



# Ohio Department of Health Vaccines for Children (VFC) Vaccine Management Plan

- All Ohio VFC providers are required to use this vaccine management plan to document vaccine handling and storage protocols.
- This document must be maintained at a location accessible to all health care personnel handling vaccines and near the vaccine storage units at your facility.
- All health care personnel handling vaccines at this practice must adhere to the protocols described in this document and must review the protocols at least annually.

Name of Office / Clinic	
ODH VFC Number	
Original Plan Date:	

**VACCINE STORAGE PRACTICES LISTED IN THIS DOCUMENT ARE THE PRIMARY RESPONSIBILITY OF:**

Vaccine Coordinator	Primary Phone Number	Secondary Phone Number
Back-up Vaccine Coordinator	Primary Phone Number	Secondary Phone Number

**1. RESPONSIBILITIES OF HEALTH CARE PERSONNEL WHO HANDLE VACCINES**

The responsibilities of the primary vaccine coordinator and the back-up vaccine coordinator include the following vaccine management activities:

- Adjust the temperature of the vaccine storage unit as necessary to maintain correct temperatures.
- Document the temperatures on the ODH-supplied temperature logs for each storage unit twice each day.
- Provide annual training of health care personnel who are responsible for administering vaccines (or who may be required to transport vaccine in any emergency) to follow the vaccine management plan. A log sheet with the staff member’s name and date of training is attached for use at the end of this document.
- Review temperature logs weekly to ensure that vaccine temperatures are recorded properly and verify that no temperature excursions occur.
- Act as the lead and back-up vaccine contacts for the office.
- Act as the lead and back-up emergency vaccine plan coordinators.
- Manage all vaccine usage including: access to the ImpactSIIS system; order VFC vaccine using ImpactSIIS; reconcile VFC vaccine inventories in ImpactSIIS at least monthly; monitor vaccine storage conditions daily; assure vaccine loss is minimized; and assure all vaccine shipping, receiving, packaging and transportation is performed according to current policy.

**2. VACCINE STORAGE & HANDLING BASICS**

**A. Vaccine Storage Units**

Providers must have appropriate equipment that can store vaccine and maintain proper conditions. The current Centers for Disease Control and Prevention (CDC) recommendation for the types of storage units includes the following:

1. Purpose-built or pharmaceutical/medical-grade units, including door-less and dispensing units.
2. Stand-alone refrigerator and freezer units—these units can vary in size from a compact, under-the-counter style to a large, stand-alone, pharmaceutical-grade storage unit.

3. Combination household refrigerator/freezer unit, using only the refrigerator compartment to store vaccines—a separate stand-alone freezer should then be used to store frozen vaccines.

**Note: Dormitory-style refrigerators are not acceptable for storage of any vaccines.** These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment.

- Vaccine storage units must be able to maintain required vaccine storage temperatures.
- Vaccine storage units must be large enough to hold your maximum vaccine needs.
- Vaccine storage units must be able to use the ODH-supplied data logger (EL-USP-TP-LCD) with a glycol thermistor probe (ODH maintains the calibration certificate).

#### B. Vaccine Handling Practices

- Open and correctly store vaccine shipments as soon as they arrive at your health care facility.
- Maintain proper vaccine storage temperatures:
  - **Refrigerator**      **36°F to 46°F**    **(2°C to 8°C)**
  - **Freezer**            **5°F or below**    **(-15°C or below)**
- Place the ODH-supplied data logger in the middle of each vaccine storage unit away from the coils, walls, floor and cold air vent.
- Use the ODH-supplied VFC temperature log to record the following information:
  - Time of each temperature check.
  - Check the box indicating the color of the data-logger LED indicator light (green or red).
  - Min/Max temperature using the ODH-supplied data logger (only in the AM).
  - Vaccine storage unit temperature (do this twice each day: AM and PM).
  - If temperatures are out-of-range, or if the red LED is flashing on the data logger, immediately place a **“Do Not Use”** sign on the vaccines, maintain the vaccine in the storage unit and call the ODH Immunization Program during weekday business hours from 8 a.m. – 5 p.m. at 1 (800) 282-0546. ODH personnel will discuss the situation and determine the next steps of action.
- Retain the temperature logs in your practice for at least three years.
- Store vaccines in the middle of the refrigerator or freezer compartment away from the coils, walls, floor and cold air vent.
  - **Do not** store vaccines against the walls (or sides), in the doors, in the vegetable bin or in the bottom of the refrigerator / freezer unit.
- Ensure stored vaccines have space around their containers for cold air circulation.
- Store extra ice packs in the door of the *freezer*.
- Place water bottles labeled **“DO NOT DRINK”** in the *refrigerator* door to stabilize temperatures.
- Label **“VFC”** vaccines and **“private stock”** vaccines so that inventories are not mixed.
- Physically separate VFC vaccines from private stock vaccines in separate containers in the refrigerator and freezer unit(s).
- Check the refrigerator/freezer doors to ensure they are closed at the end of each day.
- Place **“Do Not Unplug”** signs near the vaccine storage units’ electrical outlets and circuit breakers.
- Store and rotate vaccines according to expiration dates. Use vaccines with the shortest expiration dates first.
- If you think vaccines will not be used and the vaccines are within 90 days of the expiration date, contact your VFC Immunization Consultant for instructions.
- Conduct an inventory of your VFC vaccines at least once each month (this will prevent running out of vaccine and the need to borrow vaccine).
- **Do not** store food in the vaccine storage units.

### 3. VACCINE SHIPPING, RECEIVING AND COLD CHAIN FAILURES

- A. Staff accepting vaccine deliveries must be aware of the importance of maintaining the cold chain and of the need to notify appropriate staff of the arrival of the vaccine so that it can be handled and stored appropriately.

At this practice, the Vaccine Coordinator and the Back-up Vaccine Coordinator are responsible for the following

procedures:

- Upon receipt of a vaccine shipment, examine the container and contents for physical damage.
  - Verify that the shipping time is less than 48 hours or that it is received by the specified date documented by the manufacturer (if the shipping time is greater than 48 hours, this can result in cold chain failure).
  - Check the cold chain temperature monitors in the vaccine container(s) to see if temperatures were out of the recommended range.
  - Cross-check the contents and expiration dates with the packing slip.
  - Check to make sure that refrigerated vaccines and the diluents are cold or room temperature, but not frozen.
  - Check to make sure that frozen vaccines (Varicella or ProQuad) are 5°F or below (-15°C or below).
  - Check for the correct type and quantity of diluents.
- B.** If there are any discrepancies with the packing slip, concerns about the viability of the vaccine, or possible cold chain failures with the vaccine shipment, immediately notify your practice’s Vaccine Coordinator.
- If you suspect the vaccines may not be viable:
    - Mark the vaccine or diluents as “Do Not Use;”
    - Store the vaccine under proper conditions; and
    - Contact the ODH Immunization Program during weekday business hours from 8 a.m. – 5 p.m. at 1 (800) 282-0546.
  - ODH personnel will review the vaccine temperatures and determine what further action is necessary.
  - If the vaccine shipment was incorrect or the cold chain determined to be compromised, ODH will instruct you to contact McKesson Specialty Shipping at 1 (877) 836-7123. This must occur on the same day as shipment receipt.

**4. EMERGENCY PLAN (For Vaccine Relocation)**

**A. Responsible Personnel**

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 and after business hours including these actions:

- Open the provider office after regular business hours to get to the vaccine;
- Alert the emergency relocation site about the need to relocate vaccine (during regular or after hours);
- Pack the vaccines for shipment (during regular or after hours);
- Transport the vaccines to the emergency relocation site (during regular or after hours).

Vaccine Coordinator	Primary Phone Number	Secondary Phone Number
Back-up Vaccine Coordinator	Primary Phone Number	Secondary Phone Number

If the Vaccine Coordinator and Back-up Vaccine Coordinator are not available, the person(s) listed below will relocate the vaccine:

Staff Name	Primary Phone Number	Secondary Phone Number

**B. Procedures for Emergency Transport of Vaccine**

Vaccine potency must be protected by maintaining the cold chain at all times during relocation and transport. Always inform ODH at 1 (800) 282-0546 or (614) 466-4643 during weekday business hours from 8 a.m. – 5 p.m. 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. ***Please note that a residence is not a sufficient first option for an emergency relocation site but may be a viable last resort.***

Emergency Relocation Site Name	Emergency Relocation Address:
Relocation Contact Name(s):	Relocation Contact Phone Number:

During vaccine transport, the following guidelines must be followed:

- An ODH-supplied data logger must be placed in the vaccine transport container with the vaccine.
- If vaccines are maintained in an insulated cooler, the temperatures must be checked and recorded hourly.
- 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.
- When transporting vaccines in vehicles, use the passenger compartment - not the trunk.
- **For additional guidelines, see <http://www.immunize.org/clinic/storage-handling.asp>.**

**Emergency Transport and Short-Term Storage Guidelines for Refrigerated Vaccines**

Use the following procedures for packing vaccine when refrigerated vaccines need to be transported. These procedures should keep all vaccines (except Varicella vaccine) within recommended temperatures for 12 hours during transport and/or temporary storage. The procedures should also maintain recommended temperatures if the cooler is exposed to outside air temperatures as low as -4°F for one of those 12 hours.

Assemble Packing Supplies

1. It is best to use qualified containers specifically designed for vaccine transport. Containers are qualified through laboratory testing under controlled conditions. If you do not have qualified containers, it is acceptable to use hard plastic Igloo-type coolers or a Styrofoam™ cooler from a previous vaccine shipment. Attach a “Vaccines: Do Not Freeze” label to the cooler.
2. Use “conditioned” frozen water bottles. Condition frozen water bottles by holding them under running tap water or submerging them in a sink filled with tap water until the block of ice can spin freely when the bottle is rotated. Phase change material (PCMs) can also be used to transport vaccines.
3. Use the ODH-supplied data logger.
4. Use 2 pieces of corrugated cardboard.
5. Use two 1-inch layers of bubble wrap. Insufficient bubble wrap can cause the vaccine to freeze.

Pack the Vaccine

1. Spread conditioned water bottles or PCMs to cover the bottom of the cooler.
2. Place a piece of cardboard over the water bottles.
3. Place a 1-inch layer of bubble wrap on top of the cardboard. The bubble wrap is to be placed above the cardboard and below the vaccine.
4. Stack layers of vaccine boxes on the bubble wrap.
5. Place the glycol for the ODH-supplied data logger in with the boxes of vaccine on the layers of bubble wrap. Assure that it is connected to the data logger.
6. Completely cover the vaccine with a 1-inch layer of bubble wrap.

7. Place another piece of cardboard on top of the bubble wrap to completely cover the bubble wrap.
8. Spread “conditioned” water bottles or PCMs on top of the cardboard.
9. Fill the cooler to the top with bubble wrap. Place the Vaccine Transfer Form on top of the bubble wrap. (Note: temperatures may go above 46°F for a short time while packing – this is acceptable.)
10. The data logger should be placed on the outside of the cooler with a temperature log. Assure that it is attached to the probe in glycol.
11. The lid on the cooler should be attached securely (tape may be needed).

As soon as you reach the destination site, check the vaccine temperature using the data logger.

- If the temperature is between 36°F and 46°F (2°C-8°C), put it in the refrigerator.
- If the temperature is below 36°F or above 46°F, place the vaccine in a refrigerator with temperatures between 36°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. Contact the ODH VFC program during regular business hours at 1 (800) 282-0546.

### **Transport and Short-Term Guidelines for Freezer Vaccines**

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 purchase or rent.

If Varicella-containing vaccines must be transported and a portable freezer unit is not available, you should use the process for transporting refrigerated vaccine outlined above. 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*).

According to the vaccine manufacturer, immediately upon arrival at the alternate storage facility:

- a. Place the vaccines in the freezer 5°F or below (-15°C or below) and label “DO NOT USE.” Any stand-alone freezer that reliably maintains a temperature 5°F or below (-15°C or below) is acceptable for storage of Varicella-containing vaccines.
- b. Document the time the vaccines are removed from the container and placed in the alternate storage unit.
- c. Note that transporting frozen vaccines in a cooler with conditioned water bottles is considered a temperature excursion, so contact ODH during weekday business hours from 8 a.m. – 5 p.m. at 1 (800) 282-0546 for further guidance.

## **5. VACCINE ORDERING BASICS**

- A. Order VFC vaccine in accordance with the actual vaccine need. Avoid stockpiling or a build-up of excess vaccine inventory. When it is time to order, the site should typically have a 3 to 4-week supply of on-hand vaccine inventory.
- B. Vaccine orders must be made through the ImpactSIIS software application on-line. A vaccine reconciliation process (inventory count) must be completed at least 5 days prior to any VFC vaccine order using ImpactSIIS.
- C. Depending on the volume of patients reported to the ODH Immunization Program and order history, practices are typically requested to order VFC vaccine quarterly. A practice should contact the ODH Immunization Program during weekday business hours from 8 a.m. – 5 p.m. at 1 (800) 282-0546 or (614) 466-4643 for more information on ordering cycles.
- D. After the VFC vaccine order is delivered to the provider, the vaccine order must be received electronically using the ImpactSIIS on-line software for the vaccine inventory to be added correctly to the inventory count.

**6. INVENTORY CONTROL GUIDELINES**

The vaccine storage and inventory practices listed below are the responsibility of the following staff member(s):

Staff Name	Note: The vaccine coordinator may delegate this duty to another staff member, however the vaccine coordinator must still oversee this activity.

- At least 5 days prior to each vaccine order (and preferably once each month) conduct a physical count of VFC vaccines and record the vaccine amounts in ImpactSIIS using the reconciliation process.
- Always place vaccines with shorter expiration dates in front of those with later expiration dates so that they can be used first (“first-in, first-out”). Short-dated vaccines should be checked at least every four weeks in case the expiration date order gets out of sequence.
- Vaccines are checked for expiration dates every \_\_\_\_\_ week(s).
- Vaccines are rotated every \_\_\_\_\_ week(s).
- Notify your assigned ODH VFC Consultant during weekday business hours from 8 a.m. – 5 p.m. at 1 (800) 282-0546 of vaccines that are within 90 days of expiration and will not likely be used.
- Develop and maintain complete, accurate and separate stock records for both public and private stock vaccines. VFC providers must track and monitor VFC inventory on-line using the ImpactSIIS system reconciliation process. VFC providers are not required to have separate storage units for the public and private sector vaccines, but vaccine stock supplies must be clearly labeled and separated between the public and private vaccine supplies.
- This practice differentiates public vaccine stock from private vaccine stock by (check each that applies).

Labeled Baskets     Labeled Shelves     Separate Storage Units     Other: \_\_\_\_\_

**7. VACCINE EXPIRATION AND SPOILAGE GUIDELINES**

- A.** If vaccine becomes spoiled or expired, the Vaccine Coordinator or the Back-up Vaccine Coordinator will be responsible for reporting these vaccines to the ODH VFC Consultant. Assigned health care personnel must:
- Quarantine the suspected spoiled vaccine in the storage unit until the vaccine manufacturers and ODH determine the vaccine to be either viable or non-viable.
  - Do not administer the suspected spoiled vaccine. Post a sign on the vaccine storage unit indicating that the vaccine must not be used until viability is determined.
  - Call ODH at 1 (800) 282-0546 during weekday business hours from 8 a.m. – 5 p.m. to report the suspected spoilage.
  - Send data logger information from your vaccine storage unit to ODH to review the recorded temperatures.
  - Email a brief summary of the suspected vaccine spoilage to the ODH VFC Consultant.
  - If the vaccine is determined to be spoiled or expired, complete a VFC Vaccine Transfer Form with the spoiled or expired vaccine listed.
  - Email the vaccine transfer form to [vaccine@odh.ohio.gov](mailto:vaccine@odh.ohio.gov) with the subject: “Return Label Request”. ODH will submit the request for a return label from McKesson Specialty Shipping. The label may take a couple weeks to arrive depending on the number of labels requested.
  - Review and confirm the spoiled or expired VFC vaccine information with the ODH VFC Consultant.
- B.** CDC requires this vaccine to be returned to McKesson to receive excise tax credits.
- Upon receipt of the return shipment label, package the vaccine in one of the original vaccine shipping containers, apply the return label to the box, tape and seal the box and present the package to the package courier service listed on the return label the next time a delivery is made to your site.
  - **Do not** call McKesson Specialty Shipping directly to arrange a pickup or you will be charged for the pickup.
  - For any questions, please call the ODH Immunization Program during weekday business hours from 8 a.m. – 5 p.m. at 1 (800) 282-0546.

C. NEVER return the following:

- Vaccines drawn-up into the syringes but not administered.
- Broken vials.
- Used syringes with or without needles.
- Multi-dose vials that have been partially used (some vaccine has already been withdrawn).

**The items listed above should be reported as “Wastage” and must be properly disposed of as medical waste.**

## 8. DATA LOGGER PROCEDURES

- A. The data logger thermometer is a logger with a small LCD screen, a USB interface and separate temperature probe encased in glycol (thermistor probe). The glycol bottle and the data logger are calibrated together and must remain paired to each other. Do not mix and match glycol bottles with other data loggers. ODH supplies data logger thermometers to all VFC providers to monitor temperatures within refrigerator and freezer units storing VFC vaccines.
- B. The ODH VFC consultant assigned to the provider’s territory will distribute data loggers during site visits as necessary to ensure each provider has a data logger thermometer with a current calibration. Each thermometer will have a calibration expiry of 2 years when it leaves the calibration center. The consultant will retrieve all old loggers when the new ones are activated and installed at the provider office.
- Each logger will have a sticker of calibration attached to it that will show the expiration date of the calibration. **If the VFC provider has a logger that is within 2 months of calibration expiration, please contact the VFC program at 1 (800) 282-0546.**
- C. The Centers for Disease Control and Prevention (CDC) and ODH require providers to perform the following actions to ensure the proper storage and handling of VFC vaccine:
- Twice each day, view and document temperatures from each storage unit containing VFC vaccine (e.g. AM/PM each day that the office is open) to include time, date, and initials of staff person recording temperatures. The temperatures are to be recorded on the ODH-provided temperature log. Note: if you can see an arrow on the LCD, then you are looking at the min/max temperature and not the current temperature.
  - **During the AM temperature check, record the Min/Max temperatures using the ODH-supplied data logger. Clear out the values from the previous day. (See details listed below).**
  - **Each morning view and document the minimum (coldest) and maximum (warmest) temperatures on the logger by pressing the button on the data logger. The maximum temperature will display with an arrow pointing upward on the display. Push the button again and the minimum temperature will appear and will have an arrow pointing downward. Press and hold the button to reset and clear the min/max readings. “Clr” should appear on the screen indicating that the min/max readings have been cleared. Assure that there is no arrow on the LCD screen.**
  - Document the color of the LED light flashing on the data logger (red or green).  
\*Note: the LED will flash every 20 seconds. Make sure the logger is viewed long enough for the LED to flash. **If the LED is flashing red, quarantine the vaccine and immediately contact the ODH VFC program** during weekday business hours from 8 a.m. – 5 p.m. at 1 (800) 282-0546.
  - Ensure the glycol probe is standing upright and is located in the center of the storage unit and not directly under the cold air return in the unit.
- D. The VFC program encourages each provider to download and view the temperature data at least monthly. Instructions for downloading can be found online at ODH’s website under the Immunization Program, VFC Manual Section 4: Temperature Monitoring. The information can be found here:  
<https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/Immunization/Vaccines-for-Children-VFC/>

**9. REVIEW AND UPDATE VACCINE MANAGEMENT PLAN**

At a minimum, the entire vaccine management plan must be reviewed and updated annually. The plan must also be reviewed and updated when there is a change in personnel who have responsibilities specified in the plan.

Date Vaccine Management Plan Reviewed	Reviewed By: (Print)	Reviewed By: (Signature)

**10. DOCUMENT STAFF TRAINING ON VACCINE MANAGEMENT (INCLUDING STORAGE AND HANDLING)**

Document when staff have completed the CDC You Call the Shots Modules, when they participated in a VFC Compliance Site Visit or list other training completed by staff.

Date	Trainee	You Call the Shots Modules (write date completed)		Other VFC Training (Site visit, MOBI, etc.) Enter Training Type and Date
		VFC Module	S/H Module	