Vaccine Storage and Handling Guidelines

Defense Health Agency
Public Health Division
Immunization Healthcare

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Introduction

Vaccination efforts have been among the most successful and cost-effective ways of preventing and er adicating diseases throughout the world. The success of military vaccine programs depends heavily on vaccinators following proper vaccine storage and handling practices to ensure vaccine potency and stability.

The Immunization Healthcare Branch (IHB) analyzed temperature sensitive loss trends based on reported vaccine losses during the period of October 2010 to September 2012. The analysis identified the following: the primary cause of loss is from failure to place vaccine in an appropriate storage unit, the second most common cause of loss is from placing vaccine in the wrong storage unit (freezer vs. refrigerator), and the third leading cause of loss was due to alarm system failures. All of these losses could have been prevented if proper storage and h andling practices were in place and followed.

By understanding and implementing proper vaccine storage and handling practices, staff in immunization clinics, medical homes, and other healthcare facilities can play a critical role in improving the health of Service members and other beneficiaries.

The purpose of this document is to assist immunization clinics and ot her healthcare facilities to properly store and handle vaccines.

Protecting the Vaccine Supply

Cold Chain Management

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.

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 and freezing damages almost all refrigerated vaccines. Failure to adhere to proper storage temperatures may reduce vaccine potency, resulting in an inadequate immune response and protection against disease. Once lost, vaccine potency cannot be reversed.

Vaccines should be stored, shipped, and administered according to pharmaceutical manufacturers' instruction as outlined in the product's package insert or other guidance; and should be c onsidered potentially compromised if they have not been stored according to those guidelines.

Service members or beneficiaries immunized with compromised or expired vaccines need to be recalled by a healthcare worker and reimmmunized to make sure that they are protected against the specific vaccine preventable disease(s). Having to repeat vaccination doses can affect a large number of patients, causing embarrassment to healthcare team, increased expense for replacement product, potential liability, and diminished patient confidence in vaccines and in vaccine providers.

Good cold chain management procedures at all levels of immunization delivery 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 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 routine and emergency procedures including vaccine storage, handling, documentation, receiving,

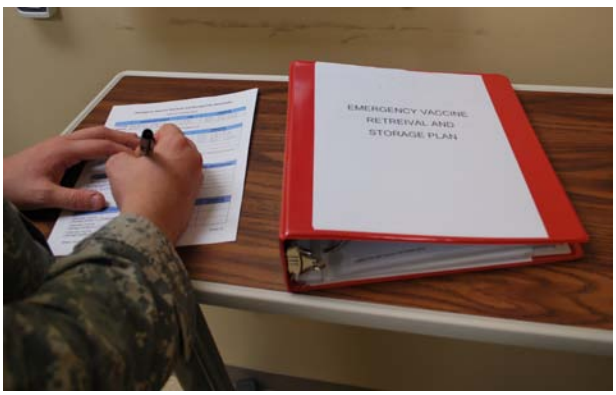
inventory management, shipping and transport.

Develop and implement a standardized staff orientation program that includes all the components of proper vaccine storage and handling practices. In addition, annually train all staff members who administer vaccines on current immunization storage & handling policies and procedures; and ensure they understand the importance of following vaccine cold chain management 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 potential compromise to the vaccine coordinator or their supervisor. Remember to document the date and type of immunization training received in the staff's training records.

Routine and Emergency Vaccine Storage & Handling Plans

To protect and safeguard vaccine inventory and minimize the potential monetary loss from improper handling, natural disasters, power outages or other emergencies the primary vaccine coordinator should develop both Routine and Emergency Vaccine Storage and Handling Plans. Plans should be kept in a visible location near all vaccine storage units.

At a minimum, the routine plan should include descriptions of the primary and back-up coordinators roles & responsibilities, summaries of the storage requirements for each vaccine and diluent, copies of immunization forms (i.e., temperature logs, emergency forms, etc.), and current POC information (i.e., coordinators, Immunization Healthcare Specialist (IHS), USAMMA, logistics, vaccine manufacturers, pharmacy, etc.). Standard Operating Procedures (SOPs)/ Operating Instructions (OIs) for the following should also be included for quick reference: requirements for storage unit temperature monitoring, correct placement of vaccine within storage unit, vaccine inventory management, transporting and receiving vaccine shipments, responding to vaccine storage and handling problems, proper disposal of vaccine and supplies, and equipment maintenance requirements.



Routine and Emergency Retrieval & Storage Plans

The Emergency Retrieval and Storage Plan should include agreements with other locations in the Military Treatment Facility (MTF) (i.e. logistics, pharmacy, lab, etc) or nearby facilities that have backup power (i.e. hospitals, health departments, or Reserve/ National Guard units), to serve as alternate storage locations during an extended power outage. Establish these agreements in advance of the emergency; and communicate and practice them with providers, healthcare workers, and janitorial staff at least annually.

Vaccine Storage & Handling Equipment

Selecting the Proper Storage Unit

When purchasing a vaccine storage unit, select one that can maintain the required

temperature range year-round and store the year's largest inventory in the middle and upper shelves without crowding. 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.

The Centers for Disease Control and Prevention (CDC) strongly recommends the use of stand-alone units as a best practice. Stand-alone refrigerators and stand-alone freezers units, are defined as self-contained unit that only refrigerates or freezes and is suitable for vaccine storage. These units can vary in size, from compact, under-the-counter style to a large, stand-alone, pharmaceutical grade storage unit.

Stand-alone storage units

An alternative to stand-alone units is to use only the refrigerator compartment of a combination household refrigerator/frost-free freezer unit to store refrigerated vaccines and a separate stand-alone freezer to store frozen vaccines. This is due to the fact that the usual household single-condenser combination refrigerator/freezer units are less capable of simultaneously maintaining proper storage temperatures in the refrigerator and freezer compartments. The refrigerators are cooled by venting cold freezer air into the refrigerated section; thus there is a real risk of freezing vaccine near the cooling vents, so be very careful not to use the top shelf of the refrigerator if the vent from the freezer opens there.

Stand-alone freezer unit

The CDC does not recommend the use of dormitory or bar-style refrigerators/freezers for ANY vaccine storage.

Do NOT use dormitory style refrigerator

Good air circulation around the vaccine storage unit is essential for proper heat exchange and cooling functions. Place the unit in a well-ventilated room, with adequate space around the sides and top. If the room temperature is too hot it is recommended that a small AC unit or extra ventilation vents are added to ensure room temperature remains stable and does not cause the refrigerator or

freezer temperatures to shift outside of normal range.

Users should conduct regular maintenance tasks that can be divided into daily, weekly, monthly, and periodic actions. For example on a daily basis check the temperature and ensure the storage unit doors are closed; on a weekly basis defrost the freezer; on a monthly basis clean the coils, motor, storage unit compartments, and check the door seals; and periodically check/clean the drain pan.

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

Maintaining the Required Storage Unit Temperature

For vaccines to remain potent and effective, they must be maintained at recommended temperature ranges, and protected from light according to manufacturer package inserts.

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

Stabilize and maintain the temperature in the refrigerator by adding buffers such as at least two or three large containers of water placed against the inside walls and in the door racks.

Water bottles as buffers in refrigerator

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. Not only will water bottles help maintain an even temperature they also help keep the temperatures stable in the event of a power failure. Stabilize and maintain the temperature in the freezer 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.

Thermometers

Thermometers are a critical part of good storage and handling practice. The freezer and the refrigerator unit or compartment should each have its own thermometer.

CDC recommends the use of a digital thermometer with a biosafe glycol-encased probe or similar temperature buffered probe (i.e. one inserted into glass beads) that will

more closely approximate the measure of liquid temperature; thus more closely matching the temperature changes experienced by stored vaccine.

To ensure valid temperature measurements, only calibrated thermometers with a certificate of Traceability and Calibration should be used. Avoid using thermometers that are not certified because they may not remain accurate over time. Periodic recalibration is necessary based on the manufacturers' recommendation. Uncertified liquid (mercury or alcohol) thermometers and dial-type household refrigerator and/or freezer thermometers are not authorized.

CERTIFICATE of CONFORMANCE & ACCURACY

This thermometer identified by Serial No. 12508
was compared with a Standard calibrated at the National Institute of Standards and Technology (NIST), formerly the National Bureau of Standards (NBS); and was found to be within one scale division. The indications of this thermometer are traceable to N.I.S.T.

The standard Serial No. is 59001
The NIST Identification No. is 119016

TEST DATE APR 23 2003

EVER-READY THERMOMETER CO. QUALITY SINCE 1942

Clifton Thomas, *Quality Control Supervisor*
Ever-Ready Thermometer Co., Inc.
226 Lackawanna Avenue
West Paterson, NJ 07424
Phone 973/812-7474 Fax 973/812-7475

THE VALIDITY OF THIS CERTIFICATE & INSTRUMENT IS ONE YEAR

Certificate of Traceability

Thermometer Placement

Proper placement of the thermometer is important since it helps the staff to most accurately identify the actual vaccine vial temperatures and to take appropriate corrective actions if necessary. In the refrigerator and freezer, it is important that the temperature probe be placed in close proximity to the vaccines being stored. The thermometer should be placed in the center of the compartment away from the coils, walls, floor, and fan in order to obtain a true reading of the temperature (never on the door).

Refrigerator thermometer placement

Freezer thermometer placement

Data Loggers and Alarm Systems

In addition to a certified thermometer, it is also recommended to incorporate a digital data logger or other continuous-monitoring temperature alarm system to alert staff of after-hour emergencies and power failures.

Data logger and continuous-monitoring alarm

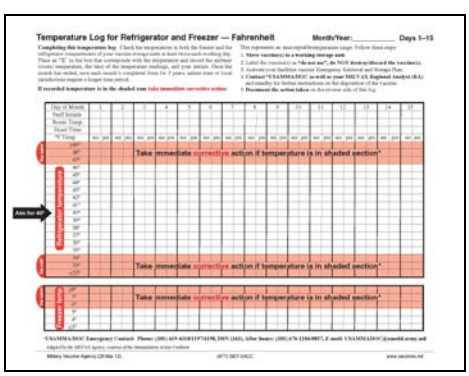
A digital data logger with detachable probe allows the reading of temperatures without opening the door. They record and store temperature information at programmable intervals (every 15, 30, 60 minutes etc.) for

24-hour monitoring. The use of digital data loggers are a CDC best practice. The stored readings can be downloaded to any computer, viewed and saved. Advanced alarm features enable email, text and phone messages whenever temperatures go out of the specified range.

Make sure whichever alarm system is used, that it is programmed with current staff contact information and it is monitored electronically and physically 24-hours a day, seven days a week. The entire alarm system from the storage unit sensor to the remote monitoring station and telephone/pager must be tested at least monthly. Keep results of alarm system testing for a minimum of three years.

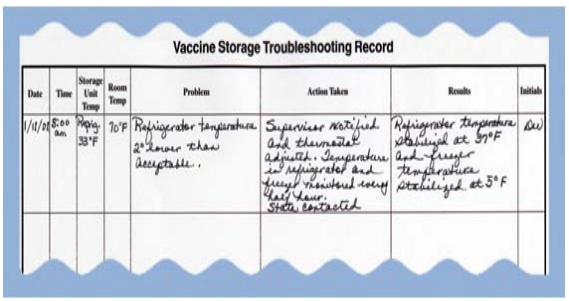
Monitoring & Recording Temperatures

Manually confirm and document on a temperature log, the date, time, and 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.



Temperature log

Under the day of the month, document initials, the time, and place an "X" on the log for the temperature that was observed. On the back of the temperature log, record date/time of any temperature deviation, mechanical malfunction, or power outage of the storage unit.


Vaccine Storage Troubleshooting Record

Date	Time	Storage Unit Temp	Room Temp	Problem	Action Taken	Results	Initials
1/1/08	8:00 am.	Refrig. 38°F	70°F	Refrigerator temperature 2° lower than acceptable.	Supervisor notified and thermostat adjusted. Temperature in refrigerator and freezer monitored every half hour. State contacted	Refrigerator temperature stabilized at 39°F and freezer temperature stabilized at 5°F	AW

Document temperature deviations on back of log

For 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.

Manual temperature checks

Conduct twice daily documentation of temperature checks even with an installed data logger and/or alarm system. Relying solely on alarm systems can lead to complacency, and inappropriate temperature may not be discovered and dealt with in a timely manner.

DoD/USCG have had many vaccine losses due to malfunctioning alarm systems (e.g., alarm battery failure). These losses could have been avoided if someone was

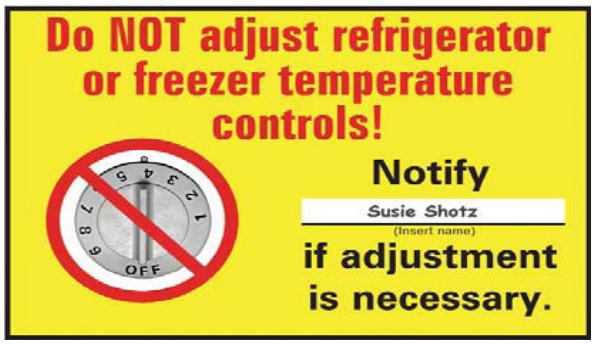
physically checking the temperatures instead of relying solely on the call system. Keep temperature logs for at least three years. State and/or local requirements may require maintaining the records for a longer period.

Adjusting Storage Unit Temperatures

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.

Digital thermostat

After 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.



Place warning sign on storage unit

Once the storage units are stable at the target temperatures the vaccines can be placed in them. Post a warning sign on the storage unit that indicates who to contact if the temperature requires adjustment.

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 outlet covers

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).

Place signs near outlets

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. If needed, multilingual stickers are on the Centers for Disease Control (CDC) website to alert non-English speaking housekeeping or clinic staff.

Label circuit breakers in fuse box

Facilities storing large vaccine inventories that don't have emergency backup power, should install a 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

Vaccine Inventory Management

Vaccine Inventory and Ordering

Managing vaccine inventory includes checking vaccine and diluent expiration dates weekly and removing expired items from usable stock. Always check the expiration date before using a vaccine. Promptly remove expired or mishandled vaccine and diluent from the refrigerator or freezer and dispose of it according to local policy. Move vaccines with shorter expiration dates to the front of the storage unit so that they are used first. A simple reminder to alert staff to a change in vaccine lot number is to place a rubber band around boxes of like lot numbers.

Inventory and rotate stock

Remember to always store opened and unopened vaccine vials in their original packaging/boxes; removing them can make inventory more difficult, can lead to administration errors, and can lead to the vaccine being exposed to fluorescent or sun light.

Order and stock adequate vaccine supply to meet the need of the beneficiary population; do not over order. 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. To estimate your vaccine need, look at the average monthly or seasonal use of each vaccine and order accordingly.

Receiving Vaccine Shipments

Notify the primary or backup vaccine coordinator immediately upon delivery of a vaccine shipment. Open, unpack, and inventory the vaccine as soon as possible to ensure the contents match the packing slip and to verify that the vaccine was stored under appropriate conditions.

Inventory/unpack vaccines as soon as shipment arrives

Check the expiration dates on the vaccines received; always use the shortest-dated vaccines first. The temperature monitors included with the vaccine shipment should be checked upon delivery, to verify that the cold chain was maintained throughout transport. Follow instructions on the monitors for reading and reporting.

If there are no issues with the shipment, unpack vaccines from the transport container and place the vaccine in the appropriate storage unit. If there are discrepancies with the packing slip or the monitor indicates a possible temperature excursion, document the monitor reading; then segregate and mark the vaccine as "Do Not Use" and place the vaccine in properly functioning storage unit. Report the event to USAMMA/DOC. Do not use or discard the vaccine until USAMMA/DOC verifies the integrity of the vaccine.

Expiration Dates, Soon to Expire Vaccines & 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. 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.

Expiration date format varies

If there are vaccines that will expire in 3 months or less that cannot be used prior to the expiration date, notify your IHS, USAMMA, logistics, 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.

Vaccine & Diluent Storage Practices

Placement & Labeling in Storage Unit

Store vaccine in the middle of the compartment, 3 inches from the walls and top of unit, allowing air to circulate around the vaccine; do not pack vaccine tightly together.

Staff can easily confuse vaccine vials within the storage unit. Label the bin, basket, slotted container, or shelf where the vaccine is stored to help staff quickly locate and choose the correct product – perhaps preventing a vaccine administration error.

HepA (Havrix, Vaqta)
Adult Formulation

Ages: 19 years and older

Use for: Any dose in series

HepA (Havrix, Vaqta)
Pediatric Formulation

Ages: 12 months through 18 years

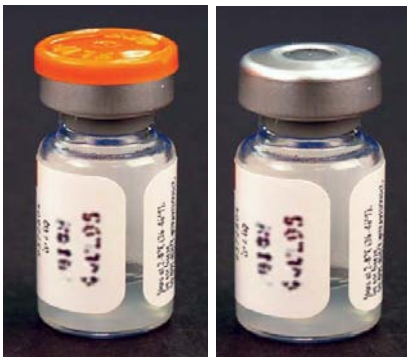
Use for: Any dose in series

Other helpful strategies to prevent administration errors include color coding the labels (e.g., one color for pediatric and one for adult vaccines), organizing the vaccine within the storage unit by age (e.g., top shelves for pediatric only vaccines, middle shelves for pediatric – adolescent - adult vaccines and the bottom shelves for adult only vaccines) or including additional information such as age indications, gender or other information unique to the vaccine on the label. Label diluent clearly, whether stored at room temperature or in the refrigerator, **NEVER** freeze diluent. If stored in the refrigerator, place diluent next to the vaccine it is to be used with.

Proper Handling of Vaccine and Diluent

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 clinic day

Multi-dose Vials:

Multi-dose vials contain bacteriostatic agents that prevent the growth of bacteria. Doses from a partially used multi-dose vial can be administered until the expiration date printed on the vial or vaccine packaging, provided the vial has been stored correctly and the vaccine is not visibly contaminated. Always check the package insert for the most up-to-date information and use aseptic technique when withdrawing vaccine from a multi-dose

vial. Mark multi-dose vials with date, time, and initials when the first dose is withdrawn. Immediately after drawing up the dose, return unused vaccine to the storage unit.

Mark opened multi-dose vials with date/time/initials

The vaccine expiration rule is different from the normal 28-day rule for medications. 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)."

Reconstituted Vaccines:

Vaccines that come as lyophilized (freeze-dried) powders are mixed with a diluent in a process known as "reconstitution" before they can be administered. Mark reconstituted multi-dose vaccine vials with the date, time, and initials when reconstituted. The expiration date for reconstituted multi-dose vials varies from product to product and the new expiration date and time will differ from that printed on the vial. Unused reconstituted vaccines kept beyond these limits should not be administered.

Mark reconstituted multi-dose vial w/date/time/initials

For example MMR vaccine, after reconstitution, must be administered within 8 hours and must be kept at refrigerator temperatures during this time. Consult the package insert for the most up-to-date information about expiration dates and times following reconstitution.

Diluents:

Diluents are not interchangeable, unless specified by the manufacturer. 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. 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. In addition, always verify with package insert the amount of diluent to utilize (i.e. smallpox, etc), since diluents vary in volume.

Manufacturer-filled Syringes:

An alternative to prefilling syringes by hand is using manufacturer-filled syringes. These syringes are prepared under sterile

conditions, and are individually labeled. As long as prefilled syringes are stored under appropriate conditions (temperature and light) they may be used until their date of expiration.

Manufacturer-filled syringe

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

The Advisory Committee on Immunization Practices (ACIP) discourages the routine practice of prefilling syringes due to the potential for administration errors, because a majority of vaccines have a similar appearance once drawn into a syringe. Vaccine doses should not be drawn into a syringe until immediately before use. In addition, the FDA does not license administration syringes for vaccine storage due to the lack of data concerning the stability and sterility of vaccine stored in end user filled (i.e., not filled by the manufacturer) syringes. Unused syringes filled by the end user should be discarded at the end of the clinic day.

In certain circumstances in which a single vaccine type is being used (e.g., in advance of an influenza vaccination campaign), filling a small number of syringes (10 at a time) can be considered. When the syringes are filled, the type of vaccine, lot number, and date of filling must be labeled on each syringe, and the doses should be administered as soon as possible.

Responding to Vaccine Storage and Handling Problems

Power Outages

When state/local officials or the installation command have reasonable cause to believe that an extended power outage may occur, either due to a planned power outage or approaching storm, activate the emergency vaccine retrieval and storage plan per facility guidelines. Take steps, in advance of the event, to pack and move vaccines to an alternate site with a working storage unit and back-up power.

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.

Potentially Compromised Vaccine Procedures

It does no good to record the temperatures of the refrigerator and freezer daily if the person

recording the temperature is not aware that a temperature above 8°C (46°F) in the refrigerator is too high or a temperature inside the freezer above 5°F (-15°C) is too high. Once a potentially compromised vaccine situation is identified, immediately move the vaccine to a working storage unit and label as "DO NOT USE," to reduce the risk of using vaccines that may have reduced potency. N otify the primary or back-up vaccine coordinator (if not available, immediate supervisor) of the potential temperature excursion.

Label vaccine as "Do Not Use"

Use the Potentially Compromised Vaccine TSMP Worksheet, found on the IHB and USAMMA websites, to document the storage unit and ambient room temperatures, the length of time the vaccines may have been exposed to the inappropriate storage temperatures, the situation surrounding the potential loss, and an inventory of the vaccines affected. Note if water bottles were in the refrigerator and/or frozen coolant packs in the freezer at the time of the event.

Submit the completed worksheet and all supporting documentation to USAMMA/DOC and your Immunization Healthcare Specialist. Stand-by for vaccine disposition, do not use or discard vaccine until disposition is given by USAMMA/DOC. Once disposition is provided, either place the vaccine back into inventory or destroy the vaccine per local policy/guidelines.

Vaccine Transport Procedures

Validated Storage Containers

Validated storage devices approved for vaccine shipping and/or transport include Endurotherm insulating shipping boxes, hard-sided plastic and/or Styrofoam™ coolers with at least 2-inch thick walls (e.g. manufacturer shipping container). T hin-walled Styrofoam™ coolers, such as those purchased at grocery stores to hold beverages, are not acceptable.

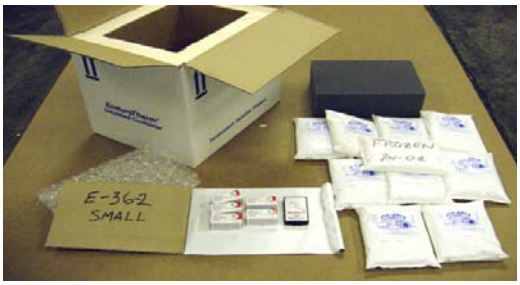
Styrofoam™ coolers

In addition, other mobile temperature management units (i.e., PX1L formerly VaxiPac or AX27L formerly VaxiCool) may be used.

Mobile Temperature Management Units

Packing Vaccine for Shipping & Transport

When shipping and/or transporting vaccines, they must be pac ked appropriately in validated containers, to maintain the required temperature. Whichever container is used, a certified calibrated thermometer must be included. Use the packing protocols found on the USAMMA/DOC website when preparing vaccines for shipping.



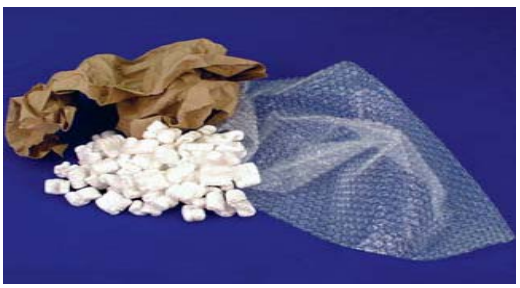
Endurotherm insulating shipping container

Pack the refrigerated vaccines first, using enough cold (refrigerated) gel packs to maintain the cold chain. T he number and placement of cold (refrigerated) gel packs inside the container will depend on container size and out side temperature. Pack frozen vaccine last using a separate insulated container, removing them from the freezer and packing them according to package insert immediately before transport.

Place thermometer near vaccine

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

Always place an insulating barrier (e.g., crumpled packing paper, bubble wrap, etc.) between the cold (refrigerated) gel packs and the vaccines to prevent accidental freezing. NEVER place vaccines directly on f rozen packs.



Use insulating barrier to protect vaccine

Document vaccine type(s), quantity, date, time, and originating facility and phon e number on t he outside of the shipping container. To identify the contents as being valuable and fragile attach labels to the outside of the container carrying refrigerated or frozen vaccines.

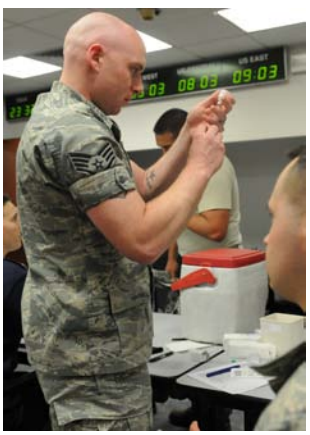
Attach labels to identify contents as vaccine

Document the storage unit temperature when

the vaccine is removed for shipping and/or transport and also at final destination to identify any temperature deviations during transport. Remember that USAMMA/DOC is always available to answer questions on redistribution or packing protocols.

Protecting Vaccines at Off-Site Clinics

Ideally, vaccines should be stored at the recommended temperatures inside a properly functioning refrigerator or freezer at an off-site clinic. If such a unit is not available, the vaccine must be maintained in a validated storage container capable of maintaining the required temperatures.



When conducting an off-site immunization clinic, such as a flu drive, certain procedures should be followed. Only pack vaccine amount expected to be used during the off-site immunization clinic; DO NOT pre-fill syringes prior to arrival at vaccination site or remove vaccine vials from their original boxes. Only one vaccine type should be administered at the individual stations to avoid administration errors. Patient flow should be monitored to avoid drawing up unnecessary doses; and at the end of the clinic day, any remaining vaccine in syringes should be discarded.

During the off-site clinic, keep the storage container closed as much as possible. Check and record temperatures a minimum of every hour. Individuals taking vaccines to an off-site clinic should fill out an issue receipt with the number and type of vaccine vials taken. The issue receipt should include a statement that the individual taking the vaccines acknowledges that they must keep the vaccine at the required temperatures. When returning the vaccine, document the number and type of vaccine vials returned and sign the issue receipt stating that the required temperatures were maintained.

Storage and Handling Resources

Immunization Healthcare Branch (IHB): Supports military vaccination programs protecting Service members, their dependents and beneficiaries; and provides educational support and training resources for military healthcare personnel. Contact IHB using the following:
(877) GET-VACC or (877-438-8222)
Email: DoDvaccines@mail.mil
Website: www.vaccines.mil
Storage and Handling Webpage:
www.vaccines.mil/Storage_and_Handling

Immunization Healthcare Specialist (IHS): Contact your IHS to discuss training needs, policy, or assistance with storage and handling issues. An IHB listing and area of responsibility can found on the IHB website:
www.vaccines.mil/map

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 or other TSMP questions during the hours of 0700-1700 EST phone: (301) 619-3017/4318 or

after hours for urgent issues only call: (301) 676-0808/1184 or contact via email at: usarmy.detrick.medcom-usamma.mbx.doc@mail.mil.
For additional information visit the USAMMA website at:
www.usamma.amedd.army.mil/doc.cfm

Centers for Disease Control and Prevention (CDC): Has various storage & handling tools, documents, videos, and training resources available at the following website:
www.cdc.gov/vaccines/recs/storage/default.htm

Immunization Action Coalition (IAC): Has storage and handling tools that can be customized for individual use, available at the following website:
www.immunize.org/handouts/vaccine-storage-handling.asp

Storage and Handling Reference List

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

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. www.cdc.gov/vaccines/pubs/pinkbook/index.html

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). www.cdc.gov/mmwr/pdf/rr/rr6002.pdf

Centers for Disease Control and Prevention, Vaccine Storage and Handling Toolkit. www.cdc.gov/vaccines/recs/storage/toolkit/default.htm

SB-8-75-11, Department of the Army Medical Department Supply Bulletin. Section 3-58: Temperature Sensitive Medical Products (TSMP) Storage and Handling. www.vaccines.mil/documents/1608_SB_8-75-11_Nov_2012.pdf

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

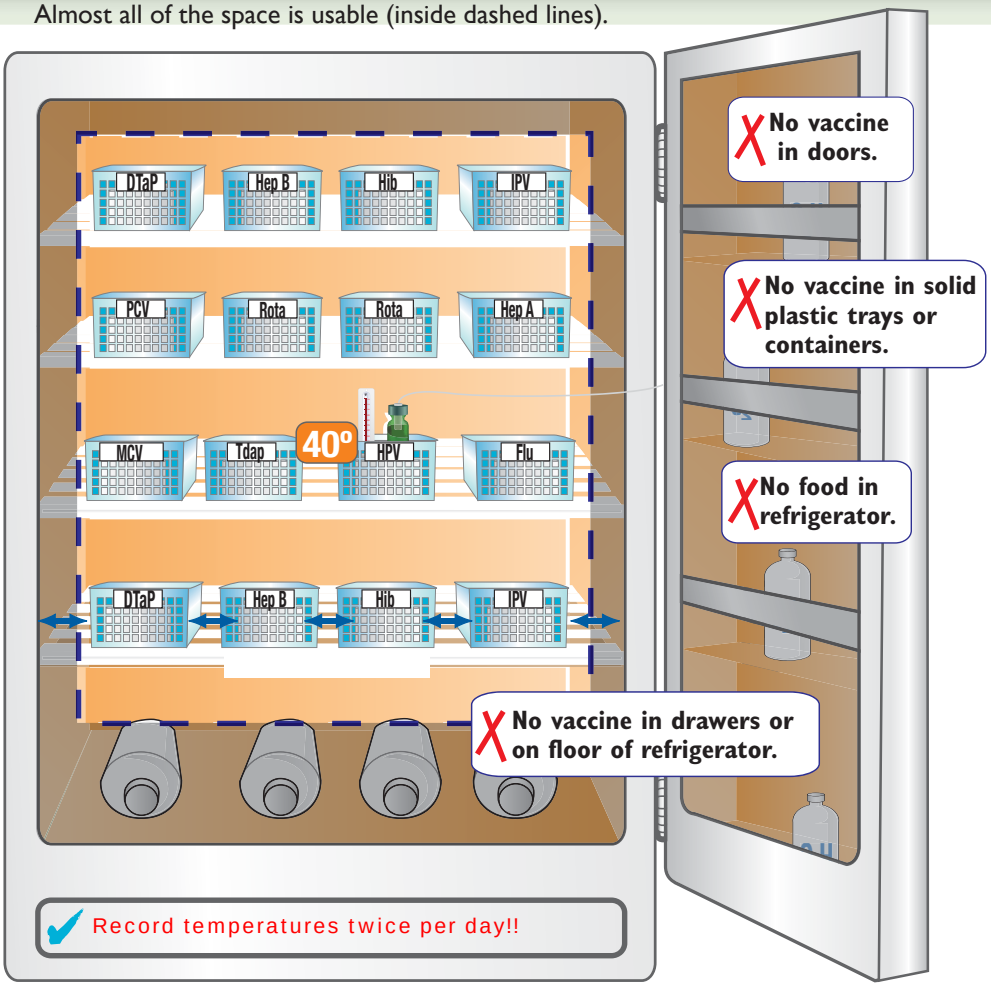
Vaccine Refrigerator Setup

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

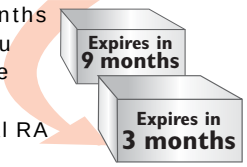
Refrigerator-only Unit

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.

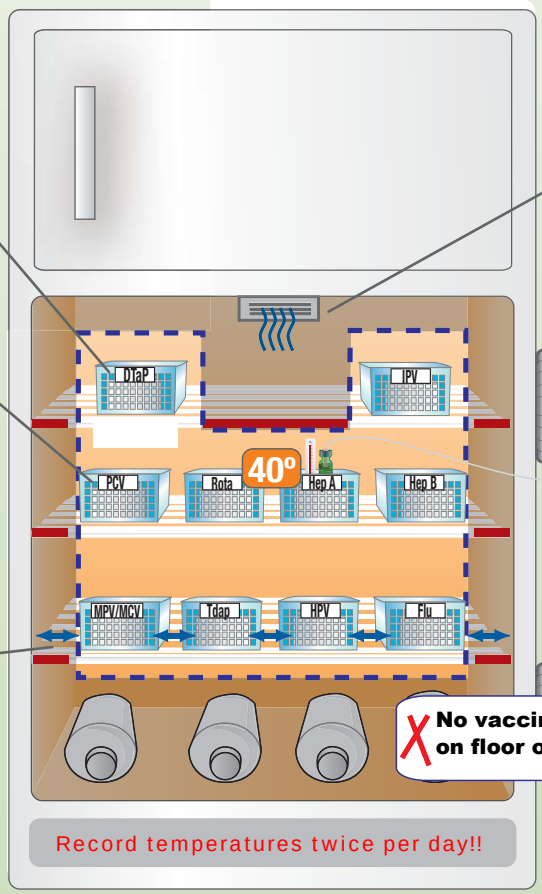
✔ **Group vaccines by pediatric, adolescent, and adult types.**

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

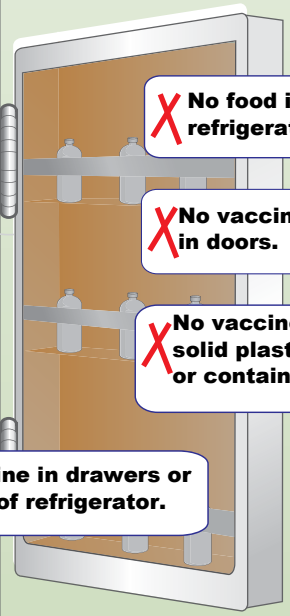
✔ Keep vaccines in their original boxes until you are ready to use them.

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

✔ Use buffers to stabilize refrigerator temperature.



✗ Keep 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.**

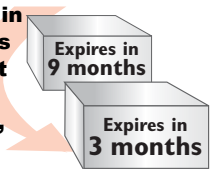
✗ **No vaccine in doors.**

✗ **No vaccine in solid plastic trays or containers.**

✗ **No vaccine in drawers or on floor of refrigerator.**

✔ **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.**

Below 35°F is too cold!

Above 46°F is too warm!

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

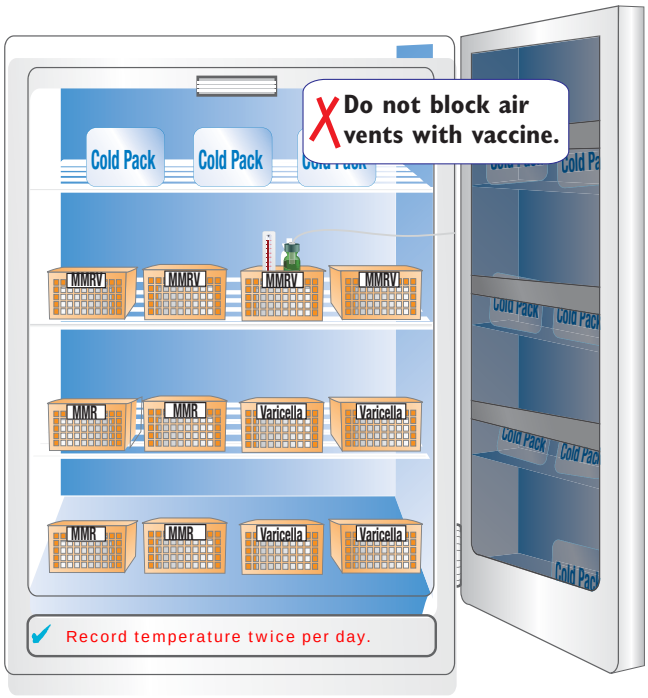
Carefully organizing vaccines in a freezer helps vaccine and facilitates vaccine inventory management.

Stand-alone freezer

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

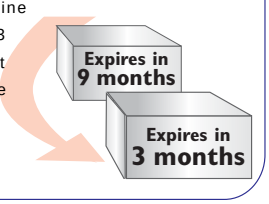
✔ Place thermometer in the center of the freezer away from walls, floor and fan.

✔ 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.



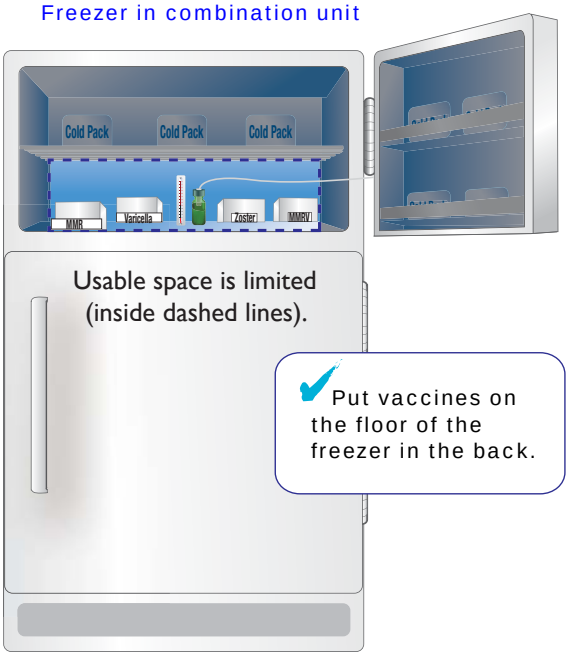
✔ **Keep temperatures 5°F or colder.**

Chest Freezer

✔ Keep vaccines with shorter expiration dates on top.

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.

Freezer in combination unit



✔ Put vaccines on the floor of the freezer in the back.

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.

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.

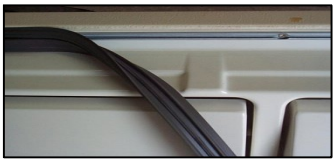
1. Clean the inside of the storage units

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

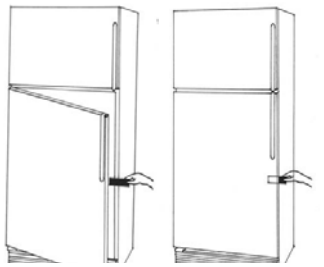
Refrigerators and freezers have flexible door seals that prevent cold air from escaping when doors are closed. If the seal does not seal completely, cold air escapes. This can cause temperatures to fluctuate in the unit. **Do Not Unplug the Unit.**



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 301-619-3017/4318.

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
MenHibrix (Hib-MenCY)	GlaxoSmithKline	Hib-MenCY	0.9% sodium chloride	Immediately	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:

1. 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 re-constitution, 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.*

2. Before reconstituting, check labels on both the lyophized 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

3. 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

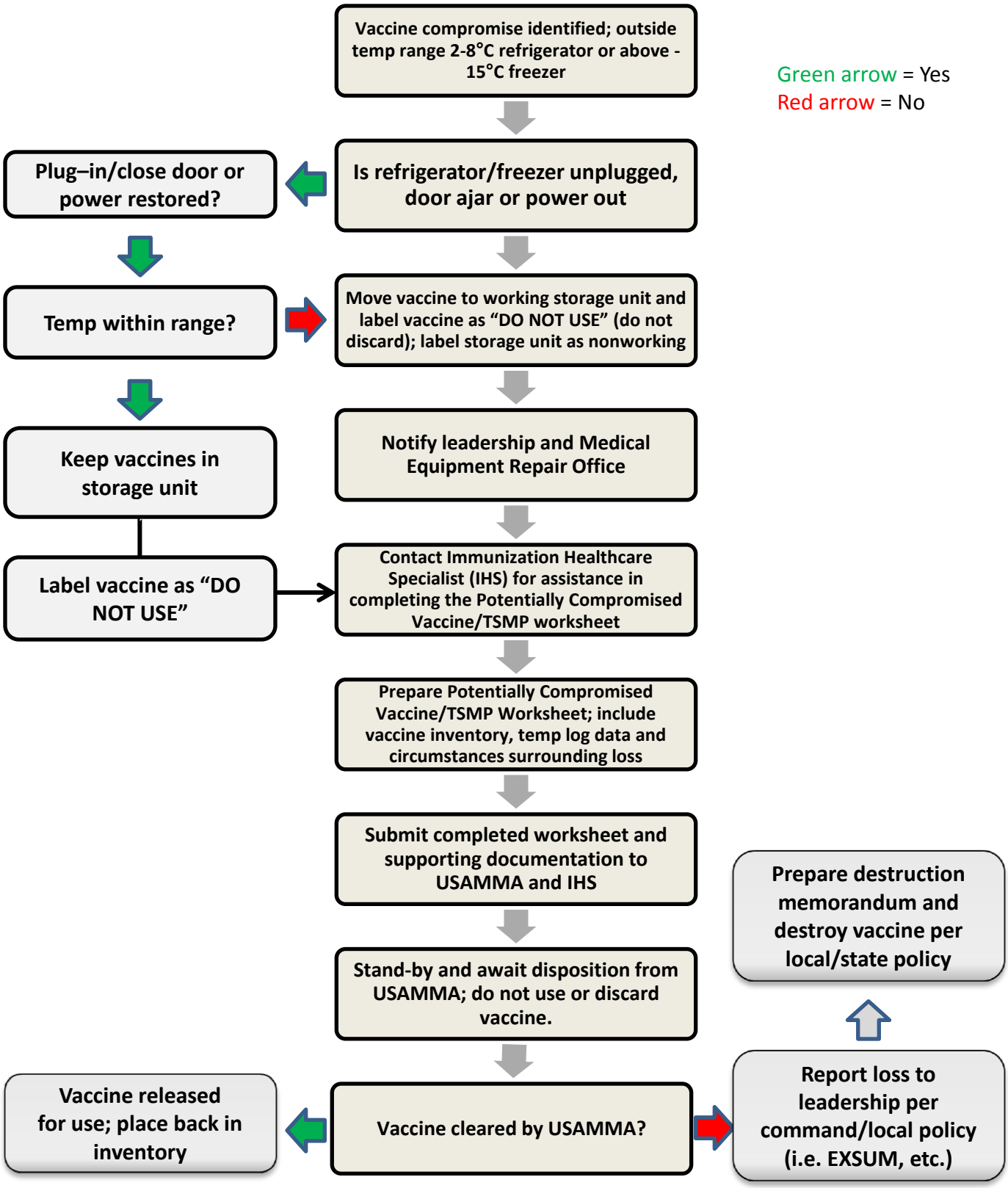
4. Check the appearance of the reconstituted vaccine.
   - Reconstituted vaccine may be used if the color and appearance match the description on the package insert.
   - If there is discoloration, extraneous particulate matter, or obvious lack of resuspension, mark the vial as "DO NOT USE," return it to the proper storage conditions, and contact United States Army Medical Material Agency/Distribution Operation Center (USAMMA/ DOC) or the vaccine manufacturer.

5. 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).

Steps to take for Potentially Compromised Vaccine Event



Potentially Compromised Vaccine/TSMP worksheet can be found at the following:
www.vaccines.mil/documents/1710_PotentiallyCompromisedVaccineTSMPWorksheet.pdf

Emergency Vaccine Retrieval and Storage Plan Worksheet

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	Address	Telephone
Alternate Vaccine Storage Facility (1)				
Alternate Vaccine Storage Facility (2)				
Alternate Vaccine Storage Facility (3)				

Emergency Vaccine Retrieval and Storage Plan Worksheet (cont.)

Emergency Resources Contact List

Emergency Resources	Contact Person (Title)	Telephone Numbers
U.S. Army Medical Materiel Agency (USAMMA/DOC) www.usamma.amedd.army.mil/doc.cfm	Operations Manager	Office: 301-619-3017/4318 DSN: 343-3017/4318 24 hours emergency line: 301-676-0808/1184
DLA Troop Support	Cold Chain Program Manager	Office: 215-737-5537 DSN: 444-5537
Pharmacy		
Medical Equipment Maintenance Office		

Resources	Company Name	Contact Person	Telephone Numbers
Electric Power Company			
Generator Repair Company			
Generator Fuel Source			
Storage Unit Repair Company			
VaxiCool Repair Company			
Temperature Alarm Company			
Certified Calibrated Thermometers			
Refrigerated/Frozen Packs			
Insulated containers or coolers			

Potentially Compromised Vaccine/TSMP Response Worksheet

Date: _____ **Service:** _____ **Component:** _____ **Phone #:** _____

Site/Clinic Name/Address: _____

POC: _____ **POC Email:** _____

Type of Site: _____ **IHS:** _____

Follow these steps in the event of a potential compromise:

1. Move vaccine(s)/Temperature Sensitive Medical Products (TSMP) to working storage unit at proper temperature, label the vaccine(s)/TSMP as "**DO NOT USE**."
2. Activate your emergency response plan. Contact your Immunization Healthcare Specialist (IHS), www.vaccines.mil/Map.
3. Complete **ALL** required information. Save completed document to your desktop using the following naming convention: PCV-TSMP_location_date.
4. When possible send completed worksheet along with copies of your temperature logs to your IHS for review, to ensure all information is appropriately documented.
5. The U.S. Army Medical and Material Agency/Distribution Operations Center (USAMMA/DOC) will provide disposition for the potentially compromised items.
6. Click the submit by email button on page 2 and it will send your completed form directly to the USAMMA/DOC mailbox; be sure to add your IHS's email to the "To:" line prior to clicking the submit button. The IHS for your region can be found at the following site: www.vaccines.mil/Map.
7. Standby for further instructions from your IHS and/or USAMMA/DOC. Do **NOT** destroy/discard the vaccine(s)/TSMP until released by USAMMA and/or IHS.
8. Contact information for USAMMA/DOC and the Defense Logistics Agency/Troop Support Medical (DLA-TSM):
   - USAMMA/DOC phone #: (301) 619-3017/4318, after hours: (301) 676-0808/1184, or email: usarmy.detrick.medcom-usamma.mbx.doc@mail.mil
   - DLA-TSM phone #: (215) 737-5537, or email: paacoldchainteam@dla.mil or DSCPColdchain@dla.mil

Required information:

1a. Temperatures recorded in F or C: _____ 1b. Air temperature of room where vaccine(s) or other TSMP located: _____

2a. Was vaccine(s)/TSMP left out of the refrigerator or freezer? _____ 2b. If YES, how long was vaccine(s)/TSMP left out of refrigerator/freezer? _____

3. Complete a.- d. below, if vaccine(s) or other TSMP was located in a refrigerator or freezer during the potentially compromising event, otherwise go to question #4:

   a. Refrigerator temp: current: _____ warmest: _____ coldest: _____ Freezer temp: current: _____ warmest: _____ coldest: _____

   b. When was the last manual temp check documented prior to this event? date: _____ time: _____ refrigerator temp: _____ freezer temp: _____

   c. Estimated amount of time the storage unit's temperature(s) was outside the normal range: refrigerator: _____ freezer: _____

   d. Were water bottles in the refrigerator? Yes ◯ No ◯ Were ice packs in the freezer? Yes ◯ No ◯

4. Prior to this event, was the vaccine(s) or other TSMP exposed to temperatures outside the recommended range? Yes ◯ No ◯
   Explain: _____
5. Identify vaccine(s) or other TSMP that were potentially compromised on the back of this worksheet (use page 3 if additional space is needed).
6. Document in the space below circumstances surrounding potential compromise of vaccine(s) or other TSMP (i.e., pharmacologic and laboratory). Include date, time, current location of vaccine(s) and/or other TSMP, personnel notified and actions taken once potential compromise was identified.

Please select all event types that apply:

Non-Preventable Loss: _____

Negligence: _____

Non-Compliance: _____

Potentially Compromised Vaccine Response Worksheet

Vaccines (or other TSMP) Stored in Refrigerator

Brand Name and Manufacturer/NDC/Part #	Lot #	Expiration Date	Quantity (# of doses)	Cost of Affected TSMP	# Vial(s) Open
(SELECT VACCINE FROM DROP-DOWN OR ENTER REQUIRED INFORMATION)					
	Total Cost of Affected TSMP:				

Vaccines (or other TSMP) Stored in Freezer

Brand Name and Manufacturer/NDC/Part #	Lot #	Expiration Date	Quantity (# of doses)	Cost of Affected TSMP	# Vial(s) Open
(SELECT VACCINE FROM DROP-DOWN OR ENTER REQUIRED INFORMATION)					
	Total Cost of Affected TSMP:				

For USAMMA/DOC use only

Save completed worksheet to your desktop using the naming convention: PCV-TSMP_location_date. Click submit by email button. Add your IHS's email to the "To:" line (find your regional IHS's email at the following site: www.vaccines.mil/Map). Click Submit button and it will send your completed form directly to USAMMA/DOC.

Submit By Email

Temperature Log for Refrigerator and Freezer — Celsius

Month/Year:_____ **Days 1–15**

Completing this temperature log: Check the temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an "X" in the box that corresponds with the temperature and record the ambient (room) temperature, the time of the temperature readings, and your initials. Once the month has ended, save each month's completed form for 3 years, unless state or local jurisdictions require a longer time period.

If recorded temperature is in the shaded zone take immediate corrective action:

This represents an unacceptable temperature range. Follow these steps:

1. **Move vaccine(s) to a working storage unit**.
2. Label the vaccine(s) as **"do not use", do NOT destroy/discard the vaccine(s).**
3. Activate your facilities vaccine Emergency Retrieval and Storage Plan.
4. **Contact *USAMMA/DOC as well as your Immunization Healthcare Specialist (IHS)** and standby for further instructions on the disposition of the vaccine.
5. **Document the action taken** on the reverse side of this log.

Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Staff Initials																														
Room Temp.																														
Exact Time																														
° C Temp	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
Too warm* ≥11°																														
Refrigerator temperature 10°					Take immediate corrective action if temperature is in shaded section*																									
9°																														
8°																														
7°																														
6°																														
Aim for 5° 5°																														
4°																														
3°																														
2°																														
Too cold* 1°																														
0°					Take immediate corrective action if temperature is in shaded section*																									
≤-1°																														

Too warm* ≥-12°																														
Freezer temp -13°					Take immediate corrective action if temperature is in shaded section*																									
-14°																														
-15°																														
-16°																														
≤-17°																														

*USAMMA/DOC Emergency Contact: Phone: (301) 619-3017/4318, DSN (343), After hours: (301) 676-0808/1184, email: usarmy.detrick.medcom-usamma.mbx.doc@mail.mil

Vaccine Storage Troubleshooting Record

Use this page to record the details of the vaccine storage incident, including the date and time of the last known temperature within the appropriate vaccine storage range.

Date	Time	Storage Unit Temp	Room Temp	Incident	Action Taken	Results	Initials

Temperature Log for Refrigerator and Freezer — Celsius

Month/Year:_____ **Days 16–31**

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This represents an unacceptable temperature range. Follow these steps:

1. **Move vaccine(s) to a working storage unit**.
2. **Label the vaccine(s) as "do not use", do NOT destroy/discard the vaccine(s).**
3. Activate your facilities vaccine Emergency Retrieval and Storage Plan.
4. **Contact *USAMMA/DOC as well as your Immunization Healthcare Specialist (IHS)** standby for further instructions on the disposition of the vaccine.
5. **Document the action taken** on the reverse side of this log.

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Room Temp.																
Exact Time																
°C Temp	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm
Too warm*	≥11°																
Refrigerator temperature	10°			Take immediate corrective action if temperature is in shaded section*													
	9°																
	8°																
	7°																
Aim for 5°	6°																
	5°																
	4°																
	3°																
	2°																
Too cold*	1°																
	0°			Take immediate corrective action if temperature is in shaded section*													
	≤-1°																

Too warm*	≥-12°																
Freezer temp	-13°			Take immediate corrective action if temperature is in shaded section*													
	-14°																
	-15°																
	-16°																
	≤-17°																

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4. **Contact *USAMMA/DOC as well as your MILVAX Regional Analyst (RA)** and standby for further instructions on the disposition of the vaccine.
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Staff Initials															
Room Temp.															
Exact Time															
°F Temp	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm
Too warm* ≥49°															
48°			Take immediate corrective action if temperature is in shaded section*												
47°															
Refrigerator temperature 46°															
45°															
44°															
43°															
42°															
41°															
Aim for 40° 40°															
39°															
38°															
37°															
36°															
35°															
Too cold* 34°															
33°			Take immediate corrective action if temperature is in shaded section*												
≤32°															

Too warm*	Freezer temp ≥8°															
	7°			Take immediate corrective action if temperature is in shaded section*												
	6°															
	5°															
	4°															
	≤3°															

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Refrigerator temperature

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≤-17°																														

Freezer temp

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Freezer temp

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

Do NOT adjust refrigerator or freezer temperature controls!

Notify

_____

(Insert name)

If adjustment is necessary.

WARNING!
Expensive Vaccine in Storage!
AVISO! Contiene vacunas caras

DO NOT STOP POWER TO CIRCUIT BREAKER # _____

NO DESCONECTE LA ELECTICIDAD A EL CIRCUITO # _____

In event of electrical problem, immediately contact:

Si hay un problema con la electricidad, comuniquese inmediatamente con:

_____

DO NOT SWITCH OFF

VACCINE STORAGE
DO NOT TURN OFF

VACCINE STORAGE
DO NOT TURN OFF

VACCINE STORAGE
DO NOT TURN OFF

Vaccine Bin Label Examples

Staff can easily confuse the vaccines within the storage unit. Labeling the bin where the vaccine is stored can help staff quickly locate and choose the correct product – perhaps preventing a vaccine administration error. Depending on how the vaccines are organized within the storage unit (e.g., top two shelves for pediatric only vaccines, middle shelves for pediatric/ adolescent/adult vaccines and the bottom two shelves for adult only vaccines), labels can be attached to the slotted containers, the bins, or directly to the shelves where the vaccine is stored. Other helpful strategies to prevent administration errors include color coding the labels (e.g., one color for pediatric and one for adult vaccines), separating age-specific vaccines by shelf; and including additional information such as age indications, gender or other information unique to the vaccine on the label.

In addition, some vaccines must be reconstituted before administration. These vaccines have two components – a lyophilized vaccine and diluent that must be mixed together. The lyophilized vaccine should only be reconstituted or mixed using the diluent supplied by the manufacturer. Consider posting reminders or labeling the vaccine to remind staff to reconstitute certain vaccines prior to administering it.

The following labels are examples that may be used to help organize vaccines.

Adapted by MILVAX-VHCN, courtesy of the Centers for Disease Control and Prevention

Diphtheria, Tetanus and accellular Pertussis – Containing Vaccines

DTaP (Daptacel, Infarix, Tripedia)

Ages: 6 weeks through 6 years

Use for: Any dose in series

Route: IM

DTaP-IPV (KINRIX)

Ages: 4 years through 6 years

Use for: DTaP dose 5, IPV dose 4

Route: IM

DTaP-IPV-HepB (Pediarix)

Ages: 6 weeks through 6 years

Use for: DTaP & IPV: Doses 1, 2, 3
HepB - Any dose in series

Do NOT use for the HepB birth dose

Route: IM

DTaP – IPV/Hib (Pentacel)

Ages: 6 weeks through 4 years

Use for: DTaP & IPV doses 1, 2, 3, 4
Hib - Any dose in series

Route: IM

Reconstitute before using; ONLY use the manufacturer supplied diluent

Haemophilus influenza type b – Containing Vaccines

Hib (Pedvax)

Ages: 6 weeks through 4 years

Use for: Any dose in series

Route: IM

Hib (ActHIB)

Ages: 6 weeks through 4 years

Use for: Any dose in series

Route: IM

Reconstitute before using; ONLY use the manufacturer supplied diluent

Hib – HepB (Comvax)

Ages: 6 weeks through 4 years

Use for: Hib – any dose in series
HepB – any dose in series

Do NOT use for HepB birth dose

Route: IM

Hib (Hiberix)

Ages: 12 months through 4 years

Use for: Booster (final) dose only

Do NOT use for primary series doses

Route: IM

Reconstitute before using; ONLY use the manufacturer supplied diluent

Hepatitis Vaccines

HepA (Havrix, Vaqta)
Pediatric Formulation

Ages: 12 months through 18 years

Use for: Any dose in series

Route: IM

HepA (Havrix, Vaqta)
Adult Formulation

Ages: 19 years and older

Use for: Any dose in series

Route: IM

HepB (Recombivax, Engerix–B)
Pediatric Formulation

Ages: Birth through 19 years

Use for: Any dose in series

Route: IM

HepB (Recombivax, Engerix–B)
Adult Formulation

Ages: 20 years and older

Use for: Any dose in series

Route: IM

HepA – HepB (Twinrix)

Ages: 18 years and older

Use for: Any dose in series

Route: IM

Human Papillomavirus Vaccines

HPV2 (Cervarix)

FEMALES ONLY

Ages: 9 through 26 years of age

Use for: Any dose in series

Route: IM

Protect from light at all times

HPV4 (Gardasil)

FEMALES and MALES

Ages: 9 through 26 years of age

Use for: Any dose in series

Route: IM

Protect from light at all times

Measles – Mumps – Rubella Vaccine

MMR (M-M-R II) - *LIVE*

Ages: 12 months and older

Use for: Any dose in series

Route: SC

Reconstitute before using; ONLY use the manufacturer supplied diluent

Protect from light at all times

MMRV – located in varicella section

Influenza Vaccines

LAIV (FluMist) - *LIVE*

Ages: 2 years through 49 years

Dosage: 0.1 mL into each nostril

Route: Intranasal – **DO NOT** Inject

IIV (Fluzone)

Ages: 6 months and older

Dosage: 0.25 mL 6 to 35 months of age
0.5 mL 3 years and older

Route: IM

IIV <u>High-Dose (Fluzone)</u>

Ages: 65 years and older

Dosage: 0.5 mL

Route: IM

IIV <u>Intradermal (Fluzone)</u>

Ages: 18 years through 64 years

Dosage: 0.1 mL

Route: Intradermal in deltoid via manufacture microinjection syringe

IIV <u>(Afluria)</u>

Ages: 5 years and older
(9 years and older per ACIP guidelines)

Dosage: 0.5 mL

Route: IM

IIV: _____
(Product Name)

Ages: _____
Dosage: _____

Route: IM

Meningococcal Vaccines

MCV4 (Menactra)

Ages: 9 months through 55 years

Use for: Any dose in series

Route: IM

Protect from light at all times

MCV4 (Menveo)

Ages: 2 years through 55 years

Use for: Any dose in series

Route: IM

Reconstitute before using; ONLY use the manufacturer supplied diluent

MPSV4 (Menomune)

Ages: 2 years and older

Use for: Any dose in series

Route: SC

Reconstitute before using; ONLY use the manufacturer supplied diluent

Hib-MenCY (MenHibrix)

Ages: High-risk children 2 months through 15 months of age

Use for: Any dose in series

Route: IM

Reconstitute before using; ONLY use the manufacturer supplied diluent

Pneumococcal Vaccines

PCV13 (Prevnar 13)

Ages: 6 weeks through 5 years of age

High-risk persons: 5 years of age and older

Use for: Any dose in series

Route: IM

PPSV 23 (Pneumovax 23)

Ages: 65 years of age and older

High-risk persons: 2 years of age and older

Maximum of two (2) doses in a lifetime

Route: SC or IM

Poliovirus Vaccine

IPV (Ipol)

Ages: 6 weeks and older

Use for: Any dose in series

Route: SC or IM

Rotavirus Vaccines

RV1 (Rotarix) - *LIVE*

Ages: 6 weeks up to 8 months 0 days
Maximum age for 1st dose is 14 weeks 6 days

Route: **Administer orally - DO NOT inject**

Reconstitute before using
ONLY use the manufacturer supplied diluent

Protect from light at all times

RV5 (RotaTeq) - *LIVE*

Ages: 6 weeks up to 8 months 0 days
Maximum age for 1st dose is 14 weeks 6 days

Route: **Administer orally - DO NOT inject**

Protect from light at all times

Tetanus Toxoid Vaccine

TT (Generic)

Ages: 7 years and older

This vaccine should only be used if:

Td or Tdap is not available or if the patient needs a tetanus-containing vaccine and has a severe life-threatening allergy to Td or Tdap

Route: IM

Tetanus and Diphtheria Containing Vaccines

Td (Decavac)

Ages: 7 years and older

Use for: Primary series & booster doses

Route: IM

DT (Generic)

Ages: 6 weeks through 6 years

Use for: Primary series & booster doses

ONLY for children with a contraindication or precaution to pertussis vaccine

Route: IM

Tetanus, diphtheria and accellular pertussis Vaccines

Tdap (Adacel, Boostrix)

Ages: 7 through 10 yrs – use for primary series or booster dose if pertussis protection is needed

Ages: 11 yrs & older – use for primary series or booster dose

Route: IM

Varicella – Containing Vaccines

VAR (Varivax) - *LIVE*

Ages: 12 months and older

Use for: Any dose in series

Route: SC

Reconstitute before using; ONLY use the manufacturer supplied diluent

Protect from light once reconstituted

MMRV (ProQuad) - *LIVE*

Ages: 12 months through 12 years

Use for: Any dose in series

Route: SC

Reconstitute before using; ONLY use the manufacturer supplied diluent

Protect from light at all times

ZOS (Zostavax) - *LIVE*

Ages: 50 years and older

Use for: One lifetime dose

Route: SC

Reconstitute before using; ONLY use the manufacturer supplied diluent

Protect from light at all times

Travel Vaccines

Rabies (Imovax)

Ages: All age groups

Use for: Any dose in series & booster

Route: IM

Reconstitute before using; ONLY use the manufacturer supplied diluent

Rabies (RabAvert)

Ages: All age groups

Use for: Any dose in series & booster

Route: IM

Reconstitute before using; ONLY use the manufacturer supplied diluent

JE (Ixiaro)

Ages: 2 months of age and older

Use for: Any dose in series & booster

Dosage: 0.25 mL 2 months to 3 years
0.5 mL 3 years of age and older

Route: IM

YF (YF-Vax) - *LIVE*

Ages: 9 months of age and older

Use for: Any dose & booster

Route: SC

Reconstitute before using; ONLY use the manufacturer supplied diluent

Typhoid (Typhim Vi)

Ages: 2 years of age and older

Use for: Any dose & booster

Route: IM

Typhoid (Vivotif) - *LIVE*

Ages: 6 years of age and older

Use for: All doses in series & booster

Route: Oral – 4 doses on an alternate day interval (1, 3, 5 & 7)

Military Specific Vaccines

AVA (BioThrax)

Ages: 18 through 65 years of age

Use for: Any dose in series & booster

Schedule: 0 & 4 weeks, 6, 12, and 18 months

Route: IM

Smallpox (ACAM2000) - *LIVE*

Ages: Adult population

Use for: Any dose & booster

Route: Percutaneous 15 jabs of a bifurcated needle

Reconstitute before using; ONLY use the manufacturer supplied diluent

Adenovirus - *LIVE*

Ages: 17 through 50 years of age

Use for: One-time dose in military recruits

Route: Oral (2 enteric-coated tablets, (1) type-4 and (1) type-7)

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To contact the Immunization Healthcare Branch:

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

DoDvaccines@mail.mil

www.vaccines.mil