Description of Icons

This list shows the symbols you will see throughout the toolkit:

lcon	Description
2	CDC recommendation that applies to anyone who handles and stores vaccine. It is particularly relevant to VFC providers or other health care providers who receive vaccines purchased with public funds.
	Best practice
1	Take immediate action!

Vaccine Transport to Off-site or Satellite Facilities

"Transport" has a different meaning than "shipping," which usually involves a professional carrier and a longer distance and time period for moving vaccines between locations. Transport involves the movement of vaccine over a short time frame and distance between providers. The time needed to transport should be fewer than 8 hours and vaccine should be placed in a stable storage unit as quickly as possible. **CDC does not recommend any shipment of vaccines from your vaccine supply or any routine transport of vaccines.**

Vaccines should only be transported when absolutely necessary (e .g ., for a mass immunization clinic, in an emergency, or to ensure vaccines that are about to expire† can be used rather than wasted) . Frozen varicella-containing vaccines should never be transported except in an emergency.

CDC does not recommend reshipping vaccines after receiving them from a commercial distributor or manufacturer because doing so would put the cold chain, and ultimately, the viability of the vaccines, at risk.

Transport of Refrigerated Vaccines

Vaccines that will be used at an off-site or satellite facility should be delivered directly to that facility. If that is not possible, transport of vaccines should be done using a portable vaccine

refrigerator with a temperature monitoring device placed with the vaccines. If this is not available, *qualified containers and pack-outs* can be used with a temperature monitoring device. If you must transport vaccines, transport only what is needed for the workday. The total time for transport and workday should be a maximum of 8 hours. If you must transport vaccines in non-commercial vehicles, use the passenger compartment—not the trunk.

Immediately upon arrival at an off-site/satellite facility, vaccines should be stored in an appropriate storage unit with a temperature monitoring device, and temperatures should be read and recorded a minimum of 2 times during the workday.

If vaccines cannot be stored in an on-site storage unit, they should be kept in the portable vaccine refrigerator during an off-site clinic:

- <u>Place a temperature monitoring device</u> (preferably with a probe in a thermal buffer) as close as possible to the vaccines, and read and record temperatures at least hourly.
- Keep the container closed as much as possible.
- Remove only 1 multidose vial or 10 doses at a time for preparation and administration by each person administering vaccines.

Transport of Diluents

Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccines and diluents for reconstitution. Follow the manufacturer's guidance for specific temperature requirements.

Diluents that contain antigen (e.g., DTaP-IPV diluent used with Hib lyophilized vaccine and MenCWY diluent used with MenA lyophilized vaccine) should be transported with the corresponding vaccines at refrigerator temperature.

If diluents that are stored at room temperature (68°F to 77°F or 20°C to 25°C) are going to be transported with refrigerated vaccines, they should be refrigerated in advance for as long as possible so they do not raise the container temperature when placed with refrigerated vaccines.

If you have concerns about vaccines or diluents that may have been compromised (exposed to inappropriate conditions or temperatures or handled improperly), label them "DO NOT USE" and store them in appropriate refrigerated conditions (set apart from other vaccines). Immediately contact your <u>immunization program</u>* or <u>vaccine manufacturer(s)</u> for guidance. Do not discard the vaccines or diluents unless directed to do so by the immunization program or manufacturer.

Emergency Transport

CDC recommends all vaccine providers have emergency plans and SOPs for transporting vaccines. Portable vaccine refrigerators are recommended when vaccines must be transported. Qualified containers and pack-outs can be used in an emergency. See the section on Emergency Vaccine Storage, Handling, and Transport Preparations for more information related to emergency transport.

Immunization programs: <u>www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html</u> Packing Vaccines for Transport during Emergencies: <u>www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf</u> †If you are a VFC provider, or have other vaccines purchased with public funds, and must transfer vaccine to another facility so it can be used before it expires, contact your immunization program (<u>www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html</u>) for guidance on vaccine transport.



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

An agreement with an alternative facility should allow you to store vaccines when:

- Severe weather conditions are expected. If there is reasonable cause to believe weather circumstances might impact your facility, implement emergency procedures in advance of the event.
- Equipment fails or power cannot be restored before the storage unit temperature rises above the recommended range.

Always make sure you can have 24-hour access to the alternative facility.

If an Alternative Vaccine Storage Facility is Not Available

If you cannot find an alternative vaccine storage facility with a backup generator within a reasonable distance, or if you cannot reach your alternative facility, *you can use qualified containers and pack-outs** to store vaccines temporarily and safely at your facility. Always place a temperature monitoring device with the vaccines. Temporary storage containers should remain closed, and vaccines should only be stored for as long as the qualified containers and pack-outs are validated to maintain proper storage temperatures.

*Packing Vaccines for Transport during Emergencies: www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf

Accessing Your Building After Hours

An emergency situation can arise outside of business hours, and having a relationship with your facility's building manager and/or security staff can be essential to protecting your vaccines. Meet with the manager and/or security personnel regularly and always introduce them to new staff members. Your storage and handling SOPs should have written instructions for accessing your vaccine storage units when the building is closed.

Provide anyone who needs access to vaccine storage units during an emergency with written instructions, a building diagram/map, and locations of:

- Spare batteries
- Flashlights
- Keys
- Locks
- Circuit breakers
- Packing materials

Keep information on after-hours building access and security procedures (including alarm codes) with the SOPs, and also make sure relevant staff members (and building management and security staff, if appropriate) have copies of this information available at home.

Power Outages

R During a power outage, never open the storage unit door until power is restored or it is determined that vaccines need to be packed in separate storage containers and/or transported to an alternative storage facility.

Monitoring Unit Temperature during a Power Outage

Units with Outside Temperature Monitoring Devices

If you can monitor the temperature of the storage unit from the outside without opening the door, take the following steps:

- Record room temperature (if possible) and the temperature inside the unit as soon as the power goes out.
- Record minimum and maximum temperatures reached inside the unit during the outage.
- If temperatures have fallen outside of the recommended range, follow your procedures for <u>out-of-range temperatures/excursions</u>.
- If you are unsure how long the power interruption will last, or you determine power will not be restored in time to maintain proper temperatures inside the unit, implement your <u>emergency</u> <u>vaccine storage, handling, and transport procedures</u>.

Units without Outside Temperature Monitoring Devices

If you cannot monitor the temperature inside the unit without opening the door, wait until the power is restored, then take the following steps:

- Record the room temperature (if possible) and the temperature inside the unit.
- If using a digital data logger, document the length of time power was off and the minimum and maximum temperatures during that period.
- If temperatures inside the unit have already fallen outside of the recommended range, follow your procedures for <u>out-of-range temperatures/excursions.</u>
- If you are unsure how long the power interruption will last, or you determine power will not be restored in time to maintain proper temperatures inside the unit, implement your <u>emergency</u> <u>vaccine storage, handling, and transport procedures.</u>

The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) offers general guidance concerning storage and use of temperature-sensitive biological products that have been involved in temporary electrical power failure or flood conditions, <u>Impact of</u> Severe Weather Conditions on Biological Products .†

Vaccine Transport Containers and Materials

For the safe transport and storage of vaccines, proper supplies are essential. Your facility should have a sufficient supply of materials needed for emergency vaccine transport of your largest annual inventory.

Appropriate materials include:

- Portable vaccine refrigerator/freezer units† (recommended)
- Hard-sided insulated or Styrofoam[™][†]
- Coolant materials: frozen 16 .9- or 8-ounce <u>water bottles that can be conditioned</u> or 4°C to 5°C <u>phase change materials</u> (PCMs)
- Insulating materials such as bubble wrap or corrugated cardboard—enough to form two layers per container
- Digital data logger for each container

Do not use soft-sided coolers. Most commercially available soft-sided coolers are poorly insulated and likely to be affected by room or outdoor temperatures.

Coolant Materials

Frozen water bottles can be used as coolant packs if they are *properly conditioned*, which should take only a few minutes:

- Hold the bottles under running tap water or submerge them in a sink filled with tap water until you can easily see a layer of water forming near the surface of the plastic.
- Once the ice block inside the bottle can spin freely, the bottle is ready to be used for packing. The inner block of ice will continue to melt while maintaining a constant temperature in the cooler.
- Use appropriate insulating materials, such as bubble wrap, to protect vaccines from direct contact with the water bottles.

<u>Phase change materials</u> (PCMs) at 4° C –5° C (39° F –41° F) can also be purchased to maintain proper temperatures. Follow the manufacturer's instructions for use to reduce the risk of freezing vaccines during transport.

Do not use frozen gel packs or coolant packs from vaccine shipments to pack refrigerated vaccines. Even if they are conditioned or appear to be "sweating," they can still freeze vaccines.

†If these items are not available, the manufacturer's original shipping boxes may be used for emergency transport.

Emergency Vaccine Packing and Transport

Improper packing for transport is as risky for vaccines as a failed storage unit. To help make sure your vaccines arrive safely, follow your facility's emergency retrieval and transport SOPs. These should include, at a minimum, the following procedures and protocols:

Packing

- If possible, suspend vaccination activities before the onset of emergency conditions to allow more time for packing and transport.
- Contact the alternative vaccine storage facility before packing any vaccine to confirm their generator is working and they can accept your vaccines for storage.
- Take an inventory of your vaccines and <u>record actions</u> taken to protect the vaccines. Be sure to note whether there were water bottles in the unit at the time of the event.
- Open unit doors only when absolutely necessary and only after completing all preparations for packing and moving vaccines.
- Use appropriate materials for packing.CDC has compiled recommendations on the methods and materials to use for emergency vaccine transport, <u>Packing Vaccines for</u> <u>Transport during Emergencies.</u>*

Transport

- Identify primary and backup vehicles and drivers in advance.
- Consider renting a refrigerated truck if you have a large quantity of vaccines or need to transport vaccines an extended distance.
- If using a noncommercial vehicle, only transport vaccines inside the passenger compartment (not in the trunk).
- Move transport containers directly to a preheated or precooled vehicle.
- Avoid leaving containers in areas where they are exposed to direct sunlight.
- Check vaccine temperature upon arrival at the alternative vaccine storage facility, and store vaccines at recommended temperatures immediately.
- Check with your <u>immunization program</u>* for additional guidance and resources on emergency transport of vaccines, particularly in major emergencies.

Transport of Diluents

X Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccines and diluents for reconstitution. Follow the manufacturer's guidance for specific temperature requirements.

Diluents that contain antigen (e.g., DTaP-IPV diluent used with Hib lyophilized vaccine and MenCWY diluent used with MenA lyophilized vaccine) should be transported with the corresponding vaccines at refrigerator temperature.

If diluents that are stored at room temperature (68°F to 77°F or 20°C to 25°C) are going to be transported with refrigerated vaccines, they should be refrigerated in advance for as long as possible so they do not raise the container temperature when placed with refrigerated vaccines.

Place an insulating barrier (e.g., bubble wrap) between the diluents and conditioned water bottles or phase change materials.

Never freeze diluents, not even during transport.

Transport of Varicella-containing (Frozen) Vaccines

The manufacturer does not recommend transporting frozen vaccines (varicella, zoster, MMRV).

If these vaccines must be transported during an emergency, CDC recommends using a portable vaccine freezer unit (available for rent in some areas) or qualified container and packout that maintains temperatures between -50° C and -15° C (-58° F and +5° F).

Follow these steps for transporting frozen vaccines:

- Place a calibrated temperature monitoring device (preferably with a buffered probe) in the container as close as possible to the vaccines.
- Record the time vaccines are removed from the storage unit and placed in the container, the temperature during transport, and the time at the end of transport when vaccines are placed in a stable storage unit.
- Immediately upon arrival at the destination, place vaccines in a freezer at a temperature range between -50° C and -15° C (-58° F and +5° F). Any stand-alone freezer that maintains these temperatures is acceptable.

Do not use dry ice, even for temporary storage. Dry ice might expose the vaccines to temperatures colder than -50° C (-58° F).

If necessary, varicella-containing vaccines that have not been reconstituted may be transported at refrigerator temperatures between 2° C and 8° C (36° F and 46° F). Varicella-containing vaccines can be refrigerated for up to 72 continuous hours before reconstitution. **Transported varicella- containing vaccines cannot be put back in the freezer. They must be used or discarded.**

Transport of Multidose Vials

If absolutely necessary, a partially used vial may be transported to or from an off-site/satellite facility operated by the same provider, as long as the cold chain is properly maintained. However, a partially used vial cannot be transferred from one provider to another or across state lines.

Temperature Monitoring During Transport

Use a digital data logger for continuous temperature monitoring and recording while transporting vaccines:

- The digital data logger should have an accuracy of +/- .5° C (+/-1° F) .
- Place liquid or solid buffered probe material in a sealed vial directly with the vaccines.
- Keep the data logger display on top of vaccines so you can easily see the temperatures.

CDC does not recommend using cold chain monitors during transport since they provide limited data on temperature excursions that may occur.

If you have concerns about vaccines or diluents that may have been compromised (exposed to inappropriate conditions or temperatures or handled improperly), label them "DO NOT USE" and store them in appropriate refrigerated conditions (set apart from other vaccines). Immediately contact your <u>immunization program</u>* or <u>vaccine manufacturer(s)</u> for guidance. **Do not** discard the vaccines or diluents unless directed to do so by the immunization program or manufacturer.

*Packing Vaccines for Transport during Emergencies: <u>www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf</u> Immunization programs: <u>www.cdc.gov/vaccines/imz-managers/awardee -imz-websites.html</u>