



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

All VFC providers must use this vaccine management plan to document vaccine handling and storage processes. This document must be maintained at a location accessible to all staff handling vaccines and near the vaccine storage units at your facility.

### **Directions:**

- The primary vaccine coordinator must review and complete this document annually.
- All staff handling vaccines at this practice must adhere to the protocols described in this document and must review the protocols annually.
- This document must be maintained at a location accessible to all staff handling vaccines and close to the vaccine storage unit.

OFFICE / CLINIC: \_\_\_\_\_

ODH VFC #: \_\_\_\_\_ DATE: \_\_\_\_\_

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

VACCINE COORDINATOR: \_\_\_\_\_

HOME PHONE: \_\_\_\_\_ CELL PHONE: \_\_\_\_\_

BACK-UP VACCINE COORDINATOR: \_\_\_\_\_

HOME PHONE: \_\_\_\_\_ CELL PHONE: \_\_\_\_\_

### **1. RESPONSIBILITIES OF VACCINE STAFF**

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.
- Document the temperatures on the ODH-supplied temperature logs for each storage unit twice each day.
- Provide annual training of staff who are responsible for administering vaccines (or who may be required to transport vaccine in an emergency situation) to follow the office’s vaccine storage and handling plan. A log sheet with the staff member’s name and date of training is attached at the end of this document for use.
- Review temperature logs weekly to ensure that vaccine temperatures are recorded properly.
- Act as the lead vaccine contact for the office.
- Act as the lead emergency vaccine plan coordinator.
- Manage all vaccine usage including: ordering vaccine (usually on a quarterly basis); assure vaccine inventories are reviewed monthly; monitor vaccine storage conditions daily; assure vaccine wastage is minimized; and assure all vaccine shipping, receiving, packaging and transportation is done 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 minimum requirements for the types of storage units are the following:

- 1. Refrigerator that has a separate freezer compartment with a separate exterior door containing two separate thermostats; or**
- 2. Stand-alone refrigerator and stand-alone freezer**

**Note: Dormitory style refrigerators are not acceptable for any storage of vaccines.**

Complete the information about your vaccine storage units in the table below:

Refrigerator 1 Name	Refrigerator 2 Name	Freezer 1 Name	Freezer 2 Name	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Are able to maintain required vaccine storage temperatures.			
<input type="checkbox"/> Yes <input type="checkbox"/> No	Are large enough to hold your maximum vaccine needs.			
<input type="checkbox"/> Yes <input type="checkbox"/> No	Have working certified and calibrated thermometers in accordance with the National Institute of Standards and Technology (NIST) or the American Society for Testing and Materials (ASTM) standards. We maintain the certificates of our thermometers in _____ (location where the certificates are maintained).			
<input type="checkbox"/> Yes <input type="checkbox"/> No	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 vaccine shipments as soon as they arrive.
- Maintain proper vaccine storage temperatures:
  - **Refrigerator: 35°F to 46°F (2°C to 8°C)**
  - **Freezer: -58°F to 5°F (-50°C to -15°C).**
- Place the ODH-supplied data logger in the middle of each vaccine storage unit away from the coils, walls, floor and cold air vent.
- Record the temperature twice daily on the ODH-supplied VFC temperature log.
- Check the box indicating the color of the data-logger LED indicator light (green or red).
- 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.
- Label “VFC” vaccines to differentiate them from your private stock of vaccines.
- 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.
- As soon as vaccines are within 90 days of the expiration date and will not be used, 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.
- **Never** use vaccines that you suspect are expired or wasted. 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 at (800) 282-0546. ODH personnel will review the vaccine temperatures and determine the next steps of action.

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

**A.** Staff accepting 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, \_\_\_\_\_ (name) or \_\_\_\_\_ (name) 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 invoice.
- 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 below 5°F (-15°C).
- Check for the correct type and quantity of diluents.

**B.** If there are any discrepancies with the invoice, 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 immediately at (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 (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 business hours.

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

\_\_\_\_\_ (name) (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_ (phone)  
 \_\_\_\_\_ (name) (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_ (phone)

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

\_\_\_\_\_ (name) (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_ (phone)  
 \_\_\_\_\_ (name) (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_ (phone)

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

\_\_\_\_\_ (name) (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_ (phone)  
 \_\_\_\_\_ (name) (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_ (phone)

**B. Procedures for Transporting Vaccine**

Vaccine potency must be protected by maintaining the cold chain at all times during relocation and transport. 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: \_\_\_\_\_.

The address of the emergency relocation site is: \_\_\_\_\_.

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

\_\_\_\_\_ (name) (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_ (phone)  
 \_\_\_\_\_ (name) (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_ (phone)

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

\_\_\_\_\_ (name) (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_ (phone)  
 \_\_\_\_\_ (name) (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_ (phone)

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/catg.d/p3049.pdf>.**

**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. 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.

**Assemble Packing Supplies**

1. It is best to use hard plastic Igloo-type 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.
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.

**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. The bubble wrap is to be placed above the cold packs and below the vaccine.
3. Stack layers of vaccine boxes on the bubble wrap. Do not let the boxes of vaccine touch the cold packs.
4. Completely cover the vaccine with a 2-inch layer of bubble wrap.
5. 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).

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

- If the temperature is between 35°F and 46°F (2°C - 8°C), put it in the refrigerator.
- 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.

### **Transport and Short-Term Guidelines for Varicella Vaccine**

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.

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.

#### **Assemble Packing Supplies**

1. It is best to use hard plastic Igloo-type coolers. Attach a “Vaccines: Keep Frozen” label to the cooler.
2. Cold packs. Do not condition frozen gel packs because this vaccine should remain as cold as possible. Do not use dry ice.
3. Use the ODH-supplied data logger from the freezer.
4. Use two 2-inch layers of bubble wrap.

#### **Pack the Vaccine**

1. Spread 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. The bubble wrap is to be placed above the cold packs and below the vaccine.
3. Stack layers of vaccine boxes on the bubble wrap. Do not let the boxes of vaccine touch the cold packs.
4. Completely cover the vaccine with a 2-inch layer of bubble wrap.
5. Spread 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.
7. Assure that the lid on the cooler is attached securely (tape may be needed).
8. Record:
  - a. The time and temperature when the vaccines are removed from the storage unit and placed in the container;
  - b. The temperature during transport; and
  - c. The time and temperature at the end of transport.

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

- a. 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.
- b. Document the time the vaccines are removed from the container and placed in the alternate storage unit.
- c. Note that this is considered a temperature excursion, so contact ODH at 1-800-282-0546 for further guidance.

## 5. VACCINE ORDERING BASICS

- A. Order vaccine in accordance with the actual vaccine need. Avoid stockpiling or a build-up of excess vaccine inventory. When it is time to order, vaccine inventory should typically not exceed a four week supply of vaccines.
- B. Depending on the volume of patients reported to the ODH Immunization Program and order history, practices are typically requested to order vaccine quarterly. If needed, ODH can change the frequency of vaccine orders. A practice should contact the ODH Immunization Program at (800) 282-0546 or (614) 466-4643 for more information.
- C. Develop and maintain complete, accurate and separate stock records for both public and private sector vaccines. VFC providers are not required to have separate storage units for the public and private sector vaccines, but must be able to clearly distinguish between their public and private vaccine supplies. This practice is able to differentiate public from private vaccine stock by:

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*(List the procedure: labeled baskets or different labeled shelves).*

## 6. INVENTORY CONTROL GUIDELINES

- A. The vaccine storage practices listed below are the responsibility of the following staff member:

\_\_\_\_\_ (name).

*(The vaccine coordinator may delegate this duty to another staff member; however, the vaccine coordinator should still monitor the activity weekly).*

- At least once each month, conduct a physical count of vaccines and assess any needs.
- 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 at (800) 282-0546 as soon as vaccines are within 90 days of expiration and will not likely be used.

## 7. VACCINE EXPIRATION AND WASTAGE 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. This staff member must:
  - Quarantine the suspected wasted vaccine in the storage unit until the vaccine manufacturers and ODH determine the vaccine to be either viable or non-viable.
  - Not administer the suspected wasted vaccine. Post a sign on the vaccine storage unit indicating that the vaccine must not be used until viability is determined.
  - Call ODH at (800) 282-0546 to report the suspected wastage.
  - Send data logger information from your vaccine storage unit to ODH to review the recorded temperatures.
  - Email a brief summary of the suspected vaccine wasted to the ODH VFC Consultant.
  - If the vaccine is determined to be wasted or expired, complete a VFC Vaccine Transfer form with the wasted or expired vaccine listed.
  - Review and confirm the wasted or expired VFC vaccine information with the ODH VFC Consultant.
- B. Request a return label from the ODH VFC Consultant to retrieve the wasted or expired vaccine. ODH will submit the request for a return label from McKesson Specialty Shipping. This process may take a number of weeks. CDC requires this vaccine to be returned to McKesson to receive the 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, 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 at (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. UPDATE VACCINE RELATED DOCUMENTS**

- A.** At a minimum, the entire 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.

Last reviewed on \_\_\_\_\_ by \_\_\_\_\_  
Date Name

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

- A.** At a minimum, once a year practices should provide training to their staff on vaccine storage, handling and management plus other responsibilities specified in this plan. All new staff involved with VFC vaccine must be trained. If you have any questions, contact your ODH VFC Consultant for training assistance at (800) 282-0546.

Date of Training \_\_\_\_\_ Conducted by \_\_\_\_\_  
Date Name

Date of Training \_\_\_\_\_ Conducted by \_\_\_\_\_  
Date Name

Date of Training \_\_\_\_\_ Conducted by \_\_\_\_\_  
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