Vaccine Storage and Handling

INTERIM GUIDANCE

Introduction

In response to recent scientific studies[i] on equipment used for vaccine storage and a better understanding of best practices for vaccine storage and handling, the Centers for Disease Control and Prevention (CDC) is providing interim guidance on appropriate vaccine storage and handling practices. This guidance is intended for use by all public and private sector providers and, while recognizing that cost may be a barrier, we encourage practices to move toward implementing these recommendations as soon as possible. CDC is currently evaluating the most efficient and cost effective method to phase these recommendations in and more guidance is forthcoming.

With the goal of improving the way providers store and handle vaccines nationwide, several important changes have been made to previous recommendations issued by CDC, including:

1. Use of a biosafe glycol-encased probe or a similar temperature buffered probe rather than measurement of ambient air temperatures, and;
2. Use of digital data loggers with detachable probes that record and store temperature information at frequent programmable intervals for 24 hour temperature monitoring rather than non-continuous temperature monitoring, and;
3. Use of stand-alone refrigerator and stand-alone freezer units suitable for vaccine storage rather than combination (refrigerator+freezer) or other units not designed for storing fragile biologics, such as vaccines, and;
4. Discontinuing use of dorm-style or bar-style refrigerator/freezers for ANY vaccine storage, even temporary storage, and;
5. Weekly review of vaccine expiration dates and rotation of vaccine stock.

More detail regarding these changes and the rationale behind them is included below.

Biosafe Glycol-Encased Probes or Similar Temperature Buffered[1] Probes

CDC recommends use of a digital thermometer with a biosafe glycol-encased probe or a similar temperature buffered probe that will more closely approximate the measure of liquid temperature. A temperature buffer enables a thermometer probe to more closely match the temperature changes experienced by stored vaccine. Examples of temperature buffers are a probe inserted into a glycol-filled vial or one inserted into glass beads. CDC recommends this type of probe because studies by the National Institutes of Standards and Technology (NIST), U .S. Dept of Commerce [i] conducted in 2009 showed that compared to temperature monitors that measure ambient air temperature, the digital thermometer with glycol-encased probe more accurately reflects the temperature of the vaccine vial and does not register normal air temperature fluctuations which do not significantly impact vaccine temperature. Because the main factor affecting potency of refrigerated vaccines is exposure to freezing temperatures, it is important that glycol-encased or similar temperature buffered probes be placed among the vaccines instead of on a wall, and at least for refrigerated vaccines, in the part of the refrigerator unit where manufacturer recommended vaccine storage temperatures can best be maintained. To ensure validity of temperature measurements, only calibrated thermometers with a certificate of Traceability and Calibration should be used. Calibrated thermometers will continue to be a requirement for providers who receive VFC vaccine.

Digital Data Loggers for Temperature Monitoring

In addition to the use of a digital thermometer with a biosafe glycol-encased or similar temperature buffered probe, the thermometer should also be able to provide and store data monitoring information set at programmable intervals in an active display that allows for reading temperatures without opening the unit door. This means that the digital data logging thermometer probe should be able to remain in place and not be disturbed during data reading and recording. A detachable probe facilitates downloading temperature data without removing the probe from the storage unit, and should simplify daily use and minimize operator cause of temperature variability. The digital data logger should also include the following:

- Hi/Lo alarm for out-of-range temperatures;
- Current temperature, as well as minimum and maximum temperatures;
- Reset button ;

[1] The purpose of a temperature buffer is to slow the response time of the probe to temperature changes so that it matches the temperature changes experienced by the vaccine.

- Low battery indicator;
- Accuracy of +/- 1°F (0.5°C);
- Memory storage of at least 4000 readings, device will not rewrite over old data and stops recording when memory is full;
- User programmable logging interval (or reading rate).

These changes in the use of systems for continuous temperature monitoring mean more accurate and comprehensive monitoring of any temperature excursions to which vaccines may have been exposed, and diminish the need for opening the unit door while conducting this routine monitoring. Finally, it is a requirement for VFC providers and a recommendation for all providers that storage unit temperatures continue to be read and documented twice each workday. It is recommended that minimum/maximum temperatures be checked and documented once per day preferably in the morning. Reviewing the minimum/maximum temperatures helps to ensure that temperature excursions will be identified more quickly and corrections made that can prevent vaccine loss, as well as minimize the inaccuracy of generalizing twice daily measurements.

Stored temperature monitoring data should be downloaded and reviewed at least weekly by providers, both to ensure the timely review of the data and the appropriate response to issues. When the data is downloaded, the data logger should be reset so there is sufficient memory available. The downloaded information should be kept for a minimum of 3 years or according to individual state record retention requirements. These practices ensure that the data logger will continue to function properly with sufficient memory for accurate monitoring and that problems with storage equipment can be identified and corrected early.

Stand-Alone Refrigerator and Stand-Alone Freezer Units

CDC strongly recommends the use of stand-alone refrigerator and stand-alone freezer units, meaning a self-contained unit that only refrigerates or freezes and is suitable for vaccine storage. These units can vary in size, from a compact, under-the-counter style to a large, stand-alone, pharmaceutical grade storage unit. CDC does not recommend use of dormitory[2] or bar-style refrigerator/freezers for ANY vaccine storage. The use of these specific refrigerator/freezers is not allowed at any time for Vaccines for Children (VFC) program providers.

[2] Dormitory-style or bar-style refrigerator is defined as a small combination freezer/refrigerator unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator. Please note that there are compact, purpose-built storage units for biologics that are not considered to be dormitory-style or bar style.

The characteristics of a recommended storage unit include: 1) enough room to store the year's largest inventory without crowding and 2) sufficient room to store water bottles in the refrigerator and frozen coolant packs in the freezer to stabilize the temperature and minimize temperature excursions that can impact vaccine potency. The addition of water bottles (not gel packs) reduces the risk of freezing due to the tremendous latent heat released from water prior to freezing. In addition, frost-free or automatic defrost cycle units are preferred. Because freezing of refrigerated vaccines affects vaccine potency more than other exposure problems, it is especially important that refrigerators be selected and set up in a way that eliminates the chance of freezing vaccine. Use of stand-alone units is a best practice. Studies by NIST[i] show that 1) dormitory-style or bar-style combination units pose a significant risk of freezing vaccine even when used for temporary storage, and 2) the usual house-hold single-condenser combination refrigerator/freezer units are less capable of simultaneously maintaining proper storage temperatures in the refrigerator and freezer compartments. These refrigerators are cooled by venting cold freezer air into the refrigerated section – thus a real risk of freezing vaccine near the cooling vents. An alternative to stand-alone units is to use only the refrigerator compartment of a combination household refrigerator/freezer unit to store refrigerated vaccines and to be very careful not to use the top shelf if the vent from the freezer opens there. A separate stand-alone freezer should then be used to store frozen vaccines; this is because the freezer compartment of a combined house-hold unit should not be used for vaccine storage if the refrigerator unit is being used for that purpose.

Procedures for Efficient Management of Vaccines

Each provider practice (each location) should have written storage and handling plans, updated annually, both for routine storage and handling of vaccines, and for emergency vaccine retrieval and storage. Plans for routine storage and handling of vaccines should include detailed descriptions of the procedures for: 1) ordering and accepting vaccine deliveries; 2) storing and handling vaccines (e.g., ensuring that refrigerated vaccines are stored between 35°F and 46°F [2°C and 8°C] and frozen vaccines between -58°F and +5°F [-50°C and -15°C]); 3) managing potentially compromised vaccines (i.e., vaccine that has been exposed to temperatures outside of the recommended range defined above); 4) managing vaccine inventory (e.g., checking vaccine and diluent expiration dates weekly and removing expired items from usable stock); and 5) downloading and reviewing electronic monitoring data weekly.

Another necessary component of good practice is ensuring adequately trained vaccination personnel at all levels. This includes personnel that can serve as designated primary and back-up vaccine coordinators, both permanent and temporary staff who are familiar with proper storage and handling policies and procedures, comprehensive storage and handling training for both new staff and maintaining competence of current staff, and accountability checks to ensure protocols are followed. It is also important that a physician partner or member of management is directly involved with the responsible clinical staff – someone with a clear understanding of the vaccine replacement costs of miss-managed refrigerators and vaccine.

Frequently Asked Questions (FAQs) regarding this Interim Guidance are available on our website. The changes summarized in this Interim Guidance will also be reflected in a comprehensive update of CDC's Vaccine Storage and Handling Toolkit (target date for publication Fall 2012). In addition, CDC's posted guidance will continue to be updated as necessary to reflect best practices on vaccine storage and handling. For example, ongoing and planned studies with NIST, U.S. Department of Commerce are being conducted to better understand areas such as optimizing frequency of checking temperature recording by data loggers and packing of vaccine vial boxes for transport.

Thank you and please direct any questions to NIPINFO@cdc.gov

[i] NISTIR 7656 "Thermal Analysis of Refrigeration Systems Used for Vaccine Storage", Michal Chojnacky, Wyatt Miller, Dean Ripple, Gregory Strouse CSTL November 2009
NISTIR 7753 Michal Chojnacky, Wyatt Miller, Gregory Strouse. Thermal Analysis of Refrigeration Systems Used for Vaccine Storage, PML, September 2010