Storage & Handling
Questions and Answers

Prepared by

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STORAGE & HANDLING Vaccination Program
Questions and Answers

Vaccine Storage
- General information
- Vaccine Storage Equipment
- Temperature Monitoring
- Emergency Procedure Recommendations

Vaccine Handling
- Vaccine Diluent and Storage practices
- Vaccine Inventory Management
- Vaccine Prep and disposal
- Vaccine Packing, Shipping and Transport

Adapted from the Immunization Action Coalition (with permission) and the Centers for Disease Control and Prevention (CDC).

Vaccine Storage

General information

1) What is Cold Chain Management?
Cold Chain Management is the process of preparing temperature-sensitive medical products for shipment utilizing standardized systems and procedures, ensuring that required temps are maintained throughout the supply chain, and the validation that those conditions are met during all phases of distribution until delivery.

2) What is proper vaccine storage and handling?
Vaccines are stored, shipped, and handled 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 inadequate protection against the vaccine preventable disease.

3) Who is USAMMA/DOC?
United States Army Medical Material Agency/Distribution Operation Center (USAMMA/DOC) is a core group of highly skilled specialists within the DoD for the management, coordination, and execution of distribution services. Specifically, the packing and storage of Temperature Sensative Medical Products (TSMPs) requiring refrigeration or other special handling requirements while maintaining close in-transit visibility in support of our internal and external customers. The DOC operates under the clinical and technical direction of USAMMA's Pharmacy Consultant who is also the Deputy Director for Distribution Operations of the Military Vaccine (MILVAX) Agency.

4) How can USAMMA/DOC be reached?
For vaccines and temperature sensitive product questions contact USAMMA /DOC during the hours of 0700-1700 EST at phone: 301-619-4318, 1197, 4198/ DSN: 343-4318, 1197, 4198/Fax: 301-619-4468; after hours call: 301-676-1184, 301-676-0857, or 301-256-8072 for urgent issues only.

NIPR E-mail: USAMMADOC@amedd.army.mil.

For more information go to the following website:
http://www.usamma.army.mil/cold_chain_management.cfm

5) Who is DLA Troop Support?
DLA Troop Support provides United States armed services members with food, clothing, textiles, medicines, medical equipment, and construction supplies and equipment. The pharmaceutical division offers most vaccines for purchase by eligible DoD customers. More information can be found at the following website: http://www.dscp.dla.mil

6) What vaccine storage and handling training should immunization departments implement?
Designated primary and backup personnel should have written duties, be trained in vaccine storage and handling, and should know that immediate action must be taken to correct inappropriate storage conditions. Vaccine storage and handling practices should be reviewed annually to update all staff members on the latest policies. During new staff orientation all personnel who will be administering vaccines should be trained in proper vaccine storage and handling practices. Records should be kept of vaccine training sessions and attendees. All staff members responsible for vaccines should understand the importance of cold chain maintenance and the procedures to follow if there is a break in

the cold chain; such as immediately reporting any break in the cold chain to the vaccine coordinator or to the immediate supervisor.

7) Where can additional storage and handling information guidelines be found?
The CDC has a vaccine storage and handling toolkit available at their website and can be accessed at: www2a.cdc.gov/vaccines/ed/shtoolkit. The toolkit contains 2 videos on CD-ROM (How to Protect Your Vaccine Supply and Top 10 Storage and Handling Errors); an interactive game; resources including forms, checklists, posters, and contact information; and through guidelines on proper storage and handling.

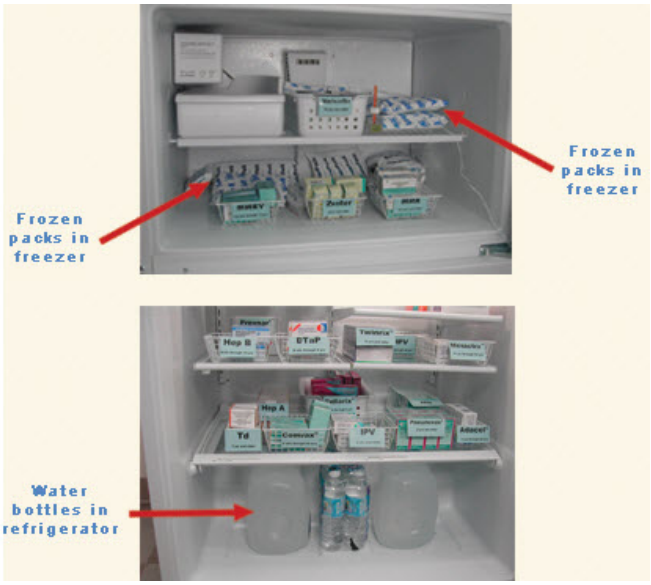
Vaccine Storage Equipment

1) Is there a DoD policy requiring certain vaccine storage equipment to be purchased?
No, clinics should follow guidance for appropriate storage equipment as outlined by the Advisory Committee on Immunization Practices (ACIP), National Center for Immunization and Respiratory Diseases (NCIRD), or service policies. Vaccine storage units must be selected carefully and used properly.

2) What are the general requirements for the type of refrigerator, freezer, or combined refrigerator/freezer unit used to store vaccines?
NCIRD recommends that any refrigerator, freezer, or combined refrigerator/freezer unit used to store vaccine must: be able to maintain required vaccine storage temperatures year-round; be large enough to hold the year's largest inventory; have a certified calibrated thermometer inside each storage compartment; and be dedicated to the storage of vaccines. A combination refrigerator/freezer for home use is acceptable if there are separate compartments, external doors and thermostat controls. High volume clinics may find separate refrigerators and freezers useful.

3) Can a dormitory style refrigerator be used to permanently store vaccines?
Small single-door (dormitory-style or bar-style) combined refrigerator/freezer units should not be used for permanent vaccine storage. Permanent storage is defined as the vaccine supply is maintained in the unit 24 hours a day/7 days a week. The freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store MMRV, varicella, and zoster vaccines. NCIRD recommends that dormitory-style refrigerators only be used to store a clinic's single-day supply of refrigerated vaccines and these vaccines should be returned to the main refrigerator storage unit at the end of each clinic day.

4) How can you stabilize temperatures in the refrigerator?
You can help stabilize the temperature in the refrigerator by adding buffers such as at least two or three large containers of water inside. Store the water bottles against the inside walls and in the door racks. Not only will water bottles help maintain an even temperature in the refrigerator with frequent opening and closing of the doors, they also help keep the temperatures stable in the event of a power failure.



5) How can you stabilize temperatures in the freezer?
You can help stabilize 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. Not only will frozen packs help maintain an even temperature in the freezer with frequent opening and closing of the doors, they will also help keep the temperatures stable in the event of a power failure.

6) What are the requirements for the vaccine storage room?
Good air circulation around the vaccine storage unit is essential for proper heat exchange and cooling functions. The unit should be placed in a well-ventilated room and should have space around the sides and top. If the room temperature is too hot it is recommended that a small AC portal unit or extra ventilation vents are added to ensure room temperature remains stable and does not cause the refrigerator/freezer temperatures to shift outside of normal range.

7) What regular maintenance should be conducted on cold chain storage equipment?
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 should be maintained. Users should conduct regular maintenance tasks that can be divided into daily, weekly, monthly and periodic actions such as: on a daily basis check the temps and ensure the storage unit doors are closed; on a weekly basis defrost the freezer; on a monthly basis clean the coils and motor, clean the storage unit compartments, and check the door seals; and periodically check/clean the drain pan. This logbook is also an ideal place to keep the instructions that came with the equipment.

Temperature Monitoring

1) What type of thermometer is best for measuring temperatures in a vaccine storage unit?
ACIP recommends a certified thermometer such as a standard fluid-filled, minimum-maximum, or continuous chart recorder. While all thermometers are calibrated during manufacturing, certified calibrated thermometers undergo a second individual calibration against a reference standard from an appropriate agency. They are then given a certificate indicating successful completion of this process. Be sure to look for a thermometer with a "traceable certificate," usually to a National Institute of Standards and Technology (NIST) or American Society for Testing and Materials (ASTM) standard.

Uncertified liquid (mercury or alcohol) thermometers and uncertified dial-type household refrigerator/freezer thermometers should not be used.

2) Where within the vaccine storage unit should the thermometer be placed?
In the refrigerator, the thermometer should be placed on the middle shelf, adjacent to the vaccine, or hanging down from the upper shelf. In the freezer, the thermometer should be suspended from the ceiling of the compartment or placed on a box or some other item so that it is in the middle of the compartment off the floor. If the thermometer indicates a temperature outside the recommended range, check that the thermometer is appropriately situated.

3) How often should temperatures be recorded for refrigerator and freezer compartments where vaccines are stored? And how should you document temperatures?
One person should be assigned primary responsibility for maintaining temperature logs, along with one backup person. All personnel responsible for vaccines should be trained and familiar with the correct storage temperatures for the various vaccines and procedures for what to do if the temperature is out-of-range. Temperatures inside refrigerator and freezer compartments should be measured and recorded on a temperature log at a minimum of at least twice a day (the room temperature should also be recorded on the log); once at the start of the day and a second time before the area is closed whether or not you have an alarm system installed. Army immunization areas must record the temperature a minimum of 4 times per day. Immediate action must be taken if the temperature is outside the recommended range for either compartment.

see:

http://www.usamma.army.mil/assets/docs/Monitoring%20Temperatures%20on%20Refrig.pdf

http://www.vaccines.mil/documents/1387VaccineRefrigeratorTempChart4xDay.pdf (Army)

http://www.vaccines.mil/documents/1383Vaccine%20RefrigeratorTempChart.pdf

4) Who should adjust the temperature of a vaccine storage unit?
Only the primary or backup vaccine coordinator should adjust the temperature of a vaccine storage unit. Limiting access to the thermostat reduces the risk that the temperatures will be adjusted inappropriately. If the thermostat requires adjustment, alert the vaccine coordinator or immediate supervisor. A warning sign should be posted on the storage unit that says, “Do not adjust refrigerator or freezer temperature controls. Notify (insert name) if adjustments are necessary”.

5) How long do you need to monitor temperatures after a refrigerator or freezer thermostat is adjusted before you know the temperatures are within the recommended range and you can safely store vaccines in them?
After the thermostat in a working refrigerator or freezer has been adjusted, check the temperature in both the refrigerator and freezer (if using a combined unit) every half hour until the temperature stabilizes. If the temperature rises or falls rapidly or is outside the recommended range, adjust the thermostat inside the unit and repeat the process. As a general guideline, NCIRD also suggests that you monitor temperatures inside the refrigerator and freezer for a week in any new (or newly repaired) unit before it is used for vaccine storage. This practice allows you to check that the unit is performing well and allows time to make any necessary adjustments before expensive vaccines are put at risk. Of course, twice daily temperature monitoring should be an ongoing practice as well.

6) Do twice daily physical temperature checks need to occur if an alarm system is in place?
Yes. ACIP still recommends twice daily temperature monitoring and recording. Alarms and continuous recording thermometers add another layer of protection but they are not a substitute for manually

checking and recording the temperatures twice daily. Relying solely on alarms can lead to complacency and inappropriate temperatures may not be discovered in a timely manner (e.g., alarm battery failure). DoD has had many vaccine losses due to failure of alarm or call systems that were not being physically checked, these losses could have been avoided if someone was physically checking the temperatures.

7) How long should temperature logs be kept?
By keeping temperature logs for at least 3 years, you can track recurring temperature problems and determine how long they have been happening. This information allows you to better define the time frame in question and take appropriate action. Archived temperature logs also show how well the vaccine storage unit is working overtime and can be used to determine when a unit may need adjustment, maintenance, or replacement, such as when temperatures are consistently at the limit or sometimes beyond the limit of the recommended temperature range.

Emergency Procedure Recommendations

1) How can you determine if vaccine has been out of a safe temp range long enough to affect its efficacy
It depends on the vaccine, the length of time it was outside of recommended storage conditions, and the environment it was in (temperature and light). Physical changes are not always apparent after exposure to inappropriate temperatures. Some vaccines may show physical evidence of altered potency when exposed to inappropriate storage conditions, such as clumping in the solution that does not go away when the vial is shaken. Other vaccines may look perfectly normal when exposed to inappropriate storage conditions. If you have any concerns about vaccines that may not have been stored or handled properly, follow your immunization program policy and immediately contact USAMMA/DOC for guidance. Do not assume that vaccine inappropriately exposed to light or to excessive temperatures must be destroyed; clearance for destruction should come from USAMMA.

2) What are the appropriate steps if a vaccine compromise is suspected?
If there are any discrepancies with the packing slip, concerns about a shipment or if you have a potentially compromised vaccine, immediately mark the vaccine and diluent as “DO NOT USE”, store them under proper conditions apart from other vaccine supplies until the integrity of the vaccine and diluent is determined. Contact USAMMA/DOC for further instructions and prepare an Executive Summary (EXSUM) routing it through the Chain of Command. USAMMA will advise you on disposition for any anthrax and smallpox vaccine as well as provide you written authorization to utilize the vaccine or dispose of the vaccine. They will pass the rest of the information onto Defense Logistics Agency – Troop Support who will validate the vaccine compromise and send you written documentation on the disposition of all other vaccines. Report all confirmed compromised vaccine losses to the MILVAX regional analyst for your installation. Reports must include; situation that resulted in loss, vaccines that were compromised, total vials/doses lost, and cost of compromised vaccines. An example of an EXSUM can be found at the following web link: http://www.usamma.army.mil/assets/docs/EXSUM%20SOP.pdf

3) What steps should be taken if the vaccine storage unit malfunctions?
The most important action to take if the vaccine storage unit is not working properly is to protect the vaccine supply. Move the vaccine to a properly functioning storage unit with internal temps within the recommended ranges, then attempt to troubleshoot the problem and correct it. Do not allow the vaccine to remain in a nonfunctioning unit for an extended period of time while you attempt to resolve the problem. If you are unsure how long the storage unit will not be functioning properly or you determine that the problem cannot be corrected in time to maintain the internal temperature within the recommended range, activate your clinics Emergency Vaccine Retrieval and Storage Plan.

4) What steps can be taken to prevent accidental loss of vaccine?

Post a DO NOT UNPLUG sticker near the electrical outlet and on the refrigerator or freezer alerting staff, janitors, and electricians not to unplug the unit. Signs warning staff to not unplug the storage unit can be found at the following site http://www.immunize.org/handouts/vaccine-storage-handling.asp. In addition, plug your vaccine storage unit directly into the outlets (never use extension cords or power strips), use a safety-lock plug or an outlet cover to reduce the chance of the unit becoming inadvertently unplugged and avoid using power outlets with built-in circuit switches (they have little red reset buttons) and outlets that can be activated by a wall switch. These can be tripped or switched off, resulting in loss of electricity to the storage unit. All storage devices and alarms should be plugged into back-up power plugs to reduce the chance of accidental loss of power to the units during an outage.

5) How should vaccines be stored over a weekend or holiday if staff is not available?
Vaccine security requires that backup equipment and backup plans are available; equipment failure can occur because of a power failure, breakdown, or normal wear and tear. A continuous-monitoring temperature alarm/notification system should be considered, especially for practices with a large inventory, to help alert staff to after-hours emergencies. Alarms should be monitored electronically and physically on a 24 hours, seven days a week basis. Simple systems sound audible alarms when the temperatures inside the storage units exceed the recommended ranges, where as sophisticated systems sound an audible alarm and alert one or more designated person(s) at a specified phone or pager number. Storage areas with restricted access should have a device installed (light indicator/audible alarm) indicating when the storage unit temperature is out of range that can be checked without physically entering the restricted area.

6) What is an Emergency Vaccine Retrieval and Storage Plan?
The Emergency Vaccine Retrieval and Storage Plan provides up-to-date information regarding procedures to follow to protect and/or retrieve vaccines as quickly as possible when a potentially compromising situation occurs such as inclement weather conditions, natural disasters, or other emergencies that might disrupt power or flood any office where vaccine is stored. The immunization clinic vaccine coordinator should develop an Emergency Vaccine Retrieval and Storage Plan and keep it in a prominent and easily accessible location near the vaccine storage units.

7) Why is it important to identify an alternate storage location?
In case of an emergency situation, having an established working agreement with at least one alternate storage facility with a backup generator where vaccine can be appropriately stored and monitored for the interim, can save thousands of dollars worth of vaccines. Ensure that advanced arrangements are made with the facility(s) to store your vaccine when weather predictions call for inclement conditions (e.g., tornadoes, hurricanes, ice, severe snowstorms), when your vaccine storage equipment cannot be repaired, or when the power cannot be restored before the vaccine storage unit temperature rises above the recommended range.

Vaccine Handling

Vaccine Diluent and Storage practices

1) What is the required refrigerator vs. freezer temperatures?
Store all vaccines according to the manufactures' package insert. Certain vaccines are sensitive to freezing temperatures and should be stored in temperatures of 35°F- 46°F (2°C-8°C). Other vaccines lose potency when exposed to increased temperatures because they contain live viruses and should be stored in the freezer at temperatures of 5°F (-15°C) or colder. An exception to the rule is for measles, mumps, and rubella vaccine (MMR) which is routinely stored in the refrigerator, but can also

be stored in the freezer (MMR in the lyophized state is not affected detrimentally by freezing temperatures).

2) What happens to vaccine contents when vaccines are not properly stored?
Excessive heat or cold exposure damages vaccine, resulting in loss of potency and once potency is lost it can never be restored. Each time vaccine is exposed to excessive heat or cold, the loss of potency increases and eventually, if the cold chain is not correctly maintained, all potency will be lost, and the vaccine becomes useless. Excessive cold exposure is as bad, if not worse than excessive heat exposure for most vaccines. If you have concerns about your vaccine supply, contact USAMMA/DOC immediately.

3) Do vaccines need to be protected from light?
Yes. HPV, MMR, MMRV, rotavirus, varicella, and zoster vaccines are sensitive to light, causing loss of potency, so must be protected from light at all times. Store these vaccines at the appropriate temperatures in their boxes with the tops on until they are needed.

4) How should vaccines be stored in the refrigerator/freezer?
Vaccines should be placed in the center of the refrigerator/freezer compartment, on the middle shelves, away from the walls, floor and doors of the unit in open containers so air can circulate around the vaccines. If the upper shelf of the refrigerator must be used for vaccine storage, it would be best to place MMR on this shelf because MMR is not sensitive to freezing temperatures. The temperature in the vegetable bins, on the floor, next to the walls, in the door, and near the cold air venting from the freezer may differ significantly from the temperature in the main body of the refrigerator so vaccines should not be stored in these areas.

5) How should vaccines be labeled in the refrigerator and freezer?
The location of each specific vaccine inside the storage unit should be clearly labeled. Vaccine products that have similar packaging should be stored in different locations within the storage unit to avoid confusion and medication errors. For example, if you have pediatric and adult versions of the same vaccine, storing them in different locations lessens the chance that someone will inadvertently choose the wrong vaccine. In addition, vaccines that have similar sounding names should be stored in different locations. For example, DT and Td vaccines might be easily confused, as could Hib and hepatitis B vaccines.

6) Can I remove the vaccine from its packaging to store more product in the refrigerator?
No. Storing loose vaccine vials outside of their boxes is not recommended. This practice makes inventory management more difficult, makes tracking expiration dates more difficult, predisposes to administration errors when vials are confused, and potentially exposes the vaccines to light.

7) Where is the appropriate place to store diluents?
Store all diluents according to the manufactures package insert. Diluents packaged separately from their corresponding vaccines can be stored at room temperature or in the refrigerator. Diluents packaged with their vaccines should be stored in the refrigerator next to their vaccines but unlike vaccines, diluents may also be stored on the refrigerator door. ACAM2000 diluent is shipped refrigerated with vaccine but should be stored on shelf at room temperature

8) Can vaccines be stored in the same unit where employees' lunches are located?
No, biologics should never be stored with food or drinks.

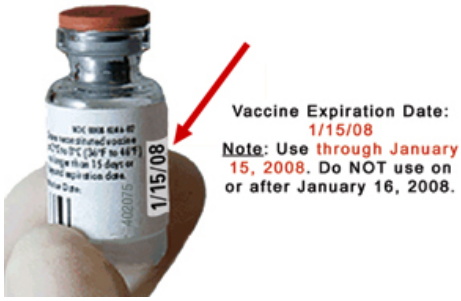
9) Is it safe to store vaccines and other biologics in the same refrigerator with lab specimens or blood products?
CDC's vaccine storage and handling toolkit states, if possible, other medications and other biologic

products should not be stored inside the vaccine storage unit. If there is no other choice, these products must be stored below the vaccines on a different shelf. This prevents contamination of the vaccines should the other products spill, and reduces the likelihood of medication errors.

Vaccine Inventory Management

1) What is the appropriate disposition for expired vaccine?
DoD activities are responsible for disposal of compromised or expired vaccine. Contact the pharmacy or logistics for specific policies regarding the disposition of unopened vials, expired vials, unused doses, doses drawn but not administered, and potentially compromised vaccine. DoD activities that provide anthrax and small pox vaccines will report vaccine inventories for destruction to their Service medical logistic agency by preparing a destruction document. The destruction document needs to be faxed to the USAMMA/DOC and must include the following information: date when the vaccine was destroyed; list of lot number(s) destroyed; number of unopened vials destroyed; method of destruction; for Navy ships, where was the vaccine acquired, i.e. FISC, another ship (include ship name), etc.; and signature block, e-mail, and phone number. For more information go to the following link: http://www.usamma.army.mil/assets/docs/Vaccine_Disposition.pdf

2) When the expiration date of a vaccine indicates a month and year, does the vaccine expire on the first or last day of the month?
When the expiration date is marked with only a month and year, the vaccine or diluent may be used up to and including the last day of the month indicated on the vial. Any unused vaccine or diluent should not be used after this month has passed. If the expiration date printed on all vaccines and diluent vials and boxes includes the month/day/year the vaccine or diluent may be used up to and including this date. Monitor and rotate your vaccine supply carefully so that vaccines do not expire.



3) What must be done to replace potentially compromised anthrax, small pox or influenza vaccine?
When a DoD activity has a potential loss of vaccine potency for anthrax, small pox or influenza vaccine

an EXSUM must be prepared and submitted to the United States Army Medical Materiel Agency (USAMMA) Distribution Operations Center (DOC) within 24 hours upon discovery of potentially compromised vaccine. The EXSUM must be routed up the chain of command for review and endorsement before faxing to the USAMMA/DOC. The EXSUM must contain the following information: detailed explanation of the circumstances surrounding the potential loss of vaccine potency, location in which the vaccine was discovered, temperature of the location in which the vaccine was discovered, list of lot number(s) affected, number of unopened vials, detailed explanation of corrective action(s) to preclude future loss of vaccine, and point of contact (POC) information to include name(s) and phone number(s). USAMMA/DOC must receive an Executive Summary (EXSUM) before replacement of vaccine will be shipped. An EXSUM is not required for vaccine that has reached its expiration date. An example of an EXSUM can be found at the following web link:
http://www.usamma.army.mil/assets/docs/EXSUM%20SOP.pdf

Vaccine Prep and disposal

1) Can vaccines be pre-filled prior to an event?
ACIP discourages the routine practice of prefilling syringes because of the potential for administration errors and sterility issues. The majority of vaccines have a similar appearance after being drawn into a syringe. In addition to administration errors, prefilling of syringes is a concern because FDA does not license administration syringes for vaccine storage. Vaccine doses should not be drawn into a syringe until immediately before administration. 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 after filling. Unused syringes filled by the end user (i.e., not filled by the manufacturer) should be discarded at the end of the vaccination session.

2) Can you prefill syringes prior to mass influenza vaccination clinic?
ACIP discourages the routine practice of prefilling syringes because of the potential for administration errors. In certain circumstances in which a single vaccine type is being used (e.g., in advance of a community influenza vaccination campaign), filling a small number of syringes (10 at a time) can be considered. When conducting an influenza clinic certain procedures should be followed: only one vaccine type may be administered at the clinic, vaccine should not be drawn up in advance of arriving at the clinic site, vaccine should be transported in the manufacturer supplied packaging, 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. Vaccine that has been drawn up and not administered must be discarded at the end of the day.

3) How long is a vaccine dose viable if it has been stored in the refrigerator in a syringe?
Disposable syringes are meant for administration of immunobiologics not for storage. This is a quality control and patient safety problem because if you do not draw up the vaccine yourself, you cannot be sure of the composition and sterility of the dose you are administering. Because of the lack of data concerning the stability and sterility of vaccine stored in syringes prefilled by providers and because of the other reasons just listed, CDC recommends that vaccines drawn into syringes be discarded at the end of the clinic day. This does not apply to manufacturer-supplied prefilled glass syringes.

4) How long can a multi-dose vial be used once it is opened and a dose is withdrawn?
Doses from a partially used multi-dose vial can be administered until the expiration date printed on the vial or vaccine packaging, provided that the vial has been stored correctly and that the vaccine is not visibly contaminated. See page 23 of the ACIP guidelines at:
http://www.cdc.gov/mmwr/PDF/rr/rr5515.pdf , an additional reference can be found at:
http://www.jointcommission.org/NR/rdonlyres/7DDACC46-9522-4DA6-B7A4-

A41F52745A7E/0/jconlineJune910.pdf The expiration date for reconstituted multidose vials varies from product to product and the new expiration date and time will differ from that printed on the vial. For example, after reconstitution, MMR vaccine must be administered within 8 hours and must be kept at refrigerator temperature during this time. Consult the package insert for the most up-to-date information about expiration dates and times following reconstitution. Unused reconstituted vaccines kept beyond these limits should not be administered.

5) What information should be marked on the multi-dose vaccine bottle once it has been opened?
Mark multi-dose vials with the date it was first opened and mark reconstituted vaccine with the date and time it was reconstituted. This is important for two reasons: some vaccines expire within a certain time after opening or after reconstitution. This may not be the same as the expiration date; and dating opened or reconstituted vials helps manage vaccine inventory by identifying which vials should be used first.

6) How long can manufacturer-filled syringes be stored once the rubber tip is removed and the needle is added?
When manufacturer-filled glass syringes are not supplied with needles, the needles should be attached just before administration. If a needle is attached to a sealed manufacturer prefilled syringe, the syringe should be used or discarded at the end of the clinic day because the sterile seal has been broken. This does not apply to prefilled syringes prepared by the manufacturer with the needle already attached. Additional information can be found at the following web link:
http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/prep_disposal.htm

7) Are vaccine diluents interchangeable?
Diluents are not interchangeable, even diluents from the same manufacturer. Therefore, use only the specific diluent provided by the manufacturer for each type of vaccine to ensure adequate potency and safety of the resulting mixture.

Vaccine Packing, Shipping and Transport

1) What SOPs should be developed for the storage and handling of vaccines?
Storage and handling SOPs must be developed and include contact information for the following: primary and back-up vaccine coordinators, Logistics, Pharmacy, Provost Marshal and Medical Maintenance personnel; refrigerator repair technicians; back-up storage areas; temperature alarm repair technician, dry ice venders; emergency repair companies, and Vaccine Manufacturers. Additional SOPs should address daily/monthly operations and maintenance of equipment, transportation of vaccines, storage and handling of vaccines when off-site, and procedures for compromised vaccine. Refer to the Emergency Vaccine Retrieval and Storage Plan worksheet found on the MILVAX website at http://www.vaccines.mil/default.aspx?cnt=disease/minidv&dID=61

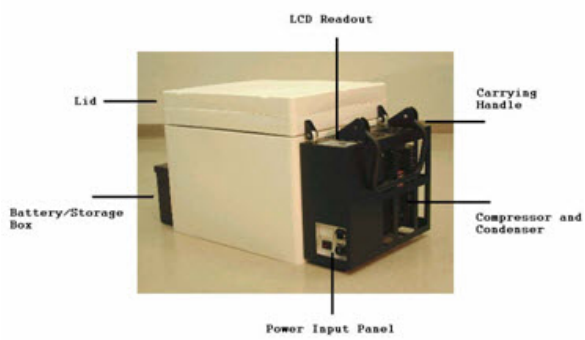
2) What type of storage devices should be used when administering immunizations offsite?
You must use validated shipping containers and packing protocols which assures product safety and efficacy. You may use hard-sided plastic insulated coolers or Styrofoam™ coolers with at least 2-inch thick walls, a VaxiCool or VaxiPac. Thin-walled Styrofoam™ coolers, such as those purchased at grocery stores to hold beverages, are not acceptable. Examples of USAMMA recommended storage devices can be found at the following link: http://www.usamma.army.mil/cold_chain_management.cfm

3) How should storage containers be labeled when transporting vaccines offsite?
Attach labels to the outside of the container to clearly identify the contents as being valuable and fragile vaccines. Record vaccine type(s), quantity, date, time, and originating facility on a label on the outside

of the container. Document the vaccine storage unit temperature at the time the vaccine is removed for transport.

4) What is a VaxiCool?

The VaxiCool is a commercially procured, high-efficiency refrigerator or freezer system designed for the local transport, temporary storage and re-distribution of temperature-sensitive pharmaceuticals. The VaxiCool has an inside dimension of 14”(length) by 10-1/2”(width) by 10”(depth), its payload can be from 1 to 400 Vials. The VaxiCool comes in two models, VXC-1 and VXC-2. The VXC-1 model is a refrigerator only; the VXC-2 is both refrigerator and freezer. When 2-12 Volt/14 Amp batteries are installed and fully charged, the VaxiCool can maintain temperatures on internal batteries for up to 5 days, when using 2-12 Volt/20 Amps it can maintain temperature for up to 6 to 7 days after being disconnected from an AC power source. Due to its insulation capabilities it can possibly add 16-24 hours more if the lid is kept closed. More information can be found at:
http://www.usamma.army.mil/cold_chain_management.cfm



VaxiCool

5) What is a VaxiPac?

The VaxiPac is a commercially procured, high-efficiency small insulated container used for transport of. It is comprised of a rugged, hard plastic material filled with Vacupanel insulation. It has an exterior dimension of 15” (length) by 7.75” (width) by 11.38” (depth) and can hold a maximum of 24 vials (a full layer consists of 12 vials). The VaxiPac should be utilized for the re-distribution of products for short movements of less than 24 hours. The container is designed to maintain the product at the appropriate temperature (2°–8°Celsius). It utilizes a specific refrigerant brick called VaxiSafe which is composed of a Phase Change Material (PCM) that hardens at 6°C.. TheVaxiSafe is the only approved refrigerant for use in the VaxiPac, ice blocks should never be used.. More information of the VaxiPac can be found at:
http://www.usamma.army.mil/cold_chain_management.cfm

6) How do I order a VaxiCool or VaciPac?

The information for ordering a VaxiCool or VaxiPac can be found at the following link:

http://www.usamma.army.mil/Assets/Docs/Equipment%20Used%20In%20Support%20Of%20Cold%20Chain%20Distribution.Pdf

7) Can vaccines be transported in a paper bag?
No, you must use an approved insulated container, such as a hard-sided plastic insulated cooler or Styrofoam™ cooler with at least 2-inch thick walls, a VaxiCool or VaxiPac with appropriate packing material and a thermometer. Refer to the USAMMA packing protocols at the following link: http://www.usamma.army.mil/cold_chain_management.cfm

8) What are the guidelines for storing vaccine during off-site clinics?
Ideally, vaccines should be stored at the recommended temperatures inside a properly functioning storage unit (e.g., refrigerator, freezer, refrigerator/freezer combination) at the off-site clinic. If such a unit is not available and the vaccine must be maintained in an insulated container, that container must be either the shipping containers the vaccines arrived in from the manufacturer, a hard-sided plastic insulated or Styrofoam™ coolers with at least 2-inch thick walls or a VaxiCool or VaxiPac. During the off-site clinic, keep the cooler closed as much as possible. A thermometer must be kept in the cooler with the vaccines, and temperatures should be checked and recorded on a temp log at a minimum of every hour.

9) What are the procedures for turning vaccine in after off-site vaccination clinic?
Unpack vaccines from the transport container and store them in their original packaging regardless of their bulkiness; this prevents the exposure of vaccines to room temperature and light. Check the temperature to ensure the vaccines have not been exposed to temperatures above 35°F or below 32°F. Then place the vaccines in the appropriate storage unit.