in appropriate conditions
  - Contact your immunization program, vaccine manufacturer(s), or both for guidance



## Resources

### CDC's Temperature Excursion Checklist

- 1. Checklist for general power loss**
  - Contact utility company
  - Determine if time to restoration is acceptable
  - Activate alternate generator if available
- 2. Checklist for presumed storage unit malfunction (Disposition of storage unit if unit is too warm, too cold, too noisy, or stopped):**
  - Check circuit breakers
  - Unit plugged in
  - Door closed
  - Door seal adequate
  - Assess location of temperature monitoring devices for temperature reading
  - Record all temperatures
  - Space between vaccines for air to circulate
  - Coils free of dust
  - Temperature adjusted gradually if not set correctly (need to recheck temperatures and record every 30 minutes)
  - Unit secured and level (if unit is noisy)
  - Screws tightened (if unit is noisy)
  - Technician called
- 3. Disposition of vaccines (If power not restored or if temperature does not begin to recover)**
  - Label exposed vaccines “Do NOT Use” and store in appropriate conditions (set apart from other vaccines)
  - Check temperature of alternate storage unit
  - Vaccines moved to alternate storage unit (move refrigerated vaccines first)
  - Document temperature excursion action taken and results
  - Immunization Program contacted
  - Manufacturer(s) contacted
  - Return vaccines determined to be usable only when storage unit is stable and resume use
  - Determine disposition of vaccines that are compromised:
    - Vaccines provided through Vaccines for Children (VFC) Program and other vaccines purchased with public funds prepared for return to distributor.
    - Vaccines purchased with private funds should be disposed of in consultation with the manufacturer(s) and according to state regulations for medical waste. Replacement plans will vary.
    - If insured against losses of this type, contact insurance representative.

# Vaccine and Diluent Placement and Labeling

- Store vaccines away from wall, coils, cooling vents, top shelf, ceiling, door, floor, and back of unit
- Keep vaccines and diluents in original packaging with lids on and store diluents with corresponding vaccine, if possible
- Stack in rows 2-3 inches apart with same type of vaccine and diluent
- Store pediatric, adult, look-alike, and sound- alike vaccines on different shelves or separately to avoid confusion
- Store refrigerated diluents with corresponding vaccines (these diluents may contain vaccine antigen)
- Use labels with vaccine type, age, and gender indications or color coding:
  - <http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-labels.pdf>
  - <http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-labels-flu.pdf>
- Do not store vaccines in the door or the deli, vegetable, and fruit crisper drawers
- Do not freeze diluents (<http://www.immunize.org/catg.d/p3040.pdf>)

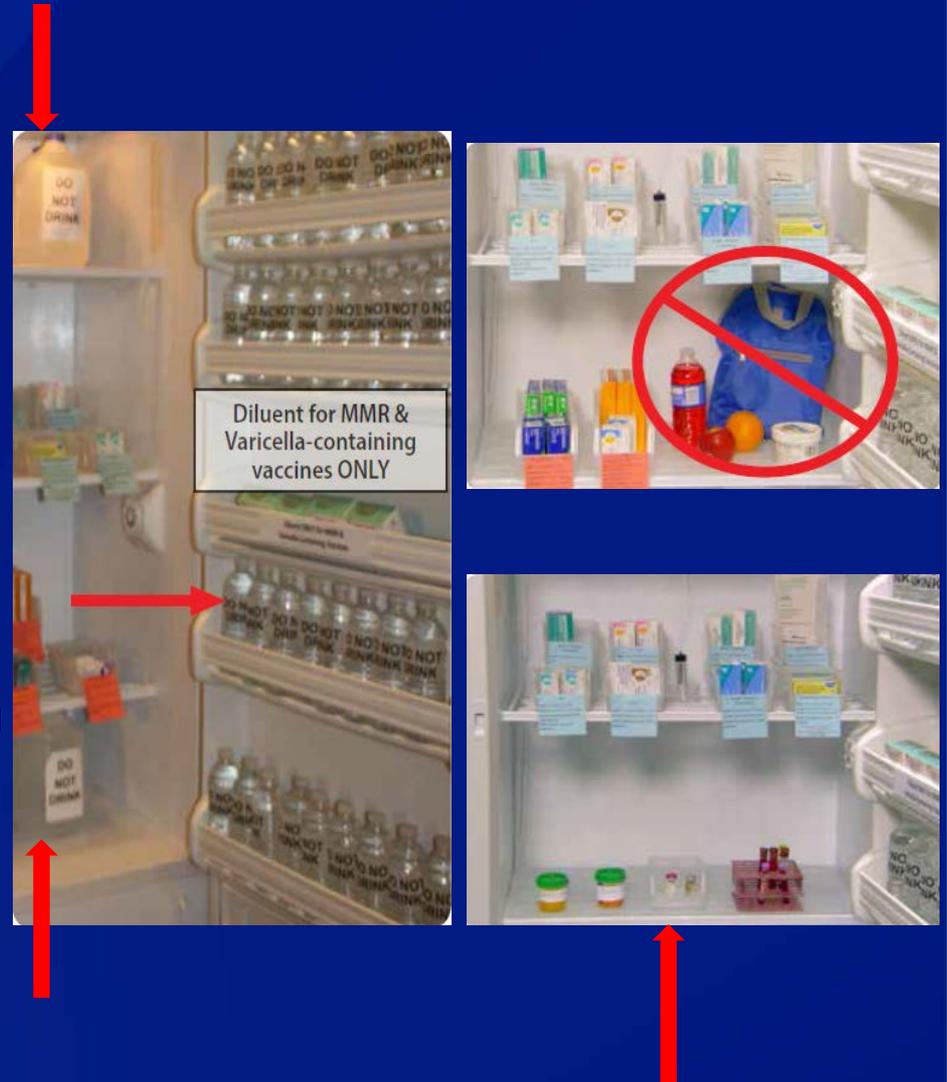
## Preventive Measures

- Plug unit directly into wall; do NOT use multi-outlet power strip
- Do NOT use power outlets with built-in circuit switches
- Do NOT use power outlets that can be activated by a wall switch
- Plug only one unit into an outlet
- Use a plug guard or safety-lock plug
- Install a temperature alarm
- Label circuit breakers and electrical outlets
- Post warning signs that include emergency contact information



## Preventive Measures

- Use water bottles in refrigerator and frozen water bottles in freezer to maintain temperature
- If other biologics must be stored in the same unit, store them **BELOW** the vaccines to avoid contamination
- Food and beverages should never be stored in the unit with vaccines
- Inspect storage unit(s) daily
- **Take immediate corrective action when there is a problem**



## Vaccine Expiration Dates

- At least 1 time each week and each time vaccines are delivered, check and arrange vaccines and diluents in storage unit according to expiration dates



- Exceptions:**
  - Reconstitution with a beyond use date or time (BUD)
  - Multidose vial with BUD once opened
  - Manufacturer-shortened expiration date

# Vaccine Transport

## ■ Off-site/Satellite Facility

- Have vaccines delivered directly to the facility, if possible
- If vaccines must be transported, limit amount to what is needed for that workday (**8 hour maximum** for transport and workday)
- Transport using a portable vaccine refrigerator or qualified container and pack-out with a calibrated continuous temperature monitoring device
- Move to an appropriate storage unit and monitor temperatures at least 2 times during the workday (hourly if must be kept in portable storage unit)

## ■ Emergency Transport

### Packing Vaccines for Transport during Emergencies

#### Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. **It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine.** In any emergency event, activate your emergency plan immediately. Ideally, vaccine should be transported using a portable vaccine refrigerator or qualified pack-out. However, if these options are not available, you can follow the emergency packing procedures for refrigerated vaccines below:

#### 1 Gather the Supplies



##### Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.



##### Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand (this normally takes less than 5 minutes).



##### Insulating material — You will need two of each layer

- **Insulating cushioning material** - Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** - Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.



- **Temperature monitoring device** - Digital data logger (DDL) with buffered probe. Accuracy of  $\pm 1^{\circ}\text{F}$  ( $\pm 0.5^{\circ}\text{C}$ ) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

#### Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of insulating cushioning material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.



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Visit [www.cdc.gov/vaccines/SandH](http://www.cdc.gov/vaccines/SandH)  
for more information, or your state  
health department.

# Vaccine Preparation

- Only open a single-dose vial when ready to use
- Once protective cap is removed, vaccine should be used. If not used, discard it at end of workday
- Once a manufacturer-filled syringe is activated (i.e., syringe cap removed or needle attached), vaccine should be used or discarded at end of workday
- Do not predraw vaccine because it increases risk for administration errors, wasted vaccine, and microorganism growth in vaccines
- General use administration syringes are not for storage
- Consider manufacturer-filled syringes for large immunization events



## Vaccine Disposal

- **Contact immunization program and/or vaccine manufacturer(s) for policies regarding disposition of unopened vials, expired vials, unused doses, and potentially compromised vaccine**
- **Open vials, activated manufacturer-filled syringes, predrawn vaccine (by a provider), and broken vials and syringes are not returnable and should be appropriately discarded**
- **Contact your immunization program or state environmental agency to ensure that your vaccine disposal procedures and any related documentation comply with state and federal regulations**

<http://www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html>

<http://www.hercenter.org/rmw/rmwlocator.cfm>

# VACCINE ADMINISTRATION

# Vaccine Administration

- **Key to ensuring vaccination is as safe and effective as possible**
- **Incorporate:**
  - Professional standards for medication administration
  - Manufacturer's vaccine-specific guidelines
  - Evidence-based safe injection practices on CDC's Injection Safety Information for Providers web page

## Staff Training and Education

- **Before administering vaccines, all personnel who administer vaccines should:**
  - Receive competency-based training
  - Have knowledge and skills validated
- **Integrate competency-based training into:**
  - New staff orientation
  - Annual education requirements
- **Ongoing education:**
  - When vaccine administration recommendations are updated
  - When new vaccines are added to the inventory

# Patient Care Before Administering Vaccines

- **Obtain complete immunization history at every health care visit:**
  - Accept only written, dated records (except influenza and PPSV23 self-report)
  - Use recommended schedule to determine vaccines needed based on age, medical condition, and risk factors
- **Screen for contraindications and precautions prior to administering any vaccine(s)**
- **Discuss vaccine benefits and risks and vaccine-preventable disease risks using VISs and other reliable resources**
- **Provide after-care instructions**

<http://www.immunize.org/catg.d/p4060.pdf>

<http://www.immunize.org/catg.d/p4065.pdf>

<http://publichealth.lacounty.gov/ip/immunization/parents/comfort-bethereE.pdf>

# Positioning and Comforting Restraint

- Encourage parent/guardian to hold child
- Sitting rather than lying down
- Be aware of syncope (fainting):
  - Have patient seated or lying down during vaccination
  - Be aware of symptoms that precede syncope
  - If patient faints, provide supportive care and protect patient from injury
  - Observe patient (seated or lying down) for at least 15 minutes after vaccination



# Procedural Pain Management

- **Evidence-based strategies to ease pain:**
  - Breastfeeding
  - Sweet-tasting liquids
  - Injection technique (aspiration may increase pain)
  - Order of injections (administer most painful vaccine last)
  - Tactile stimulation (rub/stroke area near injection site prior to and during injection)
  - Distraction
  - Topical anesthetic

<http://www.nejm.org/doi/full/10.1056/NEJMvcm1411127?query=pediatrics>

<https://www.youtube.com/watch?v=KgBwVSYqfps>

[https://www.youtube.com/watch?v=WkR\\_e1L6zxl](https://www.youtube.com/watch?v=WkR_e1L6zxl)

# Infection Control

- **Perform hand hygiene:**
  - Before preparing vaccines
  - Between patients
  - Any time hands become soiled
- **Gloves are not required 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
- **Equipment disposal:**
  - Puncture-proof biohazard container
  - Empty or expired vaccine vials are medical waste

# Vaccine Preparation

- **Prepare vaccines in a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed**
- **Use a separate, sterile syringe and needle for each injection**
  - 1-mL or 3-mL sterile syringe for each injection
  - Select the appropriate needle based on route, patient size, and injection technique
- **Inspect vaccine and diluent vials for damage or contamination**
- **Check the expiration dates on the syringe, needle, vaccine, and diluent**
- **Use only the manufacturer-supplied diluent to reconstitute a vaccine**
- **Agitate the vial to thoroughly mix the vaccine**
- **Inspect the vaccine for discoloration, precipitate, and resuspension**
- **Only the number of doses indicated in the manufacturer's package insert should be withdrawn from a vaccine vial. After the maximum number of doses has been withdrawn, the vial should be discarded, even if the expiration date has not been reached**

## **Vaccine Preparation “Nevers”**

- **Never combine vaccines into a single syringe**
- **Never transfer vaccine from one syringe to another**
- **Never draw partial doses of vaccine from separate vials to obtain a full dose**

# Route and Site

## ■ Oral (PO):

- Administer liquid inside cheek slowly down one side (between cheek and gum) toward the back of infant's mouth



## ■ Nasal (NAS):

- LAIV4 is the only vaccine administered by the intranasal route
- At the June 22 meeting, ACIP issued an interim recommendation that LAIV4 should not be used in any setting for the 2016-2017 influenza season. This recommendation was based on effectiveness data from the last 3 influenza seasons in which LAIV4 did not demonstrate statistically significant effectiveness in children 2-17 years of age in the U.S.

# Subcutaneous (Subcut) Route

## ■ Site:

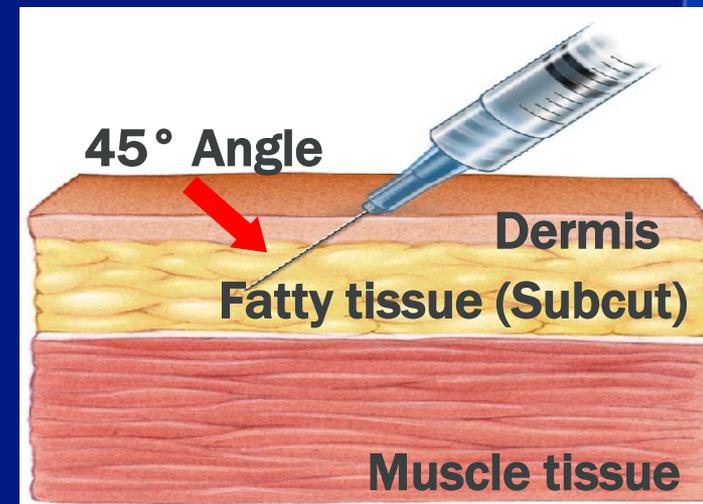
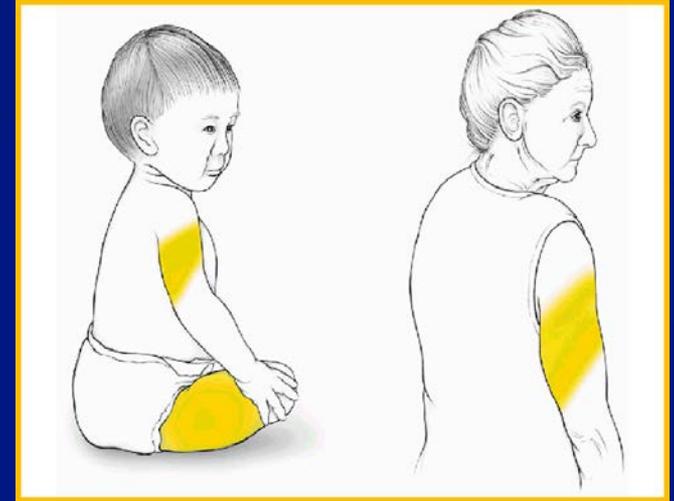
- Thigh for infants younger than 12 months of age
- Upper outer triceps of arm for children older than 12 months and adults (can be used for infants if necessary)

## ■ Needle gauge and length:

- 23- to 25-gauge needle, 5/8-inch

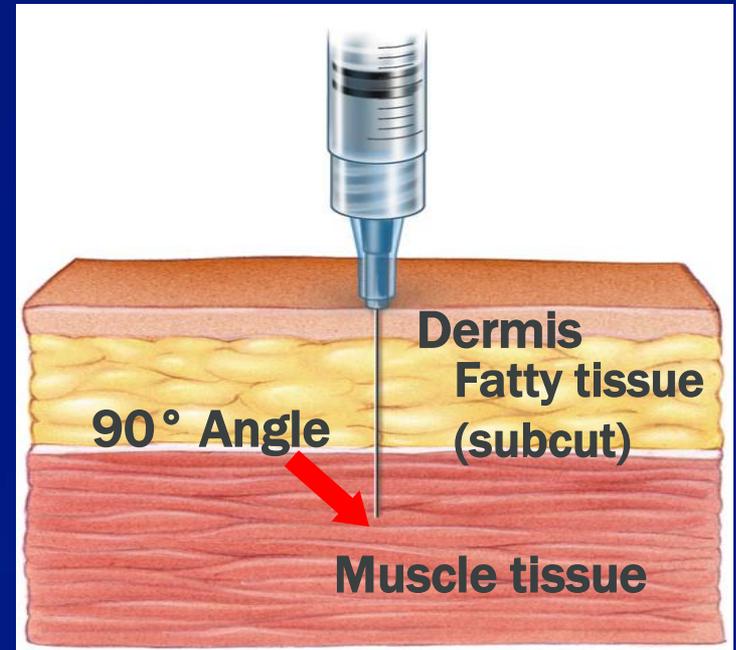
## ■ Technique:

- To avoid reaching the muscle, pinch up the fatty tissue, insert the needle at a 45° angle, and inject the vaccine into the tissue



## Intramuscular (IM) Route

- Spread the skin of the site taut between the thumb and forefinger, isolating the muscle
- Another technique, acceptable mostly for pediatric and geriatric patients, is to grasp the tissue and “bunch up” the muscle
- Insert the needle fully into the muscle at a 90° angle and inject



**Aspiration is NOT required**

# Intramuscular (IM) Route

## Infants 12 Months and Younger

### ■ Site:

- Vastus lateralis muscle (anterolateral thigh)

### ■ Needle gauge and length:

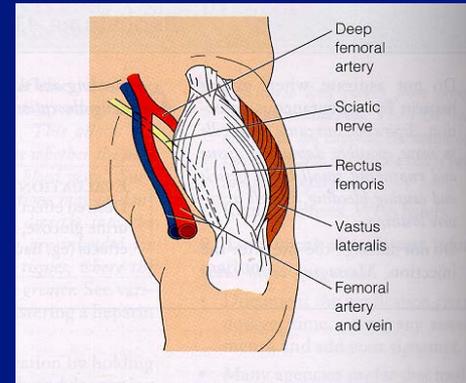
- 22- to 25-gauge
- Neonates and preterm infants: 5/8-inch (adequate only if the skin is stretched flat between thumb and forefinger)
- 1 month and older: 1-inch



# Intramuscular (IM) Route 1 through 2 Years

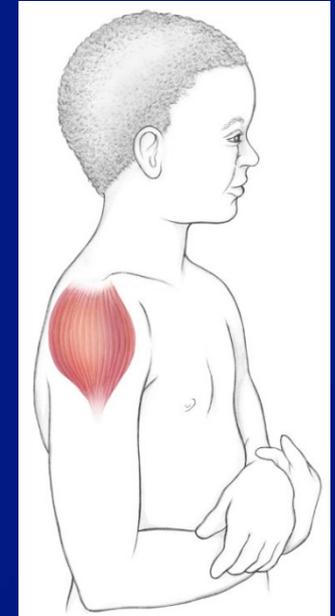
## ■ Site:

- Vastus lateralis muscle (anterolateral thigh) is preferred
- Deltoid muscle (upper arm) may be used if the muscle mass is adequate



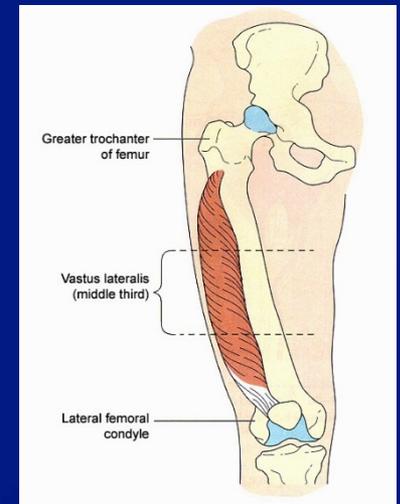
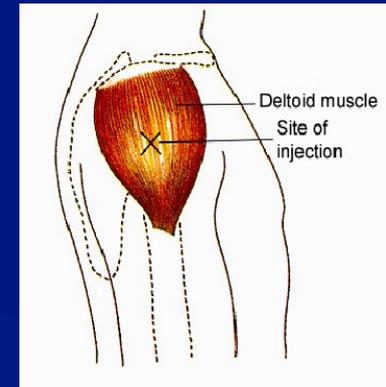
## ■ Needle gauge and length:

- 22- to 25-gauge
- 5/8- to 1-inch (5/8-inch adequate only for the deltoid muscle and only if the skin is stretched flat between thumb and forefinger)



# Intramuscular (IM) Route 3 through 18 Years

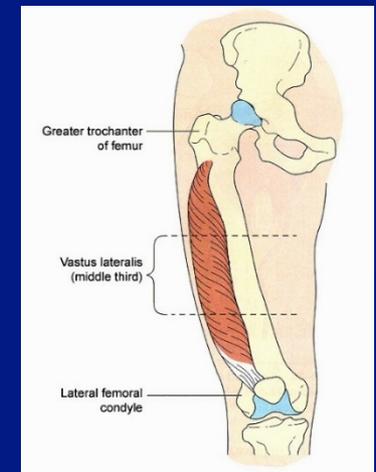
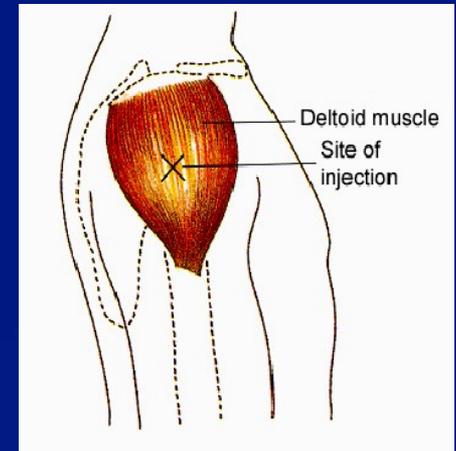
- **Site:**
  - Deltoid muscle (upper arm) is preferred
  - Vastus lateralis muscle (anterolateral thigh) may be used
- **Needle gauge and length:**
  - 22- to 25-gauge
  - 5/8- to 1-inch
- **Most young children in this age range require a 5/8- or 1-inch needle:**
  - 5/8-inch needle is adequate only for the deltoid muscle and only if the skin is stretched flat between thumb and forefinger
- **Older children and adolescents require a 1-inch needle**



# Intramuscular (IM) Route

## Adults 19 Years and Older

- **Site:**
  - Deltoid muscle (upper arm) is preferred
  - Vastus lateralis muscle (anterolateral thigh) may be used
- **Needle gauge: 23- to 25-gauge**
- **Needle length varies with patient size**



# Intradermal (ID) Route

- **Site:**

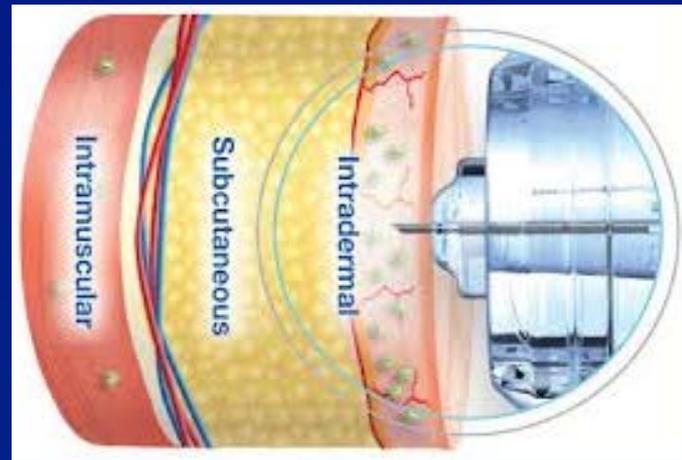
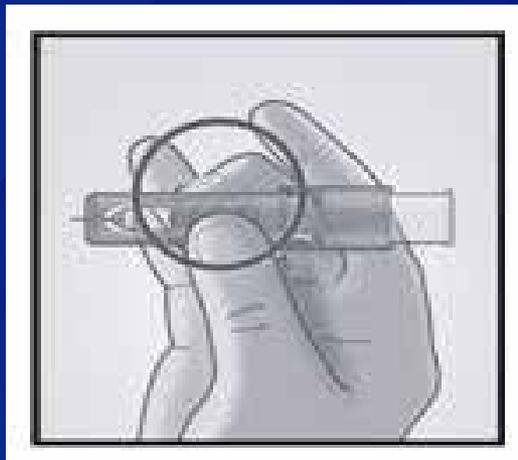
- Deltoid region of upper arm

- **Needle gauge and length:**

- 30-gauge, microneedle

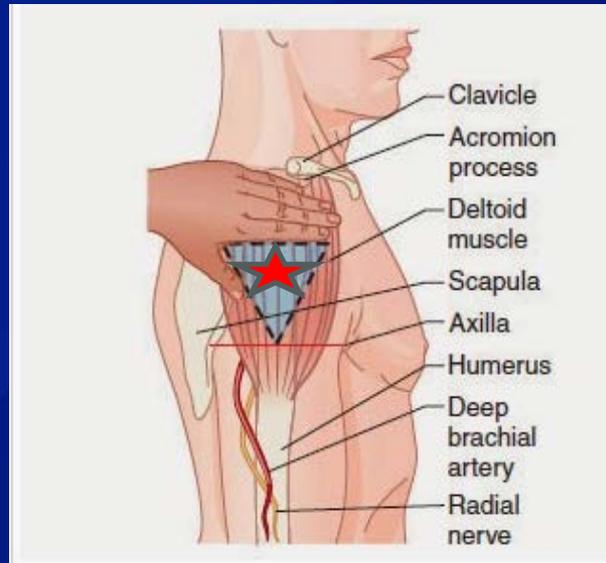
- **Technique:**

- Hold the syringe between the thumb and the middle finger and using a short quick motion, insert the needle perpendicular to the skin



# Common Errors

## Too High



## Too Low



**“No Butts”**

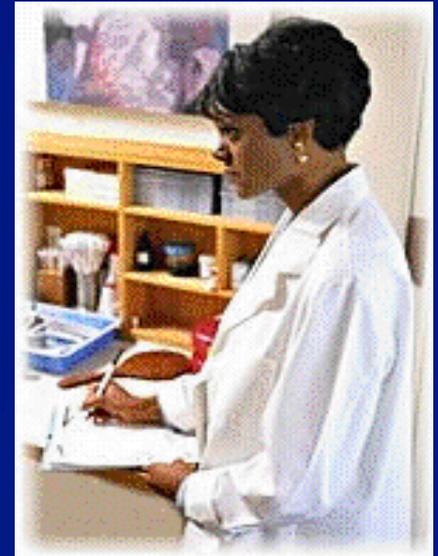
## Multiple Vaccinations

- **Separate injections by at least 1 inch (or more if possible)**
- **Use a separate limb for most reactive vaccines (e.g., tetanus toxoid-containing and PCV13), if possible**
- **Use combination vaccines when appropriate to reduce the number of injections**

# Documentation

## ■ Required documentation:

- Date of administration
- Vaccine manufacturer
- Vaccine lot number
- Name and title of person who administered vaccine and address of clinic or facility where permanent record will reside
- Vaccine Information Statement (VIS)
  - Date printed on the VIS
  - Date VIS given to patient or parent/guardian



## ■ Best practice documentation:

- Vaccine type (ACIP abbreviation)
- Route
- Dosage (volume)
- Site

