The Ultimate Guide to Meeting CDC Guidelines for Vaccine Storage

Helmer Scientific
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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) or other public vaccine stock programs 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 reduced efficacy of vaccinations. Revaccination may be necessary if the administered vaccines were compromised due to inappropriate temperatures or improper handling and patient confidence in vaccination programs may be compromised. These types of errors can also translate into a significant financial loss when vaccines require staff troubleshooting to determine if product is suitable for use, or if product cannot be used and must be disposed.

Storing vaccines appropriately 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 may 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. This Ultimate Guide is designed to provide highlights from the Vaccine Storage and Handling Toolkit related to appropriate storage and monitoring of vaccines. Because the toolkit is continuously updated by the CDC, we recommend periodically reviewing information on the CDC's website.

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REFRIGERATOR AND FREEZER RECOMMENDATIONS

Selecting appropriate storage equipment is critical to maintaining the safety of vaccines to avoid temperature excursions that could affect the viability of vaccines. The CDC Vaccine Storage and Handling Toolkit helps guide healthcare providers towards equipment designed for vaccine storage. The Toolkit recommends using purpose-built or pharmaceutical-grade units but also allows for other types of storage equipment. However, units not specifically designed for vaccine storage can be more likely to have warm and cold spots which puts refrigerated vaccines at greater risk of damage (including freezing). In addition, the freezer compartment in a household combination unit is not recommended for storage as it is likely not capable of maintaining the correct temperatures for frozen vaccines. These are just some of the reasons the CDC recommends using purpose-built or pharmaceutical-grade equipment.

Note: The CDC Vaccine Storage and Handling Toolkit has been updated to reflect that COVID-19 vaccines may require different storage and monitoring recommendations when compared to other vaccines. This guide will cover information related to COVID-19 vaccines, but please review the COVID-19 Vaccine Storage and Handling addendum for additional information.

Vaccine Storage Units: Refrigerator and Freezer Recommendations
***Adapted from the CDC Vaccine Storage and Handling Toolkit*[1]**

Selecting Appropriate Equipment

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.

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.)

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.

Ensuring Appropriate 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.

Assessing 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 Vaccine Storage and Handling Toolkit has been updated to provide detailed recommendations around temperature monitoring best practices as well as temperature monitoring devices and calibration. Best practices, as defined in the CDC Vaccine Storage and Handling Toolkit, recommend using Digital Data Loggers (DDLs) that continuously monitor vaccine temperatures, versus less sophisticated systems that only track minimum and maximum temperatures. DDLs may be independent monitoring systems, however, some vaccine refrigerators and freezers will have integrated DDLs that align with CDC recommendations. Temperature monitoring systems are a critical component of safe vaccine management, and for this reason CDC recommends that providers have back-up systems available in case the primary system fails.

Note: The CDC Vaccine Storage and Handling Toolkit has been updated to reflect that COVID-19 vaccines may require different storage and monitoring recommendations when compared to other vaccines. This guide will cover information related to COVID-19 vaccines, but please review the COVID-19 Vaccine Storage and Handling addendum for additional information.

Manufacturers of purpose-built or pharmaceutical-grade units may perform testing including temperature mapping to ensure that temperature probes are in the most appropriate location to safeguard vaccines. The CDC recommendations no longer require relocating probes to the same storage location as vaccines, if the manufacturer has already optimized a standard probe location.

Water bottles may be recommended for the top shelf, floor, and door racks on some units to help maintain stable temperatures. However, water bottles are not recommended or required with certain purpose-built or pharmaceutical-grade units. The CDC recommends following the manufacturer's instructions related to the use of water bottles to stabilize temperatures.

Monitoring Temperature Recommendations
Adapted from the CDC Vaccine Storage and Handling Toolkit[1]

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.

ROUTINE MAINTENANCE & TROUBLESHOOTING FOR VACCINE STORAGE UNITS

Routine maintenance is essential for keeping vaccine storage units in operation and to help enable extended equipment life. The CDC Vaccine Storage and Handling Toolkit makes recommendations related to properly maintaining vaccine storage units. It is also recommended to follow manufacturer's recommendations for your vaccine storage unit as preventative maintenance recommendations can vary by unit.

Note: Cables and wires that enter the refrigerator or freezer cabinet through door may interfere with a good door seal and may affect temperature. Many purpose-built refrigerators and freezers include specialized probe ports to allow cables and wires from DDLs and monitoring systems to enter the cabinet without risk to door gaskets.

Regular Maintenance of Vaccine Storage Units and Temperature Monitoring Devices
Adapted from the CDC Vaccine Storage and Handling Toolkit[1]

Maintenance

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

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.

COVID-19 VACCINE ADDENDUM

New vaccines for COVID-19 include unique storage and handling recommendations. For this reason the CDC now includes a COVID-19 Vaccine Addendum as part of the Vaccine Storage and Handling Toolkit. Providers that participate in US-based COVID-19 vaccination programs are required to sign a COVID-19 Vaccination Provider Agreement. This agreement ensures that COVID-19 vaccines are appropriately stored, handled, and monitored and that providers will comply with immunization program guidance related to temperature excursions. In addition, the provider agreement lists documentation and vaccine disposal requirements.

The COVID-19 Vaccine Addendum also accounts for the fact that certain COVID-19 vaccines require ultra-low temperatures (-60C to -90C) for long-term storage. Vaccines with ultra-low temperature storage may utilize specialized storage and monitoring equipment. In addition, the CDC also includes special considerations and guidance related to appropriate transport of these vaccines to help ensure they remain within the correct temperature ranges.

As the storage and handling guidelines for new COVID-19 vaccines continue to evolve, and because each vaccine has different instructions for preparation and administration, the COVID-19 Vaccine Addendum includes product-specific information for each vaccine. For the most current information, please refer directly to the CDC Vaccine Storage and Handling Toolkit.

CONCLUSION

Safe and effective vaccine storage is an essential part of protecting the population from devastating diseases that may be prevented with vaccinations. The CDC Vaccine Storage and Handling Toolkit includes essential information on proper storage, handling, monitoring, and administration of vaccines. Following CDC recommendations can help ensure that your facility is appropriate safe-guarding these life-saving products.

Information is directly adopted from the CDC Vaccine Storage and Handling Toolkit. Please consult with your state and local programs for specific direction regarding vaccine storage and handling requirements in your facility.

[1] ***CDC Storage and Handling Toolkit, 2021***

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