MDPH Vaccine Management Unit 2025
Vaccine Transport SOP

Office/Practice Name	Pin Number

Purpose: To ensure that the vaccine cold chain during vaccine transport is maintained for optimum potency. This document ensures that each site has a plan and materials to move vaccines in the circumstances of a planned transport of vaccines or an emergency event.

Transport SOP Instructions: Review and update the document annually, when vaccine management policies change, and when staff with designated vaccine management and/or vaccine transport responsibilities change.

- Post on/near vaccine storage unit(s) and where vaccines are packaged for transport.
- In addition to your site's Vaccine Coordinators and Medical Director, all staff transporting vaccines including "only emergency transport" must read, sign, and adhere to the protocols described in this document.
- When completed, upload this document into MIIS under the "Agreement to Comply" tab.

Introduction to Vaccine Transport:

Anytime state-supplied vaccines are moved off-site, the vaccines must be monitored by an external digital data logger device, *regardless of the transport unit method you are using*. Do not add vaccines to the transport cooler until the external data logger device is reading in-range temperatures. Ensure refrigerated vaccines are **never transported on frozen/refrigerated ice packs**.

The Vaccine Program advises that practices conducting off-site and mobile clinics have portable vaccine storage units to transport and store their state-supplied vaccines. For any other transport of vaccines, emergency or planned, it is recommended to utilize a qualified container/pack-out or have all materials available to follow the CDC Conditioned Water Bottle Transport System.

Transport Types:

Transport packing methods differ between the two transport circumstances.

Emergency Transport:

Emergency transport is defined as the transport of vaccines off-site due to an unforeseen circumstance. All sites must have an emergency transport plan.

Emergency transport requires the use of one of the three approved types of packing methods:

- Portable Vaccine Storage Units (portable vaccine refrigerator/freezer)
- Qualified Containers and Pack-Outs

- CDC Pack-Out for Emergency Transport (conditioned water bottle transport system)
    - For step-by-step guidance on packing a cooler for emergencies using the conditioned water bottle method, see CDC's Packing for Emergency Transport.

Note: Cooler packs that arrive with your vaccine orders are not suitable for use after they arrive. Please discard and follow the guidance on your transport method listed in the table below.

Planned Transport:
Planned transport is defined as the transport of vaccines off-site for scheduled off-site/mobile clinics, regular transfers to a satellite facility, or planned re-location of vaccine stock. A portable refrigerator/freezer is always the preferred method for any site hosting mobile or off-site clinics. *Sites that are not planning on hosting mobile or off-site clinics should utilize qualified containers/pack-outs or follow the CDC conditioned water bottle transport system*. Sites that have regular planned transfers, mobile clinics, etc. must have a planned transport plan in addition to their emergency transport plan.

Planned transport requires the use of:

- Portable Vaccine Storage Units (portable vaccine refrigerator/freezer)
- Qualified Containers and Pack-Outs
    - Always follow instructions specific to the portable refrigerator/freezer or qualified container/pack-out being used.

** The CDC conditioned water bottle transport system should not be used for planned transport. **

Packing Methods:

Transport Method	Emergency Transport	Planned Transport (Off-Site Clinic, Satellite Facility, or Re-Location of Stock)
Portable Vaccine Storage Unit	Yes	Yes
Qualified Container and Pack-Out	Yes	Yes
CDC Conditioned Water Bottle Transport System	Yes	No* (see one exception below)

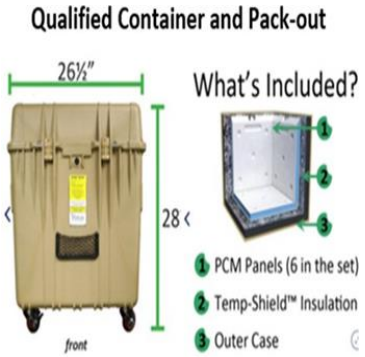
Portable Storage Units

A type of powered refrigerator, freezer, or Ultra-Cold (UTC) freezer unit specifically designed, and purpose built for use during vaccine transport. These units should include an internal fan, sturdy handles, lockable latch, and a programmable digital thermostat. Despite having a programmable digital thermostat, an external digital data logger is still required for vaccine transport. These active units are "qualified" to maintain desired temperatures for 4-5 days in the event of a power loss. For proper use, follow the directions stated in the manufacturer instructions.

Qualified Container and Pack-outs

A type of container and supplies specifically designed and purpose built for use when packing vaccines for transport. They are passive containers that do not require a power source and are "qualified" through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time (traditionally 3-5 days) without the use of electricity, ice, or buffering materials. For proper use, follow directions stated in manufacturer instructions. *Please note that these units are not recommended for sites completing off-site clinics, but only for planned transport.

**While the MDPH Immunization Division does not recommend or endorse a specific qualified container or pack-out, here are a few brands that meet MDPH qualifications: The TempArmour™ Vaccine Carrier; Vericor Cool Cube™ 96 at Refrigerated Temps*



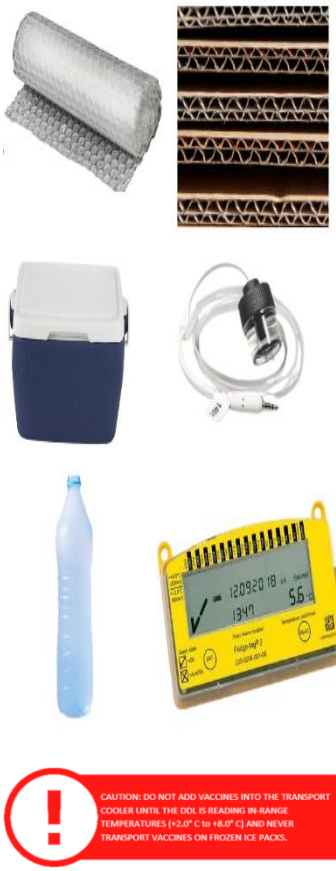
Conditioned Water Bottle Transport System

This is for emergency transport only; the only exception is if there is a designated pharmaceutical grade units located on site of vaccination where the vaccines can be stored during the clinic or after the transfer.

Traditional hard sided coolers are not meant to be opened and closed frequently therefore increasing the likelihood of non-viable vaccines if this method is treated the same as a qualified container and pack out or a portable fridge. This method can maintain appropriate temperatures for up to 8 hours if the cooler is not repeatably opened and is packed correctly.

When transporting vaccines using the conditioned water bottle transport method a site must ensure to have enough materials to move all the site's state-supplied vaccine inventory in an emergency. The materials needed to move vaccines are listed below:

a. Digital data logger
b. Spare or primary glycol bottle from the fridge/freezer
c. Hard-sided cooler
d. Bubble wrap
e. Corrugated cardboard
f. Enough frozen/conditioned water bottles to create a layer of water bottles at the bottom of the cooler and at the top of the cooler.



Always follow the [CDC's Packing for Emergency Transport] guidelines when moving state-supplied vaccines.

GUIDANCE SPECIFIC TO FROZEN VACCINE (EXCLUDING ULTRA-COLD FROZEN VACCINE)

If a vaccine is transported frozen:

- A portable freezer is the BEST practice. All other options increase the likelihood of a vaccine excursion.
- Use a portable vaccine freezer or qualified container and pack-out that maintains temperatures between -50.0° C to -15.0° C (-58.0° F to +5.0° F).
- Do NOT use dry ice, even for temporary storage or emergency transport.

<u>If transporting frozen vaccines in the event of an emergency remember to use frozen water bottles!</u>

Transporting Vaccines:

Prior to Moving the Vaccines:

- All state-supplied vaccines must have a digital data logger (DDL) attached to the vaccine transport cooler throughout transport to monitoring vaccine temperatures.
- If transferring **all** of your vaccine due to a power outage or refrigerator malfunction, ensure that the **primary data logger is always kept with the state-supplied vaccine.** If only moving a smaller amount of state-supplied vaccine, a **backup** DDL must be used for the transport.
- Use separate packing containers for refrigerator stored vaccines and freezer stored vaccines. Label outside of packing container 'Must Store in Refrigerator' or 'Must Store in Freezer'.
- Place the glycol bottle in each transport cooler near the vaccine to monitor the temperatures. Ensure that the cord of the glycol bottle is attached to the digital data logger, so that temperatures are recorded.
- Record the time the vaccines were placed in the transport cooler and the time when the vaccines were removed from the transport cooler, so that temperatures during transport can be easily reviewed.
- Transport single-dose vaccine vials or pre-filled syringes whenever possible. Multi-dose vials should be unpunctured at the time of transfer to a mobile/off-site clinic. DO NOT TRANSFER OPEN MULTI-DOSE VIALS AT ANY TIME.
- Vaccines transported using the CDC conditioned water bottle transport system should only be moved to one location and immediately stored in a pharmaceutical grade refrigerator/freezer upon arrival at the destination.

Upon Arrival at the Destination:

- Do not administer the vaccine until viability is confirmed. If temperatures excursion occurred during transport, immediately halt vaccine administration, and label the storage unit they are being stored in as "DO NOT USE". Additionally, please submit a Temperature Excursion Issue in the MIIS to verify vaccine viability.
- Upload the transport temperature log into MIIS (under reason code Transport/Temporary Storage) to document temperatures during transit. Note the time the vaccines were placed in the cooler and the time the vaccines were removed from the cooler in the "notes section"

Clinical Considerations:

- If conducting an off-site or mobile clinic, document the time and temperature when vaccines were administered to patients. In the event of a temperature excursion during the clinic, clinical staff would be able to identify which doses were given to patients after the excursion occurred.
- In cases where additional staff are on-site to assist with vaccination efforts, it must be noted that the individual responsible for transporting the vaccines is ultimately responsible for proper vaccine storage throughout the duration of the clinic.

Transport Materials Table:

Please fill out the table below with the transport method(s) located on Page 2, that your site will utilize to move state-supplied vaccines in the event of an emergency or planned transport. If your practice orders both refrigerated and frozen state-supplied vaccines, **you must designate at least two separate coolers**, each equipped with the necessary materials capable to transport **all of your vaccines in the event of an emergency**.

	Example: Fridge Vaccines	Example: Freezer Vaccines	Cooler 1	Cooler 2
Transport Method	Conditioned Water bottle Transport Method	Conditioned Water bottle Transport Method		
Cooler Name	Blue Transport Cooler	Blue Transport Cooler		
Cooler Storage location	In the closet next to the vaccine Storage	In the closet next to the vaccine Storage		
Refrigerated or frozen vaccines?	Fridge vaccines	Freezer vaccines		
What transport materials does your site carry?	8 frozen water bottles in the fridge to be conditioned, corrugated cardboard, and bubble wrap.	8 frozen water bottles, corrugated cardboard, and bubble wrap.		
Where are the transport materials and backup DDL stored?	Transport materials in storage closet. DDL sitting atop the main fridge.	Transport materials in storage closet. DDL sitting atop the main fridge.		
Please provide the manufacturer name, model, and ID of the back-up DDL.	Berlinger Fridge Tag 2L ID #130500069742	Berlinger Fridge Tag 2L ID #130500069743		

	Cooler 4	Cooler 5	Cooler 6	Cooler 7
Transport Method				
Cooler Name				
Cooler Storage location				
Refrigerated or frozen vaccines?				
What transport materials does your site carry?				
Where are the transport materials and backup DDL stored?				
What type of DDL is the back-up DDL and what is the backup DDL ID?				

Overall Mobile Clinic Plan:

Please only complete this section of the Vaccine Transport SOP if your site intends to conduct off-site or mobile clinics. Indicate N/A if this doesn't pertain to your site.

1. Staff Responsibilities Who will be responsible for moving and administering these vaccines? How will your site ensure the transport unit is in range before moving the vaccines? Who will be monitoring vaccine temperatures during the transport of vaccines, and at what intervals of time will the temperatures be manually checked?	
2. Vaccine Transport What type of vaccine will your site be transporting (refrigerated and/or frozen vaccines)? What is the maximum estimated quantity of vaccine that your site would be required to move for an off-site or mobile clinic? What power source is being used during transport if utilizing a portable storage unit?	
3. Clinic Locations Where will your site be moving these vaccines for off-site/mobile clinics? What is the estimated distance to the clinic? What is the estimated time of travel to and from the location? If conducting clinics at multiple locations, what is the further distance/travel time the vaccines will be in transit for?	
4. Clinic Details What is the cadence of off-site/mobile clinics that your site will be conducting?	
5. Clinic Supplies How will your site track which vaccines and in what quantities will be transported to/from the clinic?	

Vaccine Management During the Mobile Clinic:

1. Staff Responsibilities Who will be responsible for administering vaccines when on-site? (provide credentials) Who will be responsible for monitoring vaccine temperatures during the clinic?	
2. Vaccine Wastage Protocols What protocols are in place to prevent wastage during the clinic? Will vaccine wastage that occurs during the clinic be reported into MIIS during the clinic or once the vaccines are returned to your main location? How will vaccine wastage be tracked during the clinic?	
3. Temperature Excursion Protocols What protocols will on-site staff follow in the event of a temperature excursion during the clinic? Please describe in detail. When/how frequently will temperatures be manually checked during the clinic?	
4. Vaccine Storage Where will the vaccines be stored during the off-site/mobile clinic? If using a portable storage unit for storage during the clinic, what power source will be used to maintain proper temperatures?	
5. Vaccine Administration How will your site track/document vaccines that have been administered during the clinic? When/how will these doses be documented?	

Please Note: All staff who are involved in the vaccine transport process for your site must review and sign this SOP. At a minimum, both Vaccine Coordinators and the Medical Director must sign this SOP.

This SOP was created and completed by:	
Name	
Title	
Date of Completion	
Signature	

Medical Director:

Name (First & Last)	
Signature	

Date	Employee Name	Employee Signature