

## Vaccine Storage and Handling

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Vaccines for Children QI Coordinator






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## General Vaccine Storage and Handling

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### Storage & Handling Common Errors

<ul style="list-style-type: none"> <li>Designating only one person to be responsible for the storage and handling of the vaccines</li> <li>Not recording the minimum/maximum daily</li> <li>Documenting out-of-range temperatures on the temp log but not taking action</li> <li>Refrigerating vaccine in a way that could jeopardize its quality</li> </ul>	<ul style="list-style-type: none"> <li>Leaving refrigerator or freezer door open</li> <li>Discarding multi-dose vials 30 days after they are opened</li> <li>Storing food and drinks in the vaccine storage unit</li> <li>Not having emergency plans for a power outage or natural disaster</li> </ul>
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### Vaccine Storage and Handling

- An effective cold chain relies on three main elements:
  - Well-trained staff
  - Reliable storage and temperature monitoring equipment
  - Accurate vaccine inventory management

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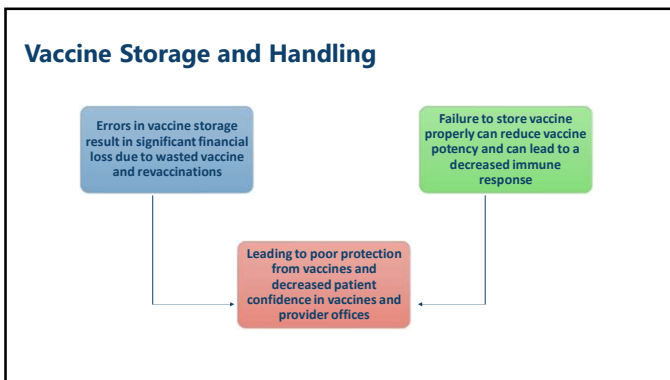
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### VFC Contacts

- Designate a primary and a back-up contact at the facility
  - Oversees proper receipt and storage of vaccine deliveries
  - Organizing vaccines within storage units
  - Setting up temperature monitoring devices
  - Checking and recording minimum/maximum temperatures once daily
  - Responding to temperature excursions
  - Removing expired vaccine from storage units
  - Ordering vaccines
  - Maintaining all required documentation
  - Monitoring operation of storage equipment

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### Vaccine Storage and Handling

- All vaccines, **except** varicella, MMR®II, and MMRV must be stored in the refrigerator at **36°F - 46°F (2 - 8°C)**
  - Optimal refrigerator temperatures are **39 °F - 42°F (4 - 6°C)**
- MMRV and varicella vaccine must be stored in the freezer at **-58°F to 5°F (-50°C to -15°C)**
  - Optimal freezer temperatures are **3°F or colder (≤ -17°C)**
- MMR®II and Moderna COVID-19 vaccine can be stored in the refrigerator or freezer
  - Priorix® MMR vaccine **MUST** be stored in the refrigerator only

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### Vaccine Storage and Handling

Protect the following vaccines from light:  
 Afluria®, Areovy®, Bexsero®, FLUAD®, Fluarix®, Flublok®, Flucevax®, Flumist®, Gardasil 9®, Hibervax®, IPOL®, Jynneos®, M-M-R II®, Menveo®, Moderna COVID-19®, Pfizer COVID-19®, PrevHenviro®, Priorix®, ProQuad®, Recombivax®, Rotarix®, RotaTeq®, Shingrix®, Varivax®, Vaxelis®, Vaxneuvance®

Unconstituted lyophilized (freeze-dried) MMRII® may be frozen or refrigerated. Priorix® can only be stored in the refrigerator

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

COVID-19 (Moderna)<sup>‡</sup>  
**MMR** II<sup>§</sup>  
**MMRV** <sup>‡</sup>  
**VAR** <sup>‡</sup>

**Store In Ultra Cold Freezer**  
 Between -90°C & -60°C (-130°F & -76°F)

COVID-19 (Pfizer <5 and Pfizer 5-11 years)

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

COVID-19<sup>‡</sup>  
 DTaP, Tdap, Td  
 HepA  
 HepB<sup>‡</sup>  
 HepA-HepB  
 Hib<sup>‡</sup>  
 9vHPV<sup>‡</sup>  
 Influenza<sup>‡</sup>  
 IPV<sup>‡</sup>  
 Meningococcal ACWY<sup>‡</sup>  
 Meningococcal B<sup>‡</sup>  
 MMR <sup>‡§</sup>  
 MPOX<sup>‡</sup>  
 Pneumococcal<sup>‡</sup>  
 Rotavirus<sup>‡</sup>  
 RSV<sup>‡</sup>  
 Shingrix<sup>®‡</sup>

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### Vaccine Storage Best Practice

**Sample Refrigerator**

- Check label VFC and provide vaccines.
- Group vaccines pediatric, adolescent, adult.
- Label shelf space or baskets to make vaccines easy to find.
- Position vaccines on baskets 2 inches away from walls, floor, and other baskets.
- Store vaccines in original packaging with printed expiration date on front.
- Eligible vaccines may be stored next to refrigerated vaccines unless manufacturer states otherwise. Never store eligible in the freezer.
- If necessary, multiple doses or biologics may be stored in a different vial.

**Sample Chest Freezer**

**VFC Field Rep:**

**Refrigerator temperatures:** 36°F - 46°F

**Freezer temperatures:** 5°F - 15°F

**Do not:**

- Block air vents.
- Stack baskets on top of each other.
- Store vaccines in drawers.
- Keep food or beverages.

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### Vaccine Storage

- Vaccine should always be stored in the original packaging, as light causes loss of vaccine potency
- Food and beverages should never be stored in a unit with vaccine
- Place water bottles on the top shelf, floor and in the door racks
- When possible, store diluent with the corresponding refrigerated vaccines
- Store each vaccine in a labeled container

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### Vaccine Storage Equipment

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### Data Loggers

- All storage units that contain VFC/VFA or state-supplied vaccine must use a continuous recording data logger
- Back-up data loggers are also required in the event that the data logger would malfunction or quit working
  - Required even if facility has a built-in temperature monitoring system
- Vaccine orders will not be approved without a data logger temperature chart
  - Any provider that does not submit monthly data logger temperature charts will be notified in NDIIS when the vaccine order is placed
- All data logger temperature logs, including transport data loggers, should be submitted to the Immunization Unit at [dohtemplogs@nd.gov](mailto:dohtemplogs@nd.gov) monthly in either PDF, Excel or Word

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### Data Logger Temperature Logs

- \*New\*** Temperature logs are now being logged monthly in the NDIIS by ND HHS staff once they have been reviewed

Temperature Logs are out of date!

Temperature Logs are up to date.

Temperature Logs

SUBMITTED DATE	LOGGING PERIOD
12/5/2024	Nov 2024
11/5/2024	Oct 2024

Rows per page: 5 1-2 of 2

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### Data Logger Temperature Logs, CONT

- Providers will still be able to submit their vaccine order in NDIIS but orders will be flagged for temperature log review and will not be processed
- Vaccine orders will be returned to providers who have not submitted their data logger temperature logs

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### Data Logger Requirements

- The following are additional recommended characteristics for these devices that are required of all data loggers:
  - Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand or Teflon®)
  - Alarm for out-of-range temperatures
  - Current, minimum, and maximum temperature indicator
  - Low-battery indicator
  - Accuracy of +/-0.5° C (+/-1°F)
  - Memory storage for at least 4,000 readings
  - Recommended maximum logging interval (or reading rate) of every 30 minutes that can be programmed by the user

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### Thermometer Calibration

- Thermometers should be calibrated annually or according to the manufacturer's recommendation
- The calibration testing gives information on the level of accuracy of the thermometer
- It is recommended to have high levels of accuracy is +/- .5°C (+/- 1°F)
- If the calibration testing result shows the thermometer is not accurate within +/- .5°C (+/- 1°F) range the thermometer should be replaced

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### Min/Max Temperature Requirement

- All providers are required to document minimum/ maximum temperatures once daily
  - Preferably at the start of the clinic day
  - Providers can continue to check temperatures twice daily and record if that is their preference
  - Clinic staff should visually check temperatures each time a vaccine storage unit is entered to ensure that correct temperatures are being maintained throughout the day
  - CDC does require that staff initials, date, time and min/max temperature are documented with each temperature check

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### Vaccine Storage and Temperature Monitoring Equipment

- To fully ensure the safety of vaccines, the following equipment is recommended:
  - Stand-alone refrigerator(s) with enough space to accommodate your maximum inventory without crowding
  - Stand-alone freezers with enough space to accommodate your maximum inventory without crowding
- Dormitory units must NEVER be used to store state-supplied or VFC/VFA vaccine
  - Regardless of reason or duration
- Before vaccine can be placed in a new storage unit the min/max temperature should be monitored for seven days and remain in-range
- Use of the freezer compartment of a household combination unit is not allowed

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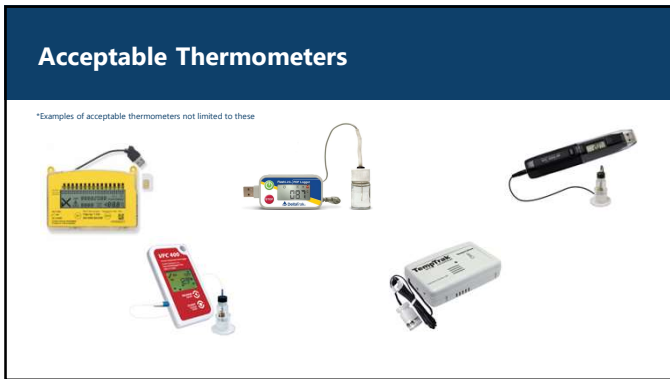
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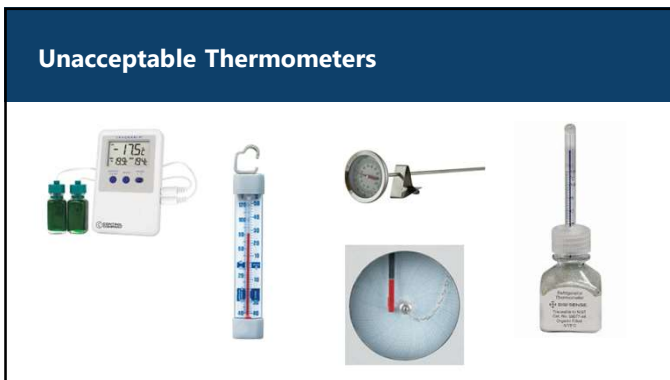
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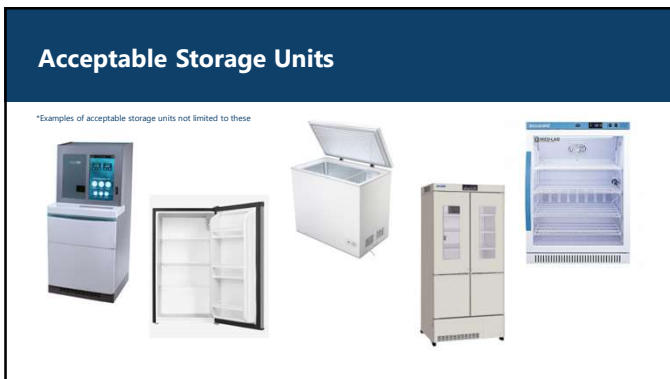
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### Temperature Excursion

- Temperature out-of-range: **ACT IMMEDIATELY**
- Notify primary or backup vaccine coordinator
- Record temperature on temperature log
- Isolate affected vaccine and mark "DO NOT USE"

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### Temperature Excursion CONT.

- Vaccine manufacturers should be contacted **first** to determine vaccine viability, followed by the ND HHS
- Do NOT assume that vaccine is not viable
- Do not discard any vaccine until the ND HHS has been notified
- Vaccine manufacturer phone listing <https://www.hhs.nd.gov/storage-and-handling>
- Once the vaccine manufacturers have been contacted ND HHS should be notified of the excursion
  - This can be done by emailing [vaccine@nd.gov](mailto:vaccine@nd.gov) or completing the Temperature Excursion Report form [https://ndhealth.co1.qualtrics.com/jfe/form/SV\\_5chlQNgm1ts43y5](https://ndhealth.co1.qualtrics.com/jfe/form/SV_5chlQNgm1ts43y5)

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### Temperature Excursion CONT.

- Actions may include:
  - Repositioning thermometer probe in central location of storage unit
  - Rechecking temps in ½ to 1 hour
  - Adding additional water bottles/frozen water bottles to unit
  - Adjusting storage unit thermostats
  - Relocating vaccine, if necessary
  - Persistent temperature problems may require the purchase of a new storage unit

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### Temperature Excursion CONT.

- All actions must be recorded and submitted monthly with temperature logs to [dohtemplogs@nd.gov](mailto:dohtemplogs@nd.gov)
- **Even one out-of-range temperature, especially on the cold side, may result in the need for revaccination!**

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### Excursion Tools and Stability Calculators

Manufacturer	Contact
GlaxoSmithKline	<a href="https://gskusmedicalaffairs.com/stability-calculator/">https://gskusmedicalaffairs.com/stability-calculator/</a>
Merck	<a href="https://www.merckmedicalportal.com/s/tem">https://www.merckmedicalportal.com/s/tem</a>
Moderna	<a href="https://tools.modernamedinfo.com/en-US/excursion/introduction-landing-page">https://tools.modernamedinfo.com/en-US/excursion/introduction-landing-page</a>
Pfizer	<a href="https://www.pfizermedicalinformation.com/stability-calculator">https://www.pfizermedicalinformation.com/stability-calculator</a>
Sanofi Pasteur	<a href="https://www.sanofimedicalinformation.com/s/7PN&amp;language=en_US&amp;CN=US">https://www.sanofimedicalinformation.com/s/7PN&amp;language=en_US&amp;CN=US</a>
Non-viable Merck VFC shipments ONLY	<a href="https://cdcsipping.merck.com/">https://cdcsipping.merck.com/</a>

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### Excursion Tools and Stability Calculators CONT.

- Provide the tool with the temperature excursion information and the tools will provide the stability guidance
- This guidance needs to be saved as documentation for the excursion
- Instances when the tool *may* not work:
  - Multiple excursions
  - An excursion that contains both a warm and cold excursion
  - Extreme temperatures have been reached
  - Further information is needed to provide guidance

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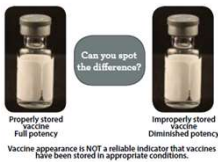
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### Vaccine Storage and Handling

- Vaccines exposed to freezing temperatures may not appear frozen
- Manufacturers must always be contacted as to the viability of the vaccine



Properly stored vaccine Full potency

Improperly stored vaccine Diminished potency

Can you spot the difference?

Vaccine appearance is NOT a reliable indicator that vaccines have been stored in appropriate conditions.

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### Updated Temperature Excursion Guidance

- If providers are able to reset their data logger, alarms triggers should be set at 30 minutes outside of the acceptable temperature range, whether it be warm or cold
- Email [vaccine@nd.gov](mailto:vaccine@nd.gov) for assistance in resetting data loggers or to find out if your data logger can be reset
- For those who are not able to reset their data loggers the updated excursion time frame will need to be in place by January 1, 2026 which should give providers enough time to replace data loggers as they expire
- In the meantime, previous excursion time frame will still be honored. Most brands of data loggers should be able to be reset

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### Common Excursion Reasons

- Door left ajar
- Vaccine not stored correctly upon receipt
- Unit failure
- Power outage
- Placing warm/cold packs in storage units

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Vaccine Transport

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**Vaccine Transport**

- Vaccine transport is discouraged whenever possible
- If providers must transport vaccine, data loggers **must** be used at all times
- Transport temperature charts must be submitted to the immunization unit anytime VFC vaccine is transported
- Temperatures should be checked and documented every hour
- Paper temperature logs <https://www.hhs.nd.gov/storage-and-handling>
- VFC/VFA 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

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**Vaccine Transport CONT.**

- All vaccines transfers (between providers) must be approved by the immunization unit
- The total time for transport alone or transport plus clinic workday should be a maximum of 8 hours unless guidance from the manufacturer differs
- Frozen vaccine must be transported in a frozen transport cooler
- Do not use frozen gel packs or coolant packs from original vaccine shipments to pack refrigerated vaccines
- Vaccine transport recommendations <https://www.hhs.nd.gov/storage-and-handling>

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### Vaccine Transport Coolers



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### Routine Vaccine Transport System Recommendations

Container	Transport for Off-Site Clinic, Satellite Facility or Relocation of Stock
Portable Vaccine Refrigerator or Freezer	Yes
Qualified Container and Packout	Yes
Conditioned Water Bottle Transport System	No
Manufacturer's Original Shipping Container	No
Food/Beverage Coolers	No

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### 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>



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Emergency Vaccine Transport System Recommendations	
Container	Emergency Transport
Portable Vaccine Refrigerator or Freezer	Yes
Qualified Container and Packout	Yes
Conditioned Water Bottle Transport System	Yes
Manufacturer's Original Shipping Container	Yes (last resort only)
Food/Beverage Coolers	No

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**Vaccine Orders, Returns, Wastages and Expirations**

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**Vaccine Ordering**

- We ask that providers only order once per calendar month
  - Please contact the Immunization Unit ([vaccine@nd.gov](mailto:vaccine@nd.gov)) prior to placing additional orders
- Vaccine orders are submitted to the ND HHS Immunization Unit via NDIIS by providers for review and approval
  - Order minimum – 1 month
  - Order maximum – 3 months
- Providers should allow up to 2-3 weeks for vaccine deliveries

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### Vaccine Ordering, CONT

- Ordering vaccine in the NDIIS is now real time
- Last 30 (min) and 90 (max) calendar days for doses administered
- The inventory is based on the vaccine reconciliation that providers are required to complete within 7 days of every vaccine order
- Providers can over the order maximum, a detailed comment is needed

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### Distribution System

Non-frozen vaccine is shipped directly to your clinic from centralized distributor (McKesson).

- Vaccines are generally shipped on Monday, Tuesday and Wednesdays.
- Flu and COVID-19 Moderna and Novavax will be shipped separately and is generally overnighted.

Varicella and MMRV vaccines are shipped directly from Merck.

- Varicella and MMRV can ship any day Monday through Friday.

Pfizer COVID-19 vaccines are shipped directly from Pfizer and are generally overnighted.

It is incredibly important to keep the NDIIS up-to-date with accurate address, contact and business hour information each time a vaccine order is placed.

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### Never Frozen Pfizer COVID-19 Vaccine Packing Slip

Lot No.	Qty	Exp Date	Lot No.	Qty	Exp Date
70138101020287	11,000 EA	01/15/25	70138101020287	11,000 EA	01/15/25
70138101020287	1,000 EA	01/15/25	70138101020287	1,000 EA	01/15/25

As of January 1, 2025, all information contained on this Pfizer COVID-19 Vaccine Packing Slip (PSL) will be provided through a secure electronic portal. Transmission instructions and information are available at: <https://www.pfizer.com>. For more information, please contact your local Pfizer representative or visit <https://www.pfizer.com>.

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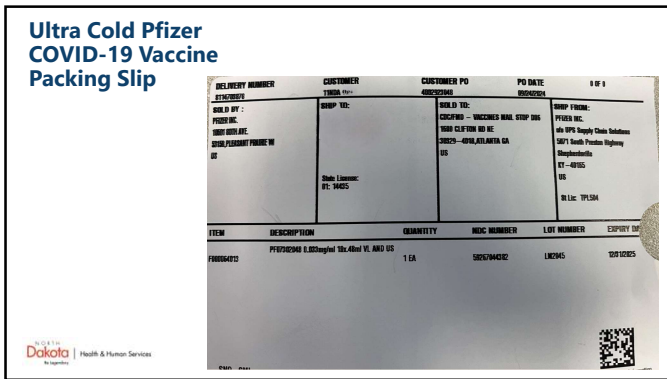
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**Distribution System CONT.**

- **DO NOT** ship viable vaccine to McKesson
- **DO NOT** ship viable or non-viable vaccine to the ND HHS
- **DO NOT** contact UPS for vaccine returns or your facility may be charged!
- **DO NOT** refuse any vaccine shipment even if the vaccine is passed the viable date

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**Vaccine Deliveries**

- Any issues with vaccine deliveries should be reported the day the shipment is received
  - Vaccine issues not reported the same day will result in the vaccine not being replaced by McKesson and will result in vaccine loss
- For viability concerns please reach out to McKesson using the phone number supplied with the vaccine shipment, if the shipment is received after McKesson's operational hours, please leave a voicemail

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### Vaccine Deliveries CONT.

Steps for handling compromised vaccine:

1. Accept the shipment
2. Open the shipment immediately, inspect the vaccine and check the temperature monitor
3. Place the vaccine in the appropriate storage unit
4. Keep all vaccine packaging as CDC may ask for pictures of the vaccine shipping container and contents
5. Contact McKesson, Merck (if frozen) or Pfizer (for COVID-19 vaccine) using the contact information on the packing slip

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### Vaccine Deliveries Cont.

- For any delivery issues, such as viability issues or missing product, please reach out to the Immunization Unit by phone or email **AFTER** McKesson, Merck or Pfizer have been contacted
  - Phone: 701-328-2378 or 800-472-2180
  - Email: [vaccine@nd.gov](mailto:vaccine@nd.gov)
  - **Contacting the Immunization Unit does not replace the need to contact McKesson**

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### McKesson Shipment Temperature Indicators

Refrigerated Vaccine Shipments	Frozen Vaccine Shipments
<p>Refrigerated shipments include a warm temperature indicator. Only warm indicators used to be activated prior to shipping.</p> <p>McKesson Distribution Center may utilize two different warm temperature monitors.</p> <p>The 3M Monitor Mark shown left or the SpecLine monitor shown below.</p>	<p>Frozen shipments include an electronic log alert monitor.</p>
<p>Beginning in Spring 2024, McKesson will begin to use TagAlert monitors for both Warm and cold monitoring. These are the similar monitors as what is used in the Frozen vaccine shipments.</p>	

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### Merck Shipments

- Merck has implemented a new reporting process for CDC/VFC vaccine shipping or delivery issues for varicella and MMRV vaccines and diluent
- Providers need to report all shipping or delivery issues the day the shipment is received
- Providers no longer call Merck to report any issues, all issues need to be reported using the CDC/VFC Vaccine Inquiry Tool

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### Merck Shipments CONT.

- The CDC/VFC Inquiry Tool can be accessed using <https://cdcshipping.merck.com/>
  - Can also be found <https://www.hhs.nd.gov/storage-and-handling>
- All direct ship orders from Merck are identifiable by the Purchase Order (PO) number. The PO number can be found on the vaccine packing slip or shipping label
- Once an issue is successfully reported, the reporting individual will receive an immediate confirmation email and then a follow-up communication from Merck within 5 business days

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How to find the PO# on the packing slip

The image shows a Merck Packing Slip. A callout box on the left says: "The PO# can be found here on the packing slip. In this example, the PO# is 4001234567." A red box on the slip highlights the "Purchase Order Number" field, which contains the value "4001234567".

**Merck Packing Slip**

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**Merck Shipping Label**

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### Vaccine Wastage vs Return

- **Wastage**
  - Nonviable vaccine that is not able to be returned to McKesson. This includes broken vaccine vials or syringes, vaccine drawn into a syringe but not administered, lost or unaccounted for vaccine and partially used multi-dose vials
  - Vaccine being returned to McKesson must be entered as a vaccine return and should not be entered on this tab

- **Return**
  - Nonviable vaccine that needs to be returned to McKesson because it is expired, spoiled because of a temperature excursion or because of a vaccine recall. Multi-dose vials (MDV) can only be returned if no doses have been drawn from the vial

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### Vaccine Wastage vs Return CONT.

Return	Wastage
Any unopened MDV vaccine including COVID-19 vaccine	Open IPV or MDV influenza
Partially used boxes of vaccine	Broken syringe/vial
Full unopened boxes of vaccine	Vaccine drawn up and not administered
	Pandemic vaccine (COVID19)



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### Expiration Date vs Beyond Use Date (BUD)

- **Expiration Date**
  - The final day that the vaccine can be administered
  - Vaccine past the expiration date that is printed on the vial/prefilled syringe and box should not be administered
  - The expiration date is determined by the manufacturer

- **BUD**
  - The last date or time that a vaccine can be safely used after it has been transitioned between storage states or reconstituted/punctured for patient use
  - The BUD varies by product
  - This is determined at the provider office when the vaccine has been transitioned or reconstituted/punctured

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### Expiration Date vs Beyond Use Date (BUD) CONT.

Expiration Date	BUD
Open multidose vial of IPOL	Pfizer COVID19 vaccine 6m-4 years and 5-11 years once placed in the refrigerator
Open multidose vial of influenza	Moderna COVID19 vaccine once placed in the refrigerator
All routine vaccines	Vaccines once reconstituted

The vaccine expiration date, not the BUD, should be entered as the expiration date in NDIS and provider EMRs.

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### Vaccine Expiration Dates

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### Vaccine Reconstitution

Vaccine	Time allowed
Abrysvo	4 hours
ActHib	24 hours
Arexvy	4 hours
COVID-19 Pfizer	12 hours
Hiberix	24 hours
M-M-R II	8 hours
Menveo (two vial)	8 hours
Pentacel	Immediately
Priorix	8 hours
ProQuad	30 minutes
Rotarix	24 hours
Shingrix	6 hours
Varivax	30 minutes

[https://www.immunize.org/wp-content/uploads/catg\\_d/p/3340.pdf](https://www.immunize.org/wp-content/uploads/catg_d/p/3340.pdf)

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Dakota Health & Human Services

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### Vaccine Ordered and Expired/Wasted

In 2023 ND HHS ordered 99,427 doses of vaccine with a total of \$9,212,239.72, excluding influenza and COVID19 vaccine

In 2023 providers wasted/expired 6,635 total doses of vaccine with a total of \$540,228.19 , excluding influenza and COVID19 vaccine

- 824 of these doses were due to storage and handling resulting in \$82,620.17

In 2023 there were 62 total temperature excursions

- 45 were reported by providers
- 17 were found by ND HHS staff on monthly review of temperature logs

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### Return/Wasted Reasons

Most common reasons for returns/wastages:

- Expired
- Spoiled in transit
- Unit failure (unit too warm or unit too cold)
- Vaccine drawn up and not administered
- Broken vial/syringe

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**Resources**

CDC's Vaccine Storage and Handling Toolkit  
<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

CDC's Vaccine Storage and Handling home page  
<https://www.cdc.gov/vaccines/hcp/admin/storage/index.html>

Immunize.org Vaccine Storage & Handling  
<http://www.immunize.org/clinic/storage-handling.asp>

North Dakota Immunization Unit  
<https://www.hhs.nd.gov/storage-and-handling>

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**Change the Conversation:  
 Motivational Interviewing and  
 Vaccine Hesitancy**

 **December 16 & 19**  
**12:00pm CT**

**FREE CE available!**

Presented By:  
**Jon Ulven, Ph.D., L.P.**

**SCAN ME** 

https://bit.ly/192CPEa

**NDSU** CENTER FOR IMMUNIZATION RESEARCH AND EDUCATION 

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**Holiday Shipping**

- Vaccine orders placed before December 12, 2024, should still be shipped prior to January 2025
- There will be very limited shipping after December 13th and vaccines ordered after that day may not arrive until January 2025

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## Post-Test

### Post-test

- Nurses interested in continuing education credit, visit [Successfully complete the five-question post-test to receive your certificate:](https://ndhealth.co1.qualtrics.com/jfe/form/SV_29xutyImPYU9VBA)
- Credit for this session will be available until January 8, 2025.

This presentation will be posted to our website:  
[www.hhs.nd.gov/immunizations](http://www.hhs.nd.gov/immunizations)

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## Staff Members

### Immunization Unit

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