Vaccine Management: Storage and Handling

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Presenter Disclosure Information

• I, Pejman Talebian, 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 presentations.
  o I have no relationships to disclose.

• I may discuss the use of vaccines in a manner not approved by the U.S. Food and Drug Administration.
  o But in accordance with ACIP recommendations.
Learning Objectives

• Summarize principles of vaccine management
• Describe current vaccine storage and handling recommendations
• Describe preventative measures to maintain refrigerator and freezer temperatures
• Discover a new tool to monitor vaccine temperatures
• List steps to protect vaccine in the event of a power outage or emergency
Why is Vaccine Storage & Handling important?

“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.” -CDC

- Proper storage and handling of vaccines protect public health and have contributed to the decrease of vaccine-preventable disease rates.

- Storage and handling errors
  - Decrease potency and reduce effectiveness and protection
  - Cost thousands of dollars in wasted vaccine and revaccination
  - Loss of patient confidence
• All vaccine storage and handling and VFC requirements and recommendations are detailed in the Guidelines for Compliance with Federal and State Vaccine Administration Requirements.

• Available on our website: www.mass.gov/dph/imm and click on ‘Vaccine Management’
Vaccine Storage and Handling

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) 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
Vaccine Management

• Each provider should designate one staff member to be the Vaccine Coordinator and one back up person who is able to perform the same responsibilities.

• The Vaccine Coordinator must train other staff responsible for managing the vaccine supply.
Vaccine Management Plans

• Providers should have written vaccine management standard operating procedures (SOP) which are reviewed or updated annually or when there is any change or a new Vaccine Coordinator.

• All staff who are responsible for handling or administering vaccines must acknowledge reading the practice’s SOP by signing and dating the document.
Components of Vaccine Management
Standard Operating Procedure (SOP)

- Proper storage and handling of vaccines
- Vaccine receiving
- Procedure for vaccine relocation in the event of power or equipment failure
- Vaccine ordering and inventory control
- Handling damaged or expired vaccines
- Protocols for response when vaccine is stored out of temperature range
- A sample copy of MDPH’s SOP for Vaccine Management can be found on our website
Updating SOP

• Update SOP annually or with any changes.
  - Have all staff who handle or administer vaccines read the updated SOP and sign and date the last page.
  - Post the SOP on the vaccine refrigerator.
  - Have any new staff member read and sign the SOP as part of their training.
Vaccine Coordinator Responsibilities

• Order vaccine and oversee inventory
• Receive vaccine and refrigerate/freeze immediately
• Provide proper storage and handling
• Handle damaged, wasted and expired vaccine
• Respond when vaccine is out of required temperature range
  o If have state-supplied vaccines contact MDPH Vaccine Unit to determine if vaccine has been damaged (617-983-6828)
  o If only have private purchase vaccines contract the vaccine manufacturer directly
Vaccine Inventory Management

- Limit access to authorized personnel
- Order vaccines regularly, do not stockpile
- Organize vaccine with shortest shelf life in front
- Conduct and log vaccine inventory monthly
- Rotate vaccines and monitor expiration dates
Receiving Vaccine

• Examine shipment immediately upon arrival
• If problems (for state-supplied vaccines), report to MDPH within two hours
• Check contents against packing slip
• Check vaccine expiration dates
• Examine contents for damage
• Check temperature monitor
• Immediately place in appropriate storage
• Keep a shipping box on hand to use when returning any damaged or expired vaccine
Vaccine Storage

- Maintain refrigerator temperature between 2°C and 8°C (36°F and 46°F).
- Maintain freezer temperature between -50°C and -15°C (-58°F and +5°F) for Varivax, ProQuad, and Zostavax vaccines.
- Place temperature data logger in a central area of the storage unit, adjacent to the vaccines and away from any air vents.
Common Adult Vaccines

**Refrigerator**
- Hepatitis A
- Hepatitis B
- Human Papillomavirus (HPV)
- Measles, Mumps, Rubella (MMR)
- Meningococcal Conjugate (MCV4)
- Meningococcal Group B
- Pneumococcal Conjugate
- Pneumococcal Polysaccharide
- Tetanus and Diphtheria (Td)
- Tetanus, Diphtheria, Acellular Pertussis (Tdap)

**Freezer**
- Varicella
- Zoster
- Measles, Mumps, Rubella (MMR)
Vaccine Storage Units

- CDC and MDPH strongly recommend stand alone refrigerators and stand alone freezers.
- MDPH now requires a pharmacy grade refrigerator for all sites that administer vaccines to children and highly recommends for all practices.
- A stand alone freezer that can maintain the proper temperatures is acceptable.
Pharmaceutical Grade Refrigerator

• Although there is no clear description of a pharmaceutical refrigerator, we have identified the following characteristics:
  - Internal fans to disperse cold air throughout the unit, eliminating cold pockets of air
  - Wire racks to allow better air flow
  - No storage bins, or shelves on door
  - Typically, pharmaceutical grade refrigerators have a narrow operating range (less than 2 degrees C or 3 degrees F)
Loading Vaccines

• Keep vaccines in original manufacturer packaging
  o Don’t remove individual vials from cardboard boxes
• Place vaccine boxes in trays
• Organize vaccines by type, state/private, to facilitate quick retrieval and minimize time with refrigerator door open
• Avoid over-filling refrigerator and hindering air circulation
  o Do not store vaccines on the bottom shelf or near vents
Stabilize your refrigerator temperatures by placing water bottles where vaccine should not be stored (on bottom shelf)

Store cold packs in the refrigerator as part of emergency preparedness, in case you need to transport vaccine during an emergency.
Unacceptable Vaccine Storage
Unacceptable Vaccine Storage
Monitor Temperatures

• Record temperatures twice daily
  • First thing in the morning
  • End of the work day
  • Temperature logs must be retained for at least 3 years
  • Monitor for out-of-range temperatures
• Place temperature logs on front of unit
Appropriate Temperature Monitoring & Documentation

• NIST certified calibrated digital data loggers for continuous 24-hour temperature monitoring for all vaccine storage units at all pediatric providers (any site that administers vaccines to those <19 years of age) is now required by MDPH and is strongly recommended for all adult providers.

• These data loggers should have a biosafe glycol-encased detachable temperature probe.

• The data logger must record the minimum and maximum temperature each day.

• Providers must still physically acknowledge the high/low temperatures at least twice daily.
Appropriate Temperature Monitoring & Documentation

• Immediate action must be taken if temperatures are out of range.
• For state-supplied vaccines, report all vaccine storage issues, including temperature excursions, to:
  o Vaccine Management Unit at 617-983-6828.
• For privately purchased vaccines, contact each manufacturer to determine if you can continue to administer their vaccine.
Data Loggers

- Come in all shapes and sizes
- Must be NIST certified
- Able to measure product temperature with a detachable probe
MDPH Has Provided Fridge-tag2L® Logger to All Pediatric Providers

- NIST certified
- No software required; easy to install and use
  - Simple YouTube instructional videos
- All pediatric practices have received them for all their vaccine storage units
  - All practices can purchase units at state pricing
Fridge-tag 2L® Loggers

Refrigerator

Freezer
Closer Measurement of Vaccine Temperature

• Fridge-tag2L® Logger measures the temperature of a 5 ml glycol solution
• Most vaccines are 1 ml or less
• Minimum and maximum temperatures being measured more closely reflect the temperature of the vaccine and with more sensitivity to temperature fluctuations
• Traditional bottle thermometer measures the temperature of a 30 ml glycol solution
Documenting Temperature

- With the Fridge-tag2L® you can document temperatures 2x/day, with the time and min/max temp by pressing the ‘Read’ button 2x/day.
- Infographic on MDPH website [www.mass.gov/dph/imm](http://www.mass.gov/dph/imm) under ‘Vaccine Management’.
Reviewing temp logs

Events - records the time the 'Read' button is pressed. There should be two times for each day the office is open.

Avg. Temp. - records the average temperature measured each day. Ideally should be around 5°C.

Lower Alarm Limit - shows status (ok or ALARM), the minimum temperature, time below the limit, and the earliest time that an alarm was triggered.

Upper Alarm Limit - shows status (ok or ALARM), the maximum temperature, time above the limit, and the earliest time that an alarm was triggered.
Upper alarm limit

<table>
<thead>
<tr>
<th>Status</th>
<th>Max. temp.</th>
<th>Duration out of range</th>
<th>Alarm trigger time</th>
<th>Alarm ambient temp.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ok</td>
<td>-25.4°C</td>
<td>0min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ok</td>
<td>-26.4°C</td>
<td>0min</td>
<td></td>
<td></td>
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<tr>
<td>ALARM</td>
<td>-10.7°C</td>
<td>6h 7min</td>
<td>01:14h</td>
<td>+13.6°C</td>
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</tr>
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<td>-11.0°C</td>
<td>9h 34min</td>
<td>01:48h</td>
<td>+14.1°C</td>
</tr>
<tr>
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<td>11h 19min</td>
<td>02:15h</td>
<td>+13.8°C</td>
</tr>
<tr>
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<td>02:54h</td>
<td>+13.7°C</td>
</tr>
<tr>
<td>ok</td>
<td>-12.1°C</td>
<td>7h 18min</td>
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<td></td>
</tr>
<tr>
<td>ok</td>
<td>-12.6°C</td>
<td>4h 45min</td>
<td></td>
<td></td>
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<td>+14.4°C</td>
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<td>+13.9°C</td>
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<td>09:27h</td>
<td>+14.1°C</td>
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<td>1th 13min</td>
<td>00:00h</td>
<td>+13.6°C</td>
</tr>
<tr>
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<td>11h 9min</td>
<td>00:20h</td>
<td>+14.3°C</td>
</tr>
<tr>
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<td>8h 35min</td>
<td>02:20h</td>
<td>+13.8°C</td>
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<td>8h 31min</td>
<td>02:45h</td>
<td>+13.5°C</td>
</tr>
<tr>
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<td>7h 25min</td>
<td>00:00h</td>
<td>+14.1°C</td>
</tr>
<tr>
<td>ALARM</td>
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<td>9h 26min</td>
<td>00:56h</td>
<td>+13.4°C</td>
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<td>+13.0°C</td>
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<td>+12.9°C</td>
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<td>02:44h</td>
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<td>-9.3°C</td>
<td>11h 58min</td>
<td>00:00h</td>
<td>+13.0°C</td>
</tr>
<tr>
<td>ALARM</td>
<td>-9.3°C</td>
<td>11h 25min</td>
<td>00:18h</td>
<td>+13.1°C</td>
</tr>
<tr>
<td>ALARM</td>
<td>-8.9°C</td>
<td>11h 22min</td>
<td>00:00h</td>
<td>+12.9°C</td>
</tr>
<tr>
<td>ALARM</td>
<td>-9.7°C</td>
<td>10h 47min</td>
<td>00:25h</td>
<td>+13.8°C</td>
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<td>01:51h</td>
<td>+13.1°C</td>
</tr>
<tr>
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<td>11h 58min</td>
<td>01:11h</td>
<td>+13.3°C</td>
</tr>
<tr>
<td>ALARM</td>
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<td>11h 55min</td>
<td>01:25h</td>
<td>+13.4°C</td>
</tr>
<tr>
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<td>-10.4°C</td>
<td>10h 30min</td>
<td>04:16h</td>
<td>+13.1°C</td>
</tr>
<tr>
<td>ALARM</td>
<td>-9.9°C</td>
<td>8h 11min</td>
<td>00:00h</td>
<td>+13.6°C</td>
</tr>
</tbody>
</table>
### Fridge Tag Example #2

Upper Alarm Limit – shows ALARM, with a maximum temp of +11.4°C, with 3h 23min out of range with an alarm triggered time 21:39h (9:39PM)

<table>
<thead>
<tr>
<th>Status</th>
<th>Max. temp.</th>
<th>Cumulative daily time above the limit</th>
<th>Alarm trigger time</th>
</tr>
</thead>
<tbody>
<tr>
<td>In progress</td>
<td>+4.7°C</td>
<td>0min</td>
<td></td>
</tr>
<tr>
<td>ALARMI</td>
<td>+16.2°C</td>
<td>12h 7min</td>
<td>00:00h</td>
</tr>
<tr>
<td>ALARMI</td>
<td>+11.4°C</td>
<td>3h 23min</td>
<td>21:39h</td>
</tr>
<tr>
<td>ok</td>
<td>+6.6°C</td>
<td>0min</td>
<td></td>
</tr>
<tr>
<td>ok</td>
<td>+10.4°C</td>
<td>26min</td>
<td></td>
</tr>
</tbody>
</table>

Continues at Midnight for 12h 7m
Fridge Tag Example #3

Upper Alarm Limit – shows ALARM, with a maximum temp of +11.5°C, with 4h 53min out of range with an alarm triggered time 20:19h (8:10PM)

<table>
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<th>No.</th>
<th>Date (MM/dd/yyyy)</th>
<th>Events*</th>
<th>Average temp.</th>
<th>Status</th>
<th>Min. temp.</th>
<th>Duration out of range</th>
<th>Alarm time</th>
<th>Alarm temp.</th>
<th>Status</th>
<th>Max. temp.</th>
<th>Duration out of range</th>
<th>Alarm time</th>
<th>Alarm temp.</th>
<th>Status</th>
<th>Duration</th>
<th>Alarm time</th>
<th>Signature / notes</th>
<th>Action taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>31</td>
<td>01/31/2016</td>
<td></td>
<td>+5.3°C</td>
<td>ok</td>
<td>+4.8°C</td>
<td>0min</td>
<td></td>
<td></td>
<td>ok</td>
<td>+6.2°C</td>
<td>0min</td>
<td></td>
<td></td>
<td>ok</td>
<td>0min</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>32</td>
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<td></td>
<td>+5.3°C</td>
<td>ok</td>
<td>+4.8°C</td>
<td>0min</td>
<td></td>
<td></td>
<td>ok</td>
<td>+6.1°C</td>
<td>0min</td>
<td></td>
<td></td>
<td>ok</td>
<td>0min</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>33</td>
<td>01/29/2016 am</td>
<td></td>
<td>+5.5°C</td>
<td>ok</td>
<td>+4.6°C</td>
<td>0min</td>
<td></td>
<td></td>
<td>ok</td>
<td>+7.1°C</td>
<td>0min</td>
<td></td>
<td></td>
<td>ok</td>
<td>0min</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>34</td>
<td>01/29/2016 pm</td>
<td></td>
<td>+4.4°C</td>
<td>ok</td>
<td>+4.2°C</td>
<td>0min</td>
<td></td>
<td></td>
<td>ok</td>
<td>+7.0°C</td>
<td>0min</td>
<td></td>
<td></td>
<td>ok</td>
<td>0min</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>35</td>
<td>01/29/2016 pm</td>
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<td>+4.4°C</td>
<td>ok</td>
<td>+4.2°C</td>
<td>0min</td>
<td></td>
<td></td>
<td>ok</td>
<td>+7.0°C</td>
<td>0min</td>
<td></td>
<td></td>
<td>ok</td>
<td>0min</td>
<td></td>
<td></td>
<td></td>
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</table>

Continues at Midnight for 12h 25m
### Upper Alarm Limit
- Shows ALARM, with a maximum temp of +13.0°C, with 30min out of range with an alarm triggered time 16:56h (4:56PM)

<table>
<thead>
<tr>
<th>No.</th>
<th>Date (dd.MM.yyyy)</th>
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<th>Status</th>
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<th>Duration out of range</th>
<th>Alarm trigger time</th>
<th>Status</th>
<th>Max. temp.</th>
<th>Duration out of range</th>
<th>Alarm trigger time</th>
<th>Alarm ambient temp.</th>
<th>Ext. sensor connection error</th>
<th>Status</th>
<th>Duration</th>
<th>Alarm trigger time</th>
<th>Signature / notes</th>
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<td>+5.0°C</td>
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<td>ok</td>
<td>+5.7°C</td>
<td>0min</td>
<td></td>
<td></td>
<td></td>
<td>ok</td>
<td>0min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>32</td>
<td>30.01.2016</td>
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<td>+5.3°C</td>
<td>ok</td>
<td>+5.0°C</td>
<td>0min</td>
<td></td>
<td>ok</td>
<td>+5.7°C</td>
<td>0min</td>
<td></td>
<td></td>
<td></td>
<td>ok</td>
<td>0min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>33</td>
<td>29.01.2016</td>
<td></td>
<td>+4.9°C</td>
<td>ok</td>
<td>+5.0°C</td>
<td>0min</td>
<td></td>
<td>ok</td>
<td>+5.8°C</td>
<td>0min</td>
<td></td>
<td></td>
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<td>0min</td>
<td></td>
<td></td>
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<tr>
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<td>ok</td>
<td>+5.6°C</td>
<td>0min</td>
<td></td>
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<td>+6.2°C</td>
<td>0min</td>
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<td></td>
</tr>
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<td>+5.6°C</td>
<td>0min</td>
<td></td>
<td></td>
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<td>0min</td>
<td></td>
<td>ok</td>
<td>+5.9°C</td>
<td>0min</td>
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<td></td>
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<td>57</td>
<td>02.01.2016</td>
<td></td>
<td>+5.6°C</td>
<td>ok</td>
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<td>+5.9°C</td>
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Documentation of excursion

- Best practice to use a sample ‘Documentation of Temperature Troubleshooting’ on MDPH website
- Keeps a record of temperature excursions available
Temperature Adjustment

- If a refrigerator is running on the cold side, or is slowly becoming colder, you should take action.
- Never adjust the refrigerator temperature control with vaccine in unit.
- Remove vaccine to another refrigerator/freezer.
- Adjust temperature of unit.
- Wait until you have 3 successive readings one hour apart within range before returning vaccine to the unit.
Power Failure

- If you lose power for extended period, follow your emergency plan:
  - pack vaccine
  - transport to prearranged site
  - notify MDPH Vaccine Unit, if state-supplied

- When power returns:
  - do not adjust the temperature control in unit
  - allow unit to return to proper temperature range
  - return vaccine to unit
Safeguard Power Supply

• Use a plug guard or safety-lock plug
• Place “Do Not Unplug” sign on storage unit, outlet and “Do Not Disconnect” on circuit breakers
• Consider installing a temperature alarm
• Do not use extension cords
Safeguard Power Supply

Protect plug and outlet

Plug in unit to a nearby outlet.
Secure plug with a guard/cover.
Post "Do Not Unplug" signs near outlet.

WARNING! Do Not Unplug
ADVERTENCIA NO DESCONECTE EL REFRIGERADOR

Always avoid disruption of power

Do not use extension cords.
Do not plug more than one appliance into an outlet. This will prevent tripping of circuit breakers.
Safeguard Power Supply

- Do not use extension cords.
- Do not plug more than one appliance into an outlet. This will prevent tripping of circuit breakers.
- Do not use outlets that are controlled by wall switches.
- Never unplug the vaccine refrigerator or freezer.

If you experience a power failure, do not open refrigerator/freezer doors. If it lasts more than 4-6 hours, call the VFC Program.

- VFC Program Office (877) 243-8832
- VFC Field Representative

www.eziz.org

California Department of Public Health Immunization Branch
Vaccine Storage & Handling Questions

- MDPH Vaccine Management Unit
  (617) 983-6828

- MDPH Division of Epidemiology and Immunization
  (888) 658-2850
  (617) 983-6800 (24x7)

- Always consult with MDPH Immunization Program before removing improperly stored state-supplied vaccine from the storage unit
  - If the temperature of the vaccine goes out of range, either too high or too low, call the MDPH Vaccine Management Unit immediately!
And thanks to you...

To all of the Medical Directors, Back-up Vaccine Coordinators, RNs, MAs, other office staff involved with immunizations at provider offices and, especially, to the Vaccine Coordinators,

Thank you for all you do to take care of vaccines and, in turn, take care of your patients and protect them from vaccine preventable diseases!
QUESTIONS?

Thank You!