

The Presentation will begin shortly. There will be no audio until then.

vaccine management

Outline

- Vaccine storage and handling
 - Personnel
 - Appropriate equipment
 - Refrigerator and freezer units
 - Thermometers
 - Temperature monitoring
 - Managing non-viable vaccine
 - Vaccine transport
- New requirements for 2014
- Online Resources

Personnel

- All providers must have a primary and back-up vaccine coordinator.
- Both coordinators should receive required training on vaccine storage and handling and Vaccine For Children Program.
 - The trainings are requirements for 2014 VFC enrollment.
 - Providers were to complete these trainings by November 27, 2013.
- The primary or back-up vaccine coordinator should review policies with all staff including newly hired staff.
- Temperature monitoring is the responsibility of all staff administering vaccine.
- All personnel that immunize patients should have access to NDIIS and at least 1 person must have access to the vaccine ordering module.

Personnel Cont.

- NDIIS users must not share login ID's or passwords.
- Primary contacts should notify Thor support when an employee leaves the practice to have access to NDIIS removed.
- The primary and back-up contacts are responsible for training new staff on VFC requirements as well as vaccine practices.

Storage Units

- CDC recommends stand-alone refrigerators and freezers
- Vaccine storage units must maintain the required temperatures for vaccine storage
- Units must accommodate the largest vaccine inventory of the year without crowding.
- If vaccine storage units are new or repaired, temperature must be checked twice daily for one week before the unit is used for vaccine storage.

Storage Units That
Are Not
Recommended

- **Dormitory style refrigerators are not allowed to be used for vaccine storage**
- The freezer part of combination unit is not recommended for vaccine storage
- Units with manual defrost cycle are not recommended
 - Providers need another storage (back-up) unit when they manually defrost the unit

Purchasing New
Storage Units

- Please use the refrigerator and freezer purchasing guide available at the Immunization Program website
 - www.ndhealth.gov/Immunize/Providers/
- Consult with the immunization program if you need further information
- After purchasing a new vaccine storage unit, check the temperature twice daily for a week to ensure it maintains temperature before storing vaccine in the unit

Units With Built-in
Thermometers

- If your unit has a built-in thermometer, make sure the glycol bottle is placed at the center of the unit, close to vaccine
 - Otherwise it may not measure the right temperature
- The built-in thermometer needs to be recalibrated regularly
- Cost of recalibration of built-in thermometers could be higher, the immunization program encourages providers to use external thermometers

Thermometers

- CDC recommends the use of a thermometer with:
 - Accuracy of +/- 0.5°C / +/- 1°F
 - Thermometer with probe in glycol
 - Alarm system for out-of-range temperatures
 - Current, minimum and maximum temperature readings
 - Reset button
 - Low battery indicator
 - Continuous data monitoring

Thermometers cont.

- CDC recommends the use of thermometer with
 - Memory of at least 4000 recordings
 - A thermometer display which can be placed outside the refrigerator/freezer to ease reading
 - If your clinic wants to purchase a centralized continuous temperature monitoring system, please make sure that it fulfills the CDC recommendations.

Thermometers cont.

- **All VFC providers are required to use a calibrated thermometer with certificate of calibration.**
- Calibration testing should conform to ISO 17025
 - Certificate should have:
 - Documented uncertainty level
 - Measurement result of the device
 - Instrument pass/fail testing
 - Date of calibration
 - Serial number and model number
 - OR
 - Certificate should identify ILAC/MRA signatory body accredited laboratory and should have:
 - Model number
 - Serial number
 - Date of calibration

The Benefits of Using Data Loggers

- Continuous temperature monitoring devices (data loggers) monitor and record temperature all the time at a preset interval
- Provide an indication of the length of time a storage unit has been operating outside the recommended vaccine storage temperature
- All providers are encouraged to purchase data loggers when buying new thermometers

Replacing Vaccine Due to Equipment Failure

	State Cost	Private Replacement Cost
• Pentacel-	\$56.02 per dose	\$80.43
• MMRV-	\$95.11 per dose	\$150.28
• HPV-4	\$100.85 per dose	\$135.45
• PCV13-	\$107.12 per dose	\$135.80
• MCV-4	\$82.12 per dose	\$112-114.02- brand dependent

In North Dakota, \$6,922,390.89 worth of vaccines were sent out for VFC and state providers in 2012.

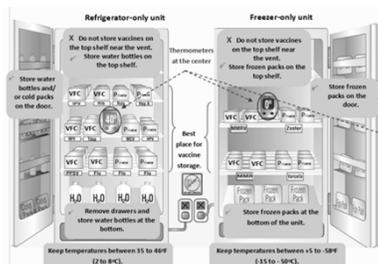
Average price of a data logger is about \$170

The price of a refrigerator or freezer \$1500-5000

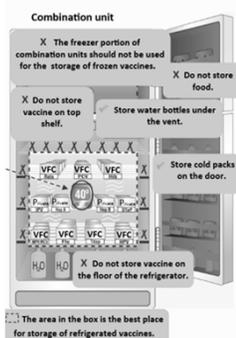
Data Logger Pilot Test

- The immunization program is currently pilot testing different data loggers at several volunteer provider offices
- One or two data loggers will be selected and will be recommended for all providers in the state who do not currently have one that meets CDC specification
 - More information will be available in the future about a possible application process to receive data loggers
- After delivery of the data loggers, temperature logs will still be required in addition to the use of continuous temperature monitoring to ensure that someone is checking unit temperatures daily

Setting Up Vaccine Storage Units



Combination Units



Old Thermometers



- Old thermometers used by providers are made of Ethylene Glycol, a toxic substance
 - Please check the chemical in the glycol bottle and avoid contact with the chemical
- Ethylene glycol should be disposed of appropriately, it can be poured into a toilet and flushed
- Newer thermometers are made from propylene glycol, a less toxic substance
 - Please use the same safety procedure

New Temperature Logs

- Provider ID must be included on the log for identification
- Has minimum and maximum temperature readings
- Has a column to record out-of-range temperatures
- The temperature logs are separated by freezer and refrigerator
- Temperature logs must be faxed to 701-328-0355 monthly, prior to ordering vaccine
 - If any excursions are written on the temperature log, the troubleshooting guide must be faxed also.
- All providers should shift to the new temperature log

The temperature log has the confidential fax number at the bottom

Temperature Excursions

- All out-of-range temperatures are considered an excursion.
- The vaccine troubleshooting guide is available at the immunization program website www.ndhealth.gov/Immunize/Documents/Providers/Forms/Troubleshooting.pdf
- It provides step by step instructions on how to respond to out of range temperatures. It includes:
 - Phone number of vaccine manufacturers
 - Has a table where you can record the out of range temperature
 - Has steps you can take to adjust your refrigerator when the temperature is out of range for a shorter period of time
 - Factors that lead to out of range temperatures

What Steps Should I Take?

1. Contact your primary or back-up vaccine coordinator
2. Document temperature
 - Minimum
 - Maximum
 - Duration of temperature excursion
3. Label the vaccine "Do Not Use"
4. Store at the appropriate temperature
 - If the unit is not maintaining temperature, transfer to other vaccine storage unit that has a thermometer
5. Contact the manufacturers
 - Do not discard vaccine before contacting the manufacturer
 - If vaccine is wasted report to the immunization program

Please fill out the form and send to the immunization program when you have out of range temperatures

Vaccine Storage Troubleshooting Guide

IF YOU NOTICE A TEMPERATURE EXCURSION:

1. Contact the primary or backup vaccine coordinator.
2. Document the current, minimum and maximum temperatures, duration of temperature excursion and the time when problem was discovered in the table below.
3. Label the vaccine "Do Not Use."
4. Store at the appropriate temperature. If your unit is not maintaining the appropriate temperature, transfer the vaccine to other storage units. Do not allow vaccines to remain in a unit while trying to fix it.
5. Contact the manufacturer for further guidance on use of the vaccine using the phone numbers provided below. Do not discard vaccine before contacting the manufacturer. If vaccine is wasted, report to the immunization Program.

Storage unit is too cold
 $< 2^{\circ}\text{C}$ (35°F) for refrigerator
 Colder than -20°C (-8°F) for freezer

Storage unit is too warm
 $> 8^{\circ}\text{C}$ (46°F) for refrigerator
 Warmer than -15°C ($+5^{\circ}\text{F}$) for freezer

Factors that may cause temperature excursion ($+2^{\circ}\text{C}$)

Thermometer placement: Place at the center and check the temperature every 30 minutes.
Control knob: Adjust to a warmer position, check temperature every 30 minutes.

Factors that may cause temperature excursion (-2°C)

Power supply: Insert the plug into the wall socket, turn on the control knob and check if you have power supply.
Door: Close the door properly. Check the door seal and hinges.
Thermometer placement: Place at the center and check the temperature every 30 minutes.
Control knob: Adjust the control knob to a colder position and check temperature every 30 minutes.
Air circulation: Check if your unit has good air circulation.
Reorganize your vaccines.
Motor and coils: Clean the motor and the coils if it has dust or call a technician for help.

Vaccine manufacturers and their phone numbers

Merck & Co. Inc.	877.829.6372
GlaxoSmithKline	877.266.8368
Novartis	800.246.7668
Sanofi Pasteur	800.822.2483
MedImmune, Inc.	877.633.6411
Pfizer	800.999.9384

Document the information in the table when temperature excursion occurs

Date	Time	Duration	Staff				Temperature	Problem/Action taken	Result
			Initials	Current	Minimum	Maximum			

- Use a certified and calibrated thermometer with probe in glycol that measures liquid temperature for vaccine storage unit.
- Store water bottles in refrigerator and frozen packs in freezer to minimize the risk of temperature excursion.
- Use the appropriate vaccine storage unit to ensure vaccine viability.

North Dakota Immunization Program 800.471.2180 or 701.328.3186. www.ndhealth.gov/immunize/

- Document the duration of temperature excursion
- The viability of the vaccine depends on the duration temperature excursion
- Manufacturers need the information to make the right decision about the viability of vaccines
- Add up the time if the excursion occurred at different times

Temperature
Excursion

- After contacting the vaccine manufacturers, if the vaccine is non-viable remove from your storage unit
- Fill out the vaccine wastage form and submit to the Immunization Program
- You can submit the paper form or fill out the form online at:
www.ndhealth.gov/Immunize/Providers/Wastage.aspx

Vaccine Wastage
Due to Expiration

- Check your refrigerator/freezer for expired vaccines weekly
- Report expired vaccine to the Immunization Program using the vaccine wastage form
- Once you submit the vaccine wastage form, you will get a packing slip from the Immunization Program and a shipping label from McKesson
- Send unopened vials to McKesson within 6 months
- Do not send open vials, dispose of them according to your facility's policy

Return and
Wastage Form

- When completing the return and wastage form be sure to complete it entirely.
- Pay close attention to the codes for returning or wasting the vaccine and choose the one that matches most closely.
- Wastages and returns must be completed in a timely manner. Open vials and drawn syringes must still be reported using the wastage form but may be disposed of following your provider site protocol.

Administered expired or non-viable vaccine



- That is a serious vaccine administration error, you must inform the patient about the error
 - The dose should be repeated
- If the expired dose or non viable vaccine is a live virus vaccine, you should wait at least 4 weeks to repeat the dose
- If the expired dose is inactivated vaccine, the dose should be repeated as soon as possible

Shelf Lives of Reconstituted Vaccines

Vaccine	Expiration after reconstitution	Storage
MMR	8 hours	Store at the 2°C- 8°C
Menveo (MCV4)	8 hours	Can be stored at or below 77°F or 25°C for 8 hours
Varicella and MMRV/ shingles	30 minutes	May be stored at room temperature 68-77
Pentacel DTaP/IPV/Hib	30 minutes	Store at the 2°C- 8°C
Act HIB/Hiberix	24 hours	Store at the 2°C- 8°C
Menomune (MPSV4) single dose	30 minutes	Store at the 2°C- 8°C
Menomune (MPSV4) multidose	35 days	Store at the 2°C- 8°C
TriHIBit (DTaP/Hib)	30 minutes	Store at the 2°C- 8°C
Rotarix	24 hours	Store at the 2°C- 8°C

Avoiding Vaccine Administration Errors

- These seven “rights” helps you to avoid vaccine administration errors
 - **The right patients:** screen the patient to see which vaccine is needed and which vaccine should be avoided
 - **The right vaccine:** check your vial three times, expiration date
 - **The right time:** appropriate age and interval
 - **The right dosage:** dosage is based on age
 - **The right route:** oral, IM, SC
 - **The right site:** based on the age of the patient
 - **The right documentation:** document the correct lot number... in the NDIIS

Vaccine Transport

- The Immunization Program prepared a vaccine transport guide to help when bringing vaccine offsite for any reason.
- The guide has a list of pre-qualified vaccine transport coolers that are available for purchase.
- The guide is available at: www.ndhealth.gov/Immunize/Documents/Providers/Forms/Vaccine_transport.pdf

Vaccine Transport Recommendations

- CDC recommends the use of portable refrigerators and freezers for vaccine transport
- Frozen vaccines
 - Vaccine manufacturers do not recommend transportation of frozen vaccines
 - If the vaccine must be transported , a portable freezer must be used
 - Dry ice should not be used for transportation of frozen vaccines
- Vaccine should be placed in the passenger compartment of a vehicle, not the trunk

Vaccine Transport Recommendations

- The Immunization Program requires providers to use a calibrated thermometer during vaccine transport
 - Vaccine temperatures should be monitored every 30 minutes during vaccine transport
- Vaccines should be packed with their original package
- Opened multidose vaccine should not be transported
- Staff participating in vaccine transport should be educated on the maintenance of the vaccine cold chain
 - Encourage your staff to review the vaccine transport recommendation

Vaccine Transport Recommendations

- Diluents should be transported with the corresponding vaccines
- Diluents that do not contain antigens can be transported at room temperature or refrigerated
 - MMR, varicella and zoster
- Diluents that contain antigen and some others should be transported at refrigerated temperature requirements
 - ActHIB, MPSV4, MCV4 and Pentacel



New For 2014

- Providers should use the new temperature log with minimum and maximum temperatures in addition to current temperatures.
- Providers should use the Troubleshooting Guide for temperature excursions to ensure that all steps are completed.



What will be assessed for 2014 VFC visit?

- Thermometers
- Certificate of calibration
- Temperature logs
- Vaccine Management Plan
- Immunization related education completed in the previous 12 months
- Appropriate storage units
- Storage unit set up



Some Preventable Vaccine Storage and Administration Errors that Occurred in North Dakota in 2013



- HPV vaccine given to a pregnant woman
- FluMist given to a patient older than 49 years
- Expired DTaP given to a child
- Pediatric dose of Hepatitis A vaccine given to an adult
- Thermometer placed under the vent of a refrigerator lead to recall of over 100 vaccine doses
- Vaccine was stored in a facility that was closed for summer, the temperature was not monitored
- Staff were not trained about vaccine storage and upon receipt, vaccine shipment left outside

Error Numbers so far in 2013

- 828 Minimum interval violations excluding vaccine
- 104 Minimum interval violations for Live Virus vaccines
- Over 100 doses with "Vaccine Storage and Handling Error" as a comment for being invalid
- 46 doses given after expiration and/or recall
- 606 minimum age violations
 - excluding Hepatitis B as part of the Pediarix vaccine administered at 4 months

Online Resources

- The immunization program has many resources for meeting all requirements of the VFC program .
 - Temperature logs
 - "Do Not Unplug" signs
 - Troubleshooting Guide for temperature excursions
 - Return and Wastage forms
 - Guidance for thermometer and storage unit purchasing
 - Best practices for storage and handling
 - VFC policies
 - Vaccine administration algorithms and schedules

Continuing Education Credit

1.0 Contact Hours for nursing credit will be available by completing the post-test at the end of this presentation or by going to www.ndhealth.gov/immunize/posttest.

The post-test will be available until 5pm, December 25, 2013.

The recorded presentation will be archived on the immunization program website .

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