

The Center for Disease Control and Prevention Vaccine Storage Recommendations for Vaccine Administration Sites

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Healthcare providers across the country are in various stages of implementing changes to meet CDC recommendations for vaccine storage. In 2014 the CDC released these guidelines as part of a Vaccine Storage and Handling Toolkit based on studies conducted by the Advisory Committee on Immunization Practices (ACIP) and the National Institute of Standards and Technology (NIST). The results of these studies indicated that the refrigeration and freezer systems used to store vaccines in clinics and hospitals continued to be a major risk point.

Vaccine Storage Challenges and Risks:

Failure to properly manage vaccine inventories can reduce potency, leading to ineffective vaccinations and poor protection against preventable, yet devastating diseases.

Refrigerators are required to maintain temperatures between 35°F and 46°F (2°C and 8°C). Freezers are required to maintain temperatures between -58°F and +5°F (-50°C and -15°C). Exposing vaccines to temperatures above or below these ranges for even a few minutes can result in patient safety issues. Exposing refrigerated vaccines to freezing tends to have the greatest risk, as freezing vaccines that contain aluminum adjuvants to increase immune responses can result in a permanent loss of potency (2). Unless the vaccine is visibly frozen at the time of inspection, clinicians cannot use visual checks to accurately determine which vaccines may have been damaged as a result of exposure to improper temperatures.

Indirect costs related to ineffective or repeat vaccinations are extensive but very difficult to measure. One estimate, based on reported cases of ineffective vaccines due to improper storage, is that individual states lose over \$3M a year (1). According to a Department of Health and Human Services report, "Vaccines for Children Program - Vulnerabilities in Vaccine Management" released in 2012, 76% of 45 healthcare sites included in a study had vaccines that were exposed to inappropriate temperatures for at least a 5 hour period due to the use of inadequate refrigerators and freezers. These 34 providers had over 9000 Vaccines for Children doses, worth approximately \$370,000 (3). The value of vaccines on hand and at risk in a specific facility will vary, but this value may be between \$15,000 and \$75,000. Healthcare systems that receive government-funded vaccine through programs such as Vaccines for Children (VFC) should be very aware of these financial risks. VFC providers routinely have agreements with State Departments of Health that include financial restitution policies which require providers to replace vaccines deemed non-viable due to provider negligence, including improper storage, on a dose-for-dose basis. These same provider agreements also include terms that allow for compliance site visits and unannounced inspections, further increasing provider risk (4). Based on these direct and indirect cost risks related to improper vaccine storage, the CDC will continue to strengthen vaccine storage programs to help control costs and improve public and privately administered vaccinations.

CDC Recommendations for refrigerators and freezer selection:

The CDC has revised guidelines related to selecting appropriate refrigerators and freezers that will be used for sensitive and expensive vaccine storage. These guidelines are in place to help ensure that vaccines are only stored in refrigerators and freezers that maintain temperature consistently across all storage locations (temperature uniformity), and that required temperature ranges are restored quickly after routine door openings (temperature recovery). According to the CDC Vaccine Storage and Handling Toolkit, healthcare



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professionals should not use household combination units. These units typically use single compressor systems that are not designed to consistently maintain temperatures in both the freezer and refrigerator compartments. Because these units work by circulating air from the freezer compartment to the refrigerator compartment, vaccines are at high risks of being exposed to freezing temperature, as well as other significant temperature fluctuations by storage location. The CDC also has strict recommendations to discontinue the use of “dormitory” style units. These units usually have a single outer door with the freezer compartment located within the refrigerated area. These types of units have demonstrated unacceptable performance for vaccine storage, regardless of the storage location within the chamber, or the size of the unit. The CDC does not recommend these types of units even for temporary storage (1).

Because of stringent temperature ranges required for proper vaccine storage, the risks to public health if vaccines are exposed to unacceptable temperature ranges, and the limitations of many refrigerators and freezers to meet requirements, the CDC has included guidelines for recommended storage equipment. One CDC recommendation includes the use of pharmaceutical or medical grade units that meet vaccine storage guidelines (1). These medical grade units can utilize special designs best suited to protect vaccines. Forced air refrigeration is one example of a design element used to safely and effectively store vaccines. Forced air systems allow for more usable storage space, and decrease risk of user placing vaccines in areas of the refrigerator that do not maintain required temperatures. Medical-grade cold storage is also designed to quickly recover to set temperature after door openings, which can be a frequent event for any vaccine administration site. These systems typically utilize specially designed drawers and shelves to enable proper air circulation, which also assist in temperature uniformity and recovery. Finally, medical grade refrigeration enables precise temperature control and set points, alarms, and can include built-in temperature monitoring that meets CDC recommendations related to calibration.

Conclusion:

Ensuring facilities are using proper cold storage systems designed to maintain required temperature ranges of sensitive and expensive vaccines is a priority for the CDC, and has resulted in the release of new guidelines and recommendations. Following CDC recommendations will help ensure the effectiveness of vaccinations, reduce cost associated with discarded vaccines, as well as reduce the direct and indirect costs of revaccination.

For additional information please reference the Center for Disease Control and Prevention website: <http://www.cdc.gov/vaccines/recs/storage/> or contact Helmer Scientific: <http://www.helmerinc.com/products/pharmacy.html>.

1. US Department of Health and Human Services. Centers for Disease Control and Prevention. Vaccine Storage and Handling Toolkit. May, 2014. <http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf>
2. Journal of Pharmaceutical Science. Vaccines with Aluminum-Containing Adjuvants: Optimizing Vaccine Efficacy and Thermal Stability. August, 2010. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3201794/>
3. US Department of Health and Human Services, Office of the Inspector General. VFC Program Vulnerabilities in Vaccine Management. June, 2012. <http://oig.hhs.gov/oei/reports/oei-04-10-00430.pdf>
4. New York State Department of Health. Vaccines for Children Provider Agreement and Profile. May, 2014. <https://www.health.ny.gov/forms/doh-3836.pdf>

