


Vaccine Storage & Handling


Presented by Erica Davis
November 2, 2016



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WHY?

- Improper storage and handling can damage fragile and expensive vaccines.
- Once viability is lost, it cannot be regained.
- Vaccine that was improperly stored or handled may not protect patients from disease.
- Children deserve fully-potent vaccines.




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Inactivated Vaccines

(Refrigerator)

- Adjuvants are added to vaccines to enhance the immune response to an antigen. When temperatures are **too cold (32°F or below)**, the antigen and adjuvant bond is **immediately** and irreversibly broken*.
- Temperatures that are **too warm (above 46°F)** cause **gradual** damage to the vaccines.



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*W. Kurzatkowski et al. Structural damages in asorbed vaccines affected by freezing. Biologicals (2013), 41: 71-76.

4

Live Vaccines

(Freezer)

- Temperatures that are **too warm (above 5°F)** cause damage that is **rapid** or “quick”.
- Varicella does not tolerate any heat.




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WHAT?

- Proper Storage Units
- Data Logging Thermometers
- Accessories



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Storage Units



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Storage Units

- Must be large enough to hold your largest inventory of vaccines without excessive crowding or obstruction of air flow
- Placed in a well-ventilated room
- Plugged directly into wall outlet (no extension cords or power strips)



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Thermometers

- Required to have a digital data logging thermometer with a valid and current certificate of calibration in each vaccine storage unit
- Main readout unit (temperature display) on outside of storage unit
- External, detachable temperature probe encased in biosafe glycol
- One backup thermometer available on site (but not in storage unit) in case primary thermometer malfunctions or needs calibration




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Thermometers

Detachable probe in glycol



Temperature display kept on outside of unit



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Thermometers

Detachable temperature probe

- To be kept in liquid-filled bottle
- Cable length > 1 m preferred

Continuous temp monitoring

- At least one reading/15 min

Memory storage : 4000 readings

- ~ 39 days recording at one rdg/15 mins
- Device stops recording when memory is full, reset after data download

Operating range: -20 °C to 40 °C

- (for refrigerated vaccine monitoring)

Uncertainty: ± 0.5 °C

- In the range of -1 °C to 15 °C
- Often listed as device "accuracy"

Resolution: ± 0.1 °C

Battery life: 6 months minimum

Integrated Liquid Crystal Display (LCD) with minimum:


- Last measured temp displayed in °C or °F
- Hi/Lo alarm status indicator

Alarm capabilities

- Factory set, end-user adjustable
- Alarm activation at 2 °C (low) and 8 °C (high)

Download/ archival software


- Download data via standard computer ports (e.g., USB)
- Graphical presentation of date/time/temperature data
- Display alarm configuration details and total time outside high/low thresholds
- Data export capability (e.g., csv, Excel, txt)



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Water Bottles



Place water bottles in the refrigerator and freezer where vaccine storage is prohibited:

- Under cooling vents
- Refrigerator door
- Floor level




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Storage Baskets

If your storage unit has glass shelves, you will need plastic mesh storage baskets to keep vaccines from getting too cold.





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Stickers

“Do Not Unplug” stickers should be placed on each storage unit, by the outlets, and notification placed on the circuit breaker.





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HOW?


- Trained Vaccine Coordinators
- Appropriate Storage
- Temperature Monitoring
- Written Plan


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Trained Staff

- Each VFC site needs ONE Vaccine Coordinator and at least ONE Back-up Coordinator
- CDC requires annual training on vaccine storage and handling for vaccine coordinators
- All staff should be trained on basic storage and handling



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VACCINE OVERSIGHT

- Oversee proper receipt and storage of vaccine shipments
- Oversee proper vaccine transport
- Ensure current Vaccine Information Statement is being used
- Maintain all appropriate storage and handling documentation as set by the Centers for Disease Control and Prevention (CDC)
- Maintain storage equipment in compliance with CDC standards and manufacturer's guidelines
- Maintain records, including Vaccines for Children (VFC) program documentation
- Report and return vaccine within 30 days of expiration or spoilage
- Keep staff trained on basic vaccine storage and handling practices and the importance of handling vaccines properly on an annual basis and when new staff is hired

VACCINE STORAGE

- Store and label vaccines in the storage unit(s) following CDC guidelines
- Keep vaccines organized within the storage unit(s) and inspect storage unit(s) daily
- Check stock weekly and rotate when a shipment arrives so vaccine closest to its expiration date will be used first
- Promptly remove expired vaccine from the storage unit(s) so it is not administered to patients
- Work with the Kentucky Immunization Program to transfer vaccines close to expiration

TEMPERATURE MONITORING

- Keep a digital data logging thermometer with a current certificate of calibration for every vaccine storage unit
- Read and document storage unit temperatures a minimum of twice per workday (at the beginning and end of the workday)
- Read and document storage unit minimum and maximum temperatures each workday morning
- Download, review and send to the KY Immunization Program stored temperature monitoring data at least monthly
- Respond to any possible temperature excursions using the emergency protocol

INVENTORY MANAGEMENT

- Place vaccine orders, assuring an adequate stock of vaccine without under or overstocking
- Label your private stock separately from your public stock
- Maintain a regular schedule to count vaccine inventory at least once a month
- Complete Returns and Reconciliations in the Kentucky Immunization Registry as needed




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Appropriate Storage

- ✓ Store only vaccine in vaccine storage units.
- ✓ Keep refrigerator temperatures between 35°F to 46°F. Aim for 40°F.
- ✓ Keep freezer temperatures at 5°F or below.
- ✓ Keep vaccines in their original boxes until you are ready to use them. Some vaccines are sensitive to UV light (i.e. HPV, MMR, MMRV, rotavirus, varicella, and zoster vaccines).




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Appropriate Storage

- ✓ Separate the VFC vaccine supply from privately purchased vaccine.
- ✓ Place vaccine in breathable plastic mesh baskets and clearly label baskets by type of vaccine.
- ✓ Keep baskets 2-3 inches from walls and other baskets.




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Appropriate Storage

- ✓ Place vaccines with shorter expiration dates to front of shelf.
- ✓ Transfer short-dated vaccine.
 - ✓ If you have vaccine that will expire in 3 months or less, contact KIP to see if other VFC providers can use the vaccine prior to the expiration date.




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Temperature Monitoring

- Post temp log on door of every storage unit
- Document the min/max temp daily
- Record the temperature twice daily
 - In morning upon arrival to clinic and evening upon clinic closure
 - Regardless of type of thermometer
 - If a reading is missed, leave the log space empty



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Temperature Monitoring

REFRIGERATED VACCINE TEMPERATURE LOG
DAYS 1-15

°F

Instructions: Place a "✓" in the box that corresponds with the temperature. If the temperature is not on the grid, write the actual temperature in the "other" box. Record the minimum and maximum temperatures in the morning. If any temps are out of range, document action taken on Vaccine Storage and Handling Incident Report.

Month/Year: _____ Refrigerator Model/Location: _____
VFC PIN: _____

This log is required for KIP/VFC vaccines.

Day	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX
Staff initials																														
Time																														
other	TOO WARM!																													
49																														
48																														
47																														
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42																														
41																														
40																														
39																														
38																														
37																														
36																														
35																														
34	TOO COLD!																													
33																														
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other																														

Date of inspection of expiration dates and inventory rotation: Week One _____ Week Two _____
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Temperature Monitoring

Record the min/max temp from previous 24 hours

Staff initial when documenting temps

Write in the time the temp was checked

REFRIGERATED VACCINE TEMPERATURE LOG
DAYS 1-15

°F

Instructions: Place a "✓" in the box that corresponds with the temperature. If the temperature is not on the grid, write the actual temperature in the "other" box. Record the minimum and maximum temperatures in the morning. If any temps are out of range, document action taken on Vaccine Storage and Handling Incident Report.

Month/Year: _____ Refrigerator Model/Location: _____
VFC PIN: _____

This log is required for KIP/VFC vaccines.

Day	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX
Staff initials																														
Time																														
other																														

Date of inspection of expiration dates and inventory rotation: Week One _____ Week Two _____
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Temperature Monitoring

REFRIGERATED VACCINE TEMPERATURE LOG
DAYS 1-15

°F

Instructions: Place a "2" in the box that corresponds with the temperature. If the temperature is not on the grid, write the actual temperature in the "other" box. Record the minimum and maximum temperatures in the morning. If any temps are out of range, document action taken on Vaccine Storage and Handling Incident Report. Keep this log for 3 years.

Month/Year: _____ Refrigerator Mode/Location: _____
VFC PIN: _____

This log is required for KIP/VFC vaccines.

Day	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN	MAX
Staff Initials																														
Time																														
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other																														

TOO WARM!

TOO COLD!

TAKE IMMEDIATE ACTION
if too warm or too cold!

Date of inspection of expiration dates and inventory rotation: Week One _____ Week Two _____
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In the event of a temperature excursion:

- Isolate affected vaccine vials and mark them as "DO NOT USE"
- Store affected vaccines under appropriate conditions until viability determined
 - Either your original storage unit if temps are in range or in your approved back-up location
- Download data from LogTag
- Contact KIP (if you've submitted a recent order)
- Contact vaccine manufacturers
- Document all actions taken on the Storage and Handling Incident Report and submit to KIP

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Temperature Monitoring

VACCINE STORAGE & HANDLING INCIDENT REPORT

Provider Name:		VFC PIN:	Person Completing Report:	
Affected storage unit: <input type="checkbox"/> Refrigerator <input type="checkbox"/> Freezer	Water bottles in use: <input type="checkbox"/> Yes <input type="checkbox"/> No	Date & Time of Event:	Duration: hours, minutes	
At the time the problem was discovered, what was the storage unit temperature?			Room temperature?	
Description of Event:				
Corrective Action(s) Taken:				State Immunization Program Notified: <input type="checkbox"/> Yes <input type="checkbox"/> No
Vaccine manufacturers notified: <input type="checkbox"/> Yes <input type="checkbox"/> No				
Results	Manufacturer Information		Vaccine Status	
	Manufacturer:	Case ID:	<input type="checkbox"/> viable <input type="checkbox"/> not viable	
	Contact Name:		<input type="checkbox"/> viable until new expiration date:	
	Manufacturer:	Case ID:	<input type="checkbox"/> viable <input type="checkbox"/> not viable	
	Contact Name:		<input type="checkbox"/> viable until new expiration date:	
	Manufacturer:	Case ID:	<input type="checkbox"/> viable <input type="checkbox"/> not viable	
Contact Name:		<input type="checkbox"/> viable until new expiration date:		
Manufacturer:	Case ID:	<input type="checkbox"/> viable <input type="checkbox"/> not viable		
Contact Name:		<input type="checkbox"/> viable until new expiration date:		
Additional Comments:				

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Temperature Monitoring

- Keep all temperature logs and incident reports for 3 years
 - *This includes the 1st page of DDL reports.
- Have readily available for field staff during site visits




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Vaccine Management Plan

- MUST BE REVIEWED/UPDATED AND SIGNED ANNUALLY
- Should contain the following:
 - Primary and alternate (back-up) vaccine coordinators
 - Proper vaccine storage and handling practices
 - Vaccine shipping and receiving procedures
 - Vaccine emergency plan
 - Vaccine ordering procedures
 - Inventory control (e.g. stock rotation)
 - Vaccine wastage
 - Staff training and documentation of training on vaccine storage and handling



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Questions ?

Erica Davis
Erica.Davis@ky.gov
(502) 564-4478 ext. 4269
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