



Texas Department of State
Health Services

Vaccine Storage and Handling

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Storage & Handling Topics

- Storage Units
- Water Bottle Requirement
- Vaccine Storage
- Temperature Recording Requirements
- Data Loggers
 - Requirements
 - Placement
 - Certificate of Calibration



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Storage & Handling Topics (cont'd)

- Storage Unit Power Supply
- Temperature Excursions
- Room Temperature Thermometers
- Vaccine Transport in an Emergency
 - Supplies for Transport
 - Vaccine Packing for Transport
- Managing the Cold Chain



Storage Units

CDC Approved Storage Units

- Pharmaceutical grade (purpose-built)
- Commercial grade/household stand alone
- Combination (Refrigerator/Freezer)
 - Only use the refrigerator
 - Obtain a stand-alone freezer



Storage Units

NO DORMITORY STYLE UNITS

Single exterior door with an interior freezer compartment



Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.

Source: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>



Storage Units

- Large enough to hold the year's largest inventory without crowding
- NO food or drinks stored with vaccine



Do NOT store food or beverages inside a vaccine refrigerator or freezer.

Source: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>



Water Bottle Requirement

- Sufficient number of water bottles
- Labeled "DO NOT USE"
- Placement:
 - Unit door
 - Top shelf
 - Floor
 - Vegetable/fruit bins
 - Near the vent
 - Along the walls



Vaccine Storage

- Central area of the unit
- Do not store in:
 - Vegetable bins
 - Meat drawers
 - The door
 - The floor

Vaccines must be stored and/or stacked to allow cold air to circulate freely.



Vaccine Storage

- 2-3 inches between vaccine and the walls
- Store each type of vaccine or diluent in a separate container
- First in, first out
- When possible, store diluent with the corresponding refrigerated vaccine
- Labels shelves and containers to clearly identify vaccine and diluent



Vaccine Storage

- Store vaccines with similar packaging or names (pediatric and adult) on different shelves
- Clearly label pediatric or adult
- Keep vaccines in original packaging with lids closed
- Do not pack a unit too tightly
 - restrict air circulation
 - impact vaccine temperature
- Separate privately purchased vaccine from TVFC vaccine



Temperature Requirements

- Refrigerator temperature range 36°F and 46°F (2°C and 8°C)
- Freezer temperature range -58°F and +5°F (-50°C and -15°C)
- New or repaired storage unit:
 - 10 business days of temperature readings/recordings
 - 10 business days of minimum/maximum temperatures readings/recordings



Temperature Recording Requirements

- Temperature logging is mandatory (even if data logger is used)
- Temperature Recording Form (EC-105)
 - Must be on or near all units that store TVFC vaccines
 - Maintain for 5 years
- Check and document temperatures twice daily of all units
- Check and document min/max once daily



Data Logger Requirement

Effective January 1, 2018

Data loggers will be required as the primary and back up thermometers



Digital data loggers

Source:
<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>



Data logger Requirements (cont'd)

- Buffered material
 - liquid (ex glycol, ethanol, glycerin)
 - loose media (ex sand, glass beads)
 - solid block (ex Teflon®, aluminum)
- Centrally located probe
- Current certificate of calibration
- One back-up data logger
 - with a current certificate of calibration
 - with a different expiration date
 - stored outside of unit



Data logger Requirements (cont'd)

Data logger required capabilities:

- Alarm for out-of-range temperatures
- Display current temperature, as well as min/max temperatures
- Low battery indicator
- Accuracy of +/- 1°F (0.5°C)
- Memory storage of at least 4,000 readings (device will not rewrite over old data and stops recording when memory is full)
- User-programmable logging interval (or reading rate)
- Detachable probe



Data Logger Probe Placement

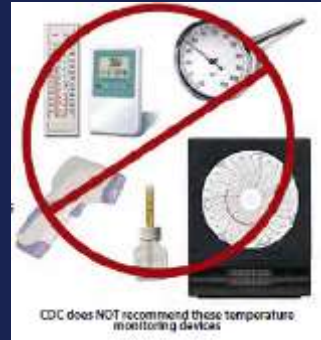
- The probe must be placed as close to the vaccine as possible.
 - centrally located,
 - main body,
 - away from walls, ceilings, cooling vents, doors, floor, and back of the unit
- The probe must not be
 - suspended from wire shelves
 - suspended from the ceiling of the unit



Data Logger Requirements (cont'd)

Not allowed

- fluid-filled, bio-safe liquid temperature monitoring devices
- bi-metal stem thermometer
- food thermometer
- household mercury thermometer
- chart recorders
- infrared temperature monitoring devices



Source: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>

Storage Unit Power Supply

- Protect unit's power supply by
 - plug directly into wall outlet
 - install plug guard
 - install DO NOT UNPLUG sign
 - install DO NOT DISCONNECT

Source: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>

Storage Unit Power Supply

- Do NOT use multi-outlet power strips
- Do NOT use outlets with built in circuit switchers (GFCI)
- Do NOT use outlets that are activated by a wall switch



Temperature Excursions

Temperature excursions

- place vaccines in a vaccine quarantine bag and label "DO NOT USE"
- store vaccines under appropriate conditions
- contact vaccine manufacturer to obtain viability information
- contact responsible entity (DSHS HSR or LHD)
- complete the vaccine storage troubleshooting record (page 3 of EC-105)



Source: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>

Room Temperature Thermometers

A thermometer to record room temperature is necessary when an excursion occurs in a vaccine storage unit.



Emergency Vaccine Transport

Emergency transport situations

- Equipment failure
 - Power outages
 - Severe weather conditions
 - Natural disasters
-
- ✓ Do not leave vaccine in a non-functioning unit
 - ✓ Keep unit doors closed during a power outage
 - ✓ Transporting frozen vaccine requires special care



Emergency Vaccine Transport

Be prepared

- completed Vaccine Management Plan
- back-up data logger
- flashlight with spare batteries
- vaccine transport materials
- after hours access to building



Emergency Vaccine Transport (cont'd)

Vaccine Transport Containers and Materials

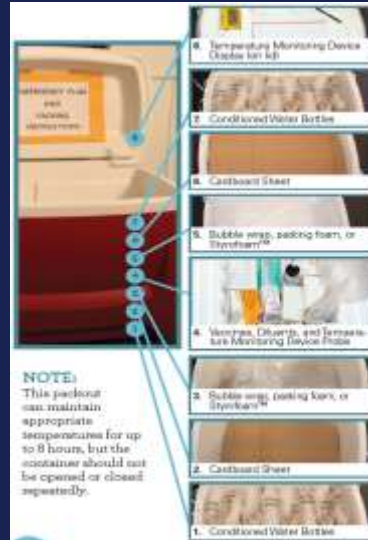
- portable vaccine fridge/freezer
- hard-sided (or Styrofoam) insulated cooler
- frozen water bottles
- insulating material (bubble wrap and corrugated cardboard cut to cooler size, two layers each per container)
- data logger



Emergency Vaccine Transport (cont'd)

Packing vaccines in an emergency

- conditioned frozen water bottles
- corrugated cardboard
- bubble wrap
- vaccines
- data logger probe



Source: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>

Emergency Vaccine Transport

Cold Chain Documentation (EC-105)

- Date and time transfer began
- Temperature of unit when vaccine removed
- Temperature of transport container when vaccines placed inside
- Temperature(s) recorded during transport
- Date and time transport was completed
- Temperature of unit at receiving facility



Managing the Cold Chain

- exposure to heat, cold, or light can result in loss of vaccine potency
- potency cannot be restored
- continued exposure to improper conditions reduces potency further
- Improper handling results in loss of potency



Source: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>

Managing the Cold Chain

Compromised cold chain:

- no physical indication of compromise
- not effective in protecting
- increase in disease cases



Source: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>

Managing the Cold Chain

Four elements of effective cold chain:

- well-trained staff
- reliable storage units
- valid temperature monitoring equipment
- accurate vaccine inventory management

All clinic staff should be trained on proper storage and handling of vaccines



Questions



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Thank You!

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