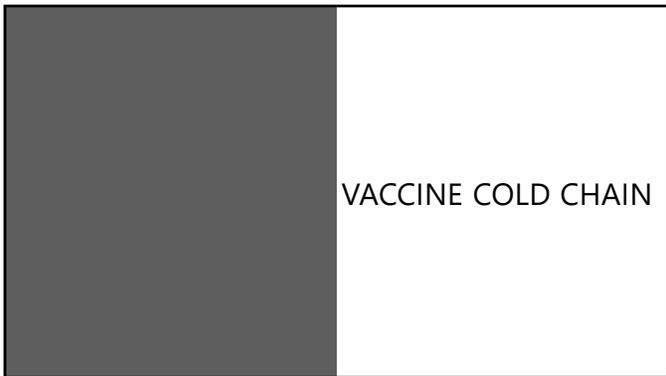
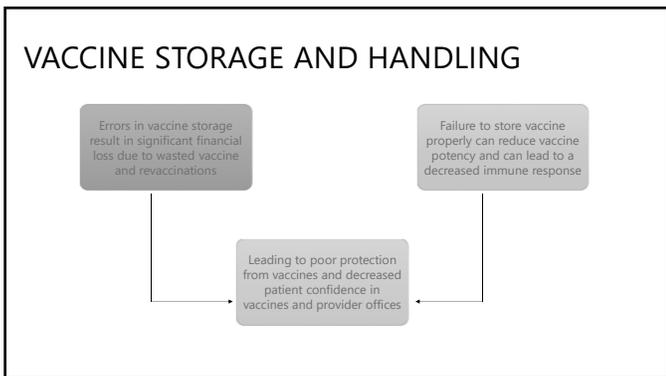




1



2

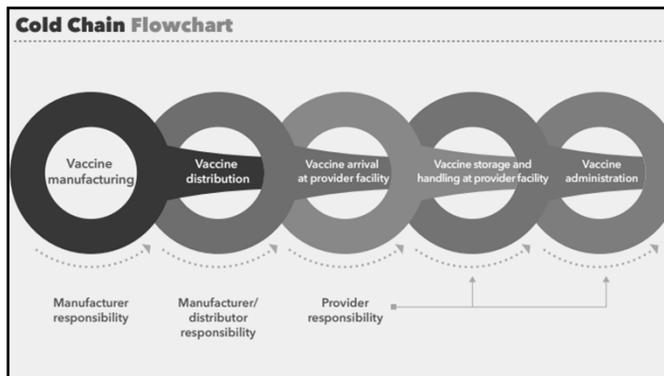


3

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.

4



5

VACCINE STORAGE AND HANDLING

Store In Freezer
Between -50°C & -15°C (-58°F & +5°F)

VAR[‡]
Zostavax[®] †
MMRV[‡]
MMR[‡]

Store In Refrigerator
Between 2°C & 8°C (36°F & 46°F)

Diphtheria toxoid-, tetanus toxoid-, and Pertussis (DT, DTap, DTap-HepB-IPV, DTap-IPV, DTap-IPV/Hib, Tdap, TD)
HepA
HepB
HepA-HepB
Hib[‡]
9vHPV[‡]
IPV[‡]
Meningococcal (MenACWY-D, MenACWY-CRM[‡], MenB-AC, MenB-FHbp[‡])
MMR[‡]
Pneumococcal (PCV13 and PPSV23)
Rotavirus[‡]
Shingrix[®] †

[†] Protect the following vaccines from light: Varivax[®], Zostavax[®], ProQuad[®], M-M-R II, Hiberix[®], Garadi 9[®], Afluria[®], FLUAD[®], Fluara[®], Flublok[®], Flucevax[®], Fluarix[®], Fluvirin[®], Flumist[®], IPOL[®], Menveo[®], Bexsero[®], Rotarix[®], Shingrix[®]

[‡] Unconstituted lyophilized (freeze-dried) MMR may be frozen or refrigerated

6

TEMPERATURE MONITORING

- 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.

7

TEMPERATURE MONITORING

- 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.

8

STORAGE & HANDLING DON'TS

- 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.

9

STORAGE AND HANDLING DO'S

- 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.

10

STORAGE AND HANDLING DO'S

- 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.

11

STORAGE AND HANDLING DO'S

- 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

12

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.

13

VACCINE TRANSPORT

14

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.

15

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.

16

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.

17

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>.

18

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.

22

EMERGENCY 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."

23

EMERGENCY TRANSPORT

- 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.).

24

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.

25

EMERGENCY TRANSPORT OF VACCINE

- Hard-sided coolers or Styrofoam® vaccine shipping container
- Conditioned frozen water bottles
- Insulating material
- Temperature monitoring device
- <https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf>



26

OFFICE CLOSURES

27

PROVIDER 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.

28

PROVIDER OFFICE CLOSURES

- Data logger temperature charts must also be submitted to the immunization program monthly. All temperature excursions must be reported and followed up on accordingly.

29



30

POWER OUTAGE

- 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.

31

POWER OUTAGE

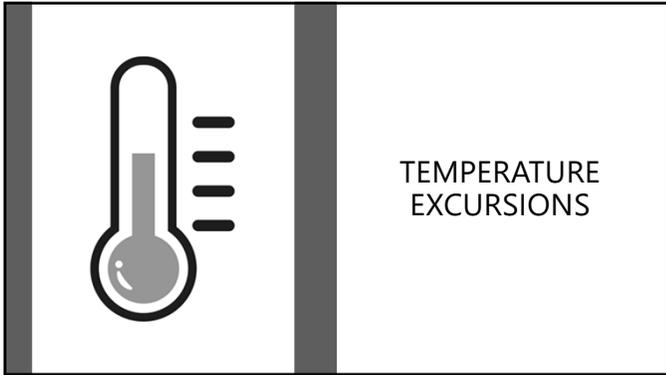
- If the power outage occurs outside of clinic hours and a temperature excursion takes place, follow the appropriate steps as you would during any excursion.
- Having generators on-site prevent the need to transport vaccines to an alternative storage unit.
- A backup battery power source can also be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

32

POWER OUTAGE

- 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.

33



34

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.

35

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>.

36

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>

37

Handling a Temperature Excursion in Your Vaccine Storage Unit

Any temperature reading outside ranges recommended by our manufacturer's package inserts is considered a temperature excursion. Identify temperature excursions quickly and take immediate action to correct them. This can prevent vaccine waste and the potential need to revaccinate patients.

Notify

- Notify the primary or alternate vaccine coordinator immediately or report the problem to a supervisor.
- Notify staff by labeling exposed vaccines, VCI/NDI (USE) and placing them in a separate container apart from other vaccines in the storage unit. Do not discard these vaccines.

Document

- Document details of the temperature excursion:
 - Date and time
 - Storage unit temperature including minimum/maximum temperatures during the time of the event, if available
 - Room temperature, if available
 - Name of the person completing the report
 - General description of the event (e.g., what happened)
 - Printing a digital data logger (DDL) determine the length of time excursions may have been in effect
 - Inventory of affected vaccines
 - List of items in the unit other than vaccines (including water bottles) and problems with the storage unit and/or affected vaccines before the event
 - Other relevant information

Contact

- Contact your immunization program and/or vaccine manufacturer(s) for guidance per your standard operating procedures (SOPs).
- Be prepared to provide the manufacturer or immunization program with documentation and DDL data so they can offer you the best guidance.

Contact manufacturer for excursions:

Merck	1 800 672 6372
Sandoz Pasteur	1 800 822 2463
Bluebirdbio	1 888 825 0210
Pfizer	1 800 438 1985
Seqirus	1 855 358 8966

Correct

- If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause.
- Check the basics, including:
 - Power supply
 - Unit location
 - Thermostat settings
- If the excursion was the result of a temperature fluctuation, refer to the chapter "Vaccine Storage and Temperature Monitoring: Equipment" in CDC's Vaccine Storage and Temperature Monitoring Toolkit for detailed guidance on adjusting storage unit temperature to the appropriate range.
- If you believe the storage unit has failed, implement your emergency vaccine SOPs. Never allow vaccines to remain in a manufacturing unit.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

38

Vaccine Manufacturers' Quality Control Phone Numbers

<p>GlaxoSmithKine 888.825.5249</p> <p>www.vaccinequality.com</p> <ul style="list-style-type: none"> Bexsero® Boostrix® Engerix-B® Fluarix® FluLaval® Haavrix® HiBerna® Infanrix® Kovax® Menveo® Pediaris® Shingrix® Twintrix® Rotarix® 	<p>Merck 800.672.6372</p> <ul style="list-style-type: none"> Cardisax® IMRV® Pedvax® Pneumovax® ProQuad® Recombivax HB® RotaTep® Vaxart® Varivax® Zostavax® 	<p>Sandoz Pasteur 800.822.2463</p> <ul style="list-style-type: none"> Acq-HB® Adacel® Deplace® Fluzone® I-POL® Pentacel® Menactra® Quadracel™ Terivac® 	<p>Pfizer 800.438.1985</p> <ul style="list-style-type: none"> Preniar 13® Trumenol® 	
<p>Grifols 800.457.4626</p> <ul style="list-style-type: none"> TIG® 	<p>Protein Sciences 800.488.7099</p> <ul style="list-style-type: none"> Flublok® 	<p>Dynavax 844.889.8753</p> <ul style="list-style-type: none"> Heplisav-B® 	<p>Seqirus 855.358.8966</p> <ul style="list-style-type: none"> Altuvia® Flucelvax® Fluzone™ Fluvirin® Raphvab™ 	<p>AstraZeneca 800.236.9933</p> <ul style="list-style-type: none"> FluMist®

NORTH Dakota Health Be Legendary.™
Updated 2/2019

When a temperature in a vaccine storage unit is discovered outside of the recommended ranges, it is vital to contact the vaccine manufacturers' to determine the viability of the vaccines.
For questions please contact the North Dakota Immunization Program at 800.472.2180.

39

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.

40

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.

41



42

MERCK REUSABLES SHIPPERS

- 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.



43

MERCK REUSABLES SHIPPERS

- 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.

44

MERCK		Packing Slip		Order Complete		Page 1 of 1	
3000 Gilling Hill Road KENILWORTH, NJ 07033							
Shipped From MD Logistics 12100 New Blvd RENO, NV 89506 USA	DEA License N/A State Distributor N/A State Control Drug N/A	Ship To Example: ABC Pediatrics 123 MAIN ST - STE ABC ATLANTA, GA 30305	State License A15000X DEA License N/A	Sold To CDC Pediatric CDC Pediatric ATLANTA, GA	State License N/A DEA License N/A	Account # 30333-0000	Account # 000014200
Order No 3020000000	Order Type From CDC	Purchase Order Number 4000000000	Carrier UPS	No of Pallets 0	Drop PO#		
Ship Date 15-Sep-2020	Product must be received on or by 15-Sep-2020	Order Date 9-Sep-2020	Service Level GROUND	No of Cartons 1	Delivery No 0810000000		
Special Instructions: ST1,TUWTHF 9-4L							
Item Number	Item Description	Batch Number	NDC Number	Expiration Date	Ordered Qty	Shipped Qty	
1001794	STERILE SOLVENT FREE 10X100SE VIAL	5015961	01005435000	2-Apr-2022	2	2	
1001351	VARIANX 0.5ML 10X100SE VIAL	5015461	0005482700	24-Jun-2021	2	2	
					Total Units	4	

45

MERCK REUSABLES SHIPPERS

- 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.

46

HELP US REDUCE WASTE DO NOT DISCARD

1 Replace
Replace cooler contents

2 Reseal
Close flap 1, peel away tape backing on flap 2 and close to seal box

3 Return
Place at the front desk or designated pickup spot - we will handle the rest!

Ready for pickup sooner?
Scan this QR code

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

Copyright © 2020 Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. All rights reserved. US 2020 0888 0026

47

VACCINE PLANNING

48

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.

49

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>

50



51

NORTH DAKOTA IMMUNIZATION PROGRAM

North Dakota Immunization Program Staff

Molly Howell, MPH Program Manager	Phone: 701.328.4556 Email: mahowell@nd.gov	Mary Woinarowicz, MA NDIS Manager	Phone: 701.328.2404 Email: marywoinarowicz@nd.gov
Abbi Berg, MPH VFC/Quality Improvement Manager	Phone: 701.328.3324 Email: alberg@nd.gov	Rachel Goebel, MPH NDIS Coordinator	Phone: 701.214.7322 Email: rgoebel@nd.gov
Miranda Baumgartner VFC/QI Coordinator (West)	Phone: 701.328.2035 Email: mbaumgartner@nd.gov	Jennifer Galbraith Immunization Surveillance Coordinator	Phone: 701.328.2335 Email: jgalbraith@nd.gov
Sherrie Meixner VFC/QI Coordinator (East)	Phone: 701.541.7226 Email: smeixner@nd.gov	Carmen Cardenas, MPH NDIS Data Quality Coordinator	Phone: 701.328.4169 Email: ccardenas@nd.gov
Vacant CDC Public Health Advisor	Phone: Email:		



52

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
 - Credit for this session will not expire until July 8, 2020.
- This presentation will be posted to our website: www.health.nd.gov/immunize

53
