



**Department
of Health**

NYS Vaccines for Children (VFC) Program Training Series 5: The Vaccine Cold Chain

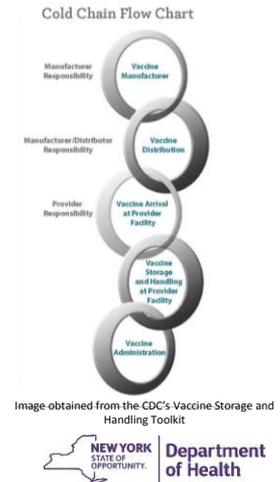
New York State Department of Health
Bureau of Immunization

Hello and welcome.

This training is intended to introduce NYS Vaccines for Children providers to the Vaccine Cold Chain and familiarize them with best practices for protecting the Vaccine Cold Chain.

What is the Vaccine Cold Chain?

- Temperature-controlled environment used to maintain and distribute vaccines in optimal condition
- Inappropriate storage conditions can cause a break in the chain and can damage vaccine
 - 30% of vaccines are lost due to temperature excursions
- Cold chain begins at the manufacturer and ends with administration of vaccine to the patient
- Appropriate storage conditions must be maintained at every link in the cold chain



The Vaccine Cold Chain, as defined by the Centers for Disease Control and Prevention or (CDC), is: “A temperature-controlled environment used to maintain and distribute vaccines in optimal condition.”

Temperature conditions (either too warm or too cold) that cause a break in the cold chain can damage vaccine, resulting in reduced potency or even in total loss of vaccine.

The National Institute of Standards and Technology (NIST) conducted a study for the CDC which estimated that 14% to 35% of vaccines are subjected to inappropriate storage temperatures as they travel through the cold chain. Also, an estimated 30% of vaccines are lost due to temperature excursions.

The cold chain begins with the storage unit at the manufacturing plant, extends through transport of vaccine(s) to the distributor, then delivery and storage at the provider facility, and ends with administration of vaccine to the patient. In order to ensure quality vaccines are given to children, vaccine manufacturers, distributors and health care providers must ALL maintain the vaccine cold chain.

Inappropriate Storage Conditions

- Excessive cold, heat or light exposure can reduce vaccine potency.
 - Potency is the vaccine's ability or strength to effectively protect against disease
- Each exposure to improper conditions results in a larger overall vaccine potency loss
 - Vaccine becomes useless once potency is lost
- A single exposure to a freezing temperature will destroy some refrigerated vaccines.

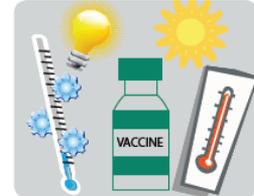


Image obtained from the CDC's Vaccine Storage and Handling Toolkit



Inappropriate vaccine storage conditions include excessive cold, heat or light exposure. This exposure can damage vaccines which can result in reduced potency or reduced effectiveness. Each time vaccine is exposed to an improper condition, the potency of the vaccine is reduced further. Once the potency is lost, it cannot be restored and the vaccine becomes unusable.

Some refrigerated vaccines can be destroyed if exposed to a freezing temperature just one time.

Which refrigerated vaccine was frozen?

Properly Stored



Improperly Stored



Can you tell which refrigerated vaccine was frozen? These images are a good reminder that vaccine appearance is not a reliable way of measuring when potency has been reduced or lost.

Inappropriate Storage Conditions

Problem

- Door left ajar
- Door left open too long during inventory check
- Overcrowded storage unit
- Incorrect thermostat adjustment
- Emergency plan not activated during power outage
- Malfunctioning unit

Solution

- Door alarm or unit with self-closing door
- Follow best practices during inventory checks
- Move overflow to another unit, buy another unit
- Only trained staff can adjust, set-point security
- Use continuous temperature monitoring
- Unit maintenance, continuous temperature monitoring



Listed on this slide are some ways vaccine can be exposed to inappropriate storage temperatures, and some tips for prevention:

In the first example, the door of the vaccine storage unit is accidentally left ajar. One simple solution would be to regularly remind staff to close the storage unit door. However, for practices with large vaccine supplies it may be necessary to purchase a door alarm or a unit with self-closing doors to prevent significant loss of vaccine.

Another example of a scenario where vaccine can be exposed to inappropriate storage conditions is during the weekly inventory check, if the door is left open for too long. Consider taking one vaccine out at a time when conducting an inventory and ensure your unit is set up appropriately. A properly set up unit will ensure your procedure is as efficient as possible. Best practices for conducting a vaccine inventory are included in training #12 of this series.

An overcrowded storage unit can lead to inappropriate storage conditions as well since this can lead to poor air circulation within the unit.

Vaccines and their containers should be in the center of the storage unit at least 2-3 inches away from the walls.

If unit does not have sufficient storage space, move a portion of the vaccine to a unit that; maintains appropriate temperature, has space available and contains a thermometer with a current, valid certificate of calibration testing.

If your unit is overcrowded, you may want to consider purchasing an additional unit. Refer to the size chart and calculator in training # 6 of this series.

If necessary, vaccines can be stored off-site in accordance with your Emergency Vaccine Management Plan until an additional unit is purchased.

Inappropriate storage conditions can also occur due to an incorrect thermostat adjustment. Ensure that only designated staff who have been trained on appropriate thermostat use can adjust the thermostat. Consider purchasing a vaccine storage unit with set-point security (where a key is required to make a thermostat change).

If an emergency plan is not activated during a power outage, vaccines can quickly become compromised. Staff should be adequately educated about timely emergency management.

VFC providers should implement their emergency plan if a power outage is sustained for more than 2 hours. Use of continuous temperature monitoring that is connected to an alarm system ensures that providers will be notified about any temperature excursions occurring after hours.

Malfunctioning or failing units can occur for various reasons, however, regular maintenance of vaccine storage units is essential to ensure that they are operating at optimal levels.

Contract with a company that can maintain and service the unit regularly. Conducting your own frequent maintenance and cleaning can also help to avoid temperature excursions.

Freezers which require a manual defrost should be defrosted regularly to ensure that the frost buildup does not affect temperatures inside the unit.

Use of continuous temperature monitoring devices such as digital data loggers allow for the download of temperature data to a computer which may reveal an otherwise unknown long-term problem with the storage unit.

Consequences of Vaccine Cold Chain Failure

- Patients not fully protected against vaccine-preventable diseases
 - Patients may need to be re-immunized
 - Loss of public trust
- Increased costs
 - Loss and replacement of vaccine
 - Staff time spent on determining patients to be re-immunized and contacting manufacturers



Patients who receive reduced potency vaccine may not be fully protected against vaccine-preventable diseases and therefore they may need to be re-immunized. This can cause damage to public trust in vaccines.

Additionally, there are increased costs associated with vaccine cold chain failure including the costs associated with the loss and replacement of vaccine and the cost in provider resources, such as the time needed to contact the manufacturers and if needed, the time needed to schedule and conduct re-immunizations.

Protecting the Vaccine Cold Chain: Proper Equipment

Storage equipment

- Best practice: standalone units*
- Proper set up of units
- Temperature monitoring equipment

Calibrated, continuous temperature monitoring device (Data Logger)

- Can record current and min/max temperatures
- Additional trainings are available

Acceptable temperature ranges:

Refrigerated vaccine: Between 36° and 46°F or Between 2° and 8°C

Frozen vaccine: Between -58°F and 5°F or Between -50°C and -15°C



Image obtained from the Nevada State Immunization Program Vaccine Storage Unit Protocol



Data logger
Image obtained from the CDC's Vaccine Storage and Handling Toolkit

*All new unit purchases must be standalone units.



Maintenance of the vaccine cold chain is very much dependent on having the proper equipment in place.

Your facility's vaccine storage equipment should be able to maintain temperatures within the acceptable temperature ranges outlined on this slide.

The use of standalone units is considered best practice (standalone units are storage units dedicated to a single temperature range). All new unit purchases must be standalone units.

The proper set up of units including proper spacing between vaccines can also be helpful in protecting the vaccine cold chain.

Appropriate temperature monitoring equipment is needed to accurately record and monitor temperatures inside of storage units.

The NYS VFC program requires the use of calibrated, continuous temperature monitoring devices with a digital display that sits outside of the storage unit. Digital data loggers are devices that continuously monitor and record temperatures of vaccine and store the data inside of the device.

Data loggers that can record current and minimum and maximum temperatures are required.

Additional trainings on selecting appropriate storage and temperature monitoring equipment are available.

Protecting the Vaccine Cold Chain: Vaccine Management Plans

- Develop comprehensive routine and emergency vaccine storage and handling plans
- Update annually and share with staff
- Keep plans near storage units and where staff can find them
- Ensure custodial and security staff have emergency contact information



Image obtained from the CDC's Vaccine Storage and Handling Toolkit



Efficient vaccine management plans are also essential to protecting the vaccine cold chain.

You should develop detailed and comprehensive routine and emergency storage and handling plans.

Update the plans and share with staff at least annually.

Make sure the plans are located near the vaccine storage units where staff can find them.

Also be sure to provide custodial and security staff contact information for reporting an emergency .

Additional information on developing vaccine management plans is detailed in training #4 of this series.

Protecting the Vaccine Cold Chain: Well-Trained Personnel

Who should be trained?

- All staff who handle or administer vaccines
- Consider staff who may accept or assist with vaccine deliveries

When should training be done?

- Annually
- When new vaccine staff are hired
- when recommendations are updated

What should training cover?

- Maintaining the vaccine cold chain and storage and handling requirements and best practices
- Storage unit temperature monitoring requirements and use of temperature monitoring devices
- Understanding what's "out of range" and corrective actions for temperature excursions



Ensuring that you have well-trained personnel is another large component of protecting the vaccine cold chain.

All staff who handle or administer vaccines should be trained including front desk or office staff who may accept or assist with unpacking large vaccine deliveries.

Staff should have training annually, when new staff are hired, and when program recommendations are updated.

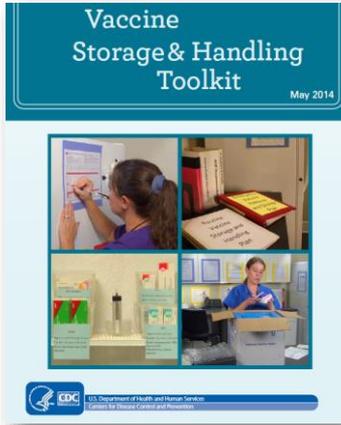
Trainings should cover information on maintaining the vaccine cold chain including vaccine storage and handling requirements and best practices

Training should also cover understanding of appropriate storage unit temperatures and use of temperature monitoring devices, if needed. Storage unit temperatures should always be recorded twice a day, when the office opens and right before the office closes.

All staff should be aware of what temperatures are considered out of range, and what steps to take during a temperature excursion.

Additional information on trainings that are available is included in training #2 of this series.

CDC's Vaccine Storage and Handling Toolkit



<http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>



The Centers for Disease Control and Prevention (CDC) has developed a Vaccine Storage and Handling Toolkit that provides best practices on vaccine storage and handling based on recommendations of the Advisory Committee on Immunization Practices (ACIP), vaccine manufacturer product information, and studies conducted by the National Institute of Standards and Technology (NIST). This toolkit is an excellent resource on all topics related to the storage and handling of vaccine.

Key Messages: The Vaccine Cold Chain

- The vaccine cold chain is a temperature-controlled environment used to maintain vaccines in optimal condition.
- Vaccine cold chain failure can cost thousands of dollars in lost vaccine and can damage the public's trust if revaccination is needed.
- Many factors contribute to the protection of the vaccine cold chain:
 - Proper storage units and temperature monitoring equipment are essential in protecting the vaccine cold chain. Standalone units and data loggers are required.
 - Routine and emergency vaccine storage and handling plans updated annually and located in areas where staff can find them.
 - Well-trained staff and awareness of procedure
- Follow best practices for vaccine cold chain protection.



The vaccine cold chain is a temperature-controlled environment used to maintain vaccines in optimal condition.

Vaccine cold chain failure can cost thousands of dollars in lost vaccine can damage the public's trust in vaccine if revaccination is needed.

Many factors contribute to the protection of the vaccine cold chain.

First, proper storage units and temperature monitoring equipment are essential in protecting the vaccine cold chain. Store vaccine in stand alone storage units or units that are only a refrigerator or only a freezer. Use continuous temperature monitoring devices or data loggers to monitoring temperatures inside the storage units.

Next, make sure your practice has detailed and comprehensive routine and emergency storage and handling plans in place. The Plans should be updated annually and located in areas where staff can easily find them.

All staff who handle or administer vaccines should be trained in vaccine storage and handling should be aware of what temperatures are considered out of range, and what steps to take during a temperature excursion.

Always follow the best practices for vaccine cold chain protection. Exceed the minimum requirement whenever possible.

Resources

Centers for Disease Control and Prevention (CDC)

Vaccine Storage and Handling Toolkit

<http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

Current Vaccine Price List

<http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html>

Keys to Handling and Storing Your Vaccine Supply

<http://www2.cdc.gov/vaccines/ed/shvideo/>

Vaccine Administration and Storage and Handling Resource Guide

<http://www.cdc.gov/vaccines/hcp/admin/downloads/vacc-admin-storage-guide.pdf>

Immunization Action Coalition (IAC)

Vaccine Storage and Handling Handouts

<http://www.immunize.org/handouts/vaccine-storage-handling.asp>

American Academy of Pediatrics (AAP)

Refrigerators, Freezers and Vaccine Storage

https://www.aap.org/en-us/Documents/immunization_vaccinestoragerf.pdf

Data Loggers and Vaccine Monitoring

https://www.aap.org/en-us/Documents/immunization_dataloggers.pdf



Here is a listing of available resources.

Additional Training for NYS VFC Providers

**Next: NYS VFC Program Training Series #6: Selecting Vaccine Storage
Units**



A number of additional trainings are available.

The next training in this series is #6: Selecting Vaccine Storage Units.