

# Vaccine Management Plan

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V.I. DEPARTMENT OF HEALTH – IMMUNIZATION  
VACCINES FOR CHILDREN PROGRAM



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## VACCINES FOR CHILDREN (VFC) 2022 VACCINE MANAGEMENT PLAN

### Vaccine Coordinator Information

This plan must be reviewed and updated annually (every 12 months) or when key staff change (primary/back-up coordinators and/or signatory). This plan must be dated and signed by the person responsible for the VMP content.

Office/Practice Name	
VFC PIN (6 Digits e.g. M00L00)	
Physical Address	
Phone Number	
Fax Number	

Medical Director/Signatory	Name:
	Email:
	Contact Number:

Primary Vaccine Coordinator	Name:
	Email:
	Contact Number:

Back-Up Coordinator	Name:
	Email:
	Contact Number:

Person(s) with 24-hour access to building, in case of emergency	Name:
	Contact Number:

Reviewed on \_\_\_\_\_ by \_\_\_\_\_  
**Date**
**Signature**

## VACCINE MANAGEMENT PERSONNEL

This section highlights key duties of designated vaccine management staff. However, all personnel working with vaccines should be familiar with VFC Program requirements and guidelines.

### **Provider of Record (Enrollee)**

- Complies with all federal vaccine management requirements, including key areas outlined in this plan.
- Designates one employee as the practice's Vaccine Coordinator, responsible for vaccine management.
- Designates one employee as the Back-up Vaccine Coordinator responsible for vaccine management when the primary Vaccine Coordinator is not available.
- Reports staffing changes regarding the Vaccine Coordinator, Back-up Vaccine Coordinator, and enrollee to the VFC Program.
- Meets and documents required orientation and annual training for the practice's vaccine management personnel.
- Ensures that vaccine management personnel are skilled and knowledgeable regarding VFC Program requirements for temperature monitoring and storage equipment.
- Ensures that the practice's vaccine inventory management is consistent with VFC Program requirements.
- Ensures that the practice's vaccine storage units meet VFC Program requirements.
- Updates and revises vaccine management plans at least annually and when necessary.
- Reviews VFC Program requirements and management plans with staff at least annually and when necessary.

## VACCINE COORDINATOR ROLES AND RESPONSIBILITIES

### **Summary**

The Vaccine Coordinator's responsibilities vary depending on the amount of vaccine the practice gives and practice protocols. The Vaccine Coordinator is responsible for all vaccine management activities, completing required VFC Program trainings, including training other (especially new) staff. In other practices, a different person may have one or more vaccine management responsibilities, such as ordering vaccines. Below is a list of essential responsibilities.

#### Receiving vaccines

- Be present when vaccine is delivered and immediately process it into inventory.
- Ensures acceptable temperature ranges have been maintained.

#### Storing vaccines

- Rotates the vaccine inventory so that vaccines with shorter expiration dates are used first.
- Ensures there are no expired vaccines in the refrigerator or freezer.
- Keep VFC Program vaccine separate from private vaccine stock.
- Perform routine cleaning on vaccine storage units.

#### Monitoring vaccine temperatures

- Use a certified calibrated continuous temperature monitoring device (data logger) to review refrigerator and freezer temperatures.
- Take immediate action if temperatures are outside acceptable ranges.
- Implement the Emergency Vaccine Management Plan, if necessary.
- Temperature logs must be maintained for three years. If you upload temperature data to VTrakS, your data will be kept for three years.

#### Ordering vaccines

- Perform a physical inventory monthly of all vaccines in stock.
- Account for doses of returned or transferred vaccines since the last order.
- Complete and submit the VFC Program vaccine order in VTrakS.

**Back-Up Vaccine Coordinator**

- Complete required VFC Program trainings.
- Meet responsibilities described above when the primary Vaccine Coordinator is not available.

**Notify the DOH Vaccines for Children Program Coordinator** immediately of any changes in the medical director, primary vaccine coordinator, or back-up vaccine coordinators via the email or phone number listed below.

<b>VI Department of Health VFC Program Coordinator</b>	Cherise Thomas, MSW
	Email: <a href="mailto:Cherise.thomas@doh@vi.gov">Cherise.thomas@doh@vi.gov</a>
	Contact Number: 340-776-1113 ext. 2225

## VACCINE STORAGE AND HANDLING

All vaccine storage and handling requirements and recommendations are in place to ensure the vaccine cold chain is maintained. The cold chain begins at the manufacturing plant, includes delivery to and storage at the provider facility, and ends with the administration of vaccine to the patient. Too much exposure to heat, cold, or light at any step in the cold chain can result in a loss of vaccine potency. Once potency is lost, it cannot be restored.

Vaccine storage and handling plans follow the “Vaccine Management Guidelines” found in the *VFC Program Manual* and the Centers for Disease Control and Prevention's (CDC) *Vaccine Storage and Handling Toolkit* found at <http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf>.

### Vaccine Storage Units

#### Equipment

- The practice uses VFC Program compliant vaccine storage refrigerator(s) and freezer(s) and maintains recommended temperature ranges:
  - Refrigerator: between 36°F-46°F (2°C-8°C)
  - Freezer: between -58°F and -5°F (-15° to -50°C)
- Storage units have adequate capacity to store vaccine supply at all times, including during peak back-to-school and flu season.
- Storage units are routinely cleaned inside, kept dust-free outside, and doors have proper seals.
- Keep maintenance and repair records on file and make them available to review upon request.

# REFRIGERATOR ROUTINE MANAGEMENT

**Refrigerator-only Unit**

Usable space for vaccine is inside dashed lines.

- ✓ Separate VFC vaccines from privately purchased vaccines and label them clearly.
- ✓ Group and label vaccines by pediatric, adolescent, and adult types.
- ✓ Place vaccine boxes in breathable plastic mesh baskets or directly on shelves.
- ✓ Always keep vaccines in original boxes. Do not open the box until you are ready to use vaccines.
- ✓ Keep baskets 2-3 inches from walls and other baskets.
- ✓ Store only vaccines in vaccine storage units. If storage of medications is necessary, store below vaccines.

- ✗ Do not block air vents.
- ✗ No vaccines in solid plastic trays or containers.
- ✗ No vaccines in doors.
- ✗ No food in refrigerator.
- ✗ No vaccines in drawers or on floor of refrigerator.

**✓ Store vaccines with the earliest expiration dates to the front of the shelf.**  
 If you have vaccines that will expire within 3 months that you will not be able to use, notify your IDOH staff rep

**✓ Keep temperatures in OK range**  
 36.0°F (2.0°C) to 46.0°F (8.0°C)



# FREEZER ROUTINE MANAGEMENT

A carefully organized freezer helps protect vaccines and facilitates vaccine inventory management. Freeze MMR, MMRV, Varicella, and Zoster vaccines.

✓ Separate the VFC vaccine supply from privately purchased vaccine and label them clearly.

✓ Group and label vaccines by pediatric, adolescent, and adult types.

✓ Place vaccine boxes in breathable plastic mesh baskets or directly on shelves.

✓ Always keep vaccines in their original boxes. Do not open the box until you are ready to use the vaccine.

✓ Keep baskets 2-3 inches from walls and other baskets.

✓ Store vaccines with the earliest expiration dates to the front of the shelf.

If you have vaccines that will expire in 3- months that you will not be able to use, Notify your IDOH staff rep

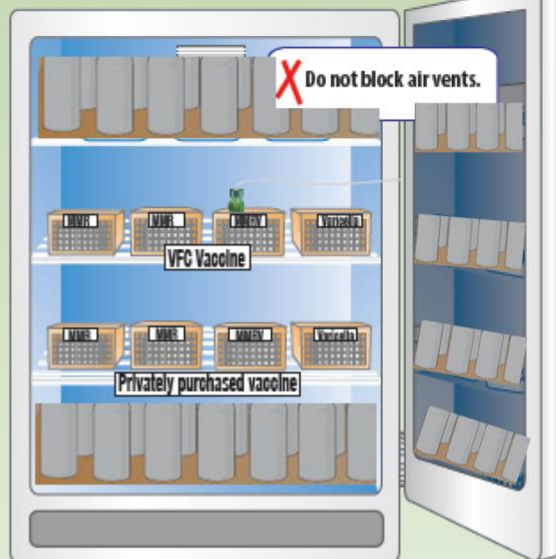


✓ Keep temperatures 5.0°F or colder.

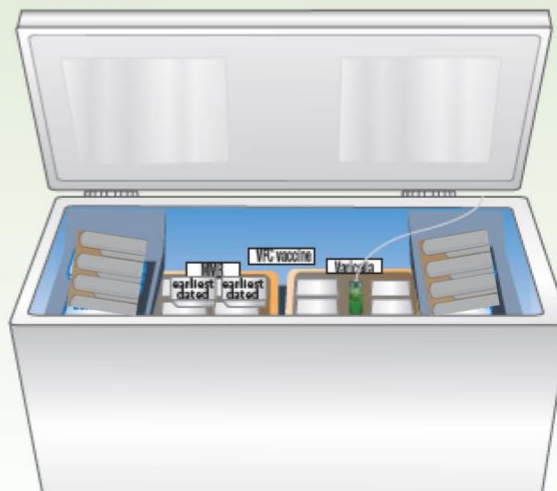
Aim for 0.0° F or colder



Upright freezer




Chest freezer



# POWER SUPPLY ROUTINE MANAGEMENT

## Safeguard Your Power Supply

### Protect plug and outlet

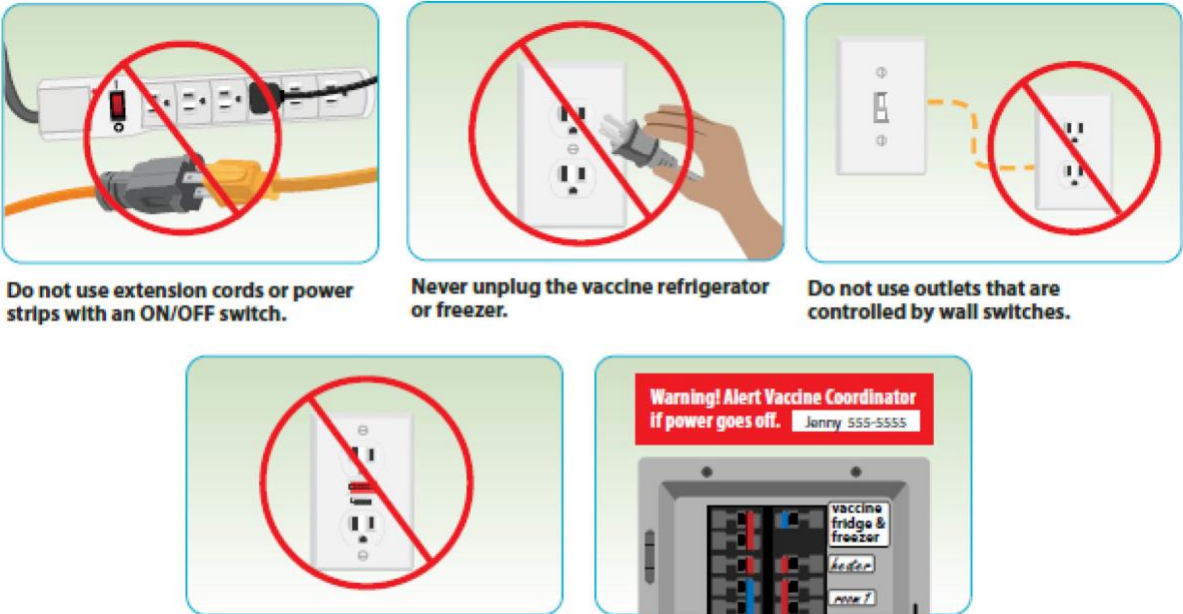


**Plug In vaccine storage unit to a nearby outlet.**

**Secure plug with a guard/cover.**

**Post "Do Not Unplug" signs near outlet.**

### Always avoid disruption of power



**Do not use extension cords or power strips with an ON/OFF switch.**

**Never unplug the vaccine refrigerator or freezer.**

**Do not use outlets that are controlled by wall switches.**

**Do not use outlets that have built-in circuit switches (they have red reset buttons).**

**Label fuses and circuit breakers. Post a sign to alert the Vaccine Coordinator any time the power goes out.**

## Power Supply

- Each unit is plugged directly into a wall outlet and is not controlled by a light switch, power strips, or surge protectors with an on/off switch.
- Extension cords are never used to connect storage units to an outlet.
- “DO NOT UNPLUG” signs are posted at each outlet and circuit breakers.

## Set-up

- Storage units are set up according to VFC Program requirements.
- Units are kept away from direct sunlight and away from walls to allow air circulation.
- Vaccine is never stored in the door, drawers, or bins. Unit drawers/deli crispers are removed.
- To stabilize temperatures, water bottles are kept in the refrigerator where vaccines cannot be stored. Frozen cold packs are kept in the freezer for similar purpose.
- VFC Program and private vaccine storage areas/shelves are marked “VFC” and “Private” to clearly identify vaccine supplies.
- The glycol-encased data logger probe is placed in the center of the unit, near the vaccines.
- The data logger’s display is securely attached to the outside of the storage unit.
- Vaccines are stored in their original packaging until administered; vaccine supply is 2-3 inches away from walls, air vents, and floor to allow space for air circulation.
- Food, beverages, and laboratory specimens are not stored in the units at any time.

## VACCINE STORAGE UNIT/LOCATIONS AND MAINTENANCE

Maintenance/Repair Company \_\_\_\_\_ Phone \_\_\_\_\_

Unit Type	Unit/Location	Brand	Model	Dates of Repair
Refrigerator				
Refrigerator				
Refrigerator				
Refrigerator				
Refrigerator				
Freezer				
Freezer				
Freezer				
Freezer				
Freezer				

Location of completed temperature logs \_\_\_\_\_

## TEMPERATURE MONITORING DEVICE LIST AND MAINTENANCE

Calibration Company/Laboratory \_\_\_\_\_

Contact \_\_\_\_\_ Phone \_\_\_\_\_

Refrigerator				
Refrigerator				

Digital Data Logger or Continuous Monitoring Systems Device Model/Serial Number	Primary?	Backup?	Calibration Expiration Date	Alarm Setting Low	Alarm Setting High

## TEMPERATURE MONITORING

### Data Loggers

- Each storage unit has a VFC Program compliant continuous temperature monitoring device or data logger accurate within +/-1°F (+/- 0.5°C).
- Each data logger has a current and valid Certificate of Calibration (also known as a Report of Calibration).
- Each data logger has a biosafe glycol-encased probe placed in the center of the storage unit in close proximity to the vaccine.
- Each data logger has a digital display of current, minimum, and maximum temperatures.
- The practice has a minimum of one back-up data logger, meeting VFC Program requirements, for use when primary data loggers fail or are being recalibrated.
- Probes are NEVER placed in the unit's doors, near or against unit's walls, underneath air vents, or on the unit floor.

### Safeguarding Vaccines, Handling and Reporting Out-of-Range Temperatures

- When an out-of-range temperature is identified, immediate action is taken to assess the situation and to prevent vaccine spoilage.
- If you find that vaccines have been “potentially spoiled”/exposed to out-of-range temperatures or to light, **Providers may not under any circumstance determine if vaccine are viable or non-viable.**
  1. Label vaccine “DO NOT USE.”
  2. Keep vaccine stored in the recommended temperature range until viability is determined by the manufacturer.
  3. If necessary, relocate vaccines according to your emergency relocation plan.
  4. Call the vaccine manufacturers and their responses concerning viability must be emailed to you.
  5. **Notify the VFC Program Coordinator at 340-776-1113 ext. 2225 or 2226.**
- The practice has an Emergency Vaccine Management Plan to follow in the case of power outage, appliance malfunction, weather conditions, or human error that may affect vaccine viability.
- When necessary to transport vaccine to another storage unit or to a predetermined site, the practice always follows VFC Program guidelines.
- Actions are documented on the VFC Program temperature log and other VFC Program forms, as appropriate.

## Temperature Monitoring and Documentation

- Read and record refrigerator and freezer temperatures twice a day, when the clinic opens and before it closes.
  - Record current temperatures on a VFC Program supplied temperature log twice a day. If available, record minimum and maximum temperatures once a day, preferably in the morning.
  - Record a.m. temperatures before opening storage units.
  - Record p.m. temperatures at the end of the day.
  - Reset MIN and MAX after each reading by pressing the memory clear button (in most data loggers).
- The person documenting the storage unit temperature initials the temperature log.
- Document temperatures on VFC Program temperature log even if the practice uses a continuously recording/graphing data logger, data logger, or remote monitoring system.
- Temperature logs are posted on the storage unit door or nearby in an accessible location.
- The practice maintains completed temperature logs for three years and makes them available for review upon request to VFC Program representatives.

## INVENTORY MANAGEMENT

### Vaccine Stock

- The practice conducts a physical vaccine inventory at least once a month and before ordering vaccine.
- The practice has enough vaccine supply to meet the needs of its VFC Program eligible patients.
- The practice must keep up to four weeks' additional supply to mitigate shortages in the event of shipment delays.
- Vaccine drawn up and not used is disposed of and accounted for properly VTrakS.
- Diluents can be refrigerated or stored at room temperature, but never frozen.

### Stock Rotation, Returns, and Transfers

- The practice organizes vaccines so those with the shortest expiration dates are used first.
- The practice returns expired and/or spoiled vaccine to McKesson for excise tax credit within six months of expiration/spoilage.
- If the practice has vaccine due to expire within three months and it will not be used:
  - Notify the VFC Program about the vaccine.
  - Request a transfer approval from the VFC Program.
  - Identify VFC Program providers in the area to contact and inquire if they may be able to use the soon-to-expire vaccines.
- If a practice transfers or transports vaccine, it follows VFC Program guidelines, and completes the appropriate transaction in VTrakS.
- If vaccine becomes spoiled or expires, staff removes it immediately from the storage unit, reports it to the VFC Program, and adjusts it out of their inventory in Florida VTrakS.
- Vaccine that is spoiled or expired must be reported to the VFC Program before a new order can be submitted.

### Vaccine Ordering

- Orders are submitted in VTrakS and placed according to assigned order frequency, vaccine usage, and take into account the inventory in stock. Orders are placed with sufficient inventory on hand to allow time for order processing and vaccine delivery
- The practice does a physical inventory before placing a vaccine order.
- Any changes to the practice's hours are reported to the VFC Program to avoid receiving vaccine shipments when the clinic is closed, or the staff is not available.

## Receiving and Inspecting Vaccine Shipments

- Staff accepting deliveries must be trained.
- The practice assumes responsibility for all VFC Program vaccine shipped to its site.
- Vaccine shipments are inspected immediately upon arrival to verify that the temperature during transport was within range, length of time the vaccine was in transit, and that the vaccines being delivered match those listed on the packing slip and order confirmation. If there are any discrepancies or a question of viability, call McKesson (1-877-822-7746) and the VFC Program within 2 hours of receipt.
- Vaccines are immediately stored according to VFC Program requirements.

## TRANSPORTING VACCINES

- When transporting vaccines in ordinary vehicles, use the passenger compartment, not the trunk.
- Consult the VFC Program for permission to transfer VFC vaccines between providers.
- It is critical to maintain the cold chain at all times during transport.
- Stay with vaccines at all times during transport and promptly unpack and place in appropriate storage units upon arrival.
- FDA requires that opened multi dose cannot be transported/transferred to other providers.

## VARICELLA-CONTAINING VACCINES

The vaccine manufacturer does not recommend transporting varicella-containing vaccines (MMR/V,VAR). If these vaccines must be transported in an emergency situation:

- They should be packed and transported in a portable freezer unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C).
- **Dry ice is never allowed.**
- If a portable freezer unit is not available and the vaccines cannot be packed in a unit that maintains +5°F or colder:
  - Varicella-containing vaccines may be transported and stored at refrigerator temperatures between 36°F and 46°F (2°C to 8°C).
  - Refrigerated varicella-containing vaccines must be used within 72 hours.
  - Remaining refrigerated varicella-containing vaccine must be discarded if it is not used within 72 hours.

Refreezing varicella-containing vaccines that are stored at refrigerated temperatures is prohibited.



## Procedure for Packing Vaccines

1. Use properly insulated container, (i.e. hard sided plastic insulated containers with at least 2-inch thick walls)
2. Validate the containers beforehand to ensure they are capable of maintaining recommended temperatures.
3. Diluents **MUST** travel with its corresponding vaccine at all times.
4. Pack enough refrigerated/frozen packs to maintain the cold chain. Do not use loose or bagged ice.
5. Place an insulating barrier (e.g. bubble wrap, crumpled brown packing paper, Styrofoam peanuts) between the refrigerated/frozen packs and the vaccines to prevent accidental freezing.
6. Do not remove vials from the original packaging and do not draw up vaccine in advance.
7. Attached labels to the outside of the container to identify the contents as valuable and fragile vaccines.
  - Place the following documentation in an envelope placed on the outside container:
  - Date and time packed
  - Originating facility
  - Vaccine types
  - Number of doses
  - Lot numbers
  - Signature of person who packed the vaccines



If vaccines must be kept in transport containers during an off-site clinic:

- The containers should remain closed as much as possible.
- Only the amount of vaccine needed at one time should be removed for administration.
- Certified thermometers should be placed in the center of the vaccines.
- The temperatures inside the containers should be read and documented at least hourly.

The contents of the container should be layered as follows:

1. Refrigerated/frozen packs
2. Insulating barrier
3. Vaccines
4. Certified thermometer in the center of vaccines
5. Insulating barrier
6. Refrigerated/frozen packs

## SUPPLIES FOR TRANSPORT



### Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.



### Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand (this normally takes less than 5 minutes).



### Insulating material — You will need two of each layer

- **Insulating cushioning material** - Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** - Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.



- **Temperature monitoring device** - Digital data logger (DDL) with buffered probe. Accuracy of  $\pm 1^{\circ}\text{F}$  ( $\pm 0.5^{\circ}\text{C}$ ) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

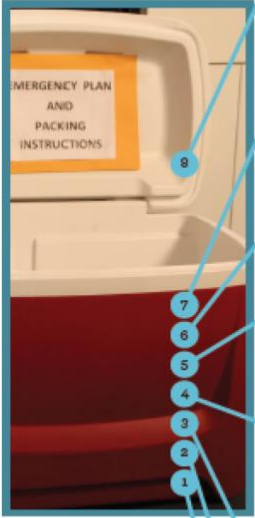
### Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of Insulating cushioning material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**

## PACKING THE VACCINE

**Conditioning frozen water bottles (this normally takes less than 5 minutes)**

- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice “sticks,” put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.



**NOTE:**  
This pack-out can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

**8. Temperature Monitoring Device Display (on lid)**

**Close lid** – Close the lid and attach DDL display and temperature log to the top of the lid.

**7. Conditioned Water Bottles**

**Conditioned frozen water bottles** – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.

**6. Cardboard Sheet**

**Insulating material** – Another sheet of cardboard may be needed to support top layer of water bottles.

**5. Bubble wrap, packing foam, or Styrofoam™**

**Insulating cushioning material** – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™

**4. Vaccines, Diluents, and Temperature Monitoring Device Probe**

**Vaccines** – Add remaining vaccines and diluents to cooler, covering DDL probe.  
**Temperature monitoring device** – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.  
**Vaccines** – Stack boxes of vaccines and diluents on top of insulating material.

**3. Bubble wrap, packing foam, or Styrofoam™**

**Insulating cushioning material** – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).

**2. Cardboard Sheet**

**Insulating material** – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.

**1. Conditioned Water Bottles**

**Conditioned frozen water bottles** – Line bottom of the cooler with a single layer of conditioned water bottles.

## STAFF TRAINING ON VACCINE MANAGEMENT AND VFC PROGRAM REQUIREMENTS

All office staff that handle or administer vaccines should receive annual training to ensure they are familiar with the **Vaccine Management Plan** and the VFC Program requirements.

V.I. Department of Health – Immunization Program | Vaccines for Children Program | 2022 Vaccine Management Plan  
Rev: 8/2022

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## SIGNATURE LOG

Staff assigned vaccine management responsibilities are to review and sign the signature page at the end of this document annually and when the plan is updated. This Plan may be reviewed by VFC Program representatives during routine and drop-in site visits. By signing, I acknowledge I have reviewed and am familiar with the information in this document.

Review Date:	
Provider of Record Name:	Signature:
Vaccine Coordinator Name:	Signature:
Back-Up Coordinator Name:	Signature:

Review Date:	
Provider of Record Name:	Signature:
Vaccine Coordinator Name:	Signature:
Back-Up Coordinator Name:	Signature: