

**Vaccine Storage  
and Handling Updates**

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North Dakota Immunization Program  
Lunch & Learn  
July 13, 2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR DISEASE CONTROL AND PREVENTION



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**Highlights**

- **Equipment**
- **Temperature monitoring**
  - Recommendations v requirements
  - Recent CDC updates on vaccine storage & handling
  - Best practices and supporting science
  - Common errors
- **Tools to support good storage & handling practices**
- **Emergency transport of vaccines**
- **Looking ahead**

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**Objectives**

Participants will be able to:

- Describe a minimum of two recent CDC recommendations on vaccine storage and handling
- Apply at least one principle of good temperature monitoring to everyday practice
- Identify 3 common vaccine storage and handling errors and strategies for prevention

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### Disclosures

- Sean Trimble is a federal government employee with no financial interest or conflict with the manufacturer of any product named in this presentation
- The use of trade names is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention or the U.S. Department of Health and Human Services
- Content will not include any discussion of the unlabeled use of a product or a product under investigational use.
- CDC does not accept commercial support.

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### Vaccine Cold Chain

Manufacturing Process



Vaccine Manufacturer Responsible

Distribution

Manufacturer & Distributor Responsible

Vaccine Arrival at Provider Office  
Vaccine Storage and Handling  
Vaccine Administration

Provider Responsible



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### Why have a good Cold Chain

Health of Patients



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**Another reason**

Vaccine can be costly and are valuable

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**Vaccine Cold Chain**



Key Areas of Vaccine Storage and Handling

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**Storage Equipment**

**Freezer**

Vaccines Between  
-50°C and -15°C  
(-58°F and +5°F)

**Refrigerator**

Vaccines Between  
2°C and 8°C  
(36°F and 46°F)

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### Adjustment to CDC's Recommended Fahrenheit Temperature Range for Refrigerated Vaccine Storage

- ❑ The new recommended Fahrenheit temperature range is 36° F - 46° F (previously 35° F - 46° F)
- ❑ The Celsius temperature range (2° C - 8° C) remains unchanged, as stated in all manufacturer package inserts for routinely recommended vaccines
- ❑ The 2016 Vaccine Storage and Handling Toolkit reflects the recent adjustment in CDC's guidance

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### Some Common Errors with Storage Equipment

- ❑ Overstocking & placing vaccine in high risk locations
- ❑ Using freezer storage in household combination unit
- ❑ Turning unit thermostat to coldest
- ❑ Leaving unit door open for long periods
- ❑ Continuing to use old, poorly functioning unit
- ❑ Not monitoring storage temperatures
- ❑ No emergency alternate storage unit plan




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### CDC storage equipment guidance

#### Recommendations:

- ❑ Use of stand-alone refrigerator and stand-alone freezer units if possible pharmaceutical grade (medical, purpose built)
- ❑ If you use a household combination refrigerator/freezer, only the refrigerator section should be used for vaccines. Do not use freezer section for frozen vaccine storage
- ❑ Avoid storage areas where vaccine can be put at risk
- ❑ Defrost cycle can cause measurable temperature increase
  - Effect is greater in household combination unit
  - Should not go over 8°C in refrigerator




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### What kind of refrigerator should I use?

Household, consumer-grade units		Pharmaceutical-grade units	
Freezerless	Dual-zone	Under-the-counter	Full-sized
			

National Institute of Standards & Technology, 2011

Dual-zone unit is acceptable for refrigerated vaccine storage only –  
 Freezer is not recommended

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### Combination Refrigerator



- ❑ Potential areas in the refrigerator section can pose a significant risk for freezing vaccine
- ❑ freezer was unable to maintain frozen vaccine storage temperatures
  - CDC does not recommend use
- ❑ Even with freezer control set to “coldest” vaccines stored inside freezer experienced thermal excursions above-15°C
- ❑ Defrost cycle caused major thermal excursions
  - Household refrigerators had possible temperature variability through out the unit.

\* Thermal Analysis of Refrigeration Systems Used for Vaccine Storage 2010

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### Household stand-alone refrigerators



- ❑ In general these units performed better than Household combination units.
- ❑ As with combination units these also tend to have temperature variability within the unit.

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### Pharmaceutical Grade Unit

- Note: Pharmaceutical Grade units can be obtained as:
  - Standalone refrigerators or Standalone Freezers
  - Combination Refrigerators and Freezer units
  - Full size or compact under/above the counter
  - May have glass doors and shelving



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### Definition of Pharmaceutical Grade Unit

AKA = Pharm Grade, Purpose Built, Laboratory Grade, or Medical Grade unit.



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### Pharmaceutical Grade Unit – Common Characteristics:

- Designed specifically for vaccine storage
- Microprocessor-based temperature control with a digital temperature sensor (thermocouple, RTD, or thermistor)
- Digital temperature display and settings
- Fan-forced air circulation – powerful fans or multiple cool air vents inside the unit promote temperature uniformity and fast temperature recovery
- Temperature alarms
- Security features (e.g., temperature set point security)
- Maintain a tightly-controlled, uniform temperature throughout the entire storage cavity – entire space is suitable for vaccine storage, no special measures required

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### Standard for Vaccine Storage Units

- Currently working to develop a new standard for vaccine Storage units
- This standard will establish minimum requirements for the materials, design, fabrication, construction, and performance of Vaccine Storage equipment.
- Units that met the standard would be identified as such




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### Vaccine Storage

Best storage practice –

- ❑ contain in original packaging
- ❑ place vaccines in center fridge space
- ❑ use designated storage trays positioned 2 to 3 inches from refrigerator walls




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### Vaccine Storage Locations

#### DUAL ZONE

DANGER! FREEZE RISK: top shelf is 2 – 5 °C colder than center of unit



1 – 2 °C warmer than center shelves. Thermally-isolated drawers are less accessible, may increase door open time

#### PHARMACEUTICAL

Avoid storing on top shelf – near cooling vent. First location to exceed max allowed temp during outages.



Many manufacturers do not recommend floor storage.

#### STANDALONE



1 – 2 °C colder than main fridge space

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### Frozen vaccine

- Frozen vaccine should be stored in plastic trays on racks or shelves in original packaging
- Although no temperature excursions occurred, in studies, vaccine placed directly on the freezer floor registered more temperature fluctuations than vaccine stored in a tray on a wire shelf

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### Temperatures in Freezers

- Factory settings or midpoint temperature settings assure appropriate frozen storage temperatures



- Ultra-low temperature laboratory freezers should not be used for frozen vaccine storage, they can achieve temperatures lower than -50°C (-58°F)
  - Household chest, household under-counter, pharmaceutical/ purpose built laboratory under-counter freezers did not reach temperatures below -50°C (-58°F)

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### Manual Defrost vs Automatic Frozen Vaccine Storage Units



- Automatic defrost cycles in stand alone pharmaceutical grade freezers did not negatively impact storage unit's ability to maintain appropriate vaccine temperature

- Manual defrost is acceptable as long as there is a back up unit to store vaccine when the unit needs to be defrosted (~1 cm of frost)
- Store vaccine in center of freezer and use supplied racks and wire shelves as top and side walls showed temperature increases during defrost cycle in testing




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### Freezers cannot maintain temperatures without power

- Without thermal ballast, many freezers will only maintain appropriate frozen storage temperatures for a short period of time
- Storing vaccines in trays and on supplied wire shelves or racks appears to provide a slight advantage during power outage situations by allowing vaccine to stay at frozen temperatures slightly longer than vaccine stored on the floor of the unit

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### Use of Thermal Ballast to Mitigate Temperature Variation in vaccine storage Unit

#### □ Use water bottles for thermal ballast in unit



- Water bottles can reduce defrost cycle impact
- Water bottles can reduce excursions caused by high frequency door open/close testing
- Can store water bottles in refrigerator and freezer



❖ Please note that some manufacturers do not recommend water bottles as thermal ballasts for certain units (pharmaceutical)

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### Equipment Key Points

- Select carefully; use properly; maintain regularly; monitor consistently
- Consult immunization program for any specific requirements
- Use Thermal Ballast when appropriate
- Plan to replace old, marginally functioning units
  - Pharmaceutical grade units tested best

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## Temperature Monitoring

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- ### Some Common Errors in Temperature Monitoring
- ❑ No one is checking temperatures on a daily basis
  - ❑ Temperature alarm has been disabled
  - ❑ Staff not trained on how to set up and read device and use data provided
  - ❑ Nothing is done about temperature excursions
  - ❑ Temperature monitoring device is not placed with vaccine
  - ❑ Device probe (sensor) is not buffered

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- ### How do I know if vaccines are being stored at correct temperatures?
- Track temperature using a reliable, accurate temperature monitoring device
- Storage unit temperature is NOT always consistent**
- ❑ Refrigeration/Freezer cycle – compressor timing
  - ❑ Air circulation patterns – spatial temperature variations
  - ❑ Use patterns – door opening, loading density, temperature set point
  - ❑ Environmental conditions – room temperature variation, power failures
  - ❑ Defrost cycle
  - ❑ Thermometer location – what are you measuring?
- National Institute of Standards & Technology 2012

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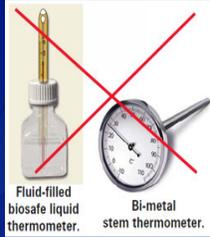
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**Which temperature monitoring device should I use?**




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**Data Loggers Provide Better Information for Storage Unit Temperature Monitoring**

- Data logger for continuous monitoring:
  - Certificate of Calibration
  - Digital temperature display
  - Detachable probe in thermal buffer



Without a continuous temperature monitoring system the likelihood of undiscovered temperature excursions occurring is high

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**CDC Temperature Monitoring Recommendations**

- Use a digital data logger
- Temperature monitoring device should be buffered
- Place in center of unit with vaccines
- Device should have valid, current Certificate of Traceability and Calibration Testing (Report of Calibration Testing)
- Read and record temperature at least 2x each workday
- Keep temperature records at least 3 years or according to state record retention requirements




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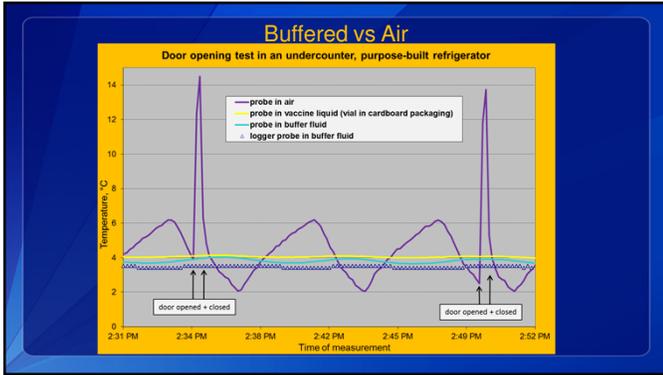
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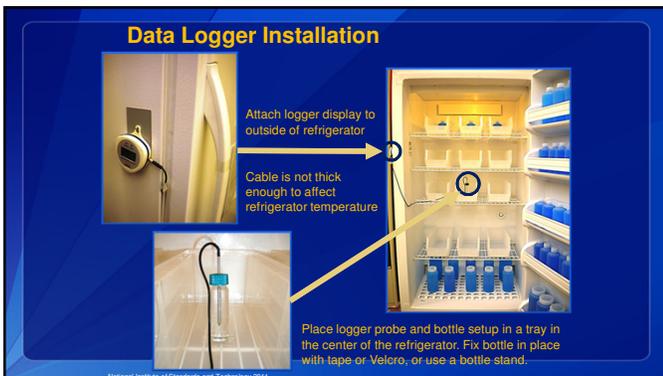
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### Even if using continuous monitoring still need to check

The reality is, we have all experienced situations in which technology has failed us

Your mom and I are going to divorce next month

what??? why! call me please?

I wrote Disney and this phone changed it. We are going to Disney.

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### Read & Record 2 x Daily

- At least 2 temperature readings each clinic day
- accompanied by the **date and time** of each reading and for accountability, the **initials of the staff/personnel** who took the temperature reading



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### Temperature Monitoring Key Points

- Use **calibrated** temperature monitoring device with Certificate of Traceability and Calibration Testing
- Calibration testing** every 1 to 2 years or manufacturer's suggested timeline. VFC providers consult immunization program
- Replace** thermometer if no longer accurate within +/-1°F (+/- .5°C)
- Use digital **data loggers**
- Have **back-up** thermometer
- Train staff** on set up, reading, and analysis of temperature data

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**HOW FAST CAN YOU BE READY?**

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### Emergency Transport Overview

- ❑ Studies found that many packing configurations froze the vaccine
- ❑ Properly packed emergency transport containers will keep the vaccine at temperatures within the appropriate range for more than 8 hours
- ❑ Qualified pack-outs and portable vaccine refrigerators are good to have if frequently encounter emergency situations

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### Guidance for Emergency Transport-- Containers

- ❑ Recommended Containers:
  - ❑ Hard sided coolers
  - ❑ Styrofoam coolers/ vaccine shipping boxes
  - ❑ Any pre-qualified cold chain transport container
  - ❑ **DO NOT USE soft-sided collapsible coolers**
    - ❑ Poorly insulated, resulting significant temperature gradients
- ❑ Should have containers that are large enough to move the provider's entire stock

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### Guidance for Emergency Transport—Coolant

- ❑ Recommended Coolant:
  - ❑ Appropriately conditioned, frozen water bottles; ice should spin in the water
  - ❑ Phase Change Material with a phase change temperature of 4 or 5 C
- ❑ **Not Recommended = frozen gel coolant packs, including those that come with vaccine shipments.**
  - ❑ They are too difficult to tell when properly conditioned and have a high risk of freezing the vaccine
- ❑ Store required quantity of coolants in the freezer, so they will be ready

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### Guidance for Emergency Transport— Temperature Monitoring

- ❑ Recommend:
  - ❑ Digital data logger with an accuracy of  $\pm 0.5$  C or better
  - ❑ Buffered probe
  - ❑ Detachable probe with vaccine, digital readout outside the container
  - ❑ Keeping the device pre-chilled (can take up to 5 hours to equilibrate)
  - ❑ Must have a current and valid certificate of calibration testing

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### LOOKING AHEAD

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### Studies Underway

- ❑ Additional quantitative information on thermal ballast
- ❑ Looking at different kinds of storage bins
- ❑ Conducting studies on methods for transporting frozen vaccine in emergency situations
- ❑ Working to develop a pack out system that can be opened and closed repeatedly

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## Future

- Working to develop voluntary, consensus standards for vaccine storage units

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## Vaccine Storage and Handling Resources

- Vaccine Storage & Handling webpage
  - [www.cdc.gov/vaccines/recs/storage/default.htm](http://www.cdc.gov/vaccines/recs/storage/default.htm)
- Vaccine Storage and Handling Toolkit
  - [www.cdc.gov/vaccines/recs/storage/toolkit/default.htm](http://www.cdc.gov/vaccines/recs/storage/toolkit/default.htm)
- Examples of vaccine labels
  - [www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-labels.pdf](http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-labels.pdf)
- You Call the Shots: Storage & Handling module
  - [www.cdc.gov/vaccines/ed/youcalltheshots.htm](http://www.cdc.gov/vaccines/ed/youcalltheshots.htm)
- The National Institute of Standards & Technology: Vaccines
  - [www.nist.gov/pml/div685/grp01/vaccines.cfm](http://www.nist.gov/pml/div685/grp01/vaccines.cfm)

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Thank you!

Questions?

Email: [IZColdChain@cdc.gov](mailto:IZColdChain@cdc.gov)

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### Type your question to the right in the chat window

After the presentation, questions may be sent to:

Molly Howell	mahowell@nd.gov
Abbi Berg	alberg@nd.gov
Lexie Barber	abarber@nd.gov
Miranda Baumgartner	mibaumgartner@nd.gov
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Dominick Fitzsimmons	ditzsimmons@nd.gov

Immunization Program : 701.328.3386 or  
toll-free 800.472.2180

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### Post-Test Information

- Post-test
  - Nurses interested in continuing education credit, visit:  
<http://www.ndhealth.gov/disease/post/default.aspx?PostID=129>
  - Successfully complete the five-question post-test to receive your certificate.
- Credit for this session is available until Tuesday, August 9, 2016.
- This presentation will be posted to our website:  
[www.ndhealth.gov/immunize](http://www.ndhealth.gov/immunize)

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