NYS Vaccines for Children (VFC) Program Training Series 7: Setting up Vaccine Storage Unit(s)

New York State Department of Health
Bureau of Immunization

Hello and welcome.

Just as selecting an appropriate storage unit is critical to ensuring the viability of refrigerated and frozen vaccine, so is the set up and preparation of your vaccine storage unit. A carefully organized vaccine storage unit helps protect vaccine and facilitates vaccine inventory management.

This training provides step by step instructions on how to set up vaccine storage equipment.

NYS VFC Program Requirements: Setting up Vaccine Storage Units

1. Notify the VFC Program any time a new/repaired unit will be set up and before a physical office move
   - 1-800-543-7468 or nyvfc@health.ny.gov
   - Refer to separate training for information on specific unit requirements
2. Demonstrated protection of vaccine storage unit power supply:
   1. Use of warning labels such as “Do Not Disconnect” posted near each storage unit’s electrical outlet and circuit breaker, and near any backup generators (if applicable) OR
   2. Appropriate policies/protocols in place to protect the power source
3. At least five business days of in-range temperatures need to be recorded in the unit prior to use
4. Separate public and private stock and label accordingly

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There are many different scenarios when you may need to set up a vaccine storage unit, these include but are not limited to:

When your physical office location moves,
when a new unit is purchased OR
When you need to empty vaccine from a storage unit so that it can be repaired.

Notify the VFC Program any time you intend to set up a new unit and/or before a physical office move. The 6th training in this series, Selecting a Vaccine Storage Unit, gives specific requirements for storage units.

The VFC program requires that you demonstrate proper protection of your vaccine storage unit’s power supply. This can be done by posting warning labels such as “Do not Disconnect” near the unit’s electrical outlets, near related circuit breakers and near any backup generators, if your office has a generator. If warning labels are not used, appropriate policies and protocols for protecting the power supply must be demonstrated.

The NYS VFC program requires that you have at least five business days of in-range temperatures recorded in the storage unit prior to use. If this cannot be demonstrated, the NYS VFC program may reject or hold vaccine orders.

The NYS VFC Program requires that VFC providers physically separate public vaccine from private vaccine stock in their refrigerator and freezer storage units. Refer to the Resources slide for a link for more information.

Vaccine Storage Unit Setup

- Place storage unit in room on dedicated circuit breaker, if possible
- Place in a well-ventilated room, away from direct sunlight and heat sources
- Leave space around the top and sides, at least 4 inches (10 cm) of space between the unit and wall
- Do not block the motor compartment
- Keep level -at least 1 to 2 inches above the floor (may have to adjust legs)
- Refer to owner's manual for additional information

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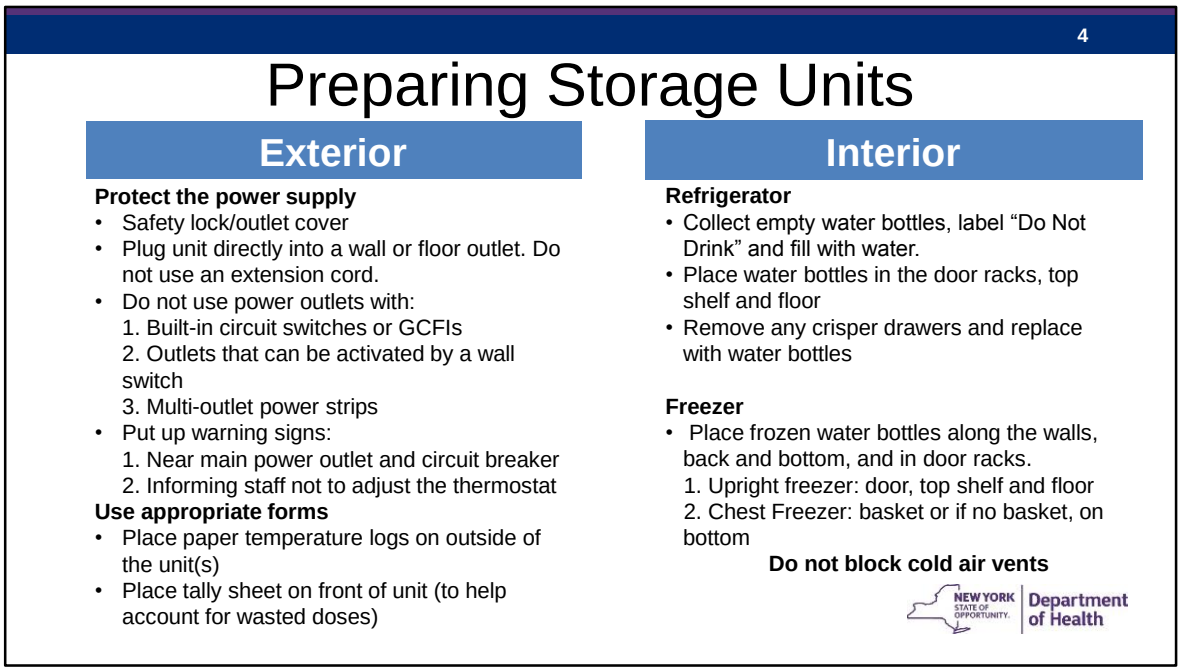
The location of your vaccine storage units within your practice is important to maintaining the vaccine cold chain.
If possible, place your vaccine storage units in an area that is on a single, dedicated circuit breaker. This helps to reduce the possibility that the power will be terminated accidentally. If you are unsure of your facility's power structure, consult with maintenance staff.

The unit(s) should be placed in a well ventilated room, away from direct sunlight and heat sources.

Allow space around the top and the sides of the unit. It is recommended to allow at least 4 inches of space between the unit and the wall, if possible, while also ensuring that the motor compartment is not blocked.

Keep the unit level, at least 1-2 inches above the floor.

Always refer to the owner's manual for additional guidance on placement and any space requirements that may be specific to your unit.



In terms of preparing the exterior of the unit, the use of a safety lock or outlet cover is strongly recommended to prevent staff from accidentally unplugging the unit.

Plug the vaccine storage unit directly into a wall or floor outlet. Do not use an extension cord. Avoid using power outlets with built-in circuit switches or Ground Flow Circuit Interrupters or GCFIs (GCFIs have reset buttons).
Don't use power outlets that can be activated or inactivated by a wall switch.
Don't use multi-outlet power strips or surge protectors.

Place warning signs near the unit's main outlet and any associated circuit breaker(s) informing staff and others not to unplug the storage unit or disconnect power. The warning sign should also indicate a contact person in the event of an electrical problem or any scheduled maintenance that needs to occur. Follow the links in this slide for examples of warning signs or by visiting the resources section of this training.

Maintenance and custodial staff should be instructed to never unplug the vaccine storage units or to notify the appropriate person if power needs to be shut off.

Place a warning sign on the front of the unit informing staff not to adjust the thermostat. Only the Vaccine Coordinator (or Back-up) should adjust the temperature.

Place the paper temperature log on the front of the unit to help facilitate the recording of twice daily temperature readings.

Consider placing a tally sheet on the front of the unit to help account for wasted

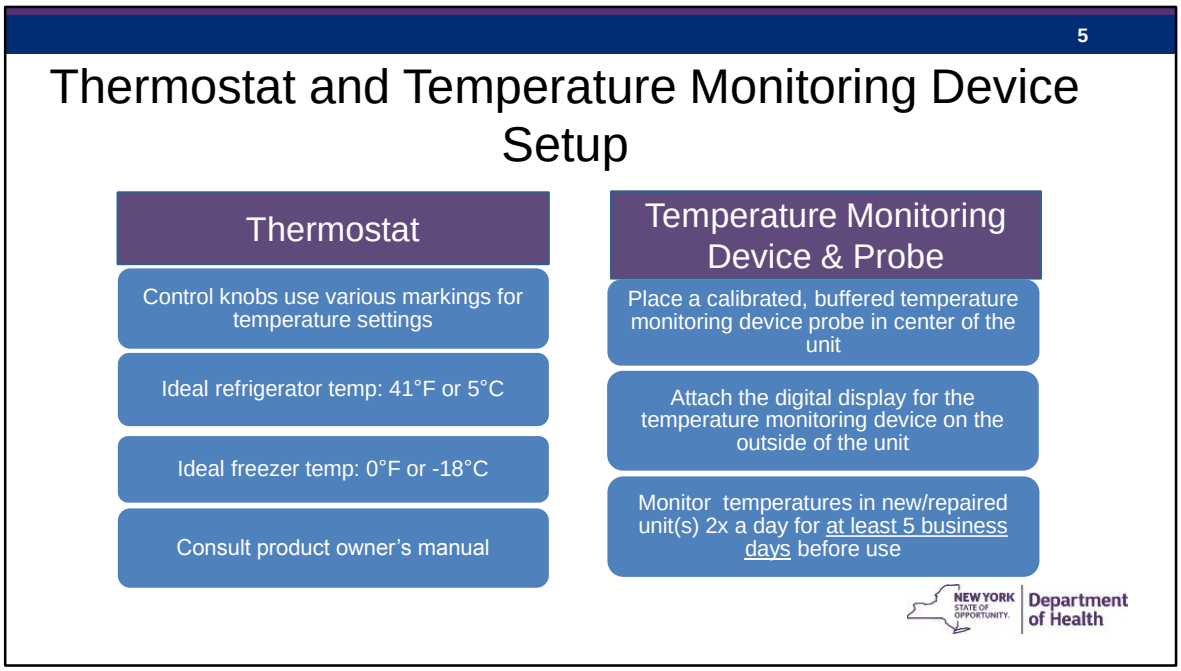
doses of vaccine (e.g., doses that were discarded after being dropped or broken, drawn up but not used, etc.)

For the interior of the refrigerator, label water bottles “Do Not Drink” and fill with water.
Remove any crisper drawers from the refrigerator and replace with the filled water bottles. Always place filled water bottles in door racks (if present), the top shelf, and on the floor.

For the interior of the freezer, place frozen water bottles throughout the unit. If you are using a standard upright freezer place frozen water bottles in the door and along the top shelf and floor. If you are using a chest freezer, place the water bottles in the basket. If there is no basket, place the frozen water bottles along the bottom of the unit.

Water bottles in the refrigerator and frozen water bottles in the freezer help to stabilize unit temperatures in the event of a power failure. Additionally, the water bottles can be used to transport vaccine during an emergency.

Do not block the cold air vents when placing water bottles inside your units. Locations of cold air vents can vary according to the model. Refer to the product manual for information.



Thermostat labels can vary depending on the type of unit being used. Markings on the control knobs can range from sequential numbers, to letters, to cold, colder and coldest type of settings. Some thermostats do not show temperatures, but rather levels of coldness. It's preferable to have a digital thermostat with an actual numeric temperature value.

The acceptable temperature range for refrigerated vaccine is between 36 and 46° Fahrenheit or between 2 and 8° Celsius. The ideal set temperature for the refrigerator is 41° Fahrenheit or 5°Celsius. The acceptable temperature range for frozen vaccine is between -58° and +5° Fahrenheit or between negative 50°and negative 15° Celsius. The ideal set temperature for the freezer is 0° Fahrenheit or -18° Celsius.

Consult your owner's manual for complete instructions on how to operate your thermostat. Several temperature adjustments may need to be made before the desired temperature is reached.

Set up the temperature monitoring device along with its buffered probe. Place the calibrated temperature monitoring device probe in the center of the unit. Follow the product instructions for installation. Many products will come standard with zip ties to secure the probe cable along the bottom of the shelves, so that it is kept out of the way when accessing vaccine.

Attach the digital display for the temperature monitoring device on the outside of the unit. The display can be placed on the door or on the side of the unit. Make sure that the display will not be disrupted by the opening and closing of the door and/or regular foot traffic.

The NYSDOH VFC Program requires that you monitor the temperatures in the

new/repaired unit(s) for at least five business days before moving vaccine into it. It may take 2 to 7 days to stabilize the temperature in a newly installed or repaired refrigerator. Likewise, it may take 2 to 3 days to stabilize in a newly installed or repaired freezer.

Storage of Refrigerated Vaccines

- Store between 36°F and 46°F (between 2°C and 8°C). Desired temp 41°F (5°C)
  - HepA
  - HepB
  - Hib
  - Human papillomavirus (HPV9)
  - Influenza (LAIV, IIV, RIV)
  - IPV
  - Meningococcal-containing (MCV4, MPSV4)
  - Pneumococcal (PCV13 and PPSV23)
  - Rotavirus (RV1 and RV5)
  - Diphtheria toxoid-, Tetanus toxoid-, and Pertussis-containing (DT, DTaP, DTaP-HepB-IPV, DTaP-IPV, DTaP-IPV/Hib, Tdap, Td)
  - MMR (should be frozen if space allows)

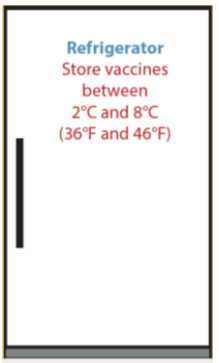


Image obtained from the CDC's Storage and Handling Toolkit

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The following vaccines should be stored in a refrigerator unit between the temperatures of 36° and 46° Fahrenheit or between 2° and 8° Celsius.

HepA
HepB
Hib
HPV Human papillomavirus (hpv9)
Influenza (LAIV, IIV, RIV)
IPV
Meningococcal-containing vaccines (including MCV4, MPSV4)
Pneumococcal vaccines (PCV13 and PPSV23)
Rotavirus (RV1 and RV5)
Diphtheria toxoid-, Tetanus toxoid-, and Pertussis-containing (DT, DTaP, DTaP-HepB-IPV, DTaP-IPV, DTaP-IPV/Hib, Tdap, Td)
MMR (optional but should be frozen, if space allows)

The ideal set temperature for refrigerated vaccine is 41°F or 5°C.

Storage of Frozen Vaccines

- Varicella-containing vaccine
  - Store in freezer between -58°F and +5°F (-50°C and -15°C) until reconstitution and administration
  - Ideal temperature = 0°F or -18°C
  - MMR
    - Best practice to store in freezer
    - Power outage (takes longer for MMR to go out of range in freezer)
- Can deteriorate rapidly after removal from freezer
  - ❑ Varivax (VAR)
  - ❑ ProQuad (MMRV)

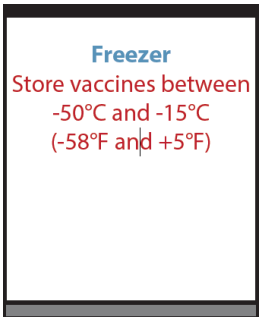

Image obtained from the CDC's Storage and Handling Toolkit

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All vaccine that contains varicella should be stored in the freezer between negative 58° and 5° Fahrenheit or between -50° and -15° Celsius) until reconstitution and administration. Again, the ideal set temperature range for frozen vaccine is 0° Fahrenheit or -18° Celsius.

MMR may be frozen or refrigerated. The vaccine manufacturer has indicated that it is best practice to freeze MMR, whenever possible. In the event of a power outage, it will take longer for the MMR in the freezer to reach an out of range temperature than if it was stored in a refrigerator.

Keep in mind that the following vaccines can deteriorate rapidly after removal from the freezer:

Varivax,
Zostavax and
ProQuad

Storage of Diluents

- Some **must** be stored in the refrigerator
- Other diluents have an option - either refrigerator or room temperature (no warmer than 77°F[25°C]
- Refer to manufacturer's product information
- **NEVER** store diluent in the freezer!
- Store with/near corresponding refrigerated vaccine
- Diluents for Pentacel (DTaP-IPV-Hib combo vaccine) and Menveo (meningococcal conjugate vaccine) contain vaccine antigen
  - Packaged together with the corresponding lyophilized vaccine and MUST be stored together.

– Additional guidance on diluents

Image obtained from CDC Keys to Storing and Handling Vaccine Supply video

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Some diluents need to be stored in a refrigerator while others have an option of being stored in either the refrigerator or room temperature. If storing diluents at room temperature, the room should reach no warmer than 77° F or 25°C.

Always refer to the manufacturer's product information to find the appropriate storage temperatures for the diluent in question.

As a reminder, diluents should never be stored in the freezer.

If possible, store diluents with their corresponding vaccine.

The diluent for Pentacel (DTAP-IPV-Hib combo vaccine) and the diluent for Menveo (meningococcal conjugate vaccine) contain a vaccine antigen and will usually come packaged with their corresponding lyophilized vaccine. These diluents must be stored along with their corresponding vaccine.

Click on the link on this slide for additional guidance on diluents.

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Vaccine Storage Unit Organization

- Plan vaccine organization while waiting to get at least 5 business days of in-range temp recordings
- Do not store food or beverages in units
- Storage of other medications and biologics in same unit as vaccine is not recommended.
- Do not crowd vaccines

Source: Centers for Disease Control and Prevention

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Transferring vaccines and diluents into a unit requires some forethought and planning on how to best organize the unit. A carefully organized vaccine storage unit helps protect vaccine and facilitates vaccine inventory management.

Temperatures must have been “in range” for at least five business days before vaccines can be moved into the unit. You can use this time to begin planning how to set up your storage unit.

Never store food or beverages in the units where you store vaccine.

Storage of other medications and biologics in same unit as vaccine is not recommended. However if it is necessary, store below vaccines and label appropriately.

Do not crowd vaccines. If you find that your unit is not large enough to accommodate your stock comfortably, you should consider purchasing a either larger unit or an additional unit.

Vaccine Storage Unit Organization

- Use trays or uncovered baskets or containers
- Place vaccine that is expiring soonest towards the front of each basket
- Put vaccine/diluent in central areas of unit
- Keep 2-3 inches of space between vaccine containers and unit walls
- DO NOT put vaccine in unit doors or near cold air vents, i.e., top shelf
- Store water bottles in the doors and top shelves of the units
- Keep vaccine/diluent in original packaging with lids closed
- Separate:
  - –private and public vaccine
  - –adult and pediatric vaccine
  - –similarly named vaccines
- Label all shelves, trays, & baskets

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For better organization, use trays or uncovered containers or baskets. Breathable plastic mesh baskets are best. Each basket should only contain one type of vaccine or diluent.

Always place vaccine that is expiring soonest towards the front of each basket.

Vaccines and diluents should be placed in the central area of the storage unit, 2 to 3 inches away from storage unit walls.

Never store vaccine in the door of the unit. The unit door is subject to temperature variations that are not stable.

Avoid placing vaccine near cold air vents, which are typically located near the top shelf. If you have to use the top shelf, place water bottles in the back, close to vent and store vaccine not sensitive to coldest temps e.g., MMR.

Place water bottles anywhere in the unit where you would not place vaccine, such as in the doors, in the top shelves, and in any vegetable bins or drawers.

Keep vaccines and diluents in their original packages with lids closed until ready for administration, this will protect the vaccines from damage due to light. Removing vaccines from their packaging also increases risk for storage and handling and administration errors.

Separate private and public vaccine. Consider dedicating one shelf to each.

Store pediatric and adult versions of the same vaccine on separate shelves to avoid confusion.
Also, keep vaccines with similar packaging and names on different shelves,

such as DTaP and Tdap OR Hib and Hep B.

Clearly label the location of each specific vaccine type and diluent. Attach labels to shelves, trays and/or baskets where each type of vaccine is stored. If diluent is stored separately from the corresponding vaccine, label the shelf, tray/basket where it is stored.

After reviewing the storage and handling protocols of all of the vaccines and their diluents, begin transferring the vaccines and diluents into the units.

Example of Properly Set up Storage Unit

Image obtained from the CDC's You Call the Shots, Vaccine Storage and Handling module

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This slide illustrates two examples of a properly set up storage unit. The image on the left shows that the storage unit has been filled with water bottles and the vaccine is not overcrowded.

Each vaccine has been left in its original packaging, placed in a basket centrally within the unit and labeled appropriately as is depicted in the image on the right. Also in the image on the right, the buffered temperature probe sits centrally in the unit with the probe wire kept out of the way.

Storage Unit Maintenance

- Perform storage unit maintenance at least monthly
  - Examples of tasks include:
    - Cleaning inside of units
    - Cleaning coils
    - Checking and emptying drain pan
    - Checking door seals
    - Monitoring frost buildup (for manual defrost units)
- Refer to guidance documents
- Refer to product manual for more complete instructions

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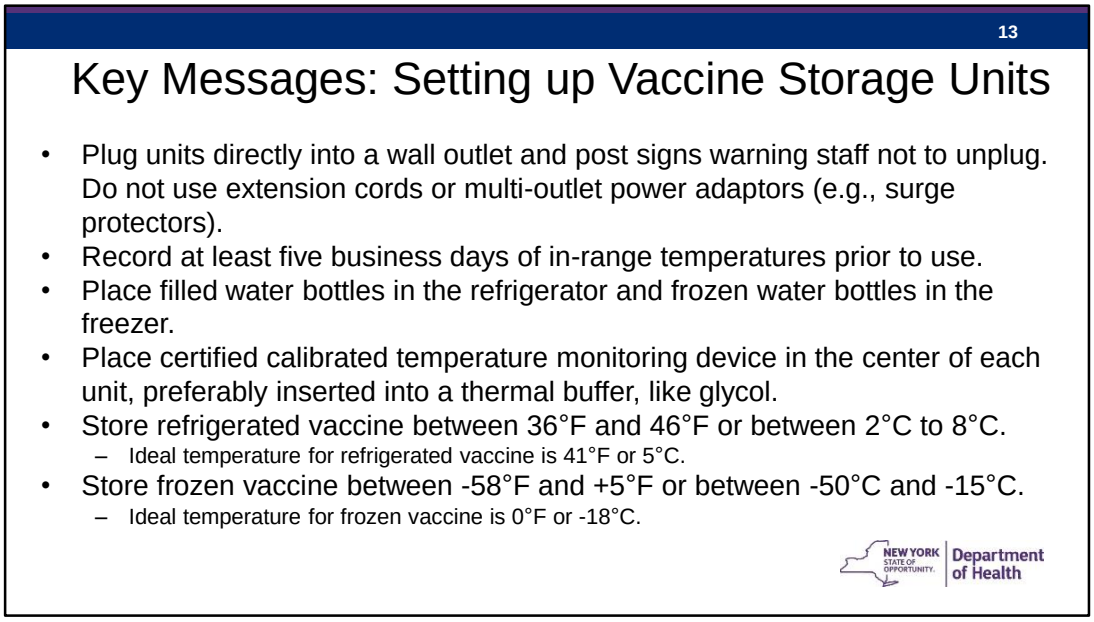
Storage unit maintenance should be performed at least monthly to ensure proper unit operation and to maintain temperatures suitable for vaccine storage. Examples of maintenance tasks include: cleaning the inside of the units, ensuring the unit coils and motor are free of dust and dirt, checking and emptying the drain pan, checking door seals and monitoring frost buildup for units that are manual defrost.

Two guidance documents are available which provide more information on maintaining vaccine storage units. Links to these guidance documents can be found in the resources section at the end of this training. You should also refer to your unit's product manual for more complete instructions on maintaining your vaccine storage units.



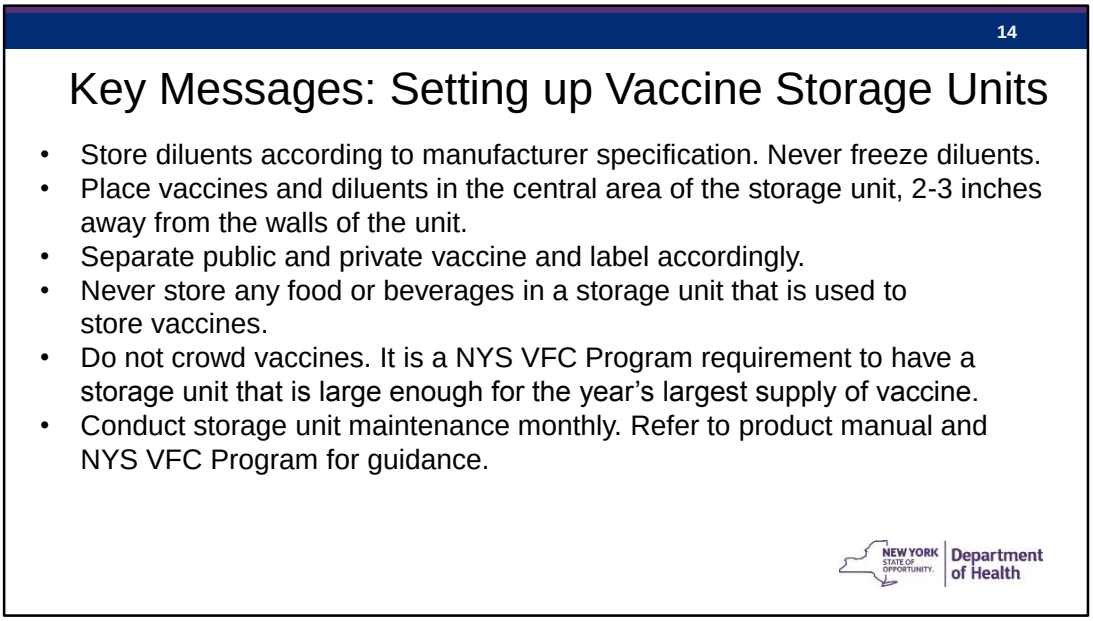
The key messages for this training are:

Plug units directly into a wall outlet and post signs that warn staff not to unplug the unit. Do not use extension cords, outlets with a ground-flow circuit interrupters or switches, or multi-outlet power adaptors (e.g., surge protectors).

Allow at least five business days of in-range temperatures to be recorded in the unit prior to use.
Place filled water bottles in the refrigerator and frozen water bottles in the freezer. These can help sustain temperatures during a power outage. The frozen water bottles can also be conditioned and used for emergency vaccine transport.

Place certified calibrated temperature monitoring device in the center of each unit, preferably inserted into a thermal buffer, like glycol.

Store frozen vaccine at or below 5° Fahrenheit or -15° Celsius and refrigerated vaccine between 36 and 46° Fahrenheit or 2 to 8° Celsius. The ideal temperature for refrigerated vaccine is 41° Fahrenheit or 5° Celsius and the ideal temperature for frozen vaccine is 0° Fahrenheit or -18° Celsius.



Here are additional key messages for this training:

Store diluents according to manufacturer specification. Never freeze diluents.

Place vaccines and diluents in the central area of the storage unit, 2-3 inches away from the walls of the unit.

Separate public and private vaccine and label accordingly.

Never store any food or beverages in a storage unit that is used to store vaccines.

Do not crowd vaccines. It is a NYS VFC Program requirement to have a storage unit that is large enough for the year's largest supply of vaccine.
Conduct storage unit maintenance monthly. Refer to product manual and NYS VFC Program for guidance.

Resources

Centers for Disease Control and Prevention (CDC)

Vaccine Storage and Handling Toolkit, Warning Signs, pages 72-78, Tally Sheet page 35

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

Immunization Action Coalition (IAC)

Printable Temperature Log for Refrigerator Fahrenheit Celsius

Printable Temperature Log for Freezer Fahrenheit Celsius

Additional Guidance on Diluents http://www.immunize.org/catg.d/p3040.pdf

Vaccine Manufacturer Product Info (package inserts) http://www.immunize.org/packageinserts/

New York State Vaccines for Children (NYS VFC) Program

Separation of Publicly-Funded Vaccine Stock
http://www.health.ny.gov/prevention/immunization/vaccines_for_children/docs/separation_public_private_vaccines.pdf

Vaccine Storage Unit Maintenance Guidance
http://www.health.ny.gov/prevention/immunization/vaccines_for_children/docs/vaccine_storage_unit_maintenance.pdf

Manual Defrost Guidance

http://www.health.ny.gov/prevention/immunization/vaccines_for_children/docs/manual_defrost_guidance.pdf

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Here is a listing of available resources.

Additional Training for NYS VFC Providers

Next: NYS VFC Program Training Series #8: Selecting Temperature Monitoring Equipment

There are a number of additional trainings available.

The next training in this series is #8 Selecting Temperature Monitoring Equipment.