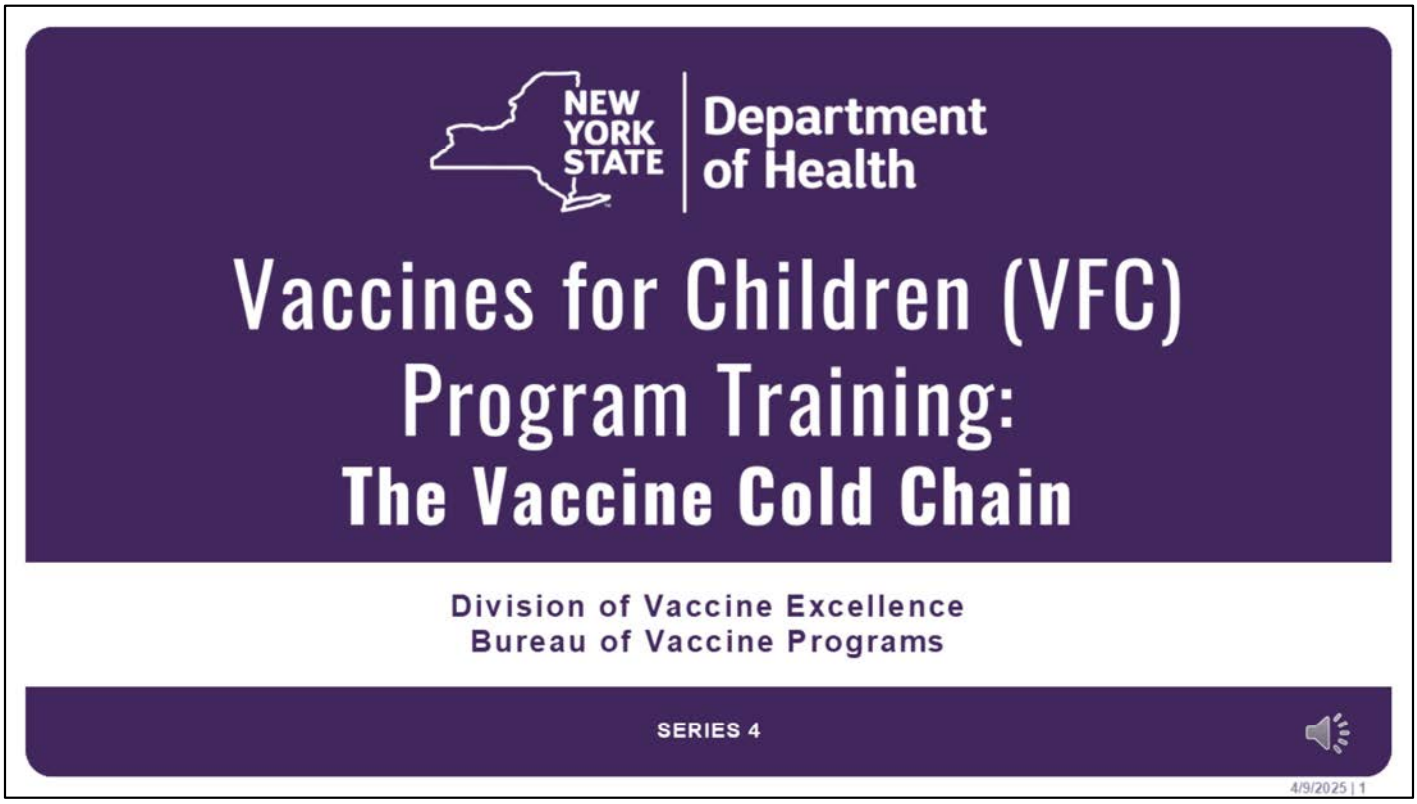
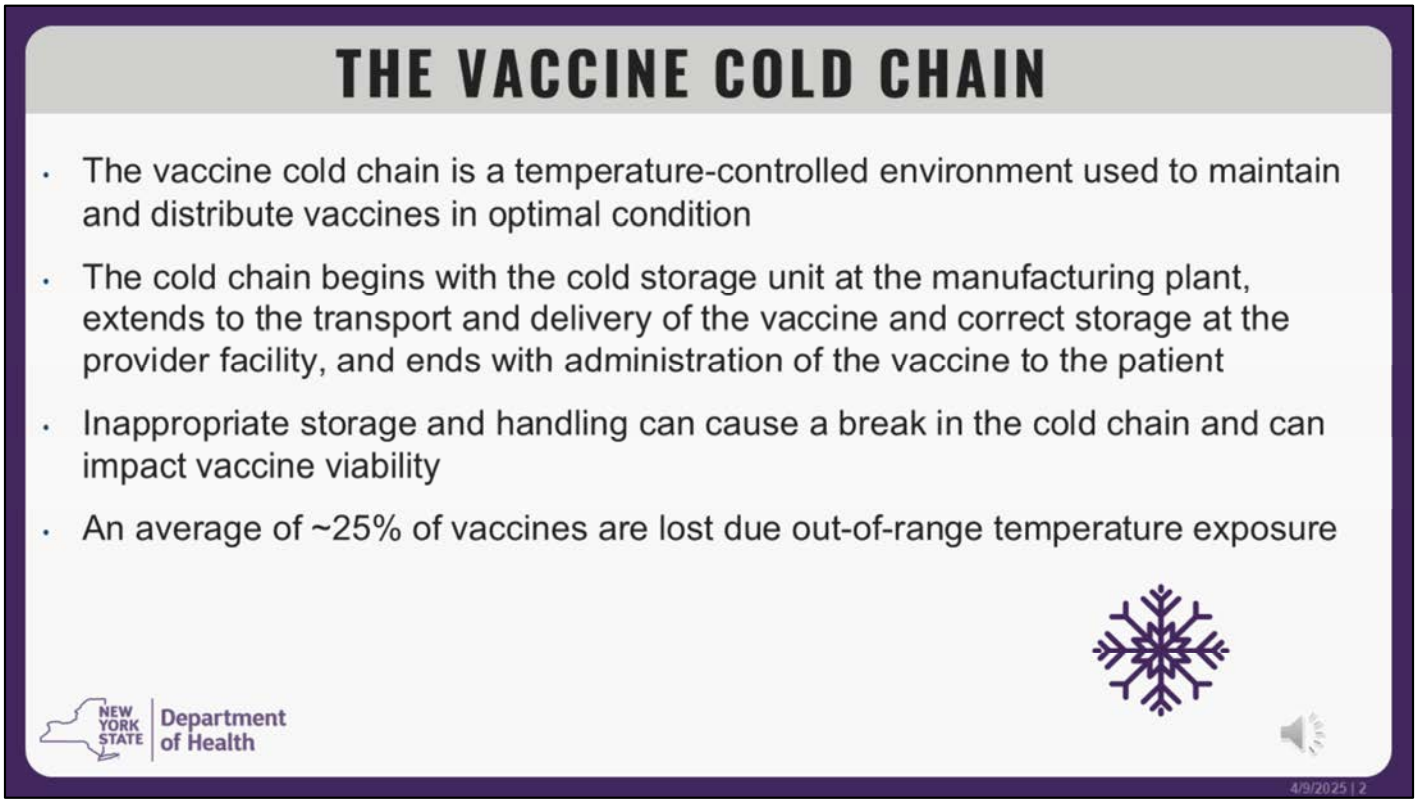


Hello and welcome. This training is intended to provide an overview of the importance of maintaining the Vaccine Cold Chain.



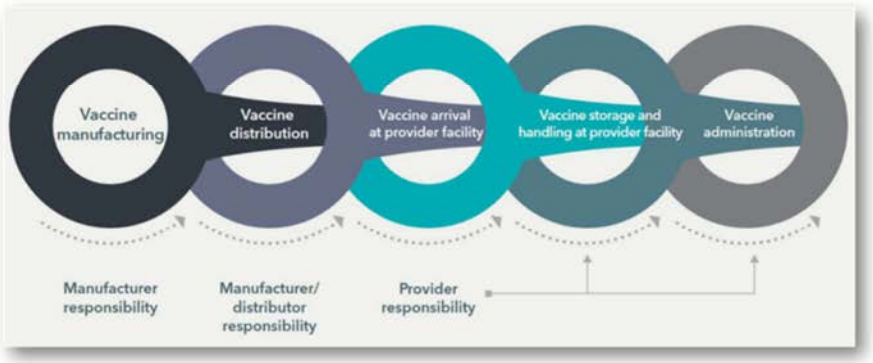
Proper storage and handling begins with an effective vaccine cold chain.

The Vaccine Cold Chain, as defined by the CDC, is: “A temperature-controlled environment used to maintain and distribute vaccines in optimal condition.”

Temperature conditions outside the acceptable range can break the cold chain and affect vaccine viability, resulting in reduced potency or total loss.

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.

THE VACCINE COLD CHAIN



This image from page 5 of CDC's Vaccine Storage and Handling Toolkit (2024)

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This flow chart outlines every point in the cold chain from manufacturer to patient and highlights the provider responsibility, which includes receipt of vaccine, storage and handling, and vaccine administration.

WHAT IS CONSIDERED IMPROPER STORAGE?

- Vaccine viability is reduced every time a vaccine is exposed to an improper condition. This may include:
  - Overexposure to out-of-range temps, either above or below acceptable storage range
  - Overexposure to direct sunlight, UV light, or fluorescent light
- Once lost, ***viability cannot be restored***

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Vaccines must be stored properly from the time they are manufactured until they are administered. Viability is reduced every time a vaccine is exposed to an improper condition. This includes overexposure to heat, cold, or direct exposure to light at any step in the cold chain. Once lost, viability cannot be restored.

IDENTIFYING NON-VIABLE VACCINE

- Vaccine appearance is **not** a reliable measure for determining vaccine viability
- The best measure is temperature data review and maintaining proper storage and handling procedures
- All out-of-range temperatures, regardless of duration must be reported to NYS VFC immediately at vaccinetempexcursion@health.ny.gov
- All excursions must be reported, regardless if the alarm/"X" is triggered

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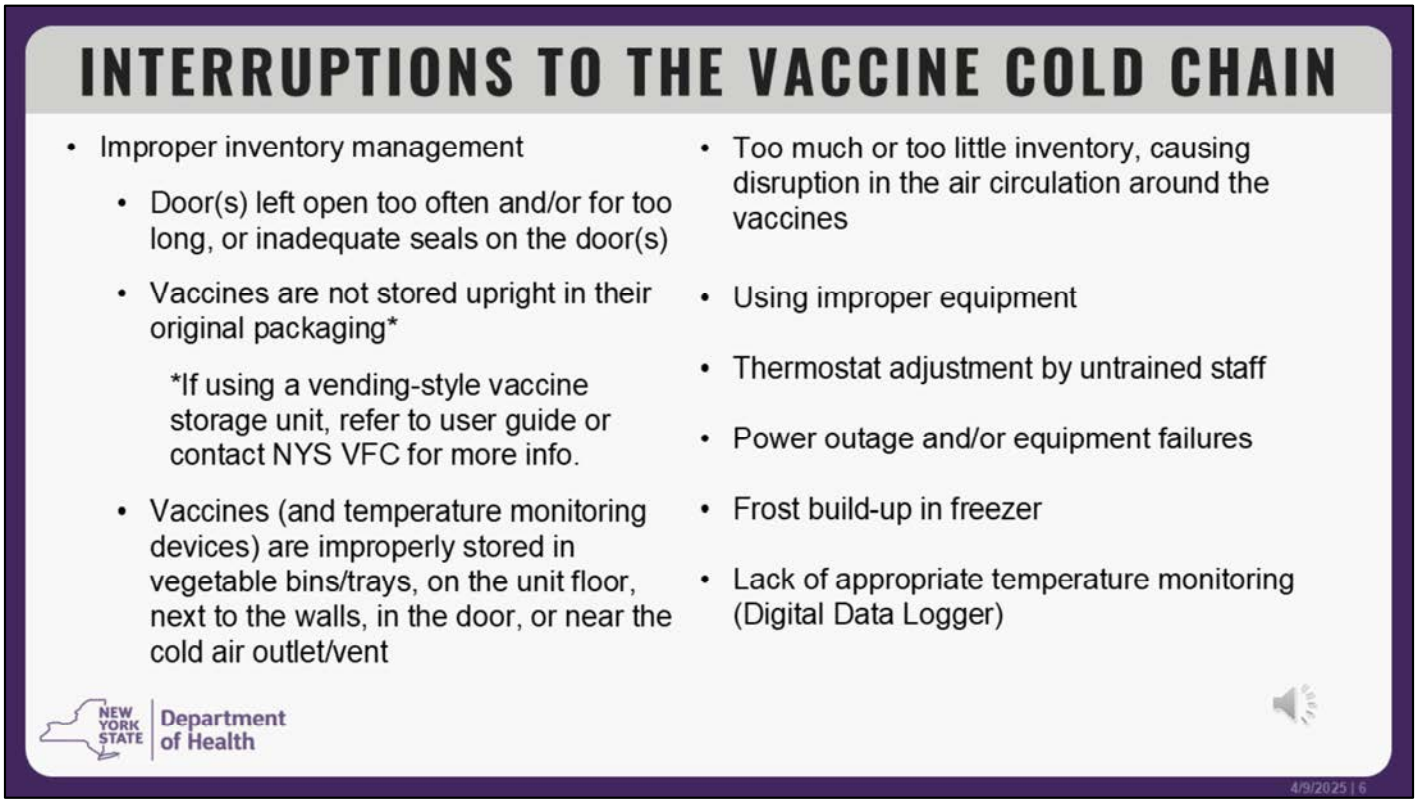
One of these vials in the image on this slide was left out of the refrigerator overnight, and then replaced in the morning. Can you tell which vial it was? Of course not!

Vaccine appearance is not a reliable measure for determining vaccine potency and/or viability. Temperature recording and data review is the best measure for tracking and identifying possible excursions and determining affect on vaccine potency and viability.

All out-of-range temperatures, known as temperature excursions regardless of duration must be reported to NYS VFC immediately at vaccinetempexcursion@health.ny.gov
All excursions must be reported, regardless if the alarm/"X" is triggered



Inventory counts can put vaccines at risk for exposure to out-of-range temperatures. Consider working on one shelf at a time throughout the day to avoid the door being open for too long at one time. Make sure vaccine products are well-organized and stored upright and in original packaging as vaccines stored in their original packaging have reduced exposure to light.

It is important to ensure that the storage unit doors are closed after each use. This can be difficult in a high-traffic office with various staff in and out of the unit. Consider using Velcro or other door latches, door alarms, or self-closing units to prevent doors left ajar.

If overcrowding is a concern for your storage unit(s), you may be required by VFC to purchase additional units for your vaccine. Please refer to the size chart in training #5 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.

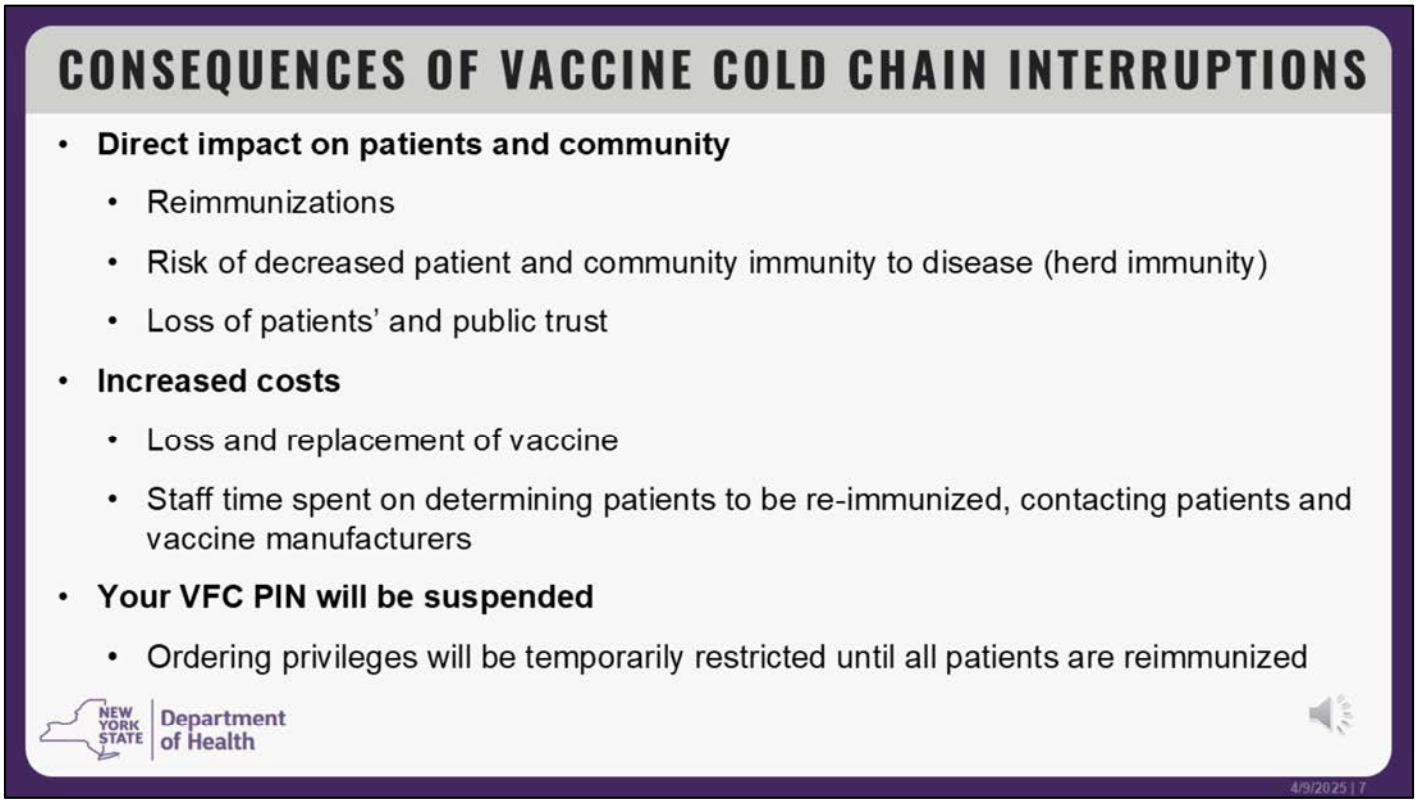
Only trained staff should be responsible for adjusting the unit's

thermostat. Consider attaching instructions for proper thermostat adjustments and settings to the unit for reference

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 (see training slide #3 on Vaccine Management Plans). 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.

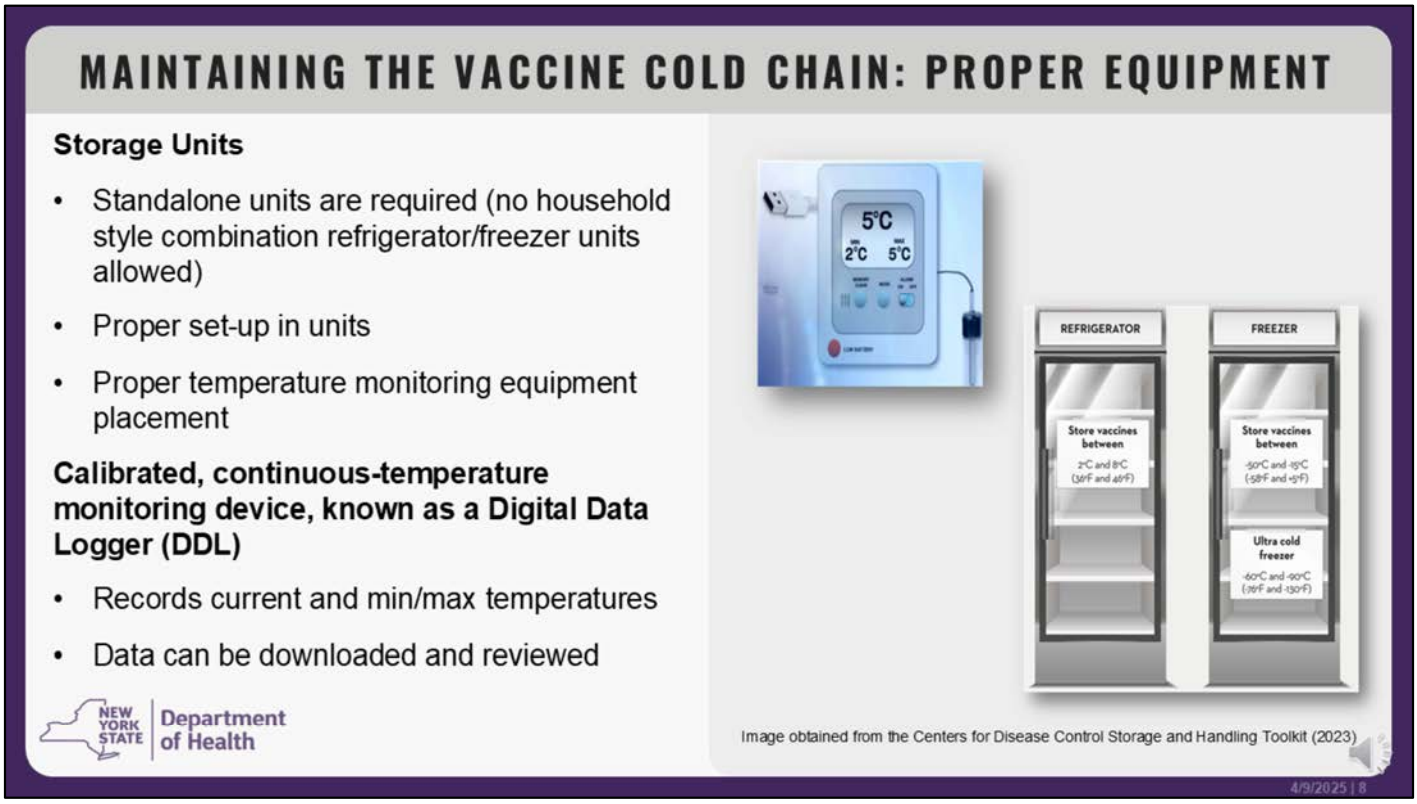
Frost build up can hinder proper door closure and air flow. Freezers which require a manual defrost should be defrosted regularly. Frost-free freezers are recommended.

Continuous temperature monitoring devices, such as digital data loggers (DDLs), support cold chain management and are a tool for identifying problems with your storage-unit. DDLs also allow for review of past temperature data to track out-of-range vaccine storage temperatures, also known as temperature excursions.



Vaccines exposed to cold chain interruption and/or failure may become non-viable. Administration of any of these doses to patients means they are not fully protected against vaccine-preventable diseases, and are recommended for reimmunization. This can affect Herd Immunity and can negatively affect the patient's and public trust of vaccines.

Additionally, there are also increased costs associated with vaccine cold chain failure, including costs associated with replacement of wasted vaccine, time spent reporting the waste, reporting any excursion that may have occurred, calling the vaccine manufacturers, and time spent contacting and scheduling patients for reimmunizations.



Not only is it considered best practice to store vaccines in standalone units, but it is required by the New York State VFC program. Proper set up of these units is fundamental in maintaining the vaccine cold chain. This includes ensuring the appropriate temperature range is set, storing vaccines away from the walls of the unit, with proper spacing allowing for airflow, and in original packaging when possible. Vaccines should only be stored in bins that are well vented, shallow, and either plastic or wire.

The NYS VFC program requires the use of calibrated, continuous-temperature monitoring devices, also known as digital data loggers (DDLs). DDLs are devices that continuously monitor, record, and store temperature data. Data can then be downloaded and reviewed to support cold chain management. Many DDLs offer alarm systems that can be utilized to prevent or interrupt temperature excursions.

As discussed in previous trainings of this series, the VFC Program requires that every enrolled provider develop detailed and comprehensive routine and emergency vaccine management plans.

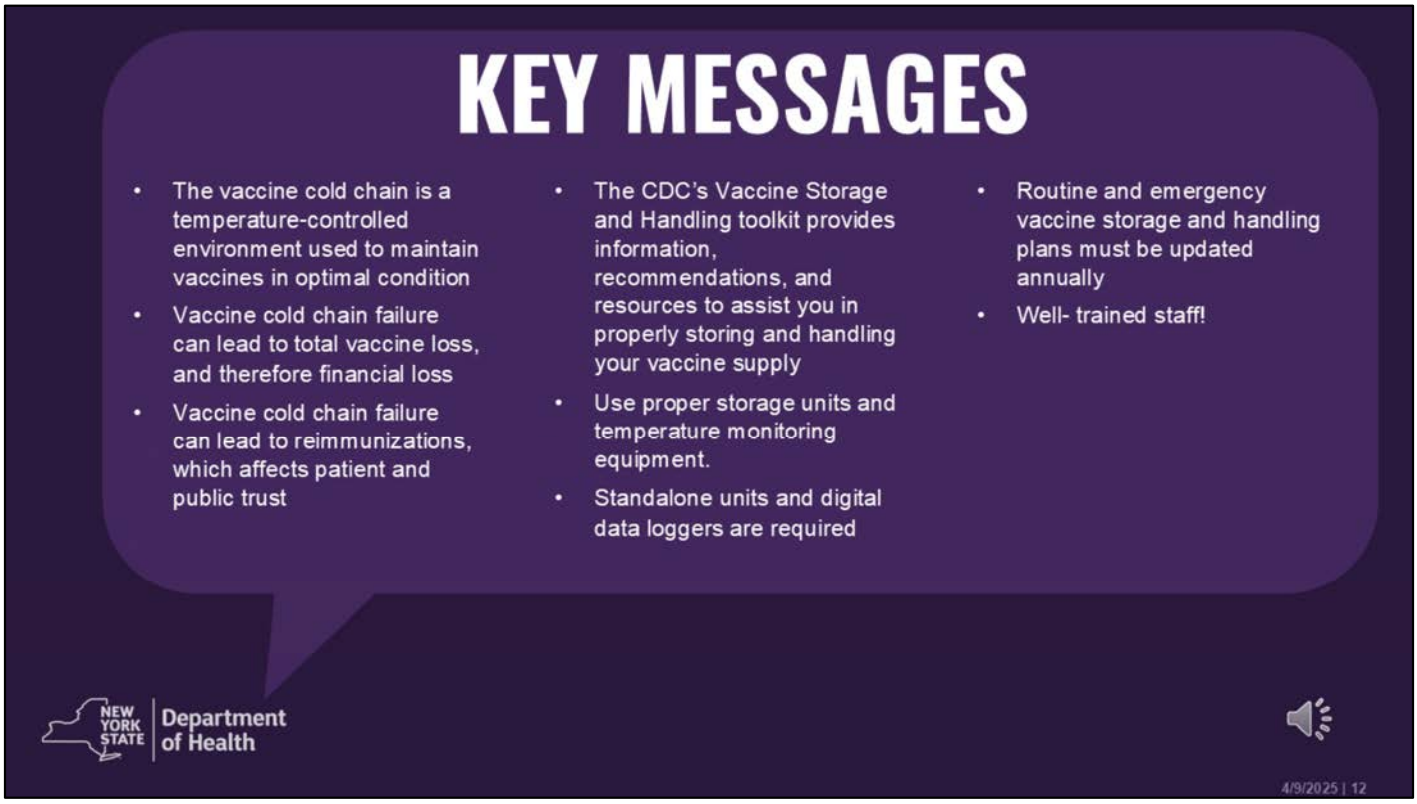
These plans must be reviewed at least annually, and any time storage and handling recommendations and/or guidelines are updated. Any updates to your plan must be reviewed with all staff involved in vaccine management. Any other staff or persons with access to your vaccine storage room or electrical panel should be aware of emergency contacts in the event of power loss or other incidents affecting your vaccines.

Successful cold chain maintenance is not possible without well-trained staff. Any staff who handle or administer vaccines should receive training, including front desk staff who accept vaccine shipments or assist with unpacking vaccine deliveries. Staff should review training annually, when program or vaccine recommendations are updated, or when new staff is hired.

Trainings should cover vaccine cold chain management through best practices for storage and handling, temperature monitoring requirements and use of temperature monitoring devices (DDLs), and an overview of out-of-range temperatures and how to report excursions. Training should outline the requirement to record minimum and maximum temperatures when the office first opens for the day

As referenced earlier in this training, The Centers for Disease Control and Prevention (CDC) Vaccine Storage and Handling Toolkit brings together best practices from the Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization, product information from vaccine manufacturers, and results of scientific studies. Implementing these best practices and recommendations will help protect your patients, safeguard your vaccine supply, and avoid the unnecessary costs of revaccinating patients and replacing expensive vaccines.

This toolkit, linked here and included in the resources document provided with this training, provides information, recommendations, and resources to assist you in properly storing and handling your vaccine supply.



The key messages from this Vaccine Cold Chain training begins with the understanding that the vaccine cold chain is a temperature-controlled environment and flow that begins with the manufacturer and ends with administration of the vaccine.

Interruption in the cold chain or total cold chain failure can lead to patients receiving non-viable vaccines, reimmunizations, and financial loss. This can also negatively affect public trust of vaccines.

Vaccine cold chain management is largely supported through use of proper storage units and temperature monitoring devices, and well-detailed routine and emergency vaccine management plans.

Finally, well-trained staff successfully implement and execute policy and procedure to maintain the cold chain.

Thank you for your participation in this training on the importance of the Vaccine Cold Chain. As always, questions can be directed to nyvfc@health.ny.gov