



Vaccine Storage and Handling Temperature Excursions

MIAP

Skills Building Conference

October 11, 2012



Disclosures

- I, Bob Morrison, have been asked to disclose any significant relationships with commercial entities that are either providing financial support for this program or whose products or services are mentioned during my presentation. I have no relationships to disclose.
- I will discuss the use of vaccines in a manner not approved by the U.S. Food and Drug Administration, but in accordance with ACIP recommendations.



Goals and Objectives

- Know what to do when the refrigerator or freezer temperature is out of range, or has been out of range
- Have a written Vaccine Management Standard Operating Procedure (SOP) that includes a plan for back up vaccine storage



Vaccine Storage Units

- CDC recommends stand alone refrigerators and freezers for vaccine storage.
- If office space is not an issue, select individual units.
- Refrigerator/freezer combinations have only one compressor. Temperatures for each compartment are achieved by directing the air flow from the compressor.
- For combination units, make sure there are separate controls for refrigerator and freezer.
- Dorm-style units are not acceptable units for vaccine storage.



Temperature Recording

- It is very important to record refrigerator and freezer temperatures at least twice daily.
- Make sure you are recording an accurate temperature by referring to the document: *Temperature Recording – Helpful Hints* located on the DPH web site www.mass.gov/dph/imm and selecting Vaccine Management.



Temperature Adjustment

- Never adjust the temperature control with vaccine in the refrigerator or freezer.
 - There is no accurate temperature setting.
 - Adjusting the temperature too much can destroy the vaccine.
- Remove vaccine to another unit before adjusting the temperature control.
- Wait until you have successive readings one hour apart before returning vaccine to the unit.



Case Study – Hospital Pharmacy

What Not To Do

- Departmental Unit refrigerator was recorded as -5°C . Called Pharmacy Department.
- Pharmacy adjusted temperature control to a warmer position – next morning temperature was at 10°C .
- Pharmacy adjusted temperature control to a colder setting – that afternoon temperature was at -1°C .



Case Study – Hospital Pharmacy cont.

- Pharmacy adjusted temperature control to a warmer setting – temperature recorded at 6⁰C that afternoon.
 - Vaccine Unit was never contacted when the temperature was recorded as out of range.
 - Departmental Unit continued to vaccinate newborns with hepatitis B vaccine.



Case Study – Hospital Pharmacy cont.

- DPH staff discovered temperature excursion during a site visit more than 2 months after the incident.
- Potentially, as many as 150 infants received damaged vaccine.
- Pediatricians were contacted and advised of the invalid birth dose, and the need for revaccination.



Vaccine Management

Standard Operating Procedures (SOP)

- Providers are required to have written procedures for Vaccine Management.
- A template SOP is available on our web site: www.state.ma.us/dph/imm and selecting Vaccine Management
- This document includes procedures for vaccine relocation in the event of a power outage or equipment failure.

Vaccine Management SOP

cont.



- Don't wait until there is a problem to develop a plan for back up vaccine storage (2 options)
- Make sure all office staff are informed
- Post the SOP in an area that is accessible to everyone (on the refrigerator) in case you are not there.



Transporting Vaccines

- Refrigerated vaccines should be transported to and from a back up facility in a cooler using refrigerated cold packs (not frozen).
- Frozen vaccines (Varivax®[®], ProQuad®[®], and Zostavax®[®]) should be transported to and from a back up facility in a separate cooler using frozen cold packs.



Temperature Control

- If you lose power, and the refrigerator temperature goes above the recommended range, let the compressor do the work.
 - Do not adjust the temperature control.
 - Adjusting the temperature control to the coldest point will not make the refrigerator get colder faster!

Vaccine Restitution – Provider Negligence



- Adjusting the temperature control with the vaccines in the unit resulting in damaged vaccine is provider negligence.
- Failure to act according to their vaccine storage back up plan resulting in damaged vaccine is provider negligence.
- Each of these incidents could result in the provider making restitution for damaged doses.



Vaccine Storage Questions

- Vaccine Management Direct Line
 - (617) 983-6828
- Always call the Vaccine Management Unit to determine if vaccine is viable after a temperature excursion
- Always consult with the Vaccine Management Unit before removing improperly stored vaccine from the storage unit