Vaccine Storage and Handling for the Immunization Provider: 2013 Updates
Immunization Program
March 2013
Objectives

• Define and discuss steps to maintain the cold chain
• Summarize Office of Inspector General report on VFC vaccine storage and handling
• Discuss new CDC storage and handling expectations
• List and discuss the components of an effective vaccine management protocol
• Describe proper maintenance and monitoring of vaccine
• Describe procedures to safeguard vaccine supply in the event of an emergency situation
Defining the Cold Chain

- The cold chain is the continual process of assuring that vaccine is stored properly
- The maintenance of the cold chain begins from the time a vaccine is manufactured and ends with the administration to a patient
- The cold chain must be maintained from
  - Manufacturer to distributor
  - Distributor to provider office
  - Provider office to patient
Why Maintain the Cold Chain?

- Vaccines are fragile
- Vaccine potency can be reduced if recommended storage guidelines are not followed
- Protection from vaccine-preventable diseases cannot be guaranteed if recommended storage guidelines are not followed
- Vaccines are costly to replace
Steps to Help Maintain the Cold Chain

• Develop a written vaccine management protocol
• Select one person as the practice Vaccine Management Coordinator
• Designate a secondary or back-up person
• Allow only necessary personnel access to vaccine supply
• Train all personnel on proper vaccine management procedures
• Post the written protocol in a location that can be accessed in an emergency situation
Office of Inspector General Report


• OIG determined that the majority of storage temperatures that were independently measured during a 2 week period were within the required ranges.

• OIG also found that VFC vaccines stored by 76 percent of the 45 selected providers were exposed to inappropriate temperatures for at least 5 cumulative hours during that period.
OIG Recommendations

As a result of the OIG report, HHS recommended that CDC continue to work with grantees and providers to ensure that:

• VFC vaccines are stored according to requirements;
• Expired vaccines are identified and separated from non-expired vaccines;
• Grantees better manage providers' vaccine inventories;
• Grantees meet oversight requirements.

CDC concurred with all four of the OIG recommendations.
CDC Response

As a result of the OIG report, CDC has:

• Created the Vaccine Storage and Handling Toolkit as a resource for all vaccine providers
• Updated VFC protocols and requirements for all VFC providers to assure vaccines are managed effectively
• Encouraged heightened provider awareness of these storage and handling issues through increased education and partnerships among health care providers who administer vaccines
• Increased VFC provider education requirements
Storage and Handling Toolkit

135 page document available for download at:

http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf
Changes in CDC Expectations

- Recommendations vs. Requirements
- New Requirements:
  - VFC provider education
    - Site visit
    - Other
  - Unannounced storage and handling visits or “Spot Checks”
  - Primary and secondary vaccine coordinators
  - Wasted/expired vaccine return within 6 months
Changes in CDC Expectations

• New Recommendations
  • Use of a biosafe glycol-encased probe or a similar temperature buffered; digital, continuous reading/recording data loggers with detachable probes
  • Use of stand-alone refrigerator and stand-alone freezer units suitable for vaccine storage rather than combination (refrigerator+freezer) or other units not designed for storing fragile biologics, such as vaccines
  • Discontinuing use of dorm-style or bar-style refrigerator/freezers for ANY vaccine storage, even temporary storage (already a requirement in Ohio)
  • Weekly review of vaccine expiration dates and rotation of vaccine stock
Developing an Effective Vaccine Management Protocol

• Should be in written format
• Should be specific to each practice
• Should be comprehensive and address all facets of vaccine management
• Should begin with procedures for the acceptance of a vaccine shipment and end with confirmation that viable vaccine was administered to a patient
• Should be updated and reviewed annually
A Comprehensive Protocol Should Include:

• The name of both a primary and secondary vaccine coordinator and a list of their responsibilities
• A description of acceptable storage units and maintenance procedures
• Procedures for receiving vaccine shipments
• Specific manufacturer storage recommendations for each vaccine stored by practice
Comprehensive Protocol (con’t.)

• Procedures for temperature monitoring
• Information regarding routine inventory control and vaccine ordering
• Specific measures to handle emergency situations and potential vaccine wastage
• Procedures for transporting vaccine
• Policies for vaccine administration
Primary & Secondary Vaccine Coordinators

- Should be named in the vaccine management protocol
- Should be updated if staff changes are made
- Should be knowledgeable regarding all aspects of vaccine management
- Should be able to train new staff
Responsibilities of Primary Coordinator

• Check in new shipments to guarantee accuracy and notify appropriate agency if there has been a breach in the cold chain

• Monitor and record temperatures or review temperatures recorded by delegated staff

• Conduct routine inventory and place appropriate vaccine orders
Responsibilities of Primary Coordinator (cont’d)

- Schedule maintenance checks on both storage equipment and monitoring devices
- Supervise transport of short-dated vaccine
- Implement protocol during an emergency situation
- Train all new staff on proper vaccine management
Who is Responsible for Proper Vaccine Storage and Handling?

Everyone!
Proper Vaccine Storage

For Refrigerated Vaccine:
- Store at 35°- 46°F (2°- 8°C)
- Do not freeze

For Vaccine Stored in Freezer:
- Store at ≤ 5°F (≤ -15°C) or colder
- MMR can be stored in the freezer

For Diluent:
- Store per manufacturer recommendations
- Store refrigerated diluent with corresponding vaccine
- Do not freeze
You May Need a New Storage Unit if:

- Your current unit is 10 years old or older
- Your vaccine usage is increasing
- The seals on the current unit are loose or leaking air
- Maintenance calls on current unit are increasing
- You view ice or water in your unit
- Your recorded temperatures have become unstable
Proper Vaccine Storage

For All Vaccines:

• Keep written manufacturer recommendations for each vaccine
• Store away from walls and air vents inside storage unit
• Do not remove from the original packaging
• Do not store in closed containers
• Whole boxes may be stored in slotted or solid-sided, labeled bins
Proper Vaccine Storage (con’t.)

For All Vaccines (cont.):

• Some vaccines should not be exposed to light (i.e., MMR, HPV, etc.)
• Store vaccines with similar packaging apart from each other
• Label and separate privately purchased and state-supplied vaccine
• Do not store in doors, drawers or vegetable bins
Additional Safety Measures for Vaccine Storage

- Label refrigerator, freezer and outlet with “DO NOT UNPLUG” signs
- Label circuit breaker with a “DO NOT UNPLUG” sign
- Plug unit directly into wall outlet (Avoid power strips)
- Use plug guard
- Place water bottles in doors or vegetable bins in refrigerator
- Place icepacks in freezer
- Have a copy of the storage and handling protocol in close proximity
Temperature Monitoring

• Temperatures for both the refrigerator and freezer must be observed and recorded twice per day each day the office is open
• Temperatures must be recorded twice daily even if the practice has a continuous, automatic recording device
• Only temperature logs that indicate the allowable minimum and maximum ranges should be used
• Temperature logs should be saved for a period of 3 years
• Temperature logs should be printed with an emergency contact number
# Temperature Log Example

<table>
<thead>
<tr>
<th>REFRIGERATOR/FREEZER TEMPERATURE LOG (FAHRENHEIT)</th>
<th>Month: _________ Year: ________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day of the month</td>
<td>1</td>
</tr>
<tr>
<td>------------------</td>
<td>---</td>
</tr>
<tr>
<td>Staff initials</td>
<td></td>
</tr>
</tbody>
</table>

**IF RED LED→**

**F. Temp.**

| AM | AM | AM | AM | AM | AM | PM | PM | PM | PM | PM | PM | PM | PM | PM | PM | PM |
|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| 49+| 48+| 47+| 46+| 45+| 44+| 43+| 42+| 41+| 40+ | 39+ | 38+ | 37+ | 36+ | 35+ | 34+ |

**IMMEDIATELY IMPLEMENT YOUR EMERGENCY MANAGEMENT PLAN**

**IF RED LED→**

**F. Temp.**

| AM | AM | AM | AM | AM | AM | AM | AM | AM | AM | AM | AM | AM | AM | AM | AM | AM | AM |
|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| 9+ | 8+ | 7+ | 6+ | 5+ | 4+ | 3+ | 2+ | 1+ | 0+ | < 0 |    |    |    |    |    |    |

**IMMEDIATELY IMPLEMENT YOUR EMERGENCY MANAGEMENT PLAN**

**IF RED LED→**

**TARGET**

**TOO COLD**

**TOO WARM**

***IF YOU INDICATE THAT THE RED LED HAS BEEN ILLUMINATED OR IS FLASHING, PLEASE CONTACT YOUR OHC CONSULTANT ASAP! 1 (800) 252-0546***

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Out-of Range Temperatures

- Document out-of-range temperature
- Keep vaccine stored in appropriate storage unit if current temperature is in range
- Take steps to storage temperatures back in range through thermostat adjustment or move vaccines to back up location and document all actions taken
- Mark vaccine as “DO NOT USE”
- Contact ODH Immunization Program at 1-800-282-0546
- Contact vaccine manufacturers and request written responses
- Call ODH immediately if the red LED light blinks on the data logger
Emergency Situations

Can be planned for in advance are usually related to:

- Power outages or interruption of supply
- Natural disasters
- Storage equipment malfunctions or failures
- Substantial temperature variance with no identifiable explanation

Need to be reviewed case-by-case to determine appropriate action.
Emergency Preparedness Plans

• Should be in written format and provided to all staff
• Should contain contact information for:
  – Primary and Secondary Vaccine Coordinators
  – Other Personnel to implement plan
  – Local power company
  – Emergency vaccine storage site
  – ODH Immunization Program
Emergency Response Documents

Emergency Management Plan:
http://www.odh.ohio.gov/~/media/ODH/ASSETS/Files/dis/immunizations/vfcemergencymanagementplan.ashx

Emergency Response Worksheet:
http://www.odh.ohio.gov/~/media/ODH/ASSETS/Files/dis/immunizations/vfcvaccineemergencyresponseworksheet.ashx
When to Move Vaccine

Vaccine should be moved to an established emergency location if:

- Power will be interrupted for more than 2 hours
- Storage unit is malfunctioning
- Storage unit is not working
- Other situations in which temperature cannot be quickly stabilized
Transporting Varicella in an Emergency Situation

- Do not transport using refrozen shipping packs from original Merck shipment
- Do not transport using dry ice
- Thermometer should be used to monitor temperature during transport
- Contact both ODH Immunization Program and the vaccine manufacturer if temperature does not remain in the recommended range during transport
Transporting Refrigerated Vaccines

- Maintain the cold chain at all times
- Transport vaccine in a styrofoam or other approved container
- Transport with ice or cold packs
- Transport diluent with appropriate vaccine
- Monitor temperature with thermometer
- Contact both ODH Immunization Program and the vaccine manufacturer if temperature does not remain in the recommended range during transport
Take Home Messages

• Always Maintain the Cold Chain
• Develop and Utilize a Comprehensive Storage and Handling Protocol based on the CDC’s Vaccine Management Tool Kit
• Train All New Staff
• Take Immediate Action in an Emergency Situation
Resource Information

ODH Immunization Program

- Telephone 1-800-282-0546
- Fax 1-614-728-4279

National Immunization Program

- Telephone 1-800-CDC-INFO
- Email nipinfo@cdc.gov
- Website www.cdc.gov/nip