Vaccine Storage and Handling and Vaccine Administration

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

Pink Book Webinar Series
July 11, 2018
VACCINE STORAGE AND HANDLING
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 Best Practices

https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm
Vaccine Storage and Handling Standard Operating Procedures (SOPs)

- Develop, follow, and update plans and 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

- Provide training for all staff that receives deliveries and handles or administers vaccines:
  - New employee orientation
  - Annual refresher training
  - When recommendations are updated
  - When new vaccines are added

www.cdc.gov/vaccines/ed/youcalltheshots.htm
Vaccine Ordering and Deliveries

- Conduct a monthly vaccine and diluent inventory
  - Avoid overstocking

- Arrange deliveries when vaccine coordinator or alternate (backup) coordinator is on duty and notify them when delivery arrives
Vaccine Ordering and Deliveries

- 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, isolated 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
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.

Water bottles on top shelf, in door, and on unit floor
Temperature Monitoring Devices (TMD)

- CDC recommends the use of a specific type of TMD known as a digital data logger (DDL) for continuous temperature monitoring and recording.
- The DDL should be set to measure and record temperatures no less frequently than every 30 minutes.
- The DDL should have a current and valid Certificate of Calibration (also known as a Report of Calibration).
Temperature Monitoring Device

CDC recommends DDLs with the following features:

- Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®)
- Alarm for out-of-range temperatures
- Low-battery indicator
- Current, minimum, and maximum temperature display
- Recommended uncertainty of +/-0.5° C (+/-1° F)
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures no less frequently than every 30 minutes
Temperature Monitoring

- Post temperature log on each storage unit door or nearby in readily accessible, visible location
- Check and record storage unit minimum and maximum temperatures at the start of each workday
- If your device does not display min/max temperatures, then check and record the current temperature a minimum of 2 times (at the start and end of the workday)
- Record:
  - Min/max temperature (current temperature if no min/max temperature)
  - Date
  - Time
  - Name initials of person checking and recording temperature
  - Any actions taken if a temperature excursion occurred
- If a reading is missed, leave log entry blank
Temperature Monitoring

- Review storage unit temperature readings and review continuous DDL software or website information at least 1 time each week

- Keep ongoing file of temperature data, including hard copies and electronic data, for 3 years
**Temperature Excursion**

- If stored vaccines have been exposed to temperatures outside recommended ranges:
  - Immediately notify the primary or alternate vaccine coordinator
  - Label vaccines “Do NOT Use”
  - Store vaccines in appropriate conditions separate from other vaccines
  - Contact your immunization program, vaccine manufacturer(s), or both for guidance
  - Be prepared to move all vaccines to a different unit if the temperature in the main storage unit has gone out of range

---

Vaccine and Diluent Placement and Labeling

- Store vaccines away from walls, coils, cooling vents, top shelf, ceiling, door, floor, and back of unit
- Keep vaccines and diluents in original packaging with lids closed
- Arrange in rows of same type of vaccine or diluent 2-3 inches apart
- Store pediatric, adult, look-alike, and sound-alike vaccines on different shelves
- Store refrigerated diluents with corresponding vaccines (these diluents may contain vaccine antigen)
- Use labels with vaccine type and age and gender indications or color coding: https://www.cdc.gov/vaccines/hcp/admin/storage/index.html
Vaccine and Diluent Placement and Labeling

- Do not store vaccines in the door or the deli, vegetable, and fruit crisper drawers

- Do not freeze diluents

- Vaccines with Diluents: How to Use Them
  
  www.immunize.org/catg.d/p3040.pdf
Preventive Measures

**DO:**
- Plug unit directly into wall
- 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

- **DON’T:**
  - Use power outlets with built-in circuit switches
  - Use power outlets that can be activated by a wall switch
  - Use multi-outlet power strip
Preventive Measures

- Use water bottles in refrigerator and 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 (if not available, use 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**

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.

www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html
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
  - Manufacturers’ vaccine-specific guidelines
  - Evidence-based safe injection practices on CDC’s Injection Safety Information for Providers web page

https://www.cdc.gov/injectionsafety/providers.html
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

Before Administering Vaccines

- Review the 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

https://www.cdc.gov/vaccines/parents/tools/tips-factsheet.pdf
http://immunize.org/handouts/discussing-vaccines-parents.asp
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 Strategies

- **Pharmacological**
  - Topical anesthetics
  - Sweet-tasting solutions

- **Physical**
  - Breastfeeding
  - Positioning – parent holding the infant or young child
  - Sitting upright rather than lying down
  - Tactile stimulation

- **Psychological**
  - Distraction (i.e., games on smart phones)
  - Deep breathing (i.e., young children can blow bubbles)

- **Procedural**
  - Order of injection: administer the vaccine most painful when injected last
  - Rapid injection without aspiration

- **Process intervention**
  - Educating and training staff; implementing a planned approach to address procedural pain management

Procedural Pain Job Aids

Reducing Vaccine Injection Pain in Children
A Guide for Health Care Providers

**Preparation:**
- Review this evidence-based guide
- Provide parent/caregiver with information and tools
- Discuss pain management strategies

**Procedure:**
Combine strategies to improve pain relief

**Practice and Documentation**
1. Assess pain
2. Document pain score
3. Assess parent and child satisfaction
4. Refine and plan approach for next vaccine

**Document:**
- Age of child
- Vaccines given
- Pain-relieving strategies used
- Pain score
- Parent/child satisfaction


www.sickkids.ca/pdfs/Learning/32833-CMAJ%20HELPinKIDS%202010%20Appendix%202%20Clinician%20Tool.pdf
Infection Control

- Perform hand hygiene:
  - Before preparing vaccines
  - Between patients
  - Anytime 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

https://www.cdc.gov/handhygiene/index.html
Vaccine Preparation

- Inspect vaccine and diluent vials for damage or contamination
- Check the expiration dates on the syringe, needle, vaccine, and diluent
- Select a separate sterile needle for each injection based on route, patient size, and injection technique
- 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 except when specifically approved by the FDA and packaged for that specific purpose.

- 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

- **Intranasal (NAS):**
  - LAIV4 is the only vaccine administered by the intranasal route

https://www.cdc.gov/vaccines/hcp/admin/resource-library.html
https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6304a4.htm?s_cid=mm6304a4_w
https://www.cdc.gov/mmwr/volumes/67/wr/mm6722a5.htm?s_cid=mm6722a5_w%20
Subcutaneous Injection (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 Injection (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 Injection (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 Injection (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 Injection (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
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
Shoulder Injury Related to Vaccine Administration

- Shoulder injury related to vaccine administration (SIRVA) was added to the Vaccine Injury Compensation Table in March 2017
- Shoulder injuries related to vaccine administration are injuries to the musculoskeletal structure of the shoulder, including the ligaments, bursa, and tendons
  - They are thought to occur as a result of the unintended injection of vaccine antigen and/or trauma from the needle going into and around the underlying bursa of the shoulder
  - Symptoms include shoulder pain and limited mobility after the injection
Shoulder Injury Related to Vaccine Administration and Vaccine Administration Best Practices

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

www.cdc.gov/vaccines/hcp/administrator-vaccines.html

www.cdc.gov/vaccines/hcp/infographics/call-the-shots.pdf
Intradermal Injection (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
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
Federally 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
VACCINE ADMINISTRATION ERRORS
Vaccination error reports 1 number and percentage 2 of all VAERS reports 3 by year, 2000–2016

1 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
## Number of VAERS Reports by Error Group, 2000–2016

<table>
<thead>
<tr>
<th>Vaccination Error Groups&lt;sup&gt;1&lt;/sup&gt;</th>
<th>N (% total errors)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage and Dispensing</td>
<td>37,782 (57)</td>
</tr>
<tr>
<td>Inappropriate Schedule</td>
<td>10,662 (16)</td>
</tr>
<tr>
<td>Wrong Vaccine</td>
<td>4,996 (8)</td>
</tr>
<tr>
<td>Incorrect Dose</td>
<td>4,772 (7)</td>
</tr>
<tr>
<td>Administration Errors</td>
<td>3,382 (5)</td>
</tr>
<tr>
<td>General Error</td>
<td>2,634 (4)</td>
</tr>
<tr>
<td>Accidental</td>
<td>504 (1)</td>
</tr>
<tr>
<td>Product Quality</td>
<td>442 (1)</td>
</tr>
<tr>
<td>Equipment</td>
<td>434 (1)</td>
</tr>
<tr>
<td>Contraindication</td>
<td>281 (&lt;1)</td>
</tr>
<tr>
<td>Product Labeling/ Packaging</td>
<td>124 (&lt;1)</td>
</tr>
<tr>
<td><strong>Total Errors</strong>&lt;sup&gt;2&lt;/sup&gt;</td>
<td><strong>66,013</strong></td>
</tr>
</tbody>
</table>

<sup>1</sup>Vaccination error groups contain multiple MedDRA Codes

<sup>2</sup>Vaccination error groups are not mutually exclusive: Total Vaccination Error Reports = 63,759
**Strategies to Prevent Errors**

- Establish an environment that values reporting and investigating errors as part of risk management and quality improvement.
- Use best practices for storing, handling, preparing, and administering vaccines.
- Take immediate action and isolate affected vaccine(s) if there is a temperature excursion.
- Promptly remove expired vaccines from the storage unit.
- Only administer vaccines you have prepared and triple-checked.
- Be familiar with current recommended immunization schedules: [https://www.cdc.gov/vaccines/acip/index.html](https://www.cdc.gov/vaccines/acip/index.html)
- Use standing orders when possible: [www.immunize.org/standing-orders/](http://www.immunize.org/standing-orders/)
What if a Vaccination Error Occurs?

- Inform the patient/parent of the error
- Determine the status of the patient
- Explain any needed next steps
- Know how to correct the error
  - Contact your local health department, vaccine manufacturer, or nipinfo@cdc.gov for guidance
  - Not all errors require revaccination
- Record the vaccine as it was given on the medical administration record
- Contact the immunization information system for additional information as needed
Reporting Vaccination Errors to VAERS

- VAERS accepts all reports

- VAERS encourages reports of clinically significant adverse health events

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

https://vaers.hhs.gov/reportevent.html