Vaccine Storage and Handling: Best Practices

MA Adult Immunization Conference

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Disclosure

I, Shumethia Seal, have been asked to disclose any significant relationships with commercial entities that are either providing financial support for this program or whose products or services are mentioned during my presentations.

I have no relationships to disclose.

I may discuss the use of vaccines in a manner not approved by the U.S. Food and Drug Administration but in accordance with ACIP recommendations.

Why does vaccine storage and handling matter?

1. Potency – Once potency is lost, the vaccine supply cannot be used. Loss of potency can be due to overexposure to heat or cold. **Potency cannot be restored.**

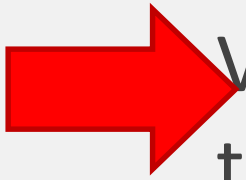
2. Limited Protection – When non-viable vaccine is administered patients can remain unprotected from serious, vaccine-preventable diseases.

3. Costly – Revaccinating patients and replacing vaccines will result in added cost.

4. Loss of Confidence in vaccines.

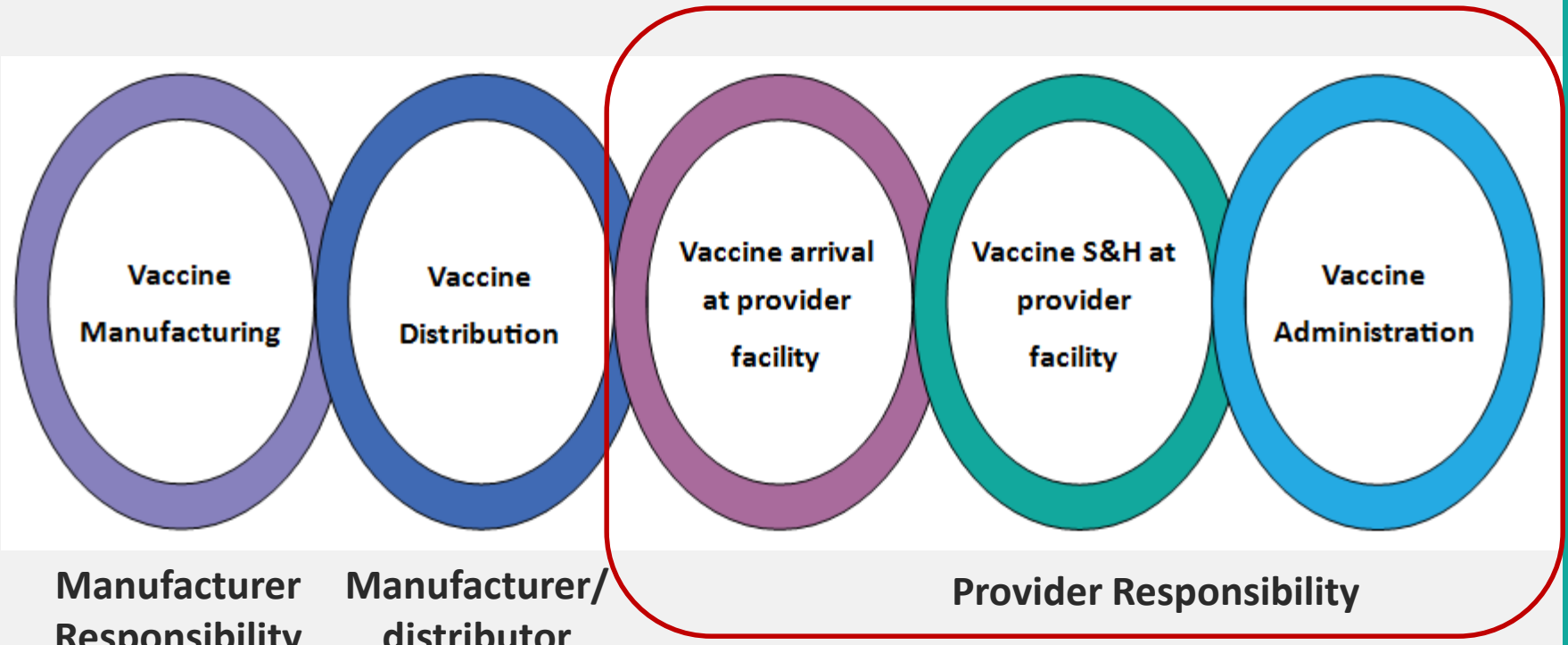
What is the most frequent vaccine administration error related to storage and dispensing?

- Expired
- Wrong diluent used
- Vaccine stored outside proper temperatures administered



Vaccine Cold Chain

Proper storage and handling begins with an effective vaccine cold chain.



An effective cold chain relies on five main elements:

1. Well trained staff
2. Reliable Storage Unit
3. Reliable Temperature Monitoring Equipment
4. Accurate vaccine inventory management
5. Robust emergency and transport plans

Staff and Training

All staff who administer vaccines should be trained on appropriate vaccine storage and handling.

- During new employee orientation
- Annually, as a refresher for all staff involved in immunization and vaccine S&H activities
- When new vaccines are added to inventory
- When recommendations for S&H of vaccines are updated
- Whenever there are changes to staff or vaccine management polices

All facilities should have a designated Primary Vaccine Coordinator.

The Primary Vaccine Coordinator must

- Ensure all vaccines are stored and handled correctly
- Be an expert on facility's storage and handling standard operating procedures
- Make sure that other staff is trained on vaccine management policies
- Appoint an alternate vaccine coordinator to act in absence of the primary coordinator and be an expert in routine and emergency SOPs.

The Primary and Alternate Vaccine Coordinators are primarily responsible for vaccine management.

Vaccine Storage Units

Recommended Storage Units

- Pharmaceutical Grade or Purpose Built Units
  - Designed specifically for the storage of vaccines
  - Microprocessor-based temperature control
  - Digital thermometer sensor
  - Fan-forced air circulation
  - Generally have wire racks
  - Should not have “vegetable or fruit” bin drawers for storage

- If facility administers frozen vaccine, a separate freezer unit is necessary.

Household-grade units are acceptable for storing adult vaccines at adult-only practices, but this is not the best practice.

- Designed for home use
- Freezer compartment cannot be used
- If household unit is used to store adult vaccines, sites should monitor temperatures closely to ensure vaccine is not freezing
- Not acceptable to store state-supplied pediatric vaccines

Prevent vaccine loss by maintaining vaccine storage units.

- Vaccine storage units need regular maintenance
- One unit should be plugged into each electrical outlet
- Use a safety lock plug or cover for electrical outlet
- Post ‘DO NOT UNPLUG’ warning signs on storage units and electrical outlets
- Label fuses and circuit breakers
- Avoid using outlets that can be tripped or switched off

Vaccines should be arranged in storage units to prevent loss and misuse.

- Vaccine storage units should have enough space to accommodate maximum inventory without crowding
- Store vaccines away from walls, coils, cooling vents, and back of unit
- Keep refrigerated diluents with corresponding vaccines
- Keep vaccines and diluents in original packaging with lids closed
- Place pediatric, adult, look-alike, and sound-alike vaccines in different shelves or areas of the unit

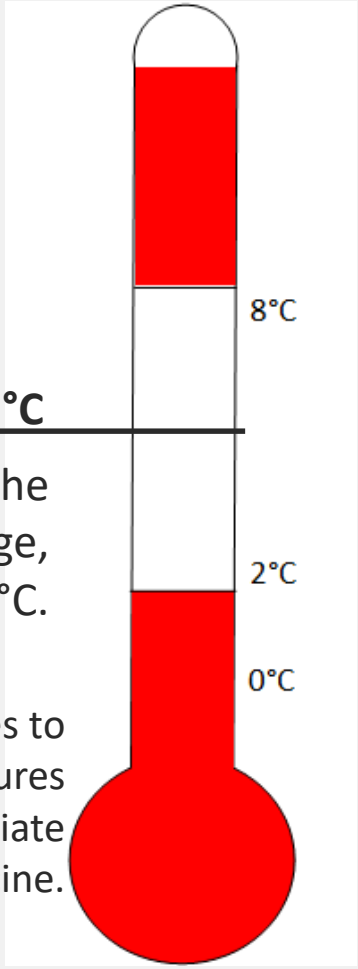
Best Practices

- **Do not** store any vaccine in a dormitory or bar-style combined refrigerator/freezer unit under any circumstances
  - Dorm-style units pose significant risk of freezing vaccines, even when used for temporary storage
- Storage units should be in a well ventilated room which allows for air circulation around the outside of the storage unit
- Ensure storage unit door opens and closes smoothly and properly seals
- New units should be monitored for 48 hours before storing vaccine

Temperature Monitoring

Recommended Temperature Ranges

Refrigerator



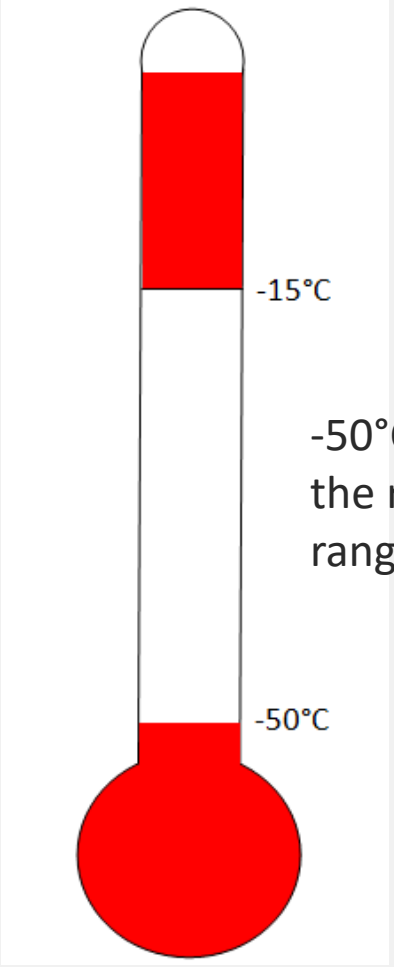
Strive for 5°C

2°C to 8°C is the required range, but aim for 5°C.

Exposing vaccines to freezing temperatures can result in immediate loss of vaccine.

Warming vaccines can shorten vaccine shelf life

Freezer



-50°C to -15°C is the required range.

Pay attention to the amount of time freezers are in defrost cycle.

The only way to be certain of vaccine storage unit temperatures is to monitor with a temperature monitoring device (TMD).

The recommended Temperature Monitoring Device (TMD) is a Digital Data Logger (DDL).

Digital Data Loggers are the recommended tool for monitoring temperatures.

Digital Data Loggers

- Continuously record temperatures
- Use a buffered probe which will mimic how vaccines are responding to temperatures
- Have a report that can be analyzed after downloaded from the device or the cloud
- Alarm for temperatures that are outside of the set range
- Have a valid Certificate of Calibration testing

*Digital Data Loggers are required to monitor Pediatric State-Supplied Vaccine.

Monitoring Vaccine temperature and equipment daily can ensure viability of your vaccine supply.

- Implement routine temperature monitoring activities to help
  - Identify temperature excursions quickly
  - Correct excursions quickly
  - Prevent loss of vaccines and revaccination

- Some routine temperature monitoring activities are:
  - Checking DDLs at least twice a day to identify daily minimum and maximum temperatures
  - Keeping a temperature troubleshooting log to keep track of maintenance and any excursions

Best Practices

- Keep storage unit temperature data for three years to analyze long term trends
- Make sure digital data logger is calibrated to ensure accuracy
- Be aware of your digital data loggers capacity to ensure that data isn’t lost
- Use a DDL for each vaccine storage unit
- Have a back-up DDL for emergency transport
- Mishandling a DDL can affect it’s accuracy, be careful to not drop device

Vaccine Inventory Management

Providers are responsible for maintaining the Vaccine Cold Chain upon delivery.

- Ensure staff is available to accept vaccine deliveries
- Staff should immediately notify one of the vaccine coordinators when vaccines are delivered
- Vaccines must always be immediately checked upon arrival
  - Examine for damage
  - Ensure that appropriate vaccine types and quantities were received
- Store vaccine in correct storage unit

Check your physical inventory weekly.

- Count all vaccine and diluent doses to make sure that your physical inventory matches your inventory in the MIIS or your electronic medical system
- Always check expiration dates and remove any expired vaccine
- Ensure that you are recording the correct lot number when administering vaccine

Order and stock enough vaccine to meet patient needs.

- Storing a larger volume than needed increases the risk of wasting vaccines if they expire or are compromised
- If you order from the state, we recommend ordering monthly and keeping 2 to 2.5 months worth of supply on hand at all time
- When possible, avoid placing last-minute orders to lessen the risk of running out of vaccines

State-supplied vaccine should be disposed by processing a 'Storage/Handling Issue'.

- Expired/Compromised vaccine will be sent to the distributor for federal excise tax credit

- Report expired or damaged vaccine through "Storage/Handling Issue" function in the MIIS
    - Immediately remove from the refrigerator/freezer
    - Label "Do Not Use"
    - Package for return to McKesson

- Open/contaminated vaccine does not need to be returned, but still needs to be reported in the MIIS

Report immunization data to the MIIS registry.

- All immunization should be reported to the Massachusetts Immunization Information System (MIIS)
- If you haven't yet done so, contact the MIIS Help Desk to begin the process of sending immunization data to the registry
- Call 617-983-4301 or email MIISHelpDesk@state.ma.us for help

Emergencies and Vaccine Transport

All sites should maintain Standard Operating Procedures (SOP).

Train staff on routine vaccine Storage and Handling and emergency SOPs

SOPs

- Help facilities stay organized
- Serve as a reference and training tool
- Ensure proper Vaccine Management procedures are followed
- Ensure problems are identified, reported, and corrected

Keep SOPs near vaccine storage units and make sure your staff knows were to find them

Prepare for emergencies.

- Equipment failures, power outages, severe weather, or natural disasters happen suddenly and can compromise vaccine storage conditions
- Establish a working agreement with at least one back-up facility, even if you have a generator as back-up equipment
- Vaccine may remain inside a non-functioning unit as long as appropriate temperatures are maintained
- Having an on-site generator may prevent the need to transport vaccines to a back-up
- In the event of a power outages don’t open storage units until power is restored or if vaccine needs to be moved

Vaccine should not be routinely transported.

If transport is required, take appropriate precautions to protect vaccine.

- The total time for transport alone or transport plus clinic day should be a maximum of 8 hours
- Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccine and diluents for reconstitution
- Your facility should have a sufficient supply of transport materials
- Vaccine should be transported using a TMD

Best Practices for Vaccine Transport

- Include vaccine packing and transport protocols in your SOPs
- Opened Multi-dose Vials shouldn't be transferred from one provider to another
- Do not use dry ice, even for temporary storage
- Use a TMD, preferably a DDL, for monitoring and recording temperatures while transporting vaccines
- Vaccine should be stored in an appropriate storage unit with a TMD upon arrival at the back-up location

Take immediate action to correct temperature excursions.

Notify

- Notify the primary or back-up vaccine coordinator
- Notify staff by labeling exposed vaccines as **"Do Not Use"**

Document

- Document details of the temperature excursion

Contact

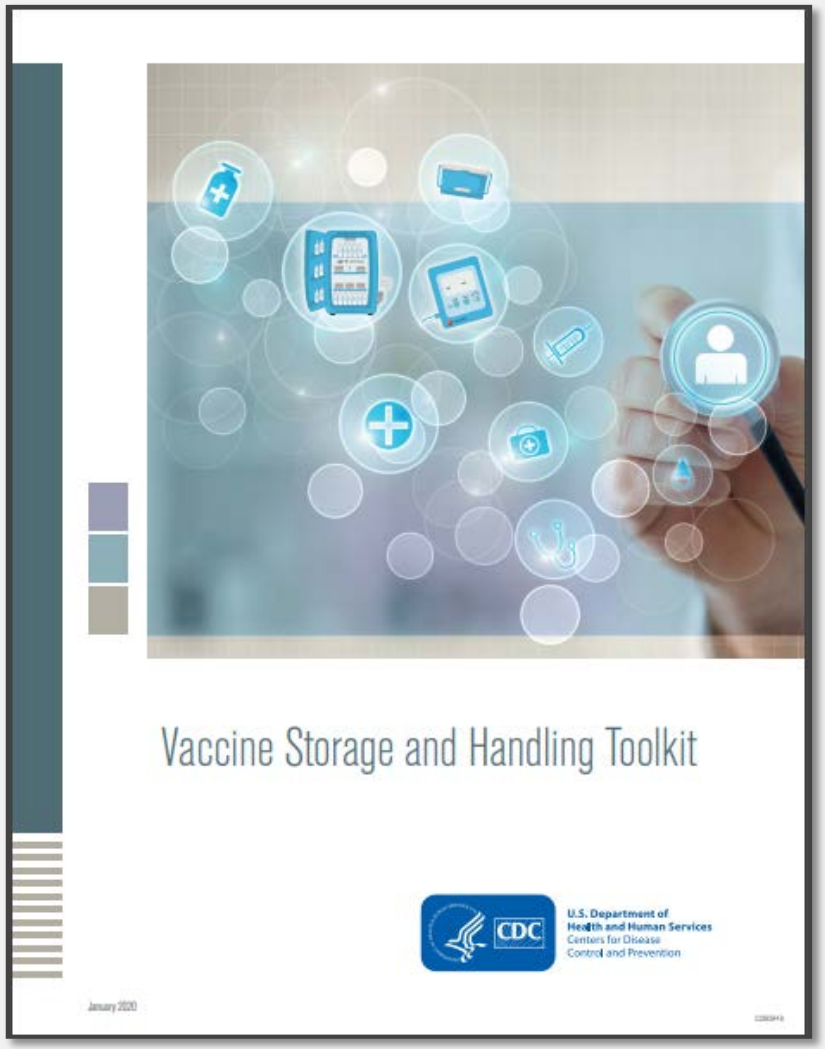
- If vaccine is state-supplied contact the Vaccine Management Unit
- If vaccine is private contact vaccine manufacturers directly

Correct

- Do not disconnect temperature alarm until the cause of the excursion has been determined
- Check the basics like the power supply, unit door, and thermostat

Vaccine Storage and Handling Resources

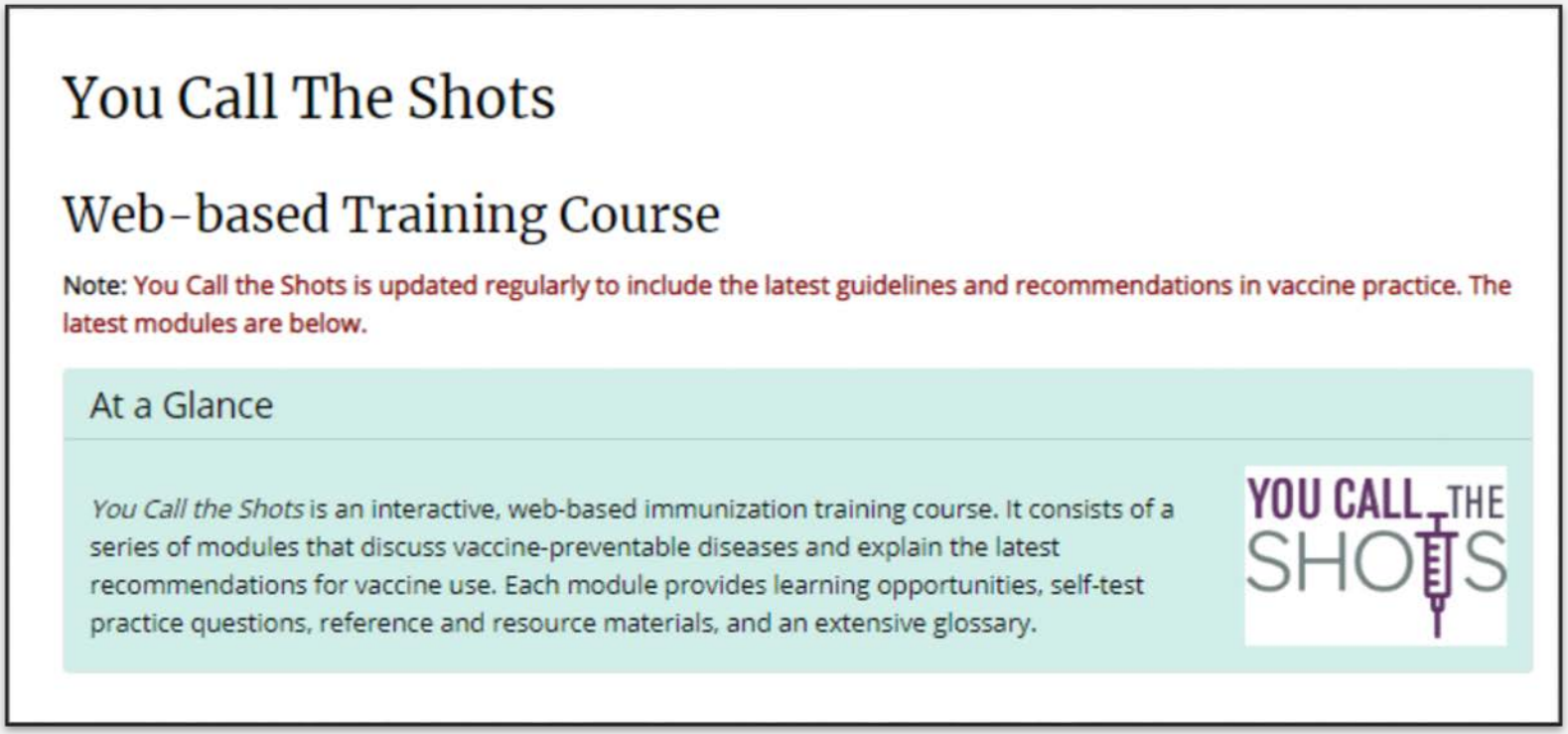
CDC Vaccine Storage and Handling Toolkit



https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit-2020.pdf

You Call The Shots: Vaccine Storage and Handling

https://www.cdc.gov/vaccines/ed/youcalltheshots.html



MDPH Immunization Division Vaccine Management Resources

https://www.mass.gov/resource/vaccine-management

RESOURCE

Vaccine Management

Enrollment and compliance with state Vaccine Program, including policies and practices related to ordering, inventory maintenance, and storage and handling.

BINDER ORGANIZATION: Bureau of Infectious Disease and Laboratory Sciences
Department of Public Health

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Thank you for your participation!

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