VFC Vaccine Storage, Handling & Transport

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Questions

During today's webinar, please use the chat to ask your questions so the Hawaii VFC Program subject matter experts can respond directly.

We will be answering your questions at the end of the presentation.

Housekeeping

QA Team:

- Please ensure you are muted throughout the presentation unless you are speaking.
- Please monitor the chat for questions.

Attendees:

- Please enter all questions into the chat, as these will be answered at the end of the presentation.
- Today's session is being recorded. Slides and webinar recordings will be uploaded to: https://health.hawaii.gov/docd/for-healthcare-providers/vaccination-resources/vaccines-for-children-program-vfc/
- To be added to the Hawaii VFC Program email list, please email your request to hawaiivfc@doh.hawaii.gov. In the subject line of the email, please write EMAIL LIST.

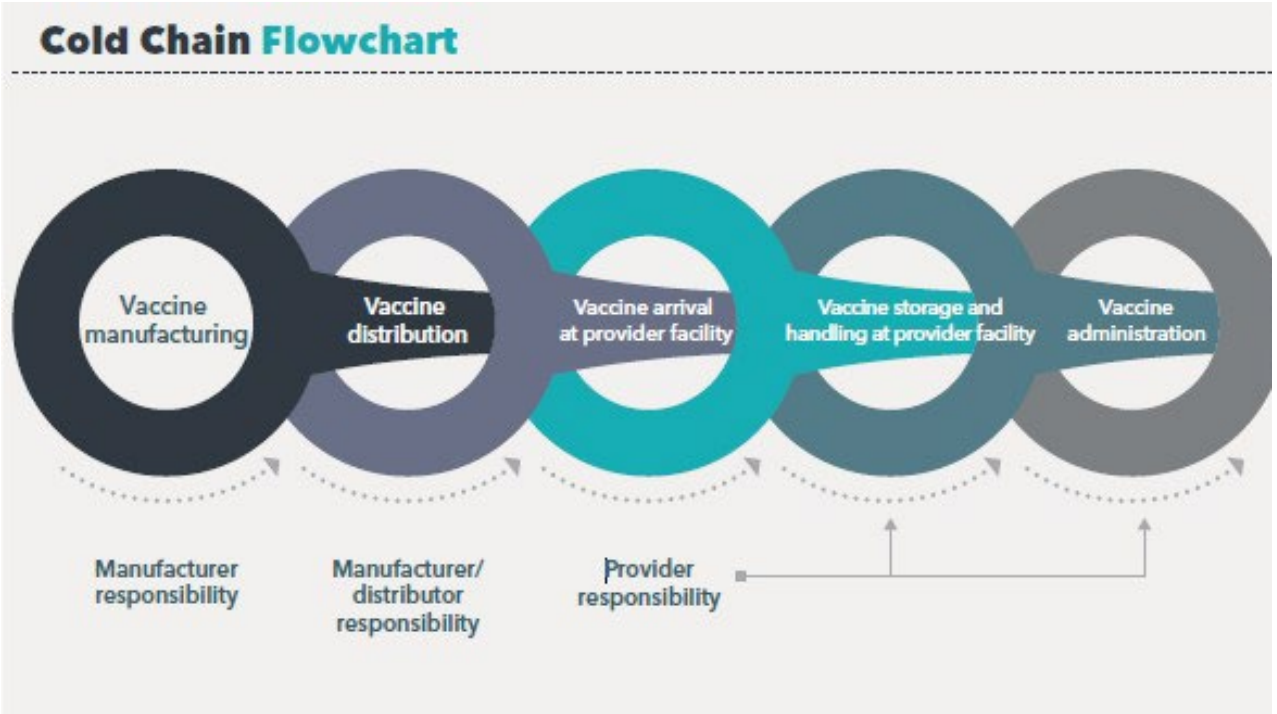
Objectives

- By the end of this presentation, attendees should:
  - Know how to properly store and handle VFC vaccine
  - Be familiar with the acceptable modes of VFC vaccine transport
  - How to ensure vaccine remain viable during planned and unplanned vaccine transport

VFC Vaccine Storage & Handling

Vaccine Cold Chain

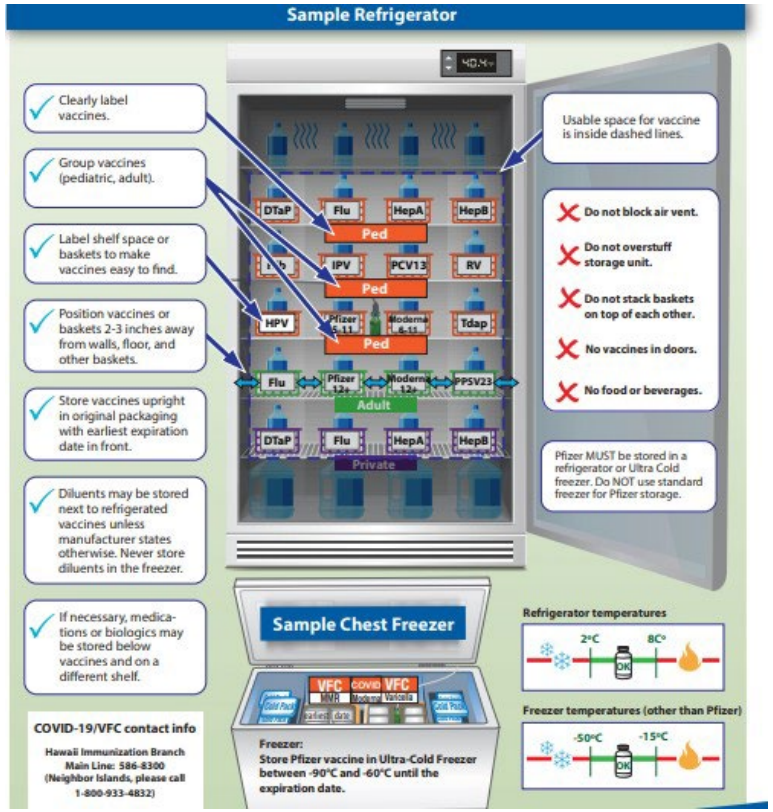
- Proper vaccine storage and handling begins with an effective **vaccine cold chain**
  - Cold chain: a temperature-controlled supply chain that includes all vaccine-related equipment and procedures.
- If the cold chain is not properly maintained, vaccine potency may be lost, resulting in an unusable vaccine supply



Vaccine Storage Units

- It's important that your facility has proper storage and monitoring equipment that is set up correctly, maintained appropriately and repaired as needed
- Types of Vaccine Storage units:
  - Purpose-built/Pharmaceutical-grade
    - CDC & HDOH VFC Program-recommended
  - Household
    - Combination (refrigerator section only)
    - Stand-alone
    - Absolutely NO Dorm/Bar-style units
  - Doorless/Vending style

Vaccine Storage Units
(continued)



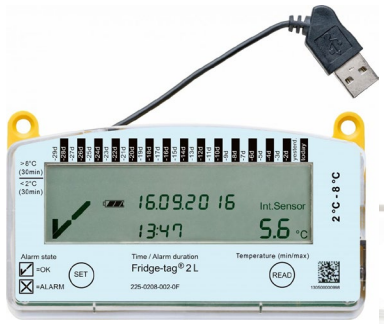
- Store vaccine in their original packaging
- Position vaccine and diluents 2 to 3 inches from the unit walls, ceiling, floor and door; arrange in rows to allow proper air circulation
- Label shelves & containers (i.e. VFC vs. Private, Pediatric vs. Adult)
- If possible, store diluent with corresponding refrigerated vaccine. Never store diluent in a freezer
- Avoid placing/storing any items other than vaccine, diluents and water bottles in storage units
- Place vaccines and diluents with the earliest expiration dates in front of those with later expiration dates

Vaccine Storage Units
(continued)

- VFC providers who are currently using both sections of a household/commercial combination refrigerator/freezer unit to store VFC vaccine will be required to purchase a stand-alone freezer unit after **July 1, 2024**
  - You may continue to use the refrigerator section of the combination unit should you wish to do so
  - If freezer excursions are found in the freezer section of the combo unit *prior* to July 1, 2024, a new stand-alone unit will need to be purchased **ASAP**.
- **Purchasing a new unit?** We ask that VFC Providers alert the HDOH VFC QA Team prior to purchasing to ensure that the new unit meets all VFC Program requirements.
  - Once procured, we also ask that providers allow the unit to stabilize for a few days then submit at least 5 days of stable, within appropriate range, temperature data before moving/transferring any vaccine into the new unit.

Temperature Monitoring Device (TMD)

- Digital Data Logger (DDL)
  - Provide detailed info on all temperatures recorded at preset intervals
  - Buffered temperature probe used
    - Air-probes for ultra-cold units
- Each VFC vaccine storage unit requires a DDL temperature monitor
- VFC providers are also required to have one back-up DDL in the event that vaccine need to be transported (emergency/non-emergency) or the primary DDL breaks or malfunctions



- DDL requirements:
  - Detachable probe that best reflects vaccine temperatures
  - Alarm for out-of-range temperatures
  - Low-battery indicator
  - Current, minimum, maximum temperature display
  - Recommended uncertainty of +/- 0.5˚C (+/- 1˚F)
  - Logging interval that can be programmed to record temps at least every 30 minutes
  - Certificates of Calibration

Temperature Monitoring Device (TMD) – Wireless/Electronic Monitoring Systems

- Wireless/electronic continuous temperature monitoring systems allow a clinic to monitor temperatures in real-time on a remotely connected device.
  - Common examples: SensoScientific, AccuShelf
- VFC Providers who elect to use a wireless/electronic TMD are still required to:
  - Ensure system meets all VFC temperature monitoring DDL requirements
  - Perform all required temperature monitoring documentation
  - Submit monthly temperature monitoring documentation

Temperature Monitoring

Temperature ranges:

- Refrigerator: 2˚C to 8˚C (36˚F to 46˚F)
- Freezer: -50˚C to -15˚C (-58˚F to +5˚F)
- Ultra-cold: -90˚C to -60˚C (-130˚F to -76˚F)

VFC Providers are required to:

- Check min, max and current unit temperatures each workday
- Routinely download and review DDL data
- Respond to any out-of-range temperatures promptly and alert the HDOH VFC QA Team of each excursion event
- Submit temperature logs monthly regardless of vaccine order placement

Temperature Monitoring (continued)

- Monthly temperature logs should include:
  - Min/Max temperatures (once per workday)
  - Current temperature (twice per workday – start & end)
  - Date
  - Time
  - Name/initial of person who checked and recorded the temperature

Power Supply

- Power disruption can result in destruction of entire vaccine supply; precautions should be taken to protect the storage unit's power supply
  - One storage unit per electrical outlet
  - Safety-lock/outlet cover
  - "DO NOT UNPLUG" warning signs for outlet and circuit breaker
  - Use caution when using power outlets that can be tripped/switched off
  - Avoid using:
    - Built-in circuit switches
    - Outlets that can be activated by a wall switch
    - Multi-outlet power strips

Responding to Temperature Excursions

- Any temperature reading outside the recommended range in the manufacturers' package insert is considered a temperature excursion.
- If a temperature excursion is found, VFC providers are required to respond promptly.
- Temperature excursion protocol:
  - Identify & Notify
  - Download and Evaluate
  - Contact Vaccine Manufacturers & the HDOH VFC QA Team
- Specific information regarding the temperature excursion protocol can be found:
  - 'Temperature Excursion' tab in the HDOH VFC Toolkit
  - HDOH VFC QA Team webinar on Temperature Excursions.

Vaccine Transport

General Transport Requirements & Reminders

- The CDC does NOT recommend routine transport of vaccines. If transport does occur, vaccines should only be transported using appropriate packing materials that provide maximum protection.
- Different transport situations necessitate different methods for packing:
  - **Emergency Transport:** requires either portable vaccine storage units, qualified containers and pack-outs or the conditioned water bottle transport system
  - **Planned transport:** requires either portable vaccine storage units or qualified containers and pack-outs. The conditioned water bottle transport system is **NOT** acceptable for planned transporting of vaccine.

Transport Method Requirements: Emergency versus Planned

Transport Method	Emergency Transport	Planned Transport (Off-site Clinic, Satellite Facility, or Relocation of Stock)
Portable Vaccine Storage Unit (preferred)[1]	Yes	Yes
Qualified Container and Pack-out[2]	Yes	Yes
Conditioned Water Bottle Transport System[3]	Yes	**No**

Transport Methods

1. Portable Vaccine Storage Unit - A type of **powered** refrigerator or freezer unit specifically designed for use during vaccine transport. These are passive units that require a power source to function. Some active units are "qualified" to maintain desired temperatures for a set amount of time in the event of a power loss. For proper use, follow directions stated in manufacturer instructions.

2. Qualified Container and Pack-out: A type of container and supplies specifically designed 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 (i.e., Cool Cubes, TempArmour, etc.). For proper use, follow directions stated in manufacturer instructions.

3. Conditioned Water Bottle Transport Method: Method outlined according to CDC's Packing for Emergency Transport. This is for ***emergency transport only***; it cannot be used for planned transport such as off-site clinics, transport to a satellite facility, or relocation of stock. If packed correctly, this method can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

1. Portable Vaccine Storage Unit (PREFERRED)

Planned or Emergency

2. Qualified Container & Pack-Out

Planned or Emergency

3. Conditioned Water Bottle Transport

Emergency ONLY

Emergency Transport Packing Instructions & Schematic can be found here:
Packing Vaccines for Transport During Emergencies (hawaii.gov)

Materials for Transport

VFC providers are required to have materials for vaccine transport available at all times. Such materials include:

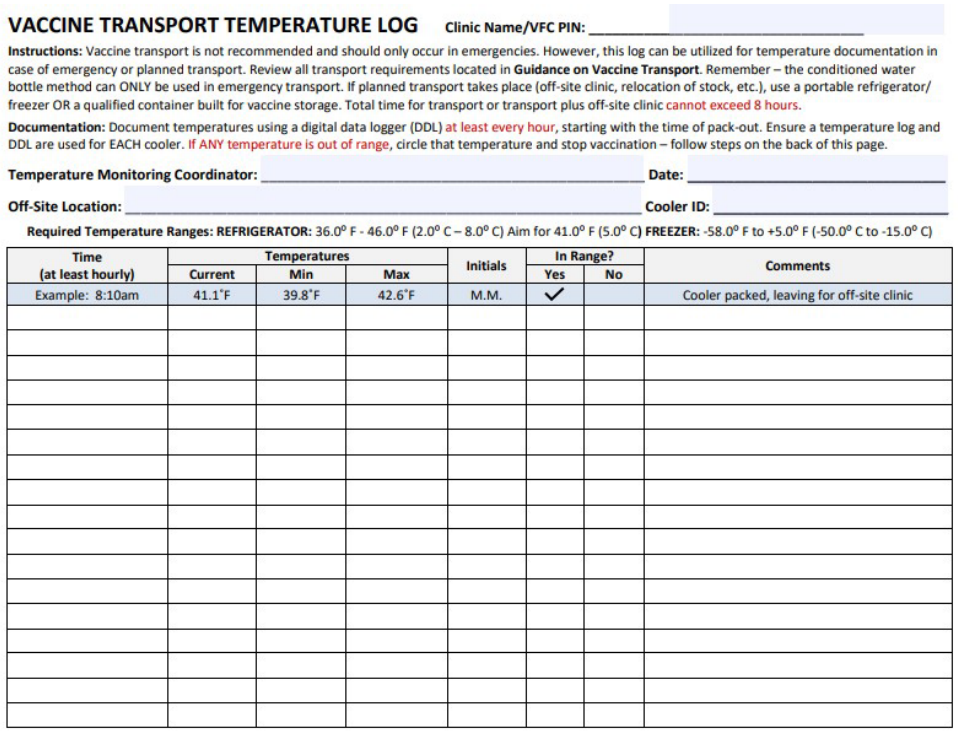
- Portable vaccine storage units
- Qualified containers and pack-outs
- Phase Change Materials (PCMs) for vaccine-specific coolers
- Hard-sided insulated containers or Styrofoam
- Frozen water bottles to be used in the conditioned water bottle transport system
- Digital data logger
- Insulating materials: bubble wrap and cardboard
- Vaccine Transport Log

The use of dry ice, coolant packs from shipments or soft-sided food/beverage coolers are NOT permitted for vaccine transport

Packing and Monitoring Vaccine During Transport

- Providers should follow manufacturer's guidance when using a portable unit/qualified container and pack-out designed for vaccine transport
  - i.e. "conditioning processes"
- Do not use frozen gel packs/coolant packs from original vaccine shipments to pack refrigerated vaccine
  - They can still freeze vaccines even if they are conditioned or appear to be "sweating"
- Never freeze diluents, even during transport
- Transporting Opened Multidose Vials: A partially used vial **cannot** be transferred from one provider to another. If necessary, a partially used vial may be appropriately transported to or from an off-site/satellite facility operated by the same provider

Packing and Monitoring Vaccine During Transport (continued)



VACCINE TRANSPORT TEMPERATURE LOG **Clinic Name/VFC PIN:** _____

Instructions: Vaccine transport is not recommended and should only occur in emergencies. However, this log can be utilized for temperature documentation in case of emergency or planned transport. Review all transport requirements located in **Guidance on Vaccine Transport**. Remember – the conditioned water bottle method can ONLY be used in emergency transport. If planned transport takes place (off-site clinic, relocation of stock, etc.), use a portable refrigerator/ freezer OR a qualified container built for vaccine storage. Total time for transport or transport plus off-site clinic cannot exceed 8 hours.

Documentation: Document temperatures using a digital data logger (DDL) at least every hour, starting with the time of pack-out. Ensure a temperature log and DDL are used for EACH cooler. If ANY temperature is out of range, circle that temperature and stop vaccination – follow steps on the back of this page.

Temperature Monitoring Coordinator: _____ **Date:** _____

Off-Site Location: _____ **Cooler ID:** _____

Required Temperature Ranges: REFRIGERATOR: 36.0° F - 46.0° F (2.0° C – 8.0° C) Aim for 41.0° F (5.0° C) **FREEZER:** -58.0° F to +5.0° F (-50.0° C to -15.0° C)

Time (at least hourly)	Temperatures			Initials	In Range?		Comments
	Current	Min	Max		Yes	No	
Example: 8:10am	41.1˚F	39.8˚F	42.6˚F	M.M.	✓		Cooler packed, leaving for off-site clinic

- Calibrated TMD (preferably DDLs) should be placed with the vaccine during transport
- Monitor and document temperatures during transport via the Transport Log
  - Time and temperatures at the start, during and end of transport
  - If transport is longer than 1 hour, document temperatures hourly
- If an excursion occurs during transport or at off-site clinics, do not use vaccine until viability information is obtained and the HDOH VFC Team has provided guidance

Frozen Vaccine Transport

CDC and Merck do not recommend transporting varicella-containing vaccines.

If these must be transported in an emergency:

It's best practice to use a portable freezer

- For O'ahu providers: you may contact the HDOH VFC Program to receive a loaner, if available

A portable vaccine freezer or qualified container and pack-out must maintain temperatures between -50°C to -15°C (-58°F to +5°F)

Do not use dry ice, even for temporary storage or emergency transport

Be sure to unpack and store vaccine in back-up location freezer immediately upon arrival

Questions?

For HIR technical/login issues please contact Registry Help Desk at (808) 586-4665, 1-888-447-1023 (toll-free), or registryhelp@doh.Hawaii.gov

For Immunization Clinical Consultation, please call the Hawai'i Immunization Branch at (808)286-8349

For any VFC-related questions/concerns, feel free to contact any member of our VFC QA Team

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