Vaccine Storage and Handling

Donna L. Weaver, RN, MN
Nurse Educator
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Disclosures

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

www.cdc.gov/vaccines/recs/storage/toolkit/default.htm
Vaccine S&H Cold Chain

- A temperature-controlled environment used to maintain and distribute vaccines in optimal condition

- Provider cold chain management
  - Trained personnel
  - Appropriate equipment
  - Efficient vaccine management

www.cdc.gov/vaccines/recs/vac-admin/providers-role-vacc-admin-storage.htm

Vaccine Storage and Handling Plans

- Develop and update annually
  - Routine Plan
  - Emergency Plan

- Keep plans near storage unit(s)

Vaccine Storage and Handling Plans

- Ensure staff know where to find plans and are familiar with them

- Ensure custodial/security staff are familiar with emergency notification procedures

- Review and updates plans at least annually
Vaccine Storage and Handling Training

- Designate a primary coordinator and at least one alternate (back-up) coordinator
- Coordinators should be fully trained in routine and emergency policies and procedures
- A physician partner or member of management should be directly involved with responsible clinical staff

Vaccine Storage and Handling Training

- All staff who receive deliveries and handle or administer vaccines should be familiar with storage and handling policies and procedures

Vaccine Storage and Handling Training

- Storage and handling training should:
  - Be part of new employee orientation
  - Be annual training for all staff involved in these activities
  - Occur whenever recommendations are updated and when new vaccines are added
CDC Training Resources

www.cdc.gov/vaccines/ed/youcalltheshots.htm

CDC Training Resources

http://www2.cdc.gov/vaccines/ed/shvideo/

Vaccine Storage Equipment

- CDC recommends stand-alone or pharmacy grade/purpose-built units

- Store in Refrigerator: between 2°F and 4°F (2°C and 4°C)
- Store in Freezer: at or below -10°F (-23°C)
- Temperatures over 4°C (41°F) can damage vaccines.
- Storage at temperatures above 4°C (41°F) for more than 24 hours can damage vaccines.
- Use of vaccines stored above 4°C (41°F) or below -10°F (-23°C) may result in reduced efficacy.
Vaccine Storage Equipment

- If existing equipment is a household, combination refrigerator/freezer, CDC recommends using only the refrigerator compartment for refrigerated vaccines.

Dormitory-style NOT Allowed for VFC Vaccines or Recommended for ANY Vaccine Storage

Temperature Monitoring Equipment

- CDC recommends:
  - Use calibrated temperature monitoring devices with a Certificate of Traceability and Calibration Testing (also known as Report of Calibration)
  - Use digital data loggers for continuous temperature monitoring
  - Staff should be trained and understand how to set up, read, and analyze temperature data provided by the data logger
Temperature Monitoring Equipment

- CDC recommends these characteristics:
  - Digital display on outside
  - Detachable probe in buffer
  - Alarm to alert out-of-range temperatures
  - Accuracy within (+/- 1°F)
  - Low battery indicator
  - Continuous monitoring and recording capabilities with memory that stores at least 4,000 readings
  - Display of current, minimum, and maximum temperatures

Vaccine S&H Best Practices

- Refer to manufacturers’ package inserts
  - www.immunize.org/packageinserts/
- Place vaccines and diluents with soonest expiration dates in front of those with later expiration dates
- In refrigerator, do not store vaccines in deli, fruit, and vegetable drawers, or on floor.
- Avoid the top shelf for storage
**Vaccine S&H Best Practices**

- Place vaccines/diluents 2 to 3 inches from walls
- Allow space between rows of vaccines/diluents
- Do not place near vents or pack unit too tightly
- Keep vaccines/diluents in original packaging with lids closed

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**Vaccine Storage Fact Sheets**

- www.cdc.gov/vaccines/recs/storage/downloads/storage-frozen.pdf

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**Vaccine Storage Labels**

- Clearly label vaccines and diluents and store look-alike or sound-alike vaccines and pediatric and adult formulations in different locations

- www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-labels.pdf
Vaccine S&H Best Practices

- Store food and beverages in separate refrigerator and freezer than where vaccines are stored
- NEVER store vaccines and other medications or biologics in same tray or container or bin. If possible, store products other than vaccines in different unit.

Storage Unit Temperature Monitoring

- **CDC recommends:**
  - Review and record unit temperature at least 2 times each workday
  - Download and review stored temperature data at least 1 time each week

CDC recommends:

- Maintain ongoing file of temperature data, including hard copies and downloaded data, for 3 years
Vaccine Storage Troubleshooting Record

Take IMMEDIATE CORRECTIVE ACTION

www.immunize.org/handouts/vaccine-storage-handling.asp

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 to Vaccine Expiration Dates

- Reconstitution
  - Once a lyophilized vaccine is reconstituted, there is a limited timeframe in which the vaccine can be used
Exceptions to Vaccine Expiration Dates

- **Reconstitution**
  - Once a lyophilized vaccine is reconstituted, there is a limited timeframe in which the vaccine can be used.

- **Multidose vials (MDVs)**
  - Most MDVs may be used until the expiration date on the vial unless contaminated or compromised in some way. Some MDVs have a specified timeframe for use once the vial is entered.

  3.2 **Administration Instructions**
  - Shake well before administration. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever withdraw and continue period. If either of these conditions exists, the vial should not be administered.
  - Attach a sterile needle to the prefilled syringe and administer immediately.
  - For the multidose vial, use a sterile needle and syringe syringe to withdraw the 0.5 mL dose from the multidose vial and administer immediately. A syringe with a needle less than 27 gauge is recommended for administration. It is recommended that small syringes (0.5 mL or 1 mL) be used to minimize any product loss. Use a separate sterile needle and syringe for each dose withdrawn from the multidose vial.

  3.3 **Handling Instructions**
  - The multidose vial is intended for intermittent dosing in immunocompromised patients with chronic debilitating diseases. The multidose vial can be used for 10-14 days after opening. The multidose vial and any residual contents should be discarded after 28 days.

- **Manufacturer shortened expiration date**
  - If vaccine has been exposed to inappropriate storage conditions, potency may be reduced before the expiration date. The manufacturer may shorten the expiration date.
 Exceptions to Vaccine Expiration Dates

- When vaccines must be used prior to the expiration date on the label, this is referred to as the "beyond use date" or "BUD".
- The "BUD" (date and/or time) should be noted on the label along with the initials of the person changing the date/time.

Vaccine Deliveries

- Arrange deliveries when vaccine coordinator or alternate is on duty.
- Staff should be trained to immediately notify vaccine coordinator or alternate (back-up) coordinator when deliveries arrive and ensure storage in a timely manner.

Vaccine Deliveries

- Check contents for damage and improper temperatures, and then store at proper temperatures.
Vaccine Deliveries

- If any discrepancies or concerns about contents, immediately notify your immunization program and/or vaccine manufacturer(s)
- Label vaccines “Do NOT Use” and store under appropriate conditions (set apart from other vaccines)

Vaccine Transport

- **CDC recommends:**
  - Have vaccines delivered directly to an off-site/satellite facility
  - If vaccines must be transported to off-site/satellite facility, limit amount transported to what is needed for that workday
  - Transport and workday should total no more than 8 hours

- **CDC recommends:**
  - Transport using a portable refrigerator/freezer or qualified container and pack-out with calibrated, continuous temperature monitoring device
Vaccine Preparation

- Only open a single-dose vial when ready to use. Once protective cap is removed, vaccine should be used. If not used, it should be discarded at end of workday.

- NEVER use partial doses from two or more vials to obtain a full dose.

- 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.
Vaccine Preparation

- CDC recommends:
  - Only use the diluent supplied by the manufacturer and NEVER use stock vials of sterile water or saline for reconstitution

www.immunize.org/catg.d/p3040.pdf

Vaccine Preparation

- CDC recommends:
  - Draw up vaccines only at time of administration and discard if not used by end of day
  - Only administer vaccines that you have prepared

In Summary

- 1 - Do not freeze refrigerated vaccines
- 2 - Store vaccines in equipment that maintains appropriate storage temperatures
- 3 - Store vaccine in a temperature stable location of the storage unit
- 4 - Monitor vaccine storage unit temperatures
- 5 - Immediately unpack vaccine deliveries, examine and store
- 6 - Remove expired vaccine from a storage unit
In Summary

- 7 - Provide maximum time at worst temperature when calling manufacturer about a temperature excursion
- 8 - Use equipment that maintains correct temperature for transport
- 9 - Use single-dose vials only for a single dose
- 10 - Use only the diluent supplied by the manufacturer for the vaccine
- 11 – Prepare vaccine only when ready to administer
- 12 – Only administer vaccine you have prepared

Immunization Twitter Just for You

@CDCIZlearn

is a leading source for healthcare providers on immunization training, recommendations and information across the lifespan

CDC Vaccines and Immunization Resources

- Questions? E-mail CDC:
  - Providers nipinfo@cdc.gov
  - Parents and patients www.cdc.gov/cdcinfo
- Website www.cdc.gov/vaccines
- Influenza www.cdc.gov/flu
- Vaccine Safety www.cdc.gov/vaccinesafety
Thank You! Questions?

Donna L. Weaver, RN, MN
DWeaver1@cdc.gov