



# Vaccine Management Plan

**Practice Name** \_\_\_\_\_

**PIN#** \_\_\_\_\_

Vaccine Coordinators (see page 3)		
Name	Role (e.g. RN, MA)	Home and/or Cell Phone
Vaccine Coordinator:		
Back-up Coordinator:		
2 <sup>nd</sup> Backup Coordinator ( <i>optional</i> ):		

Alternate vaccine storage location (see page 9)	
Location name	
Location address	
Phone	
Primary contact person off-hours phone #	
Secondary contact person off-hours phone #	

Regional Immunization Specialist	
Name	
Phone number	
Email address	

Person Completing This Form	
Date of completion	
Your Name	
Title	
Your Signature	

**Whenever this page is updated, fax a copy to the Immunization Program at 802-863-7395**

# Vaccine Management Plan

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### Abbreviations:

ACIP: Advisory Committee on Immunization Practices

MMR: measles, mumps, and rubella vaccine

MMRV: measles, mumps, rubella, and varicella vaccine

VDH: Vermont Department of Health

# Vaccine Management Plan

## I. Rationale

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Providers enrolled in the federal Vaccines for Children and state Vaccines for Adults Programs are entrusted with publicly-funded vaccine and must assure viability. Vaccine that is not stored under required conditions may be ineffective at producing an immune response.

Vaccine is expensive. In 2015, the value of vaccine distributed to VFC and/or VFA enrolled practices in Vermont was more than 13 million dollars.

**Failure to follow the requirements in this plan can result in liability for loss of vaccine.**

## II. Roles and responsibilities

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### A. Vaccine Coordinators

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Designate a **Primary Vaccine Coordinator** and at least one **Backup Vaccine Coordinator**.<sup>1</sup> These personnel are responsible for managing state-supplied vaccine, as described in this plan. Both should be equally knowledgeable about vaccine management, and the Backup should be capable of fulfilling all vaccine storage and handling requirements when the Primary Vaccine Coordinator is absent.

When the Primary Vaccine Coordinator or the Backup is replaced, immediately notify VDH so that the required training can be scheduled promptly.

**Training:** The Primary Vaccine Coordinator and Backup Vaccine Coordinator must complete the following training *annually* if they did not receive a VFC/VFA compliance site visit for the calendar year or if they were not present for the duration of the site visit.

1. You Call the Shots: Module 10, Storage and Handling
2. You Call the Shots: Module 16, Vaccines for Children Program [VFC providers only]

Find the modules at [www.cdc.gov/vaccines/ed/youcalltheshots.htm](http://www.cdc.gov/vaccines/ed/youcalltheshots.htm)

### B. Other staff

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All staff with vaccine storage and handling responsibility must read and sign (on the cover page) this Vaccine Management Plan annually *and* whenever changes are made to the plan.

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<sup>1</sup> The Vaccine Coordinator is sometimes referred to as the “Vaccine Contact” or “Vaccine Manager,” and should not be confused with Staff Manager or Practice Manager. An individual may be in both roles.

# Vaccine Management Plan

## III. Storage and Handling-Best Practices

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### A. Selecting storage units (refrigerators and freezers) that will reliably maintain a safe temperature-

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1. Stand-alone refrigerators and freezers are strongly recommended over combination units.
2. Combination refrigerator/freezer units must have separate doors and should have separate temperature controls for each section. Use of such units is discouraged due to documented problems managing frozen vaccine and refrigerated vaccine in this style unit.
3. Never Permitted: Dormitory or bar-style refrigerators. These are small combination refrigerator/freezer units outfitted with one exterior door and an evaporator plate (cooling coil) which is usually in an icemaker/freezer compartment in the refrigerator.
4. Freezer
  - The freezer should be self-defrosting.
  - Stand-alone freezers are strongly recommended. NIST<sup>2</sup> studies have shown that the freezer in a combination unit is unreliable for keeping frozen vaccine at the proper temperature.
  - Freezer temperature must be maintained between -50°C and -15°C (-58°F and +5°F).
5. Refrigerator
  - Stand-alone refrigerators are strongly recommended. Refrigerated vaccine may be stored in a combination unit; preferably the freezer section is not used.
  - Refrigerator temperature must be maintained between 2°C and 8°C (35°F and 46°F).
6. Consider the following to determine what size unit is required:
  - Vaccine should not be stored in the door, crisper or other bins.
  - Vaccine should be 2-3 inches from the walls and back, with space for air flow.
  - Vaccine should not be placed on the floor of the unit.
  - Vaccine should not be stored near a cooling fan or vent.
  - There should be enough room to accommodate the largest inventory of the year – typically during flu season (or back-to-school) – without over-crowding.
  - There should be space for water bottles marked “do not drink.” (See B.2 below.)
  - If medications and biologic materials need to be stored with vaccine, they should be placed below vaccine on a separate shelf to prevent possible contamination. They should not impede air flow.

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<sup>2</sup> National Institute of Standards and Technology

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## B. Preparing the unit for vaccine storage

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1. Store food and beverages in a separate storage unit, not where vaccines are stored.
2. Water bottles marked “do not drink” can be placed in the refrigerator as a thermal buffer to help protect vaccine from temperature variations. Place them in the door and on the floor. Also, place against the back and walls if possible.
3. Frozen water bottles can be placed in the freezer as a thermal buffer. Place these in the door and on the floor. Also, place frozen water bottles against the back and walls if possible.
4. A “Do Not Disconnect” notice must be posted next to every outlet where a vaccine freezer or refrigerator is plugged in. A second “Do Not Disconnect” sticker must be posted on or near the corresponding circuit breaker.<sup>3</sup>
5. Prior to use of vaccine, the storage unit(s) should be inspected by Immunization Program staff and have at least 3 consecutive days of in-range temperatures, as monitored by a thermometer supplied by the Immunization Program.

## C. Arranging vaccine in the storage unit

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1. Place vaccine with the shortest expiration dates to the front so they are used first.
  - Allow for air circulation:
    - Place vaccine as centrally as possible in the unit without crowding.
    - Avoid storing vaccine in the door, on the floor, in crisper bins, or in the space created by removing the crisper bins.
    - Keep vaccine at least 2-3 inches away from the walls, floor, coils of the storage compartment.
    - Allow air space between each large package, block, tray, or bin of vaccines.
  - Keep vaccine away from cooling vents/fans if you use a combination refrigerator/freezer unit. Place water bottles in front of such vents, but don't block air circulation.
  - Avoid use of the top shelf of the refrigerator when possible, MMR may be placed on the top shelf, if a freezer is not available for storage.
  - Keep all vaccine vials/syringes in their original boxes, including opened multi-dose vials.
  - It is best to store each type of vaccine in a separate, labeled basket or tray. Mesh containers are recommended over solid-sided ones because they allow for airflow. If solid-sided containers are used, they cannot have a lid.

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<sup>3</sup> These are available from VDH.

# Vaccine Management Plan

Vaccines to store in the freezer		Vaccines to store in the freezer <i>or</i> refrigerator		Vaccines to store in the refrigerator	
* Varicella * Zostavax * MMRV		* MMR <i>Freezer is preferred.</i>		* All others	
Diluent	* Diluents that are packaged with their vaccines (e.g. ACTHIB, Rotarix) must be stored in the refrigerator and should not be separated from the vaccine with which they are packed.				
	* Diluents that are packaged separately from their vaccines may be stored at room temperature or in the refrigerator, <i>not in the freezer</i> . This includes diluents for MMR, MMR-V, Varicella and Zoster.				

## 2. Avoid administration errors

- Label each basket/tray with the vaccine type. Labels are available for printing at [www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-labels.pdf](http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-labels.pdf)
- Separate and label privately-purchased vaccine vs. state-supplied vaccine.
- Separate and label adult vs. pediatric vaccine.
- On a multi-dose vial, mark the date it is opened. It should be used through manufacturer's expiration date printed on the vial.
- Conduct weekly inventory to assure rotation of vaccines. Short dated vaccine must be used first.
- Report vaccine administration errors to <http://verp.ismp.org/>

## D. Temperature monitoring

1. **Thermometers:** Storage unit temperatures must be continuously monitored using data loggers purchased and installed by the Vermont Immunization Program. One backup thermometer with current certificate of calibration is provided to all practices and must be available for review during the site visit.
  - **Placement** The probe in glycol must be placed centrally in the storage unit.
  - **Calibration** Vaccine thermometers must have a current certificate of calibration. VDH is responsible for recalibration services.

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- **Malfunction** If a thermometer malfunctions call the Immunization Program immediately.
- **Use a back-up thermometer to continue temperature monitoring.**

## 2. **Daily**, each day the clinic is staffed, for each vaccine storage unit:

- At the beginning of each work day, read the data logger and record using the paper log provided by the Immunization Program: the current temperature, the time and name or initials of the person taking the reading, and the overnight minimum and overnight maximum. Min/Max are automatically reset at midnight each night. In order to review Min/Max prior to midnight, press the Review button on the data logger multiple times.
- Approximately one hour before the end of the workday, read and record the current temperature on the paper log. (CDC requires that the paper temperature logs be kept for 3 years.)
- The **refrigerator** temperature must be between **2°C and 8°C** (35°F - 46°F).
- The **freezer** temperature must be between **-50°C and -15°C** (-58°F to 5°F).

### Strive for 5°

The refrigerator must be between 2°C and 8°C.

*Strive for an average reading of 5°C.*

### Freezer temperature

The freezer must be between -50°C and -15°C.

### ALARM

The word, "ALARM," displays, but is not audible.

While reading the temperature, look for the word "Alarm" on the display. When it appears, follow instructions for out of range temperature.

## 3. **Weekly**:

- Download data from each data logger. Look at the "Day Summary" tab for excursion information and alarm status for each day of recorded temperature.
- Data storage capacity is limited. If not downloaded, the data logger will stop recording and the vaccine will not be monitored.

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## 4. Respond to out-of-range temperatures, unit malfunctions and other problems

Immediately take action by contacting the Immunization Program promptly by phone and email the downloaded data file to: [ahs.vdhimmunizationprogram@vermont.gov](mailto:ahs.vdhimmunizationprogram@vermont.gov)

- Place all vaccine of questionable quality on hold in storage (*as if* it is still viable), but do not use until guidance is obtained from the Immunization Program. Refrain from making assumptions about vaccine spoilage.
- Correct obvious problems. For example, if the door is ajar – close it; if the unit is unplugged – plug it in (do not adjust the temperature control, add ice packs, or otherwise attempt to cool a refrigerator quickly, as this may lead to overcompensation and freezing).
- When emailing a data logger (.ltd), include a brief message with the practice name, pin number, your name and phone number, and if you know what caused the problem include that information.
- Do not move vaccine without approval.
- On the paper temperature log, write the date and time of the incident, and document your call to the Immunization Program and actions that you took. Monitor every half hour until the temperature remains in range. Document results of actions that were taken.

Immediately call  
800-640-4374 (24/7)  
whenever there are  
problems with a vaccine  
refrigerator or freezer.

Never move vaccine  
without prior approval  
from the Immunization  
Program

Failure to seek and  
follow VDH guidance  
for vaccine storage &  
handling or transport,  
may result in liability  
for the cost of spoiled  
vaccine.

When a vaccine storage unit will undergo maintenance or repair, contact VDH in advance for instructions regarding vaccine storage during the repair work.

## E. Alternate storage location

1. Determine a suitable back up location with a generator for vaccine storage in the event of a mechanical or power failure. An extended power outage is defined as lack of power for more than 2 hours.
2. This location CANNOT be a private home. The unit must be able to accommodate the amount of vaccine currently in storage and meet requirements outlined in this plan. Consult with the management at the alternate site to assure your vaccine can be appropriately stored, if needed.
3. Permission from the Immunization Program is required prior to moving state supplied vaccine.

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## F. Emergency Plan for a Power Outage

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NEVER move vaccine to a home, another storage unit, or to an approved location without permission from the Immunization Program. In many cases it is better to leave vaccine where it is during a power outage rather than move it.

Post these guidelines near your storage unit where they can be easily accessed. All office staff should be aware of this plan.

If the building has lost electrical power, check with building maintenance or the power company to learn if a time for the restoration of power can be determined.

1. During a short-term power outage (2 hours or less)
  - Do not open the refrigerator or freezer door until the power outage is resolved and the temperature inside the unit is within the normal range.
  - If the outage occurs during business hours, note the time of the power failure.
  - Once power has been restored, note the time and monitor the temperature until it reaches 2° to 8°C for the refrigerator and -50° to -15°C for the freezer.
  - Determine if the temperature has been out of range; if yes, contact VDH by phone, download the recorded data. and send a .ltd file to [ahs.vdhimmunizationprogram@vermont.gov](mailto:ahs.vdhimmunizationprogram@vermont.gov)
  
2. During a long-term power outage (greater than 2 hours)
  - Do not open the refrigerator or freezer door unless approval is requested and received from VDH to transport vaccines to the backup location.
  - If instructed to move vaccine:
    - Contact the alternate location to ensure their power is functional and that they can store vaccine. If they do not have power or enough space to store this vaccine, contact VDH for assistance in finding another location.
    - Follow the instructions from the Immunization Program on packing and transporting vaccine.  
<http://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf>
  - NOTE: Varicella (including both varicella and MMR-V) and zoster vaccines are extremely temperature sensitive and moving these is usually not permitted.

**Never transport vaccine unless authorized by VDH Immunization Program Staff.  
Vaccine stored in the freezer is NOT usually transported.**

# Vaccine Management Plan

## IV. Inventory management and ordering vaccine

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### A. Vaccine Ordering Schedule

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1. Each practice is assigned an ordering frequency with a 2 week window of time.
2. If it's anticipated that vaccine will run out before the next scheduled order, call the Immunization Program to discuss placing an additional order.
3. If there is not enough space in your refrigerator or freezer to store vaccine as described in this document, the unit is too small. Request an increased ordering frequency, and consider the purchase of a unit that can store the largest anticipated inventory.

### B. VTrckS and Vaccine Ordering

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1. Vaccine orders are placed and managed through the online Vaccine Tracking System (VTrckS). The technical requirements can be found at [www.healthvermont.gov/hc/imm/documents/FactSheet-ProviderTechnicalSetupVT.pdf](http://www.healthvermont.gov/hc/imm/documents/FactSheet-ProviderTechnicalSetupVT.pdf)
  2. In order to access VTrckS, each user must complete an identity proofing process.
    - The form is available at [http://healthvermont.gov/hc/imm/documents/VTrckS\\_Identity\\_Voucher.pdf](http://healthvermont.gov/hc/imm/documents/VTrckS_Identity_Voucher.pdf)
    - Instructions are at [www.healthvermont.gov/hc/imm/documents/ProviderSecurityAccess.pdf](http://www.healthvermont.gov/hc/imm/documents/ProviderSecurityAccess.pdf).
  3. A VTrckS Provider webinar and printable training slides can be located at: [www.healthvermont.gov/hc/imm/VaccineTrackingSystemVTrckS.aspx](http://www.healthvermont.gov/hc/imm/VaccineTrackingSystemVTrckS.aspx)
  4. To place an order:
    - Fax paper temperature logs back to the month of the last vaccine order to the Immunization Program the same day an order is placed (Fax: 802-863-7395).
    - Log in at <https://sams.cdc.gov>.
    - Complete Inventory on Hand, Doses Administered and Temperature Logs in VTrckS.
    - Choose Order Catalog to initiate a vaccine order.
    - All vaccine orders are reviewed by the Immunization Program. Should adjustments be necessary, you will be contacted.
    - The status, including shipping information, of vaccine orders can be checked in VTrckS anytime.
    - Enter all transfers into and out of your practice site.
    - Enter any wasted or expired doses of vaccine. See section F.
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## C. Receipt of Vaccine Shipments

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1. Most vaccines are shipped from McKesson Specialty Distribution. Freezer stable vaccines (varicella, MMR-V, and zoster) are shipped by the manufacturer, Merck.
2. Upon receipt of refrigerated vaccines, open the box and check the enclosed temperature monitoring card. If it shows that an out-of-range temperature occurred during shipping, mark the vaccine “do not use,” immediately store it in the refrigerator and call McKesson Specialty at 1-877-836-7123 *the same day*, for further instructions.
3. Verify that the packing slip agrees with the content of the shipment. If not, call McKesson Specialty at 1-877-836-7123 *the same day*. Date and sign the packing slip and keep it for your records. Do not fax it to VDH.
4. Store the vaccine promptly in the appropriate refrigerator or freezer based on the required storage temperature for the vaccine.
5. Frozen vaccines are shipped in a box with coolant packs and the lid of the box contains diluent. Remove the diluent from the lid before you discard the box. Diluent can be stored in the refrigerator or at room temperature, but not in the freezer.
6. Rotate vaccine stock to ensure use of the shorter expiration dates first.

## D. Avoiding wastage due to vaccine expiration

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1. Conduct a weekly inventory to ensure that vaccine with earliest expiration date is used first.
2. Sixty to 90 days prior to expiration, if vaccine is likely to not be used, contact the Immunization Program for assistance redistributing the vaccine to a practice that can use it. Immunization Program permission is required prior to moving state supplied vaccine.
3. **Remove** expired or non-viable vaccine from the storage unit. Mark “Do Not Use.” Refer to the Section F for instructions.

## E. Maintaining the integrity of state-supplied vaccine stocks

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Never borrow (swap) vaccine between state-supplied and private vaccine stock.

# Vaccine Management Plan

## F. Handling expired, spoiled, and wasted vaccine

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1. **Non-viable vaccine** is any vaccine that is unopened (with the cap intact) that cannot be used because it has either passed its expiration date or been spoiled due to exposure to out-of-range temperatures.
  - All expired or spoiled vaccine must be reported in VTrckS using the Return Catalog option. Print the confirmation page.
  - The Immunization Program will review the return and, upon approval, McKesson will email you a shipping label.
  - Upon receiving the shipping label, ship the vaccine in any sturdy box (packed to prevent vial breakage) to McKesson within six months of spoilage or expiration. Enclose the confirmation page as a packing slip.
  
2. **Wasted vaccine** is vaccine that has been opened but not used.
  - Reasons for waste include: because of being drawn into a syringe but not administered, opened in error, error in reconstitution; or vaccine whose sterility has been compromised by the vial being dropped or broken or open multi-dose vials that have expired.
  - All wasted vaccine must be reported in VTrckS using the Return Catalog option (even though it will not actually be returned).
  - Dispose of wasted vaccine on site in a sharps container.

The Immunization Program greatly appreciates and values the many significant contributions of Vermont primary care practices in ordering, storing, handling and administering immunizations to children, adolescents and adults.