

## POLICY AND PROCEDURE

<b>SUBJECT/TITLE:</b>	Vaccine Storage Unit Failure
<b>SCOPE:</b>	Nursing Division
<b>CONTACT PERSON &amp; DIVISION:</b>	Director of Nursing
<b>ORIGINAL DATE ADOPTED:</b>	12/12/17
<b>LATEST EFFECTIVE DATE:</b>	12/12/18
<b>REVIEW/REVISION DATE(S):</b>	3/26/18, 5/23/18, 12/11/18, 12/5/19, 9/14/2021
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## PURPOSE

The intent of this document is to provide guidelines in the event of refrigerator/freezer failure. Adherence to this standard will:

1. Maintain vaccine in optimal condition through maintaining vaccine cold chain.

## POLICY

In the event of refrigerator/freezer failure, temperatures should be monitored closely. Should the temperatures fluctuate outside of the recommended ranges vaccine cold chain must be maintained and transported to Galion Avita Hospital Pharmacy (419-468-4841).

## BACKGROUND

Vaccine must be maintained between the temperature ranges according to the CDC *Vaccine Storage and Handling Toolkit* in order to maintain vaccine efficacy.

Because of the importance of maintaining vaccine within the temperature ranges according to the CDCs current standards, extra precaution is taken to maintain fragile vaccine. At the Galion City Health Department, an emergency alert system known as **Sensaphone 1104** will contact the 4 listed employees below by phone in the event of a Refrigerator and/or Freezer temperature exceeding the acceptable range or in the event of a power failure. This alert system will call out in order, cycling until answered (max: 100x) to the following employees:

1. Emily Miller 419-512-4287
2. Lynn Corwin 419-560-3460
3. Emily Miller 419-512-4287

The phone number associated with the Sensaphone at this time is 419-777-7797.

## PROCEDURES & STANDARD OPERATING GUIDELINES

1. Should the temperature in the refrigerator be noted outside the 2°-8° C range (35°-46° F) or the freezer above -15° C (5° F or above); (by routine temperature monitor check or Sensaphone 1104 Alert message):
  - a. Check that the refrigerator/freezer is plugged in.
  - b. Check that the refrigerator/freezer doors has been properly closed.
  - c. Check the Sensaphone Monitor Probe is inserted in the Helmer Refrigerator Upper Probe Bottle.
  - d. Check the Sensaphone Monitor Probe is inserted in the ABS Med Freezer via port in back of Freezer.
2. TO SILENCE PHONE MESSAGES FROM THE SENSAPHONE 1104 – ENTER VIA TOUCH TONE PHONE KEYPAD “555”
3. Notify the Health Commissioner of failure.

4. Equipment Failure not related to Power Outage -The vaccine coordinator will call the repair service: Local - Allied Restaurant Service of Ohio 419-589-4759
  - a. Helmer Pharmacy Refrigerator Unit – 317-773-9073 or 1-800-7435637
  - b. ABS -AmericanBioTechSupply Med-Pharmacy Freezer Unit - 1-800-648-4041
5. If the malfunction is due to a power failure affecting the vaccine refrigerator:
  - a. **Contact the Galion Police Department at 419-468-5255** for information concerning estimated time required for power to be restored. A brief power interruption (**one hour or less**) should not seriously affect refrigerator temperature **as long as the refrigerator/freezer door is not opened**. If the power outage occurs after business hours, Responsible Personnel must report to the department as soon as possible if the outage is determined to last longer than 1 hour. During this time, Responsible Personnel must monitor vaccine storage unit temperatures every 15-min using the Vaccine Storage Unit Failure Temp Log. If the interruption is expected to be greater than one hour in length, or if the refrigerator/freezer door is opened, contact the Responsible Personnel to advance further in preparation to maintain the vaccine cold chain. All employees are able to enter the building afterhours by code entry using the back door.
6. Responsible Personnel
  - a. In the event the refrigerator or freezer malfunctions, the facility has a power failure, a natural disaster occurs, or some other emergency compromises appropriate vaccine storage conditions, vaccines may need to be transported to another location. The Vaccine Coordinator or the Back-up Vaccine Coordinator will be responsible for making decisions about relocating the vaccines during normal business hours.

The following persons(s) will open the provider office after regular business hours to get to the vaccine:

<u>Emily Miller</u>	(name)	<u>(419) 512- 4287</u>	(phone)
<u>Lynn Corwin</u>	(name)	<u>(567) 560- 1515</u>	(phone)

The following person(s) will alert the emergency relocation site after regular business hours so they are prepared to receive the vaccine:

<u>Emily Miller</u>	(name)	<u>(419) 512- 4287</u>	(phone)
<u>Lynn Corwin</u>	(name)	<u>(567) 560- 1515</u>	(phone)

The following person(s) will pack the vaccines for shipment after regular business hours:

<u>Emily Miller</u>	(name)	<u>(419) 512- 4287</u>	(phone)
<u>Lynn Corwin</u>	(name)	<u>(567) 560- 1515</u>	(phone)

7. Procedures for Transporting Vaccine
  - a. Vaccine potency must be protected by maintaining the cold chain at all times during relocation and transport.
  - b. **Always inform ODH at (800) 282-0546 or (614) 466-4643 about your intention to transport VFC vaccines**, the location where the vaccines will be transferred to, and the number of vaccine doses to be transferred. If it is necessary to move the vaccine outside normal business hours, please proceed and contact the ODH Immunization Program the following business day.

The name of the emergency relocation site is: Galion Avita Hospital Pharmacy.

The address of the emergency relocation site is: 269 Portland Way S, Galion, OH 44833.

The following person(s) will transport the vaccines to the emergency relocation site:

<u>Emily Miller</u>	(name)	<u>(419) 512- 4287</u>	(phone)
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Lynn Corwin (name) (567) 560- 1515 (phone)

The following person(s) will receive the vaccines at the emergency relocation site:

Emily Miller (name) (419 ) 512 - 4287 (phone)

Lynn Corwin (name) (567 ) 560 -1515 (phone)

8. During vaccine transport, the following guidelines must be followed:
  - a. An ODH-supplied data logger must be placed in the vaccine transport container with the vaccine.
  - b. If vaccines are maintained in an insulated cooler, the temperatures must be checked and recorded hourly.
  - c. The vaccines should not be left unattended. Stay with the vaccines at all times during transport and promptly place into appropriate storage units upon arrival.
  - d. When transporting vaccines in vehicles, use the passenger compartment not the trunk.
  - e. **For additional guidelines, see <http://www.immunize.org/catg.d/p3049.pdf>.**
9. Transport and Short-Term Storage Guidelines for Refrigerated Vaccines
  - a. Use the following procedures for packing vaccine when refrigerated vaccines need to be transported. These procedures should keep all vaccines (except varicella containing vaccine) within recommended temperatures for 12 hours during transport and/or temporary storage. It will also maintain recommended temperatures if the cooler is exposed to outside air temperatures as low as - 4°F for one of those 12 hours.
    - i. Assemble Packing Supplies
      1. It is best to use hard plastic coolers. Attach a “Vaccines: Do Not Freeze” label to the cooler.
      2. “Conditioned” cold packs. Condition frozen gel packs by leaving them at room temperature for 1 to 2 hours until the edges have defrosted, and packs look like they’ve been “sweating.” Cold packs that are not conditioned can freeze vaccine. Do not use dry ice. You can also condition frozen gel packs by running under warm water.
      3. Use the ODH-supplied data logger.
      4. Use two 2-inch layers of bubble wrap. Insufficient bubble wrap can cause the vaccine to freeze.
    - ii. Pack the Vaccine
      1. Spread conditioned cold packs to cover only half of the bottom of the cooler.
      2. Completely cover the cold packs on the bottom of the cooler with a 2-inch layer of bubble wrap.
      3. The bubble wrap is to be placed above the cold packs and below the vaccine.
      4. Stack layers of vaccine boxes on the bubble wrap. Do not let the boxes of vaccine touch the cold packs.
      5. Completely cover the vaccine with a 2-inch layer of bubble wrap. Spread “conditioned” cold packs to cover only half of the bubble wrap. Make sure that the cold packs do not touch the boxes of vaccine.
      6. Fill the cooler to the top with bubble wrap. Place the ODH-supplied data logger and the Return or Transfer of Vaccines Report form on top of the bubble wrap. It is acceptable for temperatures to go above 46°F while packing.
      7. Assure that the lid on the cooler is attached securely (tape may be needed).
    - iii. As soon as you reach the destination site, check the vaccine temperature.
      1. If the temperature is between 35°F and 46°F (2°C - 8°C), put it in the refrigerator.
      2. If the temperature is below 35°F or above 46°F (2°C - 8°C), contact your ODH VFC representative or the VFC program during regular business hours at 1-800-282-0546. Then place the vaccine in a refrigerator with temperatures between 35°F and 46°F (2°C - 8°C), quarantine the vaccine and label the vaccine “Do Not Use.” Be sure to keep the ODH-supplied data logger with the vaccine.

# 10. Transport and Short-Term Guidelines for Varicella-Containing Vaccine

- a. The vaccine manufacturer does not recommend transporting varicella-containing vaccines (MMRV, VAR, and VZV). If these vaccines must be transported (e.g., during an emergency), CDC recommends transport in a portable freezer unit that maintains the temperature between -58°F and 5°F (-50°C and -15°C). Portable freezers may be available for rent. If varicella-containing vaccines must be transported and a portable freezer unit is not available, do NOT use dry ice.
- b. Varicella-containing vaccines may be transported at refrigerated temperatures between 36°F and 46°F (2°C and 8°C) for up to 72 continuous hours prior to reconstitution (refer to varicella-containing vaccines in CDC's *Vaccine Storage and Handling Guide*). If varicella-containing vaccines must be transported at refrigerated temperatures, follow these steps.
- c. Assemble Packing Supplies
  - i. Use hard plastic Igloo-type coolers. Attach a label stating "Vaccines: Keep Frozen" to the cooler.
  - ii. Cold packs. **Do not** condition frozen gel packs because this vaccine should remain as cold as possible.
  - iii. Do not use dry ice.
  - iv. Use the ODH-supplied data logger from the freezer.
  - v. Use two 2-inch layers of bubble wrap.
- d. Pack the Vaccine
  - i. Spread cold packs to cover only half of the bottom of the cooler.
  - ii. Completely cover the cold packs on the bottom of the cooler with a 2-inch layer of bubble wrap. The bubble wrap is to be placed above the cold packs and below the vaccine.
  - iii. Stack layers of vaccine boxes on the bubble wrap. Do not let the boxes of vaccine touch the cold packs.
  - iv. Completely cover the vaccine with a 2-inch layer of bubble wrap.
  - v. Spread cold packs to cover only half of the bubble wrap. Make sure that the cold packs do not touch the boxes of vaccine.
  - vi. Fill the cooler to the top with bubble wrap. Place the ODH-supplied data logger and the Emergency Response Worksheet form on top of the bubble wrap.
- e. Assure that the lid on the cooler is attached securely (tape may be needed).
- f. Record:
  - i. The time and temperature when the vaccines are removed from the storage unit and placed in the container;
  - ii. The temperature during transport; and
  - iii. The time and temperature at the end of transport.
- g. According to the vaccine manufacturer, immediately upon arrival at the alternate storage facility:
  - i. Place the vaccines in the freezer between -58°F and +5°F (-50°C and -15°C) and label "DO NOT USE." Any stand-alone freezer that reliably maintains a temperature between -58°F and 5°F (-50°C and -15°C) is acceptable for storage of varicella-containing vaccines.
  - ii. Document the time the vaccines are removed from the container and placed in the alternate storage unit.
  - iii. Note that this is considered a temperature excursion, so contact ODH at 1-800-282-0546 for further guidance.
  - iv. Place exposed vaccines in a clearly labeled container with cold packs. Transfer vaccines from the malfunctioning fridge to other vaccine refrigerator. Call the Galion Avita Hospital pharmacy (419-468-4841) for storage of long term power outage.

# 11. Complete the Vaccine Response Work Sheet. Do not use vaccines until advice is obtained from the Vaccine Manufacture and Ohio Department of Health. Always state the reason for your call.

- a. Merck- 1-877-VAX-MERCK (1-877-829-63725)
  - i. RotaTeq
  - ii. PedvaxHIB
  - iii. MMRII

- iv. Varivax
- v. ProQuad
- vi. VAQTA
- vii. Recombivax HB
- viii. Gardasil 9
- b. Sanofi- 1-800-822-2463
  - i. Pentacel
  - ii. Daptacel
  - iii. Adacel
  - iv. Tenivac
  - v. IPOL
  - vi. ActHib
  - vii. Menactra
  - viii. Fluzone
- c. Pfizer 1-800-438-1985
  - i. Prevnar 13
- d. GSK- 1-800-496-3772
  - i. Havrix
  - ii. Engerix
  - iii. Pediarix
  - iv. Kinrix
  - v. Fluarix
  - vi. Rotarix
- e. Contact the VFC consultant at 1-800-282-0546 or (614) 466-0247 (Jean Lantz)
- 12. Document occurrence using "Clinical Incident – Occurrence Report."
- 13. When power is restored, the vaccine is to be collected from the Galion Avita Hospital Pharmacy and transported back to the GCHD following the same procedure as stated above. Inventory of the vaccine must be confirmed before leaving the Galion Avita Hospital Pharmacy.
- 14. Log the data from the data logger upon return to GCHD onto a computer using the EasyLog USB program.

## CONTRIBUTORS

The following staff contributed to the authorship of this document:

- 1. Emily Miller RN, DON
- 2. Lynn Corwin RN, Vaccine Coordinator

## APPENDICES

Appendix A: Vaccine Storage and Handling Toolkit <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>

Appendix B: Vaccine Management Plan (Q:/Policies & Procedures)

Appendix C: Emergency Response Worksheet (Q:/Policies & Procedures)

Appendix D: Clinical Incident – Occurrence Report (Q:/Nursing/Incidence Reporting)

Appendix E: Vaccine Storage Unit Failure Temp Log

## REFERENCE FORMS

CDC. (June 2016). *Vaccine Storage and Handling Toolkit* Retrieved from

<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>

The Ohio Department of Health (December 2014). *ODH VFC Vaccine Management Plan*. Retrieved from

<http://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/bid/immunizations/vaccine-protocol-manual/Final-Protocol-Manual/Storage-and-handling/14-ODH-Vaccine-Management-Plan-122014.pdf?la=en>

**SIGNATURES**

*Andrea Barnes*

Health Commissioner

09 / 13 / 2021

Date