Vaccine Shipments

Disclaimer: State or local health department immunization programs may recommend or require different vaccine shipment and transport practices from those described here. The information presented here is meant to provide general guidelines only. Contact the state or local health department immunization program for details.

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. It is important to establish a routine, systematic process for handling vaccine shipments and vaccine transport. Each facility should develop its own written standard operating procedures (SOPs), covering every aspect of vaccine shipping: receiving, storing, packing, and transportation. Written SOPs are useful for reference, training, and evaluation of staff performing the work and should be included in the Routine Vaccine Storage and Handling Plan (see section on Storage and Handling Plans).

The SOP should specify that the vaccine is attended at all times during transport, that it is promptly placed into appropriate storage units upon arrival, and that it is transported in the minimum needed quantity to avoid unnecessary loss of expensive vaccine.

Without SOPs there can be no assurance that proper procedures will be followed or that problems will be identified, reported, and corrected. You may want to test various materials and packing configurations to find out what works best for your situation before developing your SOPs.

The SOP should specify that the vaccine is:

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 and Unpacking Vaccine Shipments

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.

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 upon arrival.

Picking Up Vaccine Shipments

In some states, providers pick up vaccine from public depots and might be required to supply their own coolers for vaccine transport. In this case, the state health department immunization program will provide guidance regarding the appropriate coolers. 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 (see Checking the Condition of a Shipment in this section).

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

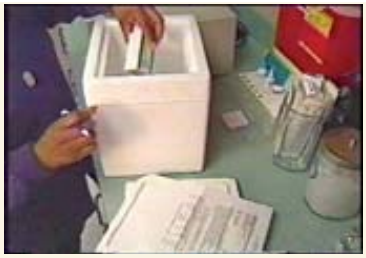
Checking the Condition of a Shipment

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

- Examine the shipping container and its contents for any 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.

Examine the shipping container and its contents for any signs of physical damage.

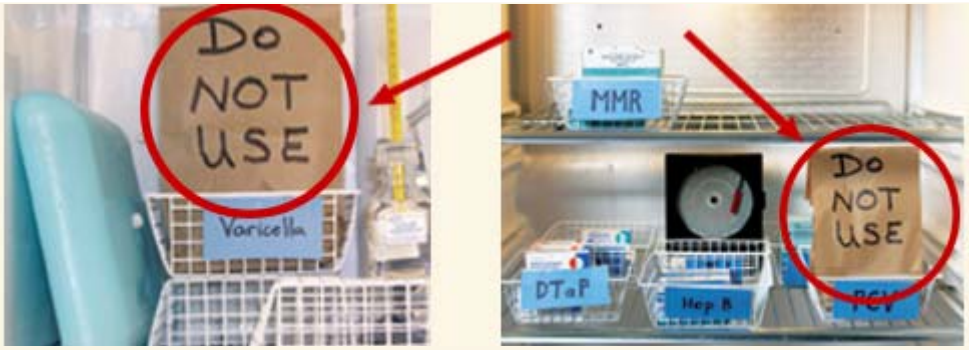
- Crosscheck the contents with the packing slip to be sure they match.
- Check the vaccine expiration dates to ensure that you have not received any vaccine or diluent that is already expired or that has a short expiration date (see Expiration Dates in the Vaccine Inventory Management section for details).
- Check that lyophilized (freeze-dried) vaccine has been shipped with the correct type and quantity of diluent for reconstitution.



Crosscheck the contents with the packing slip to be sure they match.

- Examine the vaccine and diluent for heat or cold damage:
  - Check the cold chain monitor(s) (CCM) to see if the vaccine or diluent has been exposed to temperatures outside the recommended range during transport.
  - Check that inactivated vaccines are cold but not frozen. Refrigerated packs should still be cold. Frozen packs can be melted but the package should still be cold. Vaccines should not be in direct contact with refrigerated/frozen packs. There should be an insulating barrier between the vaccine and the refrigerated/frozen packs, such as crumpled brown packing paper, bubble wrap, or some other barrier.
  - Check that measles/mumps/rubella (MMR) vaccine is cold or frozen.
  - Check that MMRV, varicella, and zoster vaccines are frozen and that dry ice is present in the shipping container. Dry ice must be handled carefully (see Handling Dry Ice in the Resources section for details).
  - Check that diluent is cool or at room temperature. Diluent should not be in direct contact with refrigerated/frozen packs. There should be an insulating barrier between the diluent and the refrigerated/frozen packs, such as crumpled brown packing paper, bubble wrap, or some other barrier. The diluent for varicella vaccine may be shipped with its vaccine but should not be placed in the container with the dry ice.

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 vaccine manufacturer and the state health department immunization program for further guidance (see Handling Inappropriate Vaccine Storage Conditions [Light and Temperature] in the Storage Troubleshooting section for details).

Storing and Documenting Vaccine Shipments Upon Arrival

After the vaccine shipment has been checked according to the procedures described in this section (see Checking the Condition of a Shipment), immediately store the vaccine and diluent at the recommended temperatures and record the arrival of each vaccine and diluent noting all the details as outlined in the stock records (see section on Vaccine Inventory Management). Do not leave the shipment unattended. The vaccines inside might warm to inappropriate temperatures and become unusable. All staff who may accept packages for the clinic must be aware that vaccine shipments require ⚠**immediate attention**. Staff who do not routinely handle vaccines but who accept vaccine shipments should alert the primary vaccine coordinator (or the designated backup person) as soon as vaccine shipments arrive so that they may be stored properly.

All staff who may accept packages for the clinic must be aware that vaccine shipments require immediate attention.

Transporting Vaccine to Off-Site Clinics

General Recommendations

The best assurance of vaccine efficacy is to minimize the number of times vaccines are handled and transported. If vaccine transportation to another location is required, it is critical that vaccine potency is protected by maintaining the cold chain at all times.

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When a multidose vial is used, Food and Drug Administration (FDA) regulations require that it be used only by the provider's office where it was first opened. A partially used vial may be transported to or from off-site clinics operated by the same provider as long as the cold chain is properly maintained. However, such a vial may not be transferred to another provider or transported across state lines. While there is no defined limit to the number of times vaccine may be transported to different clinic sites, multiple transport increases the risk that vaccine will be exposed to inappropriate storage conditions.

Transporting Varicella-Containing Vaccines

Varicella-containing vaccines should be transported on dry ice in a frozen state to maintain potency. If these vaccines must be transported to off-site clinics and dry ice is not available, single-antigen varicella vaccine and MMRV may be transported at 35° to 46° F (2° to 8° C); however, this will greatly reduce the shelf life of these vaccines. Single-antigen varicella vaccine and MMRV that are stored at 35° to 46° F (2° to 8° C) must be discarded 72 hours after removal from the freezer. Single-antigen varicella vaccine and MMRV that are removed from the freezer and transported at 35° to 46° F (2° to 8° C) must be labeled with the **date and time** they were removed from the freezer. Only **single-antigen** varicella vaccine and MMRV

may be transported and stored at 35° to 46° F (2° to 8° C). Zoster vaccine must be maintained at +5° F (-15° C) at all times, and must be transported on dry ice. Once removed from the freezer, none of these vaccines may be refrozen. Because of the risk of vaccine wastage, the National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention strongly discourages transport of these vaccines to off-site clinics. Consult your state health department immunization program for advice and details.

Transporting Diluent

Diluent should travel with its corresponding vaccine at all times to ensure that there are always equal numbers of vaccine vials and diluent vials for reconstitution. Additionally, the diluent must always be of the correct type and from the same manufacturer as the vaccine it accompanies.

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Diluent may be transported or shipped at room temperature or inside the same insulated cooled container as its corresponding vaccine. If transported inside cooled containers, diluent must not be in direct contact with refrigerated/frozen packs because of the potential for freezing. Refrigerate diluent in advance if it is to be carried in the insulated transport container so that it does not raise the temperature of the refrigerated vaccines.

Diluent for MMR, MMRV, varicella, and zoster vaccines may be transported at room temperature at 68° to 77°F (20° to 25°C), but must never be transported inside a container with dry ice.

Packing Vaccine for Transport to Off-Site Clinics

Different state health department immunization programs may recommend or require different vaccine transport practices and procedures. Contact your state health department immunization program for specific policies regarding vaccine transport, details on how to pack vaccine and diluent for transport, and procedures for maintaining the cold chain in the field.

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.

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

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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. For detailed instructions, see Chart of Refrigerated/Frozen Pack Needs for Different Climates in the Resources section.
3.	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. A layer of toweling is not sufficient as a barrier. The contents of the container should be layered 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.

You may also see Maintaining the Cold Chain During Transport in the Resources section for general guidelines.

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

If vaccine must be maintained in an insulated cooler during an off-site clinic, keep the cooler closed as much as possible. At a minimum, vaccine temperatures should be checked and recorded hourly.

the vaccines, and temperatures should be checked and recorded periodically to ensure that the cold chain is not broken. The National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention recommends that, at a minimum, vaccine temperatures be checked and recorded **hourly**.

Shipping Vaccine to State Health Departments or Vaccine Manufacturers

Shipping Vaccine with a Short Expiration Date or Other Usable Vaccine

Occasionally, providers may need to return vaccine with a short expiration date or other usable publicly purchased vaccine to the immunization program. Contact the state health department immunization program for detailed instructions on returning these vaccines. Some state health department immunization programs may permit the transfer of vaccine with a short expiration date or other usable vaccine to another provider. Consult your immunization program for specific policies regarding vaccine transfers.

Shipping Unusable Vaccine

Expired vaccine, wasted vaccine, and vaccine that has lost its potency because of inappropriate storage conditions may be returned to the vaccine manufacturer or to the state health department immunization program under certain circumstances. Contact the vaccine supplier, which may be the vaccine manufacturer or the state health department immunization program, for detailed instructions on returning these vaccines. If the vaccines are publicly purchased, contact the state health department immunization program for instructions on returning vaccines for excise tax credit. In general, expired, wasted or mishandled vaccine may be shipped via the U.S. mail or by other available modes of shipment (e.g., UPS™, FedEx®). Do not return loose vials in an envelope. Pack the vials in a box with packing material to avoid breakage.
Returned unusable vaccine is not considered to be hazardous material, so no special warning signs or special handling notices are necessary.