Vaccine Storage and Handling Toolkit

National Center for Immunization and Respiratory Diseases

Vaccine Storage and Handling Plans

General Recommendations

All healthcare providers who administer vaccines should evaluate their cold chain procedures to ensure that vaccine storage and handling guidelines are being followed. Each office should develop and adhere to a detailed written Routine Vaccine Storage and Handling Plan. This plan should include all aspects of routine vaccine management, from ordering vaccines and controlling inventory to storing vaccines and monitoring storage conditions. A written plan will help vaccine providers stay organized and will provide quality assurance of proper vaccine management.



Develop and adhere to a Routine Vaccine Storage and Handling Plan.



Each office needs an Emergency Vaccine Retrieval and Storage Plan.

In addition, each office should have a detailed written Emergency Vaccine Retrieval and Storage Plan in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions. Establishing a set of written plans for both daily and emergency situations helps assure the continued viability of vaccines. These plans should be easily accessible to staff and should be kept near the vaccine storage unit(s).

Many components of the routine and emergency plans will be the same for every practice but some of the details may vary depending on local policies. Consult your agency or local or state health department immunization program, as appropriate for your situation, for any special instructions.

Routine Vaccine Storage and Handling Plan

The information below is provided as a guideline for developing a Routine Vaccine Storage and Handling Plan for the protection and maintenance of your vaccine supply.

Whenever there is a question about the integrity of the vaccine, follow your state health department immunization program policy and contact either the manufacturers quality control office or the immunization program for guidance.

You may also use the Routine Vaccine
Storage and Handling Plan Worksheet in the
Resources section to help organize your plan.
Consult your agency, local health department,
or state health department immunization
program, as appropriate for your situation, for
any special instructions or forms. Whenever

there is a question about the integrity of the vaccine, follow your state health department immunization program policy and contact either the manufacturers quality control office or the immunization program for guidance.

Each Routine Vaccine Storage and Handling Plan should include the following information:

Up-to-date contact information

- For the primary and backup vaccine coordinators who are responsible for routine vaccine storage and handling (see the section on <u>Vaccine Personnel</u>)
- For the state or local health department immunization program (see <u>State Immunization</u> Program Contact Information in the Resources section)
- For the manufacturers of the vaccines in your inventory (<u>Manufacturer Quality Control</u> <u>Office Telephone Numbers</u> in the Resources section)
- For the refrigerator and freezer maintenance and repair company(s)
- For the vaccine storage unit alarm company (if applicable)
- For the sources of packing materials and certified calibrated thermometers
- Descriptions of the roles and responsibilities of the primary and backup vaccine coordinators (see the section on <u>Vaccine Personnel</u>)
- Summaries of the storage requirements for each vaccine and diluent in your inventory (see the sections on <u>Vaccine Storage Practices</u> and <u>Selected Biologicals</u>)
- Protocols for vaccine storage unit temperature monitoring (see the section on <u>Temperature Monitoring</u> and <u>Thermometers</u> in the Vaccine Storage Equipment section)
- Protocols for vaccine storage equipment maintenance (see the section on <u>Vaccine</u> Storage Equipment)
- Protocols for the correct placement of vaccine within storage units (see <u>Vaccine</u> Storage Locations and Positioning in the section on Vaccine Storage Practices)
- Protocols for responding to vaccine storage and handling problems (see the section on <u>Storage Troubleshooting</u>)
- Protocols for vaccine inventory management (contact your state health department immunization program for details and see the section on <u>Vaccine Inventory Management</u> for general guidelines)
- Protocols for transporting and receiving vaccine shipments (contact your state health department immunization program for details and see the section on <u>Vaccine Shipments</u> and <u>Maintaining the Cold Chain During Transport</u> in the Resources section for general guidelines)
- Policies for preparing vaccine for administration (see the section on <u>Vaccine</u> Preparation and Disposal)
- Protocols for proper disposal of vaccines and supplies (contact your state health department immunization program for details and see the section on <u>Vaccine Preparation</u> and Disposal for general guidelines)
- Samples of the forms used in your vaccination program (contact your state health

department immunization program for details and see the <u>Resources</u> section —e.g., temperature logs, stock records, tally sheets)

Keep your Routine Vaccine Storage and Handling Plan in a prominent and easily accessible location near the vaccine storage units. Also establish a checklist of procedures and post it on all vaccine storage units (see Checklist for Safe Vaccine Handling and Storage in the Resources section).

All staff members who administer or handle vaccines in any way should be familiar with the Routine Vaccine Storage and Handling Plan (see <u>Training</u> in the Vaccine Personnel section).



Staff members should be familiar with the Routine Vaccine Storage and Handling Plan.

Emergency Vaccine Retrieval and Storage Plan

General Guidelines

To protect the vaccine inventory and to minimize potential monetary loss, every facility that stores vaccine should have a written Emergency Vaccine Retrieval and Storage Plan. Various situations may compromise vaccine storage conditions, such as equipment failures, power outages, or natural disasters. The Emergency Vaccine Retrieval and Storage Plan should provide up-to-date information regarding procedures to follow to protect and/or retrieve vaccines as quickly as possible when a potentially compromising situation occurs. Post the Emergency Vaccine Retrieval and Storage Plan on or near the vaccine storage equipment. Ensure that all staff (current and new) read the plan and understand it. Also ensure that janitorial and security staff are aware of the plan and know the procedures to follow to notify designated personnel about any problems with the vaccine storage equipment. Review and update the contact lists in the plan quarterly; review and update the entire plan annually.

When state officials, local officials, or providers have reasonable cause to believe that weather conditions, natural disasters, or other emergencies might disrupt power or flood any office where vaccine is stored, emergency procedures should be implemented **in advance of the event**.

Whenever there is a question about the integrity of the vaccine, follow your state health department immunization program policy and contact either the manufacturer's quality control office or the immunization program for guidance.

The information below is provided as a guideline for developing an Emergency Vaccine Retrieval and Storage Plan for the protection of vaccine inventories before and during emergency situations. You may also use the Emergency Response Worksheet in the Resources section to help organize your response. Consult your agency, local health department, or state health department immunization program, as appropriate for your situation, for any special instructions or forms. Whenever there is a question about the integrity of the vaccine, follow your state health department immunization program policy and contact either the manufacturers quality control office or the immunization program for guidance.

Advance Preparations

Well in advance of any emergency situation you should have the following personnel, equipment, information, and protocols in place:

- Designated primary and backup vaccine coordinators with emergency contact information. Record this information in the <u>Emergency Vaccine Retrieval and Storage Plan</u> <u>Worksheet</u> found in the Resources section. In addition to their routine vaccine storage and handling duties (see the section on <u>Vaccine Personnel</u> for details), the primary and backup vaccine coordinators should:
 - Monitor the operation of the vaccine storage equipment and systems;
 - Track inclement weather conditions;
 - Set up and maintain a monitoring/notification system during times of inclement weather or other conditions that might cause a power outage (a continuous-monitoring temperature alarm/notification system should be considered, especially for practices with large inventories);
 - Ensure the appropriate handling of the vaccine during a disaster or power outage;
 - Ensure 24-hour access to the building and vaccine storage unit(s); and
 - Ensure that sufficient fuel is on hand to continuously run the generator for at least 72 hours if the facility has a backup generator.
- Emergency staff contact list in order of contact preference. Determine whether all or certain persons on the list should be contacted in the event of a vaccine storage emergency or if the first person reached is sufficient. Include the primary and backup vaccine coordinators on the list. Record the names (in order) and contact information in the Emergency Vaccine Retrieval and Storage Plan Worksheet.
- Vaccine storage unit specifications. For each vaccine storage unit in your facility, identify the type of unit (e.g., refrigerator, freezer, combination refrigerator/freezer), the brand name, the model number, and the serial number. Record this information in the Emergency Vaccine Retrieval and Storage Plan Worksheet. These specifications may be useful for the repair company.
- Alternate vaccine storage facility or facilities. Establish working agreements with at least one alternate storage facility with a backup generator where vaccine can be appropriately stored and monitored for the interim (e.g., hospital, long-term care facility, state depot, Red Cross, fire station, packing plant). Make advance arrangements 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. Record the name of the alternate facility(s), the name of the contact person(s), and the telephone number(s) in the Emergency Vaccine Retrieval and Storage Plan Worksheet.



Establish at least one alternate storage facility where vaccine can be appropriately stored and monitored. This facility should have a backup generator.

- Written protocols, vehicles, and drivers for transporting vaccine to and from the alternate vaccine storage facility.
 - If the vaccine can be moved to the alternate facility before the vaccine storage temperature rises above the recommended range, it may be transported in insulated containers or coolers within ordinary vehicles inside the passenger compartment (not in the trunk because temperatures cannot be controlled inside the trunk). Make advance arrangements for a primary and backup vehicle and driver and record the contact information in the Emergency Vaccine Retrieval and Storage Plan Worksheet.





When transporting vaccine in ordinary vehicles use the passenger compartment—not the trunk.

If the location is far away or if you have a large quantity of vaccine, consider renting a refrigerated truck to transport the vaccine. In this case, joining with other practices to reduce costs may be advantageous if a refrigerated truck rental is necessary. Make advance arrangements with a local refrigeration company and an alternate and record the contact information in the Emergency Vaccine Retrieval and Storage Plan Worksheet.



A refrigerated truck can be used to transport vaccine.

- Develop written protocols for transporting vaccine to and from the alternate vaccine storage facility.
 - Establish how to load the vehicle.
 - Have preselected routes to take (and alternate routes if necessary).
 - Determine the estimated time en route.

- Written instructions for entering your facility and vaccine storage spaces in an emergency if the building is closed or if it is after hours. These instructions should include the building security/after-hours access procedure, a floor diagram and the locations of the following:
 - Doors
 - Flashlights
 - Spare batteries
 - Light switches
 - Keys
 - Locks
 - Alarms (including instructions for use)
 - Circuit breakers
 - Packing materials
- Appropriate packing materials to safely transport or temporarily store vaccine. These materials may include insulated containers, refrigerated/frozen packs, and dry ice (depending on the type of vaccine—see Written protocol for vaccine packing in this section, Maintaining the Cold Chain During Transport in the Resources section, Chart of Refrigerated/Frozen Pack Needs for Different Climates in the Resources section for general guidelines). In situations where an alternate vaccine storage facility with a backup generator cannot be identified within a reasonable distance, maintain the appropriate packing materials to temporarily and safely store vaccine at your facility. Record the names and contact information for sources of these materials in the Emergency Vaccine Retrieval and Storage Plan Worksheet.



Insulated containers.



Refrigerated/frozen packs.



Dry Ice.

- Prioritized vaccine packing list. Make a written list of which vaccines to pack first in an emergency. Contact your state or local health department immunization program for advice on prioritization. If it is not possible to pack and transport all your vaccines, use your prioritized vaccine packing list to determine the types and amounts of vaccine to save.
- Written protocol for vaccine packing. Each facility should develop its own standard operating procedures (SOPs) for packing vaccine. These instructions should be readily available for staff unfamiliar with vaccine packing procedures. Key steps that should be reflected in all SOPs are:
 - Open the refrigerator and/or freezer doors only when absolutely necessary and only after you have made all preparations for packing and moving the vaccine to the alternate storage facility.
 - Use properly insulated containers to transport the vaccine. These containers should be validated to ensure that they are capable of maintaining the vaccine at the correct temperatures. You may use the shipping containers the vaccines arrived in from the

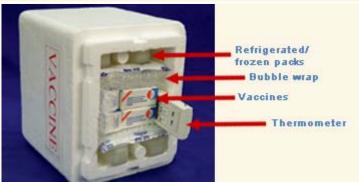
manufacturer. Alternatively, you may use hard-sided plastic insulated containers or Styrofoam[™] coolers with at least 2-inch thick walls. Thin-walled Styrofoam[™] coolers, such as those purchased at grocery stores to hold beverages, are not acceptable.

Refrigerated vaccines:

- Pack the refrigerated vaccines first, using enough refrigerated/frozen packs to maintain the cold chain. The number and placement of refrigerated/frozen packs inside the container will depend on container size and outside temperature. For detailed instructions, see Climates in the Resources section.
- Be sure to place an insulating barrier (e.g., bubble wrap, crumpled brown packing paper, Styrofoam[™] peanuts) between the refrigerated/frozen packs and the vaccines to prevent accidental freezing. The contents of the container should be layered as follows: refrigerated/frozen packs, barrier, vaccine, thermometer or temperature monitor, another layer of barrier, and additional refrigerated/frozen packs.
- Use properly placed thermometers near the vaccine to assess whether the cold chain has been broken. The thermometer should be placed next to the vaccine and should not come in contact with the refrigerated/frozen packs.
- 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.



Place bubble wrap, crumpled brown packing paper, or Styrofoam[™] peanuts between the refrigerated/frozen packs and the vaccines.



Place the thermometer next to the vaccine but not in contact with the refrigerated/frozen packs.













Attach appropriate labels to the outside of the container.

Frozen vaccines:

- Pack the frozen vaccines last, using a separate insulated container. Remove combined measles, mumps, rubella, and varicella vaccine (MMRV); varicella vaccine; and zoster vaccine from the freezer and pack with dry ice immediately before they are to be transported. At least 6 pounds of dry ice should be used in the container to maintain the vaccines in their frozen state.
- 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.



Use properly insulated containers to transport vaccine.



Dry ice should be used during transport to maintain vaccines in their frozen states.

• Written protocol for appropriately storing vaccine at the alternate vaccine storage facility. Combined measles, mumps, rubella, and varicella vaccine (MMRV); varicella vaccine; and zoster vaccine should be stored in the freezer at 5°F (-15°C) or colder. Other vaccines should be stored in the refrigerator at 35° to 46°F (2° to 8°C). There should be adequate cold air circulation around the vaccines. Each alternate vaccine storage unit should have a functioning certified calibrated thermometer in each compartment.

Temperatures inside the storage units should be monitored and recorded at least twice a day for as long as vaccine is stored in this location.

Temperatures inside the storage units should be monitored and recorded at least twice a day for as long as vaccine is stored in this location (see the sections on <u>Vaccine Storage Practices</u> and Temperature Monitoring for further details).

• Up-to-date list of <u>Manufacturer Quality Control Office Telephone Numbers</u>. An example may be found in the Resources section.

Emergency Actions

The following emergency procedures should be implemented **in advance of the event** if possible. If you have no warning and the emergency event is already occurring or has already occurred, you should still follow these procedures. Consult your agency, local health department, or state health department immunization program, as appropriate for your situation, for any special instructions. Whenever there is a question about the integrity of the vaccine, follow your state health department immunization program policy and contact either the manufacturers quality control office or the immunization program for guidance.

- Suspend vaccination activities before the onset of emergency conditions, if possible. This will allow sufficient time for packing and transporting vaccine.
- Notify staff at the alternate vaccine storage facility. Before moving your vaccine, call
 the alternate storage facility to make them aware of the situation and to ensure that their
 backup generator is working.
- Conduct an inventory of the vaccines and record the actions taken. Use the
 Emergency Response Worksheet in the Resources section. Also note if water bottles were
 in the refrigerator and frozen packs in the freezer at the time of this event.
- Pack and transport the affected vaccines according to your priority list. (see Written protocol for vaccine packing and Prioritized vaccine packing list in this section).
- Follow established vaccine transport procedures for moving vaccine. (see Written protocols, vehicles, and drivers for transporting vaccine to and from the alternate vaccine storage facility in this section).

Centers for Disease Control and Prevention