

Vaccine Storage and Handling

The Cold Chain

Cold Chain Management is the process of preparing temperature sensitive medical products for shipment utilizing approved systems and procedures. This includes ensuring that required temperatures are maintained throughout the supply chain and validating that those conditions are met during all phases of distribution until issue or administration. Cold chain management assures vaccine maximum shelf life and suitability for use by minimizing the rate of deterioration.

CDC recommends that vaccine be transported in a refrigerated or frozen state, as appropriate (refrigerate 35° – 46° F [2-8 C]; freezer 5° F [-15°C] or colder), using an insulated container or a refrigerated truck.

Storage and Handling Plans

Storage and handling errors result in the loss of millions of dollars worth of vaccine each year in the United States. To minimize loss, a vaccine plan should include all aspects of routine vaccine management, from ordering vaccines and controlling inventory to storing vaccines and monitoring storage conditions. This plan should include protocol for Emergency Vaccine Retrieval and Storage in the event of refrigerator/freezer malfunction, power failures, or other emergencies that might compromise appropriate vaccine storage conditions.

Storage and handling plans should include the following:

- Up to date contact information
- Descriptions of the roles and responsibilities of the primary and back up vaccine coordinators
- Summaries of storage requirements for each vaccine and diluent in your inventory
- Protocol for:
 - vaccine storage unit temperature monitoring
 - vaccine storage equipment maintenance
 - correct placement of vaccine within storage units
 - responding to vaccine storage and handling problems
 - vaccine inventory management
 - transporting and receiving vaccine shipments
 - preparing vaccine for administration
 - proper disposal of vaccines and supplies
- Sample DOH vaccination program forms

Advance preparations, such as designating primary and backup vaccine coordinators, maintaining an emergency staff contact list, along with clearly written protocols will help maintain the integrity of your vaccine supply.

Emergency Actions

- Suspend vaccination activities before the onset of emergency conditions, if possible.
- Notify staff at the alternate vaccine storage facility
- Conduct an inventory of the vaccines and record the actions taken
- Pack and transport the affected vaccines according to your priority list
- Follow established vaccine transport procedures for moving vaccine

Vaccine Personnel

Identify a designated Primary Vaccine Coordinator and a Backup Vaccine Coordinator. The Primary Vaccine Coordinator will be responsible for ensuring that all vaccines are handled correctly and that procedures are documented.

The Backup Vaccine Coordinator should be able to perform the same tasks as the Primary Vaccine Coordinator in the event that the primary person is unavailable.

Other staff that handle or administer vaccines should be familiar with policies and procedures for vaccine storage and handling.

Vaccine Storage Equipment

ALERT:

Effective January 1, 2006, the DC Department of Health (DOH) Immunization Program required all VFC vaccines to be stored in a standard household side by side or top/bottom refrigerator and freezer with two separate doors for each compartment. DOH no longer permits use of dormitory style refrigerator/freezers or compact, single-door units, for storage of VFC vaccines because they do not maintain adequate temperatures. As stated in the CDC National Immunization Program Vaccine and Storage and Handling Manual, "when attempts are made to cool the freezer compartment in compact, single-door units to the appropriate temperature, the temperature in the refrigerator compartment will fall below the recommended range, potentially freezing the refrigerated vaccines."

After January 1, 2006, VFC staff may retrieve all vaccines that are improperly stored in dormitory style refrigerators.

All newly installed units must be certified by the VFC Program. To have your unit certified by the VFC Program, please contact Jacob Mbafor, VFC Coordinator at (202) 576-7130 ext. 43.

A list of the units that are appropriate for storing VFC vaccines are listed below. This list is not meant to be comprehensive. The VFC Program does not endorse one brand, manufacturer or distributor of refrigerators/freezers over another.

GE Americana® 15.6 Cu. Ft. Top-Freezer Refrigerator

Model A3316ABSWW

Store SKU # 220657

Internet # HD0000009034

Catalog # 100337391

Price: \$399.00/ea

Hotpoint® 16.6 Cu. Ft. Top-Freezer Refrigerator

Model HTS17GBSWW

Store SKU # 221414

Internet # HD0000009035

Catalog # 100337395

Price: \$549.00/ea

Maytag® 15 cu. ft. Top Mount Refrigerator

Model MTB1504ARQ

Store SKU # 506983

Internet # HD0000001099

Catalog # 100049066

Price: \$549.00/ea

Maytag® 15 cu. ft. Top Mount Refrigerator

Model MTB1504ARW

Store SKU # 507621

Internet # HD0000001957

Catalog # 100089771

Price: \$569.00/ea

Frigidaire

18.2 Cu. Ft. Top Mount Refrigerator

Model: FRT18S6AW

Item #: 163312

\$519.00/ea

Refrigerators without freezers, and stand-alone freezers, may be better at maintaining the required temperatures. However, a combination refrigerator/freezer unit sold for home use is acceptable for vaccine storage if the refrigerator and freezer compartments each have a separate external door. A calibrated thermometer must be placed inside each storage compartment and checked at least twice each day.

*Food and beverages should **not** be stored in a vaccine storage unit because this practice results in frequent opening of the door and destabilization of the temperature.*

Vaccines that require storage temperatures between 35° and 46°F (2° and 8°C) may be stored in the refrigerator compartment of a household- or commercial-style refrigerator-freezer unit. Vaccines that require storage temperatures at 5°F (-15°C) or colder may be stored in the freezer compartments of such units. Small single-door (dormitory-style or bar-style) combined refrigerator-freezer units should not be used for permanent vaccine storage.

Make sure not to overstock the unit because this will impede cold air circulation and can result in temperature fluctuations that may expose the vaccines to inappropriate temperatures. Refrigerated vaccines stored in a dormitory-style unit should be returned to the main storage unit at the end of the clinic day.

Do not place vaccines directly beside or directly below the freezer compartment in a dormitory-style unit, this may expose vaccines to temperatures below the recommended range. Place cold packs (not frozen packs) or water bottles in this space to provide a temperature buffer. To reduce the risk of exposing vaccine to freezing temperatures, consider using a compact refrigerator without a freezer compartment.



Only the primary or backup vaccine coordinators should adjust the temperature of a vaccine storage unit.

Thermometers

To ensure that refrigerators and freezers are maintaining the proper temperatures for vaccine storage, The Centers for Disease Control and Prevention recommends each compartment have a certified calibrated thermometer. Certified calibrated thermometers require periodic recertification and recalibration against reference thermometers in order to remain accurate.

Place thermometers in the center of the compartment away from coils, walls, floor and fan in order to obtain a true reading. Check temperature at least twice each day. Thermometers that provide continuous recording or minimum/maximum temperatures are preferred because they are the best indicators of temperature fluctuations outside of the recommended ranges.

Out-of-range temperatures require immediate action.

Uncertified liquid (mercury or alcohol) thermometers and uncertified dial-type household refrigerator/freezer thermometers should not be used. These thermometers are not accurate enough to risk losing expensive vaccine. **Do not use thermometers that are not certified calibrated thermometers.** Generally, thermometers obtained in hardware and appliance stores are not certified instruments and are designed to monitor temperatures for domestic food storage.

Cold Chain Monitors

There are three basic types of cold chain monitors (CCMs):

1. those that indicate whether packages have reached temperatures that are too warm
2. those that indicate whether packages have reached temperatures that are too cold, and
3. those that continuously record the temperature.

These types of monitors are designed to be irreversible indicators of inappropriate temperatures. CCMs are not a substitute for twice-a-day temperature reading and recording. Every vaccine storage unit compartment should have its own certified calibrated thermometer for this purpose. CCMs should only be used to monitor the temperature of vaccine during transport.

Heat and Freeze Indicators are for single use only. Heat indicators appropriate for vaccine shipping have an activation temperature of 50°F (10°C) and a run out time of 48 hours to 7 days. Freeze indicators appropriate for shipping do not indicate the length of time vaccine has been exposed to temperatures outside the recommended range, instead indicate exposure to freezing temperatures. Freeze indicators appropriate for vaccine shipping have an activation temperature of 32°F (0°C).

Data Loggers

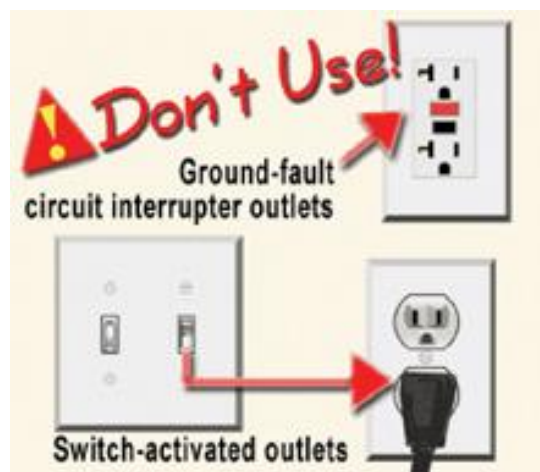
Digital data loggers are miniature, battery-operated, electronic devices that may be programmed to record temperatures at intervals throughout the day. Data loggers are capable of recording hundreds or even thousands of individual temperature readings and are available in single-use and multi-use models.

Digital data loggers used in vaccine transport have external lights that alert the user to out-of-range temperature events—a green light indicating the cold chain was properly maintained and a red light indicating inappropriate temperature exposure occurred. If a red light is displayed, the vaccine shipment must await approval for use and the device must be sent back to the manufacturer to interpret the temperature data. A special software program must be used to download the temperature data to a computer.

Vaccine Security

Power Supply

- Avoid using power outlets with built in circuit switches and outlets activated by a wall switch
- Use a safety-lock plug or an outlet cover to reduce the chance of the unit becoming inadvertently unplugged
- Post a warning sign at the plug and on the refrigerator or freezer alerting staff, janitors, and electricians not to unplug the unit
- Label 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.
- Finally, consider installing a temperature alarm to alert staff to after-hours emergencies, particularly if large vaccine inventories are maintained.



Temperature Alarms

Consider using a continuous-monitoring temperature alarm/notification system if temperatures in storage units exceed the recommended ranges or if the storage units malfunction.

Locking

Pending additional details from CDC

Vaccine Storage Practices

Appropriate Vaccine and Diluent Storage Conditions

Live Vaccines are sensitive to heat and must be stored in a continuously frozen state in a freezer at 5°F (-15°C) or colder until administration. LAIV and rotavirus vaccines are also live virus vaccines, but they should be stored in the refrigerator. Do NOT store these vaccines in the freezer.

Inactivated Vaccines are sensitive to both excessive heat and freezing. They should be stored in a refrigerator at 35° to 46°F (2° to 8°C), with a desired average temperature of 40°F (5°C). Exposure to temperatures outside this range results in decreased vaccine potency and increased risk of vaccine-preventable diseases. Inactivated vaccines may tolerate limited exposure to elevated temperatures, but they are cold sensitive and are damaged rapidly by freezing temperatures.

Freezer

Store vaccine in the middle of the compartment away from walls, coils and peripheral areas. Temperatures in the freezer door are not stable and may vary from that in the main compartment, therefore, no vaccine should be stored in the freezer door.

Refrigerator

Store vaccine in the middle of the compartment away from coils, walls, floor and cold air vents. The temperature in the door and near the floor of the refrigerator is not stable and differs from that in the middle of the compartment. For this reason, vaccine should never be stored in the vegetable bins or the refrigerator door. In a combination refrigerator-freezer unit, the top shelf of the refrigerator may be colder than the recommended temperature range because of cold air venting on it from the freezer. Refrigerated vaccines should always be stored far

enough away from the air vents from the freezer compartment to avoid freezing the vaccines.

Vaccine Spacing

Vaccine should be placed with space between the vaccine and the compartment wall, and with space between each large box, block, or tray of vaccine to allow for cold air circulation around the vaccine. Packing any vaccine storage unit too tightly will affect the temperature.

Vaccine Packaging

Vaccine products that have similar packaging or similar sounding names should be stored in different locations to avoid confusion and medication errors.

Labeling

Each specific vaccine inside the storage unit should be clearly labeled. Labels may be attached directly to the shelves on which the vaccines are sitting or the vaccine containers may be labeled.

In addition to labeling the location of vaccines, mark each opened multidose vial with the **date** it was first opened. Mark reconstituted vaccine with the **date and time** it was reconstituted. Dating these vials is important for two reasons:

1. some vaccines expire within a certain time after opening or after reconstitution. This may not correspond to the expiration date printed on the vial by the manufacturer.
2. dating opened or reconstituted vials helps manage vaccine inventory by identifying vials that should be used first.



Mark each opened multidose vial with the date it was first opened.
Mark each reconstituted vaccine with the date and time it was reconstituted.

Whenever possible, use all the vaccine in one multidose vial before opening another vial. Similarly, use all the reconstituted vaccine in one vial before reconstituting another vial. This policy helps to reduce vaccine waste.

Diluents should be clearly labeled, whether they are stored at room temperature or in the refrigerator. Label the boxes of corresponding vaccines and diluents from the same manufacturer so that they will be used together. This avoids confusion and helps to ensure that only the specific diluent provided by the manufacturer for each type of lyophilized (freeze-dried) vaccine is used. This is particularly important if you store two or more lyophilized vaccines using different diluents.

Selected Biologicals

TIV: Trivalent Inactivated Influenza Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the [Manufacturer's Quality Control](#) office or the immunization program for guidance.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.** Protect Fluarix® and FluLaval™ from light at all times by storing in original package.

NOTE: DOH no longer permits use of dormitory style refrigerator/freezers or compact, single-door units for storage of VFC vaccine because they do not maintain adequate temperatures.

Shelf Life

Formulated for use during current influenza season. Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Multidose Vials: Withdraw single dose of vaccine into separate sterile needle and syringe for each immunization. Vaccine should be administered shortly after withdrawal from the vial. Unused portions of multidose vials may be refrigerated at 35° – 46°F (2° – 8°C) and used until expired, if not contaminated or unless otherwise stated in the manufacturer's product information.

NOTE: Some multi dose vials may contain thimerosal. DOH expects that vials will be clearly labeled.

Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

NOTE: Single dose units will not contain thimerosal.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact DOH for details.

LAIV: Live Attenuated Influenza Vaccine

Shipping Requirements

Initially shipped to authorized distributors in the frozen state 5°F (-15°C). Shipped from the distributor to healthcare facilities in the refrigerated state at 35° – 46°F (2° – 8°C).

Condition upon Arrival

Refrigerate upon arrival.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the [Manufacturer's Quality Control](#) office or the immunization program for guidance.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° – 46°F (2° – 8°C). **Do not freeze or expose to freezing temperatures.** (If LAIV is inadvertently frozen, the vaccine should be moved immediately to the refrigerator and may be used until the expiration date printed on the package.)

NOTE: DOH no longer permits use of dormitory style refrigerator/freezers or compact, single-door units for storage of VFC vaccine because they do not maintain adequate temperatures.

Shelf Life

Formulated for use during current influenza season. Check expiration date on package.

Instructions for Use

LAIV is a colorless to pale yellow liquid and is clear to slightly cloudy; some particulates may be present but do not affect the use of the product. After removal of the sprayer from the refrigerator, remove the rubber tip protector. Follow manufacturer's instructions to deliver ½ dose into one nostril. Then remove the dose-divider clip and deliver the remainder of the dose into the other nostril.

NOTE: Single dose LAIV will not contain thimerosal.

Shelf Life After Opening

Single-Dose Sprayer: The vaccine should be administered shortly after removal from the refrigerator.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact DOH for details.

Vaccine Inventory Management

Vaccine Access

Limit access to the vaccine supply to authorized personnel only.

Expiration Dates

All vaccines and diluents have expiration dates by which they should be used. This date is printed on all vials and boxes. Expiration dates vary by the type of vaccine or diluent, and by the lot number. The vaccine or diluent may be used up to and including this date **unless** otherwise stated in the product package insert. Vaccine and diluent should not be used after this date has passed. 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. Unused vaccine or diluent should not be used after this month has passed.



Vaccine may be used up to and including the expiration date.

What to Do with Expired and Mishandled Vaccine or Diluent

Expired vaccine and diluent, even if they are only 1 day past the expiration date, should **never** be administered. Likewise, vaccines that have been mishandled because of inappropriate storage conditions should not be administered. If a dose of expired or mishandled vaccine is given by mistake, the dose should not be counted as valid and should be repeated, unless serologic testing indicates that an adequate response to the vaccine has been achieved. Remove expired or mishandled vaccine and diluent from the refrigerator or freezer and dispose of it appropriately. Contact the Department of Health Immunization Program regarding the disposition of mishandled or expired vaccine.

What to Do with Expired and Mishandled Vaccine or Diluent

Expired vaccine and diluent, even if they are only 1 day past the expiration date, should **never** be administered. Likewise, vaccines that have been mishandled and lost their potency because of inappropriate storage conditions should not be administered. If a dose of expired or mishandled vaccine is given by mistake, the dose should not be counted as valid and should be repeated, unless serologic testing indicates that an adequate response to the vaccine has been achieved. Promptly remove expired or mishandled vaccine and diluent from the refrigerator or freezer and dispose of it appropriately. Contact the Department of Health Immunization program regarding the disposition of mishandled/expired vaccine.

Exceptions to the Expiration Date

The expiration date printed on each vial or box assumes the vaccine has been properly transported and stored at all times and that it has not become contaminated. If vaccine has been inappropriately exposed to excessive heat, cold, or light, its potency may be reduced **before** the expiration date is reached. The only way to determine if proper transport and storage conditions have been maintained is to monitor vaccine and diluent temperatures during every link in the cold chain. The expiration date printed on each vial or box may also be invalidated after the vial is opened or reconstituted.

Expiration of Different Vaccine Products

Multidose premixed vaccine vials contain bacteriostatic agents that prevent the growth of bacteria. These vaccines can be used until the date of expiration printed on the vial unless they become contaminated.

Single-dose vials are meant for one-time use only. Do not open single-dose vials until you are ready to use them. Single-dose vials without protective caps should be discarded at the end of the clinic day.



Single dose vials are meant for one-time use only.
Once unsealed, discard vial at end of clinic day.

Once lyophilized (freeze-dried) vaccines have been reconstituted, they must be used within a specified time frame or discarded. Unused reconstituted vaccines kept beyond these limits should **not** be administered.

Recording Administered, Wasted, Spoiled, Expired, and Transferred Doses

Every dose of vaccine and diluent must be accounted for. Record every dose removed from the vaccine storage unit. Record how many doses were administered, wasted, spoiled, expired, or transferred. Contact the Department of Health Immunization Program and the vaccine manufacturer for instructions on how to dispose of these doses.

Vaccine Shipments

Standard Operating Procedures

Vaccine may be transported by either hand-carrying or shipping to another site. In both cases, the cold chain must be maintained. Vaccine should be:

1. Attended at all times during transport
2. Promptly placed into appropriate storage units upon arrival
3. Transported in the minimum needed quantity to avoid unnecessary loss of expensive vaccine

Receiving Vaccine Shipments

Arrange for vaccine deliveries to be made only when the vaccine coordinator or backup person is on duty. All staff members who accept vaccine deliveries must be aware of the importance of maintaining the cold chain and of the need to **immediately notify** the vaccine coordinator or backup person of the arrival of the vaccine shipment so that it can be handled and stored appropriately.

Picking Up Vaccine Shipments

When picking up vaccine shipments, do not place vaccine in the trunk of the vehicle. The temperature inside the trunk cannot be regulated and could become too hot or too cold for the vaccine. Deliver the vaccine directly to the facility and unpack and store it upon arrival.



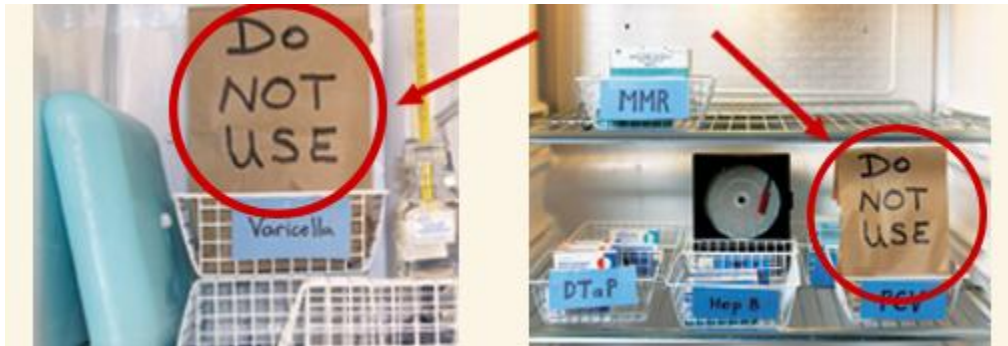
When transporting vaccine in ordinary vehicles use the passenger compartment—not the trunk.

Checking the Condition of a Shipment

When you receive your vaccine shipment, it should be examined immediately.

- Examine the shipping container and contents for signs of physical damage
- Determine if the shipping time was less than 48 hours. If the interval between shipment from the supplier and arrival of the product at the provider's office was more than 48 hours, the vaccine could have been exposed to excessive heat or cold that might have altered its integrity
- Crosscheck the contents with the packing slip to be sure they match.
- Check vaccine expiration dates to ensure that you have not received any vaccine or diluent that is already expired.
- Check that lyophilized (freeze-dried) vaccine has been shipped with the correct type and quantity of diluent for reconstitution.

- Examine the vaccine and diluent for heat or cold damage
- If there are any discrepancies with the packing slip or concerns about the shipment, immediately notify the primary vaccine coordinator (or the backup person), mark the vaccine and diluent as "DO NOT USE," and store them in proper conditions apart from other vaccine supplies until the integrity of the vaccine and diluent is determined.



If there are any discrepancies with the packing slip or concerns about the shipment, immediately mark the vaccine and diluent as "DO NOT USE," and store them in proper conditions.

Contact the Department of Health Immunization program for further guidance.

Packing Vaccine for Transport to Off-Site Clinics

The following are general guidelines for packing vaccine:

1. Use properly insulated containers to transport 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.



Use properly insulated containers to transport vaccine.

Thin-walled Styrofoam™ coolers, such as those purchased at grocery stores to hold beverages, are not acceptable.

Thin-walled Styrofoam™ coolers, such as those purchased at grocery stores to hold beverages, are not acceptable.

2. Pack enough refrigerated/frozen packs to maintain the cold chain. Do not use loose or bagged ice. The number and placement of refrigerated/frozen packs inside the container will depend on container size and outside temperature.
3. 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. A layer of toweling is not sufficient as

a barrier. Layer the contents as follows: refrigerated/frozen packs, barrier, vaccine, thermometer, another layer of barrier, and additional refrigerated/frozen packs.

4. Pack vaccines in their original packaging on top of the barrier. Do not remove vaccine vials from boxes, and do not draw up vaccine in advance.
5. Use a properly placed thermometer 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.
6. Attach labels to the outside of the container to clearly identify the contents as being valuable and fragile vaccines.



Refrigerated/frozen packs.



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



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



Attach appropriate labels to the outside of the container.

7. Record vaccine type(s), quantity, date, time, and originating facility on a label on the outside of the container.

Monitoring Temperatures During Off-Site Clinics

If vaccine must be maintained in an insulated cooler during an 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 periodically to ensure that the cold chain is not broken. At a minimum, vaccine temperatures be checked and recorded **hourly**.

This summary has been adapted from the Centers for Disease Control and Prevention “Vaccine Storage and Handling Toolkit”. The toolkit along with an accompanying video may be accessed by clicking on the link below:

<http://www2a.cdc.gov/vaccines/ed/shtoolkit/default.htm>