Vaccine Storage and Handling – Best Practices

26th Annual Massachusetts Adult immunization Conference

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Disclosure

I, Shumethia Seal, have been asked to disclose any relevant financial relationships with ACCME-defined commercial entities that are either providing financial support for this program or whose products or services are mentioned during this presentation.

I have no relevant financial 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.

Objectives

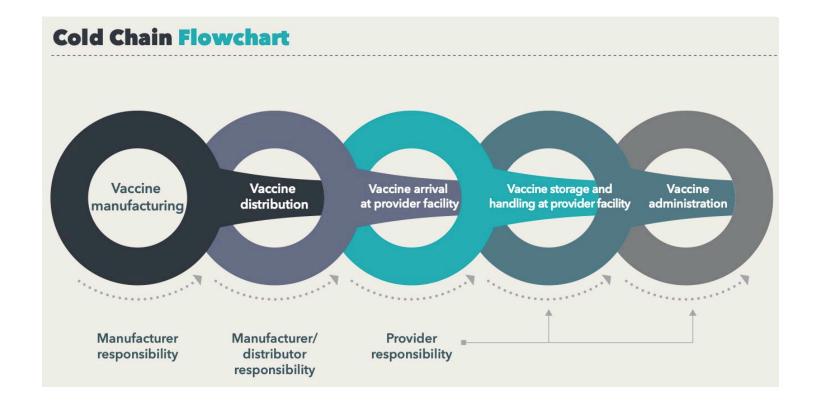
- Identify best practices for vaccine storage and handling
- Demonstrate knowledge of COVID-19 vaccine storage and handling
- Resolve common storage and handling issues
- Locate vaccine storage and handling resources

Why does vaccine storage and handling matter?

- 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.
- Limited Protection When non-viable vaccine is administered patients can remain unprotected from serious, vaccinepreventable diseases.
- Costly Revaccinating patients and replacing vaccines will result in added cost.
- 4. Loss of Confidence in vaccines.

- The vaccine cold chain is 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 a useless vaccine supply.

Proper storage and handling begins with an effective cold chain.



An effective cold chain relies on four main elements.

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

A break in the cold chain can mean extra doses for patients, increased costs for providers, and damage to public confidence in vaccines.

Training

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

All facilities should have a designated Primary Vaccine Coordinator who

- Ensures all vaccines are stored and handled correctly
- Is an expert on facility's storage and handling standard operating procedures
- Trains staff on vaccine management policies
- Appoints 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.

Standard Operating Procedures

All sites should maintain clear, detailed, and up to date Standard Operating Procedures (SOP).

SOPs should contain:

- General information contact information for vaccine manufacturers, contact information for important staff, information about storage units and back-up locations.
- Routine storage and handling including all aspects of vaccine inventory management.

Storage Units

Vaccine stored at refrigerated ranges (2°C to 8°C) can be stored in:

- 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
- Household-grade units are acceptable for storing adult vaccines at adult-only practices, but this is not the best practice. These are not acceptable to store state-supplied pediatric vaccines

Vaccine stored at freezer ranges (-50°C to -15°C) can be stored in:

A separate, standalone freezer

COVID-19 vaccine products may impact the types of vaccine storage units and temperature monitoring devices used to maintain the cold chain.

Storage Units: COVID-19 vaccine

COVID-19 vaccination providers must have proper storage and temperature monitoring equipment to mee the specific needs of the COVID-19 vaccine product they are administering.

Depending on the product, COVID-19 vaccine can be stored in:

- Ultra-Cold Storage freezer
- Thermal Shipping Container
- Pharmaceutical Grade or Purpose Built Units
- Household-grade units are acceptable for storing adult vaccines at adult-only practices, but this is not the best practice. These are not acceptable to store state-supplied pediatric vaccines
- A separate, standalone freezer

Never store in a dormitory-style or bar-style combined refrigerator/freezer unit.

Temperature Monitoring

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

The recommended Temperature Monitoring Device is a Digital Data Logger:

- 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

For Ultra-Cold Temperatures:

- May not be possible to use a buffered probe due to the ultra-cold temperature.
- May use an air probe

Monitoring vaccine storage equipment and temperatures should be a daily responsibility.

Best Practices

- Protect storage units power supply
 - Plug in only one storage unit per electrical outlet
 - Do not use GFCI outlets
 - Post "Do Not Unplug" warning signs on units and outlets
- Store vaccines in their original packaging with lids closed
- Separate vaccine supply, ex. Adult vs. Pediatric
- Don't store food and beverages with vaccines
- Check and record storage minimum and maximum temperatures daily

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

Transporting Vaccine

Vaccine should not be routinely transported.

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

- Vaccine should be transported using a DDL
- 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
- Do not use dry ice, even for temporary storage
- Vaccine should be stored in an appropriate storage unit with a TDDL upon arrival at the back-up location

Vaccine Inventory Management

Inventory management is essential to make sure that your facility has the vaccines needed.

Vaccine Delivery – Unpack and store vaccines as soon as they arrive.

- Examine shipments for damage
- Ensure that the cold chain has been maintained during shipment
- Make sure you've received all of your vaccines.

Keep an accurate count of vaccines

- Count vaccines at least monthly
- Look for expired vaccines to remove and rotate shorter dated vaccine to the front

Vaccine Ordering

Order what your facility needs to prevent wastage

Vaccine Inventory Management – COVID-19 Vaccine

COVID-19 vaccine shipments will include an ancillary supply shipment containing:

- Needles
- Syringes
- Alcohol prep pads
- Surgical masks
- COVID-19 vaccination record cards
- Vaccine needle and length guide
- Diluent and mixing supplies (based on vaccine product)
- Brands in the ancillary kit may vary.

Upon receipt, make sure that you receive all the supplies necessary to vaccinate.

Vaccine Inventory Management – Expired COVID-19 Vaccine

Monitor expiration dates of COVID-19 vaccine carefully

Pfizer-BioNTech – Expiration date is on packaging

Moderna – Scan QR code on package or lookup on the EUA website. Janssen - Scan QR code on package or lookup on the EUA website

Beyond Use Dates (BUD):

COVID-19 vaccine currently comes in multi-dose vials. Once opened, COVID-19 MDVs have a BUD. Carefully monitor BUDs to ensure that expired vaccine isn't administered.

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

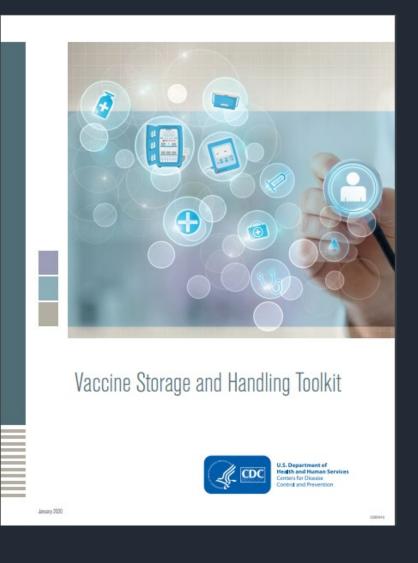
- Do not disconnect temperature alarm until the cause of the excursion has been determined
- Check the basics like the power supply, unit door, and thermostat

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
- Email MIISHelpDesk@state.ma.us for help



CDC Vaccine Storage and Handling Toolkit

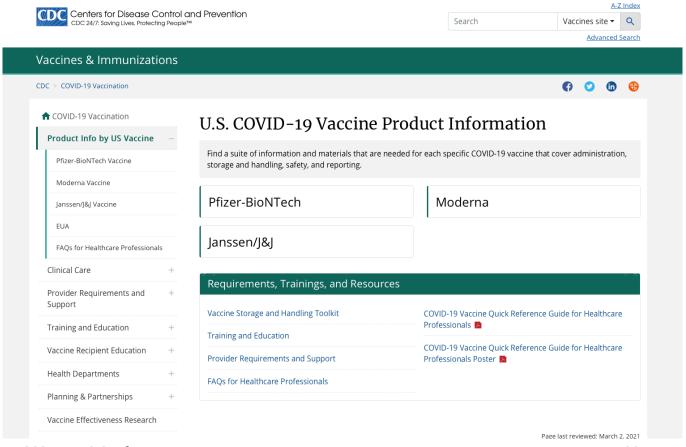
https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit-2020.pdf

A comprehensive guide that reflects best practice for vaccine storage and handling. The toolkit is updated annually.

The Toolkit has a COVID-19 Vaccine Addendum with information on Storage and Handling Best Practices for COVDI-19 vaccine.

https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

U.S. COVID-19 Vaccine Product Information



https://www.cdc.gov/vaccines/ed/youcalltheshots.ht ml

You Call The Shots: Vaccine Storage and Handling

You Call The Shots

Web-based Training Course

Note: You Call the Shots is updated regularly to include the latest guidelines and recommendations in vaccine practice. The latest modules are below.

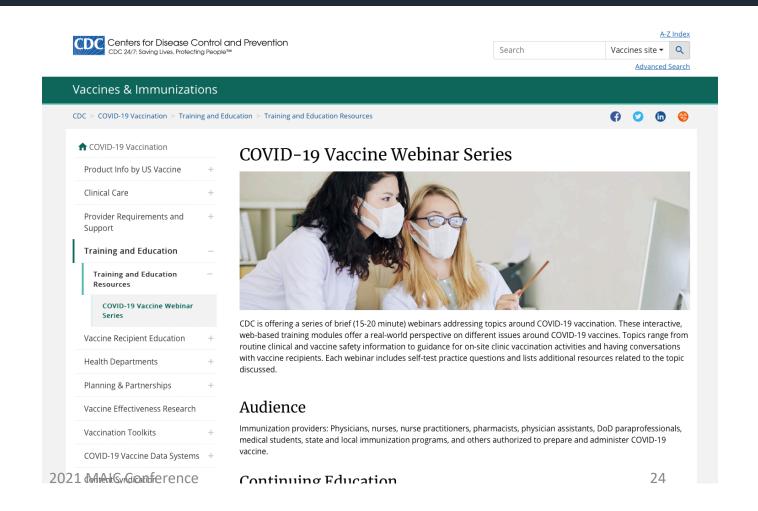
At a Glance

You Call the Shots is an interactive, web-based immunization training course. It consists of a series of modules that discuss vaccine-preventable diseases and explain the latest recommendations for vaccine use. Each module provides learning opportunities, self-test practice questions, reference and resource materials, and an extensive glossary.



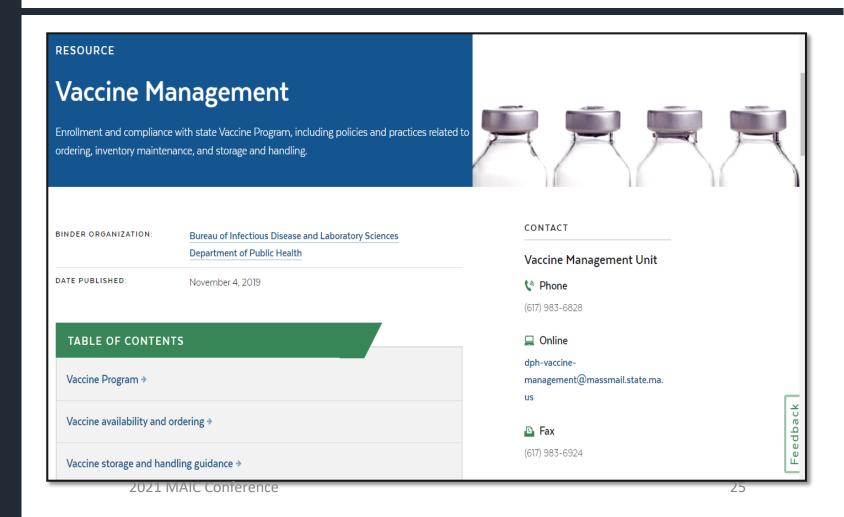
https://www.cdc.gov/vaccines/covid-19/trainingeducation/webinars.html

CDC COVID-19 Vaccine Webinar Series



https://www.mass.gov/resource/vaccinemanagement

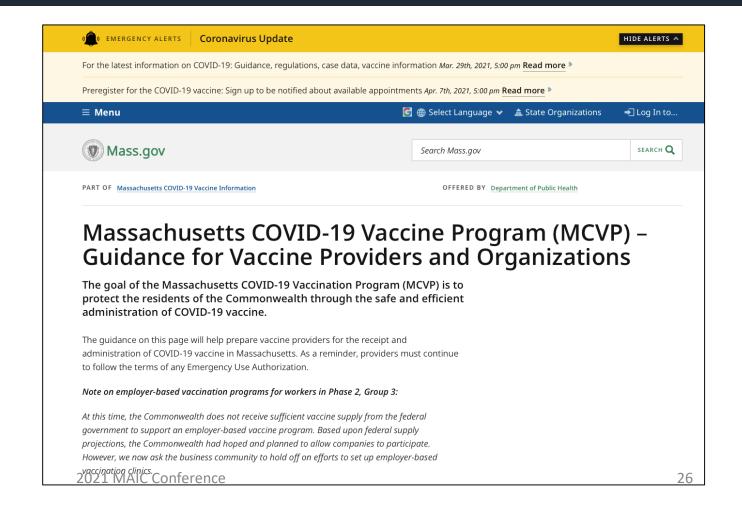
MDPH Immunization
Division Vaccine
Management Resources



4/13/21

https://www.mass.gov/info-details/massachusettscovid-19-vaccine-program-mcvp-guidance-forvaccine-providers-and-organizations

Massachusetts COVID-19 Vaccine Program (MCVP) -Guidance



Thank you for your participation! Questions?

Contact Information:

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