DoD Seasonal Influenza Vaccination Training

Cold Chain Management of the Influenza Vaccine

2010-11 Influenza Season

UNCLASSIFIED
PURPOSE: Discuss, identify, and apply cold chain management principles to the seasonal influenza vaccine

- Seasonal influenza vaccine storage requirements
- Cold chain management principles
- Transporting vaccines
- Compromised vaccine procedures
By the end of this presentation, you should be able to:

- Identify the storage requirements for the 2010-11 seasonal influenza vaccine
- Implement cold chain management principles to protect your vaccine
- Apply protocols to maintain proper temperature when transporting the influenza vaccine to offsite locations
- Outline procedures for management of potentially temperature compromised vaccine
What is Cold Chain Management?

**HEAT** = Reduced Potency

**COLD**

- **Components**
  - Transportation and storage equipment
  - Trained personnel
  - Efficient management procedures
Why Cold Chain Management is Important

Routine
Systematic
Process

Primary
Backup

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Temperatures for Influenza Vaccine

Fluzone  Afluria  FluMist

Refrigerated Storage for all Influenza Vaccine - Thermostatically controlled from 2 - 8°C or 35 - 46°F

Intranasal (Live attenuated) FluMist Trivalent Vaccine

• Manufactured by MedImmune
• 0.2mL pre-filled single use sprayer
• Storage: shipped frozen and then stored in refrigerator
• Do not refreeze!!
• Use before the expiration date
Injectable Influenza Vaccines

Fluzone
- Manufactured by Sanofi Pasteur
  - 5 mL multi-dose vial
  - 0.25 mL pre-filled syringe (pink plunger rod)
- Storage: stored in refrigerator
- Used by expiration date on package
- Do not freeze

Afluria
- Manufactured by CSL Biotherapies
  - 0.5 mL pre-filled syringe
- Storage: stored in refrigerator
- Protect from light
- Do not freeze
2 - 8 degrees Celsius or 35 - 46 degrees Fahrenheit

Do not store food in the same unit in which the vaccines are stored.

- Refrigerator Requirements
  - Large volume – pharmacy grade
  - Separate refrigerator/freezer compartments
  - Dual thermostats
  - Frost free
  - Tightly sealed doors
  - No dormitory style

- Storage Requirements
  - Certified calibrated thermometer
  - Storage of vaccines only
  - Adequate storage space

- Anticipate Failures
  - Backup plans, equipment
You must store the vaccine correctly!

- Vaccine should be stored in the middle of the compartment.
- Vaccine should be clearly labeled.
Certified Calibrated Thermometers

- Bio-safe – Reflect refrigerator temps more accurately
- Continuous – monitors temp range and duration
- Minimum-Maximum – will monitor the range
**Temperature Log for Vaccines (Fahrenheit)**

Monitoring

 Compiling this temperature log: Check the temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an “X” in the box that corresponds with the temperature and record the ambient room temperature, the time of the temperature readings, and your initials. Once the month has ended, save each month’s completed form for 3 years, unless state or local jurisdictions require a longer time period.  

If the recorded temperature is in the shaded zone, record the temperature range. Follow these steps: 1. Proper conditions as quickly as possible. 2. Call the provider to determine whether the potency of the vaccine is harmful. 3. Take immediate action in the shaded section. 4. Document the action taken on the reverse side of this log.

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Temperature</th>
<th>Location</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/1/18</td>
<td>AM</td>
<td>40°F</td>
<td>Freezer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PM</td>
<td>42°F</td>
<td>Freezer</td>
<td></td>
</tr>
</tbody>
</table>

**Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health and the California Department of Health Services.**

**TWICE A DAY**

- Temperature recorded twice a day
- Even with alarm, recommend twice a day
- Keep Temp logs for at least 3 years
Resources to Protect Your Vaccines

**WARNING**

Do not unplug the refrigerator/freeze or break circuit.
Expensive vaccine in storage.
In event of electrical problem, immediately contact:

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**Written Plan**

- Alternate storage sites
- Contact #
- Procedures to report failure

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**Checklist for Safe Vaccine Handling and Storage**

<table>
<thead>
<tr>
<th>Task</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>We have a designated person in charge of the handling and storage of our vaccines.</td>
</tr>
<tr>
<td>2</td>
<td>We have a back up person in charge of the handling and storage of our vaccines.</td>
</tr>
<tr>
<td>3</td>
<td>A vaccine inventory log is maintained that documents:</td>
</tr>
<tr>
<td>4</td>
<td>Vaccine name and number of doses received</td>
</tr>
<tr>
<td>5</td>
<td>Date the vaccine was received</td>
</tr>
<tr>
<td>6</td>
<td>Arrival condition of vaccine</td>
</tr>
<tr>
<td>7</td>
<td>Vaccine manufacturer and lot number</td>
</tr>
<tr>
<td>8</td>
<td>Vaccine expiration date</td>
</tr>
<tr>
<td>9</td>
<td>Our refrigerator for vaccines is either household-style or commercial-style. NOT dormitory-style. The freezer compartment has a separate exterior door.</td>
</tr>
<tr>
<td>10</td>
<td>We do NOT store any food or drink in the refrigerator or freezer.</td>
</tr>
<tr>
<td>11</td>
<td>We store vaccines in the middle of the refrigerator or freezer, and NOT in the door.</td>
</tr>
<tr>
<td>12</td>
<td>We stock and rotate our vaccine supply so that the newest vaccine of each type (with the longest expiration date) is placed behind the vaccine with the shortest expiration date.</td>
</tr>
<tr>
<td>13</td>
<td>We check vaccine expiration dates and we first use those that will expire soonest.</td>
</tr>
<tr>
<td>14</td>
<td>We post a sign on the refrigerator door showing which vaccines should be stored in the refrigerator and which should be stored in the freezer.</td>
</tr>
<tr>
<td>15</td>
<td>We always keep a thermometer in the refrigerator.</td>
</tr>
<tr>
<td>16</td>
<td>The temperature in the refrigerator is maintained at 35-46°F (2-8°C).</td>
</tr>
<tr>
<td>17</td>
<td>We keep extra containers of water in the refrigerator to help maintain cold temperatures.</td>
</tr>
</tbody>
</table>

**What to do in case of a power failure or another event that results in vaccines outside of the recommended temperature range**

1. Close the door tightly and/or plug in the refrigerator/freezer.
2. Store the vaccines at appropriate temperatures. Make sure the refrigerator/freezer is working properly or move the vaccines to a unit that is. Do not discard the affected vaccines. Mark the vaccines so that the potentially compromised vaccines can be easily identified.
3. Call the manufacturer and notify the local or state health department (see phone numbers below).
4. Record action taken.

* Using a recording thermometer is the most effective method of tracking the refrigerator and freezer temperatures over time. Visually checking thermometers twice a day is another effective method to identify inconsistent or fluctuating temperatures in a refrigerator and freezer.

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**Vaccines Stored in Refrigerator**

<table>
<thead>
<tr>
<th>Vaccine, manufacturer, and lot #</th>
<th>Expiration date</th>
<th># of doses</th>
<th># of affected vials</th>
<th>Action taken</th>
</tr>
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<tbody>
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Approved Vaccine Storage Containers

Do not remove the vaccine from manufacturer-supplied packaging

Designed for transportation of refrigerated vaccine for trips no longer than 24 hours in duration

Having one container at each vaccination station will help prevent vaccine compromise

2°C to 8°C

Best utilized for large scale influenza campaigns
Pre-filling Syringes

Draw vaccine only at the time of administration to ensure that the cold chain is maintained

**DO NOT** pre-draw doses before they are needed

- Increased risk of medication errors
- Wasted product
- Contaminated product

- Separate vaccination stations
- Small quantity of vaccine to meet the initial needs
  - No more than 1 vial or 10 doses
- Monitored patient flow
- Discard vaccine at end of day
Suspected Vaccine Compromise

I suspect the vaccine is compromised. What do I do?

Common causes of vaccine compromise
- Power failure
- Lack of an alarm
- Pre-filling too many syringes at a time
- Refrigerator malfunctions not reported
- Lack of recording temperature twice daily

• Isolate the affected vaccine vials or packages
• Inform your MILVAX Regional Analyst
• Contact USAMMA – Do not contact the Manufacturer
• Dispose of the vaccine if necessary (after consulting USAMMA)
• Prepare Executive Summary (EXSUM)
  ▪ Explain the incident
  ▪ Submit to USAMMADOC for vaccine replacement
• DoD activities are responsible for disposal of compromised or expired vaccine
• Destruction memorandum should be routed up the chain of command for review and endorsement before faxing to USAMMADOC
• Methods of destruction
  ▪ The flu vaccine can be disposed in sharps container, autoclaved, incinerated, or use a returns program
For more info on storage and handling

- CDC Vaccine Storage and Handling
  - http://www2a.cdc.gov/vaccines/ed/shtoolkit/default.htm
- USAMMA
- Immunization Action Coalition
  - www.immunize.org
For more information about the cold chain management please contact the U.S. Army Medical Material Agency.

www.usamma.army.mil

Distribution Operations Center (DOC) (0700-1630 EST)
Phone: 301-619-4318, 1197, 4198
DSN: 343-4318, 1197, 4198

After hours call: 301-676-1184 / 0857 for urgent issues only.

USAMMADOC@amedd.army.mil
vaccines.mil/training