Vaccine Storage and Handling:

What's Changing and What You Need to Know

It is common knowledge that inactivated vaccines must be stored in the refrigerator and live vaccines (Varicella and MMR) must be stored in the freezer, and for a long time, it's been acceptable to use any household refrigerator to store vaccines. However, in recent years the number of vaccine doses that providers are using has dramatically increased, thus decreasing the amount of usable space providers have in their refrigerators. This increase is due to new vaccines, expanded immunization recommendations, and pre-filled syringes which occupy significantly more space than vials. With the increase in vaccine usage there has also been an increase in the number of vaccine losses due to improperly stored vaccines. The average provider typically has tens of thousands of dollars worth of vaccine in their refrigerator at any given time.

Proper vaccine storage and handling of vaccines is a priority for the California Vaccines for Children (VFC) Program and the Los Angeles County Immunization Program (LACIP). Correct storage and handling of vaccines maintains the integrity and stability of vaccines administered to patients; prevents inadvertent administration of improperly stored vaccines, and prevents unnecessary vaccine wastage. Vaccine potency and effectiveness is diminished when exposed to temperatures outside the manufacturer's recommended range. All inactivated liquid vaccines are irreversibly damaged when exposed to freezing temperatures (32º Fahrenheit and below) and live vaccines can be compromised by sustained elevated temperatures.

Some of the common refrigerator problems LACIP has encountered that have resulted in damaged or wasted vaccines are:

◊ Insufficient usable space to safely store vaccines. A typical combination refrigerator-freezer has only 30% of its space acceptable for vaccine storage ("useable vaccine storage space").

◊ Significant temperature variations from shelf to shelf in the units.

◊ Improper use of inside space including:

- Shelves directly beneath the air vent
- Vaccines stored in vegetable bins or deli crispers
- Vaccines touching wall surfaces that are vulnerable to freezing temperatures

New CA VFC Vaccine Storage Equipment Guidelines

To ensure ongoing vaccine integrity, the VFC Program has developed new specifications for the types of vaccine storage units that are acceptable for the storage of vaccines supplied through the VFC Program.

Refrigerator-only units, also known as "freezer-less refrigerators" will become the required storage units for all refrigerated vaccines distributed through the VFC Program.

All providers enrolling in the VFC program or providers who experience any vaccine loss due to failure of their current unit (regardless of volume) will be expected to comply with recommendations listed below.

- **Super high volume** providers receiving more than 10,000 doses per year will be required to store VFC supplied vaccines in "pharmacy-grade or biologic grade freezer-less refrigerator" and "pharmacy-grade or biologic grade freezer-only" units. These units are designed for optimum cooling capacity and stable temperature control over the recommended range.

- **High volume** providers receiving between 2,000 and 10,000 vaccine doses per year will be required to store VFC supplied vaccines in refrigerator-only and stand alone freezer units.

- **Medium volume** providers receiving between 500 and 2,000 vaccine doses per year should strongly consider purchasing refrigerator-only and stand alone freezer units. However, providers will be allowed to keep an existing household refrigerator/freezer combination unit as long as it meets all of the following specifications:

  1) Has adequate useable vaccine storage space to store largest anticipated vaccine supply, e.g. during seasonal peaks, such as back-to-school or flu season. Providers will be required to purchase separate units in instances where unit does not have adequate vaccine storage capacity.

  2) Has dual thermostats for refrigerator and freezer.

  3) Maintains required vaccine storage temperatures without significant fluctuations.

  4) Is frost-free, and free of any visible water or coolant leaks.

  5) Has not required repairs within the past two years.

  6) Has doors that seal tightly and close properly.

  7) Has at least 3 inches of free space between vaccine and internal walls, and vaccines are stored away from cold air vent.

  8) Has no vaccine being stored in the units' vegetable bins, deli crispers, doors, or shelves directly underneath air vents.

  9) Is NOT a "dorm-style" or "under-the-counter" unit. These have poor temperature controls and are considered unacceptable for vaccine storage.

- **Low volume** providers receiving less than 500 vaccine

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doses per year will be allowed to have a combination unit if it meets required specifications (see above conditions).

Purchasing Your New Equipment: Refrigerator Specifications

Refrigerator-only units are quite common and often found in food, beverage and floral industries where products must be stored strictly at +40°F. The cost of purchasing a refrigerator-only unit can range from $400 to $4,000 for a refrigerator-only unit sold at a major appliance retailer, and from $4,000 to $9,000 dollars for a biologic or pharmacy grade unit sold by specialty distributors. Compared to the annual dollar amount of VFC vaccines stored by a medium volume provider, which may be up to $50,000, the purchase of a refrigerator-only unit can prove to be quite an investment for providers and prevent costly vaccine losses that providers may be held financially responsible for.

Tips for Purchasing a New Refrigerator-Only Unit:

Optimal Refrigerator Features

- Unit must maintain uniform temperatures between 35-46°. Units that have a preset temperature at 40°F (5°C) are preferable.
- Unit must have adequate usable space.
- Unit must have an automatic defrost cycle.
- Unit must have an NSF certified temperature gauge
- "Negative pressure self-closing doors" (doors that close automatically) and built-in thermometers are highly desirable.
- Security locks, wire racks, and visible temperature displays are ideal.

Unacceptable Refrigerator Features

- Units with visible cooling plates or open coiling located in the back wall of the unit.
- Exposed internal coiling or exposed cooling plates.

Other Storage and Handling Recommendations:

- The refrigerator temperature is maintained between 35-46° F (2-8°C), (Aim for 40∞ F)
- The freezer temperature is maintained below 5° F (-15°C), (Aim for 0∞F)
- Use only certified thermometers. If your thermometer uses batteries, replace them every 6 months.
- Place thermometers in the center of both the refrigerator and freezer. Post a temperature log on the doors.
- Check and record refrigerator and freezer temperatures twice a day, first thing in the morning and last thing at the close of business. Check to make sure that the door is shut. If the temperature is out of range, immediately contact LACIP.
- Post "Do Not Un-plug" warning signs on the refrigerator and freezer doors, electrical outlets, and circuit breakers.
- Rotate vaccine stock by placing shorter expiration dates in front. Call LACIP if you have any vaccine that will expire within 3 months.
- Keep vaccine in original packaging until using it.
- Designate one staff member to be the primary vaccine coordinator and at least one person to be back up.
- Have an emergency plan for extended power outages and freezer or refrigerator malfunctions.

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