VACCINE STORAGE REQUIREMENTS

Increased vaccine usage has also meant an increase in the amount of vaccine lost due to improper storage. Now, more than ever, we need to be certain that refrigerators and freezers meet all the specifications needed to protect the potency of valuable vaccine. Having the right storage equipment can protect your patients' health and your facility against costly vaccine replacement, inadvertent administration of compromised vaccine, and other consequences (e.g., costs of revaccination, loss of patient confidence in your practice, liability). In addition, investing in reliable temperature monitoring devices is less expensive than replacing vaccines wasted due to inaccurate temperature readings.

Storage Units

1. Any refrigerator or freezer used for vaccine storage must:
    a. be able to maintain required vaccine storage temperatures year-round
    b. be large enough to hold the year's largest inventory
    c. have a certified calibrated data logger inside each storage compartment
    d. be dedicated to the storage of vaccines
        - Food and beverages must NOT be stored in a vaccine storage unit because this practice results in the frequent opening of the door and destabilization of the temperature.

2. Dorm-style refrigerators are not allowed for vaccine storage under any circumstance. A dormitory-style refrigerator is defined as a combination refrigerator/freezer unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.

3. Stand-alone freezers are required for all new VFC providers. If new providers have household combination units, only the refrigerator section may be used to store refrigerated vaccines, and only as long as appropriate temperatures are maintained. These storage units must be monitored for seven days and the temperatures documented to ensure consistent, within range temperatures are maintained before vaccine can be ordered.

4. VFC providers enrolled prior to January 1, 2013, may continue to use the refrigerator and freezer portions of household combination (refrigerator-freezer storage) units as long as they maintain appropriate temperatures for vaccine storage. If the unit fails to maintain appropriate temperatures, new purchases must be stand-alone refrigerators and stand-alone freezers. CDC does not recommend use of the freezer in these units and it is recommended that providers move towards purchasing a stand-alone freezer. Although pharmaceutical-grade units are highly recommended, commercial-grade units may be purchased.

5. A new refrigerator or freezer, or a newly repaired refrigerator or freezer, must be monitored closely for at least one week before using it for vaccine storage to ensure appropriate temperatures can be maintained. In addition, LHD staff may require existing units experiencing temperature fluctuations or being moved to a new location to be monitored for a week to ensure the unit is stable enough to store vaccine.

    It may take 2 to 7 days to stabilize the temperature between 36°F and 46°F (2°C and 8°C) in a newly installed or repaired refrigerator. Likewise, it may take 2 to 3 days to stabilize the temperature between -58°F and +5°F (-50°C and -15°C) in a newly installed

or repaired freezer. Allowing a week of refrigerator and freezer temperature readings/recordings (twice a day each workday along with a minimum/maximum temperature recording each morning) will ensure temperatures are within appropriate ranges before using units to store vaccines.

6. The temperature of the refrigerator must be maintained at 36°- 46°F (2°C- 8°C). Providers should try to maintain refrigerator temperatures in the middle of the range at approximately 41°F (5°C). Freezer temperatures must be maintained between -58°F and +5°F (-50°C and -15°C). When making adjustments to the temperature of the unit, please keep in mind that glycol probes will take longer to adjust to the new setting. Be sure to check the temperature frequently until the temperature is stable.

7. If a manual defrost freezer maintaining appropriate temperatures is currently in use, the provider MUST have a back-up plan for vaccine storage when defrosting the unit. The provider must submit an acceptable defrosting plan of action that uses a monitored storage unit or portable freezer that accurately holds freezer temperature. A frost-free unit with an automatic defrost cycle may be preferred if regular manual defrosting cannot be assured.

Things to Consider when Purchasing a New Storage Unit

1. Optimal refrigerator / freezer features include:
    a. Frost-free / automatic defrost cycle
    b. Forced air convection / circulation fan to promote air flow
    c. Temperature gauge certified, calibrated, and traceable by the National Institute of Standards and Technology (NIST)
    d. Negative-pressure doors that close automatically
    e. Security locks
    f. Wire racks (as opposed to glass)

2. Review the maintenance and warranty plans offered by the manufacturer or retailer for parts and the compressor.

3. When choosing the size of the unit, consider the largest amount of vaccine your clinic stores each year (usually during back-to-school/flu season), including private purchase vaccine.

Maximum Doses Stored (including private purchase vaccine)	Minimum Cubic Feet
>2,000	May require more than one refrigerator
1,000-2,000	40 cu. ft.
800-1,000	21 - 36 cu. ft.
400-800	16-20 cu. ft.
< 400	5 cu. ft.

4. Advantages of a pharmaceutical-grade refrigerator or freezer:
    a. Maintains temperatures well, temperatures can be pre-set at the factory
    b. Good temperature recovery when the unit has been opened to get vaccines

c. Nearly all the internal space in the unit can be used to store vaccines (usable space is much more limited in commercial household refrigerators.)
    i. CDC recommends providers follow the manufacturer's guidance to ensure that vaccines can be safely stored on the top shelf of the unit
d. Allows defrosting with minimal rises in temperature
e. Offer the option of alarm and safety features to alert you to or prevent temperature fluctuations in the cabinet
f. Includes key locks so doors can't be opened by unauthorized staff

Refrigerator/Freezer Power Back-up

Disruption in power supply is one of the causes of a costly vaccine loss. Refrigerators and freezers begin to warm quickly once the power is out. With this in mind, a clinic may want to consider adding a secondary source of power in case of emergency. If a clinic already has a back-up system, it is highly recommended that refrigerators and/or freezers are placed on that emergency power circuit.

For those clinics without one, a small back-up generator may be an option for an extra layer of protection. Backup generators should be of a sufficient capacity to run continuously for 72 hours if necessary. Plans should be made to ensure that an adequate supply of fuel is on hand.

Power Sources/ Power Strips/Surge Protectors

Storage units should be plugged directly into wall outlets. Post a **Do Not Unplug** sign next to the outlet.

Do not use outlets with a built-in circuit switch (little red reset button) or outlets that can be activated by a wall switch (could inadvertently get switched off). Do not use extension cords, multi- outlet power strips or surge protectors. If the power goes out, the power strip / surge protector may trip and anything plugged in will not turn back on when the power is restored.

Vaccine Storage Reminders

1. Vaccine must be stored in the central area of the unit, **not** in the door, drawers/bins, or directly in front of vents/blowers.

2. Refrigerated vaccine must be stored in its original box in baskets that allow good air circulation. Frozen vaccine must be stored in plastic trays on racks or shelves in the original packaging.

3. Unless a pharmaceutical storage unit manufacturer indicates that water bottles negatively impacts the functionality of the unit, place water bottles throughout refrigerator and freezer storage units in order to:
    - Stabilize or extend temperatures during a power outage,
    - Help to mitigate the effects of frequent opening/closing of door during busy clinic days,
    - Serve as physical blocks preventing the placement of vaccines in areas of the unit that are at higher risk for temperature excursions, and
    - To use conditioned frozen water bottles when packing your cooler with refrigerated vaccines for transport in an emergency.

4. MMR, MCV4, MMRV, varicella and zoster vaccines must be protected from light at all times.

5. VFC providers must store vaccines at recommended temperatures immediately upon receiving a shipment. The temperature of the refrigerator must be maintained between 36° and 46°F (2°C- 8°C). Providers should try to maintain refrigerator temperatures in the middle of the range at approximately 40°F or 5°C. Freezer temperatures must be maintained between -58°F and +5°F (-50°C and -15°C). Post the Vaccine Storage and Handling Guide (see page 27) on refrigerator storage unit.

6. Private stock and VFC stock should be clearly marked and stored separately.

7. The expiration dates of vaccines must be monitored at least monthly. Vaccine stock should be rotated and arranged in the refrigerator/freezer so that the soonest-to-expire vaccine is in front and used first. Notify the LHD of any vaccine stock that has an expiration date of six months or less, especially if the provider may not be able to utilize all of the vaccine

OPEN VIALS: Please note that vaccines received under the VFC Program are exempt from the Joint Commission ruling requiring the discard of open multi-doses vial products 28 days after the open/puncture date unless otherwise stated on the manufacturers package insert. The complete Standards FAQ Details on Multi-dose vials can be viewed at the following link: http://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFaqId=434&ProgramId=47

8. Providers must balance physical inventory with the MCIR inventory on (at minimum) a monthly basis, even if they are not ordering vaccine.

9. Vaccine usage should be monitored to ensure stock on hand accurately reflects vaccine need. All VFC providers are expected to maintain an adequate inventory of private stock vaccine for patients not eligible for VFC vaccine.

Frozen Vaccine Transport Guidance

MDHHS, CDC, and Merck do NOT recommend transporting varicella-containing vaccines. If these vaccines must be transported during an emergency, it is recommended that they be transported in a portable freezer unit using a data logger to monitor the temperatures during transport.

If a portable freezer unit is not available, as a last resort, varicella-containing vaccine that has not been reconstituted, may be transported using a portable refrigerator (recommended), insulated hard sided, or Styrofoam™ cooler for up to 72 continuous hours. A data logger must be used and temperatures must be documented at the beginning and end of transport. If transport will be longer than one hour, monitor and document the temperatures hourly. Immediately upon arrival to the backup location, label the vaccine(s) “DO NOT USE”, store the vaccine(s) in the refrigerator and contact Merck for guidance.

Varicella-containing vaccines transported at temperatures outside the required range of -58˚F to +5˚F (-50˚C to -15˚C) cannot be put back into the freezer for future use unless approved by the manufacturer.

Transported vaccine that has been exposed to refrigerator temperatures longer than 72 hours cannot be returned to the freezer. It must be used within the 72 hour time period or discarded.

.