The Ultimate Guide to Meeting CDC Guidelines for Vaccine Storage

Helmer Scientific
Revised March 2021

S3R025/B

INTRODUCTION

The safe storage of vaccines is a crucial component of protecting patients against disease. Healthcare facilities and vaccine providers should review and implement the Centers for Disease Control and Prevention (CDC) guidelines for vaccine storage and handling. These guidelines outlined in their Vaccine Storage and Handling Toolkit apply to all facilities that handle vaccines. Providers participating in the Vaccines for Children (VFC) program must pay extra attention to these guidelines and should consult their immunization program for specific recommendations and requirements.

Failure to store vaccines correctly may result in loss of patient confidence in the vaccine program. Revaccination is necessary if the administered vaccines were compromised due to inappropriate temperatures or improper handling. These errors also translate into a significant financial loss when the vaccines cannot be used and must be disposed.

Storing vaccines correctly is an essential part of providing quality patient care. To maintain vaccine effectiveness, the vaccine cold chain must be maintained. According to CDC, the vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccines in optimal conditions. It begins with the manufacturer and ends with the vaccine administration site. If the vaccine cold chain is not maintained, the vaccine will lose potency and become ineffective.

Loss of potency can result from exposure to excessive heat, cold, and/or light. Once potency is lost, it cannot be regained. Vaccine appearance is not a reliable indicator that the vaccine has been stored under inappropriate conditions.

The Vaccine Storage and Handling Toolkit reflects best practices for vaccine storage and handling from Advisory Committee on Immunization Practices (ACIP) recommendations, product information from vaccine manufacturers, and scientific studies.

The toolkit outlines CDC Recommendations, which are the minimal actions required to protect your vaccine supply as well as CDC Best Practice which outlines additional actions, practices and procedures to enhance protection of your vaccine supply.

It is important your facility has proper storage and monitoring equipment that is set up correctly, maintained appropriately, and repaired as needed. This equipment protects patients from inadvertently receiving compromised vaccine and your facility against costs of revaccinating patients, replacing expensive vaccines, and losing patient confidence in your practice.

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Vaccine Storage Units: Refrigerator and Freezer Recommendations

There are several types of vaccine storage units available. Purpose-built units are specifically designed to store vaccines. However, household-grade units are also an acceptable option for vaccine refrigeration under the right conditions.

CDC recommends the use of purpose-built or pharmaceutical-grade units designed to either refrigerate or freeze. These units can be compact, under-the-counter style or large. Purpose-built units, sometimes referred to as "pharmaceutical grade," are designed specifically for storage of biologics, including vaccines.

These units often have:

- Microprocessor-based temperature control with a digital temperature sensor (thermocouple, resistance temperature detector [RTD], or thermistor)
- Fan-forced air circulation with powerful fans or multiple cool air vents promoting uniform temperature and fast temperature recovery from an out-of-range temperature.

To fully ensure the safety of vaccines, equipment should include a recommended unit with enough space to accommodate your maximum inventory without crowding.

Household-grade units can be an acceptable alternative to pharmaceutical-grade vaccine storage units. As the name implies, these units are primarily designed and marketed for home use. However, the freezer compartment of this type of unit is not recommended to store vaccines and there may be other areas of the refrigerated compartment that should be avoided as well. If your facility provides frozen vaccine, a separate freezer unit is necessary.

A 2009 NIST study demonstrated that medical-grade units maintain required temperatures better than household and commercial combination units. Typical household, single-condenser, combination units are not capable of maintaining proper storage temperatures in the refrigerator and freezer compartments.

Most of these units have cold spots and temperature fluctuations in the refrigerator portion, which puts refrigerated vaccines at risk of freezing. Moreover, the freezer compartment in a household combination unit has proven it is not capable of maintaining the correct temperature for frozen vaccines.

Storage Unit Placement

Good air circulation around the outside of the storage unit is important. Place a storage unit in a well-ventilated room, leaving space between the unit, ceiling, and any wall. Nothing should block the cover of the motor compartment. The unit should be firm and level, with the bottom of the unit above the floor. Make sure the unit door opens and closes smoothly and fits squarely against the body of the unit. If not secured properly, unit doors pose a risk to maintaining appropriate internal temperatures of vaccine storage units. Studies find most units work best when placed in an area with standard indoor room temperatures, usually between 20° C and 25° C (68° F and 77° F). Check the manufacturer-supplied owner's manual for additional guidance on placement and spacing.

Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.

These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment. These units pose a significant risk of freezing vaccines, even when used for temporary storage. (Note: Not all small storage units are dormitory- or bar-style units. Compact, purpose-built units for biologics can be used to store vaccines.)

Storage Unit Doors

A door that is not sealed properly or left open unnecessarily not only affects the temperature in a unit, it also exposes vaccines to light, which can reduce potency of some vaccines. Consider using safeguards to ensure the doors of the unit remain closed—for example, self-closing door hinges, door alarms, or door locks.

TEMPERATURE MONITORING RECOMMENDATIONS

The revised 2019 Vaccine Storage and Handling Toolkit provides detailed recommendations around temperature monitoring best practices as well as temperature monitoring devices and calibration.

Temperature Ranges

Refrigerators should maintain temperatures between 2° C and 8° C (36° F and 46° F). Freezers should maintain temperatures between -50° C and -15° C (-58° F and +5° F). Refrigerator or freezer thermostats should be set at the factory-set or midpoint temperature, which will decrease the likelihood of temperature excursions. Consult the owner's manual for instructions on how to operate the thermostat. The only way to know the temperature where vaccines are stored is to measure and monitor it with a temperature monitoring device.

Temperature Monitoring Devices (TMDs)

Every vaccine storage unit must have a TMD. An accurate temperature history that reflects actual vaccine temperatures is critical for protecting your vaccines. Investing in a reliable device

is less expensive than replacing vaccines wasted due to the loss of potency that comes from storage at out-of-range temperatures.

CDC recommends a specific type of TMD called a "digital data logger" (DDL). A DDL provides the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a "temperature excursion"). Unlike a simple minimum/maximum thermometer, which only shows the coldest and warmest temperatures reached in a unit, a DDL provides detailed information on all temperatures recorded at preset intervals. In addition, some pharmaceutical-grade and purpose-built units have built in continuous temperature monitoring which provide all of the same benefits as a standalone DDL.

Many DDLs use a buffered temperature probe, which is the most accurate way to measure actual vaccine temperatures. Temperatures measured by a buffered probe match vaccine temperatures more closely than those measured by standard thermometers, which tend to reflect only air temperature.

Temperature data from a DDL can either be downloaded to a computer using special software or retrieved from a website. The software or website may also allow you to set the frequency of temperature readings. Reviewing DDL data is critical for vaccine viability, so it is important to decide whether independent software or a website program works best for your facility.

Keep the data for three years so it can be analyzed for long-term trends and/or recurring problems. Those receiving public vaccine may need to keep records longer as required by state regulations.

Use a DDL or other appropriate TMD for:

- Each vaccine storage unit
- Each transport unit (emergency or non-emergency)
- Have at least one backup TMD in case a primary device breaks or malfunctions.

Use DDLs with the following features:

- Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®)
    - Probes that are permanently embedded in a buffer are acceptable if the temperature monitoring system for the entire unit can be calibration-tested.
- Alarm for out-of-range temperatures
- Low-battery indicator
    - Since these devices are typically battery-operated, have a supply of extra batteries on hand.
    - 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 at least every 30 minutes
- Use DDLs with a current and valid Certificate of Calibration Testing

Certificate of Calibration Testing

Calibration testing is done to ensure the accuracy of a temperature monitoring device's readings against nationally accepted standards. A DDL's Certificate of Calibration Testing should include:

- Model/device name or number
- Serial number
- Date of calibration (report or issue date)
- Confirmation that the instrument passed testing (or instrument is in tolerance)
- Recommended uncertainty of +/-0 .5° C (+/-1° F) or less

To determine if a Certificate of Calibration Testing or Report of Calibration was issued by an appropriate entity, check to see if the certificate indicates one or more of the following items about calibration testing:

- Conforms to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 international standards for calibration testing and traceability
- Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body
- Traceable to the standards maintained by the National Institute of Standards and Technology (NIST)
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 Tolerance Class F or higher
- Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

Calibration testing should be done every one to two years or according to the manufacturer's suggested timeline. TMDs can experience a "drift" over time, affecting their accuracy. This testing ensures the accuracy of the device continues to conform to nationally-accepted standards.

Mishandling a TMD can affect its accuracy. If a TMD is dropped, hit against the side of a storage unit, or is potentially damaged in any way, its accuracy should be checked against another calibrated TMD. If there is any question about accuracy, the device should be replaced or sent for calibration testing.

Monitoring Vaccine Temperature and Vaccine Equipment

Monitoring vaccine storage equipment and temperatures are daily responsibilities to ensure the viability of your vaccine supply and your patients. Implementing routine monitoring activities can help you identify temperature excursions quickly and take immediate action to correct them, preventing loss of vaccines and the potential need for revaccination of patients.

Certain types of TMDs have significant limitations and should not be used to measure temperatures in a vaccine storage unit.

These devices can be difficult to read because they only show the temperature at the exact time they are checked. These devices may fail to detect temperatures outside the recommended range. CDC does not recommend the following TMDs:

- Alcohol or mercury thermometers (even if placed in a fluid-filled, biosafe)
- Liquid vial Bimetal stem TMDs
- TMDs used for food
- Chart recorders
- Infrared TMDs
- TMDs that do not have a current and valid Certificate of Calibration Testing

Please note: Some devices sold in hardware and appliance stores are designed to monitor temperatures for household food storage. They are not calibrated and not accurate enough to ensure vaccines are stored within the correct temperature range. Using these devices can pose a significant risk of damaging vaccines.

HOW TO HANDLE TEMPERATURE EXCURSIONS

Temperature excursions or inappropriate storage conditions for any vaccine require immediate action. Any temperature reading outside the recommended ranges in the manufacturers' package inserts is considered a temperature excursion. In general, manufacturers analyze information about the magnitude of the temperature excursion and the total amount of time that temperatures were out of range, as well as information about the vaccine in question, to determine whether a vaccine is likely to still be viable (CDC).

CDC recommends the following steps in the event of a temperature excursion:

Any staff who hears an alarm or notices a temperature excursion on the DDL should notify the primary or alternate vaccine coordinator immediately or report the problem to their supervisor.

Notify staff by labeling exposed vaccines, "DO NOT USE," and placing them in a separate container apart from other vaccines (do not discard these vaccines).

The vaccine coordinator, supervisor, or if necessary, the person reporting the problem should begin to document the event with the following information:

- Date and time of the temperature excursion
- Storage unit temperature as well as room temperature, if available (including minimum/maximum temperatures during the time of the event, if available)
- Name of the person completing the report and description of the event
- General description of what happened
- The length of time vaccine may have been affected, if using a DDL
- Inventory of affected vaccines
- List of items in the unit (including water bottles) other than vaccines
- Any problems with the storage unit and/or affected vaccines before the event
- Other relevant information

Implement your facility SOPs to adjust unit temperature to the appropriate range. At a minimum, check the TMD to make sure it is appropriately placed in the center of the vaccines.

Contact your state or local immunization program and/or vaccine manufacturer(s) per your SOPs for further guidance on whether to use affected vaccines and for information about whether patients will need to be recalled for revaccination. Be prepared to provide documentation of the event (e.g., temperature log data) to ensure you receive the best guidance.

Complete your documentation of the event, including:

- Action taken
- What you did with vaccine and how long it took to act
- Whom you contacted, and instructions received
- What you did to prevent a similar future event
- Results
- Final disposition of affected vaccines (e.g., shortened expiration date per manufacturer, discarded, or returned)
- Other comments

The Immunization Action Coalition has developed a Temperature Monitoring Log and a Vaccine Storage Troubleshooting Record to support these activities.

Responses from vaccine manufacturers to events depend on information given by the provider to the manufacturer. If different information about the same event is provided to the same manufacturer, this can lead to different recommendations on whether vaccine can be used or whether patients need to be revaccinated. In addition, each event is unique, and manufacturer recommendations based on existing stability data cannot be applied to future events that may appear to be similar.

ROUTINE MAINTENANCE & TROUBLESHOOTING FOR VACCINE STORAGE UNITS

Conducting regular maintenance on your vaccine storage units is essential for keeping them in operation and giving them a long usable life. The CDC Vaccine Storage and Handling Toolkit gives great recommendations on how to properly maintain your vaccine storage units. The toolkit also provides instructions on how to troubleshoot equipment problems and handle alarms.

Regular Maintenance of Vaccine Storage Units and Temperature Monitoring Devices

Storage units and TMDs need regular maintenance to ensure proper operation.

Never allow vaccines to remain in a malfunctioning unit for an extended period. If you believe your unit has failed, implement your emergency SOPs.

Conduct routine maintenance for all vaccine storage units and related equipment so that your equipment functions at maximum efficiency.

- Check seals and door hinges.
- Clean coils and other components per manufacturer direction.
- Defrost manual-defrost freezers.
- Clean the interior of each unit to discourage bacterial and fungal growth. Do so quickly to minimize the risk of a temperature excursion.
- Test any backup generator quarterly and have it serviced annually.

Troubleshooting Equipment Problems

Adjusting Storage Unit Temperatures

Storage unit temperatures may need to be adjusted over time. In some situations, thermostats may need to be reset in summer and winter, depending on room temperature.

Temperature adjustments should:

- Be made by the primary or alternate vaccine coordinator, based on information from the TMD and temperature monitoring log.
- Be done at a time that is not during a busy workday when the unit door is frequently opened and closed.

Remember that temperatures within any storage unit will vary slightly, even with normal use. Therefore, before making any adjustment:

- Confirm the unit is securely plugged into a power source.
- Check the temperature inside the storage unit.

Wait 30 minutes, without opening the door, to allow the temperature to stabilize and then check it again to determine if the thermostat should be adjusted.

If you believe there could be an issue with your TMD, use your backup device to confirm the temperature. If you confirm that an adjustment is needed:

1. Refer to the owner's manual for detailed instructions.
2. If using a household unit, make a small adjustment toward a warmer or colder setting by turning the thermostat knob slowly to avoid going outside the correct temperature range. If you are using a pharmaceutical grade unit, you will be able to set a precise temperature using the temperature controller.
3. Once the adjustment is made, allow the temperature inside the unit to stabilize for 30 minutes without opening the door.
4. Recheck the temperature.
5. Repeat these steps as needed until the temperature has stabilized at around 5° C (40° F) for a refrigerator or between -50° C and -15° C (-58° F and +5° F) for a freezer.
6. Consider placing additional water bottles in the unit to help improve temperature stability

Do not leave vaccines in a storage unit that does not maintain temperatures within the recommended range. If you are unable to stabilize the temperature in your unit within the required range, or temperatures in the unit are consistently at the extreme high or low end of the range, your vaccine supply is at high risk. Use your SOPs to identify an alternative unit with appropriate temperatures and enough storage space until the primary unit can be repaired or replaced.

If you are using a combination storage unit, note that adjustments to the freezer temperature can adversely affect the refrigerator compartment temperature, possibly resulting in frozen vaccines in the refrigerator.

Repeated Alarm Alerts

If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause. Do basic checks of the unit door, power supply, and thermostat settings. If the alarm continues to trigger or the temperature remains out of range, transfer vaccines to a backup unit as directed by your SOPs. A repair technician should check your equipment to determine the need for repair or replacement.

CONCLUSION

Safe and effective vaccine storage is an essential part of protecting the population from devastating disease. Providers are looking to the CDC Vaccine Storage and Handling Toolkit for essential information on proper storage, handling, monitoring, and administration of vaccines. The risks related to improper vaccine storage are too profound to ignore. At Helmer Scientific, we have been designing and manufacturing reliable, purpose-built refrigerators and freezers for over 15 years. For more information on choosing the right equipment to help meet CDC recommendations, please visit www.helmerinc.com.

All the information provided in this post is directly from the CDC Vaccine Storage and Handling Toolkit. Please consult with your state and local programs for specific direction regarding vaccine storage and handling.