Hello and welcome.

This training is intended to provide guidance to New York State (NYS) Vaccines for Children (VFC) providers on accepting vaccine deliveries.
NYS VFC Program Requirement

• Standard Operating Procedure (SOP) for Accepting a Vaccine Delivery
  – Part of Routine Storage and Handling Plan
  – Increases adherence to proper procedure and identification of problems
  – How to accept, examine and store deliveries so that cold chain is maintained immediately upon receipt of delivery

Your practice’s routine Vaccine Storage and Handling plan should include a set of Standard Operating Procedures (or SOPs) for receiving vaccine deliveries and putting them away.

Without an SOP there can be no assurance that proper procedure will be followed when vaccine is delivered, or that problems will be identified, reported, and corrected.

Efficient SOPs should cover the who, what, when, where and how of vaccine deliveries.

For example, it should include details on how to accept, examine and store vaccine deliveries so that the cold chain is maintained IMMEDIATELY upon receipt of delivery.

Procedures should be updated annually and staff should be notified annually or any other time changes are made.
Who Is Responsible for Accepting a Vaccine Delivery?

- Schedule vaccine deliveries only when vaccine coordinator or back-up are on duty
- Ensure all staff who handle deliveries are:
  - Aware of importance of maintaining cold chain
  - Aware of need to immediately notify vaccine coordinator or back-up upon arrival
  - Knowledgeable of proper procedures to follow in absence of dedicated staff
- Never leave deliveries unattended/unpacked
- Staff should refer to Storage and Handling plan for steps to take on how to store the vaccine
  - May be financially responsible for mishandled vaccine

The vaccine coordinator and back-up are usually responsible for accepting vaccine deliveries and ensuring that the cold chain is maintained. Deliveries should only be scheduled when the vaccine coordinator or back-up is on duty.

All staff members who handle vaccine deliveries must be aware of the importance of maintaining the cold chain,

the need to immediately notify the vaccine coordinator or a back-up coordinator upon arrival of a vaccine delivery

and have knowledge of proper procedures to follow in the absence of dedicated staff.

If for some reason vaccine is delivered and the vaccine coordinator or back-up will not be present for 2 hours or more, other practice staff should check, unpack and store the vaccines

as indicated by your facility’s storage and handling plan and the remainder of this training.
Remember that your practice may be financially responsible if vaccine is mishandled after the delivery has been accepted.
Steps Taken After Accepting a Vaccine Delivery

Immediately unpack the contents and inspect the delivery.
1. Check for signs of physical damage to package and contents
2. Cross-check contents with packing slip to be sure they match
3. Check expiration dates to ensure none of the expiration dates have passed or will expire soon
4. Lyophilized (freeze-dried) vaccines – ensure that they came with correct type and quantity of diluents
5. Check for heat or cold damage, including cold chain monitor if included in package
6. Take inventory to ensure all items have been received. Check for broken vials or any other kind of damage.
7. Place in storage unit as soon as possible
8. Monitor temperatures inside of storage unit after large stock received
   1. Some storage units are not able to keep in range
   2. Contact NYS VFC program at 1-800-543-7468
9. Accept Transfer in NYSIIS

Standard Operating Procedures for accepting a vaccine delivery include all of the steps that should be taken from first accepting the package to the point of unpacking it into storage units.

Always immediately unpack and inspect a vaccine delivery once you receive it.

First, check for signs of physical damage to the package and contents.

Second, cross-check contents with packing slip to be sure they match.

Next, check the expiration dates to ensure none of the expiration dates have passed or will be occurring soon.

If you've ordered lyophilized (freeze-dried) vaccines, check to see that they have been shipped with the correct type and quantity of diluents. Make sure that diluents have been shipped in separate compartments for all frozen vaccines.

Check the package for heat or cold damage and make sure a cold chain monitor has been included in the package.

Take inventory to ensure all items have been received. If you are missing any vaccine that you know was approved and shipped please call the NYS VFC program right away at 1-800-543-7468.
Place vaccine in storage units as soon as possible and monitor the storage unit for out of range temperatures after a large supply is received.

Some storage units may be incapable of maintaining appropriate temperatures after large vaccine shipments are stored in them. If this happens, contact the NYS VFC program at 1-800-543-7468.

Finally, document in the New York State Immunization Information System (or NYSIIS) that the delivery was received. This is also referred to as accepting a transfer. Don’t accept the transfer until you’ve confirmed that the contents of the shipment have been stored and handled appropriately.
When Can Vaccine Be Delivered?

- Facility should be open at least one other day than Monday for at least 4 consecutive hours to receive vaccine shipments.
- Don’t schedule vaccine deliveries right before the office is closed for a period of more than one day (i.e., for the weekend)
- Only when the vaccine coordinator or back up is on duty
- Always notify VFC immediately of any changes to delivery hours or change in key VFC personnel
- Update in NYSIIS Edit Organization screen

Your practice should be open at least one other day than Monday to receive vaccine shipments. On the day that has been designated for shipment delivery, the practice needs to be open for at least 4 consecutive hours.

Don’t schedule deliveries right before the office will be closed for more than one day, such as on a Friday afternoon. A staff person needs to be available to monitor storage unit temperatures after they have been stocked with vaccine to ensure that the temperatures stay in appropriate ranges. Some storage units may be incapable of handling a large shipment of vaccine and may behave erratically after a large shipment is added to the unit.

Again, arrange for vaccine and diluent deliveries to be made ONLY when the vaccine coordinator (or backup) is on duty. Always consider holidays, vacations, staff schedules and changes in hours of operation.

Notify the NYS VFC program anytime a change in hours or contact information occurs for either the backup or VFC coordinator to prevent any shipping errors. Organizational information should also be edited in your NYSIIS account.
Check Delivery for Heat or Cold Damage

- Is a vaccine Cold Chain Monitor (CCM) present?
  - One-time use and should be discarded
  - Not all shipments contain a CCM
- Insulating barrier between vaccines and refrigerated or frozen coolant packs
- Issues with temperatures?
  1. Label vaccine DO NOT USE
  2. Store at proper temperature
  3. Contact VFC program for guidance

A vaccine cold chain monitor (or CCM) is a single-use monitor placed in a shipping container to indicate if the container temperature gets too warm or cold.

If there is a cold chain monitor in the package, it should display whether or not the cold chain was appropriately maintained during shipment.

CCMs should be discarded after one use.

Be aware that vaccine shipped directly from the manufacturer won’t contain a CCM. The shipment should also contain an insulating barrier between vaccines and refrigerated or frozen coolant packs.

If there are any issues with the contents of the shipment, label the vaccine Do Not Use, store it at the proper temperature, and contact the VFC Program for guidance. Anytime you are unsure of how to read a CCM or if you are unsure whether the cold chain was appropriately maintained, contact the NYS VFC program.
Where Should Vaccine be Stored?

- Refer to product inserts to learn product specific storage and handling practices, save inserts in storage and handling plan
  - [http://www.immunize.org/fda/](http://www.immunize.org/fda/)
- Post a list of appropriate storage for vaccines and diluents near storage units
- Leave vaccines in their original packing and put the first to expire in front of the storage unit
- Remove any expired vaccine/diluent
- Also refer to Training #7: Setting Up a Vaccine Storage Unit
- Never leave shipping container unpacked and unattended

After confirming that the cold chain has been maintained, place the vaccine in the storage units at the recommended temperatures. Be sure to review the manufacturer product inserts that come with vaccines and diluents to learn the most up-to-date storage and handling practice for the products. For the most up-to-date package inserts click on the link on this slide. Keep copies of the inserts with your vaccine storage and handling plan.

Consider posting a list of vaccines and diluents that need to be refrigerated and those that need to be frozen near the storage units.

Next, place vaccine in the appropriate storage unit, in its original packaging, with the soonest expiration date in the front.

Be sure to remove any expired vaccines and diluents from the storage units. Remember that diluents should never be placed in a freezer.

Refer to training #7 in this series for specific recommendations on how to organize your storage unit.
Do NOT leave the shipping container unpacked and unattended as vaccines and diluents inside might warm to inappropriate temperatures and become unusable!
Storage of Refrigerated and Frozen Vaccine

**Refrigerator:** (Store between 36°F and 46°F or between 2 and 8°C)
Ideal Temp=41°F or 5°C

- HepA
- HepB
- Hib
- Human papillomavirus (HPV9)
- Influenza (LAIV, IIV, RIV)
- IPV
- Meningococcal-containing (MCV4, MPSV4, Men B)
- 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)

**Store varicella-containing vaccines in Freezer:** (Store between -58°F and +5°F or between -50°C and -15°C)
Ideal Temp=0°F or -18°C

- MMR
  - Best practice to store in freezer
  - Can deteriorate rapidly after removal from freezer:
    - Varivax (VAR)
    - ProQuad (MMRV)

The following vaccines should be stored in a refrigerator unit between the temperatures of 36° and 46° Fahrenheit or 2° to 8° Celsius. The ideal set temperature for refrigerated vaccine is 41°F or 5°C.

- HepA
- HepB
- HepA-HepB
- Hib
- Hib-HepB
- Human papillomavirus (HPV2 and HPV4)
- Influenza (LAIV, IIV, RIV)
- IPV
- Meningococcal-containing vaccines (MCV4, MPSV4, Men B)
- 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, TT)
- MMR (if refrigerated)

All vaccine that contains varicella should be stored in the freezer between -58° and +5° Fahrenheit (or between -50° and -15° Celsius) until reconstitution and administration. The ideal set temperature for the freezer is 0°F or -18°C.

It is best practice to store MMR in the freezer if space allows. Varivax and
Proquad need to be stored in the freezer.
Diluents

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

Some diluents need to be stored in a refrigerator while others can either be refrigerated or left at room temperature. Room temperatures should be no warmer than 77° or 25°C for diluent to be properly stored.

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 an antigen and will usually come packaged with their corresponding lyophilized vaccine.

These diluents must be stored along with their corresponding vaccine.

Visit the resources section at the end of this training for additional guidance on diluents.
Document in NYSIIS that delivery was received
- **Accept transfer** function
- Under Inventory header “manage transfers”
- Will auto-populate your inventory!
- Steps included in Vaccine Ordering Tutorial

After unpacking the contents of the delivery, document in the New York State Immunization Information System (or NYSIIS) that the delivery was received. This is also referred to as accepting a transfer. This can be done by selecting the Manage Transfers option in the Manage Inventory module in NYSIIS.

A vaccine ordering tutorial is available on the Health Commerce System (HCS) which details how to accept a transfer in NYSIIS. A link is available in the resources section of this training.
Key Messages: Accepting a Vaccine Delivery

- Developing comprehensive Standard Operating Procedures (SOPs) for vaccine deliveries are a critical part of your practice’s vaccine storage and handling plan.
- The primary vaccine coordinator and backup coordinator are the primary staff responsible for vaccine deliveries.
- Vaccine deliveries should be scheduled only when the vaccine coordinator or back-up is on duty. Always notify VFC immediately of any changes to delivery hours or change in coordinators.
- All staff members who accept vaccine deliveries must be aware of the importance of maintaining the cold chain and the need to immediately notify the vaccine coordinator or alternate (back-up) coordinator upon arrival.
- Immediately unpack and inspect the delivery. If a CCM is present, check for heat or cold damage. If damage is suspected, mark vaccines do not use, store as if viable, and contact the VFC program for guidance.
- Keep a list of vaccines and diluents that need to be refrigerated and those that need to be frozen for quick reference. Remember that diluents should never be placed in a freezer.

The following are the key messages for this training module:

- Developing comprehensive Standard Operating Procedures (SOPs) for vaccine deliveries are a critical part of your practice’s vaccine storage and handling plan. The primary vaccine coordinator and backup coordinator are the primary staff responsible for vaccine deliveries. Vaccine deliveries should be scheduled only when the vaccine coordinator or back-up is on duty. Always notify VFC immediately of any changes to delivery hours or change in coordinators.

- All staff members who accept vaccine deliveries must be aware of the importance of maintaining the cold chain and the need to immediately notify the vaccine coordinator or alternate (back-up) coordinator upon arrival.

- Immediately unpack and inspect the delivery. If a CCM is present, check for heat or cold damage. If damage is suspected, mark vaccines do not use, store them as you would viable vaccines, and contact the VFC program for guidance.

- Keep a list of vaccines and diluents that need to be refrigerated and those that
need to be frozen for quick reference. Remember that diluents should never be placed in a freezer.
Here is a listing of available resources.
Additional Training for NYS VFC Providers

Next: NYS VFC Program Training Series #15: Vaccine Disposal and Returns

There are a number of additional trainings available.

The next training in this series is #15: Vaccine Disposal and Returns.