Vaccine Storage and Handling

Quick Reference Guide

This is an adaptation of the CDC Vaccine Toolkit to be used only as a reference guide. Complete information on vaccine storage and handling can be found at:

http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf

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Effect of Temperature on Vaccines

- Live vaccines tolerate freezing.
- Live vaccine potency deteriorate rapidly after removal from freezer and exposure to light.
- Inactivated vaccines are damaged by exposure to freezing temperatures.

Cold Chain

- Vaccines must be stored properly from the time they are manufactured until they are administered to your patients

Vaccine Storage and Handling Guidelines

- Develop and maintain detailed written protocol for staff to follow
- Assign primary vaccine management responsibilities to one person
- Designate a back-up vaccine management person
- Provide staff training on vaccine storage and handling.
- All staff assigned to vaccine storage and handling responsibilities must complete a vaccine storage and handling training to be determined by The Office of Immunization at the Department of Health

Vaccine Storage Requirements

- Maintain required temperature range at all times
- Stand alone refrigerator units are recommended for refrigerated vaccines
- Stand alone freezer units are recommended for frozen vaccines
- Vaccine storage unit must be large enough to hold year’s largest vaccine inventory
- Vaccine storage units must be dedicated to vaccines only (no food or beverages)
- Dorm style refrigerators (freezer inside fridge compartment) are not acceptable for vaccine storage

Prefilling Syringes

The CDC and state health department recommends that providers draw up vaccines only at the time of administration, DO NOT pre-draw doses before they are needed as this:

- Increases the risk for administration errors
- Increases vaccine wastage
- May result in bacterial growth in vaccines that do not contain a preservative
**Temperature Monitoring**

- Manually check temperatures twice a day even if using continuous temperature recording device
  - Check once at opening and once at closing
- Use temperature log for both refrigerator and freezer units
- Keep temperature logs for 3 years
- Take *immediate action* when the temperature is outside the recommended range:
  1. Contact each vaccine manufacturer
  2. Report when temperatures were last taken and current temperatures
  3. Keep a log and follow recommendations
  4. Report issue and actions to HEALTH vaccine coordinator at 222-4639
- Do NOT administer mishandled vaccine without first contacting the manufacturer
- Use OSMOSSIS to report and return vaccines - DO NOT DISCARD unless instructed to do so by HEALTH
- Each refrigerator and freezer unit must have a temperature recording device
- Use a certified calibrated thermometer

**Recommended Temperatures**

<table>
<thead>
<tr>
<th>Refrigerator</th>
<th>Freezer</th>
</tr>
</thead>
<tbody>
<tr>
<td>35°F - 46°F (2°C -8°C)</td>
<td>5°F (-15°C) or colder</td>
</tr>
<tr>
<td>Optimum 40°F (5°C)</td>
<td>Optimum 0°F (-20°C)</td>
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</tbody>
</table>

**Vaccine Inventory Control**

- Conduct a vaccine inventory at least once per month (weekly inventory is ideal)
- Avoid stocking excessive vaccine supplies. Limit inventory to a min 30-day / max 120-day supply
- Monitor expiration dates
  - Rotate stock using shorter expiration dates first
- If vaccines are 4 months from expiring and will not be used before the expiration date:
  a. Locate another SSV enrolled provider that is willing to have vaccines transferred for use
  b. Record transfer information in OSMOSSIS
  c. Use vaccine transport protocols when transferring vaccines (see Appendix A-cold chain)
  d. *Opened multi-dose vials cannot be transferred to another practice*
- Never use expired vaccine or diluent.
- Report expired or wasted vaccines via OSMOSSIS immediately

**Emergency Relocation of Vaccine Planning**

- Develop and keep a current **VACCINE STORAGE DISASTER PLAN**. Have the written plan available for all staff to see and present it at each routine site assessment visit (see Appendix B)
- Plan includes identifying a back-up site with a generator in the event of equipment failure or power outage
Vaccine Storage

• Remove vegetable bins and replace with bottles of water (not for drinking) to stabilize refrigerator

• Water bottles (not for drinking) can also be stored in the doors to help stabilize refrigerator temperatures

• **NEVER** store vaccines in the door or other compartments in the refrigerator/freezer

• Avoid storage on top shelf-near cooling vent or on the bottom shelf

• Best storage practice – place vaccines in center of fridge space, 2-3 inches from refrigerator/freezer walls

**Examples of recommended vaccine storage unit types:**

**Combination units** are acceptable for refrigerated vaccine storage only-do not use the freezer for vaccines or food storage
Dorm Style Refrigerators

Effective 12/31/2009, per CDC, dorm style refrigerators can no longer be used to store VFC/state supplied vaccines.

Any questions, please contact:
Sue Duggan-Ball @ 222-1580 or Mark Francesconi @ 222-5988

A Dorm Style Refrigerator is classified as any size refrigerator with one external door and having a freezer within the refrigerator compartment.

CDC recommends stand-alone units, meaning self-contained units that only refrigerate or freeze, and are suitable for vaccine storage.

The CDC recommends that, if using a combination refrigerator/freezer unit, the refrigerator unit only be used, and a separate stand-alone freezer be used for frozen vaccines.
Certified Calibrated Thermometers

All SSV providers are able to receive a state supplied DataNet continuous recording system.

Providers are responsible for maintenance and to have the temperature units calibrated* every 2-years.

*Calibration may be performed by companies that calibrate other medical equipment for your practice.

Preventive Measures

- Post a warning sign above the plug and on the refrigerator
- Label fuses and circuit breakers
- Use locks or Velcro straps to keep doors closed securely

Labels are available from HEALTH
## Storage of Vaccine Products

**Store only vaccines in the refrigerator**

**Stock vaccines using shorter expiration dates first**

**Never leave vaccine outside the refrigerator**

**Don’t store vaccines on door shelves, in vegetable/fruit bins or drawers**

**Check and log temperature twice a day**

**Store full water bottles of water on the bottom shelves and doors to help maintain temperature**

**Open the door only when necessary**

**Keep refrigerated vaccine between 35°F and 46°F and the freezer between -58°F and +5°F**

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## Storage of Non-Vaccine Products

### Food and Beverages

*Never store food or beverages inside the vaccine refrigerator or freezer.*

This practice results in frequent opening of the storage unit door and greater chance for temperature instability and excessive exposure to light. It may also result in spills and contamination inside the compartment.

### Medications and Other Medical Supplies

If possible, other medications and other medical supplies should not be stored inside the vaccine storage unit. If there is no other choice, these products must be stored below the vaccines on a different shelf. This prevents contamination of the vaccines should the other products spill, and reduces the likelihood of medication errors.

*Bodily fluids should never be stored with vaccines*
Vaccine Shipments:
It is important to establish routine, systematic procedures for handling vaccine shipments

Receiving Vaccine Shipments
• Arrange for vaccine deliveries to be made only when the vaccine coordinator or alternate coordinator is on duty (consider holidays, vacations, staff schedules, and changes in hours of operation).
• All staff members (including non-medical staff) must be aware of the importance of maintaining the vaccine cold chain and need to immediately notify the vaccine coordinator of the arrival of vaccines so that they can be handled and stored properly.

Checking the Condition of the Shipment
• Examine the shipping container and its contents for any signs of physical damage.
• Cross check the contents with the packing slip to be sure they match.
• Check the vaccine lot # and expiration dates to be sure that you have not received any vaccines or diluents that have already expired or will expire soon.
• Check that the correct amount and type of diluents have been shipped.
• Check the hot/cold temperature strips to determine if vaccines or diluents have been exposed to temperatures outside the recommended range.
• Vaccines that require diluents will arrive in the same shipping container.
• For varicella-containing vaccines, the diluents should be in a separate compartment of the same container.
• Check that the vaccines were stacked properly. There should be an insulating barrier (such as bubble wrap or Styrofoam pellets) between the vaccines and the refrigerated or frozen coolant packs.
• Immediately store vaccines in the proper vaccine storage unit.
  1. Rotate vaccines using shorter expiration dates first.
  2. Label vaccines ie: Pedi/State, Adult/State, or Adult/Private
  3. Be sure there is appropriate space between vaccines for air flow

If there are any discrepancies with the packaging slip or concerns about the shipment, identify the vaccines with a marking or label, separate from other vaccines, store the vaccines under appropriate conditions, do not use, and call the immunization program for guidance.
Appendix A

Transporting Vaccine—Follow the Cold Chain

General Recommendations:
If vaccines must be transported during an emergency or to another site, it is critical that vaccine potency is protected by maintaining the vaccine cold chain at all times.

Guidelines:
The facility standard operating procedure should specify that the vaccines are:

- Attended to at all times during transport;
- Not placed in the trunk of the vehicle;
- Delivered directly to the facility;
- Promptly unpacked and placed into appropriate storage units upon arrival

Packing Vaccines and Diluents for transport

1. Use an insulated cooler
2. Place a layer (at least 2 inches) of coolant packs in the transport container
3. Place an insulated barrier layer on top of the coolant packs (e.g., bubble wrap, cardboard, or Styrofoam pellets)
4. Place a thermometer on top of the barrier.
5. Stack the vaccines on top of the barrier and next to the thermometer, ensuring the vaccines do not touch the coolant packs
6. Place another insulating barrier on top of the vaccines
7. Place another layer of coolant packs on top of the insulating barrier layer, ensuring there is no direct contact between the coolant packs and the vaccine
8. Place a final insulating layer (at least 2 inches) on top of the coolant packs
9. Include an inventory list of vaccines in the container
10. Diluents* should be transported with their corresponding vaccines to ensure that there are always equal numbers of vaccine vials and diluent vials for reconstitution

*Diluents may be transferred in the vaccine container or in a separate package if refrigeration is not necessary.
Appendix A (cont.)

Transporting Frozen Vaccines

**Note:** The CDC recommends transport of frozen vaccines in a portable freezer unit that maintains proper temperatures. If a portable unit is not available, please follow these steps when transporting frozen vaccine:

1. Use the same packing layers as noted for transporting refrigerated vaccines.
2. Frozen vaccines must be packed and transported in a separate container from refrigerated vaccines.
3. Coolant packs must be frozen. DO NOT use dry ice.
4. Place a thermometer in the container to track the temperature. Place it as close to the vaccine as possible.
5. Record the temperature of the vaccines in the permanent storage unit. Record the time the vaccines are removed from the permanent storage unit and placed in the transport container.
6. Immediately upon arrival at the alternate storage facility:
   - Record the temperature of the vaccines and the time the vaccines are removed from the transport container and placed in the alternate storage unit. The alternate storage unit temperatures should be between -58°F and +5°F (-50°C and -15°C).
   - During travel the vaccine may have been exposed to a temperature excursion, a temperature outside of proper range. Before using the vaccine, follow and complete step 7.
7. Place a temporary ‘DO NOT USE’ label on the vaccine box. Next, contact the vaccine manufacturer (Merck @ 1-800-637-2590) for vaccine handling instructions and determination of vaccine viability. Merck will ask for the times and temperatures that were recorded in previous steps. Record and follow recommendations made by the manufacturer.
8. Put vaccine returns in a box with the list of vaccines to be returned (printed from OSMOSSIS) and a courier will be dispatched to pick it up.
   - **Return** - expired or spoiled vaccines that are in their original packaging or in original condition. (re-constituted vaccines cannot be returned)
9. If it is determined that a vaccine cannot be used, label the vaccine ‘DO NOT USE’ and report the wasted vaccine, using the OSMOSSIS reporting process, to the Office of Immunization. **Do not discard** wasted vaccines without first obtaining consent from HEALTH.
   - **Waste** – vaccines that are no longer viable and no longer in their original condition; reconstituted, damaged, pre-drawn, etc…