Vaccine Storage and Handling

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Missouri Webinar
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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
Topics

- **Equipment**
- **Temperature monitoring**
  - Recommendations vs requirements
  - Recent CDC updates on vaccine storage & handling
  - Best practices and supporting science
  - Common errors
- **Tools to support good storage & handling practices**
Vaccine is costly and valuable
The Price of Prevention: Vaccine Costs Are Soaring

By ELISABETH ROSENTHAL  JULY 2, 2014

A Fort Knox of Vaccines
Dr. Lindsay Irvin keeps about 20 different vaccines, worth about $34,000, in this refrigerator. This represents her current supply, which is about half the value that would be present at the start of the camp season or before school starts. A few of the most expensive and common vaccines are listed.

<table>
<thead>
<tr>
<th>DTaP</th>
<th>Prevnar 13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphtheria,</td>
<td>Pneumococcal</td>
</tr>
<tr>
<td>tetanus,</td>
<td>disease</td>
</tr>
<tr>
<td>pertussis</td>
<td>10 doses at $135</td>
</tr>
<tr>
<td>48 doses at</td>
<td></td>
</tr>
<tr>
<td>$25</td>
<td></td>
</tr>
<tr>
<td>TOP SHELF TOTAL $6,864</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Menactra</th>
<th>MMR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meningitis</td>
<td>Measles, mumps, rubella</td>
</tr>
<tr>
<td>and others</td>
<td>23 doses at $56</td>
</tr>
<tr>
<td>20 doses at</td>
<td></td>
</tr>
<tr>
<td>$112</td>
<td></td>
</tr>
<tr>
<td>2ND SHELF TOTAL $9,302</td>
<td></td>
</tr>
</tbody>
</table>

Government-Purchased Shots
Vaccines provided at no cost to doctors for children on Medicaid or who fall into certain medically underserved categories. 275 doses at $42

3RD SHELF TOTAL $11,610

FluMist
These were not used, and their value is a total loss. 90 doses at $22

4TH SHELF TOTAL $2,043

Varicella
Chickenpox. 43 doses at $94

FREEZER TOTAL $4,048
Bad Batches Of Hartford Healthcare Vaccines
Thousands in Connecticut may need a second shot of the same vaccine.
Hartford Healthcare Medical Group announced that many of its patients vaccinated for the flu, pneumonia, and other diseases over the last year and a half need to be re-vaccinated. The health network determined almost 4,000 had been injected at four of its primary care providers where the vaccines may not be any good because of refrigeration problems.

Posted 7:07 PM
July 18, 2014
FoxCT News
CDC’s Role in Vaccine Management
Why does CDC provide guidance on vaccine storage and handling?

- Assure protection of public health
- Prevent errors, need for revaccination, unnecessary waste and spoilage
- Resource for best practices and science based recommendations
- Utilize field experience and reports to improve practices
- Ensure oversight of publically funded vaccines:
  - Vaccines for Children program –
    - 44,000 providers
    - nearly $4 billion annually
CDC encourages providers to

- refer to the manufacturer’s product information/package inserts for storage and handling guidance for individual vaccines
- consult your immunization program for specific recommendations and VFC requirements on storage & handling
- move toward implementing storage & handling best practice recommendations as soon as possible
Storage Equipment
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
Recent updates in CDC storage equipment guidance

Recommendations:

- Use of stand-alone refrigerator and stand-alone freezer units and pharmaceutical grade (medical, purpose built)
- Use of refrigerator section only of household combination refrigerator/freezer
  - 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
<table>
<thead>
<tr>
<th>Household, consumer-grade units</th>
<th>Pharmaceutical-grade units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freezerless</td>
<td>Under-the-counter</td>
</tr>
<tr>
<td>Dual-zone</td>
<td>Full-sized</td>
</tr>
</tbody>
</table>

Dual-zone unit is acceptable for refrigerated vaccine storage only – do not use freezer compartment.
Combination Refrigerator NIST Studies

- 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

* Thermal Analysis of Refrigeration Systems Used for Vaccine Storage 2010
Vaccine Storage Location in Refrigerator

Best storage practice –

- contain in original packaging
- place vaccines in center fridge space
- inside designated storage trays positioned 2 to 3 inches from refrigerator walls
Vaccine Storage Methods and 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.
Manufacturer recommends no floor storage, but vial TC maintained at 2 – 8 °C throughout testing

FREEZERLESS
1 – 2 °C colder than main fridge space

Best storage practice – place vaccines in center fridge space, contained in original packaging, cardboard boxes, and/or plastic trays to minimize thermal excursions
Use of Thermal Ballast to Mitigate Temperature Variation in Stand Alone Unit

- Use water bottles for thermal ballast in stand alone unit
  - Water bottles in stand-alone refrigerator 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
Water Bottle Placement

Helps to:
- stabilize temperatures
- minimize effects of frequent door open/closing
- when placed in risky storage areas will prevent inappropriate vaccine placement.
Equipment Key Points

- Select carefully; use properly; maintain regularly; monitor consistently

- Consult immunization program for any specific requirements

- Plan to replace old, marginally functioning units
  - Pharmaceutical grade units tested best
Temperature Monitoring
Some Common Errors in Temperature Monitoring

- Temperature monitoring device is not placed with vaccine
- Device probe (sensor) is not buffered
- 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
How do I know if vaccines are being stored at correct temperatures?

Track temperature using a reliable, accurate temperature monitoring device

Refrigerator temperature is NOT always consistent

- Refrigeration 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?
<table>
<thead>
<tr>
<th>Storage Type</th>
<th>Recommended Temperature Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freezer</td>
<td>Between -58°F and +5°F (between -50°C and -15°C)</td>
</tr>
<tr>
<td>Refrigerator</td>
<td>Between 35°F and 46°F (between 2°C and 8°C)</td>
</tr>
</tbody>
</table>

Check the individual PI for recommended storage temperatures.
Which temperature monitoring device should I use?
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
- Have a back up thermometer
Data Loggers Provide Better Information for Storage Unit Temperature Monitoring

- **Data logger for continuous monitoring:**
  - Calibrated
  - Digital temperature display
  - Detachable probe in thermal buffer

- **Backup thermometer**

Without a continuous temperature monitoring system the likelihood of undiscovered temperature excursions occurring is high.
Any Temperature Monitoring Device Should be Buffered

- Should measure vaccine vial temperature, not air
- Buffered probe is a temperature probe immersed or inserted into:
  - A vial filled with liquid (glycol, ethanol, glycerin)
  - A vial filled with loose media (sand, glass beads)
  - A solid block of material (Teflon®, aluminum)
Data Logger Installation

Attach logger display to outside of refrigerator

Cable is not thick enough to affect refrigerator temperature

Place logger probe and bottle setup in a tray in the center of the refrigerator. Fix bottle in place with tape or Velcro, or use a bottle stand.
What is a “valid” and “up to date” Certificate of Calibration Testing?

CHECKLIST FOR CERTIFICATE OF CALIBRATION/VALIDATION/TESTING REPORTS

A

If Certificate Identifies an Accredited Laboratory:

☐ ILAC/MRA Signatory body accredited Laboratory

The following table lists the accredited laboratories:

<table>
<thead>
<tr>
<th>A2LA</th>
<th>L-A-B</th>
<th>ACLASS</th>
<th>IAS</th>
<th>PJLA</th>
<th>NVLAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

AND

☐ Name of Device (Optional)
☐ Model Number
☐ Serial Number
☐ Date of Calibration (Report or Issue Date)
☐ Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty = +/- 1F (0.5C)

B

If Certificate Does Not Identify an Accredited Laboratory:

☐ Name of Device (Optional)
☐ Model Number
☐ Serial Number
☐ Date of calibration testing (Report or Issue Date)
☐ Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty = +/- 1F (0.5C)
☐ Statement that calibration testing conforms to ISO 17025
Certificate Of Calibration
Digital Thermometer W Thernistor Probe
Report No. 0926

Customer: TAGE HOSPITAL
185 GRAFT RD
TOWNS, VA 00216

Make: TROL COP
Model: 41CC with P10PROBE
Serial #: 8042

Date Received: 09/26/2012
Calibration Date: 09/26/2012

Customer Specified Due Date: 09/2013
PO#: 011513
Contact: JAY BELCHER
Temperature: 21.6 TO 21.8 °C / RH% 47 TO 47
CONDITION RECEIVED: IN SPEC
Item Returned: IN TOLERANCE
Equipment Location: LAB

Calibration Location: SCH Temperature Laboratory
Notes: CALIBRATED AT CUSTOMERS SPECIFIED POINTS OF USE ONLY!

<table>
<thead>
<tr>
<th>Nominal</th>
<th>Actual (STD)</th>
<th>Measured (UUT)</th>
<th>Deviation (UUT)</th>
<th>Units</th>
<th>Tolerance (±)</th>
<th>Uncertainty (±)</th>
<th>Pass/Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.028</td>
<td>0.08</td>
<td>0.05</td>
<td>°C</td>
<td>0.20</td>
<td>0.09</td>
<td>PASS</td>
</tr>
<tr>
<td>20</td>
<td>20.017</td>
<td>20.15</td>
<td>0.13</td>
<td>°C</td>
<td>0.22</td>
<td>0.09</td>
<td>PASS</td>
</tr>
<tr>
<td>35</td>
<td>35.003</td>
<td>35.20</td>
<td>0.20</td>
<td>°C</td>
<td>0.24</td>
<td>0.09</td>
<td>PASS</td>
</tr>
</tbody>
</table>

Deviation rounded to the readability of UUT

The measurement traceability and calibration process used for conformance verification of the above instrument meets or exceeds the requirements of 17025:2005. The reported uncertainties reflect those of type B (Systematic errors associated with the standards and the procedure used), and type A (Random errors of the process). The type A and type B uncertainties where calculated in accordance with NIST technical Note 1297 using the RSS method and are reported at the coverage factor k=2 to approximate a confidence level of 95%. The date as it appears on this report does not imply that the instrument will maintain its accuracy for any given length of time unless supported with further documentation (e.g. statistical etc.) which affirms such stability and is the responsibility of the end user. Many factors may contribute to instrument in-accuracy over time such as drift, environment, transportation, frequency of use etc. The reported results reflect readings obtained at the time of test only. The reported uncertainties reflect those associated with the calibration process itself and not the instrument under test. If the UUT is a digital electronic measurement instrument add 0.6 of the least significant digit to the above stated uncertainty. The instrument is considered to be in-tolerance based on the observed results (Deviation or departure from nominal value) falling anywhere within its specified tolerance limits without consideration of applied uncertainty. This document shall not be reproduced except in full without the written approval of QC Services, Inc.

Procedure Used QCS 3015 (ORIG) (QCSSTD 030106-3)

TRACEABLE STANDARDS USED:

<table>
<thead>
<tr>
<th>Instrument</th>
<th>S/N</th>
<th>Cal Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluke 1522</td>
<td>A6C265</td>
<td>10/2012</td>
</tr>
<tr>
<td>ERTCO-EUTECHNICS</td>
<td>304526</td>
<td>01/2013</td>
</tr>
<tr>
<td>HART SCI 1502</td>
<td>885552</td>
<td>04/2013</td>
</tr>
</tbody>
</table>

Certified by: Howard
Date: 09/26/2012
Approved By: Richard
Title: Metrologist
Date: 09/26/2012

Example 1

Good Certificate
Meets all items under "A" from the Checklist
Why a Back up Thermometer?

Would you drive around continuously without a spare tire?

Should always have thermometer to assure that vaccine is stored at correct temperature

- Ideally, providers should have the back-up thermometer on site
- CDC recommends that all thermometers (including back up) used to monitor vaccine storage be data loggers
Even if using continuous monitoring still need to check

The reality is, we have all experienced situations in which technology has failed us
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
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 analyze temperature data
Resources on Proper Vaccine Storage and Handling

- **Keys to Storing and Handling Your Vaccine Supply** is a video designed to decrease vaccine storage and handling errors and preserve the nation’s vaccine supply by demonstrating to immunization providers the recommended best practices for storage and handling of vaccines. (Video is a winner of the Winter/Spring 2014 Web Health Award) NEW MAY 2014

- These storage and handling fact sheets illustrate best practices for both refrigerated and frozen vaccines. Written in plain language, they include assessments to reinforce key points. While they are CDC-developed and branded fact sheets, each contains an area where you can insert your agency’s logo.

  - [Vaccine Temperature Best Practices for Refrigerated Vaccines—Fahrenheit (F) [2 pages]]

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**Vaccine Storage and Handling**

**Recommendations and Guidelines**

**At a Glance**

Proper vaccine storage and handling practices play a very important role in protecting individuals and communities from vaccine-preventable diseases.

Vaccine quality is the shared responsibility of everyone, from the time vaccine is manufactured until it is administered.
Storage and Handling

Keys to Storing and Handling Your Vaccine Supply

Keys to Storing and Handling Your Vaccine Supply is presented as a web-on-demand video. It was posted for CE credit on April 17, 2014. CE credit is available until April 17, 2016.

**Description:** This product is designed to decrease vaccine storage and handling errors and preserve the nation’s vaccine supply by demonstrating the recommended best practices for storage and handling of vaccines.

**Audience:** Immunization Providers (Physicians, Nurses, Nurse Practitioners, Pharmacists, Physician’s Assistants, DoD Paraprofessionals, Medical Students, etc.)

**Speakers:** Donna Weaver, RN, MN, Nurse Educator, NCIRD/CDC and JoEllen Wolicki, BSN, RN, Nurse Educator, NCIRD/CDC

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**Video:** [View Video](#) (opens in new window)

**Continuing Education Info:** [Download CE factsheet](#)

The course number for this program is **WD2215**. CE expiration date: 4/17/2016

Important information for obtaining continuing education will be provided during the course; please make note of course number and verification code. After viewing the video, participants can go to CDC’s online learning system at [www.cdc.gov/tceonline/](http://www.cdc.gov/tceonline/) to register for and obtain CE credit. Consult the above CE information factsheet for specific details. General instructions are available in the [CE How to Guide](#).

**Print**

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Page last updated: May 14, 2014

Content source: [National Center for Immunization and Respiratory Diseases](#)
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)
Thank you!

Questions?

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Email: iqs4@cdc.gov