

Vaccine for Children (VFC) and NH Immunization Program (NHIP)

Vaccine Providers Vaccine Management Plan

OVERVIEW

The New Hampshire Immunization Program (NHIP) uses a combination of federal and state funds to purchase vaccines to administer, at no cost, to all children in NH from birth through the age of 18 years of age. Patients who are on Medicaid, Uninsured, or American Indian/Native Alaskan are provided vaccine through the Federal Vaccine for Children's Program (VFC).

All providers are required to develop, maintain and implement plans for routine and emergency vaccine management. These plans must be reviewed and/or updated annually or more frequently if changes occur. All information in the plan must be current and have a "review date" and signature to verify that the plan is up-to date. All providers and staff will comply with the NHIP guidelines and procedures related to the management and administration of the New Hampshire Immunization Program vaccines.

The Vaccine Management Plan must contain all of the following components:

- Contact information of the current Primary Vaccine Coordinator and at least one Assistant (back-up) Coordinator,
- Proper vaccine storage and handling practices including temperature monitoring,
- Vaccine ordering procedures and accountability,
- Proper transport and receiving procedures- maintaining the cold chain,
- Proper handling and inventory control,
- Proper processes to avoid vaccine wastage,
- Detailed emergency plan,
- Staff training (and documentation) on vaccine management including storage and handling,
- Review/Revised documentation and signature of person responsible for its contents.

Your practice may use its own plan as long as it meets or exceeds all of the requirements listed above or use this document as a template, adding specific information pertinent to your office.

VACCINE MANAGEMENT

IMPORTANT NUMBERS AT A GLANCE

This information should be reviewed periodically and changes made as needed.

PRACTICE NAME: _____ PIN #: _____

VACCINE MANAGEMENT PLAN is located: _____

DETAILED EMERGENCY PLAN is located: _____

PRIMARY VACCINE COORDINATOR: _____

CONTACT NUMBER: _____

ASSISTANT VACCINE COORDINATOR: _____

CONTACT NUMBER: _____

PRACTICE MANAGER: _____

CONTACT NUMBER: _____

For Power Outages

ELECTRIC COMPANY NAME: _____

ELECTRIC COMPANY PHONE: _____

VACCINE TRANSFER INFORMATION

LOCATION: _____

CONTACT NAME: _____

PHONE: _____

OTHER IMPORTANT CONTACT INFO IN CASE OF EMERGENCY:

QUESTIONS OR CONCERNS?

CALL

NH IMMUNIZATION PROGRAM

603-271-4463 OR 603-271-4482 OR 1-800-852-3345 x 4482

Proper
Vaccine
Management
and
Storage
is critical to
keeping
vaccine safe.

**Vaccine for Children (VFC) and NH Immunization Program (NHIP)
Vaccine Providers Vaccine Management Plan**

Practice Name: _____ PIN _____

Address: _____

Phone _____ Fax: _____

THIS PLAN WILL BE KEPT EASILY ACCESSIBLE AND AVAILABLE FOR ALL STAFF

DESIGNATION / RESPONSIBILITY OF VACCINE MANAGEMENT STAFF

The practice will designate an individual to be the Primary Vaccine Coordinator and an Assistant/back-up Vaccine Coordinator, in the event the Primary Coordinator is unable to perform his or her responsibilities. The Primary Vaccine Coordinator will be trained by the NHIP. The practice must notify NHIP within 24 hours of any changes in key staff.

Responsibilities of the Primary Vaccine Coordinator include:

- Keeping the practice current with all guidelines, policies, procedures and recommendations,
- Assuring proper storage of vaccines and monitoring storage conditions daily,
- Ordering, reporting of vaccines,
- Controlling inventory, including stock rotation, to minimize vaccine wastage,
- Transportation of vaccine including receiving, packing and transferring as necessary, and
- Implementing standard procedures in the event of storage temperature excursion and reporting the event to NHIP.

All Primary and Assistant Vaccine Coordinators will complete the following training *prior* to being given the responsibility of their duties. (<http://www.cdc.gov/vaccines/ed/youcalltheshots.htm>) **All** staff is encouraged to review **all** the training modules available.

- ✓ You Call the Shots: Vaccine Storage and Handling Module
- ✓ You Call the Shots : Vaccines for Children Module

All training and education relative to immunizations and vaccine management must be documented.

All practice staff must notify the Primary or Assistant Vaccine Coordinator any time:

- A vaccine shipment arrives,
- The refrigerator or freezer is out of range or in the “danger zone”, or
- There is any situation that may affect the safety of the vaccine.

VACCINE DOCUMENTATION & ADMINISTRATION

- Providers enrolled in the program should maintain a supply of all routinely recommended vaccines for the populations that they serve.
- All children will be screened for VFC eligibility and VFC status will be documented appropriately in the patient's record at each immunization visit.
 - **VFC eligibility criteria: 0 through 18 years of age, Medicaid eligible, uninsured, underinsured, and/or American Indian/Alaskan Native.**
- Vaccines will be prepared immediately before administration and will not be pre-drawn (exception: for mass vaccination clinics where one vaccine is being offered such as a flu clinic, up to 10 doses of vaccine may be pre-drawn).
- The most currently approved Vaccine Information Statement (VIS) for each dose of state supplied vaccine will be provided to the parent/guardian prior to administering the vaccine.
- Refer to package insert accompanying the vaccine for proper dose, route, site, and needle size.
- Immunization records must be maintained according to federal law and contain:
 - Name of the vaccine,
 - Date the vaccine administered,
 - Date the VIS was given,
 - Publication date of the VIS,
 - Manufacturer and lot number of the vaccine,
 - Name and title of person administering the vaccine, and
 - Name and address of practice or clinic where're vaccine was administered.
- An immunization record will be maintained and kept for 10 years.
- All records related to the VFC program will be kept for a minimum of three (3) years.
- A fee can never be charged for state supplied immunizations (including VFC funded vaccine).
- The vaccine administration fee for non-Medicaid, VFC eligible children will not exceed the current state cap.
- No patient through the age of 18 will be denied a vaccine due to the inability to pay the administration fee.
- Any adverse effects will be reported to the Vaccine Adverse Event Reporting System (VAERS).

VACCINE ORDERING, ACCOUNTABILITY, and RECEIVING

Ordering

- Vaccine will be ordered through the Vaccine Ordering Management System (VOMS) of the state's Immunization Information System (IIS) - *VaxNH*.
- Only trained staff will be given access to the system. Contact NHIP at 603-271-4482 or email vaxnh@dhhs.state.nh.us for information on training.
- Vaccine orders for this practice will be completed approximately every _____ weeks
- Under emergency circumstance, vaccine may be ordered using the most updated NHIP Emergency Vaccine Order form. This requires prior approval. Call NHIP 603-271-4463 for more information on emergency ordering.

Reporting

- Doses administered and accurate current inventory must be reported with each order.
- Proper reconciliation must be done at each ordering event.
- All expired, spoiled, wasted or transferred vaccine must be reported in VOMS as soon as possible.

Receiving Vaccine

- The Vaccine Coordinator or Assistant Coordinator will be notified immediately when a shipment of vaccine arrives.
- The vaccine order arrives either by Fed X or UPS. Trained vaccine management staff will immediately open the shipment and check the temperature monitors. If the vaccine has been "out of range", notify NHIP within 2 hours of delivery to determine if the vaccine is viable.
- Compare the quantities and lot numbers of each vaccine to the McKesson Packing List. If there are any discrepancies, note them on the McKesson Packing List.
- **All** vaccine, including any vaccine in question, must be stored at appropriate temperatures immediately after the package is delivered and checked in. Any vaccine in question will be marked "do not use" until manufacturer and/or NHIP have determined viability.
- The receiving process is completed by confirming, in VOMS, the amount received for each presentation.
- All records related to the VFC program will be kept for a minimum of three (3) years. These records must be available for review upon request.

VACCINE INVENTORY CONTROL

- Vaccines will be stored and rotated according to expiration dates with vaccines having the shortest expiration dates used first.
- If vaccines are within **90 days of expiration** and will not be used, they should be transferred to another VFC Provider in the area or call NHIP for assistance.
- All vaccine that is compromised (e.g. expired or deemed non-viable due to temperature excursion) will be removed from the storage unit and clearly labeled. This vaccine will be returned to McKesson by following the NHIP vaccine return procedures.
- All vaccine that is wasted due to malfunction of syringe, broken vial, pre-drawn and not used, or any other situation where the vaccine *cannot* be returned to McKesson, will be reported to NHIP according to the vaccine wastage procedures.
- All returns and wastage will be reported in VOMS.
- Only one lot number will be used at a time from a single storage unit.
- Vaccines in multi-dose vials that do not require reconstitution can be used through the expiration date printed on the label as long as the vaccine is not contaminated unless indicated otherwise by the manufacturer.
- Vaccine may be used through the last day of the month indicated expiration if no day is specified. Example: Expiration date 10/2016. This vial of vaccine expires at the end of the on October 31, 2016
- To be sure there is accurate vaccine accountability; inventory will be done, at a minimum, monthly whether a vaccine order is being placed or not.
- Vaccine inventory will be completed in this office Weekly Monthly Other _____

VACCINE STORAGE AND HANDLING

Storage Units

- Stand-alone refrigerators and freezers are strongly recommended. Combination storage units must meet the minimum requirements of having a separate freezer compartment with a separate exterior door and containing two separate thermostat controls.
- Any refrigerator or freezer unit used for vaccine storage must be able to maintain proper vaccine storage temperatures year-round and be large enough to hold the year's largest inventory including influenza vaccine.
- Dorm style refrigerators (small combination refrigerator/freezer units with one exterior door and a small ice maker/freezer compartment contained inside) are not permitted at any time.

- Refrigerator units must be maintained between 2°C-8°C. Freezer units must be maintained between -15°C to -50°C.
- Any NEW storage unit must have a minimum of 3 days of “stable” temperatures recorded before vaccines can be moved into the new refrigerator or freezer. NHIP will be contacted for more information when obtaining a new storage unit.

Set up of Storage Unit

- The glycol bottle of each monitoring device will be properly placed/fastened in the *center* of the storage unit.
- Water bottles (for refrigerators) and frozen coolant packs or frozen water bottles (for freezers) should be placed throughout the unit to (1) act as a thermal buffer to stabilize temperatures and extend temperatures longer during a power outage or unit failure and (2) serve as physical barriers preventing the placement of vaccines in areas of the unit that are at a higher risk for fluctuation of temperatures. The water bottles should be marked “Do Not Drink”.
- State vaccines will be stored on a separate shelf from practice purchased vaccines, or placed in separate baskets that are clearly labeled.
- All state supplied vaccine will be labeled accordingly by writing “state” on the box.
- Vaccines will be stored in the middle of the shelf in such a way that air can circulate freely and not stored near the cooling fan or vent of the unit.
- Vaccines will be stored in the original packages and, because several vaccines are light sensitive, tops of boxes will not be removed.
- Vaccines will be stored in a separate refrigerator from food or drink.
- Vaccines will not be stored in the door, in vegetable bins, or against the sides or the back of the refrigeration/freezer unit.
- Merck vaccine diluent will be stored in the door or outside the refrigerator.

Other Safety Points

- Refrigerator/freezer doors will be checked to assure they are closed and, if possible, locked at the end of each day. Velcro strips help assure the door has been properly closed tight.
- Steps will be taken to protect the power source for all vaccine storage equipment by means of warning labels, back-up generators, and/or developing appropriate policies/protocols.
 - Safety outlet covers will be placed on open area/exposed outlets to avoid accidental unplugging of units.
 - Storage units will not be plugged into surge protectors or GFI outlets.
 - Inform maintenance and cleaning personnel not to unplug storage units.
 - Have a “**Do Not Unplug**” sign near the outlet (or on the unit if outlet is not accessible) and a notice on the circuit box indicating breaker switch connected to storage units.

Storage Unit Temperature Monitoring

- Refrigerator units will be maintained between 2°C-8°C.
 - Freezer units will be maintained between -15°C to -50°C
 - Each refrigerator and freezer unit must have a certified calibrated 27/4 monitoring device that meets or exceed the following specifications
 - ✓ **Detachable Bio safe glycol-probe** or similar buffered solution, that remains in the refrigerator or freezer.
 - ✓ **Continuous Monitoring.** The ability to record and save temperature information 24 hours a day. Measures at least one reading every 15 minutes.
 - ✓ **A digital display on the outside of the unit.** An outside reading allows the temperature to be monitored without opening the unit door keeping the temperature inside colder longer.
 - ✓ **The ability to display the minimum and maximum temperatures** between readings.
 - ✓ **A Hi/Lo alarm**, audible or visual for out-of-range temperatures.
 - ✓ **The ability to download and transmit** temperature information by email or fax.
 - ✓ **Low battery indicator.**
 - ✓ **A current certificate of calibration** that is traceable to the National Institute of the Standards and Technology (NIST).
 - ✓ **Accuracy of +/- 1°F (0.5°C)** This information should be contained in the Certificate of Traceability and Testing(also known as the Report of Calibration). A copy of this certificate should be readily available for any NHIP staff during a site visit.
 - The Certificate of Calibration for each monitoring unit/system must be issued either by an ILAC-accredited laboratory or, if not ILAC-accredited, certificate must contain measurement results and a statement indicating that it meets ISO 17025 standards. All certificates must contain:
 - name of device (optional),
 - model number,
 - serial number, and
 - date of calibration
- Certificates of calibration are located:

Back-up Thermometer is located:

- The buffered probe/glycol bottle will be placed/fastened in the center of the storage unit.
 - The practice will have a certified calibrated thermometer on hand to serve as a backup should the main monitoring device fail (1 refrigerator and if applicable, 1 freezer).
 - Back-up thermometers may be standard “stick” thermometers, but must be in glycol and must have a current and valid certificate of calibration (as described above).
 - The temperature of each storage unit will be monitored and recorded at the beginning and end of every workday. The minimum and maximum temperatures will be recorded each morning.

- The temperature log for each storage unit will be faxed to NHIP at the end of every month.
- Temperatures will be recorded in the VaxNH ordering system, VOMS, before an order is placed.
- A report from the 24/7 monitoring device will be reviewed and saved or printed out at the end of every month.
- NHIP will be notified immediately of any temperature alarm.

Temperature Excursions

If temperatures are found to be out of range:

1. Download the data logger and review report as soon as the alarm is discovered.
2. Secure vaccines and post a “Do Not Administer” sign until viability of vaccines has been determined.
3. Immediately call NHIP for guidance. If after hours, enact practice emergency plan for temporary storage.
4. A Temperature Excursion Incident Report must be completed and submitted to NHIP for every excursion incident.

EMERGENCY PLAN (Enter your emergency plan in this section or indicate in writing that it is an addendum at end of this plan)

Written procedures for the relocation of vaccines in case of emergency will be posted on the refrigerator and all staff will be required to know the emergency plan. The plan must include the following components and will be reviewed annually or as needed. An emergency plan is required even if facility is equipped with a generator in case of storage unit failure.

- What specific steps are taken if there is a unit failure or power outage during working hours?
- What specific steps are taken if there is a unit failure or power outage after working hours?
- Power Company name and phone number, to determine if time frame of restoration is short term or will be prolonged.
- The designated site or sites with power/generator to transfer vaccine to.
- Instructions on how to pack vaccine for transport.
- NHIP contact information to inform them of the incident.

VACCINE TRANSPORT

MAINTAIN THE “COLD-CHAIN” WHEN MOVING VACCINES!!

It is critical that vaccine potency is protected by maintaining the cold train at all times during relocation and transport. The following procedures will be followed if vaccines need to be transported due to a power failure, short expiration date, or other requests that require proper packing procedures of vaccine. If relocating large quantities of vaccine due to impending store or power/unit failure, be sure to document the inventory for accountability upon its return once the emergency scenario has been resolved. Diluents should travel with their corresponding vaccines at all times. (Keep Merck diluent separate from frozen packs in cooler.)

Preparing for transport

The following materials are needed and should be always readily available:

- ✓ Proper insulated container. (e.g. the containers that arrive from McKesson, hard sided insulated containers or styrofoam cooler with at least 2-inch thick walls)
- ✓ Several ice and/or cold packs
- ✓ Several chux, bubble wrap or other insulator to place as an insulated barrier between cold packs and vaccine
- ✓ A temperature monitoring device

Refrigerated vaccine

For frozen vaccine, contact NHIP if it is not an emergency transport (see emergency transporting of frozen vaccine on next page).

- Place ice packs in the bottom of the insulated container.
- Place a layer of insulator barrier on top of the ice packs so the vaccines do not directly touch them (to prevent freezing).
- Place vaccines on top of insulator.
- Insert temperature monitor/thermometer near the center of the vaccines, but not in direct contact with ice packs.
- Add another layer of insulator over the vaccines.
- Add layer of cold packs (not frozen) on top of insulator and add more insulator until the container is full, to keep the vaccine securely in place.
- Secure the lid of the insulated container and securely seal with tape.
- Clearly label on the outside of the container “**Vaccine – Refrigerate Immediately**”.
- Unpack vaccine immediately upon arrival and store in appropriate storage unit.
- Follow these exact procedures when transporting back to original site.

- If vaccine is transferred for reasons other than emergency, the transfer must be documented and completed in VOMS by the end of the day.

- **Frozen vaccine**

It is not advisable to routinely transport frozen vaccine but it may be transferred without authorization in an emergency using the following method.

- Diluent should not be frozen but transported/stored at room temperature
- Always pack frozen vaccine last, just before leaving to designated site.
- Place **ice** packs in the bottom of the insulated container.
- Place a thin layer of insulator on top of the ice packs (to prevent boxes from getting damp).
- Place vaccines on top of insulator.
- Insert temperature monitor/thermometer near the center of the vaccines.
- Place a thin layer of insulator on top of the ice packs.
- Insert 2 (or more) layers of frozen packs on top of insulator.
- Add more frozen packs until the container is full, to keep the vaccine securely in place.
- Clearly label the outside of the container **“Frozen Vaccine-Freeze Immediately”**.
- Unpacked frozen vaccine first when designation site is reached.
- Record temperature reading of monitor/thermometer.
- Follow these exact procedures when transporting back to original site.
- If the temperature is ever warmer than -15°C contact NHIP.

THIS PLAN WILL BE KEPT EASILY ACCESSIBLE AND AVAILABLE FOR ALL STAFF

It is a CDC requirement that this document be reviewed annually and updated as necessary.

Last revision/review date _____

Practice Manager/Clinical Coordinator _____

Print

Signature

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