

Implementing Instruction: Medical Countermeasure: **Cold Chain Management**

Cold Chain Management

This document is part of the Portsmouth City and Scioto County Health Department's Emergency Response Plan, Appendix 1: Medical Countermeasures Dispensing. It is intended to provide information that is emergent in nature and will contain limited day-to-day vaccine management. Portsmouth City and Scioto County Health Department has adopted the following documents for day-to-day vaccine management:

- Ohio Department of Health's "Vaccine For Children" Vaccine Management Plan" for Portsmouth City and Scioto County Health Departments; and
- Centers for Disease Control and Prevention's "Vaccine Storage and Handling Toolkit".

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Introduction

Some medical countermeasures will be distributed to state, regional and local public health sites with the directive that the "cold chain" process will not be broken. Cold Chain management means that proper temperature control will be maintained throughout the medical countermeasure (MCM) process including receipt, distribution and dispensing.

Vaccine is the medical countermeasure materiel likely to require cold chain management, rather climate control. Most vaccines must be maintained at refrigerator temperatures of 35 - 46 degrees Fahrenheit or 2 – 8 degrees Celsius and or

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Freezer must be maintained at temperatures at 5 degrees Fahrenheit or -15 degrees Celsius. There must be a reliable monitoring system available. The diluents that are needed to re-constitute some vaccines can be kept at room temperature, or refrigerated, whichever is more convenient. No vaccine is stored at room temperature, but a few are kept frozen until ready to dispense. Examples of frozen vaccines include: Varicella, Zoster, Oral Polio, and Yellow Fever.

Since vaccines are managed on a day-to-day basis in the health department and a "Vaccine Management Plan" already exists, see the above bulleted documents for information concerning vaccine storage and handling. The table in the reference section of this document will list common day-to-day information and where to find it in the bulleted documents above.

Maintain Refrigerated Vaccine Temperature

Monitored Vaccine Refrigerators

The Portsmouth City and Scioto County Health Departments have four (4) vaccine refrigerators designated for vaccine storage. All of the refrigerators are connected to a power source with an emergency generator backup. In the event of a power outage the generator will activate and provide power to the refrigerators until the main electrical power is restored. A test of the generator is conducted every Wednesday afternoon to ensure that the system is functioning. The refrigerators are kept in separate rooms, each with a locked door.

Each refrigerator is monitored by Accsense Monitoring System. The temperature of the refrigerators is checked and recorded. In the event that the refrigerator temperature goes out of range, the monitoring system contacts the PCHD or SCHD by phone. After hours, the Directors of Nursing (DON), PHEP Coordinator, or Health Commissioners are contacted by phone. The refrigerator will be checked and the problem corrected or vaccine moved to a functioning refrigerator.

Maintain Frozen Vaccine Temperature

Monitored Vaccine Freezers

The Portsmouth City and Scioto County Health Departments have one(1) freezer dedicated for vaccine storage. The freezers connected to a power source with an emergency generator backup. In the event of a power outage the generator will activate and provide power to the freezer until the main electrical power is restored. The freezer is kept at Southern Ohio Medical Center. The building is secured by with alarms and motion detectors.

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The freezer is monitored by Accsense Monitoring System. The temperature of the freezer is checked and recorded. In the event that the freezer temperature goes out of range, the monitoring system contacts the PCHD and SCHD by phone. After hours, the Directors of Nursing (DON), PHEP Coordinator, or Health Commissioners are contacted by phone. The freezer will be checked and the problem corrected or vaccine moved to a functioning freezer.

Power Outage

Portsmouth City and Scioto County Health Departments have a generator that automatically starts when electrical power is lost at the health department. When the generator starts it sends notification to the health department leadership of loss of power.

The Temperature Monitoring Device sends notification of signal loss when the electrical power is lost. The Director of Nursing, and/or her back-up, can monitor the TMD remotely to ensure the signal is restored and the temperature remains within established limits.

Should the generator fail, the vaccine should then be transported to the vaccine back-up site.

Temperature Excursion/Refrigeration Failure

In the event of a temperature excursion that causes the vaccine to be kept out of the recommended temperature range (refrigerated at 36°F to 46°F/2°C – 8°C; frozen at 5°F/-15°C, or colder), the following protocol will be followed:

1. The cause of the power outage, if applicable, will be determined and corrective action taken.
2. The temperature of the failed unit will be documented along with the duration of the outage as noted on the temperature log.
3. Inventory of the affected ODH vaccine will be recorded. This will include lot numbers and expiration dates.
4. The affected vaccine will be moved to a refrigerator/freezer that maintains the recommended temperature range. The vaccine will be clearly separated from the undamaged vaccine.
5. The ODH Vaccine Warehouse Supervisor will be contacted (800-282-0546) during the next business day and instructions will be followed with regard to the proper disposition of the vaccine. The vaccine will not be used unless the ODH indicates that it may be given.

See Centers for Disease Control and Prevention's "[Vaccine Handling and Storage](#)" (2019), page 34, for additional guidance.

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Emergency Storage and Transportation of Vaccine

Emergency Storage Location

Portsmouth City and Scioto County Health Departments have a Vaccine Emergency Management Plan in place, including a memorandum of understanding (MOU) with Portsmouth City and Scioto County Emergency Medical Services to store vaccine, in case of an emergency (power & generator failure, multiple malfunctioning refrigerators or freezer, etc.). To gain access to this facility, call the telephone number listed in the HAN Directory, Vaccine Tab.

Transporting Vaccine

Transportation to the emergency site would be by private vehicle in inclement weather, otherwise transportation would be to place the vaccine coolers onto a cart and walk the vaccine to the site.

Coolers and safety measures will be used per Centers for Disease Control and Prevention (CDC) recommendation during transportation to the vaccination sites. The AcuTemp system will be used to maintain cold chain management during transportation.

Using an AcuTemp Carrying Case and Coolant Packs

Transport Equipment List for the AcuTemp System	
<u>Refrigerated Vaccine Transport</u>	<u>Frozen Vaccine Transport</u>
• AcuTemp Carrying Case(s)	• AcuTemp Carrying Case(s)
• VaxiSafe packs/+7°C X 5 (per case)	• VaxiSafe packs/-15°C X 5 (per case)
• Data Logger TMD	• Data Logger TMD
• Inventory list	• Inventory list

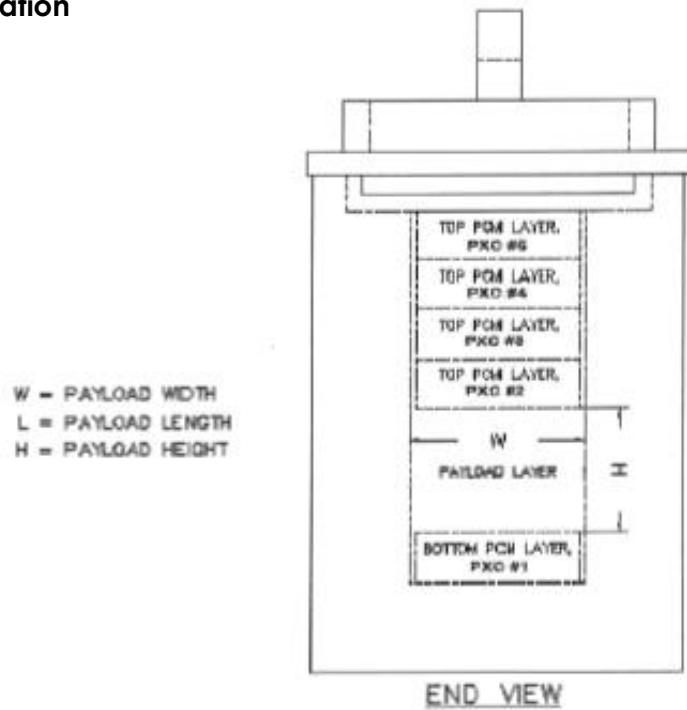
- Place one chilled/frozen VaxiSafe pack in the bottom of the carrying case, being sure to keep the pull-tab up so that the pack can be easily removed.
 - The “chilled” (+7°C) VaxiSafe pack and “frozen” (-15°C) VaxiSafe pack are not the same pack. Carefully read the labels on the packs.
- Evenly distribute the vaccine on top of the first layer of VaxiSafe. Do not exceed two (2) inches in height.

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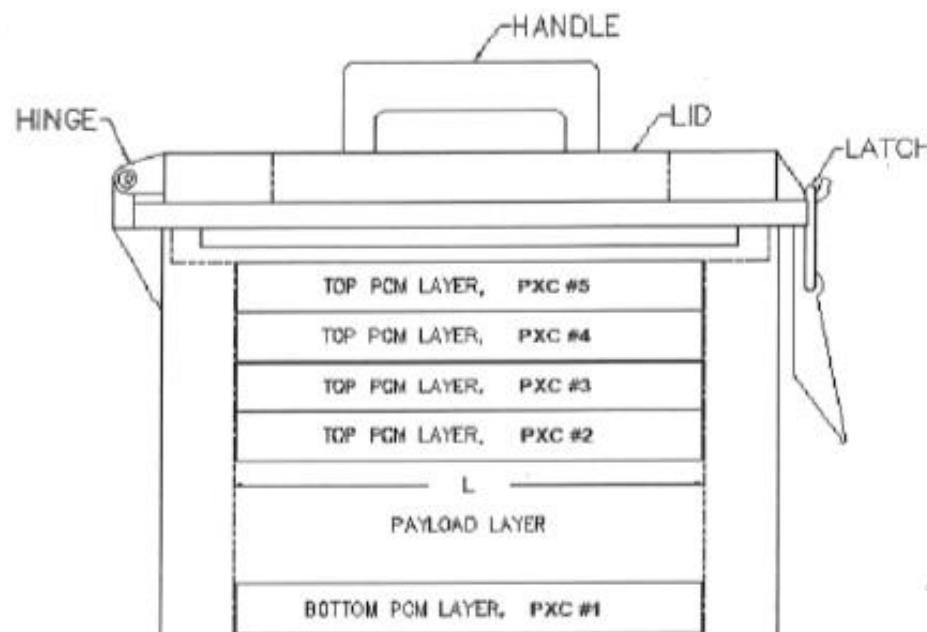
- It is recommended that a temperature monitoring device (thermometer) be placed at the vaccine level.
- Place four (4) additional VaxiSafe on top of the vaccine, being careful to keep the removal tabs up.
- Depending on the ambient temperature, refrigerated vaccine and frozen vaccine can be stored up to twenty (20) and twenty-four (24) hours, respectively. (The times noted are at an ambient temperature of 75°F)

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AcuTemp Packing Illustration



END VIEW



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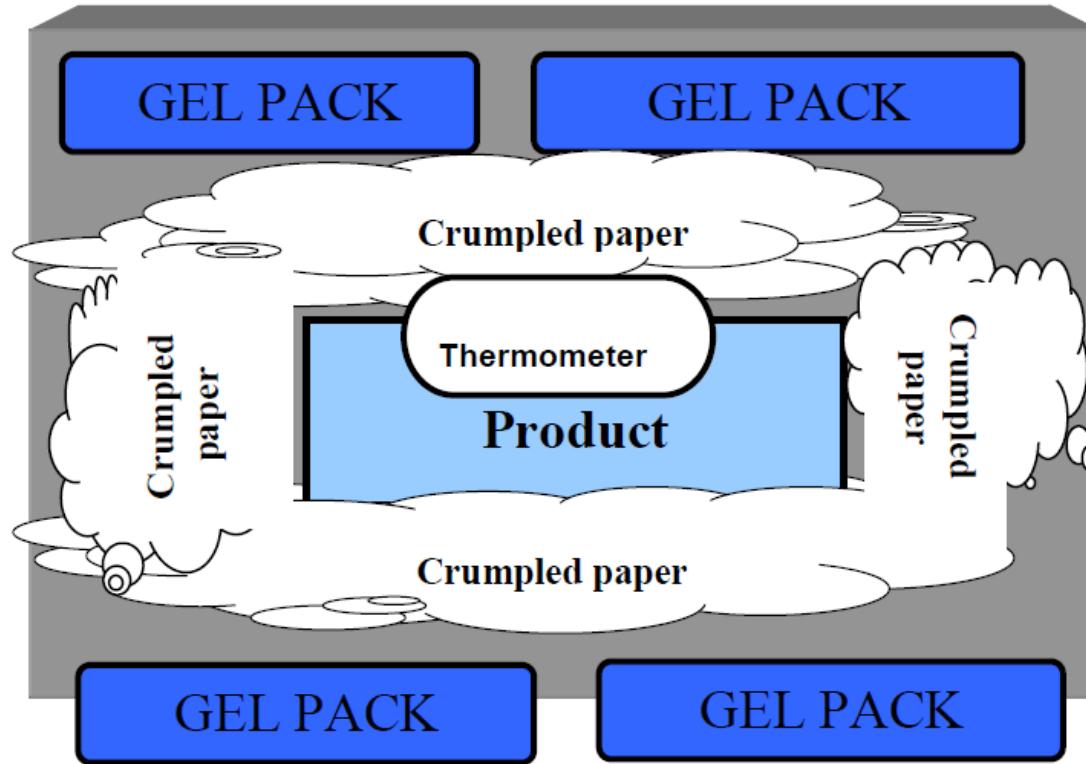
Using a Styrofoam cooler (Back-up):

Transport Equipment List for a Styrofoam Cooler	
<u>Refrigerated Vaccine Transport</u>	<u>Frozen Vaccine Transport</u>
<ul style="list-style-type: none">• Styrofoam Cooler• Refrigerated Gel Packs X 8• Newspaper or Bubblewrap• Data Logger• Inventory List	<ul style="list-style-type: none">• Styrofoam Cooler• Freezer Gel Packs X 8• Newspaper or Bubblewrap• Data Logger• Inventory List

- Place refrigerated gel packs, or frozen packs (whichever are appropriate for the vaccine to be transported) on the bottom of the cooler. Make sure the bottom surface of the cooler is completely covered.
- Next, place at least two inches of crumpled paper to separate the refrigerated/frozen gel packs from the product.
- Place the product in the center of the cooler.
- Place the thermometer/data logger directly on the product.
- Cover the product with another two-inch layer of crumpled paper on both the top and the sides of the vaccine to prevent it from shifting.
- Place refrigerated/frozen gel packs on top of the crumpled paper, so the whole top surface of the cooler is covered with gel packs.
- Place the lid on the cooler and seal the cooler shut with tape.
- Always follow proper security measures when transporting the vaccine.
- Be sure to maintain the cold chain for storage.
- Never store refrigerated vaccine in freezing temperatures (32°F / 0°C or lower).
- Never place ice directly on the product.

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SEE ILLUSTRATION FOR VACCINE PACKAGING BELOW



After an emergency, it may be necessary to assess the viability of the vaccine. The procedure for this assessment is the same as when there has been a temperature excursion. See CDC's "["Vaccine Storage and Handling"](#)", page 34

Training

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The Centers for Disease Control and Prevention (CDC) and the Vaccines for Children (VFC) program require the immunization program staff to complete annual independent study training on:

- Proper receipt and storage of medical countermeasures (MCM)/vaccines ([link](#)), and
- Packing and unpacking of MCM/vaccines ([link](#))

Other staff education and training on MCM/vaccines are provided as needed, i.e., when new staff is hired, or changes are made to the recommendations. This can include:

- Managing inventory,
- Setting up and monitoring TMDs,
- Response to temperature excursions,
- Monitoring and using equipment and systems, and
- Transportation.

See PCHD and SCHD's VFC Vaccine Management Plan for additional details of education/training requirement.

References

Topic	Reference Location
Adverse Events Reporting	PCHD and SCHD ERP, Appendix 1: MCM Dispensing, "Adve3rse Events Reporting"
Assessing whether vaccine can be used after an emergency	https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf , page 34
Determining viability of MCMs/vaccine in the event of a temperature excursion	PCHD and SCHD VFC VaccineMgmtPlan, Section 7 https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf , page 34
Disposal of vaccines and supplies	PCHD and SCHD VFC VaccineMgmtPlan, Section 7 https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf section 4

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Topic	Reference Location
Forms: Temperature conversion guide	https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf , page 35
Prescribing information	https://www.cdc.gov/vaccines/pubs/pinkbook/chapters.html Package insert for each vaccine container
Tally Sheets	https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf , page 36-8
Temperature Logs	Freezer https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/immunization/media/fahrenheit-f-temperature-log-freezer Refrigerator https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/immunization/media/fahrenheit-f-temperature-log-refrigerator
Temperature Monitoring Device (TMD) guide	https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/immunization/media/data-logger-quick-use-reference-guide
Vaccine Information Sheets (VIS).	https://www.cdc.gov/vaccines/hcp/vis/current-vis.html
Handling vaccines prior to administration	PCHD and SCHD VFC VaccineMgmtPlan, Section 2 https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf section 5
Maintaining storage equipment and temperature monitoring devices (TMDs)	PCHD and SCHD VFC VaccineMgmtPlan, Sections 2 and 8 https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf section 3
Managing inventory	PCHD and SCHD VFC VaccineMgmtPlan, Section 4

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Topic	Reference Location
	https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf section 4
Monitor and maintain appropriate temperature at fixed locations and during transport– refrigerated vaccine	PCHD and SCHD VFC VaccineMgmtPlan, Section 4 https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf section 6
Monitor and maintain appropriate temperature at fixed locations and during transport – freeze-dried vaccine	PCHD and SCHD VFC VaccineMgmtPlan, Section 4 https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf section 5
Monitoring storage unit and temperature	PCHD and SCHD VFC VaccineMgmtPlan, Section 8 https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf section 3
Ordering Vaccine	Portsmouth City and Scioto County Health Departments (PCHD and SCHD) “Vaccine For Children” (VFC) Vaccine Management Plan (VaccineMgmtPlan), Section 5 https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf , section 4
Packing and Transporting MCMs to and from an alternative/emergency storage facility	PCHD and SCHD VFC VaccineMgmtPlan, Section 4 https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf section 4
Patient/Lot Recall	Implementing Instruction (II): Medical Countermeasures (MCM): Client Notification of Vaccine Recall
Re-certification and calibration of storage and temperature monitoring devices	PCHD and SCHD VFC VaccineMgmtPlan, Section 8
Responding to storage and handling problems	PCHD and SCHD VFC VaccineMgmtPlan, Sections 3 and 4 https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf section 3

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Topic	Reference Location
Transporting vaccine off-site	PCHD and SCHD VFC VaccineMgmtPlan, Section 4 https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf section 6
Unpacking and Storage	PCHD and SCHD VFC VaccineMgmtPlan, Section 3 https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf , Section 4
Vaccine storage unit information	Maintained in/by: DirectorS of Nursing Office
Vaccine-related Contact list	Maintained in: Scioto County HAN Directory, Tab Vaccine