Vaccine Storage and Handling

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Disclosures

- Patricia Beckenhaupt is a federal government employee with no financial interest or conflict with the manufacturer of any product named in this presentation
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- 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.

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 v 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 New York Times

HEALTH | PAYING TILL IT HURTS : Vaccines

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.

DTaP
Diphtheria, tetanus, pertussis
48 doses at $25

Prevnar 13
Pneumococcal disease
10 doses at $135

TOP SHELF TOTAL $6,864

Menactra
Meningitis and others
20 doses at $112

MMR
Measles, mumps, rubella
23 doses at $56

2ND SHELF TOTAL $9,302

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

The New York Times – July 2, 2014

Article by Elisabeth Rosenthal

Photo by Ben Sklar for The New York Times

About $34K worth of vaccine

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

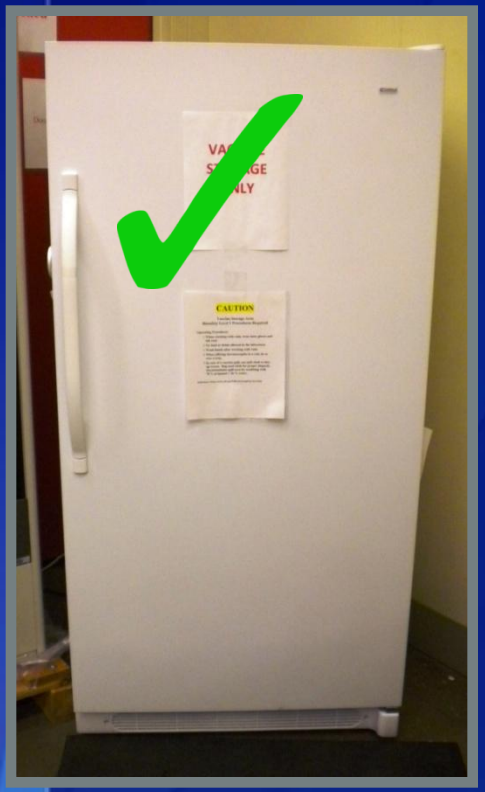
Recent updates in CDC storage equipment guidance

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

What kind of refrigerator should I use?

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



Dual-zone unit is acceptable for refrigerated vaccine storage only – do not use freezer compartment

National Institute of Standards & Technology, 2011

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

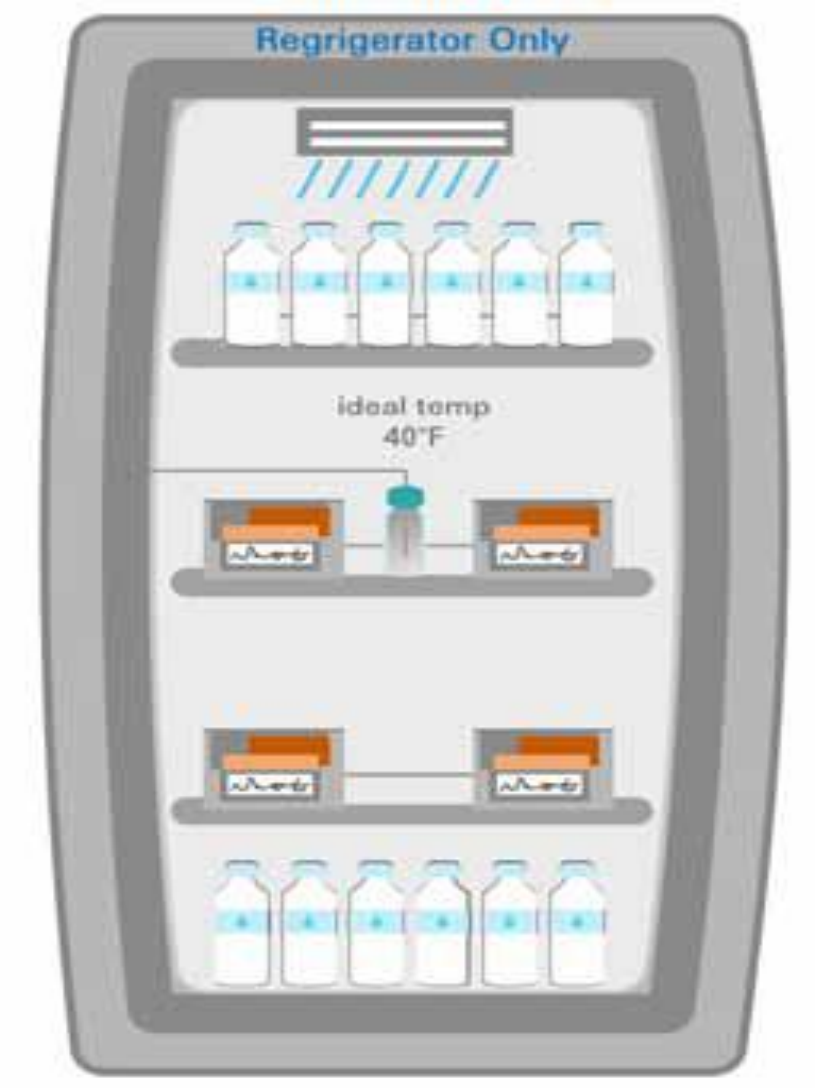
1 – 2 °C colder than main fridge space

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?

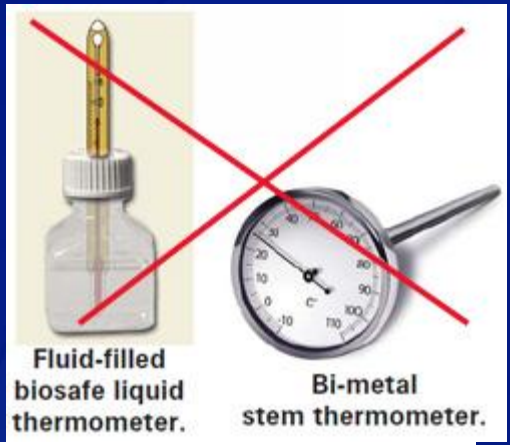
National Institute of Standards & Technology 2012

Refrigerated Vaccine Recommended Storage Temperatures

Freezer	Between -58˚F and +5˚F (between -50˚C and -15˚C)
Refrigerator	Between 35˚F and 46˚F (between 2˚C and 8˚C)

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

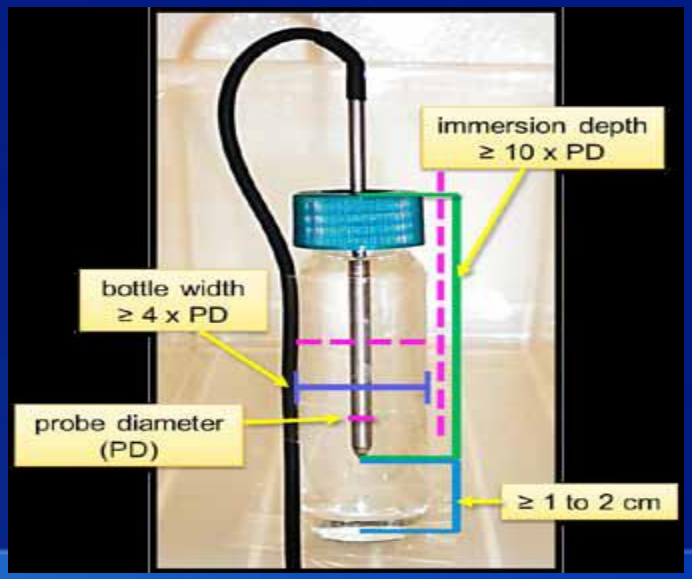
Data Loggers Provide Better Information for Storage Unit Temperature Monitoring

- 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

A2LA	L-A-B	ACLASS	IAS	PJLA	NVLAP

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 Thermistor Probe

Report No. 0926

ACCREDITED

Calibration Laboratory 23

Customer: TAGE HOSPITAL
185 GRAFT RD
TOWNS, VA 00216

Make: TROL COP

Model: 41CC with P10 PROBE

Serial # 8042

/Range: -200 TO 800 °C IN 0.01 °C DIVISIONS

Accuracy/Tolerance : +/- 0.1 % + 0.2 °C BELOW 200 °C

Item Received : IN TOLERANCE

Calibration Location: SCH Temperature Laboratory

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

Notes : CALIBRATED AT CUSTOMERS SPECIFIED POINTS OF USE ONLY !

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

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 due 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 Q.C. Services, Inc.

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

TRACEABLE STANDARDS USED:

Fluke 1522 S/N: A6C265	Cal Due : 10/2012	
ERTCO-EUTECHNICS S/N : 304526	Cal Due : 01/2013	X
HART SCI 1502 S/N 8B552	Cal Due : 04/2013	X

Certified by: Howard Richard Date: 09/26/2012

Approved By: Title: Metrologist Date: 09/26/

Example 1

Good Certificate

Meets all items under "A" from the Checklist

Why a Back up Thermometer?

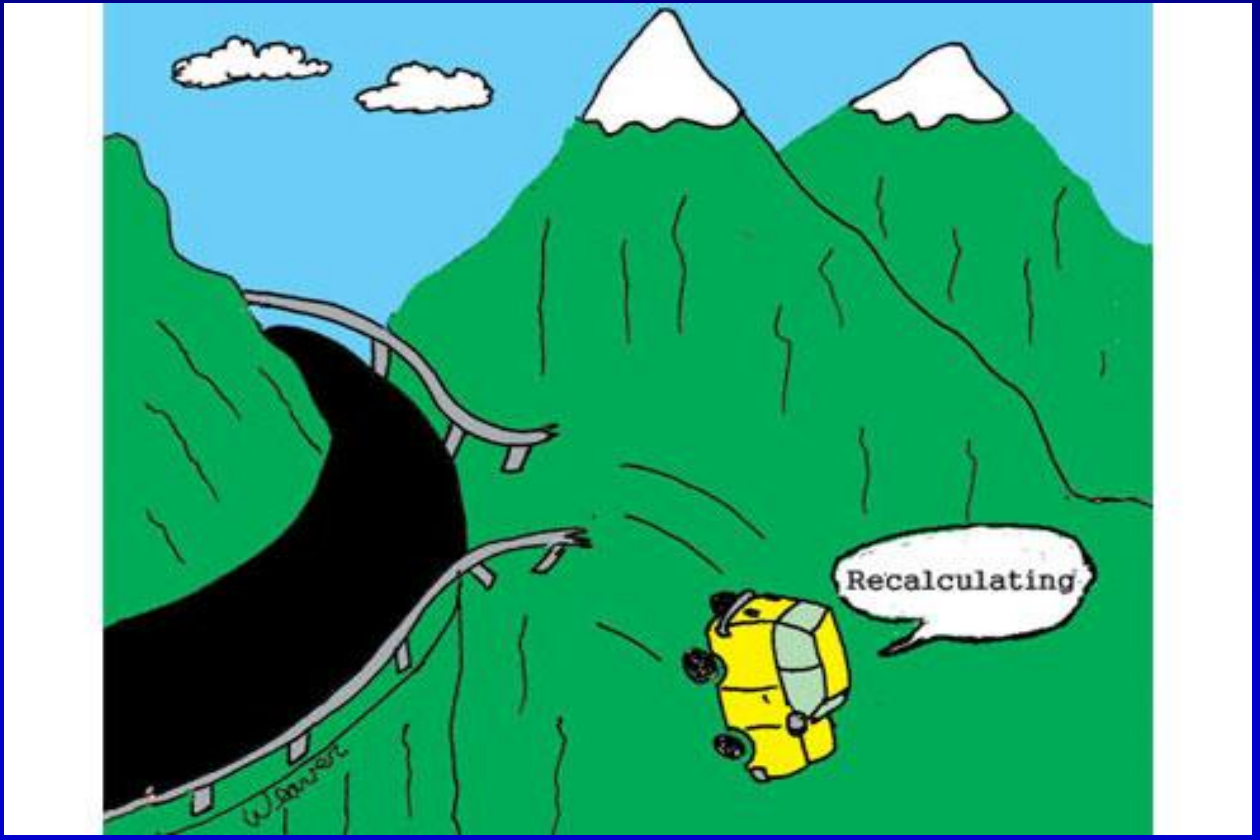
Would you drive around continuously without a spare tire?

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

http://www.cdc.gov/vaccines/recs/storage/default.htm

Vaccines: Recs/Stor...

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Centers for Disease Control and Prevention

CDC 24/7: Saving Lives. Protecting People.™

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All CDC Topics

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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.

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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CDC Medscape from WebMD

Running Time: 5:07 mins
Date Released: 06/27/2011
CDC Commentary - Make No Mistake: Vaccine Administration, Storage, and Handling
Dr. Andrew Kroger offers 7 steps to help prevent vaccine administration errors and vaccine storage and handling errors.

Storage and Handling

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Vaccine Storage and Handling
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For Questions About Vaccines Contact Us

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 to immunization providers 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

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/ 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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File Formats Help:

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Centers for Disease Control and Prevention 1600 Clifton Rd. Atlanta, GA 30333, USA
800-CDC-INFO (800-232-4636) TTY: (888) 232-6348 - Contact CDC-INFO

12:49 PM
8/12/2014

Vaccine Storage and Handling Resources

- **Vaccine Storage & Handling webpage**
  - www.cdc.gov/vaccines/recs/storage/default.htm
- **Vaccine Storage and Handling Toolkit**
  - www.cdc.gov/vaccines/recs/storage/toolkit/default.htm
- **Examples of vaccine labels**
  - 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
- **The National Institute of Standards & Technology: Vaccines**
  - www.nist.gov/pml/div685/grp01/vaccines.cfm

Thank you!

Questions?

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