MAINTAINING THE COLD CHAIN DURING A PANDEMIC
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VACCINE COLD CHAIN

Errors in vaccine storage result in significant financial loss due to wasted vaccine and revaccinations.

Failure to store vaccine properly can reduce vaccine potency and can lead to a decreased immune response.

Leading to poor protection from vaccines and decreased patient confidence in vaccines and provider offices.
COLD CHAIN

- Vaccines must be stored properly from the time they are manufactured until they are administered.
- Shared responsibility among manufacturers, distributors, public health staff, and healthcare providers.
- An effective cold chain relies on three main elements:
  - A well-trained staff.
  - Reliable storage and temperature monitoring equipment.
  - Accurate vaccine inventory management.

VACCINE STORAGE AND HANDLING

- Protect the following vaccines from light: Varivax®, Zostavax®, ProQuard®, M-M-R II, Hiberix®, Garadil 9®, Afluria®, FLUAD®, Fluarix®, Flublok®, Flucelvax®, Fluarix®, Fluvirin®, Flumist®, IPOL®, Menveo®, Bexsero®, Rotarix®, Shingrix®
- Unconstituted lyophilized (freeze-dried) MMR may be frozen or refrigerated.
Refrigerators should maintain temperatures between 2°C and 8°C (36°F and 46°F) with the optimal temperature of 5°C (40°F).
Freezers should maintain temperatures between -50°C and -15°C (-58°F and +5°F) with the optimal temperatures of ≤ -17°C (3°F) or colder.
Minimum and maximum temperatures should be documented once per day.
- Preferably in the am
- Requirement as of January 1, 2018
- Twice daily temperatures are still recommended.

With most data loggers to have an accurate min/max temperature the min/max for the previous day must be read. When pressing the read button the min/max displayed will be from midnight of that day. In order to get the min/max you must read back to the previous day.
- Example the min/max for Wednesday June 10th would be read on the morning of Thursday June 11th.

Designating only one person to be responsible for the storage and handling of the vaccines.
Not recording the minimum/maximum daily.
Documenting out-of-range temperatures on the temp log but not taking action.
Refrigerating vaccine in a way that could jeopardize its quality.
Leaving refrigerator or freezer door open.
Discarding multi-dose vials 30 days after they are opened.
Storing food and drinks in the vaccine storage unit.
Not having emergency plans for a power outage or natural disaster.
Always designate at least one back-up person.
- Back-up person should be familiar with all aspects of vaccine storage and handling.
- How to handle vaccines when shipments arrive
- How to properly record refrigerator and freezer temperatures
- What to do in case of equipment problem or power outage
- Every provider needs a written vaccine management plan.
- Do not discard vaccines prematurely.
- Do not store food and drinks in the vaccine storage unit.

Record the minimum and maximum temperature once a day.
- Check temperatures at the beginning and end of the day to determine if the unit is getting too warm.
- Keep the temperature logs for at least 3 years.
- As storage units age, recurring problems can be tracked.
- If out-of-range temperatures have been documented, it is easy to determine how long it’s been happening.

Store vaccine correctly.
- Never store vaccines:
  - In vegetable bins
  - On the refrigerator floor
  - Next to the walls
  - In the door of the unit
  - On the top shelf (underneath the cold air outlet from the freezer)
- Always store vaccines:
  - In their original packaging
  - In such a way that air can circulate
### STORAGE AND HANDLING DO'S

- Always act immediately when temperatures are out-of-range.
- Remind staff to close unit doors tightly every time.
- Check the seals on the doors on a regular basis.

### VACCINE TRANSPORT

- The vaccine cold chain should be maintained at all times during vaccine storage and transport.
- Due to the risk of temperature excursions associated with vaccine transport, the number of times vaccines are transported should be kept to a minimum.
VACCINE TRANSPORT

- If providers must transport vaccine, data loggers must be used at all times.
- Transport temperature charts must be submitted to the immunization program anytime VFC vaccine is transported.
- Temperatures should be checked every 30 minutes.
- VFC or state-supplied vaccine must be transported in qualified coolers.
- Never leave vaccine unattended in a car for long periods of time, and never store in a trunk.

VACCINE TRANSPORT

- All vaccines transfers (between providers) must be approved by the immunization program.
- Vaccine should never be stored in a transport cooler for more than 8 hours.
- Frozen vaccine must be transported in a frozen transport cooler, cannot use dry ice or transport refrigerator.
- Transport diluents with their corresponding vaccines to ensure there are always equal parts.

VACCINE TRANSPORT

- Vaccine transport recommendations and paper temperature logs for monitoring can be found on our website: https://www.health.nd.gov/immunize/storage-and-handling.
CDC RESOURCE

- Vaccine transport checklist for vaccination clinics held at off-site, temporary or satellite clinics.
  - [https://www.izummitpartners.org/content/uploads/2019/02/off-site-vaccination-clinic-checklist.pdf](https://www.izummitpartners.org/content/uploads/2019/02/off-site-vaccination-clinic-checklist.pdf)
- “Vaccination Guidance During a Pandemic”

EMERGENCY TRANSPORT

- Emergency transport usually involves relocating vaccines to protect them when a facility's ability to store vaccines is compromised (e.g., because of power loss).
- Plan for emergencies by ensuring that you have proper equipment to maintain the cold chain during transport.
EMERGENCY TRANSPORT

- CDC recommends that if emergency transport of vaccines is necessary, it should be done using a qualified container and pack-out.
- Vaccine manufacturers do not recommend re-use of shipping containers and packing material for routine transport.

DO NOT USE soft-sided collapsible coolers.
- Poorly insulated and result in significant temperature gradients
- Providers should have containers that are large enough to move their entire stock.
- Do not use frozen gel packs or coolant packs from original vaccine shipments to pack refrigerated vaccines. They can still freeze vaccines even if they are conditioned or appear to be “sweating.”

Contact the alternative vaccine storage facility before packing any vaccine to confirm it can accept your vaccines for storage.
- Note any protective measures in place at the time of the event (water bottles, battery-powered temperature monitoring device, transport to alternative facility, etc.).
EMERGENCY TRANSPORT

- Only open the unit door when you are ready to pack or power has been restored.
- If an emergency can be anticipated (e.g., weather event), suspend vaccination activities before the onset of emergency conditions to allow more time for packing and transport.

EMERGENCY TRANSPORT OF VACCINE

- Hard-sided coolers or Styrofoam® vaccine shipping container
- Conditioned frozen water bottles
- Insulating material
- Temperature monitoring device


OFFICE CLOSURES
If healthcare facilities do close or decide to discontinue vaccination at any time, all storage units that contain VFC vaccines must still have adequate storage and handling to ensure vaccine viability.

- Data loggers must still be in place and min/max temperatures be checked and recorded at a minimum of two days per week.
- If not possible, the vaccine must be transported and stored at another VFC-enrolled facility.

Data logger temperature charts must also be submitted to the immunization program monthly. All temperature excursions must be reported and followed up on accordingly.
During a power outage, only open the storage unit door if:
- Power is restored.
- It is determined the vaccine needs to be moved to an alternative location.
- If planned power outage, make alternative arrangements for vaccine to be placed at your back up facility prior to outage.

If the power outage occurs outside of clinic hours and a temperature excursion takes place, follow the appropriate steps as you would during any excursion.
- Having generators on-site prevent the need to transport vaccines to an alternative storage unit.
- A backup battery power source can also be used.
- These systems are not required by the VFC program.

In the event of inclement weather the NDDoH does not providers to intervene to stop a temperature excursion. Respond to the temperature excursion once the risk of danger has passed.
TEMPERATURE EXCURSIONS

TEMPERATURE EXCURSION STEPS

- Contact the primary or backup vaccine coordinator.
- Document the current, minimum and maximum temperatures, duration of temperature excursion and the time the problem was discovered.
- Label the vaccines as "DO NOT USE".
- Store the vaccine at the appropriate temperature. If the unit is not maintaining the appropriate temperature, transfer the vaccine to other storage units.

TEMPERATURE EXCURSION STEPS

- Vaccine cannot remain in units while they are being serviced.
- Vaccine manufacturers should be contacted first to determine vaccine viability.
  - Do NOT assume the vaccine is not viable
  - Do NOT discard any vaccines until the NDDoH has been notified
  - Notify NDDoH of temperature excursion. This can be done by phone, email or the online form https://www.health.nd.gov/immunize/storage-and-handling
 TEMPERATURE EXCURSION STEPS

- If vaccine is not viable a vaccine return or wastage should be entered in NDIIS.
- Vaccine Storage Troubleshooting Guide and the Vaccine Manufacturer Phone Numbers
  - https://www.health.nd.gov/immunize/storage-and-handling

Handling a Temperature Excursion in Your Vaccine Storage Unit

Vaccine Manufacturers’ Quality Control Phone Numbers

- Dakota
  - 605.431.4400

- Merck
  - 800.632.4555

- Novavax
  - 800.889.0753

- Pfizer
  - 800.688.7399

- Sanofi Pasteur
  - 800.858.8986

- GlaxoSmithKline
  - 800.582.7889

- Eli Lilly
  - 800.888.6177

- Johnson & Johnson
  - 800.224.7277
VACCINE STORAGE AND HANDLING
WASTAGE DUE TO EXCURSIONS

• $77,684 total of wasted vaccine from October 1, 2018 through September 30, 2019 due to temperature excursions.
• 1,395 total doses of vaccine wasted due to temperature excursions from October 1, 2018 through September 30, 2019.
• 45 temperature excursions reported to NDDoH from October 1, 2018 through September 30, 2019.
• 44 temperature excursions were not reported to NDDoH from October 1, 2018 through September 30, 2019.
• No revaccinations needed to take place from October 1, 2018 to September 30, 2019.

VACCINE STORAGE AND HANDLING
WASTAGE DUE TO EXCURSIONS

• $8,657 total of wasted vaccine from October 1, 2019 through May 31, 2020 due to temperature excursions.
• 140 total doses of vaccine wasted due to temperature excursions from October 1, 2019 through May 31, 2020.
• 37 temperature excursions reported to NDDoH from October 1, 2019 through May 31, 2020.
• 27 temperature excursions were not reported to NDDoH from October 1, 2018 through May 31, 2020.
• No revaccinations needed to take place from October 1, 2018 to May 31, 2020.
Starting on June 22, 2020, Merck will begin shipping both private and VFC orders in reusable shippers. The reusable shipping container will look different than the current Styrofoam shipping container you have been receiving.

Upon opening your reusable shipping container, providers should immediately see the Packing Slip on top of the product. By reviewing the ‘Order Type’ on the Merck packing list, you can determine if the order is a VFC or private shipment. Providers who receive both VFC and private orders from Merck, who may have relied on the differing box lids, can now differentiate their Merck orders based on the packing slip enclosed.
Information regarding proper handling of the new reusable shipping container, along with detailed return instructions, will be included in each of the reusable shipping containers.

HELP US REDUCE WASTE
DO NOT DISCARD

1 Replace
Replace outer containers

2 Reseal
Close flap 1 and reseal tape backing on flap 2 and close inner box

3 Return
Mark on the front of the shipping container pickup spot - we will handle the rest

Ready for pickup sooner?
Scan this QR code

Questions?
Call us at +1 585-760-2830

VACCINE PLANNING
COVID VACCINE PLANNING

- Plan for different presentations.
  - Frozen and refrigerated
  - Having the capability of adequately storing and transporting the vaccine
- Consider if you would have enough storage space for influenza and COVID vaccine.
- Potential for storing COVID vaccine on behalf of alternate locations such as LTC facilities.

RESOURCES

- CDC Vaccine Storage and Handling Toolkit
  https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
- CDC’s Storage and Handling webpage
  https://www.cdc.gov/vaccines/hcp/admin/storage/index.html
- ND Immunization Program Website
  https://www.health.nd.gov/immunize/storage-and-handling
- Immunization Action Coalition (IAC) Vaccine Storage & Handling
  http://www.immunize.org/clinic/storage-handling.asp

Any Questions
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**POST-TEST**

- Post-test
- Nurses interested in continuing education credit, visit http://www.ndhealth.gov/disease/post/default.aspx?PostID=216
- Successfully complete the five-question post-test to receive your certificate
- This presentation will be posted to our website: www.health.nd.gov/imunize

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6/10/2020