

The Ultimate Guide to Vaccine Storage



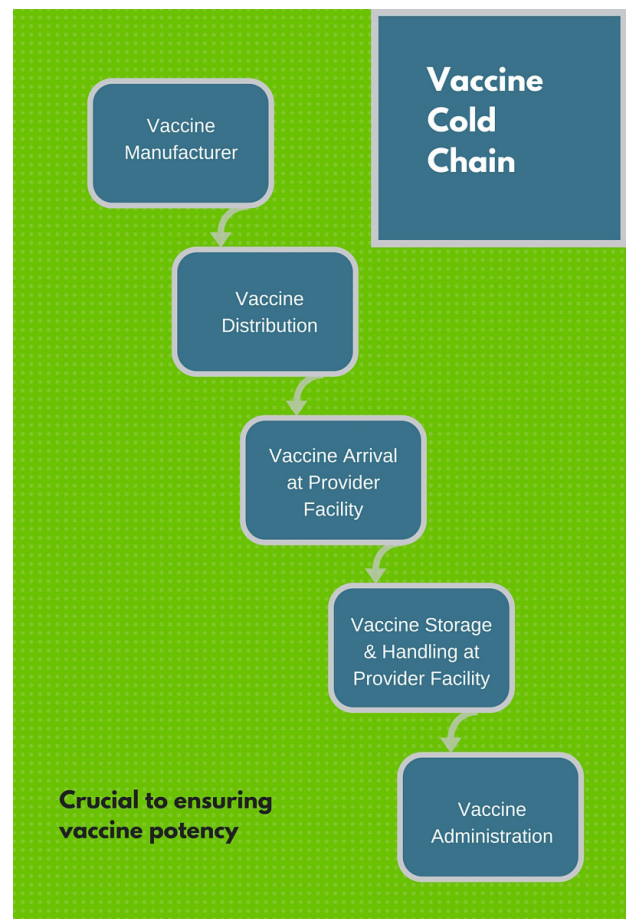
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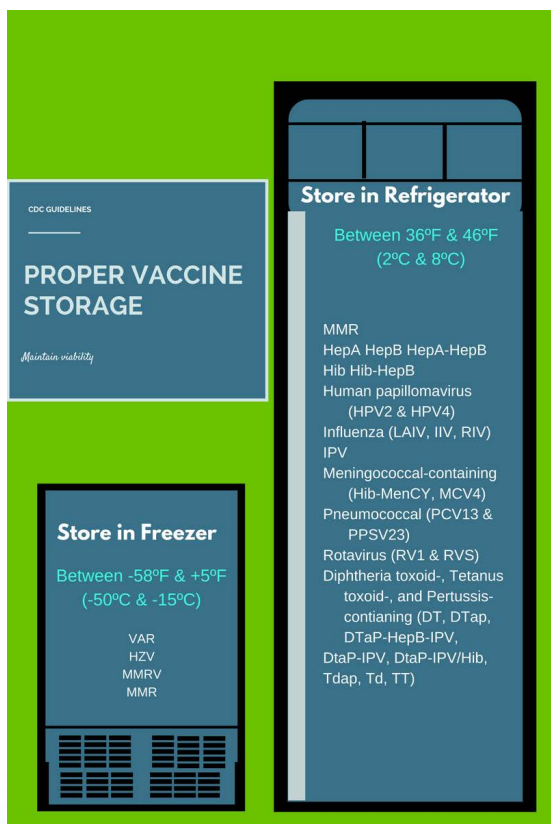
The Ultimate Guide to Vaccine Storage

Healthcare facilities across the country are working hard to understand and implement the [Center for Disease Control \(CDC\)](#) guidelines and recommendations related to vaccine storage and handling. These guidelines apply to all facilities that handle vaccines. CDC encourages providers to move toward implementing these guidelines as soon as possible. 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.

The safe storage of vaccines is a crucial component of protecting patients against disease. 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.

In order 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.





Although most vaccines must be refrigerated, some require freezing. The accompanying chart highlights what vaccines must be stored in a freezer and what ones must be stored in a refrigerator.

Choosing Vaccine Storage Equipment

Complying with these guidelines starts with choosing the right equipment to store and protect sensitive vaccines from temperature fluctuations and excursions. CDC mentions that there are different types of refrigerators and freezers available on the market. These include household, commercial, and pharmaceutical units. Household refrigerators are easily identified and the least effective at maintaining proper temperatures for storing vaccines. Commercial refrigerators are designed for food and beverage storage. Lastly, pharmaceutical/purpose built units, also referred to as medical-grade units, are specifically designed to store items such as vaccines. It is important to note that many

companies selling commercial refrigerators and freezers market their products as medical-grade refrigerators. CDC recommends stand-alone units that either refrigerate or freeze or pharmaceutical/purpose-built units. A true [medical-grade unit](#) will align with all CDC recommendations and provide protection against user error.

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.

In addition, CDC does not recommend using a dormitory-style (or bar-style) refrigerator/freezer to store vaccines for any length of time, even temporarily. This style of refrigerator is defined as a combination refrigerator/freezer that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located within the unit's icemaker compartment (inside of the refrigerator). This type of unit has proven to be completely unacceptable for vaccine storage due to its inability to maintain temperatures. Dormitory-style units have wide temperature variations throughout the unit and pose a significant risk of freezing refrigerated vaccine even when used for temporary storage. If participating in the VFC program the use of a dormitory-style refrigerator/freezer is strictly prohibited. If a smaller refrigerator or freezer is needed due to space constraints, there are plenty of medical-grade refrigerators and freezers available on the market to properly store vaccines.



The CDC does not recommend specific brands of storage units, but they do provide guidance on selecting storage units proven to maintain proper temperatures and meet the recommended guidelines.

Maintaining Temperature

The refrigerator should maintain an average temperature of around 40°F (5°C), and the freezer should maintain temperatures between -58°F and +5°F (-50°C and -15°C). Vaccines should never be stored in a unit that cannot maintain temperature range. Some medical-grade units provide further protection by not allowing the refrigerator or freezer to be set outside of the required range for storing vaccine. While household or commercial units typically have thermostats that read “MIN,” “MED,” “MAX,” or are numbered “1,” “2,” “3,” medical-grade units allow users to set an exact temperature set point providing maximum control, and security. Household or commercial refrigerator thermometers are often located in a place that could easily get bumped or adjusted causing temperature to quickly go out of range.

The CDC encourages the use of water bottles and frozen coolant packs to help maintain stable temperatures. This is only necessary in a household or commercial refrigerator/freezer. If using a household or commercial refrigerator, water bottles should be placed on the top shelf, floor, and in the door racks of the refrigerator. These should be labeled “Do NOT Drink.” In a freezer, frozen coolant packs should be placed along the walls, back, and bottom of the unit. Water bottles and coolant packs are unnecessary in a medical-grade refrigerator or freezer because these units are designed to stabilize temperatures by circulating the

air inside of the unit creating a uniform environment. This allows for additional storage space as well as protection against placing product in an unstable part of the unit. When using a medical-grade refrigerator, users do not have to worry about placing product in an area that may expose it to inappropriate temperatures or freezing. Household and commercial refrigerators may also contain deli, fruit, and vegetables drawers which negatively affect temperature uniformity. The CDC does not recommend using these drawers for storage, in fact, they recommend removing them from the unit. Some medical-grade units have built-in drawers that are completely acceptable to use. These units are specially designed with forced air refrigeration to provide proper air circulation even with the drawers in place.

It is extremely important to avoid letting the unit door stand open unnecessarily. This negatively affects temperature in the unit and may cause the unit temperature control to respond to the warmer air temperatures in the room. Higher temperatures may cause the unit to work harder and overcompensate cooling making some areas of the unit prone to freezing. Routinely check refrigerator and freezer doors throughout the workday to make sure they remain closed. The use of an open door alarm and self-closing doors may be helpful in preventing a problem. Medical-grade refrigerators and freezers often come equipped with an open door alarm and self-closing doors.

Equipment Maintenance

Keep a logbook for each piece of storage equipment. This will help with troubleshooting if any issues arise. When setting up a storage unit, follow the manufacturer's instructions related to ventilation clearances. If ventilation clearances are not provided, allow at least 4 inches (10 cm) of space between the unit and the wall and 1 to 2 inches (2.5 to 5cm) above the floor. Also ensure that the unit stands firm and level. Nothing should block the cover of the unit motor compartment. Before using the new storage unit, allow for 1 week of temperature readings a minimum of two times each workday, including a minimum/maximum temperature reading each morning. Only the vaccine coordinator or backup coordinator should adjust the refrigerator or freezer temperature. Moreover, if your facility has back-up generators, they should be tested quarterly, receive maintenance at least annually, have sufficient capacity to run continually for 72 hours, and you should have an adequate fuel supply on hand.

Check regularly for signs of wear and tear. Seals should not be torn or brittle and there should be no gaps between the body of the unit and the door when it is closed. The door should open and close properly and fit square against the unit. If it does not, the hinges may need to be adjusted to create a tighter seal.

Regular maintenance is crucial to maintaining maximum performance and extending the useful life of the unit. In a household or commercial refrigerator keep coils and the motor clean of dust and dirt build-up. Dust affects the transfer of heat from coils, and therefore, the efficiency of the unit. True medical-grade refrigerators and freezers will not have exposed coils along the walls of the unit, which prevents this issue. The inside of the unit should be cleaned regularly to prevent bacterial and fungal growth. Frost-free freezers have a drain pan at the bottom of the unit which collects water after the frost melts during the defrost cycle. You do not need to empty the pan regularly as the water should evaporate, however, you may need to clean it once in a while to prevent mold. Refer to the manufacturer's instructions for recommended cleaning schedules. This maintenance is generally not needed with medical-grade units.

Temperature Monitoring

CDC stresses documenting accurate temperature history which reflects actual vaccine temperatures. Investing in reliable temperature monitoring systems is much more cost effective than replacing compromised vaccine due to inaccurate temperature readings. CDC recommends using calibrated temperature monitoring devices with a Certificate of Traceability and Calibration Testing (also referred to as a Report of Calibration). Calibration and traceability testing is performed by a laboratory with accreditation from the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body assures that testing performed meets appropriate standards. An alternative is a laboratory or manufacturer that provides documentation that demonstrated calibration testing performed meets International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 international standards for calibration testing and traceability. CDC recommends the testing be performed by ILAC accredited laboratories. Providers are responsible for maintaining up-to-date certificates of calibration. Manufacturers of medical-grade refrigerators and freezers may be able to provide a Certificate of Calibration for the unit's built in temperature monitoring.

All temperature monitoring devices experience "drift" over time which affects their accuracy. CDC recommends calibration testing every 1 to 2 years from the last testing date or according to the manufacturer's suggested timeline which may be more frequently. VFC providers

should consult their immunization program for their required timeframe for calibration testing. You may also purchase a new temperature monitoring device with a Certificate of Traceability and Calibration Testing (also known as a Report of Calibration). If calibration testing indicates that your temperature monitoring device is no longer accurate within $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$), then it needs to be replaced. Mishandling a temperature monitoring device, such as dropping it or hitting it against a hard surface, can affect the device's accuracy. If there is any doubt whether the device is accurate or not, it should be sent for calibration testing or a new device should be obtained.

CDC recommends using a continuous temperature monitoring device for each storage unit. These devices continuously monitor the temperature to ensure users are aware if there has been a temperature excursion. Min/max thermometers only measure the warmest and coldest temperatures during a period of time. This does not provide enough detailed information to investigate how long the vaccines were out of range or what time of the day the excursion occurred. CDC recommended devices include the following:

- » Digital display on the outside of the unit that allows users to read the temperature without opening the door
- » Detachable probe housed in a bottle with a thermal buffer, such as glycol, to accurately reflect vaccine temperatures
- » Alert when temperature is out of range
- » Accuracy within $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$)
- » Low battery indicator

- » Continuous monitoring and recording capabilities
- » Display of current and min/max temperatures

Many medical-grade refrigerators will have these temperature monitoring features built into the unit as well as provide features that would be available with a digital data logger. Digital data loggers provide many of the same features as continuous temperature monitoring devices, but they also allow for the data to be downloaded and presented on a computer or retrieved from a website for further analysis. Data loggers may also allow for the user to set the desired frequency of temperature readings and review minimums and maximums over a period of time. Reviewing and recording temperatures a minimum of two times each workday, as well as minimum and maximum temperatures since the last reading, is still recommended with the use of continuous temperature monitoring devices and data loggers. Data should be downloaded and reviewed at least once per week. All facilities must keep an ongoing file of temperature data, hard copy and downloaded data, for three years.

CDC does not recommend the following temperature monitoring devices:

- » Chart recorders
- » Fluid-filled biosafe liquid temperature monitoring devices
- » Bi-metal stem temperature monitoring devices
- » Food-grade temperature monitoring devices
- » Household mercury temperature monitoring devices
- » Infrared temperature monitoring devices
- » Any device that is not calibrated

If using a household or commercial grade unit, prior to storing vaccines in a refrigerator or freezer, determine where in the unit provides the most stable temperature readings. This is where vaccines should be stored. This should be in the middle of the unit away from walls, ceiling, cooling vents, the door, the floor, and the back of the unit. Placement of vaccine in a medical-grade refrigerator or freezer should not be an issue as these units are designed to provide a completely reliable, consistent environment. Feel free to ask your manufacturer if they are able to provide temperature mapping data that shows consistent temperatures throughout different areas of the unit.

Lastly, temperature alarms are a way to alert staff of any issues. Staff must be aware of what to do if an alarm sounds. Alarms may notify staff of temperature excursions, a door ajar, equipment failure, power failure, and so on. Properly training staff on how to respond to these alarms is an important part of monitoring.

Storage and Organization

Storage and organization is an important part of maintaining vaccine potency, managing inventory, tracking expiration dates, and accurate administration. Vaccines and diluents should be placed in the central area of the unit, two to three inches away from the unit walls. They should be arranged in rows by type. Allow space between each row to help promote air circulation. Do not over pack the storage unit. This negatively impacts circulation and therefore temperature. This tends to be more of a problem in household or commercial units versus medical-grade refrigerators and freezers.

All vaccines and diluents should be kept in their original packages with lids closed until administration. Removing lids presents significant risk of storage, handling, and administration errors. CDC also advises not to store loose vials or manufacturer-filled syringes outside of their packaging. Make sure to store vaccines with similar names or packaging on different shelves in order to reduce administration error. For example, if you have a pediatric and an adult formulation of the same vaccine do not store them on the same shelf. Make sure all of your vaccines are clearly labeled. CDC provides convenient [printable labels](#) to help you accomplish this.

DTaP (Daptacel) Ages: 6 weeks through 6 years Use for: Any dose in the series Route: Intramuscular (IM) injection	DTaP-IPV (Kinrix) Ages: 4 years through 6 years Use for: DTaP dose #5 IPV dose #4 Do NOT use for DTaP doses 1 through 4 OR IPV doses 1 through 3 Route: Intramuscular (IM) injection Syringe tip cap of prefilled syringe may contain latex
DTaP (Infanrix) Ages: 6 weeks through 6 years Use for: Any dose in the series Route: Intramuscular (IM) injection Syringe tip cap of prefilled syringe may contain latex	DTaP-IPV-HepB (Pediatrix) Ages: 6 weeks through 6 years Use for: DTaP and IPV: Doses #1, #2, and/or #3 HepB: Any dose in the series Do NOT use for HepB birth dose Route: Intramuscular (IM) injection Syringe tip cap of prefilled syringe may contain latex

Trays, uncovered bins, and wire baskets can be used for organization. Some medical-grade refrigerators and freezers offer customized storage options for individual needs such as pull out drawers, pull out shelves, and pull out baskets. These storage options aid in inventory management, organization, and retrieval. Remember, the door of a household or commercial refrigerator is unsafe for vaccines storage. Crisper and vegetables drawers are also unsafe storage locations and should be removed from a unit being used to store vaccines.

Food and beverages should not be stored in any unit containing vaccines. Store these items in separate refrigerator. It is highly suggested that other medications and biologic products be stored in a different unit, but if the facility has no choice, these items may be stored below vaccines and on a dedicated shelf. This reduces the risk of contamination from a spill and helps reduce medication errors. Never store these items in the same tray or container as vaccines.

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.