



Vaccine Storage and Handling Guidelines



7 July 2011

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Introduction

Vaccination efforts have been among the most successful and cost-effective ways of preventing and eradicating diseases throughout the world. The success of these programs depends heavily upon the maintenance of vaccine potency and stability through proper vaccine storage and handling practices.

It is essential that administered vaccines retain their potency and that clinics reduce vaccine loss due to improper storage and handling procedures. By understanding and implementing proper vaccine storage and handling practices, staff in immunization clinics and other health care facilities can play a critical role in improving the health of Service members and beneficiaries.

The purpose of this document is to assist immunization clinics and other health care facilities to properly store and handle vaccines.

Definitions

Cold Chain

Cold chain management is the process of preparing temperature-sensitive medical products for shipment utilizing standardized systems and procedures, maintaining required temperatures during all phases of distribution from the time it leaves the manufacturer until administration of the vaccine to the patient.

Compromised Vaccine

Vaccine should be considered potentially compromised if it has not been stored according to manufacturer's guidelines.

Protecting the Department of Defense's Vaccine Supply

Cold Chain Management

Vaccines are sensitive biological substances that can lose their potency and effectiveness if exposed to heat, extreme cold and/or light. For example, certain vaccines lose potency when exposed to room temperature for as little as 30 minutes. Freezing damages almost all refrigerated vaccines.

Vaccines should be stored, shipped, and administered according to pharmaceutical manufacturers' instruction as outlined in the product's package insert or other guidance.



Failure to adhere to recommended specifications for proper storage and handling temperatures may reduce vaccine potency, resulting in an inadequate immune response and protection against disease. The loss of vaccine potency cannot be reversed.

Service members or beneficiaries immunized with compromised or expired vaccines need to be recalled by a health care worker and reimmmunized to make sure that they are protected against the specific vaccine preventable disease(s).

Having to repeat vaccinations due to invalid doses administered with reduced-potency vaccines can affect a large number of patients, causing embarrassment, increased expense, potential liability, and diminished patient confidence in vaccines and in vaccine providers.

Good storage and handling procedures at all immunization locations contributes to our patients receiving the highest quality healthcare possible.

Staff Designated to Monitor Vaccine Storage and Handling Practices

All locations that maintain and administer vaccines will develop and implement policies for maintaining cold chain management.

Each area where vaccines are administered should have one trained person designated as the primary vaccine coordinator and at least one designated as the back-up vaccine coordinator. These individuals should have written duties, and be experts on emergency and routine procedures including vaccine storage, handling, documentation, receiving, inventory management, shipping and transport.



All staff members who administer vaccines should understand the importance of vaccine cold chain management and storage/handling practices. They should be familiar with the appropriate action to take in the event of a break in the cold chain; such as immediately reporting any break in the cold chain to the vaccine coordinator or to their immediate supervisor.

To update all staff members on current immunization policies, review and train vaccine storage and handling practices annually. In addition, build a comprehensive staff orientation program that includes all the components of proper vaccine storage and handling practices and emergency procedures. Document in training records the date and type of vaccine training received.

Routine Vaccine Storage & Handling Plans

The primary vaccine coordinator should develop a Routine Vaccine Storage and

Handling Plan that is kept in a visible location near all vaccine storage units.

The plan should include current contact information for the primary and back-up vaccine coordinators, pharmacy, logistics, local Regional Analyst, USAMMA, vaccine manufacturers, the medical equipment repair office and storage unit alarm company.

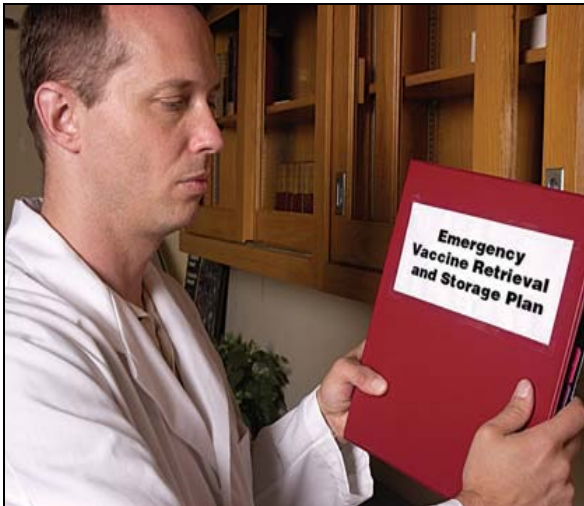
The plan should also include the descriptions of the roles & responsibilities of the primary and back-up coordinators and summaries of the storage requirements for each vaccine and diluent in the inventory.

Protocols for the following should be included in the plan for quick reference: vaccine storage unit temperature monitoring, vaccine equipment maintenance, correct placement of vaccine within storage unit, responding to vaccine storage and handling problems, vaccine inventory management, transporting and receiving vaccine shipments, proper disposal of vaccine and supplies, and samples of forms used in the immunization clinic.

Emergency Vaccine Retrieval & Storage Plan

To protect vaccine inventory and minimize the potential monetary loss from natural disasters, power outages or other emergencies, immunization facilities should develop a Written Emergency Plan to safeguard their vaccine inventories.

Arrange in advance of an emergency, with a nearby alternate facility that has backup power source, to store vaccines during a power loss. Communicate these agreements with providers and staff members.



Establish agreements with other locations within the MTF (i.e. pharmacy, lab, etc), local hospitals, health departments, or National Guard/Reserve units to serve as emergency vaccine storage locations. See pages 23-25 for samples of the Emergency Vaccine Retrieval and Storage Plan Worksheet and the Emergency Response Worksheet.

Vaccine Storage & Handling Equipment

Selecting the Proper Storage Unit

When selecting a vaccine storage unit choose it carefully and use it properly. Select a storage unit that can store the year's largest inventory in the middle and upper shelves without crowding, and that can maintain the required temperature range year-round.

Stand-alone refrigerators and freezers are recommended for storage of vaccines. A combination refrigerator/frost-free freezer for home use is acceptable if there are

separate compartments, external doors, and thermometer controls.



Commercial grade storage units

National Center for Immunization and Respiratory Diseases (NCIRD) recommends not using dormitory style refrigerators for permanent vaccine storage. Use this style of refrigerator only to store a clinic's single-day supply of refrigerated vaccines and then return the vaccines to the main refrigerator at the end of each clinic day. The freezer section of this style of refrigerator should never be used.



Do NOT use dormitory style refrigerator/freezers

Maintain refrigerator temperatures between 2°- 8°C (35°- 46°F). DO NOT expose refrigerated vaccines to freezing temperatures. **Maintain freezer temperatures at -15°C (5°F) or less.** It should never reach temperatures above -15°C (5°F).

For vaccines to remain potent and effective, maintain the recommended temperatures and protect vaccines from light according to manufacturer package inserts.

Place the unit in a well-ventilated room, with adequate space around the sides and top. Good air circulation around the vaccine storage unit is essential for proper heat exchange and cooling functions.

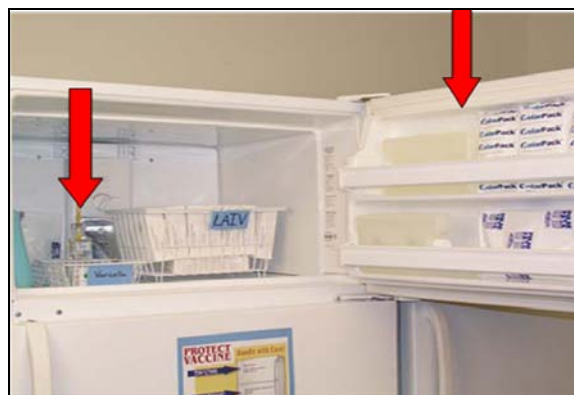
The immunization clinic should maintain a logbook which contains records indicating the serial numbers of each piece of equipment, the date each piece of equipment was installed, the dates of any routine maintenance tasks (such as cleaning), the dates of any repairs or servicing, and the name of the person performing each of these tasks.

Vaccine storage units require regular routine maintenance; a vaccine storage unit monthly care checklist can be found on page 26.

Maintaining the Required Storage Unit Temperature

In order to maintain required temperatures it is necessary to verify that the storage unit capacity is large enough to store the vaccine supply with enough room to allow air to circulate around the vaccine packages. DO NOT pack vaccines tightly together, against the walls or to the top. Allow for 3 inches around the perimeter.

Always close the refrigerator door tightly. Do not store anything else (e.g., lunches, drinks, lab specimens or biologics) in the refrigerator with vaccines.



Frozen packs as buffers in freezer to stabilize temperatures

Stabilize the temperature in the freezer, during frequent opening/closing and power outages, by adding buffers such as frozen packs along the walls, back, and bottom of the freezer compartment and inside the racks of the freezer door. In the case of a storage unit malfunction or electricity disruption, frozen packs can help keep temperatures stable.

Stabilize the inside temperature of the refrigerator by adding buffers such as at least two to three large containers of water. Store the water bottles on the bottom shelf and in the door racks.



Water bottles as buffers in refrigerator to stabilize temperatures

Thermometers

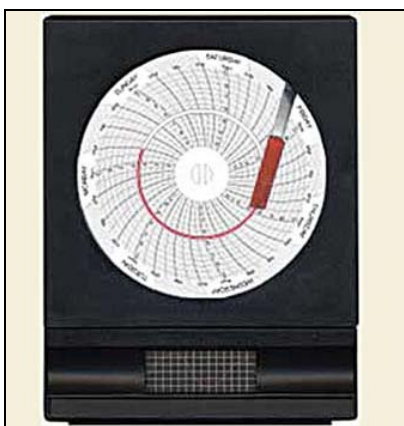
Accurate thermometer readings are essential to determine whether vaccines are maintained at the required temperature.

Storage units should have a National Institute of Standards and Technology (NIST) certified and calibrated thermometer; in each compartment (refrigerator/freezer).



Thermometer calibration certificate

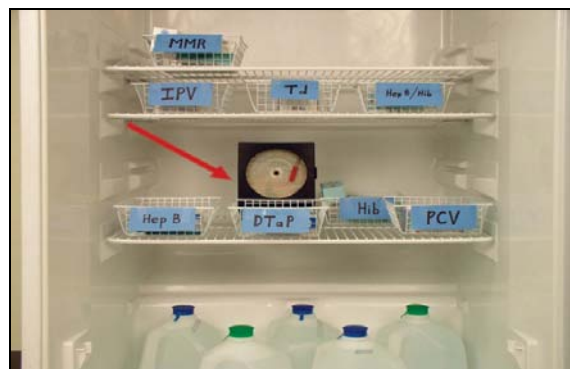
There are several thermometer types available on the market but the CDC recommends a continuous graphic recorder thermometer that monitors temperature ranges and durations which can be recalibrated at specified intervals.



Continuous graphic chart recorder thermometer

Uncertified liquid (mercury or alcohol) thermometers and dial-type household refrigerator/freezer thermometers are not authorized.

The thermometer should be placed in the center of the compartment away from the coils, walls, floor, and fan (never on the door) in order to obtain a true reading of the temperature.



Thermometer placed in center of compartment

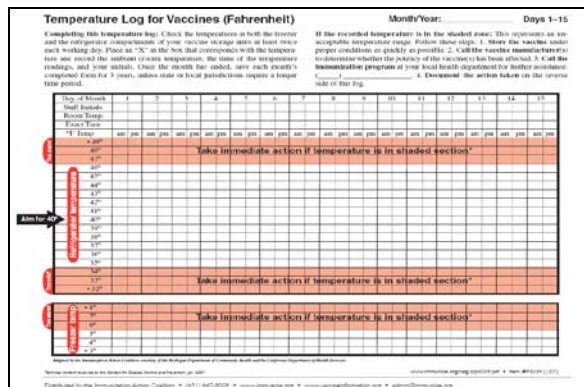
Monitoring & Recording Temperatures

Maintaining accurate and up-to-date documentation of storage unit temperatures assists in the assessment of a cold chain failure should one occur. Manually confirm the temperature of all vaccine storage units a minimum of **TWO** times per day, once at the beginning of the workday and once at the end of the workday.

This recommendation applies regardless of whether or not there is a 24-hour/7-day temperature alarm system, chart recorder thermometer, or digital data logger; they are not substitutes for manually checking and documenting the temperature twice daily.

Document the date, time, and temperature on a vaccine temperature log (examples are on pages 27-34). Under the day of the month, document initials, the time, and place an "X"

on the temp log for the temperature that was observed.



Temperature log for vaccines

On the back of the temperature log, record date/time of any temperature deviation, mechanical malfunction, or power outage of the storage unit. Keep temperature logs for at least three years. State and/or local requirements may require longer record keeping.

Vaccine Storage Troubleshooting Record							
Date	Time	Storage Unit Temp	Room Temp	Problem	Action Taken	Results	Initials
1/11/20	5:00 am	33°F	70°F	Refrigerator temperature 2° lower than acceptable.	Supervisor notified and thermostat adjusted. Temperature in refrigerator and freezer checked every half hour. State contacted.	Refrigerator temperature stabilized at 5°F and freezer temperature stabilized at 5°F	SW

Back of temperature log to record temperature troubleshooting

Only the primary or backup vaccine coordinator should adjust the temperature of the storage unit. Limiting access to the thermostat reduces the risk of the temperature being adjusted improperly.

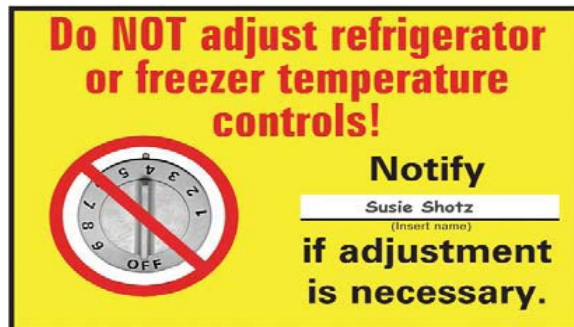
If the thermostat needs adjustment, alert the vaccine coordinator or immediate supervisor. Once the temperature has

been adjusted, check the temperature in both the refrigerator and freezer (if using a combined unit) every half hour until the temperature stabilizes.



Only vaccine coordinator should adjust thermostat

Post a warning sign on the storage unit that indicates who to contact if the temperature requires adjustment.



Place do not adjust warning sign on storage unit

Protecting the Power Supply

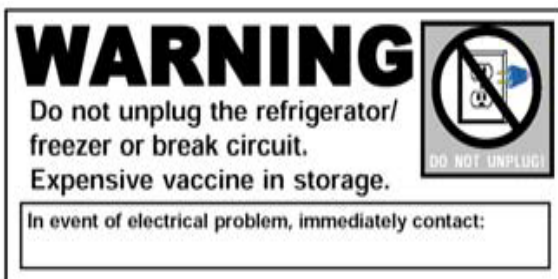
Storage units should be plugged directly into wall outlets; multi-strip outlets or extension cords should not be used.

The storage unit plugs should be secured to the electrical outlet to prevent the unit from accidentally being unplugged or turned off; the use of a safety-lock plug, an outlet cover or a cover outlet with a cage can reduce the chance of this occurring and can prevent accidental disconnection.



Safety plug lock

Place highly visible stickers by the electrical outlets to make sure that the storage unit is not unplugged (e.g., to plug in a vacuum). If needed, multilingual stickers are on the Centers for Disease Control (CDC) website to alert non-English speaking housekeeping or clinic staff.



Use DO NOT unplug signs/stickers as warning

Label the fuses and circuit breakers to alert people not to turn off the power to the vaccine storage unit. These labels should include information concerning the immediate steps to take if power is interrupted.



Label fuses/circuit breakers

Alarm Systems

Incorporate a continuous-monitoring temperature alarm and notification system as part of the storage unit to alert staff of after-hour emergencies/power failures, and to indicate whether the storage unit temperatures have been maintained.

Alarms should be monitored electronically and physically 24 hours a day, seven days a week. When the system detects a power failure, it should immediately notify an accountable person or the system should be capable of indicating that the vaccine temperature integrity was maintained during the storage period and note any deviation.

The entire alarm system from the refrigerator/freezer unit sensor to the remote monitoring station and telephone or pager must be tested at least monthly. Documentation of test should be maintained for a minimum of three years.

For vaccine storage units located in restricted access areas, assure the temperature can be checked and a light or audible alarm is installed to indicate when the storage unit temperature is out of range without having to physically enter the restricted area.

Facilities storing large vaccine inventories should install a backup generator that automatically provides power to the storage units in the event of power outage.

Backup generators should be of a sufficient capacity to run for 72 hours if necessary and plans should be made for an adequate

supply of fuel to be on hand. Test backup generators quarterly.



Back-up generator in case of power outage

Vaccine Inventory Management

Ordering Vaccines

Order and stock enough vaccine so there is an adequate supply to meet the needs of the beneficiary population; to know how much vaccine is needed, look at the monthly average amount of each vaccine used.

Do not over order vaccines. This practice leads to vaccine waste if unused vaccine expires and increases the risk of losing a large quantity of vaccine should there be a storage and handling compromise.



Monitor vaccine usage and rotate stock

Receiving Vaccine Shipments

Notify the primary vaccine coordinator or designated backup immediately upon arrival of a vaccine shipment to verify that the cold chain was maintained and the vaccine is unpacked and stored under appropriate conditions.

Upon delivery, open the package as soon as possible to be certain that the full order was received and that the order matches the packing slip.

Check the expiration dates on the vaccines received; always use the shortest-dated vaccines first.

Unpack vaccines from the transport container and store them in their original box regardless of their bulkiness. Removing vaccines from the original box exposes vaccines to room temperature and light.



Inventory/unpack vaccines as soon as shipment arrives

A temperature-monitoring device called a TempTale will be in the anthrax, flu and smallpox shipping containers. The TempTale provides complete time and temperature history on all vaccine

shipments. Collected data is evidence that the refrigerated vaccines have not been exposed to temperatures above 46°F or below 35°F, and frozen vaccines have not been above 5°F.

Locate the TempTale and the TempTale return document in the packaging. Then call USAMMA DOC case manager, they will ask for the TempTale tracking number and the TempTale readout while it is still in the box. If a sunshine icon is displayed on the screen, then the package is currently at the required temperature. To stop the temperature recording, the case manager will need to have the red button pushed until a stop sign icon is displayed.

Return the TempTale by placing it in the return envelope provided and scheduling for a carrier pick up. If overseas, fill out a complete customs invoice as well.

Place the vaccines in the appropriate storage compartment, but do not use the vaccine until USAMMA DOC reviews the TempTale data and verifies the vaccine has not been compromised during shipment.

Vaccine & Diluent Storage Practices

Placement and Labeling of Vaccines in Storage Unit

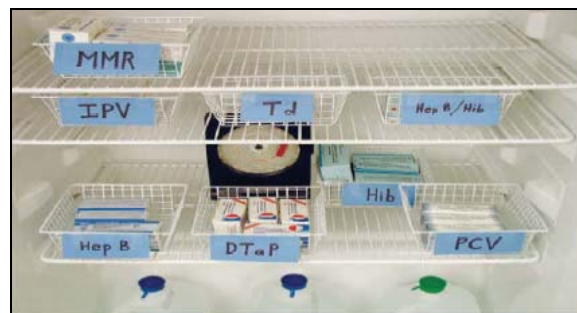
To prevent exposure to warmer temps, store vaccines on the middle shelves of the storage unit and **NEVER** store vaccines on the doors or in the vegetable bins. Leave space between the vaccine packages to allow air to circulate.



No vaccine should be stored on refrigerator/freezer doors or drawers

Always protect vaccines from sunlight and fluorescent light by storing all opened and unopened vials of vaccine in their boxes. Vaccine vials outside of their boxes makes inventory management and tracking expiration dates more difficult, exposes vaccines to light, and leads to administration errors when vials are confused.

Store each vaccine in its own specifically labeled section of the storage unit; this helps decrease the chance that someone will mistakenly administer the wrong type of vaccine.



Store vaccine in own specifically labeled section

Bins, baskets, or some other type of uncovered containers with slotted sides or openings should be used to store vaccines.

Each tray or container should only store vaccine of the same type; store adult and pediatric vaccines separately.



Attach labels directly to shelves/trays

Attach labels directly to the shelves or trays on which the same types of vaccines are sitting. Label and store vaccines & diluents in accordance with the manufacturer's package insert. (Examples of how to set up the refrigerator or freezer can be found on pages 35-37).

Check vaccine expiration dates regularly. Move vaccines with shorter expiration dates to the front of the storage unit so that they are used first. Always check expiration dates before using the vaccines and remove expired vaccines and dispose of them according to local regulations.

Label diluent clearly, whether stored at room temperature or in the refrigerator, **NEVER** freeze diluent. If stored in the refrigerator, place diluent on the lower shelves or in the door.

Storage of Vaccines and Diluents

SINGLE-DOSE VIALS: Single-dose vials are for one-time use only. Once the protective cap is removed, administer the

vaccine from the single-dose vial as soon as possible.

Do not open single-dose vials until ready to use because it may not be possible to determine if the rubber seals have been punctured, and the vaccine contaminated. Discard all single-dose vials without their protective caps at the end of the clinic day.



Discard unsealed single dose vials at end of day

MULTI-DOSE VIALS: Multidose vials contain bacteriostatic agents that prevent the growth of bacteria that allow them to be used until the date of expiration printed on the vial (which is different from the normal 28-day rule for medications). This rule holds true unless the multidose vial is not stored properly, becomes contaminated or the product package insert says otherwise.

On July 20, 2010, The Joint Commission published a FAQ sheet on its website that explained its rules for the use of multi-dose vials and their expiration dates. The FAQ sheet exempts all vaccines from the 28-day rule and states:

“The CDC Immunization Program states that vaccines are to be discarded per the manufacturer’s expiration date. The Joint Commission is applying this approach to all vaccines with the understanding that the vaccine is stored & handled appropriately (correct temperature is maintained, frequency of temperature checks, etc).”

Always use aseptic technique when withdrawing vaccine from a multidose vial. Mark the date/time and initial all multidose vials when the first dose is withdrawn. Immediately after drawing up the dose, return unused vaccine to the storage unit.



Mark multidose vials with date opened and reconstituted
multidose vials with date/time reconstituted

RECONSTITUTED VACCINES: Vaccines that come as lyophilized (freeze-dried) powders are mixed with a liquid (called a diluent) in a process known as “reconstitution” before they can be administered.

Once lyophilized (freeze-dried) vaccines have been reconstituted, they must be used within a specified period or discarded. Review package insert for allowed time between reconstitution and use (i.e. Menomune 30 minutes). Mark reconstituted

vaccine vials with the date and time it was reconstituted. See page 38, Vaccines with Diluents: How to use them for reference.

DILUENTS: Diluents are not interchangeable, unless specified by the manufacturer. Therefore, use only the specific diluent provided by the manufacturer for each type of vaccine to preserve the potency and safety of the resulting mixture.

Diluents vary in their volume. Always verify with package insert the amount of diluent to utilize (i.e. smallpox, etc). Diluents also vary in their ingredients. Some consist of sterile water only, while others may contain a second part of the vaccine, or a variety of other substances used to dissolve the lyophilized vaccine into a liquid, stabilize the reconstituted vaccine, and/or maintain the sterility of the reconstituted vaccine.

MANUFACTURER PREFILLED

SYRINGES: Manufacturer-filled syringes are an alternative to prefilling syringes by hand. These syringes are prepared under sterile conditions that meet standards for proper handling and storage, and are individually labeled. As long as prefilled syringes are stored under appropriate conditions (light and temperature) they may be used until their date of expiration.



Manufacturer prefilled syringes

Some manufactured prefilled syringes come with a needle already attached, while others need to have a needle attached prior to use. Make sure to attach the needle to the prefilled syringe just prior to administration.

If a needle is attached to the syringe or the needle cap is removed and vaccine is not administered by the end of the clinic day, discard the needle and syringe because the sterility of the syringe can no longer be confirmed.

PREFILLING SYRINGES: Although pre-filling syringes is highly discouraged because of the increased risk of administration errors and possible bacterial growth in vaccines that do not contain preservatives, a small amount of vaccine may be pre-drawn in a mass immunization setting (i.e. flu clinic) if the following procedures are followed:

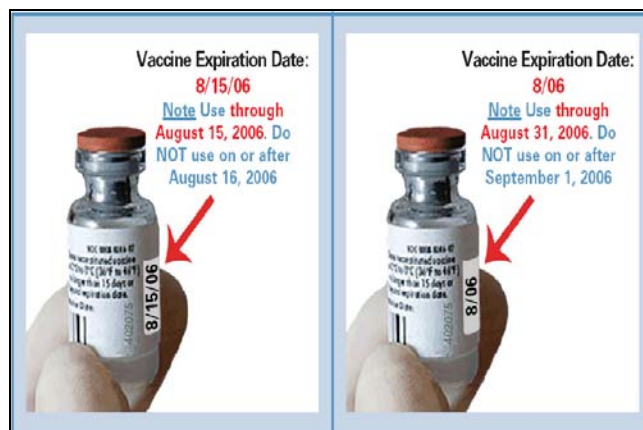
- Only one vaccine type may be administered at the clinic. If more than one vaccine type is to be administered, separate vaccine administration stations must be set up for each vaccine type to prevent medication errors.
- Vaccine should **NOT** be drawn up in advance of arriving at the clinic site. Because of the lack of data on the stability of vaccine stored in plastic syringes, the practice of drawing up quantities of vaccine hours or even days before a clinic is not acceptable.
- Vaccine should be transported to the clinic

site in the manufacturer-supplied packaging.

- Patient flow should be monitored to avoid drawing up unnecessary doses. Draw up no more than 10 syringes at a time.
- At the end of the clinic day, discard any remaining vaccine in syringes; they cannot be used on subsequent days.

Expiration Dates, Soon to Expire Vaccines, Disposition & Disposal

Use vaccine or diluent before or up to the expiration date printed on the label. Never administer expired vaccine and diluent, even if they are only one-day past their expiration date.



Expiration date may be labeled as mo/day/yr or just mo/yr

Promptly remove mishandled or expired vaccine and diluent from the refrigerator or freezer and dispose of it according to local policy.

If there are vaccines that will expire in 3 months or less that cannot be used prior to the expiration date, notify the local MILVAX Regional Analyst, USAMMA, or pharmacy

to see about redistributing the vaccines to another immunization site.

Contact the pharmacy or logistics office for specific policies regarding the disposition of unopened vials, expired vials, unused doses, doses drawn but not administered, and potentially compromised vaccine.

In general, vaccine and diluent vials, used needles, and used syringes (that may or may not contain vaccine) may be dropped into a sharps container and autoclaved, or disposed of following the procedures for all other biohazard materials per installation regulations or state law.

Administration of Exposed or Expired Vaccine

Vaccine exposed to excessive heat, cold, or light that have lost potency should not be administered. If an expired or mishandled dose of vaccine is administered, the dose may be considered invalid and may need to be repeated.

Responding to Vaccine Storage and Handling Problems

Potentially Compromised Vaccine Procedures

It does no good to record the temperatures of the refrigerator and freezer daily if the person recording the temperature of the refrigerator is not aware that a temperature above 8°C (46°F) is too high. Immediate action must be taken to correct any out of range temperatures.

Accomplish the following if there is a possible compromise:

- Label potentially compromised vaccine with the words “DO NOT USE” and place in a working storage unit, per manufactures recommendation, as if the vaccine was not compromised. **DO NOT** leave vaccine in malfunctioning vaccine storage unit.



Label potentially compromised vaccine with the words DO NOT USE and place in properly functioning storage unit

- Record the room temperature and the temperature inside the refrigerator and freezer at the time the problem was discovered. In addition, record the length of time the vaccine was potentially exposed to out-of-range temperatures and note if the refrigerator had water bottles and the freezer had frozen packs at the time of the event.
- Inventory the vaccines affected by this event, and report all potentially compromised vaccine losses through Service-specific channels, USAMMA DOC and to the local Military Vaccine Agency Regional Analyst (RA). The RA

will provide assistance in managing and documenting the incident.

- Prepare an Executive Summary (EXSUM), which must include the following: description of the incident, temperature of the refrigerator or freezer when discovered, brand/lot #/number of unopened vials or syringes of vaccines potentially compromised, the cost (broken down by each type of vaccine and then total), and the corrective action taken.
- Never use or discard the vaccine until USAMMA confirms the compromise and the facility has assessed the situation.

Power Outages

When state officials, local officials, or the installation command have reasonable cause to believe that a power outage may occur, emergency procedures should be implemented in advance of the event and steps should be taken to pack and move vaccines to an alternate site with a working storage unit per the facilities' emergency plan.

If there is a power outage in the building where vaccines are being stored activate the Emergency Vaccine Retrieval and Storage Plan per facility guidelines.

Record the room temperature, duration of power outage, and temperature(s) inside the unit(s) as soon as possible after power is restored. This will provide data on the maximum duration the vaccines were exposed to elevated temperatures.

If the temperature inside the refrigerator has exceeded the recommended range of 35° to 46°F (2° to 8°C) or if the temperature inside the freezer has risen above 5°F (-15°C), record the duration of incorrect temperature exposure and contact USAMMA for further guidance.

Procedures to Follow after Power Supply is Restored

Record the time and temperature of storage unit when the electrical supply is restored and again when the thermometer reading is within the recommended range.

Set empty refrigerator unit temperature to 40°F and set freezer unit to 5°F or lower. Adjust the temperature in small increments and continue to monitor until the target temperature is reached.

Record temperatures twice per day for a minimum of 5 working days, once they are stable at the target temperatures then place the vaccines in the unit.

Vaccine Transport Procedures

Protecting Vaccines at Off-site Immunization Sessions

- Only pack vaccine amount expected to be used during the immunization session /clinic. **DO NOT** prefill syringes prior to arrival at vaccination site. **DO NOT** remove vaccine vials from their original boxes.
- Maintain the required temperature and safeguard the potency of administered vaccine by minimizing the number of times the container is opened during an immunization session/clinic.



Endurotherm insulating shipping containers



Styrofoam™ coolers

- Vaccine in an approved insulated container **MUST** have the temperature checked and documented every hour.
- Individuals taking vaccines to an off-site clinic should fill out a issue receipt with the number/type of vials taken and sign that they understand they must keep the vaccine at the required temperatures. When returning the vaccine, document the number and type of vaccine vials returned and sign a verification that the required temperatures were maintained.

Validated Shipping/Transport Containers

Always ship/transport vaccines in validated insulated containers capable of maintaining the required temperatures. Validated storage devices approved for shipping/ transport include the Endurotherm insulating shipping containers, Styrofoam™ coolers with at least 2-inch thick walls (e.g. manufacturer shipping container), VaxiPac, or the VaxiCool.

Use the VaxiPac to transport small quantities of refrigerated vaccines (up to 24 vials) for less than 24 hours. The refrigerant for the VaxiPac are two silver coolant bricks called VaxiSafe, which protect the vaccine against varying temperatures.



VaxiPac and VaxiSafe (silver brick)

Only use the VaxiSafe with the VaxiPac coolers. Do not use gel/frozen packs and do not place VaxiSafe coolant packs or the VaxiPac in the freezer.

The VaxiSafe coolant packs must be chilled to 4°C for at least 24 hours in an accurate temperature-controlled cooler or refrigerator before being packed. Make sure to store VaxiSafe flat to avoid physically deforming the shape or packaging of the VaxiSafe.

The VaxiCool is a high efficiency freezer or refrigerator system designed for local transport and temporary storage of up to 400 vials of vaccine; it is not intended to be a daily storage unit. Plug the unit into a power outlet or use the battery system that can last 6 to 7 days when fully charged.



VaxiCool is a high efficiency refrigerator or freezer

Packing Vaccines for Transport or Shipping

When transporting or shipping vaccines, they must be packed appropriately in validated containers to maintain the required temperatures. Go to the link for USAMMA for proper packing protocols: http://www.usamma.army.mil/cold_chain_management.cfm

Include calibrated thermometers to track temperatures hourly in all transport storage containers. Document the storage unit temperature when the vaccine is removed for transport and when the shipment is

received to identify any temperature deviations during transport.

Document vaccine type(s), quantity, date, time, and originating facility and phone number on the outside of the transportation containers. To identify the contents as being valuable and fragile attach labels to the outside of the containers carrying refrigerated or frozen vaccines.



Attach labels to identify contents as fragile

Vaccine Packing Practices:

- Pack the refrigerated vaccines first, using enough cold (refrigerated) packs to maintain the cold chain. The number and placement of cold (refrigerated) packs inside the container will depend on container size and outside temperature.
- Pack frozen vaccine last using a separate insulated container, removing them from the freezer and packing them with dry ice (or according to package insert) immediately before transport.
- Always place an insulating barrier (e.g., crumpled packing paper, bubble wrap, etc.) between the cold (refrigerated) or frozen packs and the vaccines to prevent accidental freezing. **NEVER** place vaccines directly on frozen packs.



Always use insulating barrier (i.e. crumpled paper, bubble wrap, etc) to protect vaccine from accidental freezing

- The contents of the container should be layered as follows: cold (refrigerated) or frozen packs, barrier, vaccine, thermometer or temperature monitor, another layer of barrier, and additional cold (refrigerated) or frozen packs.
- Place thermometers near the vaccine, and not in direct contact with the frozen or cold (refrigerated) packs, to assess whether the cold chain has been broken.



Place thermometer near vaccine not in direct contact with frozen or cold packs

Remember that USAMMA is always available to answer questions on redistribution or packing protocols.

Storage and Handling Resources

Military Vaccine Agency (MILVAX):

supports DoD vaccination programs protecting Military Service Members, their dependents and beneficiaries; and provides educational support and training resources for DoD healthcare personnel. Contact the MILVAX Agency using the following:

1- (877) GET-VACC or (877-438-8222)

Email: vaccines@amedd.army.mil

Website: www.vaccines.mil

Storage and Handling Webpage:

<http://www.vaccines.mil/storageandhandling>

MILVAX Regional Analysts (RA): Contact the nearest RA to discuss training needs, policy or assistance with storage and handling issues. A RA listing and area of responsibility can be found at the MILVAX website:

<http://www.vaccines.mil/POCmap>

USAMMA/DOC: United States Army Medical Material Agency/Distribution Operation Center is the DoD agency responsible for managing and coordinating the packing and storage of Temperature Sensitive Medical Products (TSMPs). For vaccine TSMP questions contact them during the hours of 0700-1700 EST at phone: (301) 619-4318, 1197, 4198 or after hours for urgent issues only call: (301) 676-1184, 0857, or (301) 256-8072 or email them at

USAMMADOC@amedd.army.mil.

For additional information go this website:

http://www.usamma.army.mil/cold_chain_management.cfm

Centers for Disease Control and Prevention (CDC): have various storage & handling tools, documents, videos, and training resources available at the following:

<http://www.cdc.gov/vaccines/recs/storage/default.htm>

Immunization Action Coalition (IAC): have storage and handling tools that can be customized for individual use, available at the following:

<http://www.immunize.org/handouts/vaccine-storage-handling.asp>

Additional Resource List

Army Regulation (AR) 40-562, BUMEDINST 6230.15A, AFJI 48-110, CG COMDTINST M6230.4F, Immunizations and Chemoprophylaxis. Available at http://www.vaccines.mil/documents/969r40_562.pdf

Centers for Disease Control and Prevention. General Recommendations of Immunizations. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2011; Vol. 60 (No. 2).

Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book). Atkinson W, Wolfe S, Hamborsky J, eds. 12th ed. Washington DC: Public Health Foundation, 2011; 61-74.

Centers for Disease Control and Prevention (CDC). Notice to Readers: Guidelines for Maintaining and Managing the Vaccine Cold Chain. Recommendations of the Advisory Committee on Immunization Practices. MMWR 2003; 52(42); 1023-1025.

Centers for Disease Control and Prevention, Vaccine Storage and Handling Toolkit. Available at <http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/shipments.pdf>

Department of the Army, MEDCOM Memorandum, "Safeguarding Temperature Sensitive Medical Products (TSMP)," dated 05 March 2010. Available at <http://www.usamma.army.mil/assets/docs/SAFEGUARDING%20TSMP.PDF>

SB-8-75-11, Department of the Army Medical Department Supply Bulletin. Section 3-65: Temperature Sensitive Medical Products (TSMP) Storage and Handling (pg 62) Available at <https://www.vaccines.mil/storageandhandling>

The Joint Commission, Standards Frequently Asked Question Details. Available at http://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFaqId=143&ProgramId=1

U.S. Army Medical Materiel Agency (USAMMA)/Distribution Operations Center (DOC). Available at http://www.usamma.army.mil/cold_chain_management.cfm

Vaccine Coordinators

	Vaccine Coordinators	Title	Telephone (Home and Cell)
Primary			
Backup			

Emergency Staff Contact List

	Name	Title	Telephone (Home and Cell)
1.			
2.			
3.			
4.			
5.			
6.			

*List contacts in order of preference. Determine whether all or certain persons on the list should be contacted or if the first person reached is sufficient. Include the primary and backup vaccine coordinators on the list.

Vaccine Storage Unit Specifications

Type of Unit (Refrigerator, Freezer, VaxiCool)	Brand	Model Number	Serial Number

Alternate Vaccine Storage Facility(s)

	Location	Contact Person (Title)	Address	Telephone (Home and Cell)
Alternate Vaccine Storage Facility (1)				
Alternate Vaccine Storage Facility (2)				
Alternate Vaccine Storage Facility (3)				

Emergency Resources Contact List

Emergency Resources	Contact Person (Title)	Telephone Numbers (Home and Cell)
U.S. Army Medical Materiel Agency (USAMMA) Website: www.usamma.army.mil	Operations Manager	24 hours emergency line: 301-676-1184/0857 DSN 343-4318
DLA Troop Support	Cold Chain Program Manager	Office: 215-737-5365 DSN: 444-5365
Pharmacy		

	Location	Contact Person (Title)	Telephone Numbers (Home and Cell)
Electric Power Company			
Refrigerator/Freezer Repair Company			
Alarm Company			
Generator Repair Company			
Generator Fuel Source			
VaxiCool Repair			
Medical Maintenance Department			

Emergency Response Worksheet

What to do in case of a power failure or another event that results in vaccine storage outside of the recommended temperature range

Follow these procedures:

1. Close the door tightly and/or plug in the refrigerator/freezer.
2. Ensure the vaccine is kept at appropriate temperatures. Make sure the refrigerator/freezer is working properly or move the vaccines to a unit that is. Do not discard the affected vaccines. Mark the vaccines "DO NOT USE" so that the potentially compromised vaccines can be easily identified.
3. Notify USAMMA/DOC and your local MILVAX Regional Analyst.
4. Record action taken.

Record this information*:

1. Temperature of refrigerator: current _____ max. _____ min. _____
2. Temperature of freezer: current _____ max. _____ min. _____
3. Air temperature of room where refrigerator is located: _____
4. Estimated amount of time the unit's temperature was outside normal range:
refrigerator _____ freezer _____
5. Vaccines in the refrigerator/freezer during the event (use the table below)

* Using a recording thermometer is the most effective method of tracking the refrigerator and freezer temperatures over time. Visually checking thermometers twice a day is an effective method to identify inconsistent or fluctuating temperatures in a refrigerator and freezer.

Vaccines Stored in Refrigerator

Vaccine, manufacturer, and lot #	Expiration date	# of doses	# of affected vials	Action taken

Vaccines Stored in Freezer

Vaccine, manufacturer, and lot #	Expiration date	# of doses	# of affected vials	Action taken

Other Conditions

1. Prior to this event, was the vaccine exposed to temperatures outside the recommended range? Y N
2. Were water bottles in the refrigerator and ice packs in the freezer at the time of this event? Y N
3. Other: _____

Manufacturers

Intercell USA, Inc.	(301) 556-4500
CSL Biotherapies, Inc.	(888) 435-8633
Emergent BioSolutions	(866) 300-7602
GlaxoSmithKline	(888) 825-5249
MedImmune, Inc.	(877) 633-4411
Merck & Co., Inc.	(800) 672-6372
Novartis Vaccines	(800) 244-7668
Pfizer Inc. (Wyeth)	(800) 438-1985
sanofi pasteur	(800) 822-2463

Other Resources

USAMMA/DOC phone #: (301) 619-4318/1197, after hours: (301) 676-1184/0857 MILVAX Regional Analyst phone #: _____

Adapted by the MILVAX Agency, courtesy of the Immunization Action Coalition

Monthly Care of Vaccine Storage Units

A small amount of regular maintenance is necessary to help ensure that vaccine refrigerators and freezers work properly. Follow the three steps below to keep household-style refrigerators and freezers clean.

1. Clean the inside of the storage units

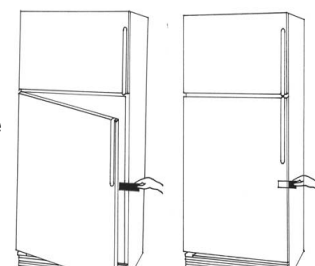
Cleaning the inside of the refrigerator and freezer will help prevent the growth of bacteria and fungus. Do not remove the vaccine from the unit to clean it. Just move the trays of vaccine as you clean. **Do Not Unplug the Unit.**

- a. Clean any spills.
- b. Wipe the inside of the compartment and the shelves with disinfectant or antibacterial wipes. Let it dry.
- c. Put the trays of vaccine back where they were.

2. Check the Door Seals

Refrigerators and freezers have flexible door seals that prevent cold air from escaping when doors are closed. If the seal does not seal completely, cold air escapes. This can cause temperatures to fluctuate in the unit. **Do Not Unplug the Unit.**

- a. Examine the seals.
 1. They should not be torn or brittle.
 2. When the unit is closed, there should be no gaps between the seals and the body of the unit.
- b. Verify that the vaccine storage unit door is sealing properly:
 1. Place a thin paper strip between the door seal and frame (see illustration)
 2. Close the door
 3. Pull the paper strip. If it moves easily or falls away by itself, the door and rubber-like seal need to be adjusted.
 4. Check all the way around the door; pay particular attention to the corners.
- c. Alert your supervisor if you suspect a problem with the seals.



Checking the door seals

3. Clean the Coils

Examine and clean refrigerator coils of dust and dirt build-up to prevent affecting the efficiency of the unit. This process should only take a few minutes; therefore, it is not necessary to transfer the vaccine to another storage unit as long as the doors remain tightly closed for duration of the cleaning.

- a. Unplug the unit. Use a soft brush, cloth or vacuum cleaner with an attachment hose to remove dust from coils.
- b. After cleaning, plug in the unit and document that the power is restored and the temperature is maintained. Avoid cleaning on Friday; accidental damage to coils could cause problems that might not be detected over the weekend.

	Jan	Feb	Mar	Apr	May	June	July	Aug	Sep	Oct	Nov	Dec
Clean*												
Seals*												
Coils*												

* Initial and date next to the completed items.

NOTE: VaxiCool Units: to maintain good operation the condenser must be kept cleaned of dust and dirt, the external electrical connectors should be kept clean, the lid gaskets should be kept clean and free of cuts and rips, and batteries should be kept charged and terminals kept clean of corrosion.

Questions/Comments: Contact 1-877-GETVACC, (877-438-8222) or USAMMA/DOC at 301-619-4318, 1197, 4198.

Vaccine Refrigerator Setup

Storing Vaccines

Carefully organizing vaccines in a refrigerator helps protect vaccine and facilitates inventory management.

Refrigerator-only Unit

Almost all of the space is usable (inside dashed lines).

✓ Place vaccine in breathable plastic mesh baskets and clearly label baskets by type of vaccine.

✓ Group vaccines by pediatric, adolescent, and adult types.

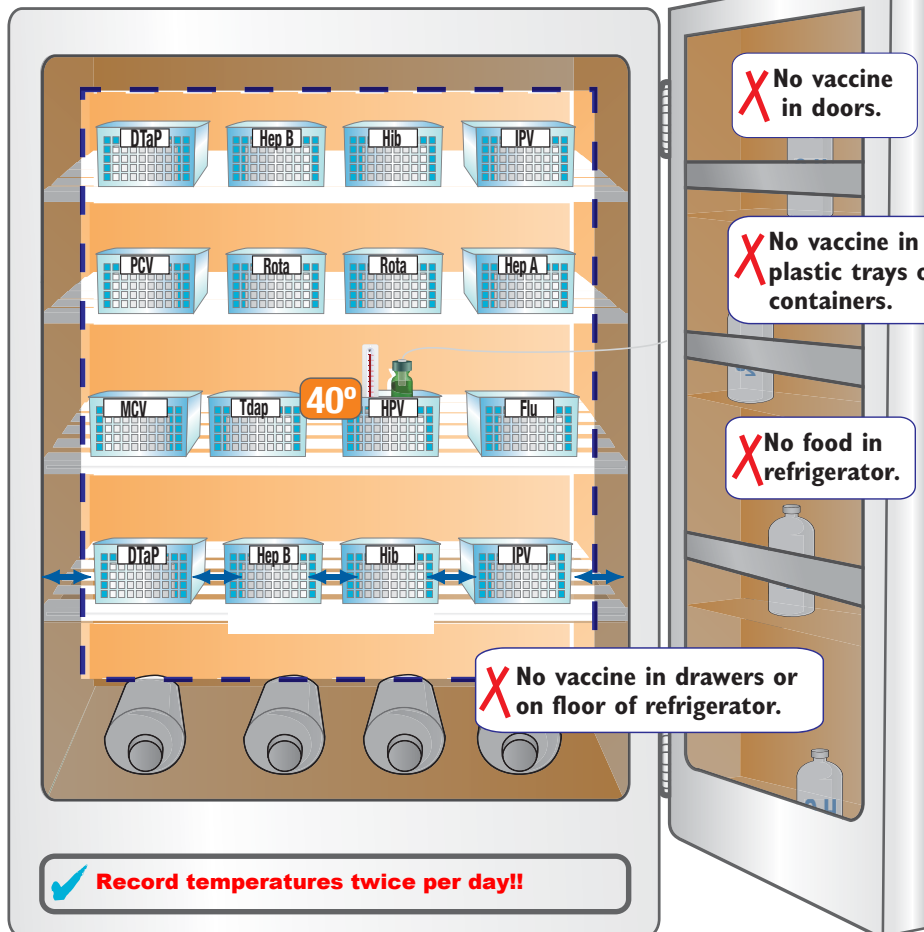
✓ Place thermometer in the center of the refrigerator away from coils, walls, floor and fan.

✓ Keep baskets 2-3 inches from walls and other baskets.

✓ Keep vaccines in their original boxes until you are ready to use them.

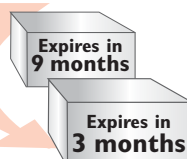
✓ Store only vaccine and other medication in vaccine storage units.

✓ Use buffers (such as water bottles) to stabilize refrigerator temperature.



✓ Keep vaccines with shorter expiration dates to front of shelf.

If you have vaccine that will expire in 3 months or less that you will not be able to use, notify USAMMA, local RA or pharmacy.



✓ Keep temperatures between 35°F to 46°F.



If you have any problems with your refrigerator, keep the refrigerator door shut and notify medical equipment repair office.

MILVAX Regional Analyst (RA): _____ MILVAX RA Phone #: _____

Adapted by the MILVAX Agency courtesy of the California Department of Public Health, Immunization Branch.

Vaccine Refrigerator Combo Setup

Storing
Vaccines

Carefully organizing vaccines in a refrigerator helps protect vaccine and facilities inventory management.

Refrigerator in a Combination Unit

Usable space is limited (inside dashed lines).

✓ Place vaccine in breathable plastic mesh baskets and clearly label baskets by type of vaccine.

✓ Group vaccines by pediatric, adolescent, and adult types.

✓ Place thermometer in the center of the refrigerator away from coils, walls, floor and fan.

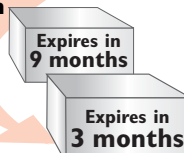
✓ Keep vaccines in their original boxes until you are ready to use them.

✓ Store only vaccine and other medication in vaccine storage units.

✓ Use buffers to stabilize refrigerator temperature.

✓ Keep vaccines with shorter expiration dates to the front of shelf.

If you have vaccine that will expire in 3 months or less that you will not be able to use, notify USAMMA, local RA, or the pharmacy.



✓ Keep temperatures between 35°F to 46°F.



✗ Keep vaccine away from all cold air vents. The vents blow in very cold air from the freezer which can damage vaccines.

✗ No food in refrigerator.

✗ No vaccine in doors.

✗ No vaccine in solid plastic trays or containers.

✗ No vaccine in drawers or on floor of refrigerator.

Record temperatures twice per day!!

If you have any problems with your refrigerator, keep the refrigerator door shut and notify the medical equipment repair office.

MILVAX Regional Analyst (RA): _____ MILVAX RA Phone#: _____

Adapted by the MILVAX Agency courtesy of the California Department of Public Health, Immunization Branch

Vaccine Freezer Setup

Storing Vaccines

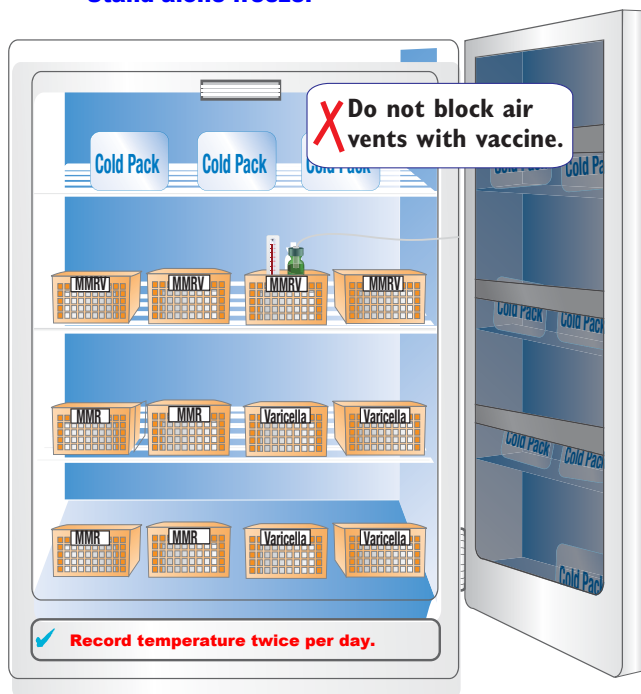
Carefully organizing vaccines in a freezer helps protect vaccine and facilitates vaccine inventory management.

Stand-alone freezer

✓ Place vaccine in breathable plastic mesh baskets and clearly label basket by type of vaccine.

✓ Place thermometer in the center of the freezer away from walls, floor and fan.

✓ Use buffers to stabilize freezer temperatures (i.e. cold packs).



✓ Keep vaccines with shorter expiration dates to the front of shelf. If you have vaccine that will expire in 3 months or less that you will not be able to use, notify USAMMA, local RA or pharmacy.



✓ Keep temperatures 5°F or colder.

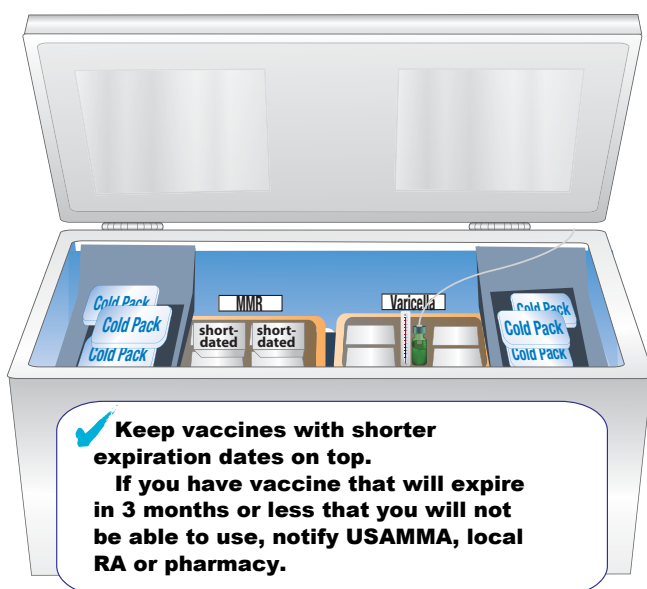
Aim for 0°F and below

Colder is better

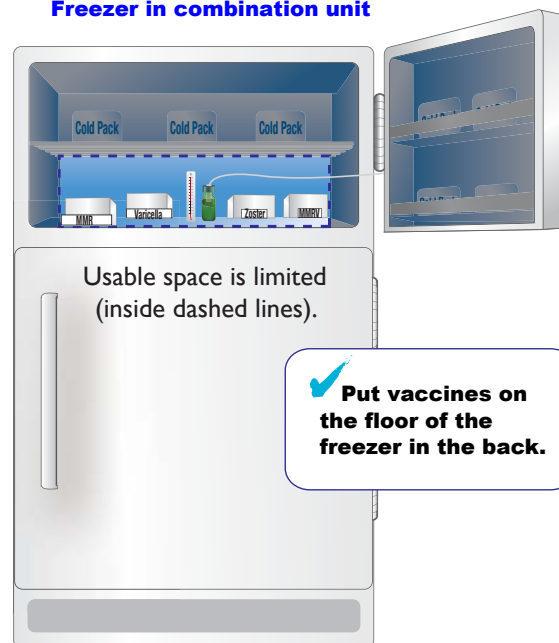
Above 5°F is too warm!



Chest Freezer



Freezer in combination unit



If you have any problems with your freezer, keep the freezer door shut and notify your medical equipment repair office.

MILVAX Regional Analyst (RA): _____ MILVAX RA Phone #: _____

Adapted by the MILVAX Agency courtesy of the California Department of Public Health, Immunization Branch.

Vaccines with Diluents: How to Use Them

The following vaccines must be reconstituted correctly before they are administered. Reconstitution means that the lyophilized (freeze-dried) vaccine powder or wafer in one vial must be reconstituted (mixed) with the diluent (liquid) in another. Only use the diluent provided by the manufacturer for that vaccine as indicated on the chart. ALWAYS check the expiration date on the diluent and vaccine. NEVER use expired diluent or vaccine.

Vaccine product name	Manufacturer	Lyophilized vaccine (powder)	Liquid diluent (may contain vaccine)	Time allowed between reconstitution and use [†]	Diluent storage environment [‡]
ACAM2000 [§] (SMA)	sanofi pasteur	ACAM2000	50% Glycerin, 0.25% phenol, sterile water	8 hrs/per day (can keep for 30 days if refrigerated)	Room temp
ActHIB (Hib)	sanofi pasteur	ActHIB	0.4% sodium chloride	24 hrs	Refrigerator
Hiberix (Hib)	GlaxoSmithKline	Hib	0.9% sodium chloride	24 hrs	Refrigerator or room temp
Imovax (RAB _{HDCV})	sanofi pasteur	Imovax	Sterile water	Immediately	Refrigerator
M-M-R II (MMR)	Merck	MMR	Sterile water	8 hrs	Refrigerator or room temp
Menomune (MPSV4)	sanofi pasteur	MPSV4	Distilled water	30 min (single-dose vial) 35 days (multi-dose vial)	Refrigerator
Menveo (MCV4)	Novartis	MenA	MenCWY	8 hrs	Refrigerator
Pentacel (DTaP-IPV/Hib)	sanofi pasteur	ActHIB	DTaP-IPV	Immediately [‡]	Refrigerator
ProQuad (MMRV)	Merck	MMRV	Sterile water	30 min	Room temp or refrigerator
RabAvert (RAB _{PCECV})	Novartis	RabAvert	Sterile water	Immediately	Refrigerator
Rotarix (RV1)*	GlaxoSmithKline	RV1	Sterile water, calcium carbonate, and xanthan*	24 hrs	Room temp
Varivax (VAR)	Merck	VAR	Sterile water	30 min	Room temp or refrigerator
YF-VAX (YF)	sanofi pasteur	YF-VAX	0.9% sodium chloride	60 min	Refrigerator
Zostavax (ZOS)	Merck	ZOS	Sterile water	30 min	Room temp or refrigerator

Always refer to the package inserts for detailed instructions on reconstituting vaccines. In general, follow these steps:

- For single-dose vaccine products (exceptions are Menomune in the multi-dose vial and Rotarix*), select a syringe and a needle of proper length to be used for both reconstitution and administration of the vaccine. Following reconstitution, Menomune in a multi-dose vial will require a new needle and syringe for each dose of vaccine to be administered. For Rotarix, see the package insert.*
- Before reconstituting, check labels on both the lyophilized vaccine vial and the diluent to verify the following:
 - that they are the correct two products to mix together
 - that the diluent is the correct volume (esp. for ACAM 2000 which comes in a 0.6 mL multi-dose vial but only 0.3mL is used for reconstitution[‡])
 - that neither vaccine nor diluent has expired
- Reconstitute (i.e. mix) vaccine *just prior to use* by
 - removing protective caps and wiping each stopper with an alcohol swab
 - inserting needle of syringe into diluent vial & withdrawing entire contents
 - injecting diluent into lyophilized vaccine vial and rotating or agitating to thoroughly dissolve the lyophilized powder
- Check the appearance of the reconstituted vaccine.
 - Reconstituted vaccine may be used if the color and appearance match the description on the package insert.
 - If there is discoloration, extraneous particulate matter, or obvious lack of resuspension, mark the vial as "DO NOT USE," return it to the proper storage conditions, and contact United States Army Medical Material Agency/Distribution Operation Center (USAMMA/ DOC) or the vaccine manufacturer.
- If reconstituted vaccine is not used immediately or comes in a multi-dose vial (i.e., multi-dose ACAM 2000),
 - clearly mark the vial with the date and time the vaccine was reconstituted
 - maintain the product at 35° – 46°F (2° - 8°C), do not freeze
 - protect live virus vaccines from light
 - use only within the time indicated on chart above

Note: Always refer to the package inserts for most recent updates for vaccine diluents.

[†] If the reconstituted vaccine is not used within this time period, it must be discarded.

[‡] Within 30 minutes or less.

* Rotarix vaccine is administered by mouth using the applicator that contains the diluent. It is not administered as an injection.

[§] Refrigerator temps should be between 35° – 46°F (2° - 8°C) and controlled room temps are between 68° - 77°F (20° - 25°C).

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To contact the MILVAX Agency:

1- (877) GET-VACC or (877-438-8222)

vaccines@amedd.army.mil

www.vaccines.mil